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(54) **MULTI-COMPONENT AMPULE**

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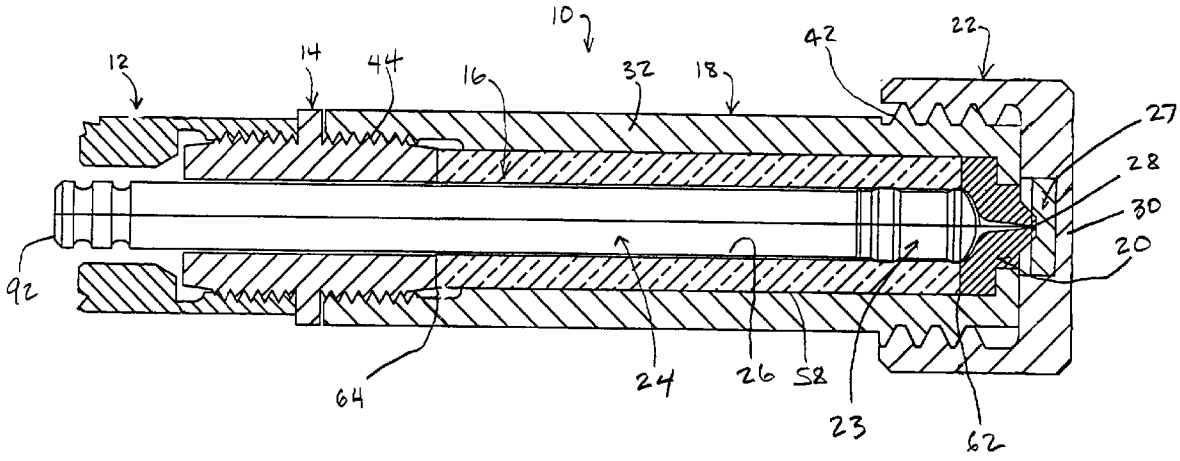
(57) **ABSTRACT**

Multi-component ampules for use with re-useable and disposable jet injectors are described which have primary and secondary packaging components. The primary packaging component includes an inner glass cylinder, an elastomeric diaphragm, and an elastomeric plunger. The secondary packaging components include a plastic outer shell and a plastic adapter. The primary packaging components allow medications and injectable suspensions to be stored for prolonged periods while the secondary packaging components provide structural integrity and adaptability for the ampule. Exemplary methods of use are also disclosed.



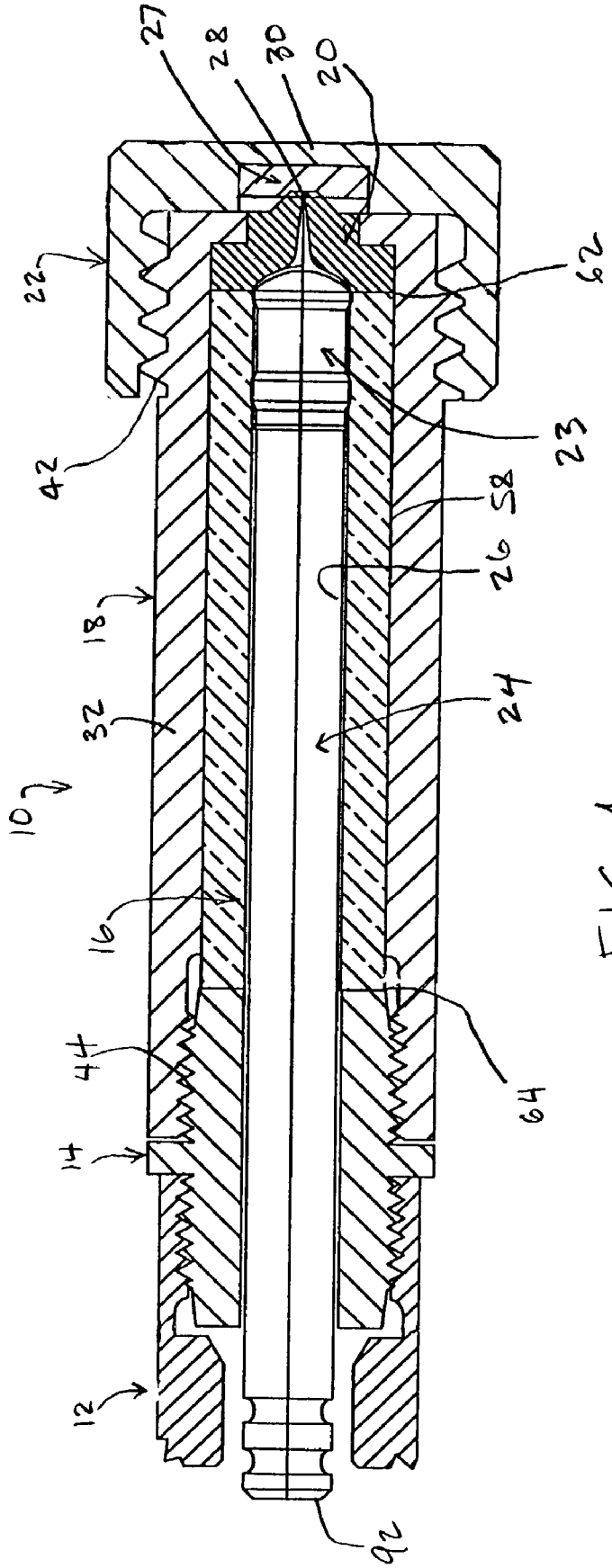


FIG. 1

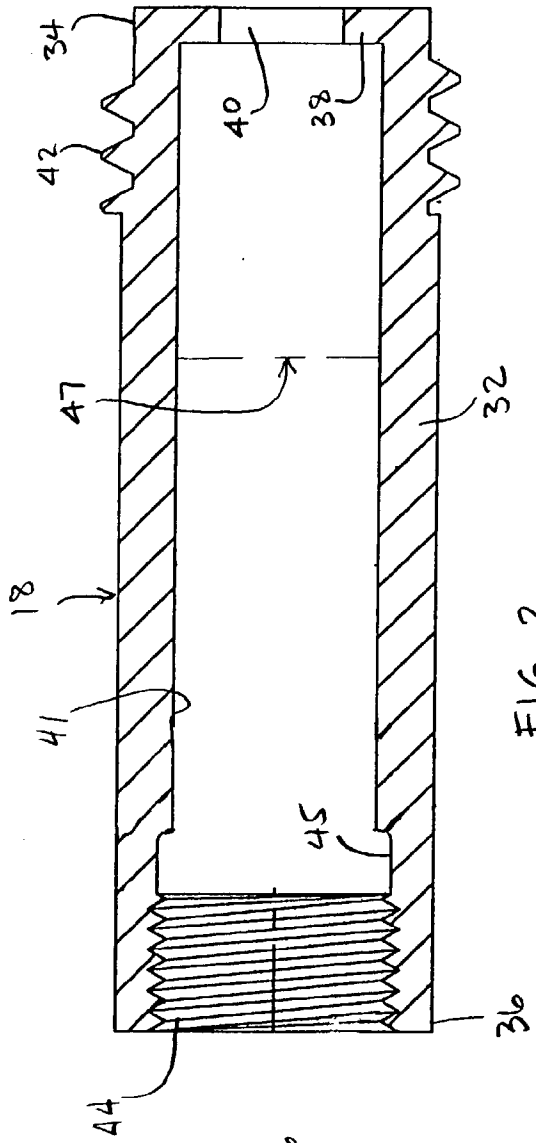


FIG. 2

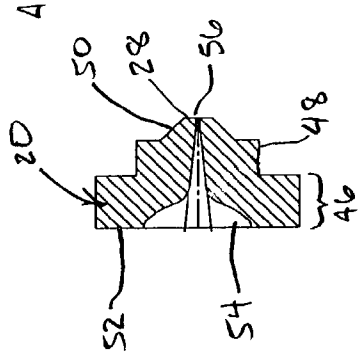


FIG. 3

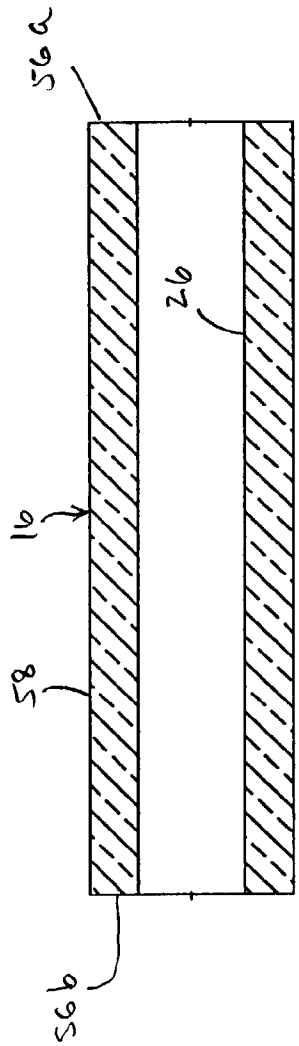


FIG. 4

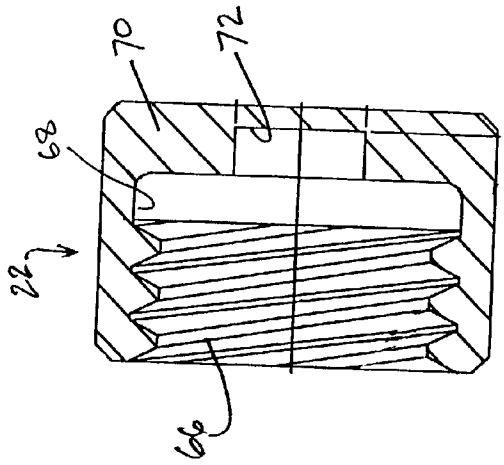


FIG. 6

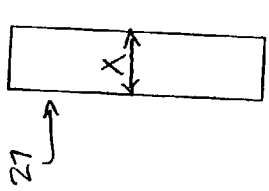


FIG. 8

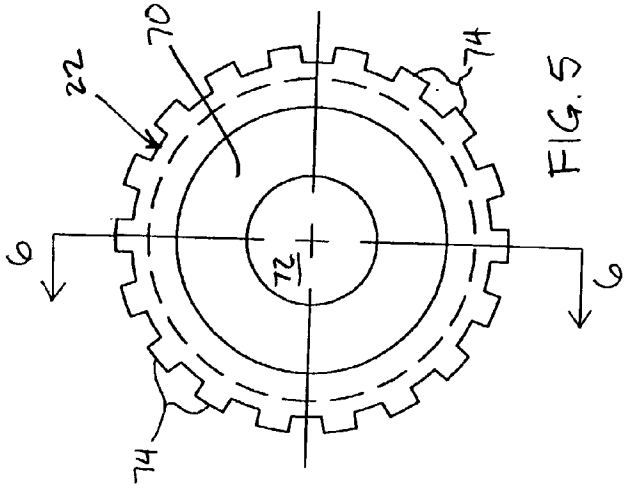


FIG. 5

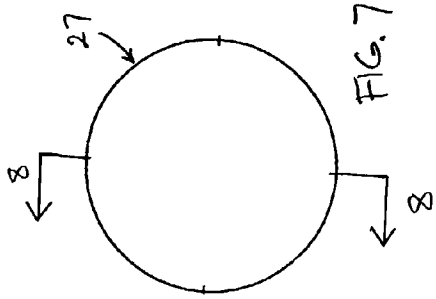


FIG. 7

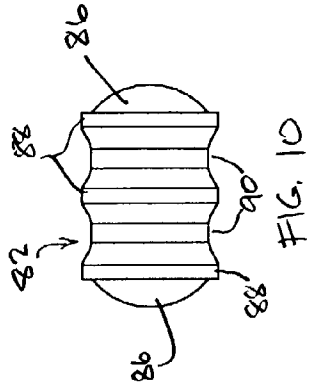


FIG. 10

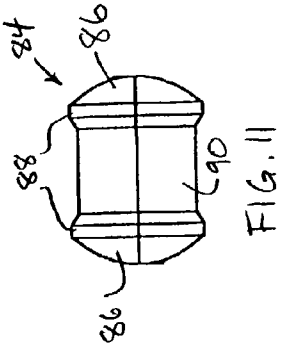


FIG. 11

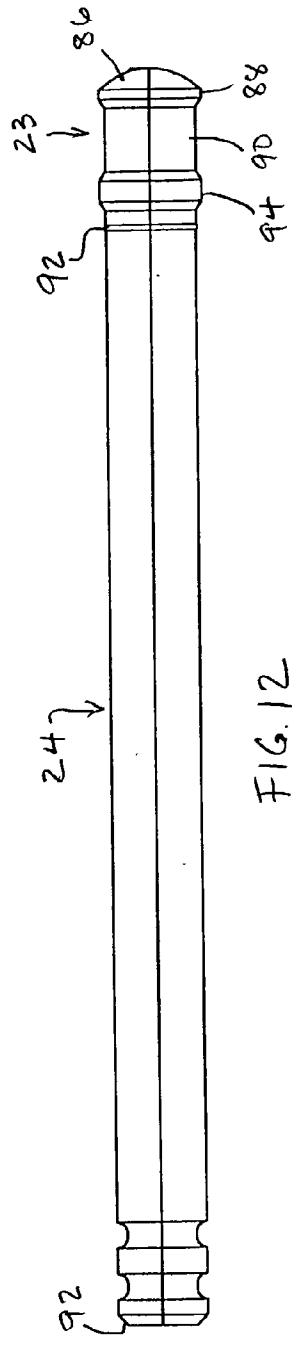


FIG. 12

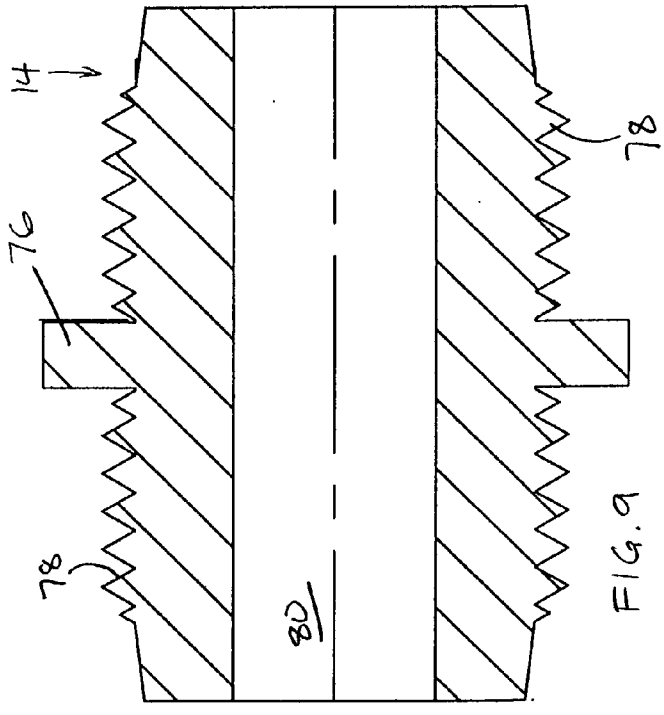


FIG. 9

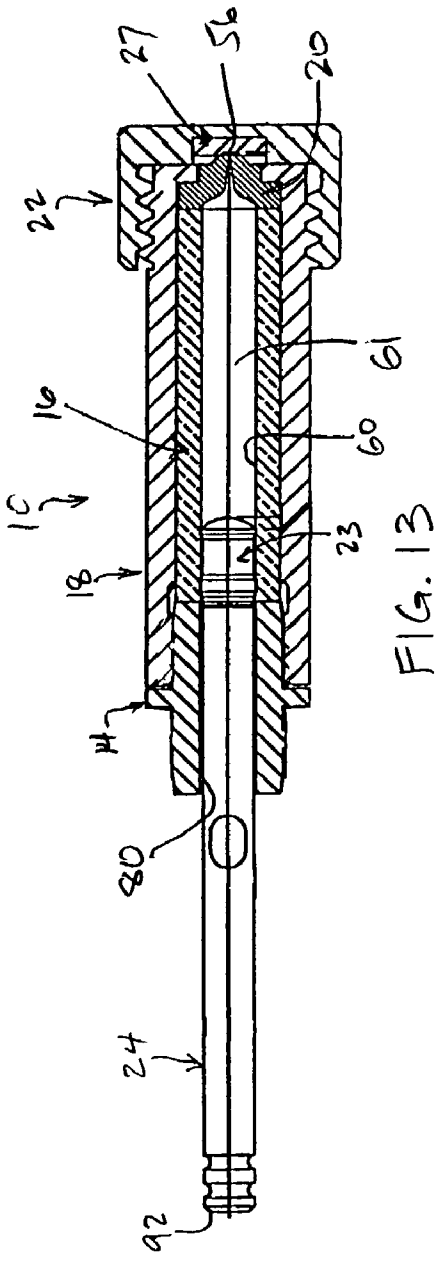

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FIG. 13

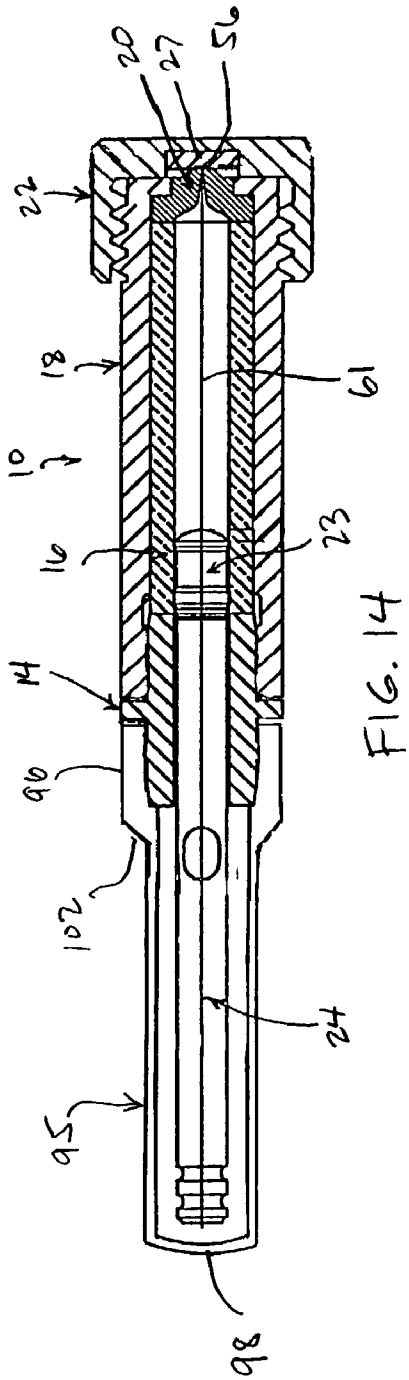
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FIG. 14

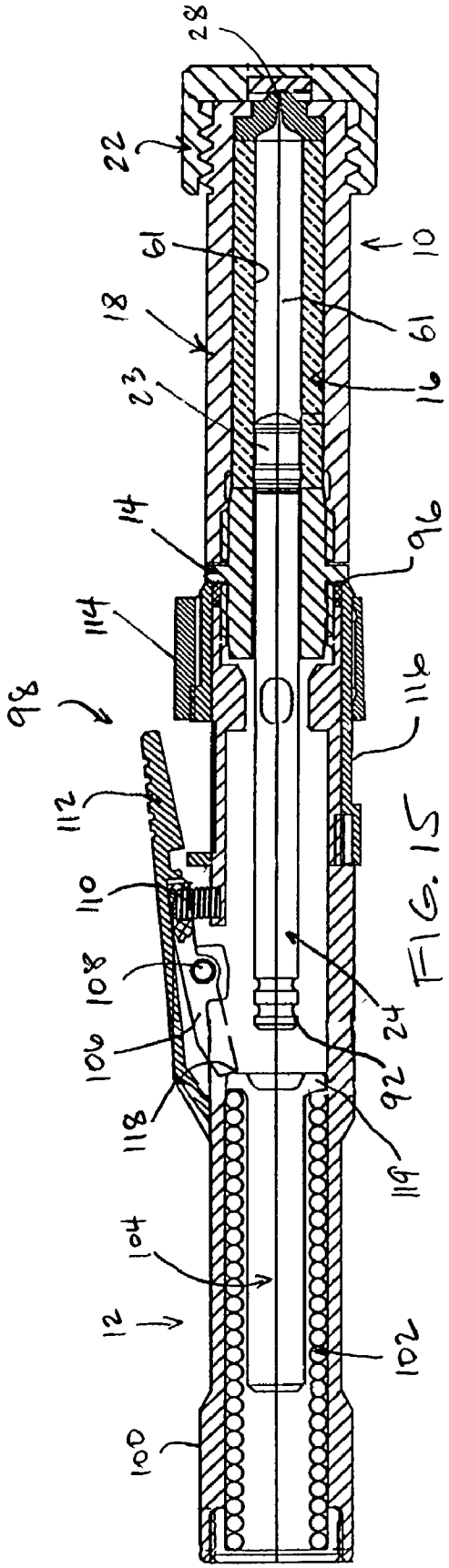
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FIG. 15

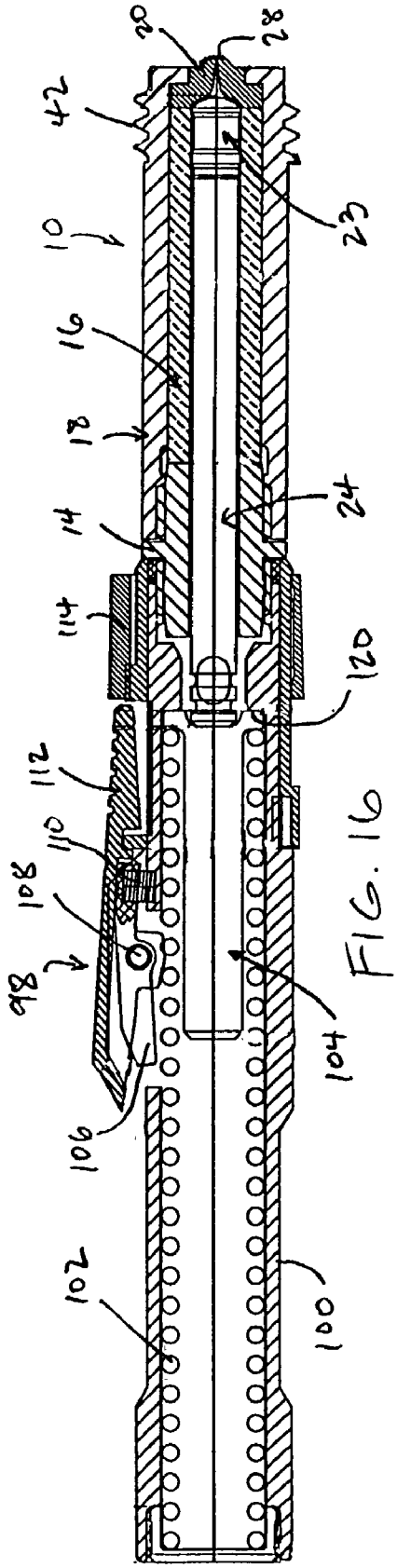
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FIG. 16

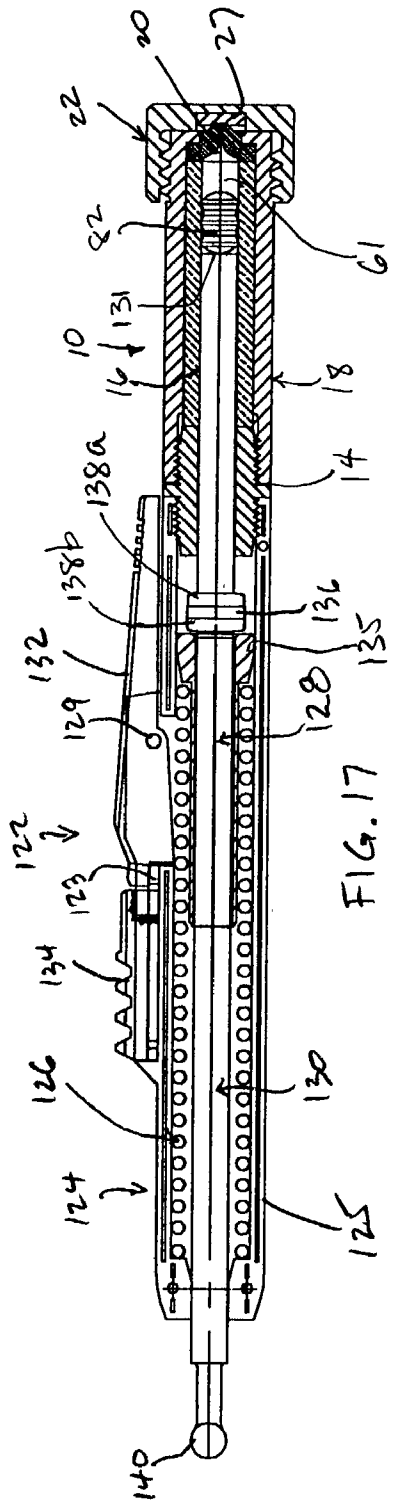
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FIG. 17

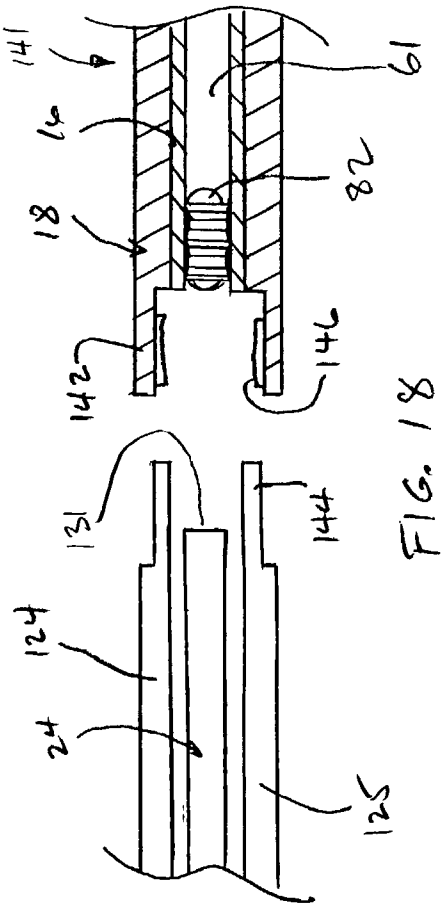
141
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FIG. 18

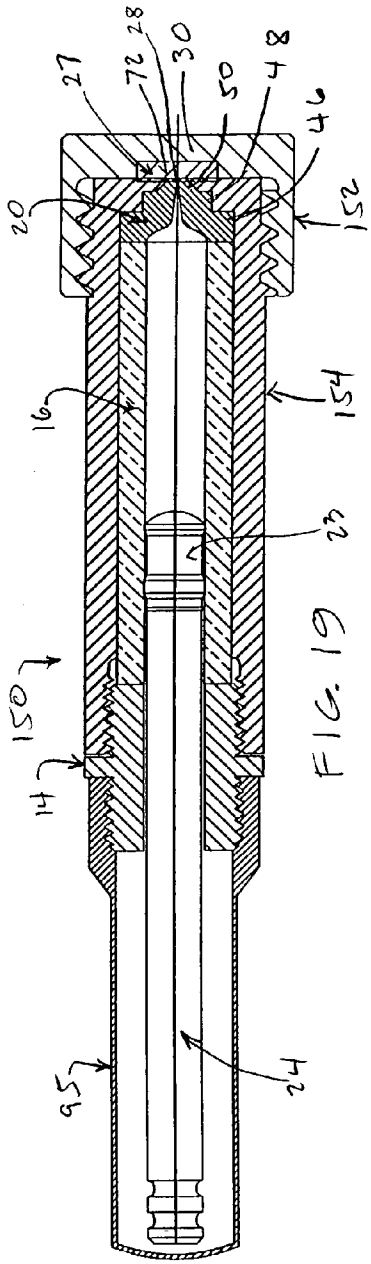

FIG. 19

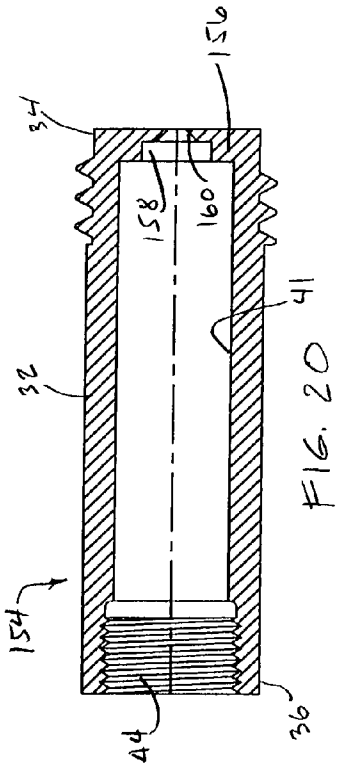

FIG. 20

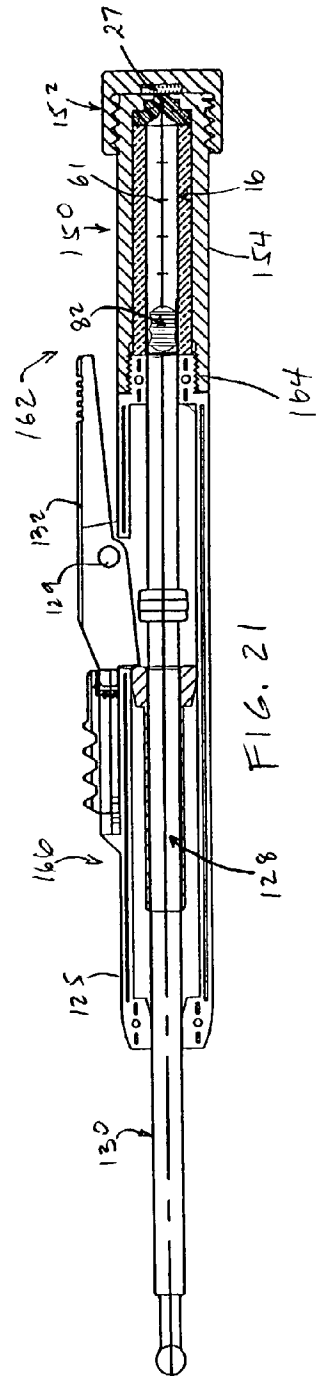

FIG. 21

MULTI-COMPONENT AMPULE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims the benefit of provisional application No. 60/374,461 entitled "Multi-Component Ampule" filed Apr. 19, 2002, the content of which is expressly incorporated herein by reference.

BACKGROUND

[0002] Jet injection devices are well known in the art for administering intramuscular and subcutaneous medications without needles. Examples of hypodermic jet injectors are described in U.S. Pat. Nos. 5,499,972; 5,569,189; and 5,704,911, their contents are hereby expressly incorporated herein by reference.

[0003] In general, these patents disclose a hypodermic jet injector device that has an ampule for holding liquid medication and a jet injector for receiving the ampule and for injecting medication contained within the ampule subcutaneously without a needle. The ampule is generally a single integral component made from a thermoplastic material that has a nozzle on one end for discharging medication, the discharge end, and an opening on the other end for securing the ampule to a jet injector, the inlet end. The inlet end further includes a connectable end, such as an end with external or internal threads or a sleeve for mechanically coupling to the jet injector. The ampule's physical characteristics such as wall thickness and diameter are determined in part by the desire delivery dosage, the plunger type, the nozzle size, and the operating pressure for delivering the medication subcutaneously without a needle.

[0004] The jet injector includes a metallic cylinder enclosed on one end, such as with a plug or cap, and open on the other end for receiving the ampule. Within the cylinder, the components of the jet injector generally include a spring, a piston, a shaft, a plunger, and a trigger. The jet injector device operates by cocking or compressing the spring, which is in mechanical communication with the piston. The trigger is used to set off the spring, which drives the piston, which then drives the shaft, and which then drives the plunger into the medication to discharge the medication out the nozzle at the distal end of the ampule. A typical operating pressure for a jet injector device to deliver medication subcutaneously without a needle is in the range of about 3,000 to 3,500 psi at the nozzle, with a much higher pressure range of about 5,000 to 6,000 psi developed during the initial thrust of the piston. Thus, a suitable ampule for use with the jet injector is one that is capable of handling the aforementioned pressure range.

[0005] Subsequent to discharging the medication, the ampule, plunger, and shaft may be separated from the jet injector and be disposed of. The injector, however, can be re-used by resetting the spring, as disclosed in the '911 patent. A new ampule, plunger, and shaft may then be connected to the jet injector by threading the ampule into the receiving end of the cylinder of the jet injector.

[0006] Another hypodermic jet injector example is disclosed in Ser. No. 09/751,525 filed Dec. 29, 2000 and entitled "Low Cost Disposable Needleless Injector System for Variable and Fixed Dose Applications", the content of which is incorporated herein by reference. The '525 serial number discloses a jet injector assembly designed for low cost production and for disposability after a single use. The disposable jet injector assembly generally comprises an ampule threadedly or permanently attached to a jet injector. Within the jet injector, the device includes a spring that is in dynamic communication with a shaft and a piston. The shaft is coaxially disposed within the piston and is moveable or slidable within the piston even when the piston is in a cocked position. However, the disposable jet injector generally comes pre-cocked or pre-set in a package from the factory and only requires filling the ampule with medication at the point of injection. The shaft has a length such that a portion of the shaft extends out from the jet injector housing to facilitate filling the ampule, by grasping and moving the extended shaft portion.

[0007] The ampule is threadedly or permanently fixed to the jet injector by adhesive, heat, or ultrasonic welding. The shaft, via the extension, allows medication to be drawn into the ampule when it is retracted from a first position to a second position, which creates a vacuum in the ampule to thereby draw in medication. The injector assembly is used by placing the discharge nozzle next to a skin and then firing the trigger, as discussed above with reference to the re-useable jet injector model.

[0008] Although both the disposable and the re-useable jet injector assemblies are effective, reliable, and economical, they suffer from at least one shortcoming. Among other things, they utilize thermoplastic ("plastic") ampules for manufacturability and for high-pressure compatibility. Plastic is relatively ductile, has a low modulus of elasticity, is highly impact resistant, and components that are made from plastic are relatively easy to fabricate. However, plastic ampules produced from plastic are generally not suitable for long term storage of medications, injectable suspensions, or the like. This is because certain ingredients that are added during the fabrication process of the plastic ampules can leach into the medication. Certain drugs or components of the drugs are also known to bind with the plastic or be absorbed by the plastic. Oxidation, degradation, and/or precipitation of the medication are also known to occur with prolonged storage of the medication in plastic ampules. It is also possible for a component of the drug to migrate through the walls of the plastic ampule, and oxygen, carbon dioxide, or other gasses may pass through the plastic into the drug. Hence, plastic ampules are generally not FDA approved for long term storage of medications and injectable suspensions.

[0009] ASTM Type I Class A and United States Pharmacopeia (USP) Type I glass are FDA approved glass for prolonged storage of medications and injectable suspensions. However, glass has a high modulus of elasticity and is highly brittle. Thus, if an ampule is made from glass, the ampule has to be sufficiently thick in order to have the hoop strength necessary to accommodate an operating pressure of about 3,000 to 3,500 psi, and about 5,000 to 6,000 psi at the start of the injection cycle. A glass ampule that is capable of withstanding this pressure range, however, can be expensive, unsightly, and undesirable when used in connection with the jet injectors described.

[0010] There is therefore a need for a multi-component ampule that is useable with conventional jet injectors, that is capable of long term storage of medications and injectable

suspensions, and that uses FDA approved materials. Additionally, there is also a need for a method of using the multi-component ampule with the conventional jet injectors.

SUMMARY OF THE INVENTION

[0011] The present invention specifically addresses and alleviates the above-mentioned deficiencies associated with the prior art assemblies. More particularly, the present invention comprises a multi-component ampule which has an inner FDA approved glass cylinder, an outer plastic housing, and an FDA approved elastomeric nozzle. Together, these components define a medicine space that is suitable for storing medications and the like for prolonged periods. The glass and the elastomer provide FDA approved primary packaging components while the plastic outer shell provide acceptable secondary packaging containment and reinforcement.

[0012] Exemplary multi-component ampules provided in accordance with practice of the present invention include ampules that have a primary packaging component and a secondary packaging component. Broadly speaking, the multi-component ampule is characterized by an inner cylinder of a first material, an outer shell of a second material, and a diaphragm of a third material.

[0013] While the primary packaging component is configured for contacting with the medication for prolonged periods, the secondary packaging component is configured for reinforcing and for covering the primary packaging component so that the primary component may be kept to a minimum thickness.

[0014] The ampules discussed herein are configured for used with either reusable spring injectors or disposable spring injectors. Depending on the connection point between the multi-component ampule and the jet injector, the ampule's outer plastic housing may be modified to permanently attach or threadedly attach to the jet injector.

[0015] Broadly speaking, the preferred multi-component ampule comprises an outer shell of a first material, an inner cylinder of a second material, and a nozzle section of a third material connected to a jet injector, which comprises a piston compressing a spring and being held by an engagement member located within a housing, wherein when the engagement member is released from the piston, the piston advances a shaft proximally to discharge the medication contained within the multi-component ampule out from the nozzle.

[0016] Thus, according to the embodiments disclosed herein, multi-component ampules with FDA approved materials for primary packaging components are useable with various conventional injector mechanisms to facilitate the administration of injections such as vaccines, hormones, local anesthetics and insulin.

[0017] It is understood that changes in the specific structure shown and described may be made within the scope of the claims without departing from the spirit of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] These and other features, aspects and advantages of the present invention will be more fully understood when considered with respect to the following detailed description, appended claims and accompanying drawings, wherein:

[0019] **FIG. 1** is a semi-schematic cross-sectional view of an exemplary multi-component ampule provided in accordance with practice of the present invention;

[0020] **FIG. 2** is a semi-schematic cross-sectional view of an outer shell shown separated from the multi-component ampule of **FIG. 1**;

[0021] **FIG. 3** is a semi-schematic cross-sectional view of a diaphragm shown separated from the multi-component ampule of **FIG. 1**;

[0022] **FIG. 4** is a semi-schematic cross-sectional view of an inner cylinder shown separated from the multi-component ampule of **FIG. 1**

[0023] **FIG. 5** is a semi-schematic end view of a cap cover shown separated from the multi-component ampule of **FIG. 1**;

[0024] **FIG. 6** is a semi-schematic cross-sectional view of the cap cover of **FIG. 5** taken at line **6-6**;

[0025] **FIG. 7** is a semi-schematic end view of a cap seal shown separated from the multi-component ampule of **FIG. 1**;

[0026] **FIG. 8** is a semi-schematic cross-sectional view of the cap seal of **FIG. 7** taken at line **8-8**;

[0027] **FIG. 9** is a semi-schematic cross-sectional view of a threaded nipple shown separated from the multi-component ampule of **FIG. 1**;

[0028] **FIG. 10** is a semi-schematic side view of an exemplary plunger provided in accordance with practice of the present invention;

[0029] **FIG. 11** is a semi-schematic side view of an alternative plunger provided in accordance with practice of the present invention;

[0030] **FIG. 12** is a semi-schematic side view of an exemplary shaft coupled to yet another alternative plunger provided in accordance with practice of the present invention;

[0031] **FIG. 13** is a semi-schematic cross-sectional view of the ampule shown in **FIG. 1** in a filled state;

[0032] **FIG. 14** is a semi-schematic cross-sectional view of the ampule shown in **FIG. 13** with a protective housing provided in accordance with practice of the present invention covering a portion of the shaft;

[0033] **FIG. 15** is a semi-schematic cross-sectional view of an exemplary re-useable jet injector assembly with the ampule of **FIG. 1** provided in accordance with practice of the present invention;

[0034] **FIG. 16** is a semi-schematic cross-sectional view of the re-useable jet injector assembly of **FIG. 15** in a spent or discharged state;

[0035] **FIG. 17** is a semi-schematic cross-sectional view of an exemplary disposable jet injector assembly with the ampule of **FIG. 1** provided in accordance with practice of the present invention;

[0036] **FIG. 18** is a partial semi-schematic cross-sectional view of the disposable jet injector assembly of **FIG. 17** with modified attachments between the jet injector and the ampule;

[0037] **FIG. 19** is a semi-schematic cross-sectional side view a multi-component ampule that has a recessed section on the distal end of the outer shell with a protective housing provided in accordance with practice of the present invention;

[0038] **FIG. 20** is a semi-schematic cross-sectional side view of the outer shell of **FIG. 19**; and

[0039] **FIG. 21** is a semi-schematic cross-sectional side view of a disposable jet injector assembly having a multi-component ampule threaded to a jet injector.

DETAILED DESCRIPTION

[0040] The detailed description set forth below in connection with the appended drawings is intended as a description of the presently preferred embodiments of the multi-component ampule in accordance with the present invention and is not intended to represent the only forms in which the present invention may be constructed or utilized. The description sets forth the features and the steps for constructing and using the multi-component ampule of the present invention in connection with the illustrated embodiments. It is to be understood, however, that the same or equivalent functions and structures may be accomplished by different embodiments that are also intended to be encompassed within the spirit and scope of the invention. Also, as denoted elsewhere herein, like element numbers are intended to indicate like or similar elements or features.

[0041] Referring now to **FIG. 1**, there is shown a multi-component ampule (herein "ampule") provided in accordance with practice of the present invention, which is generally designated **10**. The ampule **10** shown is connected to a jet injector **12** (partially shown), which may be a disposable or a reusable type jet injector, via a threaded nipple **14**. Broadly speaking, the ampule **10** shown includes an inner cylinder **16**, an outer shell **18**, a diaphragm **20**, and a cap cover **22**, herein collectively referred to as components. Together, the components provide long-term storage capability and allow the ampule **10** to be used in high-pressure applications, such as those discussed further below.

[0042] In an exemplary embodiment, the inner cylinder **16** is made from an FDA approved glass for packaging human drugs and biological products, which currently includes ASTM Type I, Class A, and United States Pharmacopeia (USP) Type I glass. However, materials other than glass are contemplated to be used for the inner cylinder **16** provided they meet FDA requirements for long term storage of injectable human drugs. These alternative materials may include Type II glass, certain plastic, and certain elastomeric components which comply with USP Elastomeric Closures for Injections requirements. Such alternative materials may include polypropylene and silicone polymer.

[0043] Materials for the outer shell **18** and the cap cover **22** are made from plastic such as polycarbonate, acrylonitrile-butadiene, or the like. Materials for the diaphragm **20** and the plunger **23** are preferably made from an elastomer such as silicone rubber, fluroelastomer and the like. As will be appreciated, the outer shell **18** is preferably transparent so that the contents may be observed during shipment and during use, such as before an injection. Together the diaphragm **20**, the plunger **23**, and the inner cylinder **16** make up part of the primary packaging containment while the outer shell **18** and the cap cover **22** make up part of the secondary packaging containment.

[0044] Also shown in **FIG. 1** is a plunger **23** and a shaft **24** disposed within the inner cylindrical bore **26** of the inner cylinder **16**. The plunger **23** is shown pushed against the diaphragm **20** as if in a fired position or a position wherein the jet injector **12** is spent, as further discussed below. The position shown also depicts a ready position for filling the ampule **10** with medication, for example, by removing the cap cover **22**, placing the tip into a medicine vial and moving the shaft proximally to draw in the medication. As shown, the plunger **23** is in a sealing engagement with the internal surface of the inner cylinder **16**, as further discussed below.

[0045] A resilient cap seal **27** is shown compressed between the cap **22** and the diaphragm **20** at the distal end of the ampule (**FIG. 1**). The cap seal **27** is disposed between the cap cover **22** and the distal end of the ampule **10** and is configured to be compressed by the cap and the diaphragm to provide compliance for the nozzle **28**. When the ampule **10** is filled with medication (for example at the factory), the compressed cap seal **27** prevents the medication from leaking from the inner cylinder **16** via the nozzle **28** and as well as preserves the medication's sterility by preventing contaminants from passing through the nozzle and into the medication. Alternatively, instead of utilizing the cap seal **27** to seal the nozzle **28**, the present embodiment may be practiced by configuring the cap **22** with a thicker cap ridge portion **30**. This cap ridge portion **30** can then contact the diaphragm **20** at about the nozzle **28** to directly compress the nozzle. The diaphragm **20**, as previously discussed, is made from an elastomer and is therefore resilient in nature. The diaphragm's resiliency allows it to be compressed against the cap ridge portion **30** to thereby provide a seal for the nozzle **28**, without the need for a cap seal **27**.

[0046] Referring now to **FIG. 2**, there is shown the outer shell **18** provided in accordance with practice of the present invention. In an exemplary embodiment, the outer shell **18** is an integrally molded unit that has a cylindrical body **32**, a distal end **34**, and a proximal end **36**. At the distal end **34**, the outer shell **18** includes an end wall **38** with an end opening **40** centrally located therein. The distal end **34** also includes external threads **42** for engaging with the cap cover **22**. However, instead of having external threads **42** to engage the cap, an aluminum shield can be removeably bonded to the outside surface of the end wall **38** to provide the necessary seal for the nozzle **28**, which is similar to a seal in an over-the-counter medicine container.

[0047] At the proximal end **36**, there is shown a set of internal threads **44** and an enlarged portion **45**. The internal threads **44** are configured to engage with the threaded nipple **14** (**FIG. 1**) for coupling the ampule **10** to the jet injector **12**. However, as further discussed below in connection with **FIG. 18**, instead of having the internal threads **44** at the proximal end, the outer shell **18** can include a smooth tapered sleeve. The tapered sleeve would allow the outer shell to telescopically fit over or into the distal end of the jet injector and be permanently affixed to the jet injector by either adhesive or welding. The enlarged portion **45** distal of

the threads **44** is a relief point for a machine tool, which may otherwise be eliminated if the threads **44** were molded instead of machined.

[**0048**] Referring now to **FIG. 3**, there is shown a diaphragm **20** provided in accordance with practice of the present invention. The diaphragm includes a base portion **46**, a top portion **48**, and a protrusion **50**, which comprises the nozzle **28**. The base portion **46** includes a base **52** and a cross-sectional area that is proximate the cross-sectional area **47** of the cylindrical bore **41** (**FIG. 2**). The top portion **48** has a cross-sectional area that is proximate the cross-sectional area of the end opening **40**. The diaphragm **20** is configured to slidingly engage with the cylindrical bore **41** of the outer shell **18** and rests within the bore at the distal end of the outer shell. In this rested position, the top portion **48** is received within the end opening **40** and is seated flushed with the external end surface of the end wall **38** (**FIG. 1**). The protrusion **50**, however, projects outward from the flushed top portion **48** to provide a distinct contact point for the nozzle **28** when placed against the skin for injection. In an exemplary embodiment, the fit between the base portion **46** and the cross-sectional area **47** of the bore **41**, and between the top portion **48** and the end opening **40** of the outer shell is preferably about zero to two thousandths total clearance.

[**0049**] As shown in **FIG. 3**, the diaphragm **20** further includes a beveled cutout **54** that terminates into an orifice **56**. The combination of the cutout **54** and the orifice **56** resembles a funnel and defines the nozzle **28** for discharging the medication. In an exemplary embodiment, the orifice **56** has an opening of about 0.005 to 0.010 inch, with a range of about 0.006 to 0.008 inch being more preferred.

[**0050**] Referring now to **FIG. 4**, there is shown an inner cylinder **16** provided in accordance with practice of the present invention. In an exemplary embodiment, the inner cylinder **16** is a cylindrical glass tube that has a first end **56***a* and a second end **56***b*. The inner cylinder **16** has an outer circumferential surface **58** configured to matingly abut against the cylindrical bore **41** of the outer shell **18**. The inner cylinder includes the inner bore **26** for containing medication, as previously discussed. When the multi-component ampule **10** is assembled (**FIG. 1**), the inner cylinder **16** is configured to abut against the base **52** of the diaphragm **20** by its first end **56***a* and against the threaded nipple **14** by its second end **56***b*. The contact at the first end **56***a* is referred to as the first interface **62** and the contact at the second end **56***b* is referred to as the second interface **64**. When the threaded nipple **14** is engaged and tightened against the internal threads **44**, the first **62** and the second **64** interfaces are loaded and the seams defined by the interfaces are sealed from leakage (**FIG. 1**).

[**0051**] Glass is highly brittle and has a high modulus of elasticity. Glass also has a narrow proportional limit and readily fails with minimum induced strain. Thus, if a glass ampule is used with a jet injector, the glass ampule will break and will explode unless it is adequately thick. This is because a pressure of about 3,000 to 3,500 psi, and about 5,000 to 6,000 psi at the start of the injection, is generally required to administer drugs subcutaneously without a needle. In the multi-component ampule **10** provided in accordance with practice of the present invention, the inner cylinder **16**, which is made from glass, is braced by the plastic outer shell **18** for reinforcement. Together, the plastic outer shell **18** and the glass inner cylinder **16** have a combined hoop strength that is sufficient to contain the pressure generated by the jet injector **12** without making the glass unnecessarily thick.

[**0052**] For the outer shell **18** to adequately brace or reinforce the inner cylinder **16**, the slack or clearance between the cylindrical bore **26** of the outer shell and the outer circumferential surface **58** of the inner cylinder should be sufficiently tight. In an exemplary embodiment, the clearance between the outer shell **18** and the inner cylinder **16** is preferably "hand-tight". That is, when the inner cylinder **16** is inserted into the outer shell **18**, the insertion should not require tools or machines but only a force produceable by the hand. In other words, the fit between the components can be a non-interference fit. Examples of hand-tight clearance is clearance ranging from about zero to four thousandths total clearance, with about zero to two thousandths total clearance being preferred, and with about zero to one thousandths total clearance being more preferred. Examples of the inner cylinder **16** wall thickness can range from about 0.07 to 0.095 inch with 0.083 inch being more preferred. Examples of the outer shell **18** wall thickness can range from about 0.085 to 0.15 inch with 0.09 to 0.10 inch being more preferred. A person of ordinary skill in the art can appreciate that other thickness and total clearances other than the aforementioned ranges can be implemented and that these figures are exemplary only. Indeed, by changing the operating pressure, by using a glass compound, by using different plastic, by using a thinner glass and a heavier shell, etc., the fit between the inner cylinder and the outer shell and the wall thickness of the individual components can vary. Thus, such variations are contemplated to fall within the scope of the present invention.

[**0053**] Referring now to **FIG. 5** and **6**, there is shown a cap cover **22** provided in accordance with practice of the present invention. The cap cover **22** comprises internal threads **66** for threadedly engaging the external threads **42** located on the outer shell **18**. The cap cover **22** includes a relief point **68** for machining the internal threads **66** but may be eliminated if the threads were molded rather than machined.

[**0054**] The cap cover **22** also includes an end wall **70** and a recessed portion **72** centrally disposed thereon. The recessed portion **72** is configured to receive a cap seal **27** (**FIGS. 1, 7**, and **8**). As previously discussed, the cap seal **27** provides the necessary seal to the nozzle **28** when compressed by the cap cover **22** and the protrusion **50** located on the diaphragm **20**. The cap seal **27** may be made from a number of FDA approved soft rubber or elastomer, such as silicone rubber. Still referring to **FIG. 5**, there is shown a series of serration members **74** circumferentially disposed along the exterior surface of the cap cover **22** for better gripping the cap cover when the same is removed. However, a smooth exterior cap surface, a dispersed array of bumps or similar gripping means may also be practiced without deviating from the scope of the invention.

[**0055**] Referring now to **FIGS. 7 and 8**, there is shown a cap seal **27** provided in accordance with practice of the present invention. The cap seal **27** shown can be made from a variety of FDA approved elastomers or thermoplastics, such as silicone rubber and PTFE. The cap seal **27** resembles

a coin in that it is circular, has a thickness X, and a cross-sectional area. The cross-sectional area is configured to fit within the recessed portion **72** located on the end wall **70** of the cap cover **22**. The fit between the cap seal **27** and the recessed portion **72** is slightly interference to slightly positive clearance. The cap seal **27** is configured to be compressed by the cap cover **22** and the nozzle **28** to provide a seal for the orifice **56**. Preferably, the cap seal **27** provides about 0.005 to 0.030 inch compression when compressed by the cap cover and the nozzle, with a range of about 0.008 to 0.015 inch being more preferred.

[**0056**] Referring now to **FIG. 9**, there is shown a threaded nipple **14** provided in accordance with practice of the present invention. In an exemplary embodiment, the threaded nipple **14** is symmetrical about a center flange **76** and has male threads **78** disposed on either side of the flange. The threaded nipple **14** also includes a bore **80**, which acts as a channel to allow communication between the jet injector **12** and the ampule **10**.

[**0057**] It can be appreciated that the threaded nipple **14** can be nonsymmetrical and may depend on the relative dimensions of the receiving end of the jet injector **12** and the size of the proximal end **36** of the outer shell **18**. For instance, the receiving end of the jet injector **12** may have a 0.5 inch threaded opening and the proximal end **36** of the outer shell **18** may have a 0.7 inch threaded opening. The threaded nipple **14** therefore will be non-symmetrical in order to accommodate the two different dimensions.

[**0058**] As discussed above, a plunger is configured to move from a proximal position to a distal position in the ampule **10** when the jet injector is fired to expel the medication out of the nozzle **28** (**FIG. 1**). The plunger moves by the action of the spring located within the jet injector, which is configured to push the piston, which then pushes the shaft, which then pushes the plunger to discharge the medication. The distal movement of the plunger compresses the medication and builds up pressure as it compresses the medication within the ampule space to deliver the necessary medication subcutaneously. The ampule space will herein be referred to as a variable medicine space, which is defined by the space between inner bore **26**, the diaphragm **20**, and the plunger. For reference purposes, this variable medicine space is labeled as medicine space **61** (**FIG. 13 & 14**, and further discussed below). The volume defined by the variable medicine space **61** will vary depending on the location of the plunger within the ampule **10**.

[**0059**] For pressure to adequately build within the medicine space **61** to a working pressure of about 3,000 to 3,500 psi, and about 5,000 to 6,000 psi at the start of the injection, the plunger must maintain a seal against the glass inner cylinder **16** as it travels distally in the inner bore **60** to discharge the medication out the nozzle **28**. Leakage or blow-by of medication around the moving plunger should therefore be reduced to a minimum or even be eliminated as leakage will decrease the pressure buildup generated by the advancing plunger

[**0060**] Referring now to **FIGS. 10 and 11**, there is shown exemplary plungers **82**, **84** provided in accordance with practice of the present invention. The exemplary plungers **82**, **84** provide satisfactory sealing against the inner bore **26** of the glass cylinder **16** for building necessary operating pressure. Referring specifically to **FIG. 10**, the plunger **82** shown is symmetrical and includes two pusher ends **86**, three marker rings **88**, and two wells **90**. The plunger **82** is symmetrical about the center marker ring **88** and is preferably practiced with a disposable jet injector, for reasons further discussed below. Due to its symmetrical configuration, the plunger **82** may be placed into the inner bore **26** of the glass cylinder **16** with either pusher end **86** in first. This flexibility facilitates automation by allowing a robotic machine to insert the plunger **82** into the ampule irrespective of the plunger orientation.

[**0061**] The plunger **84** shown in **FIG. 11** is an alternative plunger. The plunger **84** is symmetrical about the center and includes two pusher ends **86**, two marker rings **88**, and one well **90**. Both plungers **82**, **84** may be made from an acceptable FDA approved elastomer such as silicone, ethylene-propylene-diene (EPDM), and the like. Alternatively, the plungers **82**, **84** may have more than three marker rings, may have one or more marker rings with one or more a seal rings **88** (**FIG. 12**) or any combination thereof.

[**0062**] Referring now to **FIG. 12**, there is shown a shaft **24** with an over-molded plunger **23** on one end and an integrally molded ribbed section **92** on the other end. The integrally molded ribbed section **92** is configured to be pushed against by a piston as the piston is propelled by a spring to launch the plunger **23** into the inner bore **26** of the glass cylinder **16** towards the diaphragm **20** located at the distal end of the ampule **20** (**FIGS. 1 and 15**). The plunger **23** shown is another alternative plunger which includes a pusher end **86**, a receiving end **92**, a marker ring **88**, a seal ring **94**, and a well **90**. The seal ring **94** is similar to the marker ring **88** except it is slightly wider and provides more surface contact with the inner bore **26** of the inner cylinder **16**. The plunger **23** is removeably connected and co-molded to the shaft as described in the '525 serial number. The shaft **24** may be made from a number of plastic materials such as ABS, AB, polycarbonate, PVC plastic with fiberglass injection, and the like. The shaft **24** with the over-molded plunger **23** is preferably used with the reusable injector.

[**0063**] **FIG. 13** shows the multi-component ampule **10** in a filled position or ready position. The ampule **10** may be filled with medication in a sterile environment and packaged in the configuration shown. In the filled position, the shaft **24** is drawn proximally and extends beyond the proximal end of the nipple **14**. Medicine or injectable suspension of predetermined quantity is filled within the medicine space **61**, which is the space defined by the glass inner bore **60**, the diaphragm **20**, and the plunger **23**. In this filled position, the plunger **23** is withdrawn proximally but still remains in contact with the glass inner cylinder **16**. That is, the plunger **23** does not move proximally beyond the proximal end of the inner cylinder **16**, such as into the bore **80** of the nipple **14**. By limiting the maximum proximal movement of the plunger **23**, the medicine that is filled within the medicine space **61** is only in contact with FDA approved package materials for long term storage. This ensures prolonged storage capability when the medication is only in contact with the primary packaging containment, which includes the inner cylinder **16**, the plunger **23**, and the diaphragm **20**. Optionally, the exterior surface of the ampule **10** (i.e., the outer shell **18**) may have markings to identify the level or volume of medication that is filled within the ampule.

[**0064**] The filled multi-component ampule **10** shown in **FIG. 13** is configured to be received by a jet injector, such

as those shown in FIGS. **15-17**, shown in U.S. Pat. Nos. 5,499,972; 5,569,189; and 5,704911; and shown in Ser. No. 09/751,525. The jet injector may receive the ampule **10** by threading the nipple **14** into a threaded end of the jet injector **(FIG. 15)** or by permanently attaching the ampule via adhesive or welding with the jet injector **(FIG. 18)**.

[**0065**] Turning to **FIG. 14**, there is shown a filled multi-component ampule **10**, as discussed in connection with **FIG. 13**, with a protective housing **95** mounted to the proximal end of the threaded nipple **14**. The protective housing **95** can be made from a transparent thin-walled plastic such as polyethylene or polycarbonate. The protective housing **95** includes an open base **96**, an enclosed tip **98**, and a threaded internal bore **100** for threadingly engaging with the nipple **14**. As readily understood, the protective housing prevents the shaft **24** from being accidentally moved or bumped during packaging or shipping. In addition, the protective housing **95** also preserves the sterility of the medication by acting as an enclosure and eliminating leak source or path that can contaminate the medication. Although the protective housing **95** is shown with a tapered neck **102**, the protective housing can have the shape of a uniform cylinder or any variation thereof provided it serves the aforementioned functions. The filled ampule **10** with the protective housing **95** may be packaged in the manner described in the '525 serial number for shipping and storing. It is understood that the shape of the packages described in the '525 serial number will have to be modified to accommodate the ampule **10** described herein.

[**0066**] Turning to **FIGS. 15 and 16**, there is shown an exemplary use of the multi-component ampule **10** in accordance with practice of the present invention. In an exemplary embodiment, the filled ampule **10 (FIGS. 13 and 14)** can be removed from its packaging material and assembled onto the re-useable jet injector **12** by threading the nipple **14** into the receiving end **96** of the jet injector. Once the filled ampule **10** is installed, the jet injector assembly **98** is ready for injection **(FIG. 15)**.

[**0067**] The re-useable jet injector **12** shown in **FIGS. 15 and 16** is substantially the same as those disclosed in the U.S. Pat. Nos. 5,499,972; 5,569,189; and 5,704,911. Generally speaking, the jet injector **12** shown in **FIGS. 15 and 16** includes an injector housing **100**, a main spring **102** for driving a piston **104** against the shaft **24**, which in turn drives the plunger **23** into the medicine space **61** to discharge the medicine out of the nozzle **28**. The jet injector **12** also includes a trigger **106** that is pivoted on a pivoting pin **108** and held in an inward direction by a secondary spring **110**. The trigger **106** is mechanically connected to a trigger extension arm **112**, which provides the means for depressing or activating the trigger.

[**0068**] A safety ring **114** is provided at the distal end of the jet injector **12** that is in sliding engagement with a plastic sleeve **116**. When the safety ring **114** is engaged, by sliding the safety ring proximally with respect to the plastic sleeve **116** until it comes to rest under the trigger extension arm **112**, a downward movement by the trigger extension arm **112** about the pivoting pin **108** is delimited by the safety ring. The plastic sleeve **116** is in concentric relationship with the jet injector **12** and may be secured to the distal end of the jet injector by detents, tongue and groove means, fasteners, adhesive, or the like.

[**0069**] The main spring **102** is held in a compressed or cocked position by the trigger's engagement tip **118**, which engages the flange **119** on the piston **104**. As readily apparent, disengagement of the engagement tip **118** from the piston **104** by depressing on the trigger extension arm **112** will cause the main spring **102** to uncoil and propel the piston **104** distally. When so propelled, the piston **104** moves distally and pushes against the shaft's receiving end **92**, which pushes the shaft **24** distally. As previously discussed, this causes the plunger **23** to propel forward and compresses the medication, which then discharges out of the nozzle **28**. It is understood that the cap **22** must be removed and the nozzle **28** placed against the skin of a patient before the trigger is fired for an effective delivery.

[**0070**] **FIG. 16** shows the jet injector assembly **98** of **FIG. 15** in a fired or discharged state. As shown, the trigger extension arm **112** is depressed, the main spring **102** is fully uncoiled, the piston **104** is advanced distally against a stop member **120**, and the shaft **24** and plunger **23** are advanced distally toward the diaphragm **20**. It can be appreciated that the plunger **23** is preferably advanced until it contacts the diaphragm **20** so that all or substantially all of the medication is discharged out of the nozzle and into the patient **(FIG. 16)**. This maximum distal travel minimizes wastes, as certain medications can be quite costly. Although the trigger extension arm **112** is shown depressed **(FIG. 16)**, the trigger extension arm should pivot radially outward due to the secondary spring **110 (FIG. 15)** immediately upon release of the trigger extension arm by the user.

[**0071**] Referring now to **FIG. 17**, there is shown an and alternative use for the multi-component ampule **10** with a disposable jet injector provided in accordance with practice of the present invention, generally designated as **122**. The jet injector assembly **122** depicted in **FIG. 17** is a disposable type and resembles the type disclosed in the '525 serial number. The jet injector assembly **122** shown is termed disposable because once the medicine is dispensed following an injection, the entire jet injector assembly **122** is preferably discarded. The multi-component ampule **10** is used with the jet injector **124** by threading the nipple **14** to the receiving end of the jet injector in a similar manner as discussed with the re-useable model **(FIGS. 15 and 16)**. The disposable jet injector **122** is shown in a fired or dispensed position.

[**0072**] Broadly speaking, the disposable jet injector **124** includes a housing **125**, a main spring **126**, a piston **128**, a shaft **130**, a trigger **132**, and a safety device **134**. The shaft further includes a gripping ball **140**, a shoulder **136**, and first and second cushion members **138*a***, **138*b*** for limiting the distal movement of the shaft **14**. This is implemented by configuring the cushion member **139*b*** to abut the end of the nipple **14** when the shaft is propelled distally during an injection. The gripping ball **140** at the proximal end of the shaft **130** provides a gripping surface for a gripping tool (not shown) to grip and load or cock the main spring **126**, as discussed in the '525 serial number.

[**0073**] When the shaft **130** is grasped and drawn proximally (towards the left of **FIG. 17**), the cushion member **138*b*** pushes against the piston **128**, at the drum portion **135** of the piston. As the shaft **130**, cushion member **138*b***, and drum portion **135** moves proximally past the engagement tip **123** located on the trigger **132**, the engagement tip **123**

pivots downward, about a pivot point **129**, to lock the piston and the spring **126**. The contact between the engagement tip **123** and the drum portion **135** of the piston **128** maintains the spring **126** in the compressed position until the jet injector is fired (not shown). As disclosed in the '525 serial number, subsequent to cocking the jet injector assembly **122** by grasping and pulling on the shaft to lock the drum portion **135** against the engagement tip **123**, the shaft remains freely moveable. That is, the shaft **126** still freely moves within the piston **128**, as the shaft is coaxially disposed within the piston.

[**0074**] In an exemplary embodiment, the shaft **130** has a substantially flat distal end **131** (**FIG. 17**) and is not coupled to the plunger **82**, which is preferably of a symmetrical type plunger. The advantage of using a symmetrical plunger is that the disposable jet injector assembly **124** is contemplated to be assembled automatically by robotic machines. Therefore, having components that are symmetrical or that are easily recognizable by the robotic machines will facilitate the automation process. Thus, the shaft distal end **131**, since it does not attach to the plunger **82**, can take on a number of configurations including a beveled end, a cone end, a flat end, etc.

[**0075**] As readily apparent, the disposable jet injector assembly **122** shown is intended to be pre-filled and packaged with medication at the factory (as the shaft **130** and the plunger **82** are not attached to provide means for filling the ampule **10**). The pre-filled multi-component ampule **10** may be packaged and shipped either as two separate components (with the multi-component **10** pre-filled and separately packaged from the disposable jet injector) or pre-filled and packaged together as shown in **FIG. 17**. In an injection application for a separately packaged embodiment, the user simply removes the packaging material from both the disposable jet injector and the multi-component ampule and then thread the nipple **14** onto the disposable jet injector housing. Then depending on the dosage needed, the user may move the shaft **130** distally, after removing the cap **22**, to release excess medication contained within the ampule.

[**0076**] Although shown with the symmetrical plunger, the disposable jet injector assembly **122** may also be practiced with the plunger co-molded or attached to the shaft **130** and packaged with the spring pre-cocked at the factory. In this alternative application, when the end user uses the jet injector assembly **122**, he or she will have to fill the multi-component ampule **10** with medication by grasping and pulling the shaft proximally to draw in the medication.

[**0077**] **FIG. 17** shows the disposable jet injector assembly **124** in a fired or discharged state (as the spring is released). Thus, it is understood that the end cap **22** should be removed from the ampule **10** before the trigger **132** is depressed to deliver the medication subcutaneously. Although **FIG. 17** shows the plunger **82** spaced apart from the diaphragm, it is understood that the present embodiment is preferably practiced with the plunger **82** moved completely distally until it touches the diaphragm to thereby ensure that all the mediation is discharged and not wasted by remaining in the medicine apace **61**.

[**0078**] Referring now to **FIG. 18**, there is shown an alternative interface for connecting a modified multi-component ampule **141** to the disposable jet injector **124**. In the alternative embodiment, the proximal end of the outer shell **18** of the modified multi-component ampule **141** is configured to include an integrally molded coupler **142** rather than internal threads **44** as discussed with reference to **FIGS. 1 and 2**. The modified outer shell **18** can be filled with medication in a sterile environment with the cap **22** and the plunger **82** acting as seals to preserve the sterility of the medication.

[**0079**] In a corresponding fashion, the disposable jet injector **124** is configured to include an integrally molded sleeve **144**. The coupler **142** on the ampule **141** is configured to fit over the sleeve **144** on the disposable jet injector **124**. Once the coupler and the sleeve are mated, the interface between the two can be welded by heat or ultrasound or permanently affixed via adhesive. Still alternatively, the coupler **142** may be molded with spaced apart ridges **146** so that after the coupler is fitted with the sleeve **144**, heat or ultrasonic energy may be applied to the interface region to cause the ridges to melt and to fuse the jet injector and the ampule together. When implemented, the fusion provides for a more permanent attachment.

[**0080**] **FIG. 19** shows an alternative multi-component ampule **150** having a generally flushed nozzle in a filled state with a protective housing **95** provided in accordance with practice of the present invention. The alternative multi-component ampule **150** includes essentially the same components as the multi-component ampule **10** disclosed with reference to **FIGS. 1 and 14**. For example, multi-component ampule **150** includes essentially the same protective housing **95**, nipple **14**, shaft **24**, plunger **23**, diaphragm **20**, and inner glass cylinder **16**. However, the cap cover **152** and the shell **154** have been modified to provide the multi-component ampule **150** with a flushed diaphragm **20** to outer shell configuration.

[**0081**] Referring specifically to **FIG. 20**, the modified outer shell **154** includes an end wall **156** that has a recessed portion **158** and a tapered cone section **160**, which is also recessed within the end wall. The end wall **156** is configured to receive the diaphragm **20** in a flushed configuration by having a structure that corresponds to the contour of the diaphragm. For example, the tapered cone section **160** is configured to receive the diaphragm's protrusion **50**, the recessed portion **158** is configured to receive the diaphragm's top portion **48**, and the cylindrical bore **41** is configured to receive the diaphragm's base portion **46**. As a result, the nozzle **28** located on the diaphragm **20** is positioned flushed or substantially flushed with the end exterior surface of the modified outer shell **154** (**FIG. 19**).

[**0082**] With a flushed or substantially flushed diaphragm **20** to outer shell **154** arrangement, the cap cover **152** is modified to include a relatively shallower recessed portion **72** than the cap cover **22** shown in **FIGS. 1 and 6**. Among other things, this modification is implemented to take up the space that is vacated by the diaphragm's protruding nozzle section **28**, **50**. As readily apparent, by molding the cap ridge portion **30** with a relatively thicker dimension than the same dimension shown in **FIGS. 1 and 6**, the same cap seal **27** may be used to provide the necessary compliance or crushed to properly seal the nozzle **28** from leak/contamination. Alternatively, the cap cover **152** can be the same as the previously described cap cover **22** (**FIG. 6**) but the cap seal **27** is modified to have a wider thickness X' to provide the necessary compliance or crushed to seal the nozzle **28**.

Under either scenario, a cap seal **27** compression of about 0.005 to 0.030 inch is preferred, with a range of about 0.008 to 0.015 inch being more preferred.

[**0083**] Use of the multi-component ampule **150** shown in **FIG. 19** is the same as for the multi-component ampule **10** shown with reference to FIGS. **15-17**.

[**0084**] Referring now to **FIG. 21**, there is shown an alternative disposable jet injector assembly **162**, which incorporates a threaded male nipple **164** into the distal end of a disposable jet injector **166** to directly couple with the multi-component ampule **150**. In directly coupling the jet injector **166** with the multi-component ampule **150**, the threaded nipple **14**, which is used with the disposable jet injector assembly shown in **FIG. 17**, is eliminated. Although the jet injector **166** is shown without a spring, the spring is assumed to be disposed in between the piston **128** and the housing **125**, and coaxially over the shaft **130**, similar to **FIG. 17**.

[**0085**] The jet injector assembly **162** is shown in a filled state, with The multi-component ampule **150** having a symmetrical plunger **82** disposed near the proximal end of the inner glass cylinder **16** and medicine contained within the medicine variable space **61**. Preferably, medicine is separately pre-filled in the multi-component ampule **150**, under a sterile environment, before it is assembled onto the jet injector **166**. Preferably, the pre-filled multi-component ampule **150** is then assembled onto the jet injector **166** and the assembled disposable jet injector assembly **162** packaged for storage and/or shipping.

[**0086**] Although the preferred embodiments of the invention have been described with some specificity, the description and drawings set forth herein are not intended to be delimiting, and persons of ordinary skill in the art will understand that various modifications may be made to the embodiments discussed herein without departing from the scope of the invention, and all such changes and modifications are intended to be encompassed within the appended claims. Various changes to the ampule may be made including manufacturing the dimensions differently, using different FDA approved materials, changing the tolerances, etc. Other example of changes may include modifying the way the ampule is connected to the jet injector, the way the shaft and the piston are shaped/configured, and the way the plunger is shaped/configured. Accordingly, many alterations and modifications may be made by those having ordinary skill in the art without deviating from the spirit and scope of the invention.

What is claimed is:

1. A multi-component ampule comprising an inner cylinder of a first material, an outer shell of a second material, and a diaphragm of a third material.

2. The multi-component ampule according to claim 1, wherein the outer shell further comprises an opening at a distal end and a bore, wherein at least a portion of the diaphragm is disposed within the opening and wherein the inner cylinder is disposed within the bore.

3. The multi-component ampule according to claim 1, further comprising a re-usable jet injector, the jet injector is threadedly coupled to the ampule by a threaded nipple.

4. The multi-component ampule according to claim 1, further comprising a disposable jet injector, the disposable jet injector is permanently attached to the ampule by adhesive or by welding.

5. The multi-component ampule according to claim 1, wherein the first material is Type 1 glass, the second material is polycarbonate, and the third material is an approved FDA elastomer.

6. A multi-component ampule comprising an outer shell of a first material having a bore, a distal end, and a proximal end, the distal end having external threads and the proximal end having internal threads; an inner cylinder disposed within the outer shell of a second material having an external surface that is hand-tight with the bore of the outer shell, and a diaphragm that is in contact with both the outer shell and the inner cylinder.

7. The multi-component ampule of claim 6, wherein the inner cylinder is made from a glass material.

8. The multi-component ampule of claim 6, wherein the outer shell is made from a polycarbonate material.

9. The multi-component ampule of claim 6, wherein the diaphragm is made from a silicone material.

10. The multi-component ampule of claim 6, further comprising a cap cover threadedly engaged to the external threads.

11. The multi-component ampule of claim 6, further comprising a plunger, the plunger is at least partially disposed within the inner cylinder.

12. The multi-component ampule of claim 7, further comprising a threaded nipple, the threaded nipple is threadedly engaged with the internal threads of the outer shell and imparts a force against the inner shell, which imparts a corresponding force against the diaphragm.

13. The multi-component ampule of claim 8, further comprising a threaded nipple, the threaded nipple is threadedly engaged with the internal threads of the outer shell and imparts a force against the inner shell, which imparts a corresponding force against the diaphragm.

14. The multi-component ampule of claim 11, further comprising a threaded nipple, the threaded nipple is engaged with the internal threads of the outer shell and imparts a force against the inner shell, which imparts a corresponding force against the diaphragm.

15. The multi-component ampule of claim 14, further comprising a shaft and a shaft end, the shaft is partially disposed within the threaded nipple and the shaft end is either located adjacent to the plunger or is attached to the plunger.

16. The multi-component ampule of claim 15, further comprising a protective housing, the protective housing is attached to the threaded nipple and is coaxially disposed over at least a portion of the shaft.

17. The multi-component ampule of claim 6, further comprising medication, the medication is stored within the multi-component ampule.

18. The multi-component ampule of claim 11, further comprising medication, the medication is stored within the multi-component ampule.

19. A multi-component ampule comprising an outer shell of a first material having a bore, a distal end, and a proximal end, the proximal end having a coupler for sliding engagement with a sleeve; an inner cylinder disposed within the outer shell of a second material having an external surface

that is hand-tight with the bore of the outer shell, and a diaphragm that is in contact with both the outer shell and the inner cylinder.

20. The multi-component ampule of claim 17, wherein the inner cylinder is made from a glass material.

21. The multi-component ampule of claim 17, wherein the outer shell is made from a polycarbonate material.

22. The multi-component ampule of claim 17, wherein the diaphragm is made from a silicone material.

23. The multi-component ampule of claim 17, further comprising a safety seal cover attached to a distal end of the outer shell.

24. The multi-component ampule of claim 17, further comprising spaced apart ridges located on the coupler, the spaced apart ridges are configured to melt when exposed to heat.

25. The multi-component ampule of claim 17, further comprising a jet injector, said jet injector comprising a housing and a sleeve located on a distal end of the housing, the sleeve is configured to engage with the coupler.

26. The multi-component ampule of claim 24, further comprising a jet injector, the jet injector comprising a housing and a sleeve located on a distal end of the housing, the sleeve is configured to engage with the coupler.

27. The multi-component ampule of claim 25, wherein the jet injector further comprising a spring, a piston, and a shaft, wherein shaft is coaxially disposed with the piston, and wherein the piston is configured to compress the spring when the shaft is moved proximally.

28. The multi-component ampule of claim 27, wherein the shaft partially extends outside of the housing.

29. The multi-component ampule of claim 27, wherein the piston maintains the spring in the compressed position by engaging with an engagement tip.

30. The multi-component ampule of claim 26, further comprising medication, the medication is stored within the multi-component ampule.

31. The multi-component ampule of claim 17, wherein the outer shell further comprises an end wall having a recessed portion and a tapered portion for receiving the diaphragm.

32. The multi-component ampule of claim 17, wherein the diaphragm is positioned in a recessed portion of the outer shell and is substantially flushed with the outer shell's exterior end surface.

33. The multi-component ampule of claim 31, wherein the recessed portion is configured to receive a base portion of the diaphragm and the tapered portion is configured to receive a nozzle section of the diaphragm.

34. The multi-component ampule of claim 17, wherein the outer shell comprises a proximal end and a distal end, and wherein the distal end comprises an end wall and the proximal end comprises a threaded member.

35. The multi-component ampule of claim 34, wherein a symmetrical plunger is positioned within the inner cylinder.

36. A needleless jet injector assembly comprising a multi-component ampule connected to a jet injector, the multi-component ampule comprises an outer shell of a first material, an inner cylinder of a second material, and a nozzle section of a third material; the jet injector comprises a housing and a piston compressing a spring and being held by an engagement member, wherein when the engagement member is released from the piston, the piston advances a shaft proximally to discharge medication from the nozzle section.

37. The needleless jet injector assembly of claim 36, further comprising a plunger being in contact with the medication, and wherein the plunger is configured to pressurize the medication when the shaft advances proximally.

38. The needleless jet injector assembly of claim 36, wherein the multi-component ampule is connected to the jet injector by a thread engagement or by a coupler to sleeve engagement.

39. The needleless jet injector assembly of claim 36, wherein the shaft is coaxially disposed within the piston and partially extends outside of the housing.

40. The needleless jet injector assembly of claim 36, wherein the multi-component ampule further comprises a cap threadedly engaged to a distal end of outer shell.

41. The needleless jet injector of claim 36, wherein the shaft is positioned end-to-end with the piston.

42. The needleless jet injector of claim 36, wherein the outer shell further comprises an end wall having a recessed portion and a tapered portion for receiving the nozzle section.

43. The multi-component ampule of claim 36, wherein the nozzle section is positioned in a recessed portion of the outer shell and is substantially flushed with the outer shell's exterior end surface.

44. The multi-component ampule of claim 42, further comprising a diaphragm and wherein the recessed portion is configured to receive a base portion of the diaphragm and the tapered portion is configured to receive the nozzle section of the diaphragm.

45. The multi-component ampule of claim 36, wherein the outer shell comprises a proximal end and a distal end, and wherein the distal end comprises an end wall and the proximal end comprises a threaded member.

46. The multi-component ampule of claim 45, wherein a symmetrical plunger is positioned within the inner cylinder.

47. A multi-component ampule comprising an outer shell having external threads at its distal end and internal threads at its proximal end and made from a plastic material, an inner cylinder made from a glass material having a plunger disposed therein, and a nozzle section made from a silicone material; the outer shell has a cap threadedly engaged to its external threads and a nipple threadedly engaged to its internal threads; and wherein the nipple is partially covered by a protective cover, which is connected to the nipple.

48. A method for injecting medication subcutaneously without a needle, the method comprising:

taking a needleless injector assembly and firing a trigger to discharge medication into a skin, wherein the needleless injector assembly comprises:

a multi-component ampule, the multi-component ampule comprises an outer shell made from a first material, an inner cylinder made from a second material, and a nozzle section made from a third material, and

a jet injector, the jet injector comprises a spring, a piston, a shaft, and a trigger for firing the needleless injector assembly.

49. The method of claim 48, wherein substantially all of the jet injector assembly is disposed of after a single injection.

50. The method of claim 48, wherein the multi-component ampule is removable from the jet injector, and wherein only the multi-component ampule is disposed of after a single injection.

51. The method of claim 50, wherein the shaft is disposed of after single injection.

52. The method of claim 48, wherein the multi-component ampule is permanently attached to the jet injector and wherein the multi-component ampule is pre-filled with medication.

53. The method of claim 48, wherein the multi-component ampule is threadedly engaged to the jet injector after the multi-component ampule is filled with medication.

54. A multi-component ampule comprising an outer shell made from a first material, an inner shell made from a second material, and a nozzle section made from a third material; wherein the outer shell comprises a end wall and a recessed portion defined therein, and wherein the nozzle section is disposed within the recessed portion and the nozzle section is substantially flushed with the end wall's exterior surface.

55. The multi-component ampule of claim 54, wherein the outer shell comprises a threaded member on a proximal end section for engaging with a jet injector.

56. The multi-component ampule of claim 54, further comprising a diaphragm, wherein the diaphragm comprises a base section and a protruding section and wherein both the base section and the protruding section are both recessed within the end wall such that substantially none of the diaphragm protrudes from the end wall's exterior surface.

57. The multi-component ampule of claim 54, further comprising a symmetrical plunger disposed within the inner cylinder.

58. The multi-component ampule of claim 57, wherein the first material is plastic, the second material is glass, and the third material is silicone.

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