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(54) Title: BELLOWS SYRINGE FLUID DELIVERY SYSTEM

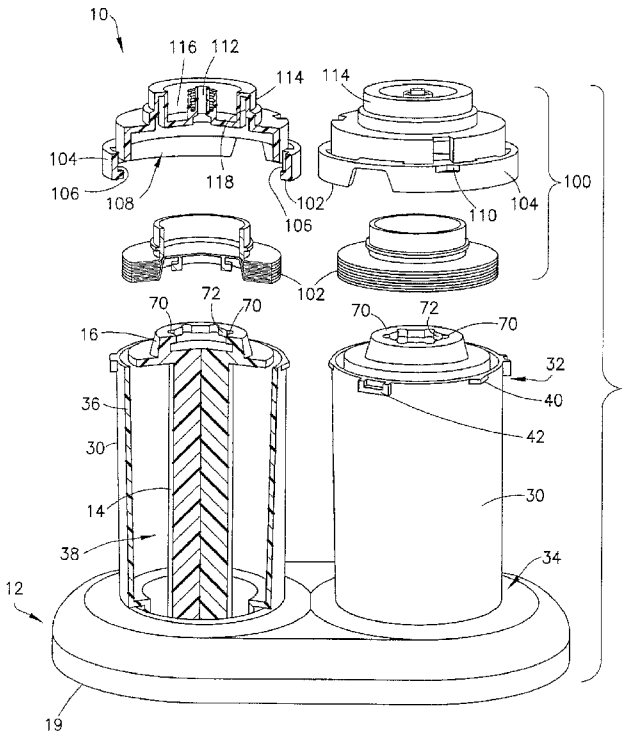

FIG. 1A

(57) Abstract: A bellows assembly for a fluid delivery system is a multi-component device that includes a cylindrical pressure jacket and a bellows syringe that is received within the pressure jacket. The bellows syringe includes a cap member and a bellows member. The bellows syringe in one embodiment is adapted to be secured to the pressure jacket by the cap member. The cap member is formed with a discharge port, which may be formed as conventional luer fitting. The discharge port is disposed coaxially within an annular wall on the outward facing side of the cap member and may be recessed within the annular wall. The bellows member is a hollow body that includes a series of bellows sections or rings. A distal end of the bellow member is formed with a discharge neck terminating in a discharge port, and the proximal end is formed with a closed end wall.

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BELLOWS SYRINGE FLUID DELIVERY SYSTEM

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present disclosure is related to the medical field and, more particularly, disposable syringes used in the medical field in which all or part of the syringe may be disposed of after a single use. The present disclosure is further related to the use of disposable syringe, ampoules, and fluid containers adapted for association with controlled, programmable fluid injection apparatuses.

Description of Related Art

[0002] Disposable ampoules containing liquid medicaments are known in the medical field for use with a reusable type holder, such as hypodermic injectors. For example, U.S. Patent No. 2,950,717 to Bouet discloses such an ampoule for use used with a syringe-type holder having at one end a hypodermic needle and, at a second end, a piston adapted to engage the disposable ampoule loaded into the syringe holder. The ampoule is in the form of bellows-like tubular element having a disk-shaped end wall adapted to engage the piston disposed in the syringe holder.

[0003] U.S. Patent No. 2,514,575 to Hein discloses a syringe that encloses a hollow flexible container used to hold medicament, which may be in the form of a liquid, emulsion, paste, and the like. The container may be connected at a proximal end thereof directly to a plunger disposed in the syringe barrel. The container is introvertable into itself so that action of the plunger toward a closed end of the syringe barrel causes the container to introvert and expel liquid or another material from the container.

[0004] U.S. Patent No. 5,147,311 to Pickhard discloses a syringe-type injection device that has a housing in which is arranged a holder for a deformable, medicament-containing ampoule having a bellows-type shape. An injection needle is provided at one end of the syringe injection device which communicates with the interior of the ampoule. A driving device is linked to the other end region of the ampoule, and which is used to dispense a medicament material held in the ampoule via the injection needle.

[0005] U.S. Patent No. 5,899,889 to Futagawa et al. discloses a prefilled syringe having a barrel with a distal end forming a needle-connecting portion and an open proximal end. A plastic tubular container is disposed in the barrel and has a flexible hollow cylindrical body used to contain a liquid medicament previously charged therein. A plunger is inserted into the

barrel through the open proximal end and is slidably held therein. The tubular container is held in the barrel so that an end or tip thereof may be placed in a lumen of the needle-connecting portion of the barrel. In use, as the hollow cylindrical body is emptied of fluid, the wall of the hollow cylindrical body is squeezed into a space between the barrel and the plunger as the plunger is pushed into the barrel.

[0006] U.S. Patent Application No. 2002/0091361 to Rosoff et al. discloses a multiple-dose syringe including a barrel with a closed end and an open end. The closed end has an injection port adapted to receive a needle. A plunger is slidably disposed through the open end of the barrel. A container is connected to an end of the plunger to move with the plunger. The container has a deformable shell with an opening at a forward end thereof. A predetermined quantity of fluid is sealed in the deformable shell by a closure member disposed over the opening. The container is slidably disposed in the barrel and includes a seal proximal to the forward end to form a first cavity in the barrel with a volume that is adjustable by moving the container in the barrel with the plunger so that fluid can be selectively drawn into and expelled from the first cavity. After at least a substantial portion of the fluid is expelled from the first cavity, the shell is configured to collapse by further pressure applied by the plunger to expel the predetermined quantity of fluid contained therein.

[0007] U.S. Patent No. 6,332,876 to Poynter et al. discloses a compressible syringe including a bellows. The disclosed syringe bellow has rearward frusto-conical bellows walls that are thicker than its forward frusto-conical bellows walls. The bellow walls converge in an apex, with the rearward frusto-conical wall at a first angle with respect to a plane perpendicular to the longitudinal axis of the syringe and intersecting the apex, and with the forward frusto-conical wall being at a second angle with respect to the plane and with the first angle being greater than the second angle. The bellows rings increase in diameter successively from the rearward to the forward portion of the syringe

[0008] U.S. Patent No. 6,620,134 to Trombley, III et al. discloses a syringe system that includes a barrel, a plunger slidably disposed within the barrel, and a collapsible cartridge in the barrel. The collapsible cartridge is inserted within the barrel and collapses as the plunger is advanced within the barrel to pressurize fluid within the collapsible cartridge. The collapsible cartridge includes a passage through which fluid passes when pressurized by the plunger.

[0009] U.S. Patent No. 6,869,419 to Dragan et al. discloses an ampoule having a body portion, a sealed end portion, and a sealed delivery portion. The ampoule is adapted for use in

a delivery syringe system for controllably dispensing a low viscosity material, such as a liquid, gel, or paste. The ampoule has sealed rear portions adapted to mate with a plunger of a syringe so as to facilitate controlled dispensing of the low viscosity material. The syringe has a plunger adapted to grasp the collapsed ampoule, facilitating removal, as well as breach openings positioned to provide controlled initial flow of the dispensed low viscosity material.

[0010] It is also known in the medical field to use bellows-type ampoules and containers in association with controlled, programmable fluid injection apparatuses. One such example may be found in U.S. Patent No. 5,000,739 to Kulisz et al. The Kulisz patent discloses a programmable pump with three separate components, namely, a driver, a reservoir, and a fluid tubing set connector. The driver provides an electromechanical assembly adapted to cause fluid to flow from the reservoir. The driver can be programmed for varying flow rates and alternating on/off delivery cycles through the control of switches externalized on the driver face. The top of the bellows reservoir includes a port, and the bottom includes a septum for filling by a needle. The tubing set connector subsequently connects to a port connector of the bellows reservoir. The tubing set connector provides an interface to any standard luer-type tubing set which then connects to a needle for infusion.

[0011] U.S. Patent No. 6,485,471 to Zivitz et al. discloses a fluid-delivery apparatus for delivering a medicament to a patient. The apparatus includes a housing defining a passageway, a bellowed ampoule positioned to lie in the passageway of the housing, and a piston. The bellowed ampoule includes a body with first and second ends and is formed to define a cavity configured to contain the medicament. The piston presses the second end of the ampoule toward the first end to dispense the medicament from the cavity. The fluid-delivery apparatus includes a piston-drive system that is configured to apply a force to the piston to dispense medicament from the ampoule. The piston-drive mechanism includes a torque-production system and an actuator system. The torque-production system includes a gear train operated by an electric motor and is adapted to apply a torque to a lead screw to move a drive nut and into engagement with the piston. The drive motor is actuated by a motor driver and engages with the gear train via a motor shaft.

[0012] Further, U.S. Patent Application Publication No. 2011/0218499 to Cahen discloses a device for injecting a fluid for medical use. The device includes a cylindrical component wherein a container for receiving the injection fluid is provided. The container has a bellows-shaped body made of deformable material and includes a tip through which fluid passes. The cylindrical component or base has a bottom wall through which an axially translatable piston rod is guided, and a top wall. The container has circular bellows-type rings. The distal end of

the piston has a shape complementing the shape of a corresponding cavity in the bottom wall of the container. An activating mechanism may be connected to the piston to impart force to the piston and eject the injection fluid from the container.

SUMMARY OF THE INVENTION

[0013] In one embodiment, a bellows syringe for a fluid delivery system is disclosed, comprising a cap member and a bellows member. The cap member defines an internal cavity and a discharge port, and further comprising a depending skirt portion. The skirt portion may comprise a plurality of radially-inward extending tab members. The bellows member is disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member, such as engagement between the tab members and the proximal end of the bellows member.

[0014] The proximal end of the bellows member is closed and a distal end of the bellows member defines a discharge port in fluid communication with the discharge port on the cap member. The closed proximal end of the bellows member may comprise depending attachment members for attaching the bellows member to a piston head of a piston element. The attachment members may be disposed in an end pocket defined in the closed proximal end of the bellows member.

[0015] The discharge port on the cap member may be recessed within an annular wall on a distal end of the cap member. The bellows member may comprise a distal end defining a discharge neck that forms a discharge port in fluid communication with the discharge port on the cap member, and the discharge neck is seated within an interior annular groove in the cap member for securing the discharge neck to the cap member. The bellows syringe may be packaged in a protector cap having an open end sealed by a removable seal.

In another embodiment, the bellows syringe for a fluid delivery system comprises a cap member, a bellows member, and a base member. The cap member defines an internal cavity and a discharge port, and further comprises a depending skirt portion comprising a plurality of radially-inward extending tab members. The bellows member is disposed in the internal cavity and held in a compressed state in the internal cavity. The base member comprises a plate portion and a central portion of optional annular shape. The plate portion comprises a plurality of upward-extending retaining tabs engaged with the catch members to maintain the bellows member in the compressed state in the internal cavity. The locations for the retaining tabs and catch members may be reversed. The proximal end of the bellows member may be closed and the central portion of the base member may be seated within an end pocket

defined in the closed proximal end of the bellows member. The central portion may define a circumferential groove and the bellows member may comprise a cooperating rib engaging the circumferential groove for securing the plate portion to the proximal end of the bellows member. The central portion defines an end pocket for receiving a piston head of a piston element, and wherein the end pocket comprises internal elements to engage the piston head.

[0016] Another embodiment described herein is directed to a bellows assembly for association with a fluid delivery system. The bellows assembly comprises a pressure jacket and a bellows syringe, which comprises a cap member and a bellows member. The pressure jacket has a distal end and a proximal end and defines a throughbore therebetween. The bellows syringe is adapted for connection to the distal end of the pressure jacket. The cap member defines an internal cavity and a discharge port, and further comprises a depending skirt portion. The skirt portion may comprise a plurality of radially-inward extending tab members. The bellows member is disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member, such as between the tab members and the proximal end of the bellows member.

[0017] The proximal end of the bellows member may be closed and a distal end of the bellows member may define a discharge port in fluid communication with the discharge port on the cap member. The closed proximal end of the bellows member may comprise depending attachment members for attaching the bellows member to a piston head of a piston element operable in the throughbore of the pressure jacket. The attachment members may be disposed in an end pocket defined in the closed proximal end of the bellows member.

[0018] A plurality of circumferentially-spaced mounting flanges may be provided on the distal end of the pressure jacket. A plurality of tabs members may further be provided on the distal end of the pressure jacket and located between each the mounting flanges, respectively. Mating or receiving slots may be defined in the skirt portion of the cap member to receive the mounting flanges for securing the bellows syringe to the distal end of the pressure jacket. The cap member may be rotated relative to the distal end of the pressure jacket to seat the mounting flanges in the mating slots in the cap member. This rotational motion may be used to cause the tab members on the distal end of the pressure jacket to engage the tab members on the skirt portion of the cap member and release the tab members on the skirt portion of the cap member from engagement with the proximal end of the bellows member.

[0019] In another embodiment, the tab members on the skirt portion of the cap member are formed as a plurality of catch members, and the bellows syringe further comprises a base

member. The base member comprises a plate portion and a central portion. The plate portion comprises a plurality of upward-extending retaining tabs engaged with the catch members to maintain the bellows member in the compressed state in the internal cavity. The locations for the retaining tabs and catch members may be reversed. The central portion may be seated within an end pocket defined in a closed proximal end of the bellows member. The central portion may define a circumferential groove and the bellows member may comprise a cooperating rib engaging the circumferential groove for securing the plate portion to the proximal end of the bellows member. The distal end of the pressure jacket may comprise a plurality of tab members each defining a transverse slot, and the plate portion may engage the transverse slots to secure the bellows syringe to the pressure jacket.

[0020] In another embodiment, a fluid delivery system is provided, comprising a power fluid injector, a pressure jacket, and a bellows syringe. The fluid injector comprises a reciprocally operable piston element. The pressure jacket has a distal end and a proximal end and defines a throughbore therebetween. The pressure jacket proximal end is engaged with the fluid injector such that the piston element is operable in the throughbore. The bellows syringe is adapted for connection to the distal end of the pressure jacket. The bellows syringe comprises a cap member and a bellows member. The cap member defines an internal cavity and a discharge port, and further comprises a depending skirt portion. The skirt portion may comprise a plurality of radially-inward extending tab members. The bellows member is disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member, such as between the tab members and the proximal end of the bellows member. The proximal end of the bellows member may be closed and a distal end of the bellows member may define a discharge port in fluid communication with the discharge port on the cap member. The closed proximal end of the bellows member may comprise depending attachment members for attaching the bellows member to a piston head of the piston element operable in the throughbore of the pressure jacket. The attachment members may be disposed in an end pocket defined in the closed proximal end of the bellows member.

[0021] In another embodiment of the fluid delivery system, the tab members on the skirt portion of the cap member may be formed as a plurality of catch members, and the bellows syringe may further comprise a base member comprising a plate portion and a central portion, typically an annular shaped portion. The plate portion comprises a plurality of upward-extending retaining tabs engaged with the catch members to maintain the bellows member in the compressed state in the internal cavity. The locations for the retaining tabs and catch

members may be reversed. The central portion may define an end pocket formed with internal elements adapted to receive radially-extendable retaining pins on a piston head of the piston element to secure the base member to the piston head.

[0022] In another embodiment of the fluid delivery system, the proximal end of the bellows member may be closed and define an end pocket formed with internal elements adapted to receive radially-extendable retaining pins on a piston head of the piston element to secure the closed proximal end of the bellows member to the piston head.

[0023] Additionally, the proximal end of the pressure jacket may be pivotally connected to the power fluid injector. Further, the pressure jacket may define a split-top opening for passage threrethrough of a fluid tubing set connected to a discharge port on the bellows member.

[0024] In another embodiment, a bellows syringe for a fluid delivery system generally comprises a cap member defining an internal cavity and a discharge port, the cap member further comprising a depending skirt portion, and a bellows member disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member. The skirt portion may comprise a plurality of radially-inward extending tab members engaged with the proximal end of the bellows member to hold the bellows member in the compressed state in the internal cavity. The proximal end of the bellows member may be closed and a distal end of the bellows member may define a discharge port in fluid communication with the cap member discharge port. The closed proximal end of the bellows member may comprise at least one attachment member for attaching the bellows member to a piston head of a piston element. The least one attachment member may be disposed in an end pocket defined in the closed proximal end of the bellows member. The at least one attachment member may comprise a button element adapted to be engaged by a piston element comprising a plurality of jaw members. The bellows member may comprise a distal end defining a discharge neck that defines a discharge port in fluid communication with the cap member discharge port, and the discharge neck may be seated within an interior annular groove in the cap member for securing the discharge neck to the cap member.

[0025] A base member may be provided as part of the bellows syringe and comprise a plate portion and a central portion, typically an annular shaped portion. One of the skirt portion and the plate portion may comprise a plurality of retaining tabs engaged with catch members provided on the other of the skirt portion and the plate portion to hold the bellows member in the compressed state in the internal cavity.

[0026] The proximal end of the bellows member may be closed and the distal end of the bellows member may define a discharge port in fluid communication with the cap member discharge port. The bellows member may comprise a distal end defining a discharge neck that defines a discharge port in fluid communication with the cap member discharge port, and the discharge neck may be seated within an interior annular groove in the cap member for securing the discharge neck to the cap member. The central portion may define a circumferential groove and the bellows member may comprise a cooperating rib engaging the circumferential groove for securing the plate portion to the proximal end of the bellows member. The central portion may define an end pocket for receiving a piston head of a piston element, and the end pocket may comprise at least one internal element to engage the piston head.

[0027] A further embodiment is directed to a bellows assembly for association with a fluid delivery system. The bellows assembly may comprise a pressure jacket having a distal end and a proximal end and defining a throughbore therebetween, and a bellows syringe adapted for connection to the distal end of the pressure jacket. The bellow syringe may comprise a cap member defining an internal cavity and a discharge port, the cap member further comprising a depending skirt portion, and a bellows member disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member. A base member may be provided as part of the bellows syringe and comprise a plate portion and a central portion, typically an annular shaped portion. One of the skirt portion and the plate portion may comprise a plurality of retaining tabs engaged with catch members provided on the other of the skirt portion and the plate portion to hold the bellows member in the compressed state in the internal cavity. The distal end of the pressure may comprise a plurality of tab members each defining a slot, and the plate portion may be adapted to engage the slots to secure the bellows syringe to the pressure jacket. Additionally, a plurality of circumferentially-spaced mounting flanges may be provided on the distal end of the pressure jacket, and a plurality of tab members may be provided on the distal end of the pressure jacket and provided between the mounting flanges, respectively. Mating slots may be defined in the skirt portion of the cap member to receive the mounting flanges for securing the bellows syringe to the distal end of the pressure jacket, such that when the cap member is rotated to seat the mounting flanges in the mating slots in the cap member, and this rotational motion causes the tab members on the distal end of the pressure jacket to engage the tab members on the skirt portion of the cap member and release

the tab members on the skirt portion of the cap member from engagement with the proximal end of the bellows member.

[0028] Yet a further embodiment is a fluid delivery system comprising a fluid injector comprising a reciprocally operable piston element having a piston head, a pressure jacket having a distal end and a proximal end and defining a throughbore therebetween, the pressure jacket proximal end engaged with the fluid injector such that the piston element is operable in the throughbore, and a bellows syringe adapted for connection to the distal end of the pressure jacket. The bellows syringe generally comprises a cap member defining an internal cavity and a discharge port, the cap member further comprising a depending skirt portion, and a bellows member disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member.

[0029] A particular embodiment is directed to a bellows syringe for a fluid delivery system comprising a cap member defining an internal cavity and a discharge port, the cap member further comprising a depending skirt portion, and a bellows member disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member.

[0030] The skirt portion may comprise a plurality of radially-inward extending tab members engaged with the proximal end of the bellows member to hold the bellows member in the compressed state in the internal cavity.

[0031] The proximal end of the bellows member may be closed and a distal end of the bellows member may define a discharge port in fluid communication with the cap member discharge port, and the closed proximal end of the bellows member may comprise at least one attachment member for attaching the bellows member to a piston head of a piston element. The at least one attachment member may be disposed in an end pocket defined in the closed proximal end of the bellows member. The at least one attachment member may comprise a button element adapted to be engaged by a piston element comprising a plurality of jaw members.

[0032] The bellows syringe may further comprise a base member comprising a plate portion and a central portion, and one of the skirt portion and the plate portion may comprise a plurality of retaining tabs engaged with catch members provided on the other of the skirt portion and the plate portion to hold the bellows member in the compressed state in the internal cavity. The central portion may define a circumferential groove and the bellows member may comprise a cooperating rib engaging the circumferential groove for securing the

plate portion to the proximal end of the bellows member. The central portion may define an end pocket for receiving a piston head of a piston element, and the end pocket may comprise at least one internal element to engage the piston head.

[0033] A further embodiment is a bellows assembly for association with a fluid delivery system comprising a pressure jacket having a distal end and a proximal end and defining a throughbore therebetween and a bellows syringe adapted for connection to the distal end of the pressure jacket. The bellows syringe may comprise a cap member defining an internal cavity and a discharge port, the cap member further comprising a depending skirt portion, and a bellows member may be disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member.

[0034] The skirt portion may comprise a plurality of radially-inward extending tab members engaged with the proximal end of the bellows member to hold the bellows member in the compressed state in the internal cavity.

[0035] The proximal end of the bellows member may be closed and a distal end of the bellows member may define a discharge port in fluid communication with the cap member discharge port, and the closed proximal end of the bellows member may comprise at least one attachment member for attaching the bellows member to a piston head of a piston element. The at least one attachment member may be disposed in an end pocket defined in the closed proximal end of the bellows member. The at least one attachment member may comprise a button element adapted to be engaged by a piston element comprising a plurality of jaw members.

[0036] The bellows syringe may further comprise a base member comprising a plate portion and a central portion, and one of the skirt portion and the plate portion may comprise a plurality of retaining tabs engaged with catch members provided on the other of the skirt portion and the plate portion to hold the bellows member in the compressed state in the internal cavity. The central portion may define a circumferential groove and the bellows member may comprise a cooperating rib engaging the circumferential groove for securing the plate portion to the proximal end of the bellows member. The central portion may define an end pocket for receiving a piston head of a piston element, and the end pocket may comprise at least one internal element to engage the piston head.

[0037] The distal end of the pressure jacket may comprise a plurality of tab members each defining a slot, and the plate portion may be adapted to engage the slots to secure the bellows syringe to the pressure jacket.

[0038] The bellows assembly may further comprise a plurality of circumferentially-spaced mounting flanges on the distal end of the pressure jacket, and a plurality of tab members on the distal end of the pressure jacket and provided between the mounting flanges, respectively. Mating slots may be defined in the skirt portion of the cap member to receive the mounting flanges for securing the bellows syringe to the distal end of the pressure jacket. The cap member may be rotated to seat the mounting flanges in the mating slots in the cap member, and the rotational motion may cause the tab members on the distal end of the pressure jacket to engage the tab members on the skirt portion of the cap member and release the tab members on the skirt portion of the cap member from engagement with the proximal end of the bellows member.

[0039] Another embodiment is directed to a fluid delivery system, comprising a fluid injector comprising a reciprocally operable piston element having a piston head, a pressure jacket having a distal end and a proximal end and defining a throughbore therebetween, the pressure jacket proximal end engaged with the fluid injector such that the piston element is operable in the throughbore, and a bellows syringe adapted for connection to the distal end of the pressure jacket. The bellows syringe generally comprises a cap member defining an internal cavity and a discharge port, the cap member further comprising a depending skirt portion, and a bellows member disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member.

[0040] The skirt portion may comprise a plurality of radially-inward extending tab members engaged with the proximal end of the bellows member to hold the bellows member in the compressed state in the internal cavity.

[0041] The proximal end of the bellows member may be closed and a distal end of the bellows member may define a discharge port in fluid communication with the cap member discharge port, and the closed proximal end of the bellows member may comprise at least one attachment member for attaching the bellows member to a piston head of a piston element. The at least one attachment member may be disposed in an end pocket defined in the closed proximal end of the bellows member. The at least one attachment member may comprise a button element adapted to be engaged by a piston element comprising a plurality of jaw members.

[0042] The bellows syringe may further comprise a base member comprising a plate portion and a central portion, and one of the skirt portion and the plate portion may comprise a plurality of retaining tabs engaged with catch members provided on the other of the skirt

portion and the plate portion to hold the bellows member in the compressed state in the internal cavity. The central portion may define a circumferential groove and the bellows member may comprise a cooperating rib engaging the circumferential groove for securing the plate portion to the proximal end of the bellows member. The central portion may define an end pocket for receiving a piston head of a piston element, and the end pocket may comprise at least one internal element to engage the piston head.

[0043] The distal end of the pressure jacket may comprise a plurality of tab members each defining a slot, and the plate portion may be adapted to engage the slots to secure the bellows syringe to the pressure jacket.

[0044] The bellows assembly may further comprise a plurality of circumferentially-spaced mounting flanges on the distal end of the pressure jacket, and a plurality of tab members on the distal end of the pressure jacket and provided between the mounting flanges, respectively. Mating slots may be defined in the skirt portion of the cap member to receive the mounting flanges for securing the bellows syringe to the distal end of the pressure jacket. The cap member may be rotated to seat the mounting flanges in the mating slots in the cap member, and the rotational motion may cause the tab members on the distal end of the pressure jacket to engage the tab members on the skirt portion of the cap member and release the tab members on the skirt portion of the cap member from engagement with the proximal end of the bellows member.

[0045] Further details and advantages of the various embodiments described in detail herein will become clear upon reviewing the following detailed description of the various embodiments in conjunction with the accompanying drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0046] **FIG. 1A** is a perspective, exploded, and partially cut-away view of adjacent bellows assemblies each incorporating a bellows syringe according to one embodiment.

[0047] **FIGS. 1B-1D** are perspective views showing a bellows assembly according to one embodiment and operational steps of attaching the bellows syringe to a cylindrical pressure jacket associated with a powered fluid injector.

[0048] **FIG. 2A** is a top perspective view of the bellows assembly.

[0049] **FIG. 2B** is a cross-sectional view taken along lines **2B-2B** in **FIG. 2A**.

[0050] **FIG. 2C** is a cross-sectional view taken along lines **2C-2C** in **FIG. 2A**.

[0051] **FIG. 3** is a sequence of cross-sectional, partial perspective, and partially cut-away views showing attachment of the bellows syringe to the pressure jacket of the bellows assembly, and operation of a plunger element in the pressure jacket.

[0052] **FIG. 4A** is a schematic cross-sectional view of the bellows syringe enclosed by a protector cap or retainer.

[0053] **FIG. 4B** is a plan view of a peel open seal for the protector cap or retainer shown in **FIG. 4A**.

[0054] **FIG. 4C** is an exploded view of the bellows syringe and the protector cap or retainer shown in **FIG. 4A**.

[0055] **FIG. 5A** is a schematic cross-sectional view of the bellows syringe enclosed by a tamper-evident seal strip.

[0056] **FIG. 5B** is a top view of the bellows syringe sealed by the tamper-evident seal strip shown in **FIG. 5A**.

[0057] **FIG. 5C** is an exploded side view of the bellows syringe and the tamper-evident seal strip shown in **FIG. 5A**.

[0058] **FIGS. 6A-6F** schematically in cross-section and in partial perspective and cut-away view illustrate another embodiment wherein a fluid container is inserted into the pressure jacket, and illustrate operational steps for interfacing a piston element to a proximal end of the fluid container.

[0059] **FIG. 7A** is a perspective, exploded, and partial cross-sectional view showing the bellows syringe and a portion of the pressure jacket of the bellows assembly.

[0060] **FIG. 7B** is a perspective and partial cross-sectional view showing the bellows syringe of **FIG. 7A**, and showing a piston element engaged with the proximal end of a bellows member of the bellows syringe.

[0061] **FIG. 7C** is a perspective and partial cross-sectional view showing the bellows syringe of **FIG. 7A**, and showing a piston element engaged with the proximal end of a bellows member and withdrawing the bellows member into the pressure jacket.

[0062] **FIGS. 7D** and **7E** are respective perspective and partial cross-sectional views of the bellows member of the bellows syringe in isolation, and further illustrating a push-in end wall of the bellows member.

[0063] **FIG. 7F** is a perspective view of the bellows member viewed on end.

[0064] **FIG. 7G** is a perspective cross-sectional view of the bellows member shown in a compressed state.

[0065] **FIG. 7H** is a cross-sectional view showing the bellows member with a rigid end part or base provided on a closed end wall of the bellows member and engagement of the piston element therewith.

[0066] **FIG. 8** is a schematic cross-sectional view of a tapered wall fluid container having rigid end part or base according to another embodiment.

[0067] **FIG. 9A** is a perspective view partially in phantom of a piston element adapted to interface with a structure on the proximal end of the bellows member or a fluid container.

[0068] **FIG. 9B** is a perspective and partial cross-sectional view of the piston element shown in **FIG. 9A**.

[0069] **FIG. 9C** is a cross-sectional view of the piston element shown in **FIG. 9A**.

[0070] **FIG. 10A** is a perspective view of a prefilled fluid container according to another embodiment and comprising a rupture-ready tip.

[0071] **FIG. 10B** is a perspective and cross-sectional view showing the fluid container shown in **FIG. 10A** loaded in a syringe connected to a dual-syringe powered fluid injector.

[0072] **FIG. 10C** is an exploded perspective view of the fluid container, syringe, and dual-syringe powered fluid injector shown in **FIG. 10A**.

[0073] **FIG. 11A** is a cross-sectional view of a fluid container according to another embodiment formed and filled by a blow-fill-cap (BFC) process.

[0074] **FIG. 11B** is a partial cross-sectional view of the fluid container of **FIG. 11A**, wherein a rigid end part or base is used to seal a wide proximal end of the fluid container.

[0075] **FIG. 11C** is a partial cross-sectional view of a modification of the fluid container of **FIG. 11A**, wherein a flexible membrane is used to seal the wide proximal end of the fluid container and further comprises an optional rigid end part or base.

[0076] **FIG. 12** is a sequence of schematic cross-sectional views showing manufacturing, filling, and sealing of the bellows member of the bellows syringe in which the proximal end of the bellows is sealed with a sealing element or plug.

[0077] **FIG. 13** is a sequence of schematic cross-sectional views showing manufacturing, filling, and sealing of the bellows member of the bellows syringe and sealing of opposing open ends of the bellows member with aseptic seals.

[0078] **FIG. 14** is a sequence of schematic cross-sectional views showing manufacturing, filling, and sealing of the bellows member of the bellows syringe, and mechanical sealing of opposing open ends of the bellows member.

[0079] **FIG. 15** is a sequence of schematic cross-sectional views showing manufacturing, filling, and sealing of the bellows member of the bellows syringe, and mechanical sealing of one open end of the bellows member while a second open end is sealed with a closure or cap.

[0080] **FIG. 16** is a sequence of schematic cross-sectional views showing manufacturing, filling, and sealing of the bellows member of the bellows syringe, and sealing of an open end by an aseptic seal and a mechanically applied interface closure or cap.

[0081] **FIG. 17** is a sequence of schematic cross-sectional views showing manufacturing, filling, and sealing of the bellows member of the bellows syringe, and mechanical sealing of an open end of the bellows member.

[0082] **FIG. 18** is a sequence of schematic cross-sectional views showing manufacturing, filling, and sealing of the bellows member of the bellows syringe, and sealing of an open end of the bellows member by a fluid connector fitting and an aseptic seal.

[0083] **FIG. 19** is a sequence of schematic cross-sectional views showing manufacturing, filling, and sealing of the bellows member of the bellows syringe, and sealing of an open end of the bellows member by a fluid connector fitting and followed by additional mechanical sealing of the open end.

[0084] **FIG. 20** is a sequence of schematic cross-sectional views showing manufacturing, filling, and sealing of the bellows member of the bellows syringe, and sealing of an open end of the bellows member by a pierceable septum.

[0085] **FIGS. 21A-21B** are respective schematic cross-sectional views of a fluid container and a bellows member wherein integral piston engagement features are formed as part of the closed end of the fluid container or bellows member as part of a molding process.

[0086] **FIGS. 22A-22B** are respectively a perspective view and a side view of a bellows portion of the bellows member wherein strengthening stiffening ribs are provided on the bellows portion prior to further molding.

[0087] **FIGS. 22C-22D** are respectively a perspective view and a side view of the bellows portion of the bellows member shown in **FIGS. 22A-22B** after molding to form the stiffening ribs as part of the bellows portion of the bellows member.

[0088] **FIGS. 23A-23B** are respectively a schematic cross-sectional view and a schematic cross-sectional and perspective view showing the bellows syringe in a compressed state prior to use according to another embodiment.

[0089] **FIGS. 23C-23D** are respectively a schematic cross-sectional view and a schematic cross-sectional and perspective view showing the bellows syringe in a compressed state after use according to the embodiment shown in **FIGS. 23A-23B**.

[0090] **FIG. 24** is a sequence of schematic cross-sectional views showing filling of the bellows member of the bellows syringe, and sealing of an open end of the bellows member by a fluid connector fitting followed by mechanical sealing to form a break-away tab.

[0091] **FIG. 25** is a sequence of schematic cross-sectional views showing filling of the bellows member of the bellows syringe, and sealing of an open end of the bellows member by a pierceable septum followed by mechanical sealing to enclose the pierceable septum.

[0092] **FIG. 26** is a sequence of schematic cross-sectional views showing filling of the bellows member of the bellows syringe, and sealing of an open end of the bellows member by mechanical sealing to form a sealed elongated discharge neck.

[0093] **FIGS. 27A-27B** are schematic cross-sectional views of the bellows syringe associated with a pressure jacket, and showing a collapsible piercing connector cap used to access the bellows member of the bellows syringe.

[0094] **FIGS. 28A-28B** are schematic cross-sectional views of the bellows syringe associated with a pressure jacket, and showing a rotational piercing element used to access the bellows member of the bellows syringe.

[0095] **FIG. 28C** is a detail view of Detail **28C** in **FIG. 28B**.

[0096] **FIG. 29** is a partial cross-sectional view showing the bellows syringe connected to a pressure jacket, and further showing a removable cap having a central button and a piercing pin or needle cannula used to access the bellows member of the bellows syringe.

[0097] **FIGS. 30A** is a schematic cross-sectional view of the bellows syringe having a cap member with a slide plate used to establish fluid communication with the bellows member, and showing the slide plate in an aligned position to establish a fluid path with the bellows member.

[0098] **FIGS. 30B** is a schematic cross-sectional view of the bellows syringe of **FIG. 30A** showing the slide plate in an unaligned position to block the fluid path with the bellows member.

[0099] **FIG. 30C** is a schematic top plan view of the bellows syringe of **FIG. 30A** and showing the slide plate in the aligned position to establish the fluid path with the bellows member.

[00100] **FIG. 30D** is a schematic top plan view of the bellows syringe of **FIG. 30B** and showing the slide plate in the unaligned position to block the fluid path with the bellows member.

[00101] **FIG. 30E** is a detail view of Detail **30E** in **FIG. 30B**.

[00102] **FIG. 31A** is a schematic cross-sectional view of the bellows syringe with a cap member with a rotational plate having an off-set feature used to establish fluid communication with the bellows member.

[00103] **FIG. 31B** is a schematic top plan view of the bellows syringe of **FIG. 31A** and showing the rotational plate in a position to block a fluid path with the bellows member.

[00104] **FIG. 31C** is a schematic top plan view of the bellows syringe of **FIG. 31B** and showing the rotational plate in a position establishing the fluid path with the bellows member.

[00105] **FIG. 32** is a partial cross-sectional view of the bellows syringe associated with a pressure jacket, and showing a cap member with a cutting blade operable via an external button and used to access the bellows member of the bellows syringe.

[00106] **FIG. 33A** is a schematic cross-sectional view showing a pressure jacket with a pivotal door having a piercing fluid connector element used to access the bellows member of the bellows syringe when loaded in the pressure jacket, and showing the pivotal door in an open position.

[00107] **FIG. 33B** is a schematic cross-sectional view showing a pressure jacket with a pivotal door as shown in **FIG. 33A**, and showing the pivotal door in a closed position.

[00108] **FIG. 34** is a perspective view of a clam shell pressure jacket body used to support the bellows member of the bellows syringe according to one embodiment.

[00109] **FIG. 35A** is a perspective view of a clam shell support scaffold used support the bellows member of the bellows syringe either alone or in combination with the embodiment shown in **FIG. 34**.

[00110] **FIG. 35B** is a schematic cross-sectional view showing the clam shell support scaffold of **FIG. 35A** supporting the bellows member of the bellows syringe.

[00111] **FIG. 36A** is a top view of a pressure jacket for supporting the bellows member according to one embodiment.

[00112] **FIG. 36B** is an end view of a pressure jacket for supporting the bellows member according to one embodiment.

[00113] **FIGS. 36C-36D** are schematic views of a fluid injector with a pivotally mounted split-top pressure jacket, as shown in **FIGS. 36A-36B**, for supporting the bellows member.

[00114] **FIG. 37A** is a top view of a pressure jacket for supporting the bellows member according to one embodiment.

[00115] **FIG. 37B** is an end view of a pressure jacket for supporting the bellows member according to one embodiment.

[00116] **FIGS. 37C-37D** are schematic views of a fluid injector with a pressure jacket, as shown in **FIGS. 37A-37B**, for supporting the bellows member and having a pivotal front end plate with a split-top opening.

[00117] **FIG. 38A** is a top view of a pressure jacket for supporting the bellows member according to one embodiment.

[00118] **FIG. 38B** is an end view of a pressure jacket for supporting the bellows member according to one embodiment.

[00119] **FIGS. 38C-38D** are schematic cross-sectional views of a fluid injector with a split-front pressure jacket, as shown in **FIGS. 38A-38B**, for supporting the bellows member.

[00120] **FIGS. 39A-39B** are schematic perspective views of a fluid injector with a pivotally mounted split-top pressure jacket body for supporting the bellows member, and the housing of the fluid injector further having an appendage for closing the split-top.

[00121] **FIGS. 40A-40B** are schematic perspective views of a fluid injector in which a split-front pressure jacket body for supporting the bellows member is telescopically connected to the housing of the fluid injector and a split-top or slot is enclosable by a roof portion of the fluid injector housing.

[00122] **FIGS. 41A-41C** are schematic perspective views of a fluid injector in which an split-top pressure jacket body for supporting the bellows member is telescopically and pivotally connected to the fluid injector housing by a slide plate.

[00123] **FIGS. 42A** is a schematic cross-sectional view a fluid injector with a split-top pressure jacket body for supporting the bellows member, with the pressure jacket body being resiliently flexible to permit opening and closing of the split-top to allow passage of a fluid tubing set through the split-top opening.

[00124] **FIG. 42B** is a transverse cross-sectional view of the pressure jacket shown in **FIG. 42A** taken along lines **42B-42B**.

[00125] **FIG. 42C** is a transverse cross-sectional view of the pressure jacket shown in **FIG. 42A** according to another embodiment.

[00126] **FIGS. 43A-43B** are schematic perspective views of a fluid injector with a pivotally connected clam shell pressure jacket hinged to the body of the fluid injector.

[00127] **FIG. 44A** is schematic perspective view of a clam shell pressure jacket which is held in a closed and locked state by a structure on the bellows member or on a fluid container.

[00128] **FIG. 44B** is a transverse cross-sectional view of the pressure jacket shown in **FIG. 44A** taken along lines **44B-44B** in **FIG. 44A**.

[00129] **FIG. 44C** is a front view of a bellows member or a fluid container adapted to interface with the pressure jacket of **FIGS. 44A-44B**.

[00130] **FIG. 44D** is a side view of a bellows member or a fluid container adapted to interface with the pressure jacket of **FIGS. 44A-44B**.

[00131] **FIG. 45** is a perspective view of a clam shell pressure jacket adapted to maintain a fluid connection between a fluid tubing set and the bellows member when under pressure.

[00132] **FIG. 46** is a schematic view illustrating a pressure jacket chuck mechanism used to support a fluid connection with the bellows syringe when under pressure according to another embodiment.

[00133] **FIG. 47** is a cross-sectional view showing use of an external connector clip used to support a fluid connection with the bellows member and a fluid connector fitting according to another embodiment.

[00134] **FIGS. 48A** and **48B** are perspective views showing a pyramidal-shaped bellows syringe shown in a collapsed state and an extended state, respectively.

[00135] **FIG. 49A** is an exploded perspective view showing another embodiment of the bellows member disposed within a pressure jacket comprising longitudinal internal support ribs or elements.

[00136] **FIG. 49B** is an end view of the bellows member and pressure jacket of **FIG. 49A**.

[00137] **FIG. 49C** is a perspective view of the bellows member partially loaded into the pressure jacket of **FIG. 49A**.

[00138] **FIG. 49D** is a perspective view showing the bellows member fully loaded into the pressure jacket of **FIG. 49A**.

[00139] **FIG. 50** is a perspective view of a fluid container having an intentionally longer axial length than a receiving pressure jacket.

[00140] **FIGS. 51A** is a perspective and partial cross-sectional view of a fluid container having a fluid connector fitting and a chuck mechanism used to secure a fluid connection to the fluid connector fitting.

[00141] **FIGS. 51B** is a perspective and partial cross-sectional view of the fluid container of **FIG. 51A** with locking finger elements of the chuck mechanism removed for clarity.

[00142] **FIGS. 51C** is a perspective and partial cross-sectional view of the fluid container of **FIG. 51A** with a locking collar of the chuck mechanism exploded from the fluid connector fitting.

[00143] **FIG. 52A** is perspective view of a fluid injector in which an open top pressure jacket is hinged to the fluid injector housing and a locking ring is used to secure the pressure

jacket to the fluid injector housing in the closed position, and showing the pressure jacket in an open position.

[00144] **FIG. 52B** is perspective view of a fluid injector in which an open top pressure jacket is hinged to the fluid injector housing and a locking ring is used to secure the pressure jacket to the fluid injector housing in the closed position, and showing the pressure jacket in the closed position.

[00145] **FIG. 53** is a perspective view of a fluid injector in which a split-top pressure jacket is hinged to the fluid injector housing and another embodiment of the locking ring is used to secure the pressure jacket to the fluid injector housing in the closed position.

[00146] **FIG. 54A** is a perspective view of the fluid injector with a split or clam shell pressure jacket that pivots open at a distal end to form a mouth opening facing the fluid injector body, with the pressure jacket shown in an opened position.

[00147] **FIG. 54B** is a side view of the fluid injector shown in **FIG. 54A**.

[00148] **FIG. 54C** is a perspective view of the fluid injector of **FIG. 54A** with the pressure jacket shown in a closed position.

[00149] **FIG. 54D** is side view of the fluid injector as shown in **FIG. 54C**.

[00150] **FIG. 55** is a perspective view of another embodiment of the bellows member of the bellows syringe having outward-extending radial tabs at the distal end and at the proximal end for engaging corresponding receiving slots in a pressure jacket.

[00151] **FIG. 56A** is a perspective view of a fluid injector having a pressure jacket with a top opening in which a disposable fluid container or bellows member is top-loaded into the pressure jacket.

[00152] **FIG. 56B** is a side view of the fluid injector of **FIG. 56A**.

[00153] **FIGS. 57** is a perspective and exploded view of another embodiment of the bellows syringe further comprising a base member and connected to a pressure jacket.

[00154] **FIGS. 58** is a perspective, exploded, and partial cross-sectional view of the embodiment shown in **FIG. 57**.

[00155] **FIG. 59** is a perspective and exploded view showing connection of the pressure jacket to a fluid injector face plate for the embodiment shown in **FIGS. 57-58**.

[00156] **FIGS. 60-61** are sequential perspective views showing attachment of the bellows syringe to the pressure jacket for the embodiment shown in **FIGS. 57-58**.

[00157] **FIGS. 62-64** are sequential perspective and partial cross-sectional views showing operation of the bellows syringe on the pressure jacket for the embodiment shown in **FIGS. 57-58**.

[00158] **FIGS. 65-66** are sequential perspective and partial cross-sectional views showing detachment of the bellows syringe from the pressure jacket for the embodiment shown in **FIGS. 57-58**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00159] For purposes of the description hereinafter, spatial orientation terms, as used, shall relate to the referenced embodiment as it is oriented in the accompanying drawing figures or otherwise described in the following detailed description. However, it is to be understood that the embodiments described hereinafter may assume many alternative variations and configurations. It is also to be understood that the specific components, devices, features, and operational sequences illustrated in the accompanying drawing figures and described herein are simply exemplary and should not be considered as limiting.

[00160] Referring initially to **FIGS. 1-2** and **7**, a fluid delivery system **10** generally comprises a powered fluid injector head **12**, such as a Stellant® powered injector platform manufactured by Medrad, Inc. Only a face plate portion **19** of the powered fluid injector head is shown in **FIGS. 1A-1D** and **7A-7C** but other figures, such as **FIG. 10C** discussed herein, illustrate a suitable fluid injector head **12** for use in the various embodiments described herein. A bellows assembly **20** comprising a cylindrical body or pressure jacket **30** and a bellows syringe **100**, may be associated with the fluid injector head **12** (hereinafter "fluid injector **12**") as described in detail herein with respect to several embodiments. As is known in the medical field, injecting contrast media into the bloodstream of patients enables visualization of various pathologies through X-Ray, Computed Tomography (CT), Magnetic Resonance (MR), or other medical imaging modalities. Contrast delivery is most effective and efficient using a powered fluid injector, such as the Stellant® powered fluid injector, that can be programmed to deliver specific amounts of contrast agent and/or saline at specific flow rates. A powered fluid injector may be used in diagnosing stroke, heart disease, cancer, vascular disease, physical injury, digestive disorder, etc. The fluid injector **12** comprises one or more linearly reciprocal piston elements **14** which each have a distal piston interface or piston head **16** adapted to engage a bellows syringe **100** of the bellows assembly **20**. The piston element or elements **14** are enclosed within a housing **18** as shown, for example, in **FIG. 10C** discussed herein, and specific details of a powered injector platform and syringe elements used therewith may be found in U.S. Patent Nos. 5,383,858 to Reilly et al.; 5,873,861 to Hitchins et al.; and 6,652,489 to Trocki et al., all assigned to Medrad, Inc. and each incorporated herein by reference for disclosure related to the foregoing elements. This

disclosure is explicitly not limited to utilizing the bellows syringe **100** with contrast media but may be used for any medicinal fluid to be delivered to a patient. The face plate portion **19** of the fluid injector **12** is specifically shown in **FIGS. 1A-1D**.

[00161] The bellows assembly **20** is a multi-component device and generally comprises a cylindrical body or pressure jacket **30** and a bellows syringe **100** that interfaces with the pressure jacket **30**. The bellows syringe **100** comprises a cap member or element **102** and a bellows member or element **120**. The bellows syringe **100** is adapted for use in CT, MR, and like procedures and operable at typical operating pressures of about 200-400 psi, as examples, and the bellows member **120** may be expanded to hold fluid volumes on the order of 200 ml. The bellows syringe **100** is adapted to be secured to the pressure jacket **30** by the cap member **102**. Each of the foregoing components is discussed hereinafter in detail.

[00162] The cylindrical body or pressure jacket **30** is a unitary, typically cylindrical body having a distal end **32** and a proximal end **34** and is typically a reusable component, while the bellows syringe **100** is typically a single-use component. The pressure jacket **30** has a sidewall **36** that defines a throughbore **38** between the distal and proximal ends **32**, **34**. The proximal end **34** is adapted to interface with the fluid injector **12** and includes mounting structure (not shown) positioned to engage the front end or face plate **19** of the housing **18** of the fluid injector **12** to properly seat the pressure jacket **30** relative to the fluid injector **12**. As an example, two opposed bayonet attachment flanges (not shown) may be provided on the proximal end **34** for interfacing with the fluid injector face plate **19** to secure the pressure jacket **30** to the fluid injector **12**. The distal end **32** of the pressure jacket **30** is formed with exterior circumferentially-spaced exterior tabs **40** and exterior circumferentially-spaced mounting flanges **42**. The mounting flanges **42** are spaced circumferentially around the distal end **32** of the pressure jacket **30**, with the tabs **40** located between the mounting flanges **42**. The pressure jacket **30** may be made of any suitable plastic material, desirably a clear plastic material, such as, but not limited to, polycarbonate, acrylic, or polyester.

[00163] Further details relating to desirable mounting structures used to properly interface the pressure jacket **30** with the fluid injector **12** may be found in the foregoing Medrad, Inc. patents which discuss similar interfacing features for securing a Stellant® CT syringe to a Stellant® fluid injector. In accordance with this disclosure, the pressure jacket **30** may have interfacing structure for attaching the pressure jacket **30** to a Stellant® fluid injector. However, this description is provided for exemplary purposes and the proximal end **34** of the pressure jacket **30** may have any suitable configuration for interfacing with any suitable powered fluid injector known in the medical field for powered fluid delivery applications.

The Stellant® fluid injector and the proximal end features of a Stellant® syringe, as described in the foregoing Medrad, Inc. patents, are provided for exemplary purposes only and should not be considered limiting. For example, the interface between the proximal end **34** of the pressure jacket **30** and fluid injector **12** may take other front-loading arrangements as disclosed in the foregoing Trocki et al. patent, or in U.S. Patent No. 7,419,478 to Reilly et al. and assigned to Medrad, Inc. (additionally incorporated herein by reference). An adapter may also be used to connect the pressure jacket **30** to the fluid injector **12** as disclosed in United States Patent No. 5,520,653 to Reilly et al., or in U.S. Patent Nos. 7,497,843 to Castillo et al. and 6,726,657 to Dedig et al., all assigned to Medrad, Inc. and incorporated herein by reference for these teachings. All of the foregoing Medrad, Inc. patents disclose various apparatus and methods for mounting a syringe body or pressure jacket to a fluid injector, whether a single-syringe fluid injector or multi-syringe fluid injector and, further, disclose various apparatus and methods for interfacing a syringe plunger with a piston element of the fluid injector. Thus, these patents are incorporated by reference into this disclosure at least for teaching apparatuses and methods for interfacing the pressure jacket **30** to the fluid injector **12** and, further, for interfacing the piston element or elements **14** of the fluid injector **12** with the bellows member **120**, or additional components or elements provided on the bellows member **120** when disposed within the pressure jacket **30**, as described herein. Further, the housing **18** of the fluid injector **12** may comprise a light ring (not shown) that can encompass all or part of the axial length of the pressure jacket **30** and all or part of the bellows syringe **100** to sterilize the pressure jacket **30** and all or part of the bellows syringe **100** with ultraviolet light (UV). Additionally, the pressure jacket **30** may comprise a barrier or membrane (not shown) within the bore **38** near the proximal end **34** of the pressure jacket **30** that acts as a barrier to keep fluid from entering the fluid injector housing **18** in the event of failure of the bellows member **120**. The barrier forms a reservoir chamber that catches spilled fluid.

[00164] In one embodiment, the cap member **102** is used to secure the bellows syringe **100** to the pressure jacket **30**. The cap member **102**, in the embodiment illustrated, comprises a depending ring or skirt portion **104** that is approximately equal to or slightly larger than the outer diameter of the pressure jacket **30**. The skirt portion **104** is formed with receiving slots **106**, such as bayonet slots, for engagement with the mounting flanges **42** provided on the distal end **32** of the pressure jacket **30**. Accordingly, when the bellows syringe **100** is mounted on the distal end **32** of the pressure jacket **30** and rotated in a clockwise or, conversely, a counterclockwise direction depending on the opening orientation of the bayonet

slots **106**, the bellows syringe **100** is secured onto the pressure jacket **30**. The cap member **102** further defines an internal cavity **108** wherein the bellows member **120** is disposed and held in a compressed, transport, or pre-use state. The bellows member **120** is typically held in a compressed and locked state or pre-use state in the bellows syringe **100** by retaining tabs **110** formed as part of the skirt portion **104** of the cap member **102** and which extend radially-inward to engage the bottom of the bellows member **120** to maintain the bellows member **120** in the compressed or pre-use state. The exterior tabs **40** are located on the distal end **32** of the pressure jacket **30** so that when the cap member **102** is placed on the distal end **32** and rotated so that the receiving slots **106** receive the mounting flanges **42**, the exterior tabs **40** engage or interact with the retaining tabs **110** and cause the retaining tabs **110** to disengage from the bellows member **120**. Thus, the retaining tabs **110** are automatically "unlocked" from the bellows member **120** as the cap member **102** is placed onto the distal end **32** of the pressure jacket **30** and the cap member **102** is rotated to secure the cap member **102** to the pressure jacket **30**. Once placed in association with the pressure jacket **30** and "unlocked", the bellows syringe **100** is then ready for use in a medical procedure. The retaining tabs **110** are formed to extend radially inward from the skirt portion **104** of the cap member **102**, and the skirt portion **104** may be formed to be resiliently flexible in the vicinity of the tabs **110** to permit the retaining tabs **110** to flex and disengage from the bellows member **120** as the cap member **102** is rotated on the distal end **32** of the pressure jacket **30** to secure the assembly of the bellows syringe **100** to the pressure jacket **30**. Alternatively, the retaining tabs **110** may be formed to be resiliently flexible on the skirt portion **104** of the cap member **102** to flex and disengage from the bellows member **120** as the cap member **102** is rotated on the distal end **32** of the pressure jacket **30** to secure the assembly of the bellows syringe **100** to the pressure jacket **30**.

[00165] The cap member **102** may be further formed with a discharge port **112**, which may be formed as conventional luer fitting. The discharge port **112** is disposed coaxially within an annular wall **114** on the outward facing side of the cap member **102** and may be recessed within the annular wall **114**, such as within an annular cavity **116** defined by the annular wall **114**, to promote sterility of the discharge port **112**. The recessing of the discharge port **112** in the annular cavity **116** aids in avoiding finger-contact with the discharge port **112** as a user loads the bellows syringe **100** onto pressure jacket **30**. Further, the cap member **102** may be formed with an interior annular recess or groove **118** for receiving and securing the discharge portion of the bellows member **120** as described further herein.

[00166] The bellows member **120**, when extended, generally comprises a hollow body that includes a forward or distal end **122**, a rearward or proximal end **124**, and an intermediate bellows portion as generally indicated by reference numeral **126**. The rearward or proximal end or portion **124** defines a closed end wall **128**. The rearward portion of the bellows portion **126** connects to the closed end wall **128**, and a forward portion of the bellows portion **126** defines a discharge neck **130** opposite the closed end wall **128**. The discharge neck **130** is adapted to be received in the interior annular recess or groove **118** in the cap member **102** and may be secured permanently therein, adhesively secured therein, or be removably secured therein such as by a friction fit connection or other suitable mechanical connection. The discharge neck **130** terminates in a discharge port **150** (see, for example, **FIGS. 7D-7F** discussed herein) that may have, according to one non-limiting embodiment, a fracturable closure seal (discussed herein) for sterility purposes, such as pierceable foil or elastomeric seal. The bellows portion **126** is formed with a plurality of bellows sections or bellows rings **132** between the neck **120** and the closed end wall **128**, which form the bellows portion **126**. The bellows sections or rings **132** are defined by frusto-conical wall sections **134** providing the bellows member **120** with a hollow interior **136**. The discharge neck **130** defines passageway **138** leading to the hollow interior **136** generally defined by the bellows portion **126** of the bellows member **120**. The closed end wall **128** may be shaped to interface directly with the piston head **16** on the piston element **14** of a fluid injector **12**. For example, the closed end wall **128** may define a receiving end pocket **140** for interfacing directly with a similarly-shaped piston head **16**. In particular, the depicted embodiment of the piston head **16** comprises a radial end flange **60** and a distal end abutment **62** shaped to match the interior shape of the receiving end pocket **140**. The closed end wall **128** may alternatively include an attached rigid base element or part that defines the receiving end pocket **140** for engaging with the piston head **16** in a like manner.

[00167] The bellows member **120** of the bellows syringe **100** essentially forms a collapsible fluid container that may be axially expanded by action of the piston element **14** once the piston head **16** is mechanically engaged in the receiving end pocket **140**. This expansion occurs as the piston element **14** withdraws axially in the pressure jacket **30**, and this axially withdrawing movement fills the hollow interior **136** of the bellows member **120** with a desired medical fluid. This axially withdrawing movement of the piston element **14** axially expands the bellows member **120** along the compressed bellows portion **126**. Once filled with the desired medical fluid, an opposite movement of the piston element **14** axially collapses the bellows member **120** along bellows portion **126** to eject the medical fluid via

the discharge neck **130** and discharge port **150**; further specific details of the operation of the bellows member **120** in conjunction with the piston element **14** are presented herein.

[00168] **FIG. 3** illustrates a sequence for attaching the bellows syringe **100** to the pressure jacket **30** to form the bellows assembly **20**. In **FIG. 3**, the pressure jacket **30** has already been connected or otherwise associated with a fluid injector (not shown in **FIG. 3**) at step **a**. The bellows syringe **100** in step **b** is secured onto the distal and **32** of the cylinder body **30** as described previously. Next, at step **c**, the piston element **14** of the fluid injector **12** is extended to engage the bellows member **120**. In this step, the piston head **16** is seated in engagement with the end pocket **140** in the closed end wall **128** of the bellows member **120** and is secured in the end pocket **140** with any suitable mechanical connection to permit the plunger element **14** to operate the bellows member **120** in the proximal and distal directions. In step **d**, the piston element **14** retracts and elongates the bellows member **120** and, in particular, elongates the bellows portion **126** by separating the bellows sections or rings **132**. In this step, the hollow interior **136** of the bellows member **120** may filled with fluid from an external sourced connected to the discharge port **112** on the cap member **102**. Once the bellows member **120** is filled with a desired amount of fluid, the piston element **14** can be controlled to the reverse direction, as shown at step **e**, to expel fluid from the hollow interior **136** of the bellows member **120**. The fluid passes through the passageway **138** defined by the discharge neck **130** and discharges from the bellows syringe **100** via the discharge port **112** on the cap member **102**. Once the fluid is dispensed from the bellows syringe **100**, the bellows syringe **100** may be removed at step **f** from the pressure jacket **30** by reversing the loading process described previously. The used bellows syringe **100** may then be discarded as medical waste. The piston element **14** is withdrawn axially in the pressure jacket **30** and, at step **g**, the pressure jacket **30** is ready for attachment of a new, sterile bellows syringe **100**.

[00169] As the bellows syringe **100** is suited for single-patient use, features may be provided to maintain the sterility of the bellows syringe **100** prior to use. Referring to **FIGS. 4A-4C**, the bellows syringe **100** may be packaged within a protector cap or retainer **22**. The protector cap or retainer **22** is generally in the form or a disposable dust cap having an open end **24**. Internal retaining tabs **26** are provided in the protector cap **22**. The retaining tabs **26** are adapted to engage mating or corresponding exterior retaining tabs **142** on the cap member **102**. The exterior retaining tabs **142** are provided on the skirt portion **104** of the cap **102**. A peel-open rear seal **28** encloses the open end **24** of the protector cap **22** and maintains the sterility of the interior space within the protector cap **22** wherein the bellows syringe **100** is

disposed. The bellows syringe **100**, as enclosed by the protector cap **22** and peel-open rear seal **28**, may be packaged in a blister package for shipment to a medical facility.

[00170] A modification or enhancement of the foregoing packaging method for maintaining sterility of the bellows syringe **100** is shown in **FIGS. 5A-5C**. In this modification or enhancement, the bellows syringe **100** is enclosed by a tamper-evident seal strip **29**. The tamper-evident strip **29** extends around the bellows syringe **100** such that the tamper-evident strip **29** covers the discharge port **112** on the cap member **102**. In the embodiments of the bellows syringe **100** shown in **FIGS. 4-5**, the cap member **102** is shown formed without the annular wall **114** surrounding the discharge port **112**. Hence, there is a need in this embodiment to protect the discharge port **112** from contamination, such as by inadvertent finger-contact with a user who is handling the bellows syringe **100**. A pull tab may be provided as part of the tamper-evident strip **29** to facilitate removal of the strip **29** from the bellows syringe **100**. The bellows syringe **100** having the tamper-evident strip **29** affixed thereto may be sealed in the protector cap **22** described above in connection with **FIGS. 4A-4C**.

[00171] Referring to **FIGS. 6A-6F** and **FIG. 8** another embodiment is schematically illustrated wherein a fluid container **220** is inserted into the cylindrical pressure jacket **30** associated with a fluid injector **12**. The pressure jacket **30** in this embodiment has the same general form as described hereinabove, and the bellows syringe **100** may likewise be used with the pressure jacket **30** and related components discussed herein with appropriate modifications to the cap member **102**, the bellows member **120**, and the pressure jacket **30**. The fluid container **220** may have a soft, pliable body **222** having a distal end **224** with a discharge port **226**, for example similar to the discharge port **112** described previously, and a proximal end **228** with a closed end wall **230**. The closed end wall **230** defines a receiving end pocket **232** therein to receive the piston head **16** of the piston element **14**, and this structure may be applied to the bellows member **120** as well, such as configuring the end pocket **140** in a similar manner to end pocket **232**. The closed end wall **230** may alternatively include a rigid base element or part that defines the receiving end pocket **232** for the piston head **16**, as shown in **FIG. 8**. Even though fluid container **220** is illustrated for use in the pressure jacket/pressure jacket **30** shown **FIGS. 6A-6F**, as noted, the bellows syringe **100** may also be used in the embodiment depicted in **FIGS. 6A-6F**. A retaining cap **44** may be associated with the pressure jacket **30** to enclose the open distal end **32** of the pressure jacket **30** and retain the fluid container **220** or the bellows syringe **100** therein. The retaining cap **44** may be formed to mechanically connect to the distal end **32** of the pressure jacket **30**, and

may comprise a discharge port **46** that is axially aligned with the discharge port **226** on the fluid container **30**. As a further alternative, a similar discharge port to the discharge port **226** may be provided on the bellows member **120** at the distal end **122** thereof so that the bellows member **120** is made suitable for use in the embodiment depicted in **FIGS. 6A-6F** without need of the cap member **102**, and use of this modified embodiment is further discussed immediately hereinafter.

[00172] In use, the fluid container **220** or bellows member **120** is loaded into the pressure jacket **30** through the open distal end **32** of the pressure jacket **30** and the retaining cap **44** is placed on the distal end **32** of the pressure jacket **30**. As an example, a threaded connection or like mechanical connection may be provided between the retaining cap **44** and the distal end **32** of the pressure jacket **30**. In the present embodiment, the piston head **16** of the piston element **14** is provided with radially-extendable retaining pins **64** which are initially recessed into the piston head **16** as shown in **FIGS. 6A-6F**. Thus, when the fluid container **220** or bellows member **120** is initially placed into the pressure jacket **30**, the retaining pins **64** are in their recessed configuration and do not interfere with the placement of piston head **16** into the respective end pockets **232**, **140** in the fluid container **220** or the bellows member **120**. Next, when the retaining cap **44** is rotated to secure the threaded or like mechanical connection between the retaining cap **44** and the pressure jacket **30**, this rotational motion may also be used to impart rotation to the fluid container **220** or the bellows member **120**, such as by a suitable inter-engagement between the discharge port **46** and the discharge port **226** on the fluid container **30** (or between a like discharge port **226** provided on the bellows member **120** and the discharge port **226**) and this rotational motion also causes the fluid container **220** or bellows member **120** to rotate on the piston head **16**. As this rotational motion occurs, the respective end pockets **232**, **140** in the fluid container **220** or bellows member **120** rotationally act upon the piston head **16** and cause the retaining pins **64** to extend radially outward from the piston head **16** to grip the body of the respective fluid container **220** or bellows member **120** in the respective end pockets **232**, **140**. The gripping connection in the respective end pockets **232**, **140** may take the form of internal structures or elements to provide fixed engagement in the respective end pockets **232**, **140** to permit an interlocked connection to be established between the end pockets **232**, **140** and the piston head **16**, (see as examples the internal structures or elements **72** in **FIGS. 7A** and internal structures or elements **1020** in **FIGS. 57-58** discussed herein). Once the piston element **14** and the affixed disposable component, either the fluid container **220** or bellows member **120**, are connected, movement of the piston element **14** in a forward/distal direction causes the fluid container

220 or the bellows member 120 to dispense fluid received into the fluid container 220 or bellows member 120 via the discharge port 226, or a like discharge port on the bellows member 120. Counter-rotation of the retaining cap 44 and pressure jacket 30 in the opposite direction from that described in the foregoing, cause the retaining pins 64 to retract radially into the piston head 16, thereby disengaging the interlocked connection between the piston head 16 and the fluid container 220 or bellows member 120. Typically, the fluid container 220 or bellows member 120 is prefilled with fluid. The pliable, yet self-supporting, nature of the fluid container body 222 permits the end wall 230 to introvert into the fluid container body 222, and a sidewall 236 of the fluid container body 222 may fold inward against itself in a manner similar to that shown in the Hein patent (U.S. Patent No. 2,514,575) described previously and incorporated herein by reference. However, it will be understood that the body 222 of the fluid container 220 is sufficiently rigid to be self-supporting when placed on end, yet pliable enough to permit the end wall 230 to introvert into the interior of the fluid container body 222 so that the sidewall 236 may fold inward against itself radially between the sidewall 236 and the interior wall of the pressure jacket 30.

[00173] Referring specifically to FIGS. 7A-7G, the bellows assembly 20, described previously in connection with FIGS. 1-3, is further shown interfacing with a fluid injector 12 and, in particular, a face plate 19 of the fluid injector 12. In this embodiment, the pressure jacket 30 of the bellows assembly 20 may interface with the face plate 19 in the manner described previously. The bellows member 120 of the bellows syringe 100 is formed such that the rotational motion used to connect the bellows syringe 100 to the cylindrical portion 30, as described previously, also connects the bellows member 120 to the piston element 14 of the fluid injector 12. In this embodiment, the closed end wall 128 of the bellows member 120 is formed with an opposing pair of attachment members or catches 144 that extend proximally from the closed end wall 128. The distal end abutment 62 on the piston head 16 of the piston elements 14 is formed with a distal end opening or cavity 66 defined by an annular end wall 68. The annular end wall 68 defines a pair of opposing slots 70 and internal structures or elements 72 for receiving and engaging the retaining pins 64. The pair of opposing slots 70 is situated so that as the bellows syringe 100 is seated onto the distal end 32 of the pressure jacket 30, the attachment members 144 on the bellows member 120 pass through the opposing slots 70. Accordingly, as the bellows syringe 100 is seated onto the distal end 32 of the pressure jacket 30 the attachment members 144 on the bellows member 120 pass through the opposing slots 70, and the rotational movement of the cap member 102 used to secure the bellows syringe 100 onto the pressure jacket 30 simultaneously causes the

attachment members **144** to seat into engagement with the annular end wall **68** and secure the bellows member **120** in engagement with the piston element **14**. In particular, in this embodiment, the attachment members **144** are adapted to seat into engagement with the internal structures or elements **72** internally of the annular end wall **68** and secure the bellows member **120** in engagement with the piston element **14**.

[00174] **FIG. 7D** shows the bellows member **120** in a state after manufacturing, typically a blow molding formation operation, and prior to associating the bellows member **120** with the cap member **102**. As illustrated, the closed end wall **128** of the bellows member **120** is formed so that the closed end wall **128** extends or projects proximally from the bellows member **120** or is "extroverted". The bellows member **120** may be provided in this configuration for attachment to the piston head **16** of the piston element **14**, as described in the foregoing. Once the connection between the attachment members or catches **144** and the annular end wall **68** of the piston head **16** is made by the methodology described above, distal movement of the piston element **14** causes the closed end wall **128** to fold inward or "introvert" into the nearest bellows section or ring **132** and into the configuration shown in **FIG. 7E**. The open discharge neck **130** may terminate in a sealed or open discharge port **150** for the bellows member **120**.

[00175] Referring to **FIG. 7H**, in a further variation of the embodiment shown in **FIGS. 7A-7G**, a rigid base element or end part **146** may be molded or otherwise affixed, such as by adhesive, to the closed end wall **128** of the bellows member **120**. The end part **146** provides a means for engagement of the piston head **16** to the bellows member **120**. For example, the end part **146** may define an end pocket similar to the end pocket **140** described previously, or may take a conventional interface form such as a suitable configuration to mate with piston heads or tips of a Stellant® powered fluid injector platform, which has a push-pin piston head arrangement comprised by the retaining pins **64** discussed previously. An advantage of the rigid end part **146** is improved predictability in the deformation of the bellows sections or rings **132** during expansion and contraction of the bellows member **120** because the piston elements **14** of the fluid injector **12** push and pull against a rigid base part or plate rather than on the body of the bellows member **120**, which is typically made of a less rigid plastic material that is capable of deformation.

[00176] In **FIG. 8**, the fluid container **220** according to a modified embodiment is provided with a rigid end part or base **234** that may be molded or otherwise affixed, such as by adhesive, to the closed end wall **230** of the fluid container body **222**. In **FIG. 8**, the fluid container **220** is further shown with a container body **222** having a sidewall **236** having an

optional tapered shape. The tapered sidewall **236** tapers at an angle of approximately 18°, or between 15-25°, and the rigid end part **234** and pliable, yet self-supporting, nature of the fluid container body **222** permits the end wall **230** to introvert into the fluid container body **222**, and the tapering of the sidewall **236** provides additional radial clearance around the circumference of the rigid end part **234** so that the material forming the sidewall **236** may gather or overlap radially outward of the circumferential edge of the rigid end part **234** as the piston element **14** moves distally or forward into the fluid container body **222**. The fluid container **220** may be formed without a tapered sidewall **236**. As illustrated in **FIG. 8**, the fluid container body **222** defines an interior space or volume **238**. Further, the discharge port **226** of the fluid container **220** is formed with an open passageway or opening **240** that is sealed by a fluid connector fitting or element **242** such as a conventional luer fitting or element. The tapered sidewall **236** may be tapered in either direction (e.g., as illustrated tapering from wide at the proximal end **228** to narrow at the distal end **224** or vice versa). The rigid end part **234** may be applied to any of the fluid container **220**, fluid container **320** (discussed herein in connection with **FIGS. 10A-10C**), or bellows member **120** in this disclosure. As noted previously, it will be understood that the body **222** of the fluid container **220** is sufficiently rigid to be self-supporting when placed on end, yet pliable enough to permit the end wall **230** to introvert into the interior of the fluid container body **222** so that the sidewall **236** may fold inward against itself radially between the sidewall **236** and the interior wall of the pressure jacket **30**. Thus, the fluid container **220** is an axially collapsible fluid container in a manner similar to the bellows member **120**, but in a different manner wherein the sidewall **236** introverts into the interior of the fluid container body **222** and folds inward against itself; and the foregoing introverting, axially collapsing feature of the fluid container **220** is equally applicable to all of the straight-sided and tapered-sided fluid containers described in this disclosure, such as fluid container **320** described herein. **FIG. 10B**, discussed herein illustrates the introverting feature of the fluid container **320**. The use of the rigid end part **234** does not materially change the foregoing introverting, axially collapsing operation of the fluid container **220** and like fluid containers described in this disclosure.

[00177] Referring next to **FIGS. 9A-9C**, another embodiment of the piston head **16** for the piston element(s) **14** of the fluid injector **12** is shown. The piston head **16** shown in **FIGS. 9A-9C** may be used in any of the various embodiments of the fluid injector **12** discussed in this disclosure. In this embodiment, the bellows member **120** or fluid container **220** comprises a button or like structure (shown in **FIGS. 24-26**) on the proximal closed end wall

128, **230** that is fits within a hole or opening **74** in the piston head **16**. In particular, as the button or like structure is received into the hole or opening **74**, the button engages a plurality of pivotal jaws **76**, which are held closed by respective torsion springs **78**, and urges the respective jaws **76** apart. Once the jaws **76** pass over the button, the torsion springs **78** cause the jaws **76** to snap onto a stem or like structure connecting the button to the closed end wall **128**, **230** of the bellows member **120** or fluid container **220**, respectively. In this embodiment, the bellows member **120** or fluid container **220** may be loaded into the pressure jacket **30** in the manner described previously to position the button or like element in axial alignment with the hole **74** in the piston head **16**. Then, the piston element **14** may be driven forward until the button or like structure is received into the hole **74** in the piston head **16**. To disconnect the bellows member **120** or fluid container **220** from the piston head **16**, at a prescribed point during a retracting movement of the piston element **14**, respective lever tabs **80** on the pivotal jaws **76** contact a surface or abutment that forces the pivot jaws **76** open, thereby permitting removal of the bellows member **120** or fluid container **220** from the pressure jacket **30**.

[00178] Referring further to **FIGS. 10A-10C**, a multi-syringe type fluid injector **12** is illustrated. In this embodiment, the fluid injector **12** is adapted to accept a disposable fluid container **320** according to another embodiment as illustrated in **FIG. 10A**. The fluid container **320** in this embodiment has a soft, pliable, yet self-supporting body **322** having a conical distal end **324** terminating in a discharge port **326**, and a proximal end **328** with a closed end wall **330**. The closed end wall **330** defines a receiving end pocket **332** therein to receive the piston head **16** of the piston element **14** of the fluid injector **12**. The closed end wall **330** may alternatively include a rigid end part or base or plate (not shown) that defines the receiving end pocket **332** for the piston head **16**, in a similar manner to other embodiments discussed previously. Even though a two (2) syringe fluid injector **12** is illustrated, the present fluid container **320** may be used in a single syringe-type fluid injector **12**. The end pocket **332** further defines a tip receptor **334** for a corresponding tip element **336** on the piston head **16** of the piston element **14**. Further, the discharge port **326** is fully sealed by a rupture ready tip **338**.

[00179] The present fluid container **320** is adapted for use as a disposable liner or prefilled container in a reusable or disposable syringe **340**, which is adapted to directly engage the fluid injector **12** and, in particular, the face plate **19** of the fluid injector housing **18**. The syringe **340** is generally operable as a pressure jacket in this embodiment, and a suitable construction for the syringe **340** and the fluid injector **12** in this embodiment may be found in U.S. Patent No. 7,419,478 to Reilly, et al. assigned to Medrad, Inc. and incorporated herein

by reference. The Reilly, et al. patent includes syringe details for the syringe **340**, and details for interfacing the syringe **340** to the fluid injector **12**. The fluid container **320** may be made by a blowing-filling-capping (BFC) technique, also referred to in the relevant field of endeavor as blow-mold-seal (BFS), wherein the fluid container body **322** is blow-molded, filled with the desired medical fluid such as contrast media, and aseptically sealed by sealing the discharge port **326** with an integrally formed/molded rupture-ready tip **338**. The BFC technique permits the fluid container **320** to be formed, filled, and sealed typically in one machine or apparatus and these steps may be accomplished under sterility maintained conditions, limiting the possibility of introducing contaminates in the formed, filled, and sealed fluid container **320**. The rupture-ready tip **338** is formed as part of the molding process at the conclusion of filling of the fluid container body **322**. A sterility-enhanced preformed and prefilled fluid container **320** results from the BFC process. The rupture-ready tip **338** may be designed for external puncture by a fluid conducting tubing set attached to the tip **338** by a user, or may be designed to reliably burst when a preset internal pressure is reached in the fluid container **320** as the piston element **14** moves distally or forward in the fluid container body **322**.

[00180] Several embodiments herein describe a process using a pre-form, which is then molded to final shape. While BFS/BFC techniques do not use pre-forms, injection-blowmolding (IBM) and injection stretch-blow-molding (ISBM) do use pre-forms, and such techniques may be used with the pre-forms set forth in this disclosure.

[00181] Referring to **FIGS. 11A-11C**, a BFC process may be used to form any of the fluid containers described in this disclosure, including fluid containers **220**, **320** and, further, bellows member **120**. In **FIGS. 11A-11C**, an exemplary BFC process may be used to form the fluid container **220** shown in **FIG. 8**, discussed previously, and this fluid container **220** is referenced hereinafter only for exemplary purposes for discussing the features and processes exemplified by **FIGS. 11A-11C**. The illustration of fluid container **220** as specifically depicted in **FIGS. 11A-11C** should not be considered limiting. In the BFC process, the fluid container body **222** is blow-molded via an open proximal end **244**, which is the wider end of the fluid container body **222**. The fluid exit end or distal end **224** is formed as the closed end of the fluid container body **222** and is the narrow end of the fluid container body **222**. The discharge port **226** in this embodiment is formed as the sealed end of the fluid container body **222**. After the fluid container body **222** is formed, the formed fluid container body **222** is filled with the desired medical fluid. Once the fluid container body **222** is filled with fluid, the rigid end part **234** is used to seal the open proximal end **244**, and the end part **234** may be

molded to or otherwise secured to the fluid container body **222**, for example, by adhesive. Once the end part **234** is installed, the fluid container **220** is ready for use as a prefilled container. In **FIG. 11C**, as an alternative, the formed fluid container body **222** may be sealed with a flexible membrane **246**. As illustrated, in this variation of the fluid container **220**, the sidewall **236** need not be tapered, as discussed previously, and the lack of tapering does not retard the ability of the fluid container body **222** to flex or roll and introvert into itself from the proximal end **228** toward the distal end **224**. Further, the end part **234** may optionally be molded to or otherwise secured to the fluid container body **222** as in previous embodiments.

[00182] Referring to **FIG. 12**, the bellows member **120** may also be formed using a BFC process. In **FIG. 12**, a sequence of molding, filling, and sealing the bellows member **120** according to an exemplary BFC process is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is provided as a molded pre-form, and followed at step **b** where the bellows portion **126** comprising bellows sections or rings **132** is formed, such as by blow-molding. At step **c**, the formed bellows member **120** is filled with fluid from an open proximal end **124** in this embodiment. At step **d**, the open proximal end **124** is sealed with a sealing element or plug **148**, to complete the prefilled bellows member **120**. In this embodiment, the discharge neck **130** is sealed closed to form a closed or sealed discharge port **150** during the blow-molding process, as filling is accomplished via the open proximal end **124**. A connector element **180** having a piercing feature or element **182** may be used to access the sealed discharge port **150** at step **e**.

[00183] Referring to **FIG. 13**, an alternative sequence of molding, filling, and sealing the bellows member **120** according to an exemplary BFC process is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is provided as a molded pre-form, but now with an open discharge port **150** at the distal end **122**, and followed at step **b** where the bellows portion **126** comprising bellows sections or rings **132** is formed, such as by blow-molding. At step **c**, an aseptic seal **184**, such as a foil membrane, is applied to the discharge port **150** which is formed as part of the discharge neck **130** of the bellows member **120**. At step **d**, the formed bellows member **120** is filled with fluid from the open proximal end **124**. At step **e**, a second aseptic seal **186** is applied to the open proximal end **124** to seal the open proximal end **124** and complete the prefilled bellows member **120**.

[00184] Referring to **FIG. 14**, another sequence of molding, filling, and sealing the bellows member **120** according to an exemplary BFC process is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is provided as a molded pre-form, again with a closed discharge port **150** at the distal end **122**, but now the

discharge port **150** is provided at the end of a discharge neck **130** having an elongated form. At step **b**, the bellows portion **126** comprising bellows sections or rings **132** is formed, such as by blow-molding. At step **c**, a break-away tab **188** is crimped or otherwise mechanically formed into the elongated discharge neck **130**. At step **d**, the formed bellows member **120** is filled with fluid from the open proximal end **124**. At step **e**, the open proximal end **124** is sealed closed, for example by a crimping or like mechanical closure process, to complete the prefilled bellows member **120**.

[00185] Referring to **FIG. 15**, another sequence of molding, filling, and sealing the bellows member **120** according to an exemplary BFC process is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is provided as a molded pre-form, but now with an open discharge port **150** at the distal end **122**, and followed at step **b** where the bellows portion **126** comprising bellows sections or rings **132** is formed, such as by blow-molding. At step **c**, a mechanical closure or cap **190** is applied to the discharge neck **130** to seal the discharge port **150**. At step **d**, the formed bellows member **120** is filled with fluid from the open proximal end **124**. At step **e**, the open proximal end **124** is sealed, for example by a crimping process or like mechanical closure process, to complete the prefilled bellows member **120**.

[00186] Referring to **FIG. 16**, another sequence of molding, filling, and sealing the bellows member **120** according to an exemplary BFC process is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is provided as a molded pre-form, but with an open distal end **122**, and followed at step **b** where the bellows portion **126** comprising bellows sections or rings **132** is formed, such as by blow-molding. The molded pre-form or formed bellows member **120** may be provided with an exterior circumferential flange **152**. At step **c**, the formed bellows member **120** is filled with fluid from the open distal end **122** in this embodiment, and the discharge neck **130** is sealed at step **d** with an aseptic membrane **192**, such as a foil membrane, or molded membrane or crimped shaped membrane. At step **e**, a mechanical interface closure or cap **194** is applied to the sealed discharge neck **130** to abut the exterior circumferential flange **152** to complete the prefilled bellows member **120**. At step **f**, the connector element **180** having a piercing feature **182**, discussed previously, may be used to access the sealed discharge neck **130** by attachment to the interface cap or closure **194** and puncturing the aseptic membrane **192**. The piercing feature **182** of the connector element **180** may be disposed within a shielded housing **196**.

[00187] Referring to **FIG. 17**, another sequence of molding, filling, and sealing the bellows member **120** according to an exemplary BFC process is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is extrusion blow-molded while retaining an open distal end **122**, followed at step **b** where the formed bellows member **120** is filled with fluid from the open distal end **122** in this embodiment. At step **c**, the discharge neck **130** is sealed using a crimping process or like mechanical process to form a closed discharge port **150** that may be punctured. For example, the connector element **180** having a piercing feature **182**, discussed previously, may be used to access the sealed discharge port **150**, such as at step **d**. The connector element **180** may be part of a press-on fluid tubing set and can be used to manually pierce the sealed discharge port **150**, or the connector element **180** may be held as part of or connected to the pressure jacket **30** and the piercing of the discharge port **150** may be accomplished during the action of loading the bellows member **120** into the pressure jacket pressure jacket **30**.

[00188] Referring to **FIG. 18**, another alternative sequence of molding, filling, and sealing the bellows member **120** according to an exemplary BFC process is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is extrusion blow-molded while retaining an open distal end **122**, followed at step **b** where the formed bellows member **120** is filled with fluid from the open distal end **122** in this embodiment, and the discharge neck **130** is sealed at step **c** by a separately-molded, drop-in fluid connector fitting **198** that is placed in the discharge neck **130**. The fluid connector fitting **198** is sealed with an aseptic seal **200** such as a foil membrane, such as at step **d**. The connector element **180**, discussed previously, having a piercing feature **182** may be used to access the sealed discharge port **150** in this embodiment. As an example, the connector element **180** may be part of a press-on fluid tubing set and can be used to manually pierce the sealed discharge port **150**, or the connector element **180** may be held as of part or connected to the pressure jacket **30** and the piercing of the discharge port **150** may be accomplished during the action of loading the bellows member **120** into the pressure jacket **30**.

[00189] Referring to **FIG. 19**, another sequence of molding, filling, and sealing the bellows member **120** according to an exemplary BFC process is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is extrusion blow-molded while retaining an open distal end **122** and an elongated discharge neck **130** in this embodiment. At step **b**, the formed bellows member **120** is filled with fluid from the open distal end **122**. At step **c**, the discharge neck **130** is closed by a separately-molded, drop-in fluid connector fitting **198** that is placed in the discharge neck **130**. The fluid connector fitting

198 is sealed by a mechanical crimping process or otherwise sealed in the discharge neck **130** at step **d** to form a break-away cover **202** at the distal end **122**. The portion of the discharge neck **130** that is used to form the break-away cover **202** may be made frangible by use, for example, of a score line, and the break-away cover **202** may be removed at step **e** to permit access to the fluid connector fitting **198**.

[00190] Referring to **FIG. 20**, another sequence of molding, filling, and sealing the bellows member **120** according to an exemplary BFC process is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is extrusion blow-molded while retaining an open distal end **122**. At step **b**, the formed bellows member **120** is filled with fluid from the open distal end **122**. At step **c**, the discharge neck **130** is sealed by a pierceable septum **204** that is placed in the discharge neck **130**. At step **d**, a cap **206** may be applied to the distal end **122** to enclose the discharge neck **130** and partially enclose the top of the septum **204**. The connector element **180**, discussed previously, having a piercing feature **182** may be used to access the septum **204** as shown at step **e**.

[00191] Referring to **FIGS. 21A-21B**, the bellows member **120** and fluid containers **220**, **320** of this disclosure may be made by a combination of injection molding and, further, blow-molding. In **FIG. 21A**, a schematic fluid container pre-form **90** is shown formed by an injection molding process. This process results in a fluid container pre-form having a distal end **92** with an open discharge port **94** and a proximal end **96** formed with integral piston engagement features **98** that are formed as part the closed proximal end **96**. In **FIG. 21B**, the pre-form **90** is blow-molded to form the bellows member **120** having the features described previously, but the bellows member **120** retains the integral piston engagement features **98** as part of the closed end wall **128** thereof.

[00192] Referring to **FIGS. 22A-22B** and **FIGS. 22C-22D**, the bellows member **120** may be formed initially as a pre-form that may be subsequently blow-molded. In the present figures, the bellows portion **126** only is shown as a tube-shaped pre-form **154** and stiffening ribs **156** may be added. The stiffening ribs **156** may be made of the same material as the pre-form or a different material, but is typically non-elastomeric material. The pre-form **154** may then be blow-molded to form the bellows portion **126** of the bellows member **120**, as shown in **FIGS. 22C-22D**, with the bellows sections or rings **132** being formed between the respective stiffening ribs **156**. These figures illustrate another method for forming the bellows portion **126** of the bellows member **120**.

[00193] Referring to **FIGS. 23A-23D**, the bellows syringe **100** may be shipped in a compressed configuration, as noted previously. In the illustrated embodiment, the bellows

syringe **100** is shipped in a first locked state which may be unlocked for use. Once used, the bellows syringe **100** may be placed in a second, permanently locked state to prevent undesirable reuse of the used bellows syringe **100**. For example, the cap member **102** may comprise a first set of locking tabs **158** and a second, interior set of locking tabs **160** disposed axially along the skirt portion **104** of the cap member **102**. A base member **162** may be provided on the end wall **128** at the proximal end **124** of the bellows member **120**. The base member **162** comprises a circumferential lip or rim **164** adapted to interface with the two (2) sets of locking tabs **158**, **160**. The base member **162** may further comprise a depending cylindrical portion **165** adapted to interface with the piston head **16** of the piston element **14** of the fluid injector **12**. The bellows syringe **100** may be initially provided in a sealed blister package and the like, with the circumferential lip or rim **164** on the base member **162** engaged with the first set of locking tabs **158** as shown in **FIGS. 23A-23B**. This engagement may be unlocked, for example, by action of the piston head **16** of the piston element **14** of the fluid injector **12**, such as when the piston head **16** initially engages piston engagement structure **166** provided in the depending cylindrical portion **165** of the base member **162**. Once the engagement between the circumferential lip or rim **164** on the base member **162** and the first set of locking tabs **158** is released, the bellows syringe **100** is operable as described previously. Once the useful life of the bellows syringe **100** has been exhausted, the piston element **14** of the fluid injector **12** may be operated to push the base member **162** into the cap member **102** so that the circumferential lip or rim **164** on the base member **162** engages with the second, interior set of locking tabs **160**, as shown in **FIGS. 23C-23D**. This second engagement may be a permanent connection so that the bellows syringe **100** cannot be reused without significant impairment of or damage to the physical components of the bellows syringe **100**. The concepts described in connection with **FIGS. 23A-23D** may be applied to any of the embodiments of the bellows syringe **100** in this disclosure.

[00194] Referring to **FIGS. 24-26**, various tubing connection elements may be associated with the bellows member **120** of the bellows syringe **100**. **FIGS. 24-26** show the bellows member **120** with a button element or like structure **168** on the proximal closed end wall **128** that is used to interface with the piston head **16** shown in **FIGS. 9A-9C**. Fluid containers **220**, **320** may also have the button element **168**, as mentioned previously in connection with fluid container **220**.

[00195] In **FIG. 24**, a sequence for molding, filling, and sealing the bellows member **120** is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is extrusion blow-molded, provided as an injection-molded component, etc.,

while retaining an open distal end **122** and an elongated discharge neck **130** in this embodiment. At step **b**, the formed bellows member **120** is filled with fluid through the open distal end **122**. At step **c**, the discharge neck **130** is closed by a separately-molded, drop-in fluid connector fitting **300** that is placed in the discharge neck **130**. At step **c**, the fluid connector fitting **300** is sealed by mechanical crimping or otherwise sealed to seal the discharge neck **130** and to form a break-away tab **302** at the distal end **122**. The break-away tab **302** is frangible and may be removed at step **d** to permit access to the fluid connector fitting **300**. Fluid may be dispensed from the bellows member **120** until empty as shown at step **e**.

[00196] In **FIG. 25**, another sequence for molding, filling, and sealing the bellows member **120** is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is extrusion blow-molded, provided as an injection-molded component, etc., while again retaining an open distal end **122** and an elongated discharge neck **130** in this embodiment. At step **b**, the formed bellows member **120** is filled with fluid through the open distal end **122**. At step **c**, the discharge neck **130** is closed and sealed by a separately-molded, drop-in septum **304** and an enclosing mechanical cap fitting **306** that is engaged with the discharge neck **130**. A fluid connector element **308** having a piercing feature or element **310** may be used to access the septum **304**. The piercing element **310** may be enclosed in a shield or housing portion **312** of the fluid connector element **308**, and a peel-away membrane or seal **314** may enclose the shield or housing portion **312** to shield the piercing element **310**. Fluid may be dispensed from the bellows member **120** until empty as shown at step **e**. The piercing element **310** is operable as the discharge port **150** in this embodiment.

[00197] In **FIG. 26**, another sequence for molding, filling, and sealing the bellows member **120** is schematically illustrated. The sequence starts at step **a** where the body of the bellows member **120** is extrusion blow-molded, provided as an injection-molded component, etc., while again retaining an open distal end **122** and an elongated discharge neck **130** in this embodiment. At step **b**, the formed bellows member **120** is filled with fluid through the open distal end **122**. At step **c**, the discharge neck **130** is closed and seal by a mechanical crimping process or like processes, and one or more circumferential grooves or recesses **316** are defined in the discharge neck **130**. Also at step **c**, the fluid connector element **308** according to the previous embodiment is attached to the discharge neck **130**. The fluid connector element **308** again has a piercing feature or element **310** enclosed within a the shield or housing portion **312**, and a peel-away membrane or seal **314** (shown in **FIG. 25**) may also be used to enclose the shield or housing portion **312** to shield the piercing element **310**. The

shield or housing portion **312** comprises one or more distal tabs **318** adapted to engage the circumferential grooves or recesses **316** defined in the discharge neck **130** of the bellows member **120**. The distal tab or tabs **318** may alternatively be a continuous rib. The circumferential groove or recess **316** in the discharge neck **130** closest to the sealed discharge port **150** provides a mounting location for the fluid connector element **308** so that the bellows member **120** may be transported. When it is desired to access the interior **136** of the bellows member **120**, the user may press down on the fluid connector element **308** so that the distal tabs **318** on the shield or housing portion **312** are displaced from engagement with the upper circumferential groove or recess **316** and engage the next circumferential groove or recess **316** located axially downward on the discharge neck **130** and the piercing element **310** simultaneously pierces the sealed discharge port **150** at the end of the discharge neck **130** of the bellows member **120**. Fluid may be dispensed from the bellows member **120** until empty as shown at step **e**. Upward-directed locking arms **319** may be provided on the bellows member **120** to engage the distal tabs **318** on the shield or housing portion **312** to secure the shield or housing portion **312** in the pierced state shown in steps **d** and **e**.

[00198] Referring to **FIGS. 27A-27B**, the bellows assembly **20** is shown with the bellows syringe **100** loaded in the cylindrical body or pressure jacket **30**. In this embodiment, a piercing connector cap **208** is provided to access the discharge port **150** at the end of the discharge neck **130** of the bellows member **120**. The cap member **102** defines a distal cavity **170** to house the piercing connector cap **208**. The piercing connector cap **208** comprises a piercing element **210** supported and activated by a collapsible body **212**. The piercing element **210** defines a central passageway **214** therethrough to permit fluid to pass through the piercing element **210**. The piercing element **210** is disposed over an opening **172** in the cap member **102**. Additionally, the collapsible body **212** comprises a connector tip **216** that coincides with the opening **172** in the cap member **102** to permit fluid to pass through the cap member **102**. In use, the piercing connector cap **208** is pressed downward by a user of the bellows assembly **20** so that the collapsible body **212** collapses into the compressed state shown in **FIG. 27B**. As the collapsible body **212** compresses downward, the piercing element **210** is pushed into the opening **172** in the cap member **102** to puncture the discharge port **150** at the end of the discharge neck **130** of the bellows member **120** and establish fluid communication with the interior **136** of the bellows member **120** via the passageway **214**. An external fluid tubing set (not shown) may be connected to the connector tip **216** to permit the contents of the bellows member **120** to be conducted to a patient. While the piercing connector cap **208** may be operated manually, a mechanical component or structure on the

external fluid tubing set may also be used to automatically activate the piercing connector cap **208**, for example, as part of the connecting process for interfacing the fluid tubing set to the connector tip **216** and, thus, establish a fluid connection with the discharge port **150** on the bellows member **120**. The piercing connector cap **208** is desirably sealed in the distal cavity **170** in the cap member **102** in a substantially fluid-tight manner.

[00199] In **FIGS. 28A-28C**, the bellows assembly **20** in another embodiment is shown with the bellows syringe **100** loaded in the cylindrical body or pressure jacket **30**. In this embodiment, the cap member **102** again defines a distal cavity **170**, and now comprises an integral or attached fluid connector tip **174** connected to the cap member **102** to permit fluid to pass through the opening **172** in the cap member **102**. A rotational piercing element **218** defining a central passageway **219** is disposed in the fluid connector tip **174**. The piercing element **218** may be in threaded engagement in the opening **172** in the cap member **102**, and an external fluid tubing set (not shown) is used to rotate the piercing element **218** in the opening **172** to a position where the piercing element **218** punctures the discharge port **150** at the end of the discharge neck **130** of the bellows member **120** and establish fluid communication with the interior **136** of the bellows member **120** via the passageway **219**. For example, the fluid tubing set may be adapted for a threaded engagement with the fluid connector tip **174** and may comprise a mechanical component or structure to engage and rotate the piercing element **218** in the opening **172**. The piercing element **218** need not be in threaded engagement in the opening **172** to effect puncturing of the discharge port **150** on the bellows member **120** as the piercing element **218** may simply be pushed into the discharge port **150** by the action of connecting the fluid tubing set to the fluid connector tip **174**. However, the threading on the piercing element **218** is desirable for use in piercing or accessing the discharge port **150**, enlarging the engagement between these two components, and securing the engagement therebetween in a similar manner to the operation of a wood screw or drywall screw.

[00200] Referring to **FIG. 29**, the bellows assembly **20** in another embodiment is shown with the bellows syringe **100** loaded in the pressure jacket **30**. In this embodiment, the cap member **102** again defines a distal cavity **170** and has a fluid connector tip **174** connected to the opening **172** in the cap member **102** to permit fluid to pass through the cap member **102**. A piercing pin or needle cannula **176** is disposed and axially movable in a central post portion **178** within the fluid connector tip **174**. A removable cap **400** is disposed over the cap member **102** and engaged with the cap member **102** by any suitably removable manner, such as being snap-fit onto the cap member **102**. The removable cap **400** comprises a central button **402**

disposed over the piercing pin or needle cannula **176** that a user may depress in the direction of arrow **A** to cause the piercing pin or needle cannula **176** to move axially downward and pierce the discharge port **150** at the end of the discharge neck **130** of the bellows member **120** to establish fluid communication with the interior **136** of the bellows member **120**. If desired, the piercing pin or needle cannula **176** may be connected to the central button **402** so that, after piercing the discharge port **150**, the piercing needle **176** may be removed along with the removable cap **400**. Alternatively, the piercing needle cannula **176** when pushed into the central post **178** in the fluid connector tip **174** may form part of the fluid conducing pathway through the fluid connector tip **174** to a fluid tubing set (not shown) connected to the fluid connector tip **174**. In either configuration, the pressing of the central button **402** establishes fluid communication with the interior **136** of the bellows member **120** in this embodiment.

[00201] Referring to **FIGS. 30A-30E**, the bellows assembly **20** in another embodiment is shown with the bellows syringe **100** loaded in the pressure jacket **30**. In this embodiment, the cap member **102** again defines a distal cavity **170** and a fluid connector tip **174** is connected to the opening **172** in the cap member **102** to permit fluid to pass through the cap member **102**. A luer-type fluid connector element **404** may be disposed in the fluid connector tip **174** in this embodiment and be in fluid communication with the opening **172**. A slide plate **406** is movable associated with the cap member **102** and, in particular, is movable transversely relative to the cap member **102** in the direction of arrow **B** to create and close a fluid path to the discharge port **150** of the bellows member **120**. For example, in one embodiment, the slide plate **406** defines an opening **408** which permits a fluid connection to be established between the fluid connector element **404** and the discharge port **150** on the bellows member **120** when the slide plate **406** is positioned to generally align the opening **408** with the fluid connector element **404** and the discharge port **150** as shown in **FIG. 30A**. When the slide plate **406** is pushed or pulled relative to the cap member **102** using a push or pull tab **410** on the slide plate **406**, the opening **408** is displaced from the connecting fluid path alignment as shown in **FIG. 30B**, which closes the fluid path. **FIGS. 30C-30D** show top views of the cap member **102** with the slide plate **406** in the unaligned and aligned positions, respectively. **FIG. 30C** shows the slide plate **406** in the unaligned position where the opening **408** is unaligned with the fluid connector element **404** and the open discharge port **150** in this embodiment to close a flow path and permit fluid flow. **FIG. 30D** shows the slide plate **406** in the aligned position where the opening **408** is aligned with the fluid connector fitting **404** and the discharge port **150** to open the flow path and prevent fluid flow. A spring-biased stopper **412** may be disposed adjacent an end of the slide plate **406** to secure the slide plate

406 in the aligned position. The spring-biased stopper 412 may be depressed by action of the slide plate 406 to permit the slide plate 406 to be placed into the blocking or unaligned position.

[00202] Referring to FIGS 31A-31C, in a variation of the bellows assembly 20 described in connection with FIGS. 30A-30E, the slide plate 406 is replaced by a rotational plate 416 that is off-center or off-axis relative to the opening 172 in the cap member 102 and alternately covers and uncovers the fluid path between the fluid connector element 404 and the discharge port 150 on the bellows member 120 depending on the rotational position of the rotational plate 416. As shown in FIGS. 31B-31C, as the rotational plate 416 is rotated relative to the cap member 102 in the direction of arrow B, the rotational plate 416 moves from a first position covering the fluid path between the connector element 404 and the discharge port 150 on the bellows member 120, as shown in FIG. 31B, to a second position wherein the fluid path between the connector element 404 and the discharge port 150 on the bellows member 120 is open or uncovered, as shown in FIG. 31C.

[00203] Referring to FIG. 32, the bellows assembly 20 in another embodiment is shown with the bellows member 120 loaded in the cylindrical body or pressure jacket 30. In this embodiment, the cap member 102 again defines a distal cavity 170 and a fluid connector tip 174 fluidly connected to the opening 172 in the cap member 102 to permit fluid to pass through the cap member 102. In this embodiment, a cutting blade 420 is provided as part of the cap member 102 and is operable via an external button 422 which is used to move the cutting blade 420 transversely in the cap member 102. As an example, the discharge port 150 at the end of the discharge neck 130 of the bellows member 120 may define a pointed tip 151 extending into the opening 172 in the cap member 102 and the cutting blade 420 may be disposed to cut the protruding or pointed tip 151 when the external button 422 is pressed, which causes lateral or transverse movement of the cutting blade 420 in the direction of arrow C. The central post 178 (see FIG. 29) in the fluid connector tip 174 may form part of the fluid conducing pathway through the fluid connector tip 174 which connects to a fluid tubing set (not shown).

[00204] Referring to FIGS. 33A-33B, the bellows assembly 20 in another embodiment is shown with the bellows syringe 100 loaded in the pressure jacket 30. In this embodiment, a pivotal door 50 is hinged to the pressure jacket 30 to close the open distal end 32 of the pressure jacket 30. The pivotal door 50 comprises a fluid connector element 52 that is integral or removably associated with the pivotal door 50. The fluid connector element 52 comprises a piercing tip or element 54 adapted to pierce the discharge port 150 at the end of the

discharge neck **130** of the bellows member **120** to establish fluid communication with the interior **136** of the bellows member **120**. A catch or lock may be provided to secure the pivotal door **50** in the closed position with the fluid connector element **52** interfaced with the discharge port **150** on the bellows member **120**. The connector element **52** may be adapted to be connected to a fluid tubing set (not shown), which may be a conventional medical fluid tubing set.

[00205] **FIG. 34** shows an embodiment of the pressure jacket **30** having a pressure jacket body **500** that is formed by two (2) clam shell portions **502, 504** that are hinged together to close around a bellows member **120** of the bellows syringe **100**. The interiors of each of the clam shell portions **502, 504** support rib support member **506** which define cut-out areas or portions **508** that are adapted to support the bellows sections or rings **132** of the bellows member **120** between the individual bellows sections or rings **132**. The rib support members **506** support the individual bellows sections or rings **132** when the bellows member **120** is under pressure and help prevent the individual bellows sections or rings **132** from bulging radially outward. An end cap **510** may be provided to support the discharge neck **130** of the bellows member **120** in the pressure jacket body **500**. The rib support members **506** are axially compressible according to the concepts described below in connection with **FIGS. 35A-35B**.

[00206] Referring to **FIGS. 35A-35B**, as an application to or augmentation of the foregoing pressure jacket **30** with a clam shell pressure jacket body **500**, a ring support scaffold **520** comprising two ring clam shell portions **522, 524** are hinged together to close around the bellows member **120** of the bellows syringe **100**. In this embodiment, the support scaffold **520** may be an external skeleton attached to the bellows member **120** to support the individual bellows sections or rings **132** for the same reasons discussed above in connection with the clam shell pressure jacket body **500** of **FIG. 34**. The clam shell portions **522, 524** comprise individual rib support members **526** which define cut-out areas or portions **528** that are adapted to support the individual bellows sections or rings **132** of the bellows member **120** between the individual bellows sections or rings **132** on the bellows member **120**. The ring support scaffold **520** may be attached to the bellows member **120** and loaded along with the bellows member **120** into the pressure jacket **30** if desired. A support base **530** may be provided to support the support scaffold **520**. The support base **530** comprises two (2) support arms **532** that extend upward from the base **520**. The support arms **532** are received in respective sets of registered openings **534** in the individual rib support members **526** to control the axial compression characteristics of the bellows member **120**. Accordingly, if

desired, the base **530** may be loaded along with the bellows member **120** and attached ring support scaffold **520** when loaded into the pressure jacket **30** as shown, for example, in **FIG. 34**. Thus, the ring support scaffold **520** may be part of the pressure jacket **30** shown in **FIG. 34** or a separate structure loaded into the pressure jacket **30** shown in **FIG. 34**.

[00207] In the embodiments shown in **FIGS. 34** and **35A-35B**, supporting the minor diameters of the bellows portion **126** helps to prevent swell to help control retained fluid capacitance in the bellows member **120** and minimize/eliminate chaotic movement of the bellows member **120** as it collapses during operation. Furthermore, the structural support supplied by the embodiments shown in **FIGS. 34** and **35A-35B** apply tension between the minor and major diameters of the bellow portion **126**, which allows for more controlled collapse. For additional control of retained fluid capacitance, the major diameter and even the sides of the bellows portion **126** could be fully supported and minimize or even eliminate the retained fluid capacitance in the bellows syringe **100**. These embodiments contemplate a flexible and movable pressure jacket. To allow for the flexibility, the materials for the pressure jacket **500** could be a high tensile strength fabric such as those constructed of Nylon® or Spectra® ballistic materials. The fabric could also be segmented like ribbons to allow for visibility of the fluid contents. The movable segments described above slide along the support arms **532** as the bellows member **120** is compressed, minimizing the chaotic collapse of the each bellows ring or segment **132**. Alternatively, the segments or individual rib support members **526** could be driven by a programmable servo-motor to provide a controlled fluid injection. This method can replace a typical motor/ball-screw arrangement in the fluid injector **12** which drives the plunger element **14**.

[00208] Referring to **FIGS. 36A-36B**, a fluid injector **12** is shown with a pressure jacket **30** with a split-top pressure jacket body **540** that is pivotally connected to the fluid injector housing **18**, such as to the face plate **19**. The split-top pressure jacket body **540** is used to support the bellows member **120** of the bellows syringe **100**, and the split-top pressure jacket body **540** defines a split-top opening **542** to allow insertion and removal of bellows member **120** while a fluid tubing set (not shown) is connected to a fluid connector **544** disposed in the discharge neck **130** of the bellows member **120**. The split-top pressure jacket body **540** may be pivotally connected to the face plate **19** of the fluid injector **12**. In this embodiment, the bellows member **120** is breach-loaded into the split-top pressure jacket body **540**.

[00209] Referring to **FIGS. 37A-37B**, a fluid injector **12** is shown with a pressure jacket **30** with a cylindrical pressure jacket body **550** that has a pivotally connected front end plate **552**. The front end plate **552** defines split-top opening **554**. In this embodiment, the bellows

member **120** is front-loaded into the pressure jacket body **550** by pivoting the front end plate **552** downward. The split-top opening **554** allows insertion and removal of bellows member **120** while a fluid tubing set is connected to a fluid connector **556** disposed in the discharge neck **130** of the bellows member **12**.

[00210] Referring to **FIGS. 38A-38B**, a fluid injector **12** is shown with a pressure jacket **30** having split-front or front-loading clam shell pressure jacket body **560** connected to the fluid injector **12**. The split-front pressure jacket body **560** comprises two (2) opposed shell portions **562, 564**, with one of the shell portions **562** pivotally connected to the face plate **19** of the housing **18** of the fluid injector **12** and the other of the shell portions **564** fixedly secured to the face plate **19** of the housing **18** of the fluid injector **12**. The front-opening nature of the pressure jacket **560** permits the bellows member **120** to be loaded therein from the front, and the pivoting shell portion **562** permits the insertion and removal of bellows member **120** while a fluid tubing set is connected to a fluid connector **566** disposed in the discharge neck **130** of the bellows member **12**.

[00211] Referring to **FIGS. 39A-39B**, a fluid injector **12** is shown with a pressure jacket **30** with another embodiment of a split-top pressure jacket body **570**. The split-top pressure jacket body **570** is used to support the bellows member **120** of the bellows syringe **100**, and the split-top pressure jacket body **570** defines a split-top opening **572** to allow insertion and removal of bellows member **120** while a fluid connector tubing set **574** is connected to the discharge neck **130** of the bellows member **120**. The split-top pressure jacket body **570** may be pivotally connected to the face plate **19** of the housing of the fluid injector **12** and, in this embodiment, the bellows member **120** is breach-loaded into the split-top pressure jacket body **570**. The fluid injector housing **18** further comprises a filling appendage **576** that extends outward to fill the split-top opening **572** when the split-top pressure jacket **570** is pivoted to the closed position.

[00212] Referring to **FIG. 40A-40B**, a fluid injector **12** is shown with a pressure jacket **30** having an open-top pressure jacket body **580** that is telescopically connected to the face plate **19** of the housing **18** of the fluid injector **12**. The open-top pressure jacket body **580** is used to support the bellows member **120** of the bellows syringe **100**. The open-top pressure jacket body **580** defines an open-top **582** to allow insertion and removal of bellows member **120** while a fluid tubing set (not shown) is connected to the discharge port **150** of the bellows member **120**. The open-top pressure jacket body **580** may be telescopically connected to the fluid injector housing **18** to extend outward therefrom to reach a loading position for the bellows member **120**, and then be retracted to a closed position relative to the fluid injector

housing **18** which encloses the open-top **582**. In this embodiment, the bellows member **120** is top-loaded into the open-top pressure jacket body **580** via the open-top **582**. The fluid injector housing **18** comprises a projecting roof portion **584** which encloses the open-top **582** of the pressure jacket body **580** when the open-top pressure jacket body **580** is in the closed position engaged with the fluid injector housing **18**. A slot opening **586** is provided in the distal end of the pressure jacket body **580** to accommodate fluid tubing.

[00213] Referring to **FIGS. 41A-41C**, a fluid injector **12** is shown with a pressure jacket **30** having split-top pressure jacket body **590** that is telescopically and pivotally connected to the face plate **19** of the housing **18** of the fluid injector **12**. The split-top pressure jacket body **590** is used to support the bellows member **120** of the bellows syringe **100**, and defines a split-top opening **592** to allow insertion and removal of bellows member **120** while a fluid tubing set (not shown) is connected to the discharge port **150** of the bellows member **120**. The split-top pressure jacket body **590** is pivotally connected to a slide plate **594** that is telescopically connected to the fluid injector housing **18**. The slide plate **594** is extendable outward from fluid injector housing **18** to reach an extended position where the split-top pressure jacket body **590** may be pivoted downward to allow breach-loading of the bellows member **120** into the pressure jacket body **590**. The split-top opening **592** in the pressure jacket body **590** may be flanked by two (2) tubular members **596**. The tubular members **596** are adapted to receive two (2) tubular support members **598** that extend outward from the face plate **19** of the fluid injector housing **18**. In use, once the bellows member **120** is loaded into the pressure jacket body **590**, the pressure jacket body **590** may be pivoted upward on the slide plate **594** until the support members **598** are aligned with the tubular members **596** provided on opposing sides of the split-top opening **592**. The pressure jacket body **590** may then be telescopically moved toward fluid injector housing **18** by the slide plate **594** and the support members **598** slide into the tubular member **596** to secure the circumferential support around the bellows member **120** and aid in supporting the pressure jacket body **590** to the fluid injector housing of the fluid injector **12**.

[00214] Referring to **FIGS. 42A-42C**, a fluid injector **12** is shown with a pressure jacket **30** comprising a split or peel-open pressure jacket body **600** that is telescopically and/or pivotally connected to the face plate **19** and the housing **18** of the fluid injector **12**. As in previous embodiments, the pressure jacket **30** is used to support the bellows member **120** of the bellows syringe **100**, and is adapted to define a split-top opening **602** to allow insertion and removal of the bellows member **120** while a fluid tubing set (not shown) is connected to the discharge port **150** of the bellows member **120**. For example, the pressure jacket body **600**

may then be telescopically and pivotally associated with to the fluid injector housing **18**, for example, on the slide plate **594** discussed in the previous embodiment, so that the pressure jacket body **600** may be extended outward from the fluid injector housing **18** and pivoted downward to permit breach-loading of the bellows member **120** therein. In this embodiment, the pressure jacket body **600** is resiliently deformable so that when the pressure jacket body **600** is in an extended telescoped position and pivoted downward, the bellows member **120** may be breach-loaded into the into the pressure jacket body **600**. The pressure jacket body **600** may be peeled or deflected open along the split-top opening **602** to allow passage of fluid tubing (not shown) through the formed split-top opening **602**. The split-top opening **602** may be formed when the two (2) side or edges **604** of the pressure jacket body **600** are pulled apart. Thus, to load the bellows member **120** into the pressure jacket body **600**, the pressure jacket body **600** is telescoped outward from the fluid injector housing **18** and pivoted downward and the bellows member **120** is breach-loaded therein. The two (2) sides or edges **604** of the body of the pressure jacket body **600** may then be pulled apart to form the split-top opening **602** to allow passage of a fluid tubing set (not shown) through the formed split-top opening **602**. The resilient sides **604** may then be released. As an alternative, as shown in **FIG. 42C**, the two (2) sides or edges **604** of the body of the pressure jacket body **600** may be provided in an overlapping configuration and are pulled apart to form the split-top opening **602** to allow passage of a fluid tubing set (not shown) through the formed split-top opening **602**. The sides or edges **604** may then be released so the resilient pressure jacket body **600** returns to its original state wherein the sides or edges **604** return to their original overlapping configuration; this configuration helps retain the shape of the pressure jacket body **600** when under pressure.

[00215] Referring to **FIGS. 43A-43B**, the cylindrical pressure jacket **30** may be pivotally connected to the housing **18** of the fluid injector **12** by a hinged connection **606**. The pressure jacket **30** may be a split-open or clam shell pressure jacket which is opened along a longitudinal hinge joint **608**. Thus, the pressure jacket **30** is formed by two (2) pressure jacket portions **610**, **612** joined by the longitudinal hinge joint **608**. The pressure jacket **30** has a closed front or distal end **32** that defines a central opening or aperture **616** for passage of a fluid tubing set (not shown) connected to the bellows member **120** or another fluid container loaded into the pressure jacket **30**. To load the bellows member in the pressure jacket **30**, the pressure jacket **30** is pivoted away from the fluid injector housing **18** along the hinged connection **606** and then opened along the longitudinal hinge joint **608**. The bellows member **120** is loaded into the pressure jacket **30**, while the fluid tubing set is passed through a

longitudinal slot **618** formed when the pressure jacket **30** is opened along the longitudinal hinge joint **608**.

[00216] Referring to **FIGS. 44A-44D**, the pressure jacket **30** is shown according to another embodiment, but having similarities to the pressure jacket **30** described above in connection with **FIGS. 43A-43B**. The pressure jacket **30** is formed again by two (2) pressure jacket portions **610**, **612** joined by a longitudinal hinge joint **608**. Additionally, in this embodiment, the pressure jacket portions **610**, **612** each have a radially-inward extending flange **620** that extends inward toward the interior of the pressure jacket **30** along the longitudinal slot **618** formed when the pressure jacket **30** is opened along the longitudinal hinge joint **608**. In this embodiment, the bellows member **120** or another fluid container adapted for use in the pressure jacket **30** comprises a locking structure, as shown in **FIGS. 44C-44D**, in the form of two (2) opposed locking flanges **622** that define a U-shaped slot therebetween **624**. The U-shaped slot **624** is provided to slidably receive therein the opposed flanges **620** on the pressure jacket portions **610**, **612** as the bellows member **120** is loaded into the pressure jacket **30** from the open rear or proximal end **34** opposite the closed front or distal end **32** of the pressure jacket **30**. Thus, the locking flanges **622** form a locking structure to maintain the pressure jacket **30** in a closed state. The pressure jacket **30** may be pivotally connected to the fluid injector housing **18** in a similar manner to that shown in **FIGS. 43A-43B**. The opposed locking tabs **622** may be provided only at the distal end **122** of the bellows member **120**, or extend part or all of the length of the bellows portion **126** to receive the opposed flanges **620** of the pressure jacket **30** as illustrated. Alternatively, the locking tabs **622** may be provided additionally or only at the proximal end **124** of the bellows member **120** to receive the opposed flanges **622** provided adjacent the open rear or proximal end **34** of the pressure jacket **30**. Moreover, as noted, the locking tabs **622** may be continuous and in the form of opposed flanges along part or all of the length of the bellows member **120** to receive the opposed flanges **622**, which may be formed continuously or intermittently along the length of the two (2) pressure jacket portions **610**, **612**.

[00217] Referring to **FIG. 45**, the pressure jacket **30**, such as the various clam shell opening pressure jacket embodiments set forth in this disclosure, may comprise structure to secure the connection of a fluid tubing set to the discharge port **150** on the bellows member **120**, or to another fluid container described in this disclosure. In **FIG. 45** a perspective view of the pressure jacket **30** in an opened state is shown to illustrate a concept of using the pressure jacket **30** to radially and axially hold the connection between a fluid tubing set and the discharge port **150**. As an illustrative example, the pressure jacket **30** may be the pressure

jacket **30** described in connection with **FIGS. 43A-43B**, but this reference to the embodiment should not be considered as limiting. In **FIG. 45**, a fluid tubing set **630** having a fluid connector **632** is fluidly connected to the discharge port **150** by any desired method. For example, the fluid connector **632** may comprise a piercing element used to access the discharge port **150**. The closed front or distal end **32** of the pressure jacket **30** may define a split-open receiving port or neck **636** for the fluid connector **632** and the discharge neck **130** of the bellows member **130**. The receiving port or neck **636** comprises a first or distal receiving recess or groove **638** that receives a radially-outward directed rim or flange **640** on the fluid connector **632**, thereby fixing the fluid connector **632** in the receiving port or neck **636** on the pressure jacket closed front or distal end **32**. Additionally, the receiving port or neck **636** further comprises a second or proximal receiving recess or groove **642** that receives a similar radially-outward directed rim or flange **644** on the discharge neck **130** on the bellows member **120**, thereby also fixing the discharge neck **130** in the receiving port or neck **636** on the pressure jacket closed front end **32**. With both the fluid connector **632** and the discharge neck **130** on the bellows member **120** secured in the radial and axial directions in the receiving port or neck **636** in the pressure jacket closed front or distal end **32**, the fluid connection interface between the fluid connector **632** and the discharge port **150** on the bellows member **120** is maintained even when the bellows member **120** is under pressure. If desired, the respective locations of the rims or flanges **640**, **644** and the respective receiving recesses or grooves **638**, **642** may be reversed.

[00218] Referring to **FIG. 46**, in another embodiment, a chuck mechanism **650** may be incorporated into an open distal end **32** of the cylindrical body or pressure jacket **30** to engage the discharge port **226** of the fluid container **220**, which is formed with an open passageway or opening **240** that is sealed by a fluid connector fitting or element **652** disposed in the discharge port **226** in this embodiment. While a fluid container **220** is illustrated in **FIG. 46**, the bellows member **120** may also be used in this embodiment. The fluid connector fitting **652** defines an annular recess or groove **654** for engagement by the components of the chuck mechanism **650**. The chuck mechanism **650** is adapted to engage the fluid connector fitting **652** so that the fluid can be drawn into the fluid container **220** or bellows member **120** and expelled therefrom while the fluid container **220** or bellows member **120** is held fixed in the pressure jacket **30** by the engagement with the annular recess or groove **654** in the fluid connector fitting **652**. The chuck mechanism **650** comprises a plurality of chuck fingers **656** that are spring-biased inward by torsion springs **658** toward a central axis **L** of the chuck mechanism **650**. A release collar **660** is spring-biased outward from the distal end **32** of the

pressure jacket **30** by one or more compression springs **662**, and the release collar **660** controls operation of the chuck fingers **656**. To operate the chuck mechanism **650** to an opened configuration for loading of the bellows member **120** in the pressure jacket **30**, a user pushes on the release collar **660** which acts on respective ends **664** of the chuck fingers **656**. The chuck fingers **656** pivot radially outward away from the central axis **L** of the chuck mechanism **650** and disengage from the annular recess or groove **654** in the fluid connector fitting **652** to permit the loading of the fluid container **220** or bellows member **120** or like fluid container into the pressure jacket **30**. The user pushes on the release collar **660** against the action of the compression springs **662** to operate the chuck mechanism **650** to the opened configuration or state. When the fluid container **220** or bellows member **120** is loaded into the pressure jacket **30**, the user releases the release collar **660** and the action of the compression springs **662** and torsion springs **658** automatically seat the chuck fingers **656** in the receiving recess or groove **654** in the fluid connector fitting **652**.

[00219] Referring to **FIG. 47**, another embodiment for securing a fluid connector fitting **670** to the discharge port **150** on the discharge neck **130** of the bellows member **120** is shown. The fluid connector fitting **670** comprises a housing or shield portion **672** that encloses a piercing element or tip **674**. The shield portion **672** has a terminal end flange **676** adapted to engage a series of annular distal recesses or grooves **678** in the discharge neck **130** of the bellows member **120**. In this embodiment, an external connector clip **680** is disposed on the discharge neck **130**. The connector clip **680** has a proximal end **682** thereof seated within an annular recess or groove **684** in the discharge neck **130**. The connector clip **680** comprises a plurality of distally-extending spring arms **686** that terminate with tapered end flanges **688**.

[00220] In use to pierce the discharge port **150**, the user presses down on the fluid connector fitting **670** causing the end flange **676** to snap out of engagement with the first or distal recess or groove **678** in the discharge neck **130** of the bellows member **120** and seat into engagement with the second or proximal recess or groove **678** in the discharge neck **130**. The movement of the fluid connector fitting **670** causes the piercing element **674** to pierce the discharge port **150** at the end of the discharge neck **130**. Further, this movement causes the spring arms **686** to deflect radially outward due to the engagement of the shield portion **672** with the tapered faces on the tapered end flanges **688** on the spring arms **686**. The spring arms **686** seat over a closed end **690** of the housing or shield portion **672** of the fluid connector fitting **670** as the end flange **676** on the shield portion **672** seats into engagement with the second or proximal recess or groove **678** in the discharge neck **130**, and the spring arms **686** secure the fluid connection established between the fluid connector fitting **670** and

the discharge port **150** on the bellows member **120** and, further, limit the possible reuse of the bellows member **120**.

[00221] Referring to **FIGS. 48A-48B**, a pyramidal-shaped bellows syringe **100** is shown. In this embodiment, the cap member **102** comprises a tapered collar **700** with three (3) depending tab members **702**. Additionally, a base member or element **704** is provided at the proximal end **124** of the bellows member **120**. The base member **704** comprise threes (3) radial catch members **706** adapted to engage the tab members **702** on the tapered collar **700**. The engagement of the tab members **702** with the catch members **706** secures the bellows syringe **100** in the collapsed state shown in **FIG. 48A**. The release of the tab members **702** from the catch members **706** may be done automatically when the bellows syringe **100** is interfaced with the pressure jacket **30**, for example, pursuant to any of the concepts described previously or hereinafter.

[00222] Referring to **FIGS. 49A-49D**, another embodiment of the bellows member **120** and pressure jacket **30** with inter-engaging longitudinal features is shown. In this embodiment, the body of the bellows member **120** is generally scallop-shaped in transverse cross section, as best shown in **FIG. 49B**, to define a series of longitudinal recesses **710**. The interior of the pressure jacket **30** is specifically shaped to receive the scallop-shaped bellows member **120** and comprises a series of longitudinal ridges **712** with intervening or separating longitudinal channels **714** shaped to receive the bellows member **120**. The longitudinal ridges **712** fit within the longitudinal recesses **710** in the body of the bellows member **120** as shown in **FIG. 49C** and support the bellows sections or rings **132** along the longitudinal and radial directions of the bellows member **120**. Thus, the bellows member **120** is keyed to fit within the interior of the pressure jacket **30** in this embodiment. The longitudinal ridges **712** also strengthen the pressure jacket **30**. While not shown, an end cap or cover may be used to enclose the bellows member **120** in the pressure jacket **30**. Further, the longitudinal recesses **710** in the bellows member **120** cause the bellows member **120** to define a series of individual lobes **716** as shown in **FIG. 46B**.

[00223] Referring to **FIG. 50**, the bellows member **120** or any of the fluid containers described hereinabove, such as containers **220**, **320** may be made longer, in the unfilled state, than the space available in the receiving pressure jacket **30** as illustrated by dashed line **720** in **FIG. 50**. As a result of this intentionally-extended axial length, when the bellows member **120** or fluid container is loaded into the pressure jacket **30**, the disposable component is always seated or "sprung" against the piston head **16** of the piston element **14** of the fluid

injector **12**, particularly when the piston element **14** is retracted to its rearmost position in the fluid injector. The solid line **722** in **FIG. 50** represents the volume of the pressure jacket **30**.

[00224] Referring to **FIGS. 51A-51C**, a fluid container such as fluid container **220** is shown with a luer-type fluid connector fitting **730** situated in the discharge port **226** at the distal end **224** of the fluid container body **222**. The fluid connector fitting **730** comprises an annular body **732** surrounding a luer-type fluid connector element **734**. The annular body **732** defines an integral end lip or rim **736**. A pressure jacket **30** adapted to accept the fluid container **220** is also shown and comprises a distal end **32** with a neck or collar **738** defining a central opening **739** for the fluid connector fitting **730** to pass therethrough. A drill-type chuck mechanism **740** is associated with the neck or collar **738** and surrounds and engages the fluid connector fitting **730**. The chuck mechanism **740** is used to secure the connected engagement between an opposing luer-type fluid connector (not shown) and the luer-type fluid connector element **734** disposed in the annular body **732** by radially compressing the annular body **732** and thereby exerting radial pressure on the two connected luer-type connectors.

[00225] The chuck mechanism **740** comprises several locking fingers **742** that are adapted to engage with the end lip or rim **736** on the annular body **732**. The locking fingers or chucks **742** are similar to locking fingers or chucks on a conventional hand-held power drill. The locking fingers or chucks **742** are actuated by a locking collar **744**. The locking collar **744** has internal tabs **746** which force radial tabs **748** on the neck or collar **738** of the pressure jacket **30** into a slot or groove **750** in the exterior of the annular body **732** when the locking collar **744** is rotated in a tightening direction. This tightening rotation of the locking collar **744** causes the locking fingers **742** to press radially inward on the annular body **732** thus compressing an internal abutment surface or wall **752** in the annular body **732** that is disposed opposite of the connection site for the luer-type fluid connector element **734** and an opposing luer-type connector element (not shown). The radial compression of the abutment surface or wall **752** assists in securing this fluid connection when under pressure. If desired, the abutment surface or wall **752** may comprise radial structures or components to physically engage the fluid connector element **734** and/or an opposed connector element (not shown) engaged therewith. While the foregoing embodiment was described in connection with fluid container **220** comprising a tapered sidewall **236**, the foregoing embodiment may be adapted for use with the bellows member **120** or any straight-walled fluid container **220**, **320** described previously.

[00226] Referring to **FIGS. 52A-52B**, a fluid injector **12** is shown that is adapted to operate with an open-top pressure jacket **30**. The pressure jacket **30** is supported by a hinged front or face plate **760** which is pivotally connected to the fluid injector housing **18**. The hinged front or face plate **760** defines a U-shaped opening **762** to receive the proximal end **34** of the pressure jacket **30**. The pressure jacket **30** in this embodiment is specifically adapted for use with the fluid container **220** comprising a tapered sidewall **236**, but this embodiment may also be adapted for use with the bellows member **120** described previously or any straight-walled fluid container. The proximal end **34** of the pressure jacket **30** may comprise a rear circumferential flange **764** for interference engagement with the U-shaped opening **762**. The fluid injector housing **18** further has a top face plate **766** above the hinged face plate **760** that has an outward extending roof portion **768** with a collar locking element **770**. The top face plate **766** further has a slide lock element **772** that is slidable vertically along the top face plate **766** along one side of the pressure jacket **30**. The slide lock element **772** is adapted to engage a locking appendage **774** on the hinged face plate **760** to secure the hinged face plate **760** in the closed position seated against the fluid injector body **18**.

[00227] The pressure jacket **30** defines a top opening **780** for receiving the fluid container **220** therein. In this embodiment, the fluid container **220** may comprise a fluid connector fitting or element **242** to engage with a fluid tubing set **782** with an end or terminal fluid connector fitting **784**. The distal end **32** of the pressure jacket **30** defines a front opening for **786** for passage of the fluid tubing set **782** therethrough. A locking ring **790** is provided on the distal end **32** of the pressure jacket **30** and is used to secure the pressure jacket **30** to fluid injector housing **18** when the hinged face plate **760** is in the closed position. The locking ring **790** is adapted to mechanically lock with the collar locking element **770** by rotating the locking ring **790** to cause internal structures or elements (not shown) on the locking ring **790** to engage the collar locking element **770**. In use, the fluid container **220** is loaded into the pressure jacket **30** through the top opening **780** when the hinged face plate **760** is pivoted to the position shown in **FIG. 52A**. The fluid tubing set **782** may be previously connected to the fluid connector fitting or element **242** on the fluid container **220**, and the tubing for this set **782** may be passed through the front opening **786** in the distal end **32** of the pressure jacket **30**. The hinged face plate **760** may be pivoted to the closed position shown in **FIG. 52B** and the slide lock element **770** on the top face plate **766** may be slid into locking engagement with the locking appendage **774** on the hinged face plate **760**, securing the same to the fluid injector housing **18** and further covering the top opening **780** in the pressure jacket **30** with the roof portion **768** extending outward from the top face plate **766**. The locking ring **790** on

the distal end **32** of the pressure jacket **30** may be rotated to secure the pressure jacket **30** to the roof portion **768** extending outward from the top face plate **766**. The locking ring **790** defines a slot **792** for passing tubing from the fluid tubing set **782** therethrough during the loading process.

[00228] Referring to **FIG. 53**, a variation of the foregoing embodiment pressure jacket **30** is shown in which the top opening **780** is formed as a split-top opening. In this embodiment, the fluid container **220** is breach loaded into the open proximal end **34** of the pressure jacket **30** and the tubing of the fluid tubing set **782** is passed through the split-top opening **780**. The locking ring **790** in this embodiment also defines a slot **792** for passing the tubing of the fluid tubing set **782** therethrough. Additionally, in this embodiment, the roof portion of the top face plate **766** is formed as an appendage to enclose the split-top opening **780** in the pressure jacket **30** and the slot **792** in the locking ring **790**. Further, the top face plate **766** and hinged face plate **760** are generally ring-shaped in this embodiment. Other than the foregoing specified differences, the embodiments of **FIGS. 52A-52B** and **FIG. 53** are substantially identical.

[00229] Referring to **FIGS. 54A-54D**, another embodiment of the pressure jacket **30** is shown having a split or clam shell configuration. In this embodiment, the pressure jacket **30** comprises two (2) opposed portions or sections **796**, **798**, with the first portion or section **796** fixed to and extending outward from the face plate **19** of the fluid injector housing **18**. The second pressure jacket portion **798** has an end **800** pivotally connected to a distal end **802** of the first pressure jacket portion **796**, so that the second pressure jacket portion **798** opens upward from the first pressure jacket portion **796** to form a mouth opening **804** facing the fluid injector housing **18**. The bellows member **120** or one of the fluid container embodiments described previously may be top-loaded into the first or lower pressure jacket portion **796** through the mouth opening **804**. A suitable opening (not shown) may be provided in the closed distal end **32** of the pressure jacket **30** to permit fluid connecting tubing (not shown) to be connected to the disposable component held in the first and second pressure jacket portions **796**, **798**.

[00230] Referring to **FIG. 55**, an embodiment of the bellows member **120** of the bellows syringe **100** is shown that has a first pair of outward-extending radial tabs **810** at the distal end **122**, such as extending outward from the discharge neck **130**, and a second larger pair of outward-extending radial tabs **812** at the proximal end **124**. The respective pairs of radial tabs **810**, **812** may engage corresponding receiving slots (not shown) in the various embodiments of the pressure jacket **30** set forth in this disclosure. The respective pairs of radial tabs **810**,

812 are of different sizes so that the bellows member **120** can be keyed into the pressure jacket **30** in only one orientation, hence, the corresponding receiving slots in the pressure jacket **30** are formed to only accept the corresponding pairs of radial tabs, either radial tabs **810** or radial tabs **812**.

[00231] Referring to **FIGS. 56A-56B**, a fluid injector **12** is shown in which the top of the pressure jacket **30** is open to define a top opening **820** to accept the bellows member **120** or another fluid container therein. The pressure jacket **30** has a partially closed distal end wall **32** that has a conical shape to accept a similarly shaped distal end **122** of the bellows member **120**, or a similarly shaped distal end **224** of fluid container **220**. The conical distal end **32** defines a vertical opening **822** so that tubing associated with a fluid tubing set (not shown) may be passed through the vertical opening **822** as the bellows member **120** is loaded into the pressure jacket **30**. The disposable container in this embodiment, such as bellows member **120** or fluid containers **220**, **320**, may be loaded into the pressure jacket **30** in a similar manner to a caulking tube being loaded into a caulking gun, with the pressure jacket **30** and conical distal end **32** thereof having a similar configuration to a mechanical caulking gun.

[00232] Referring to **FIGS. 57-66**, another embodiment of the bellows assembly **20** as shown and discussed in connection with **FIGS. 1-3** and **7** is depicted in connection with a fluid injector face plate **19** of the fluid injector **12**. In view of the similarities in the present embodiment in comparison to the embodiment shown in **FIGS. 1-3** and **7**, only specific differences will be discussed herein. In the present embodiment, the bellows syringe **100** comprises the cap member **102**, the bellows member **120** and, now, a base member **1000** adapted to engage the bellows member **120** and the cap member **102**. The base member **1000** is formed with a flat plate portion **1002** and a central annular portion **1004** defining a circumferential exterior groove **1006**. The central annular portion **1004** is adapted to seat within the receiving end pocket **140** in the bellows member **120**, and the receiving end pocket **140** comprises a cooperating internal rim or rib **1008** for engaging the circumferential exterior groove **1006**. The bellows member **120** is again intended to be disposed within the interior cavity **106** in the cap member **102** and held therein in a compressed, pre-use state. However, in the present embodiment, the retaining tabs **110** formed as part of the skirt portion **104** of the cap member **102** in the previous embodiment are now replaced by receiving catch members **1010** on the skirt portion **104**. The plate portion **1002** comprises upward-extending retaining tabs **1012** which engage the receiving catch members **1010** on the skirt portion **104** to maintain the bellows member **120** in the compressed or pre-use state. Thus, the bellows member **120** is seated onto the annular portion **1004** of the base member

1000 in this embodiment, with the annular portion **1004** disposed within the end pocket **140** in the bellows member **120** and the cooperating internal rim or rib **1008** in the end pocket **140** engaged in the circumferential exterior groove **1006** in the annular portion **1004**. Further, the bellows member **120** is held in the compressed or pre-use state by the inter-engagement between the upward-extending retaining tabs **1012** on the base member **1000** with the receiving catch members **1010** on the skirt portion **104** of the cap member **102**. Thus, in this embodiment retaining tabs **1012** are in the opposite location than the tab members **110** of the embodiment shown in **FIGS. 1-3** and **7**. Moreover, it will be appreciated that the locations for the retaining tabs **1012** and the catch member **1010** may be reversed if desired. Additionally, the bellows member **120** may comprise a conical portion **131** that seats into the interior cavity **108** of the cap member **104**; the conical portion **131** defines the discharge port **150**, as shown in **FIGS. 57-58**.

[00233] In the present embodiment, the distal end **32** of the pressure jacket **30** is modified to comprise a plurality of tab members **1014** each defining a lateral or transverse slot **1016**, generally formed as bayonet slots. The flat plate portion **1002** is adapted to engage the bayonet or transverse slots **1016** to secure the bellows syringe **100** to the pressure jacket **30**. The proximal end **34** of the pressure jacket **30** is adapted to engage the face plate **19** of the fluid injector **12** in any suitable manner. Further details relating to desirable mounting structures used to properly interface the pressure jacket **30** with the fluid injector **12** may be found in the Medrad, Inc. patents incorporated by reference previously, which discuss interfacing features for securing a Stellant® CT syringe to a Stellant® fluid injector. Additionally, the piston head **16** of the piston element **14** shown in various views in **FIGS. 57-66** may have the radially-extendable retaining pins **64** discussed previously in connection with **FIGS. 6A-6F**, and the overall shape of the piston head **16** shown in **FIGS. 6A-6F**.

[00234] Referring to **FIG. 59**, the pressure jacket **30** is connected to the face plate **19** by inserting the proximal end **34** into the receiving opening or aperture in the face plate **19**. Next, as shown in **FIGS. 60-61**, the bellows syringe **100** is connected to the distal end **32** of the pressure jacket **30**. This connection is made by placing the flat plate portion **1002** of the base member **1000** onto the distal end **32** of the pressure jacket **30** so that the upward-extending retaining tabs **1012** are disposed between the tab members **1014** on the distal end **32**. The cap member **102** of the bellows syringe **100** is then rotated in the appropriate direction represented by arrow **R** to seat the flat plate portion **1002** into the transverse slots **1016** in the tab members **1014** on the distal end **32** of the pressure jacket **30**. This engagement secures the bellows syringe **1000** to the pressure jacket **30**. Referring further to **FIGS. 62-63**,

the piston element **14** is driven forward so that the piston head **16** engages an end pocket **1018** in the central annular portion **1004** further having internal elements or structures **1020** (see **FIG. 58**), similar to internal elements or structures **72** discussed previously, that receive the retaining pins **64** on the piston head **16** so that the base member **1000** becomes engaged with the piston head **16**. The piston element **14** may be driven sufficiently forward to cause automatic release of the upward-extending retaining tabs **1012** on the base member **1000** with the receiving catch members **1010** on the skirt portion **104** to release the bellows member **120** from the compressed or pre-use state. The bellows member **120** may be expanded as the piston element **14** retracts in the pressure jacket **30** as shown in **FIG. 64**. When the medical procedure using the bellows syringe **100** is completed, the piston element **14** may be driven forward to the initial position shown in **FIG. 65** which permits the upward-extending retaining tabs **1012** on the base member **1000** to reestablish a connection with the receiving catch members **1010** on the skirt portion **104** thereby again placing the bellows member **120** in a compressed, now post-use state. The bellows syringe **100** may be removed from the pressure jacket **30** by reversing the attachment procedure described previously and discarded as medical waste, as shown in **FIG. 66**.

[00235] While embodiments of a bellows syringe or fluid container fluid delivery system and methods of use and operation thereof were provided in the foregoing description, those skilled in the art may make modifications and alterations to these embodiments without departing from the scope and spirit of the invention. Accordingly, the foregoing description is intended to be illustrative rather than restrictive. The invention described hereinabove is defined by the appended claims and all changes to the invention that fall within the meaning and the range of equivalency of the claims are to be embraced within their scope.

THE INVENTION CLAIMED IS:

1. A bellows syringe for a fluid delivery system, comprising:

a cap member defining an internal cavity and a discharge port, the cap member further comprising a depending skirt portion; and

a bellows member disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member.

2. A bellows syringe as claimed in Claim 1, wherein the skirt portion comprises a plurality of radially-inward extending tab members engaged with the proximal end of the bellows member to hold the bellows member in the compressed state in the internal cavity.

3. A bellows syringe as claimed in Claim 1, wherein the proximal end of the bellows member is closed and a distal end of the bellows member defines a discharge port in fluid communication with the cap member discharge port, and wherein the closed proximal end of the bellows member comprises at least one attachment member for attaching the bellows member to a piston head of a piston element.

4. A bellows syringe as claimed in Claim 3, wherein the at least one attachment member is disposed in an end pocket defined in the closed proximal end of the bellows member.

5. A bellows syringe as claimed in Claim 3, wherein the at least one attachment member comprises a button element adapted to be engaged by a piston element comprising a plurality of jaw members.

6. A bellows syringe as claimed in Claim 1, further comprising a base member comprising a plate portion and a central portion, and wherein one of the skirt portion and the plate portion comprises a plurality of retaining tabs engaged with catch members provided on the other of the skirt portion and the plate portion to hold the bellows member in the compressed state in the internal cavity.

7. A bellows syringe as claimed in Claim 6, wherein the central portion defines a circumferential groove and the bellows member comprises a cooperating rib engaging the circumferential groove for securing the plate portion to the proximal end of the bellows member.

8. A bellows syringe as claimed in Claim 6, wherein the central portion defines an end pocket for receiving a piston head of a piston element, and wherein the end pocket comprises at least one internal element to engage the piston head.

9. A bellows assembly for association with a fluid delivery system, comprising:

a pressure jacket having a distal end and a proximal end and defining a throughbore therebetween; and

a bellows syringe adapted for connection to the distal end of the pressure jacket, comprising:

a cap member defining an internal cavity and a discharge port, the cap member further comprising a depending skirt portion; and

a bellows member disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member.

10. A bellows assembly as claimed in Claim 9, wherein the skirt portion comprises a plurality of radially-inward extending tab members engaged with the proximal end of the bellows member to hold the bellows member in the compressed state in the internal cavity.

11. A bellows assembly as claimed in Claim 9, wherein the proximal end of the bellows member is closed and a distal end of the bellows member defines a discharge port in fluid communication with the cap member discharge port, and wherein the closed proximal end of the bellows member comprises at least one attachment member for attaching the bellows member to a piston head of a piston element operable in the throughbore of the pressure jacket.

12. A bellows syringe as claimed in Claim 11, wherein the at least one attachment member is disposed in an end pocket defined in the closed proximal end of the bellows member.

13. A bellows assembly as claimed in Claim 11, wherein the at least one attachment member comprises a button element adapted to be engaged by a piston element comprising a plurality of jaw members.

14. A bellows assembly as claimed in Claim 9, further comprising a base member comprising a plate portion and a central portion, and wherein one of the skirt portion and the plate portion comprises a plurality of retaining tabs engaged with catch members provided on the other of the skirt portion and the plate portion to hold the bellows member in the compressed state in the internal cavity.

15. A bellows assembly as claimed in Claim 14, wherein the central portion defines a circumferential groove and the bellows member comprises a cooperating rib engaging the circumferential groove for securing the plate portion to the proximal end of the bellows member.

16. A bellows assembly as claimed in Claim 14, wherein the central portion defines an end pocket for receiving a piston head of a piston element, and wherein the end pocket comprises at least one internal element to engage the piston head.

17. A bellows assembly as claimed in Claim 14, wherein the distal end of the pressure jacket comprises a plurality of tab members each defining a slot, and the plate portion is adapted to engage the slots to secure the bellows syringe to the pressure jacket.

18. A bellows assembly as claimed in Claim 10, further comprising:

a plurality of circumferentially-spaced mounting flanges on the distal end of the pressure jacket, and a plurality of tab members on the distal end of the pressure jacket and provided between the mounting flanges, respectively; and

mating slots defined in the skirt portion of the cap member to receive the mounting flanges for securing the bellows syringe to the distal end of the pressure jacket,

wherein the cap member is rotated to seat the mounting flanges in the mating slots in the cap member, and wherein the rotational motion causes the tab members on the distal end of the pressure jacket to engage the tab members on the skirt portion of the cap member and release the tab members on the skirt portion of the cap member from engagement with the proximal end of the bellows member.

19. A fluid delivery system, comprising:

a fluid injector comprising a reciprocally operable piston element having a piston head;

a pressure jacket having a distal end and a proximal end and defining a throughbore therebetween, the pressure jacket proximal end engaged with the fluid injector such that the piston element is operable in the throughbore; and

a bellows syringe adapted for connection to the distal end of the pressure jacket, comprising:

a cap member defining an internal cavity and a discharge port, the cap member further comprising a depending skirt portion; and

a bellows member disposed in the internal cavity and held in a compressed state in the internal cavity by engagement between the cap member and a proximal end of the bellows member.

20. A fluid delivery system as claimed in Claim 19, wherein the skirt portion comprises a plurality of radially-inward extending tab members engaged with the proximal end of the bellows member to hold the bellows member in the compressed state in the internal cavity.

21. A fluid delivery system as claimed in Claim 19, wherein the proximal end of the bellows member is closed and a distal end of the bellows member defines a discharge port in fluid communication with the cap member discharge port, and wherein the closed proximal end of the bellows member comprises at least one attachment member for attaching the bellows member to a piston head of a piston element operable in the throughbore of the pressure jacket.

22. A fluid delivery system as claimed in Claim 21, wherein the at least one attachment member is disposed in an end pocket defined in the closed proximal end of the bellows member.

23. A fluid delivery system as claimed in Claim 21, wherein the at least one attachment member comprises a button element adapted to be engaged by a piston element comprising a plurality of jaw members.

24. A fluid delivery system as claimed in Claim 19, further comprising a base member comprising a plate portion and a central portion, and wherein one of the skirt portion and the plate portion comprises a plurality of retaining tabs engaged with catch members provided on the other of the skirt portion and the plate portion to hold the bellows member in the compressed state in the internal cavity.

25. A fluid delivery system as claimed in Claim 24, wherein the central portion defines a circumferential groove and the bellows member comprises a cooperating rib engaging the circumferential groove for securing the plate portion to the proximal end of the bellows member.

26. A fluid delivery system as claimed in Claim 24, wherein the central portion defines an end pocket for receiving a piston head of a piston element, and wherein the end pocket comprises at least one internal element to engage the piston head.

27. A fluid delivery system as claimed in Claim 24, wherein the distal end of the pressure jacket comprises a plurality of tab members each defining a slot, and the plate portion is adapted to engage the slots to secure the bellows syringe to the pressure jacket.

28. A fluid delivery system as claimed in Claim 20, further comprising:

a plurality of circumferentially-spaced mounting flanges on the distal end of the pressure jacket, and a plurality of tab members on the distal end of the pressure jacket and provided between the mounting flanges, respectively; and

mating slots defined in the skirt portion of the cap member to receive the mounting flanges for securing the bellows syringe to the distal end of the pressure jacket,

wherein the cap member is rotated to seat the mounting flanges in the mating slots in the cap member, and wherein the rotational motion causes the tab members on the distal end of the pressure jacket to engage the tab members on the skirt portion of the cap member and release the tab members on the skirt portion of the cap member from engagement with the proximal end of the bellows member.

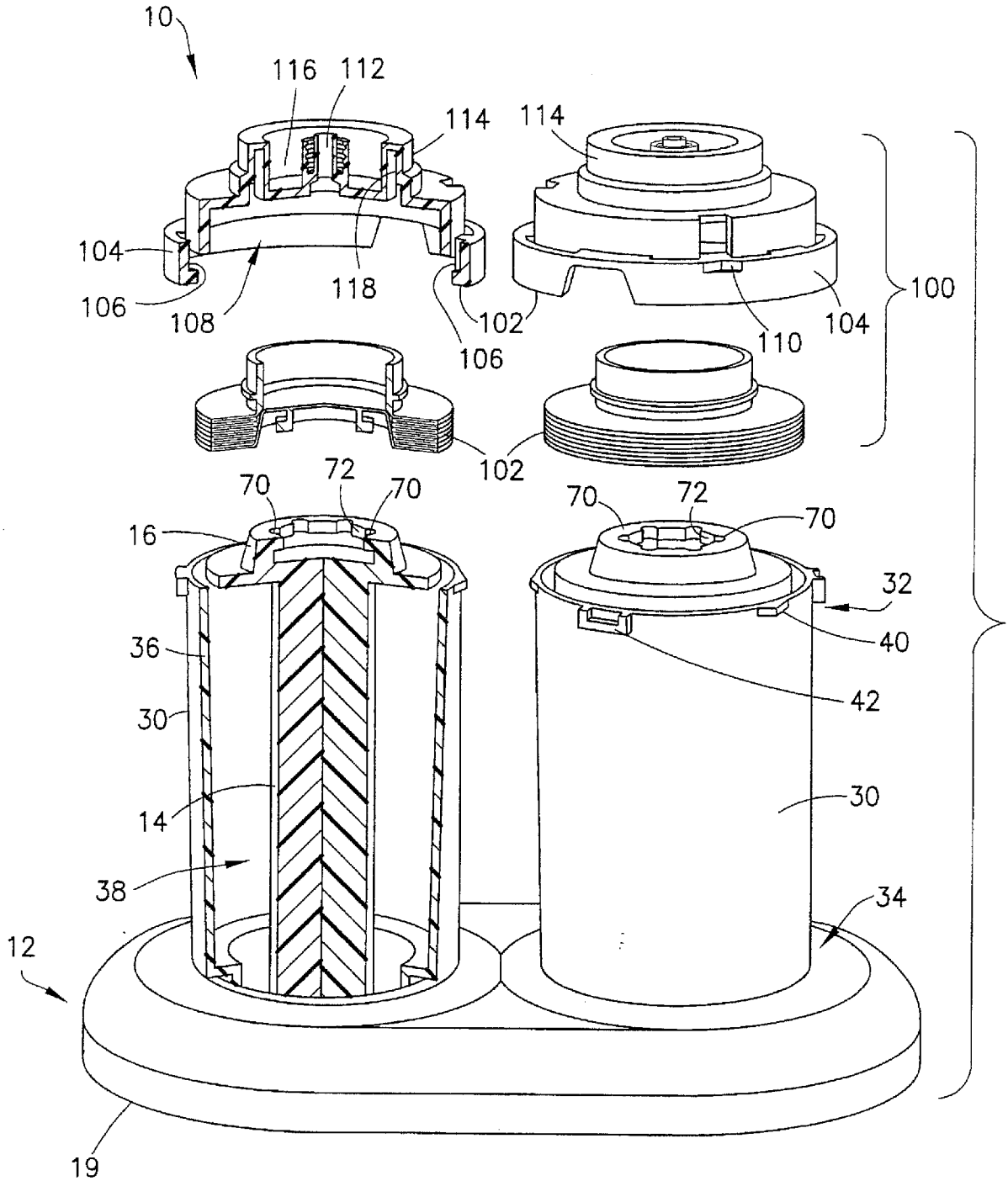
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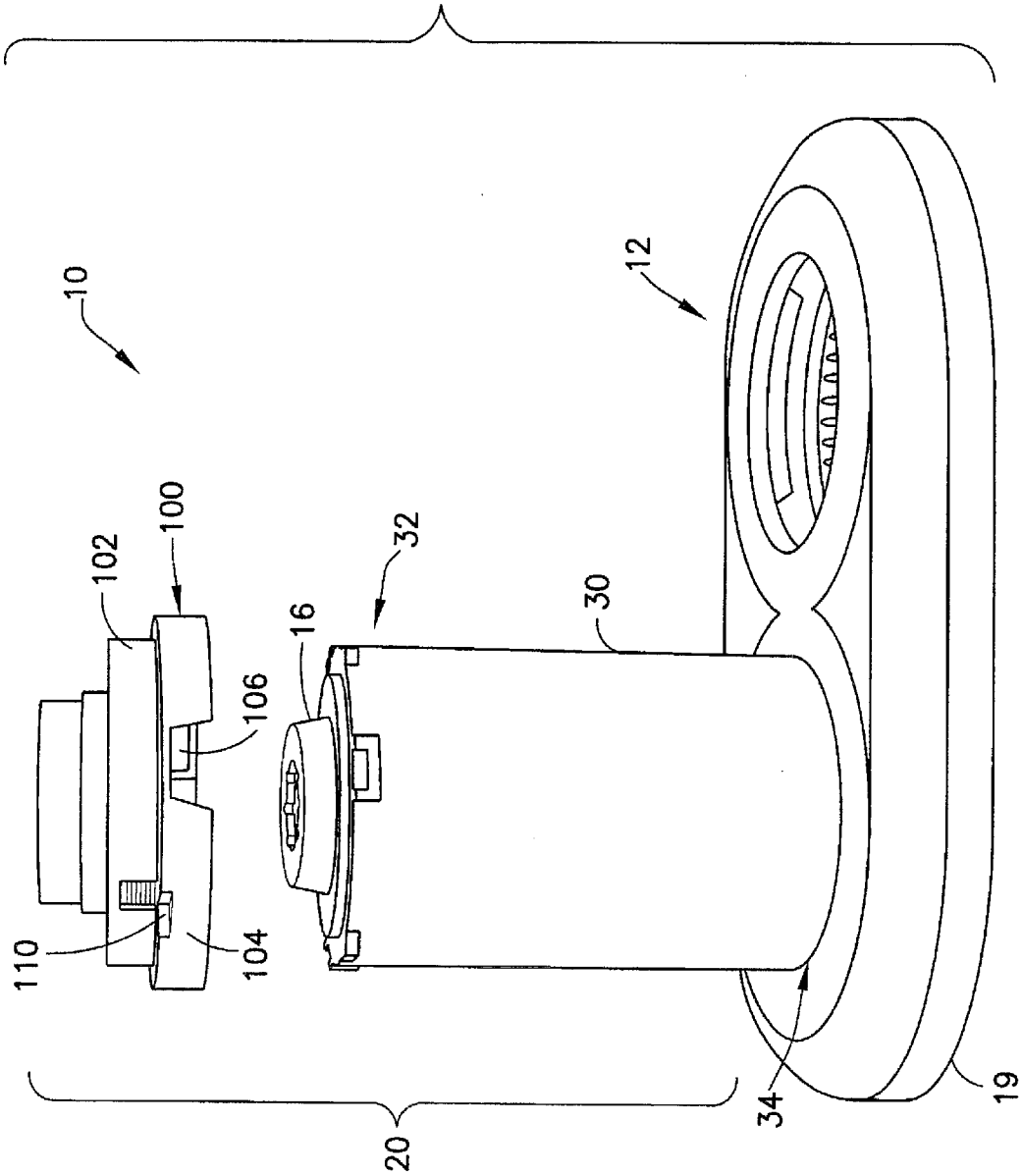
FIG.1A

FIG.1B



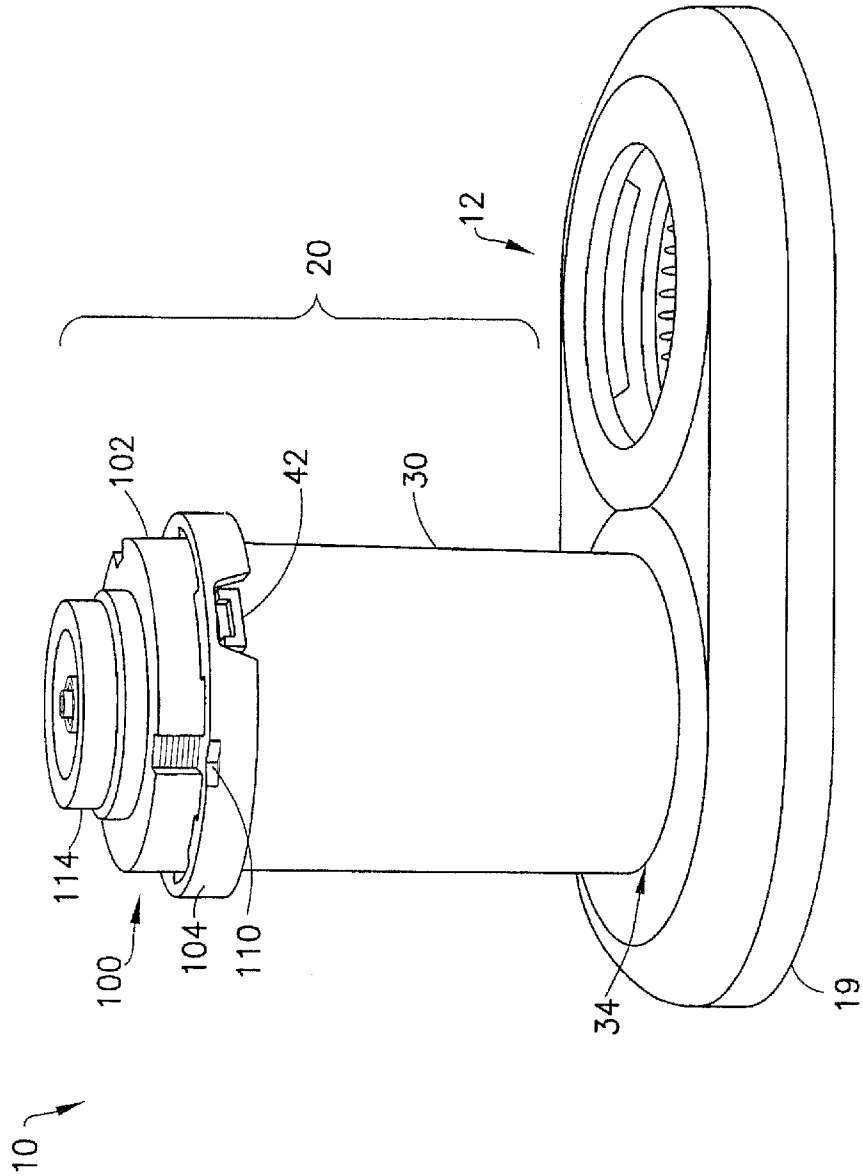


FIG.1C

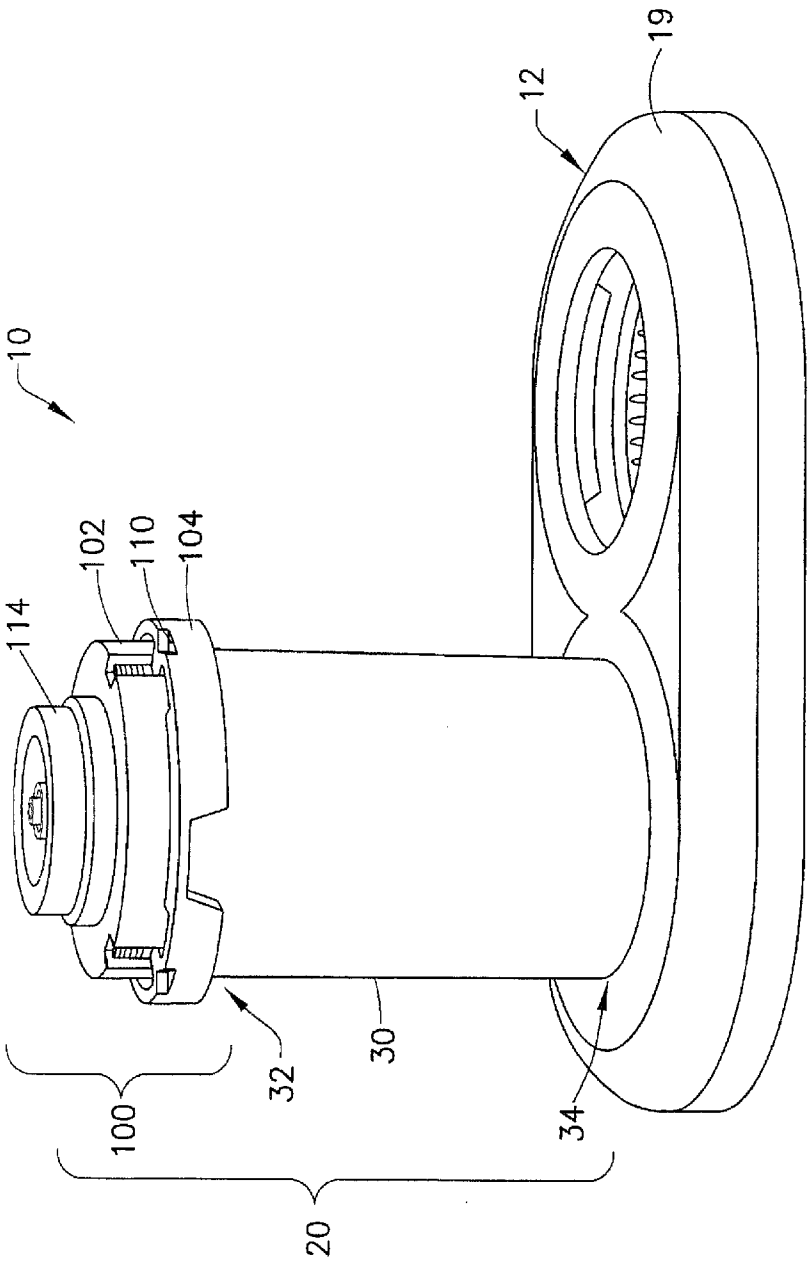


FIG.1D

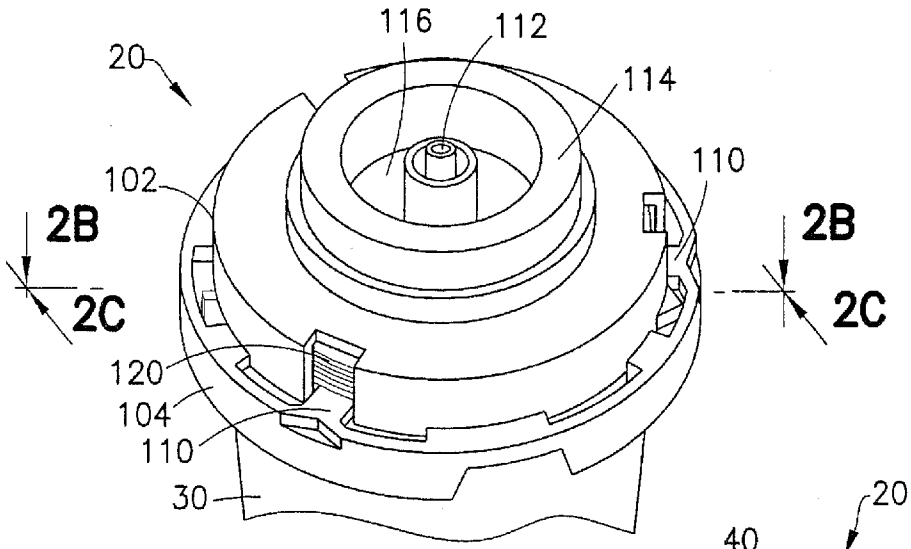


FIG.2A

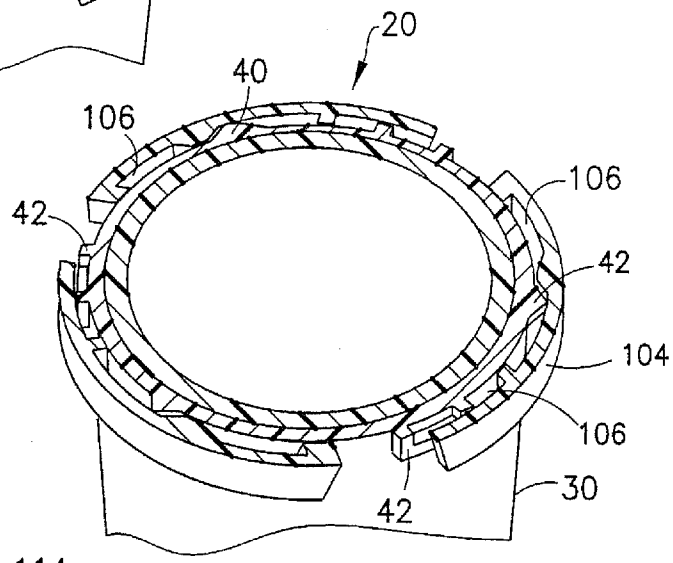


FIG.2B

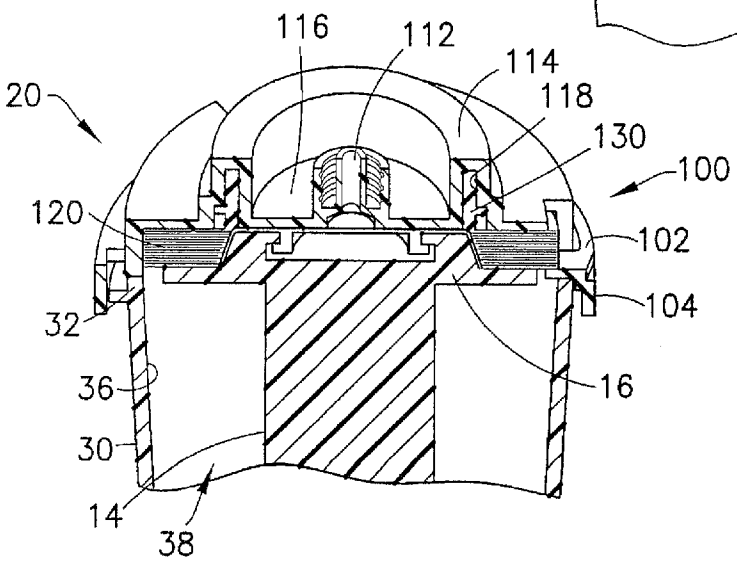
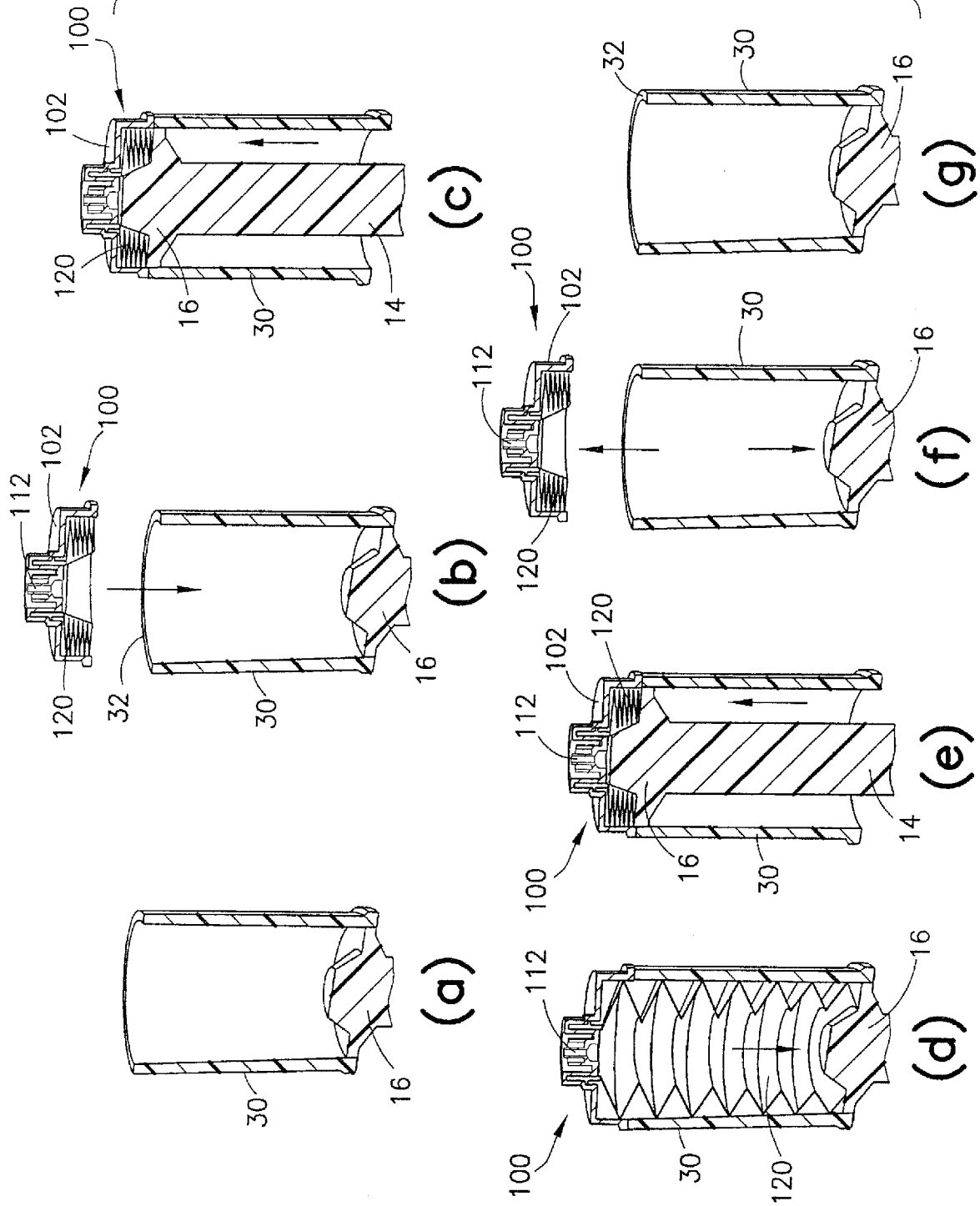


FIG.2C

FIG.3


(a)
30
16
(b)
100
102
112
120
32
30
16
(c)
100
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14
(d)
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112
16
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120
(e)
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(g)
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16

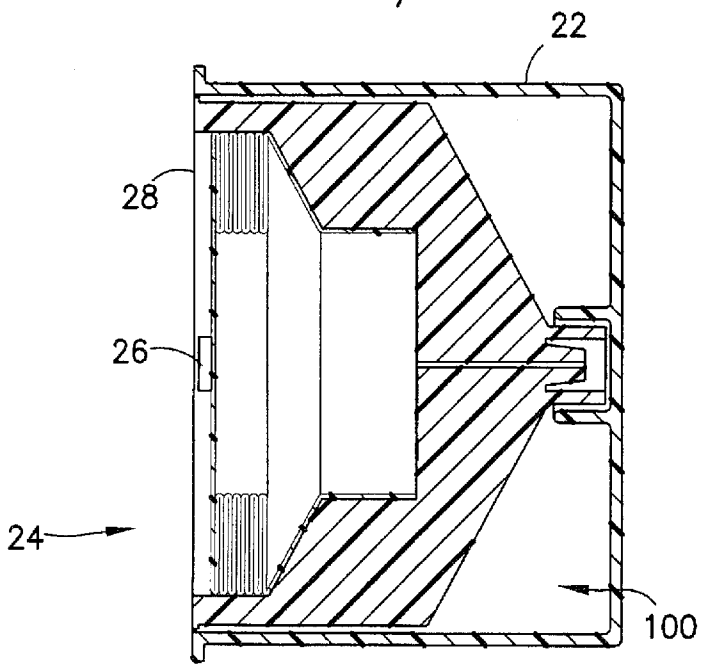

FIG.4A

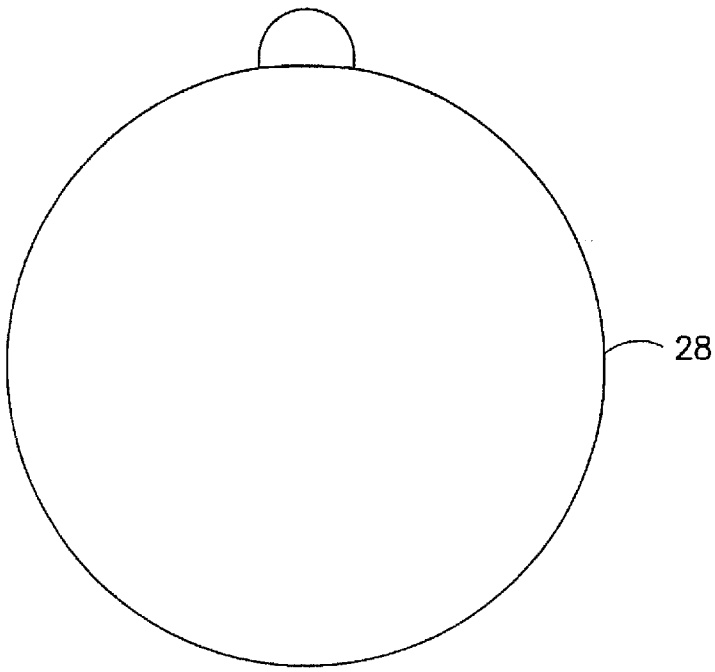

FIG.4B

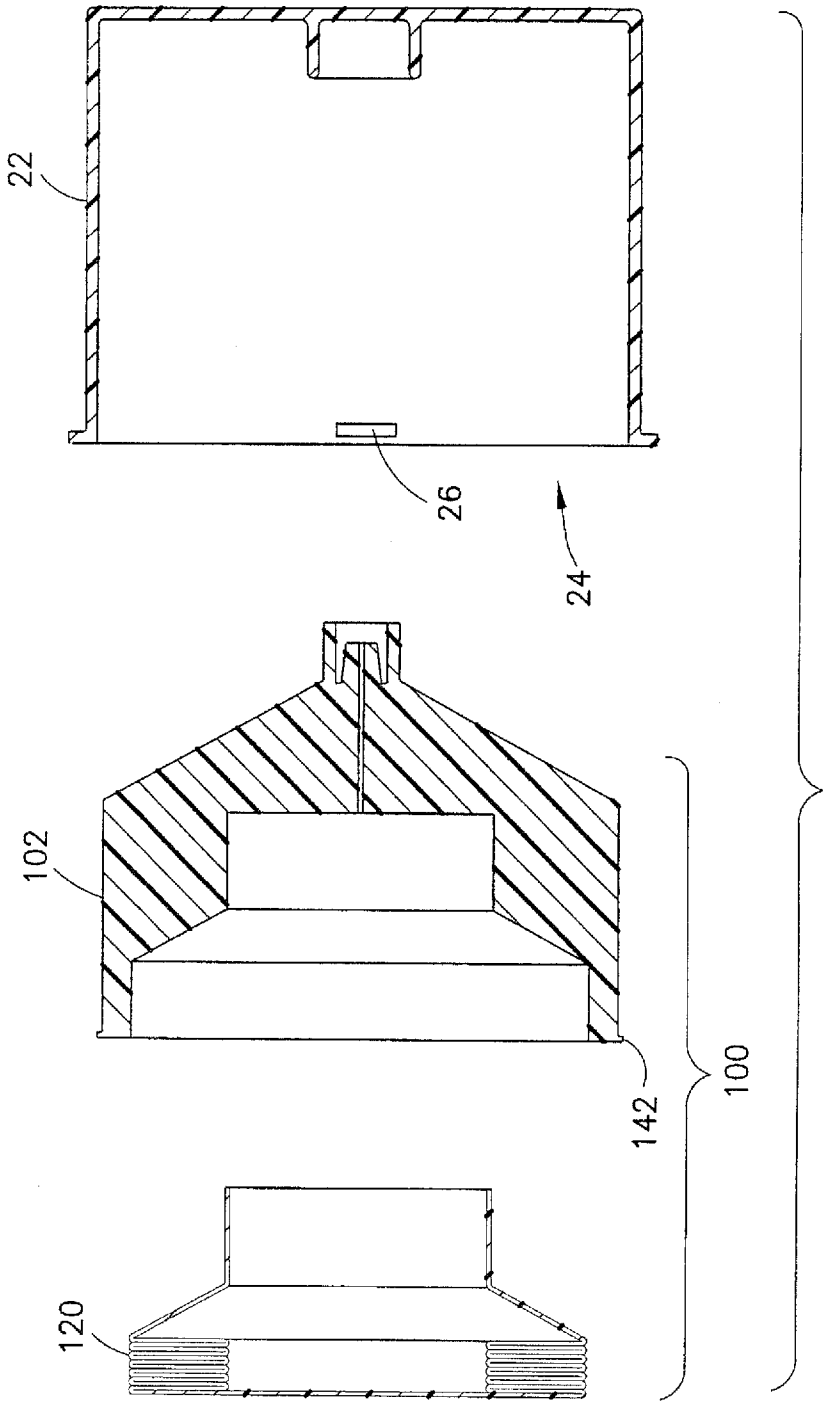

FIG. 4C

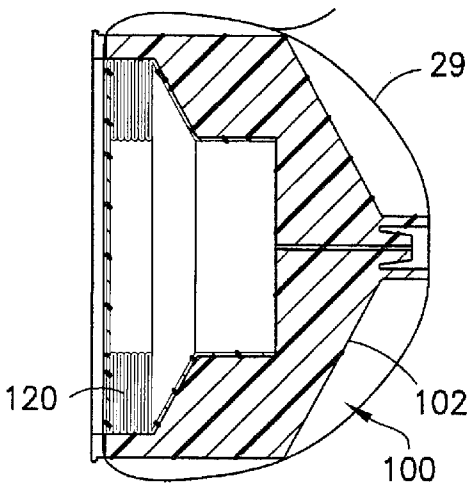

FIG.5A

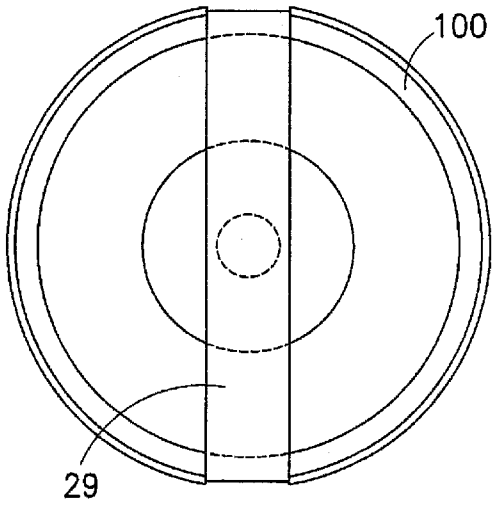

FIG.5B

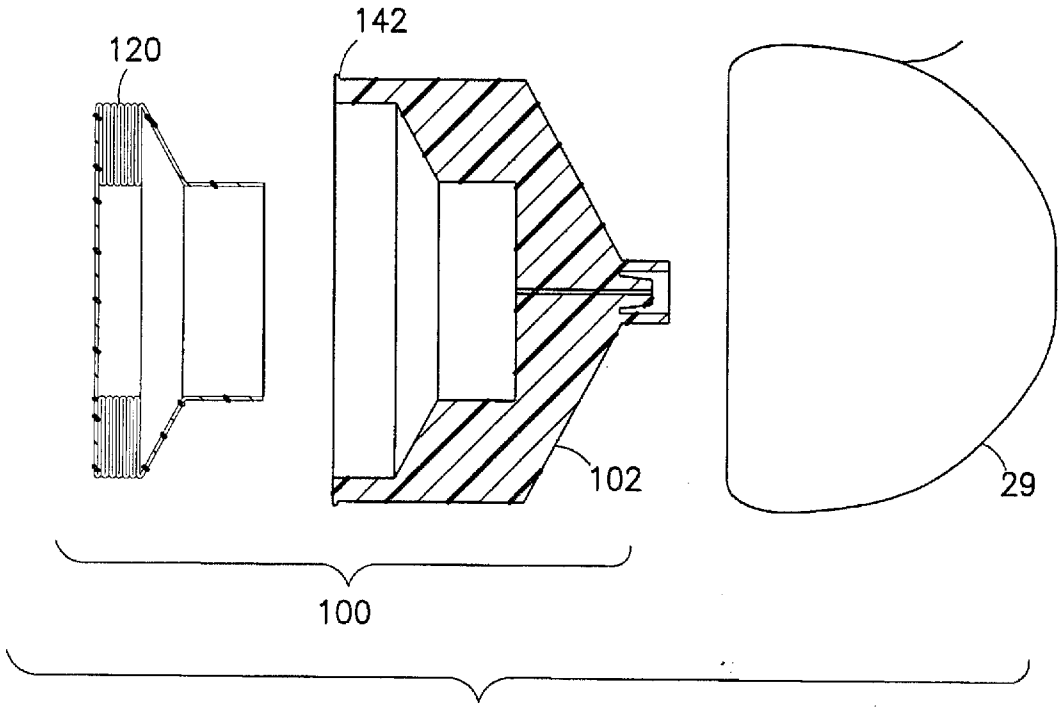

FIG.5C

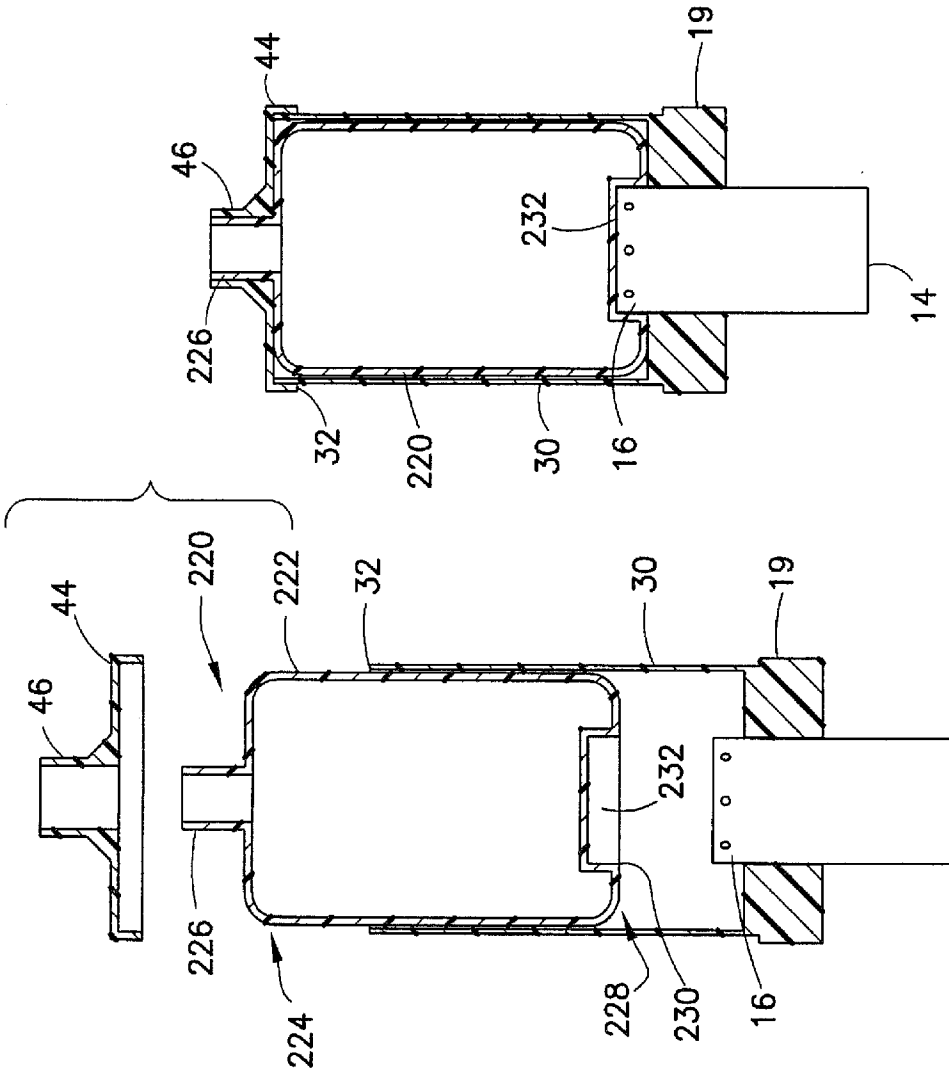

FIG.6C

FIG.6B

FIG.6A

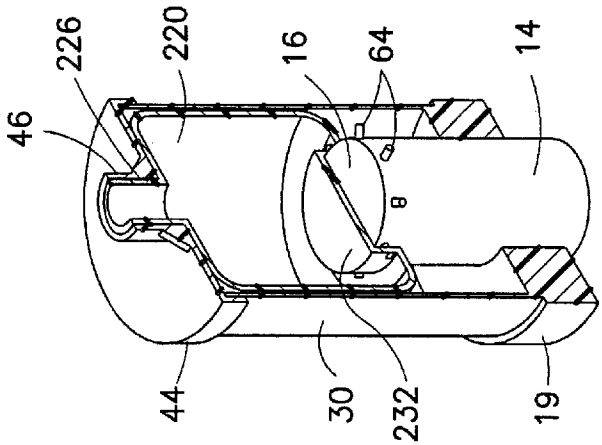

FIG.6F

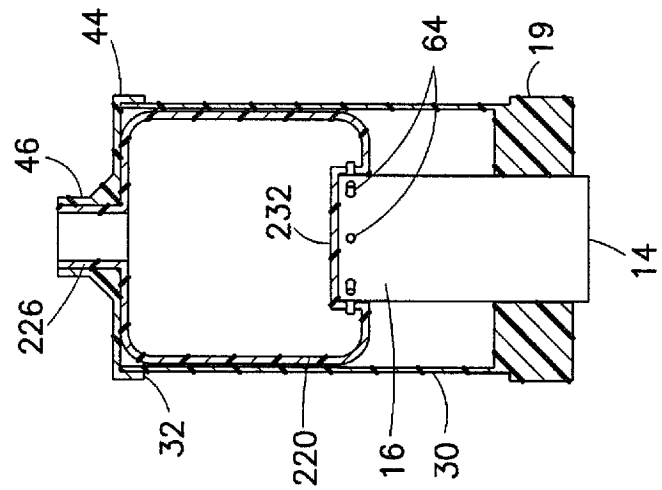

FIG.6E

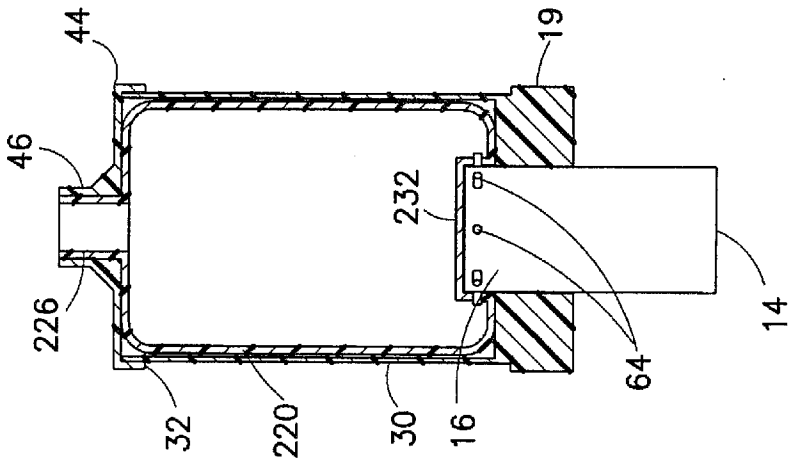

FIG.6D

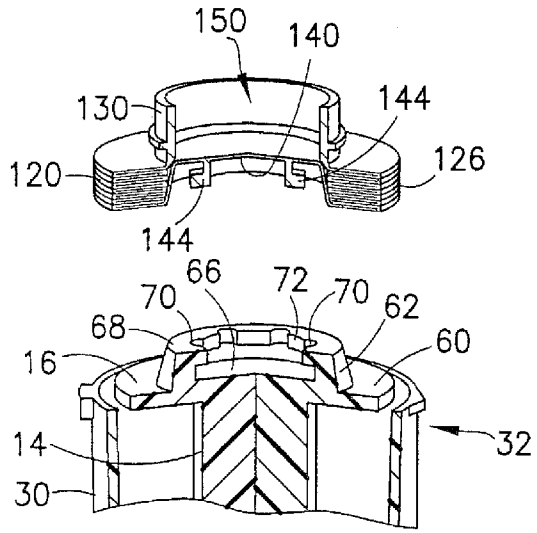
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FIG.7A

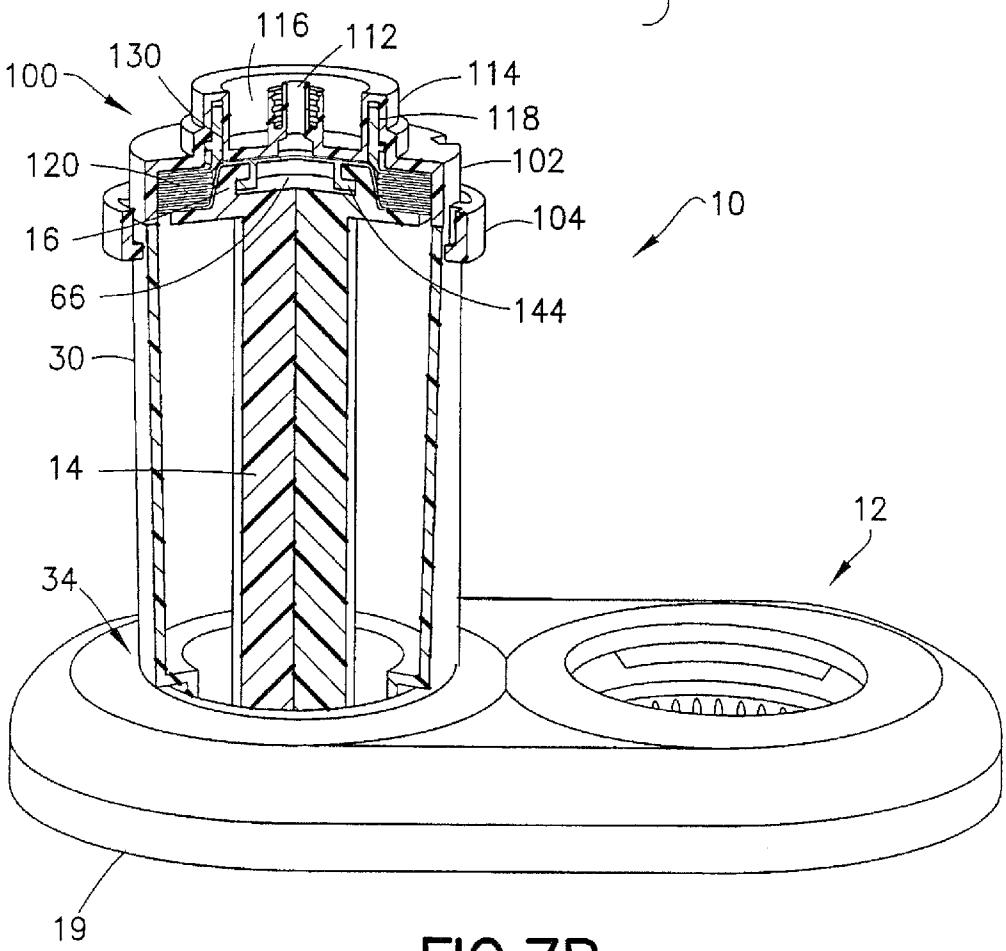
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FIG.7B

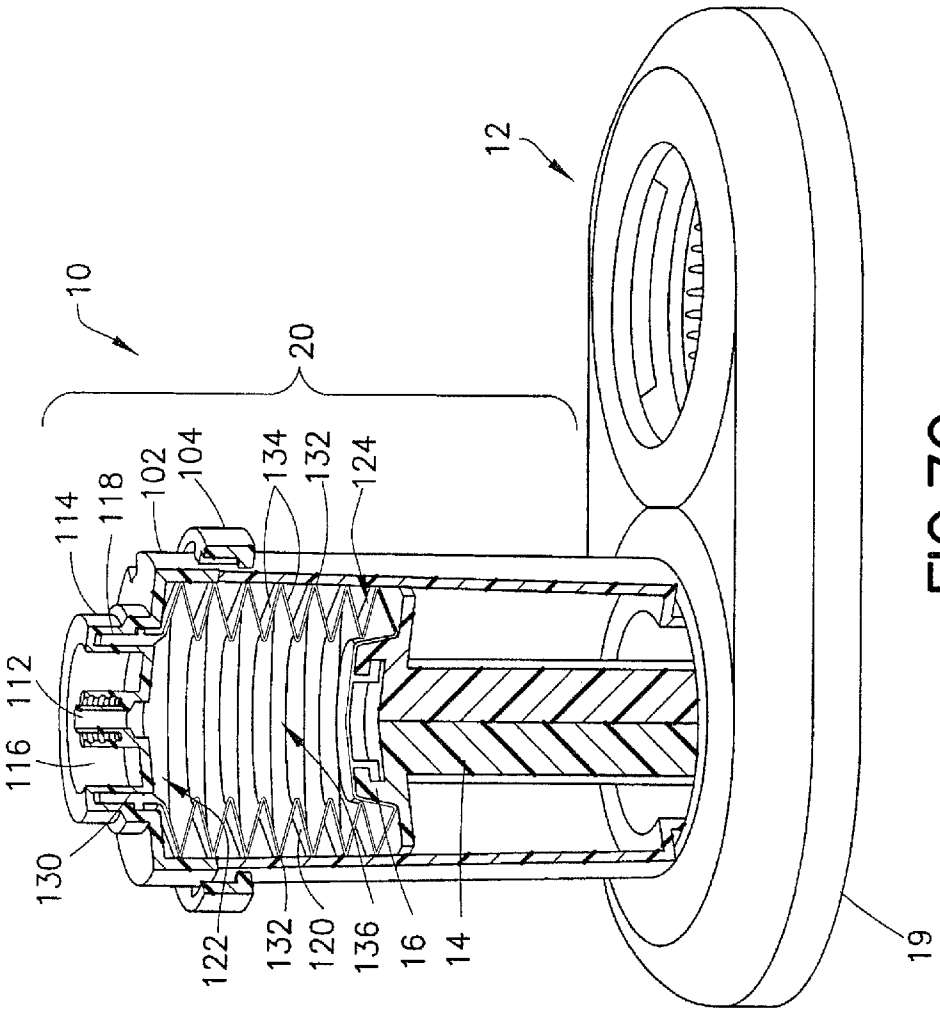
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FIG.7C

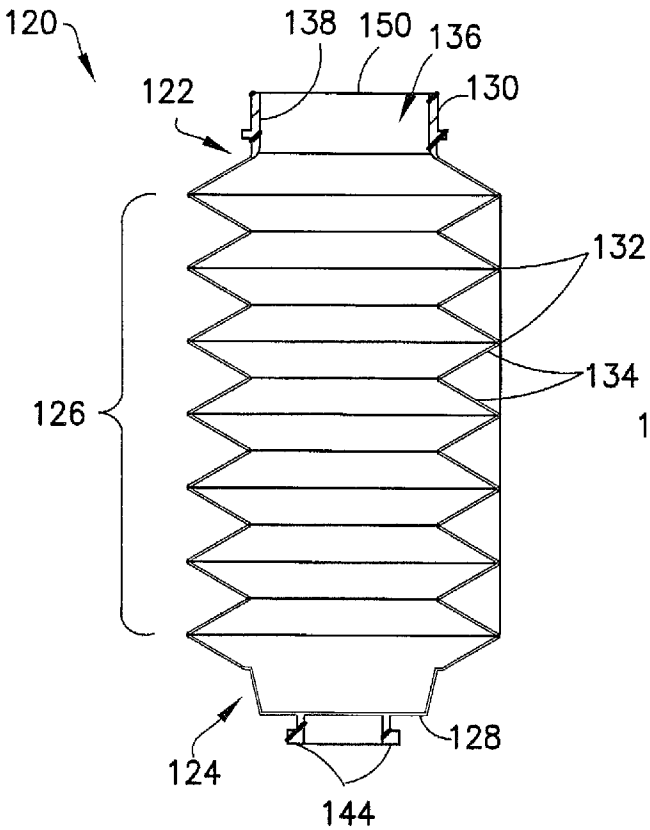
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FIG.7D

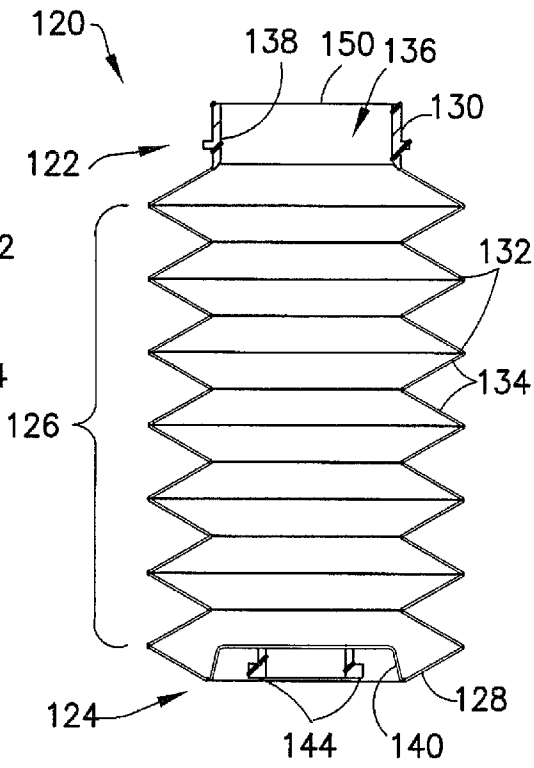
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FIG.7E

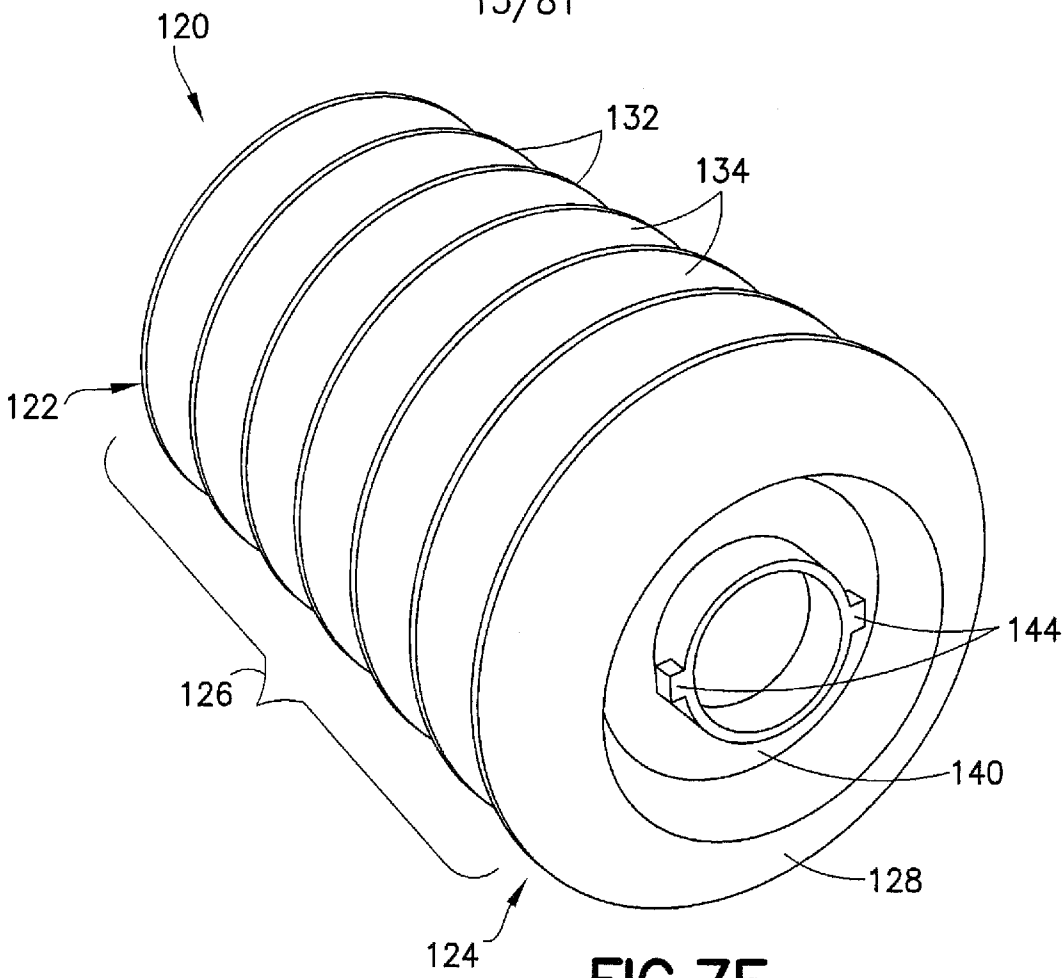

FIG.7F

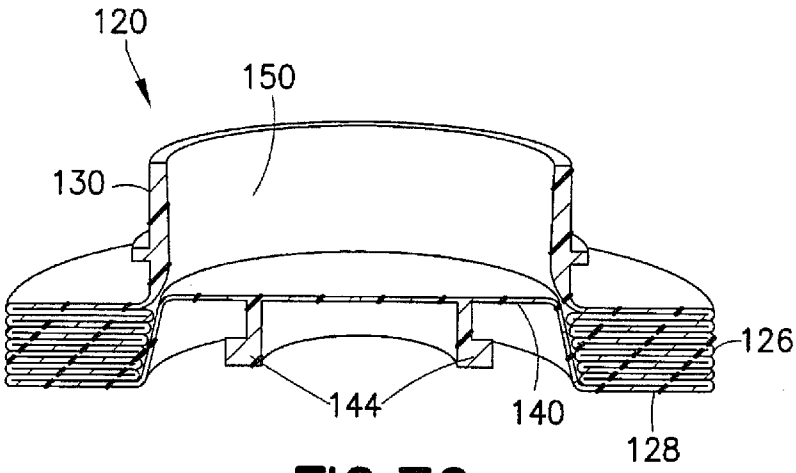

FIG.7G

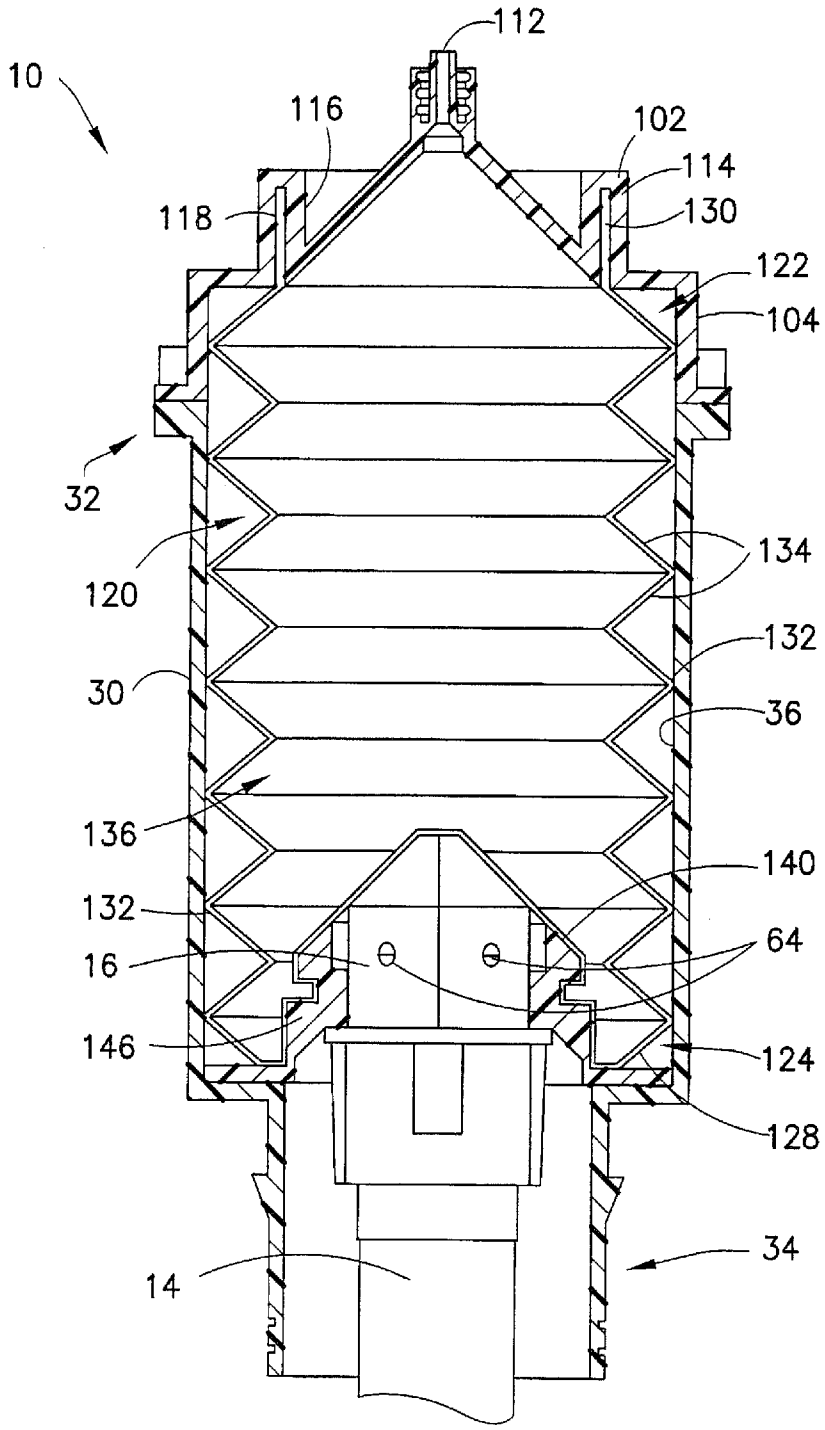
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FIG.7H

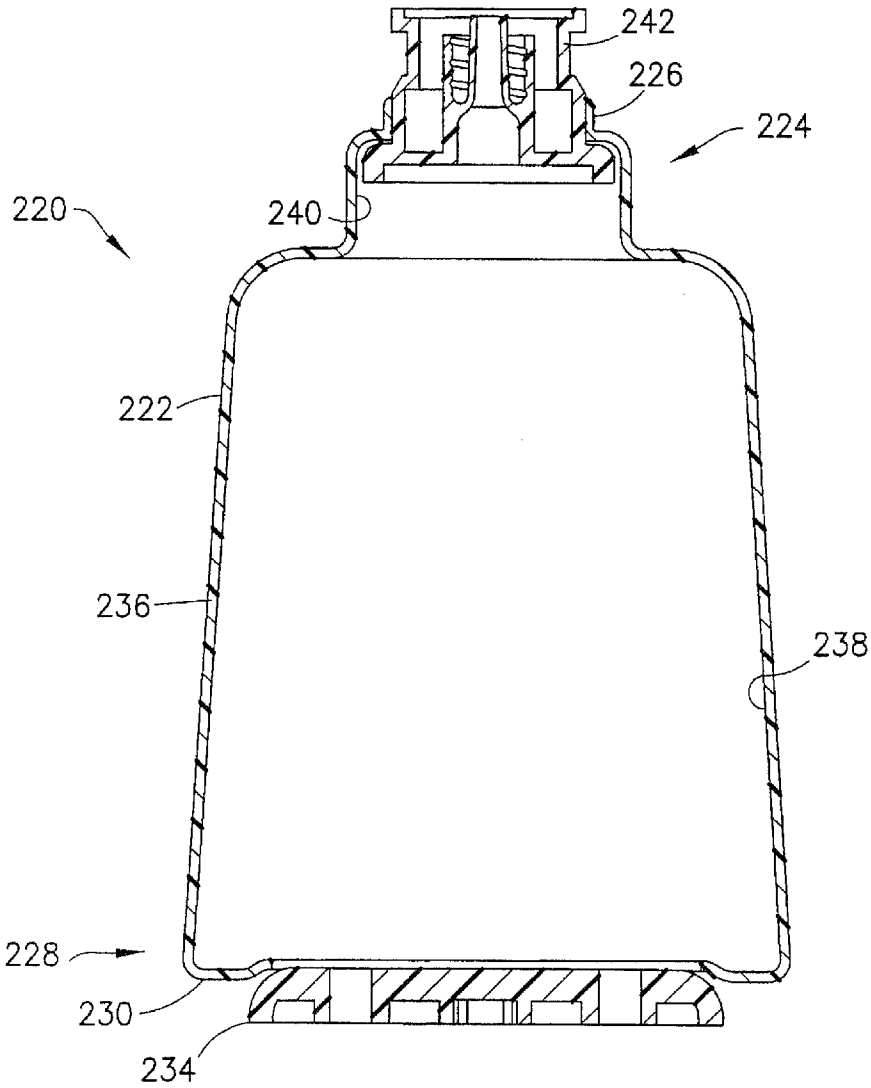

FIG.8

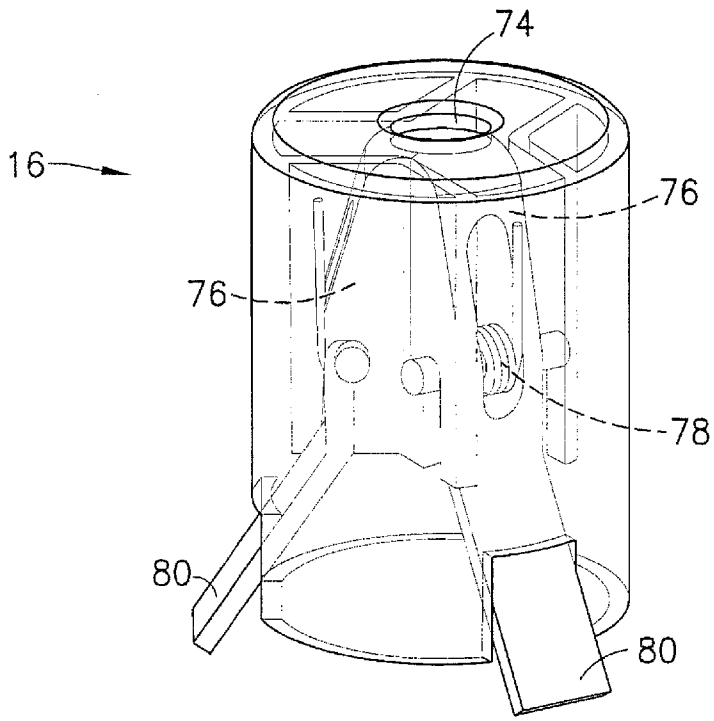

FIG.9A

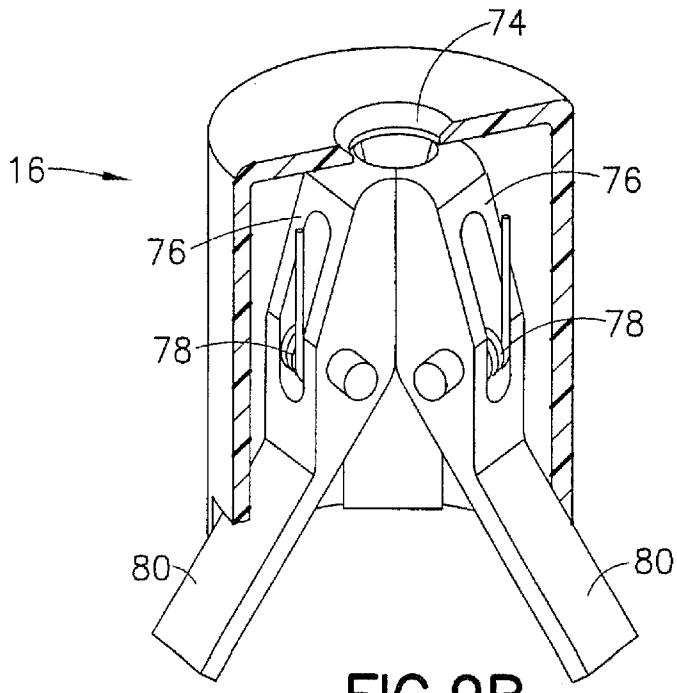

FIG.9B

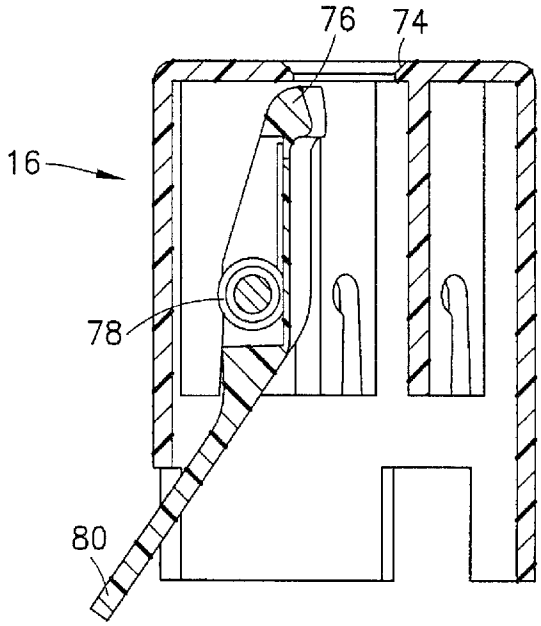

FIG.9C

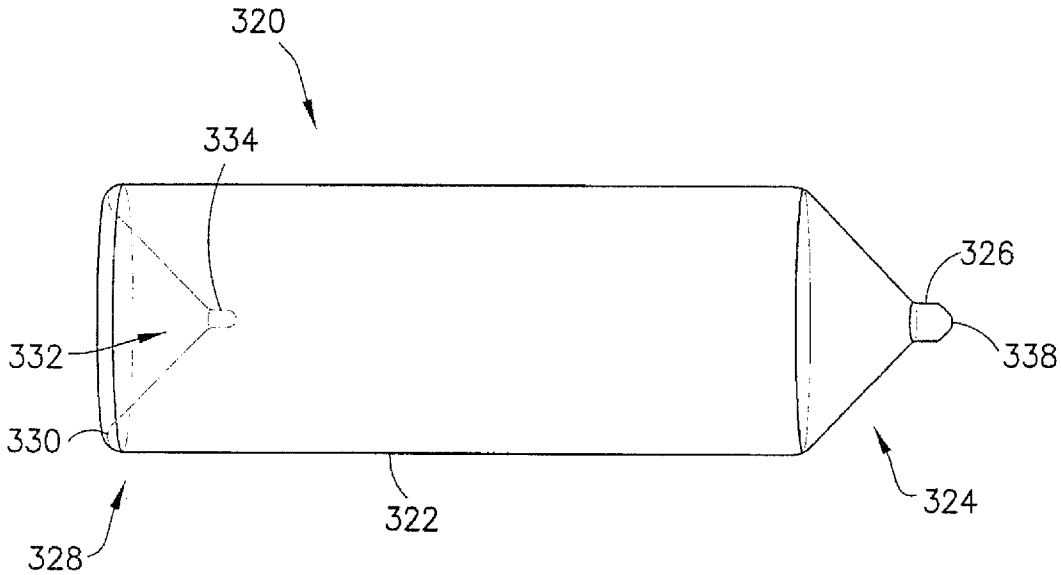

FIG.10A

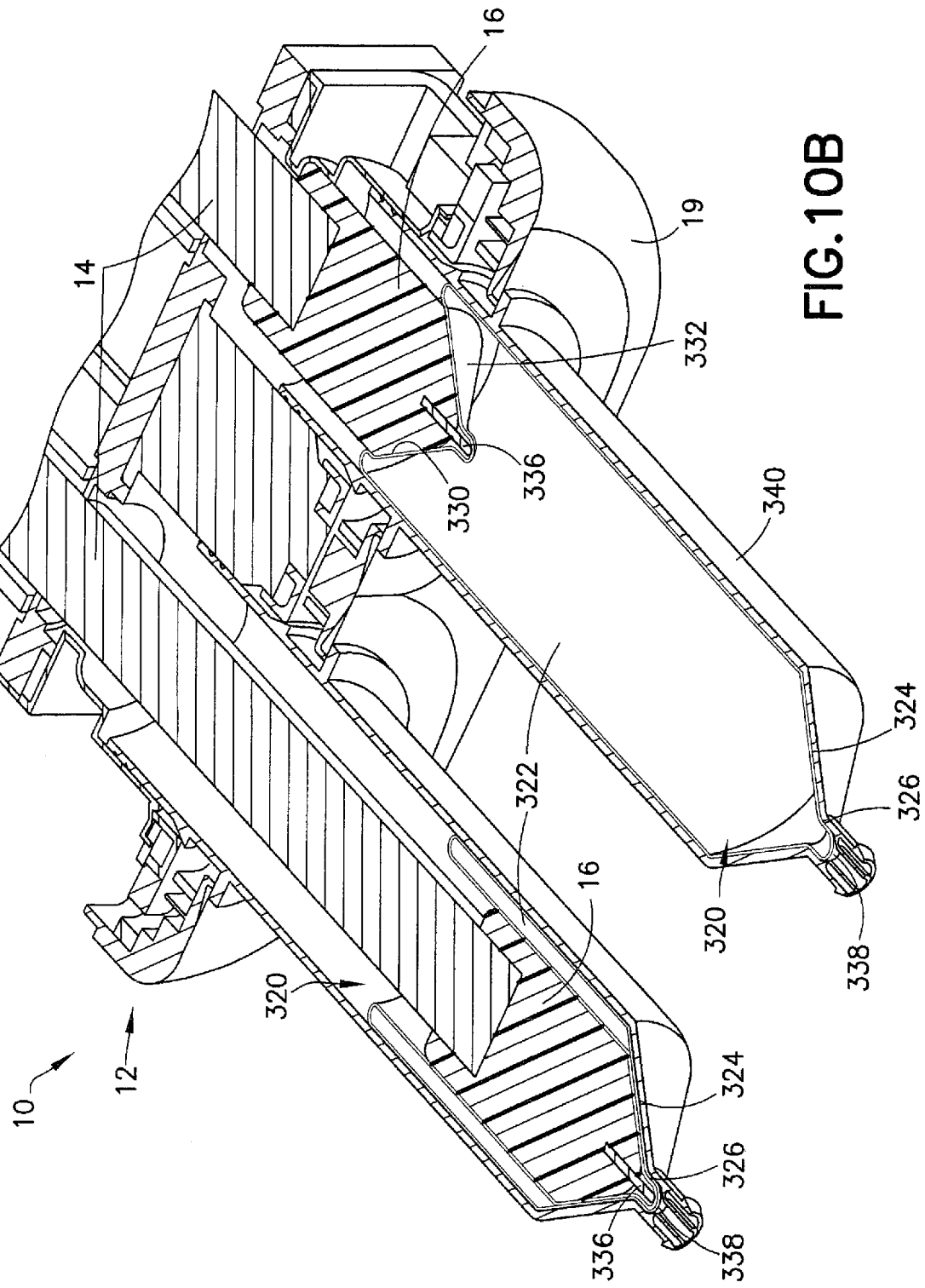
16
19
14
332
330
336
340
324
322
326
320
338
16
320
324
326
336
338
10
12

FIG.10B

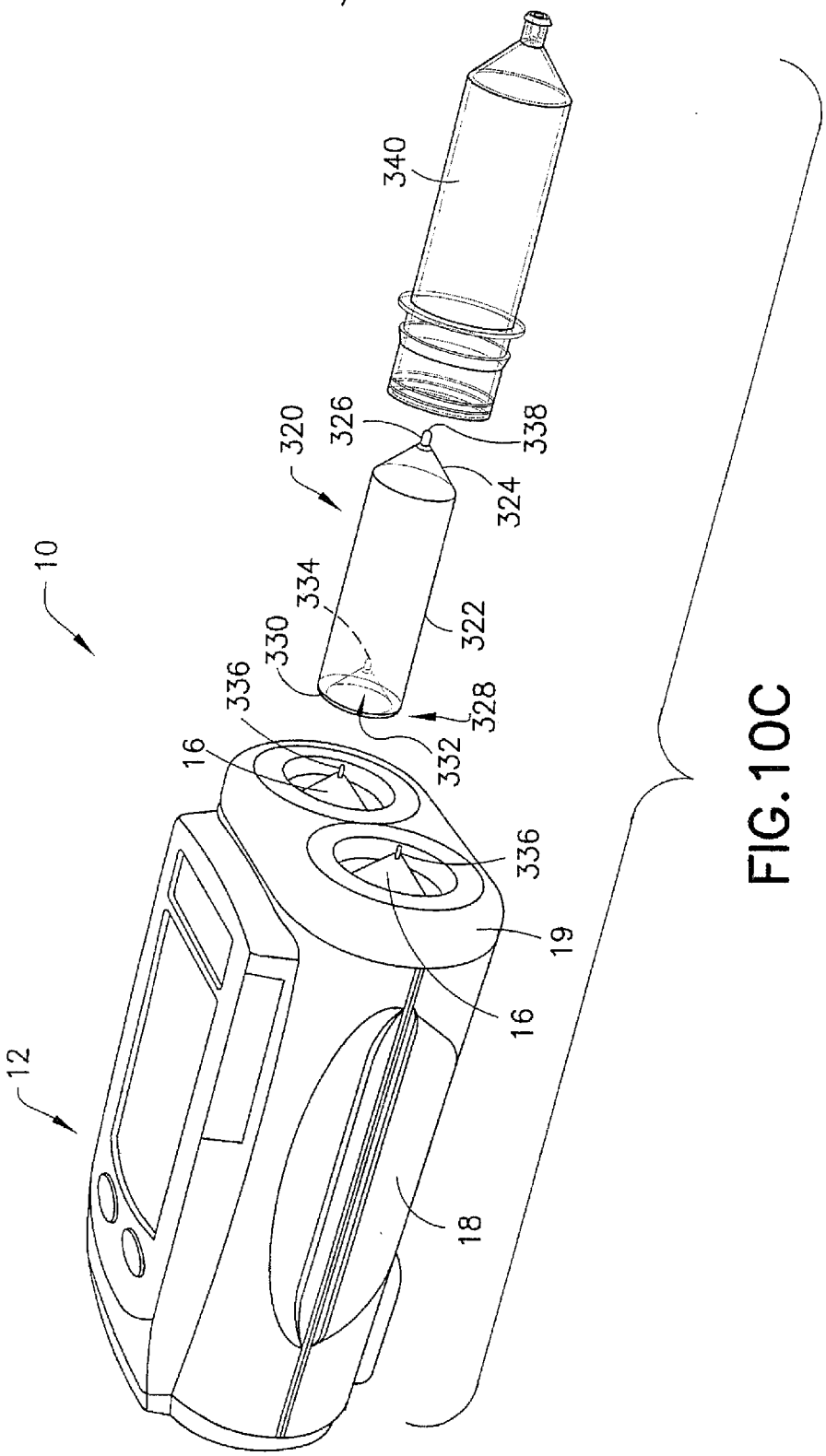

FIG.10C

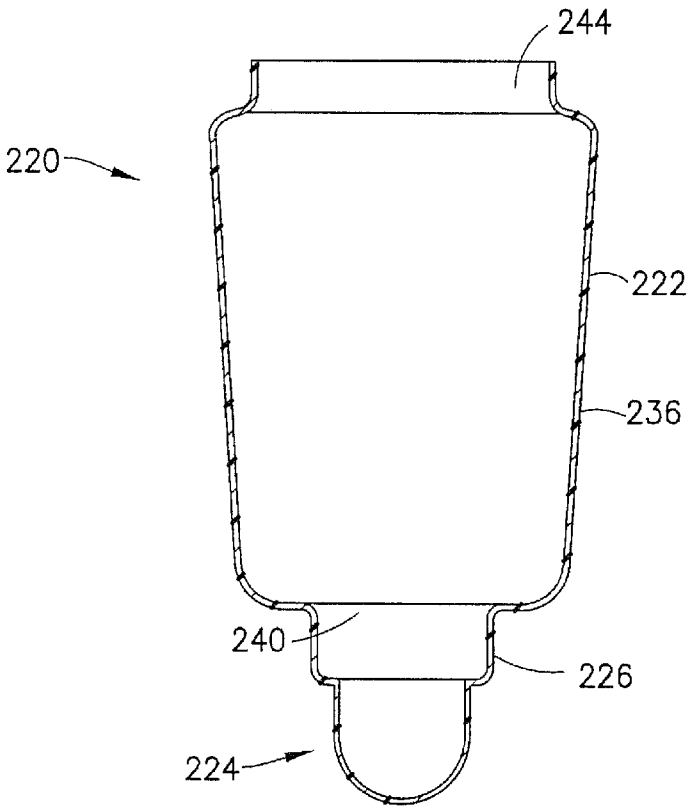

FIG.11A

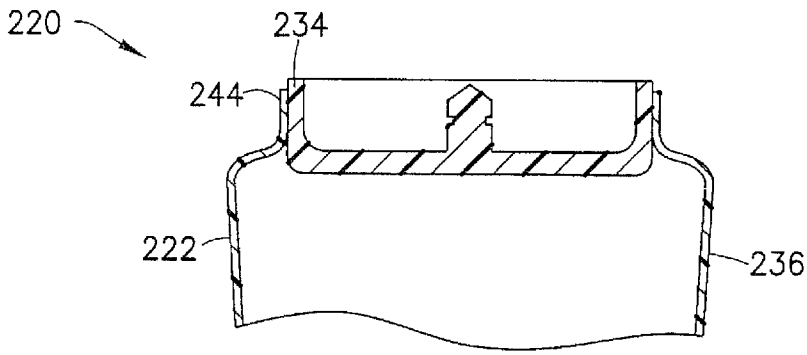

FIG.11B

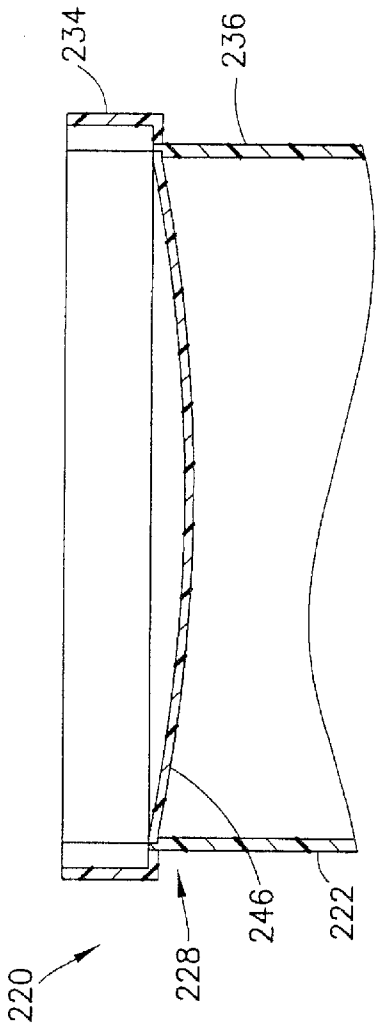

FIG.11C

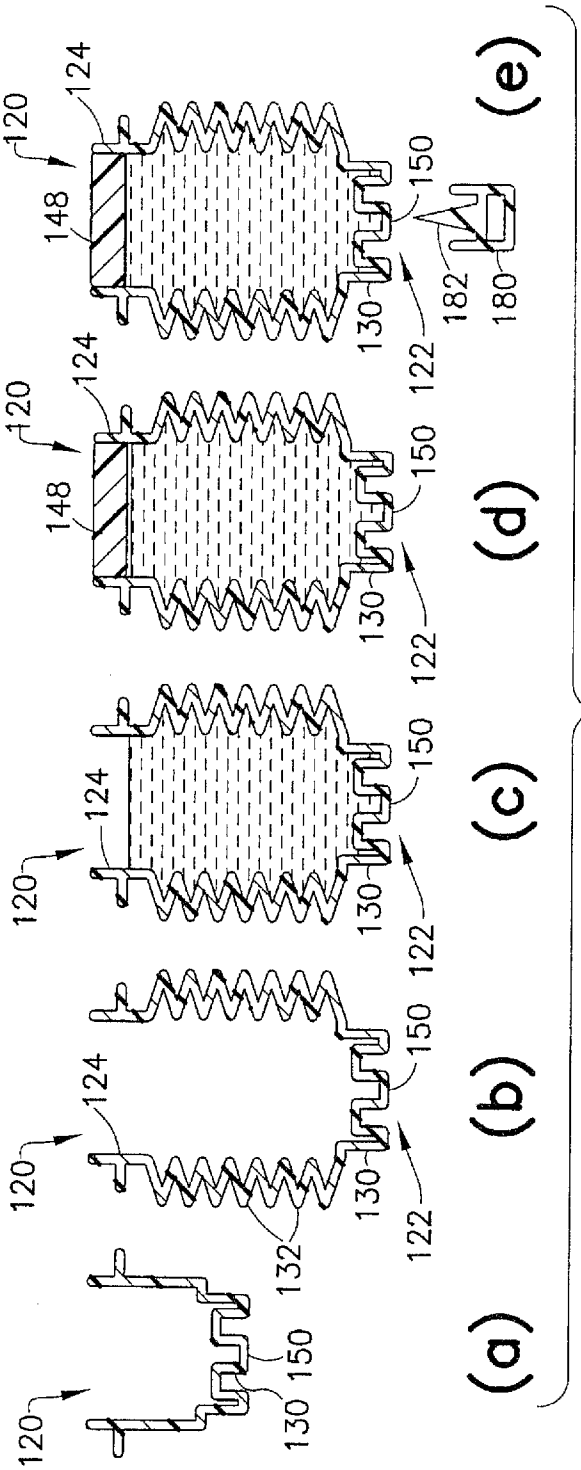

FIG.12

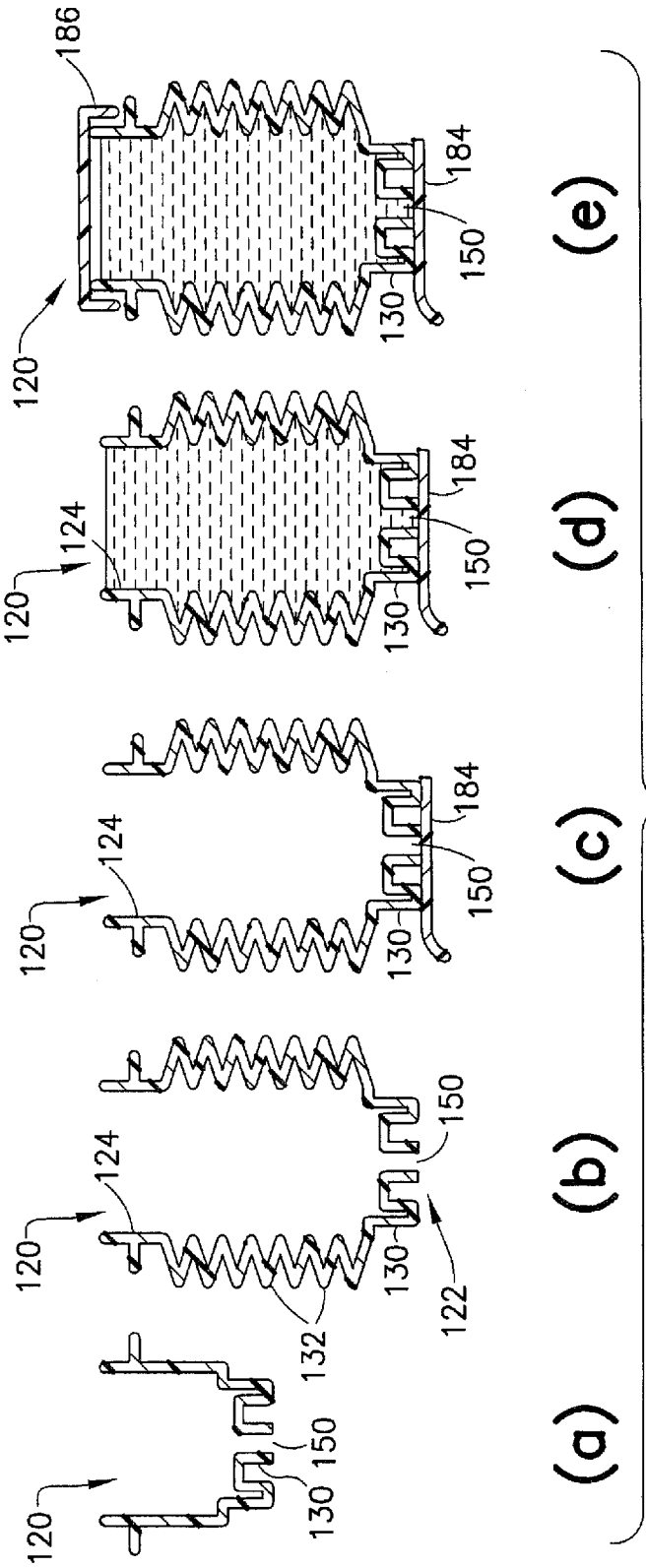

FIG.13

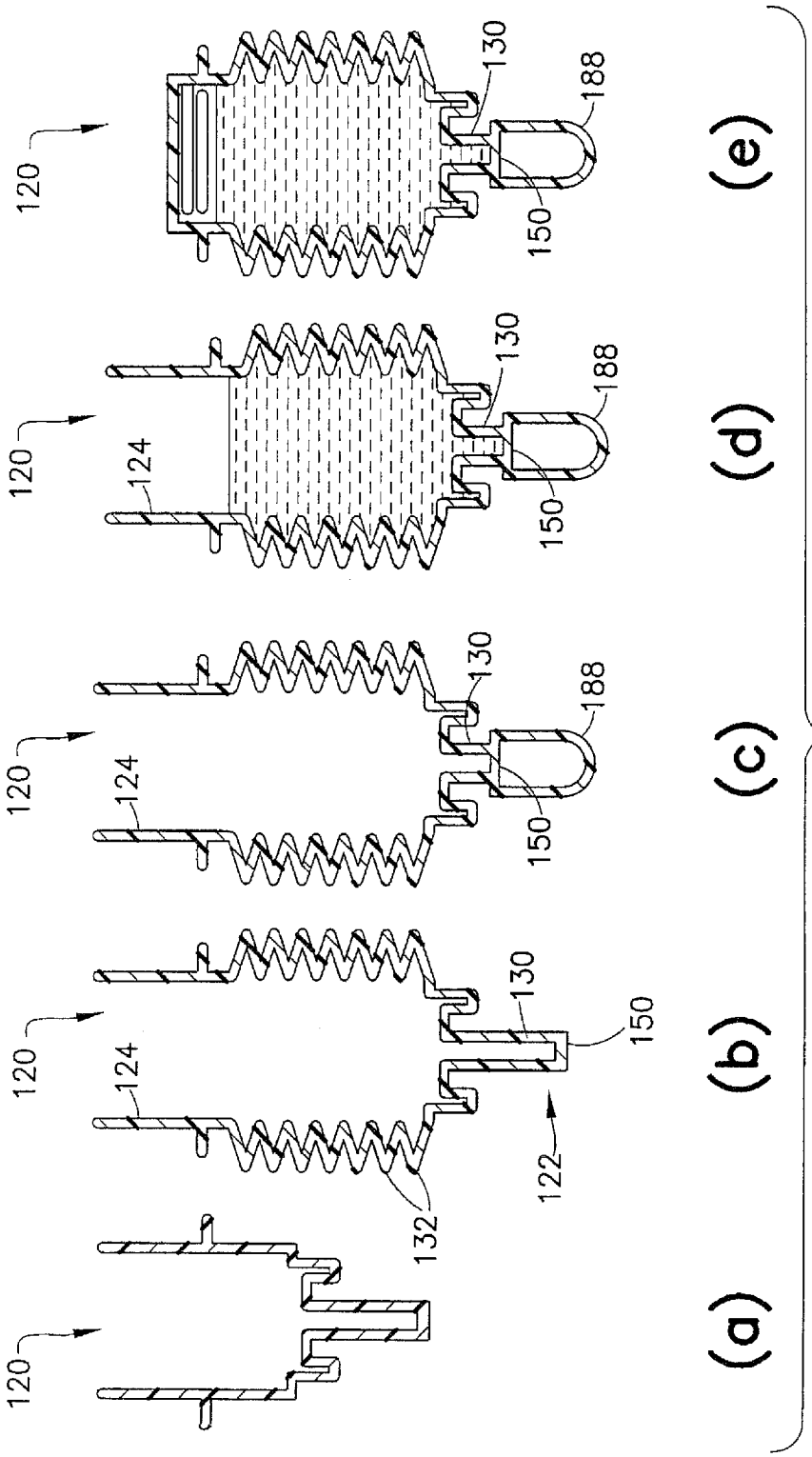

FIG.14

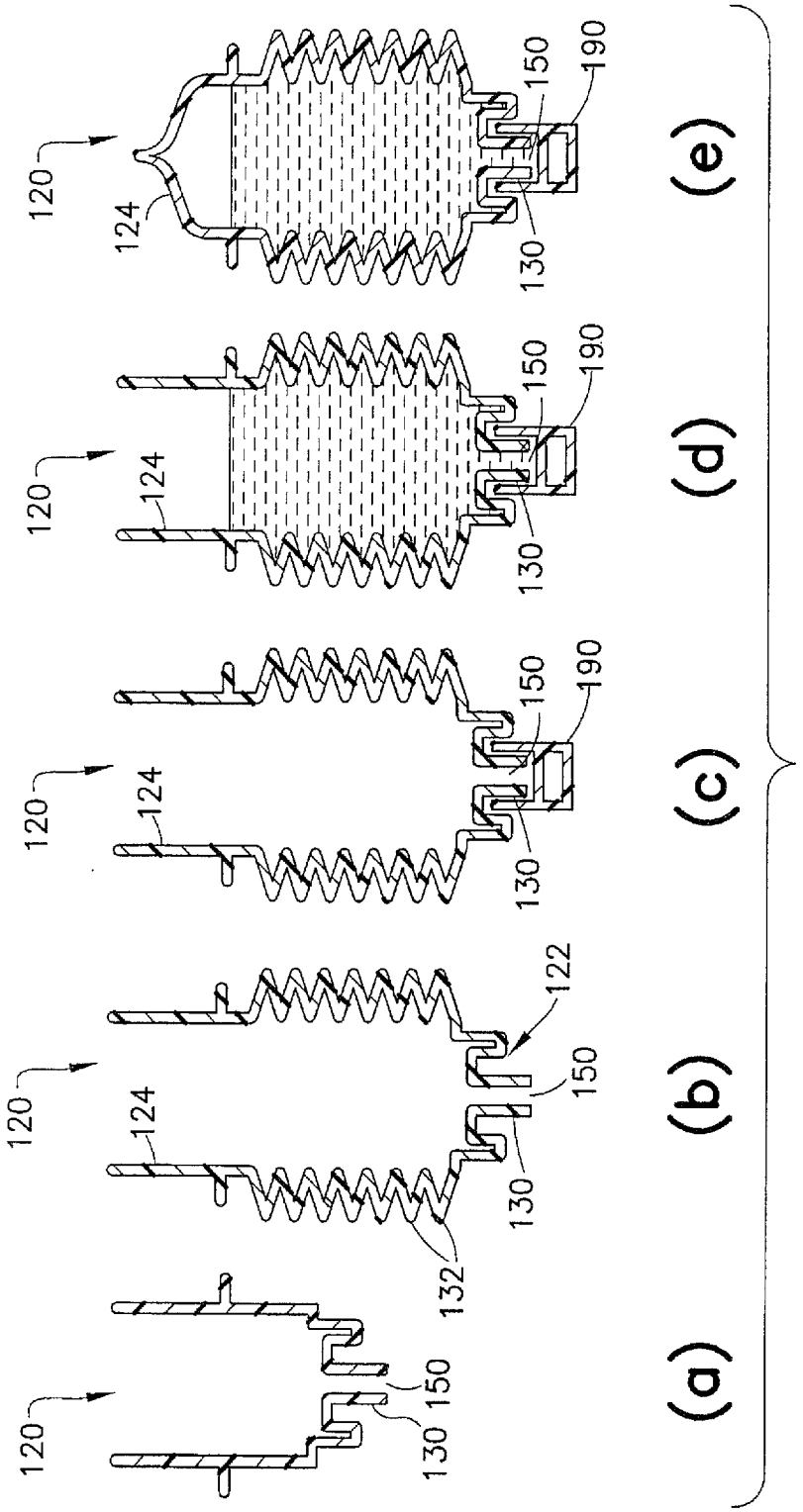

FIG.15

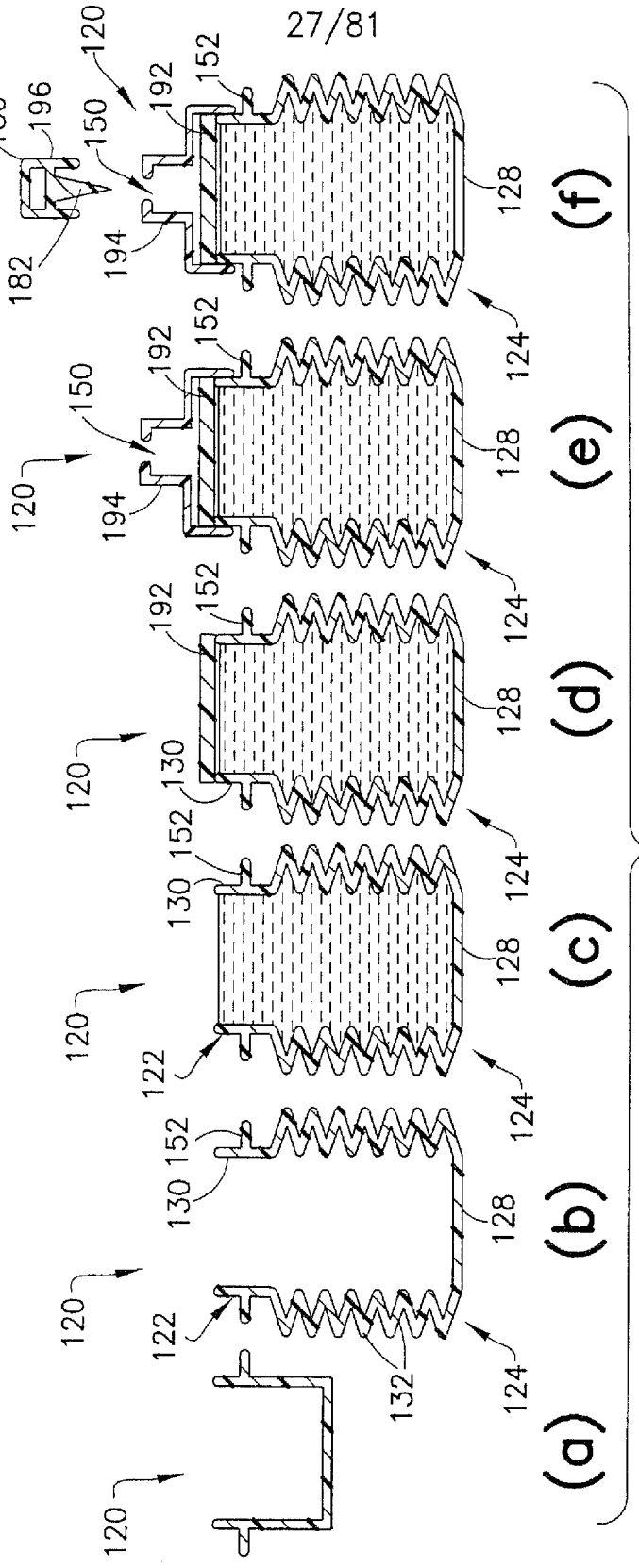

FIG.16

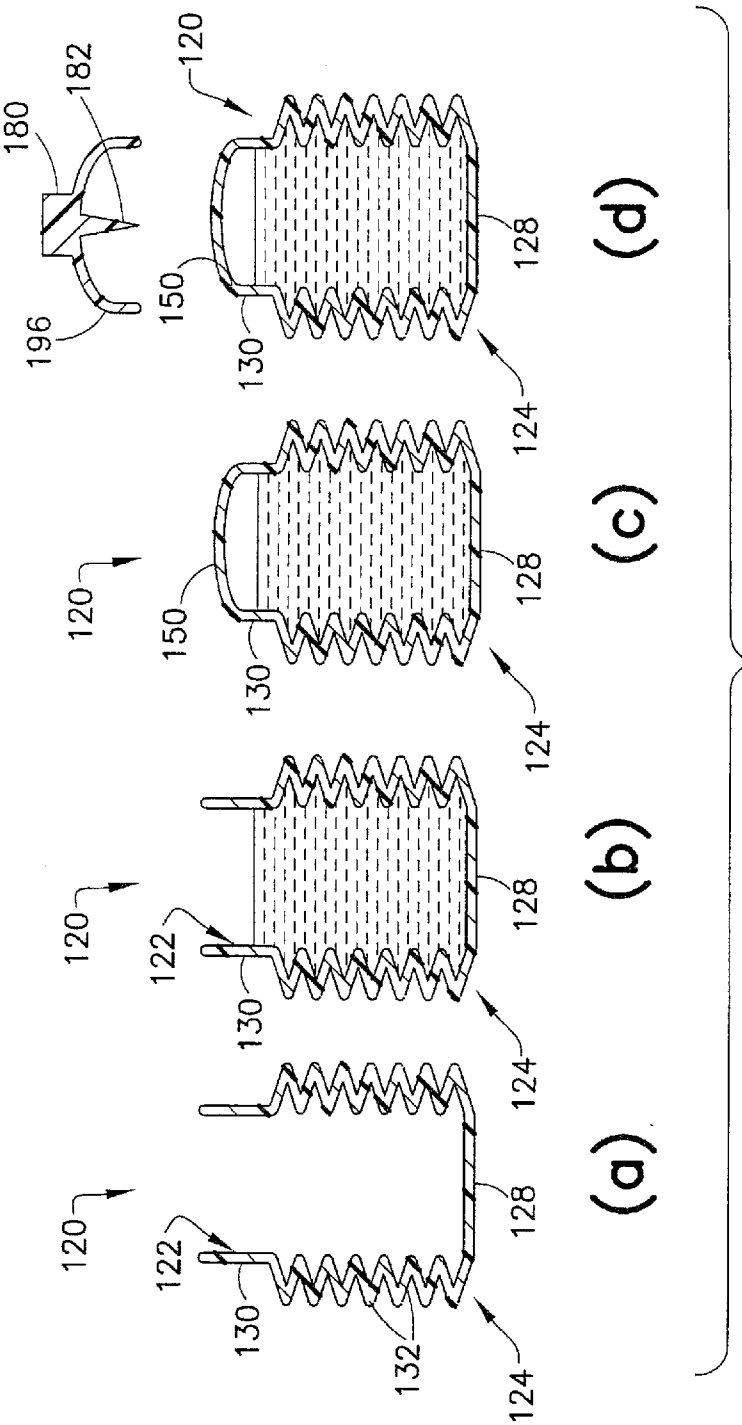
120
182
180
196
150
130
128
124
(d)
120
150
130
128
124
(c)
120
122
130
128
124
(b)
120
122
130
132
128
124
(a)

FIG.17

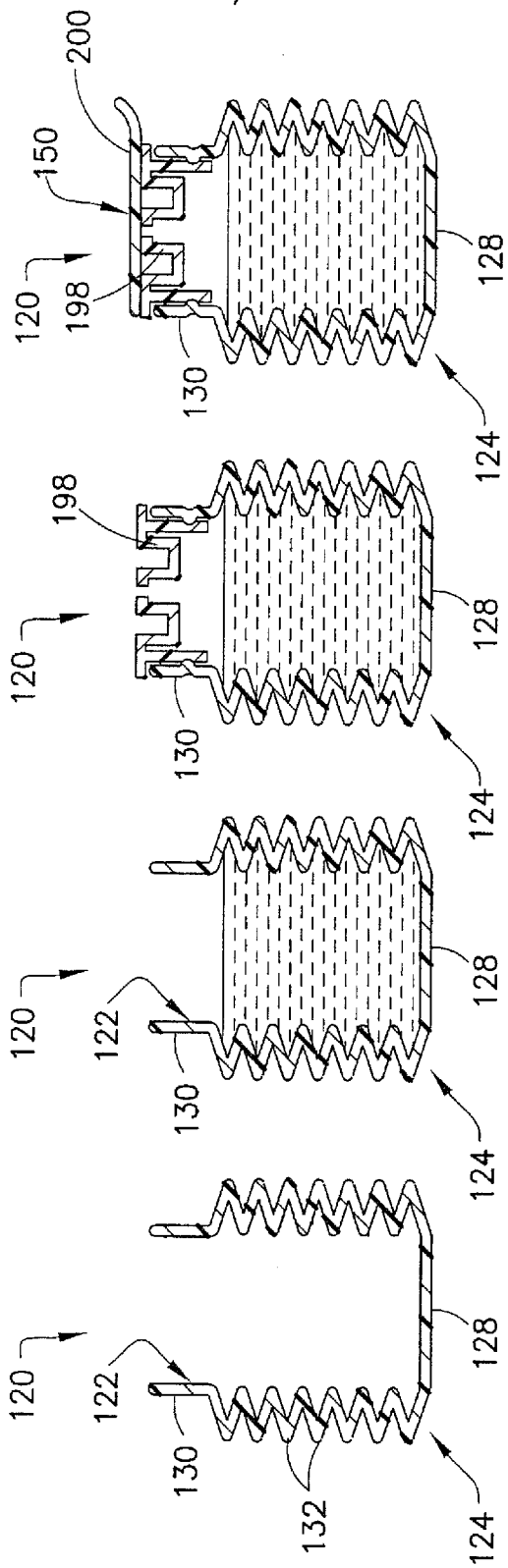

FIG.18

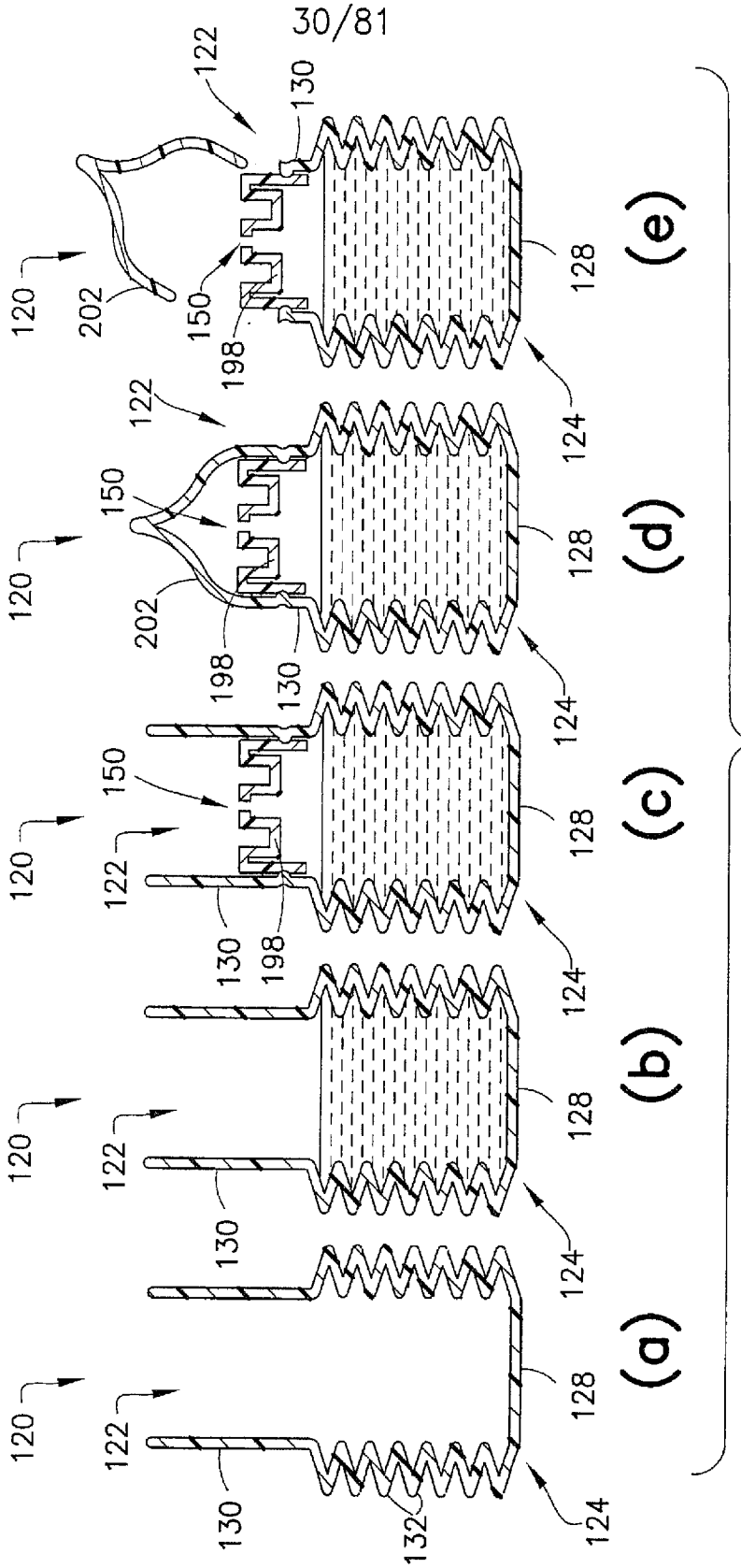

FIG.19

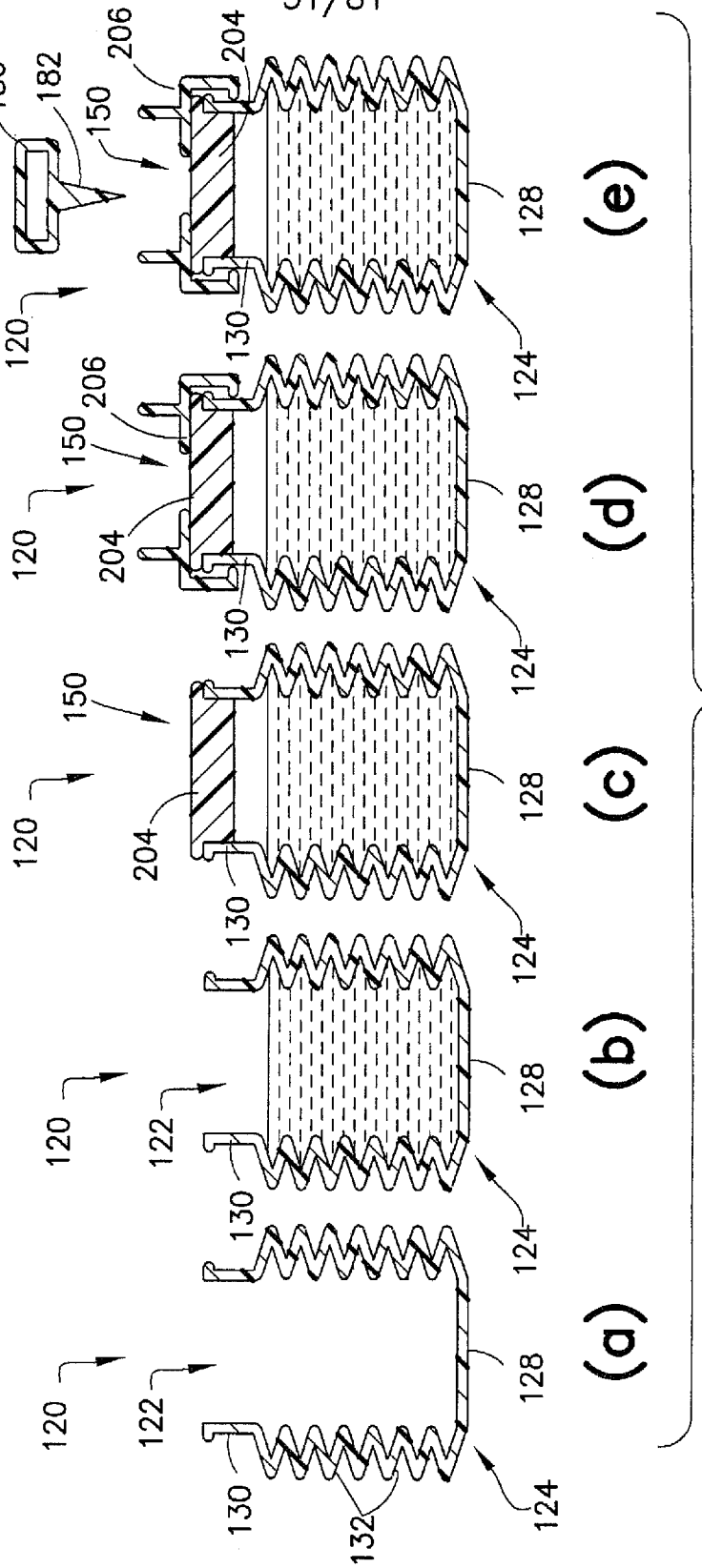

FIG.20

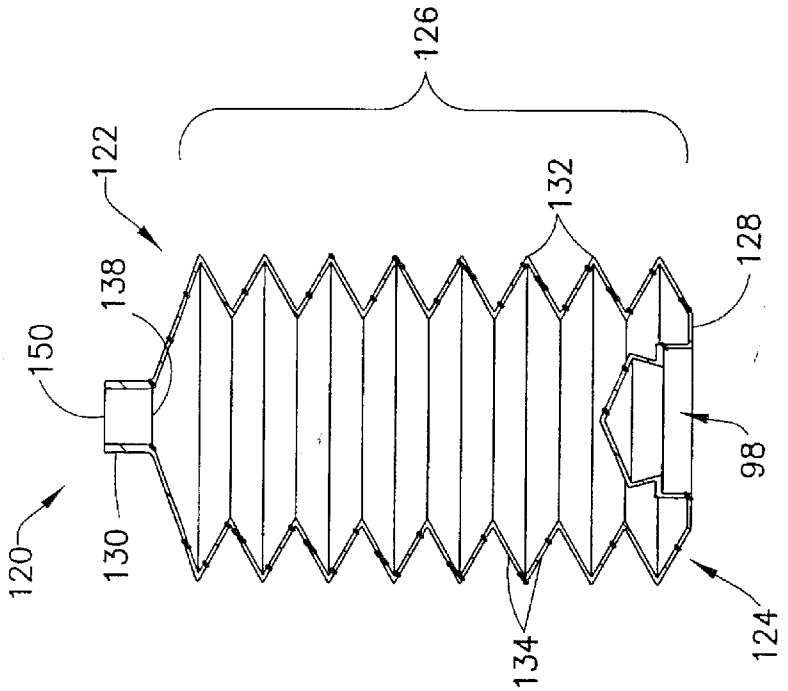

FIG.21B

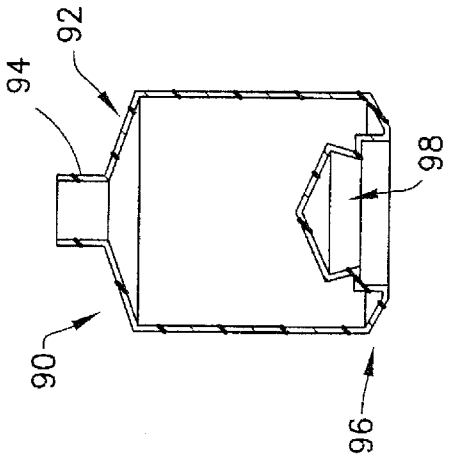

FIG.21A

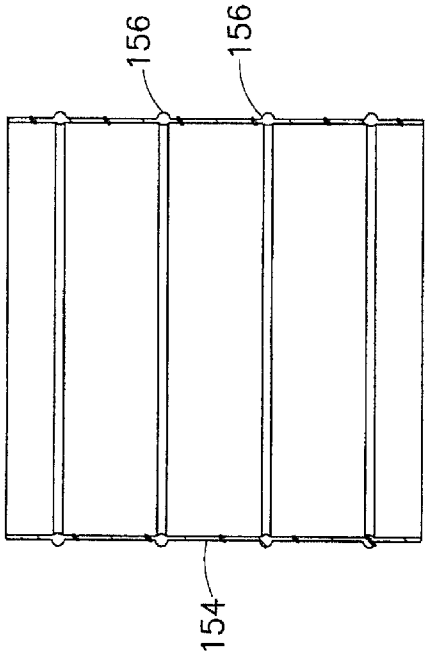

FIG.22B

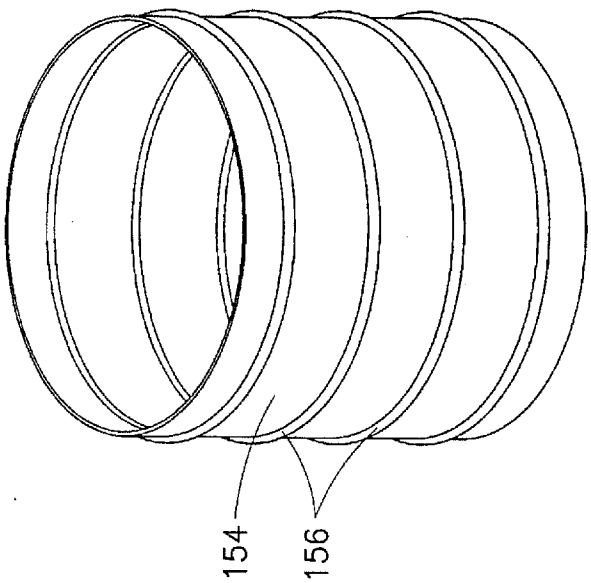

FIG.22A

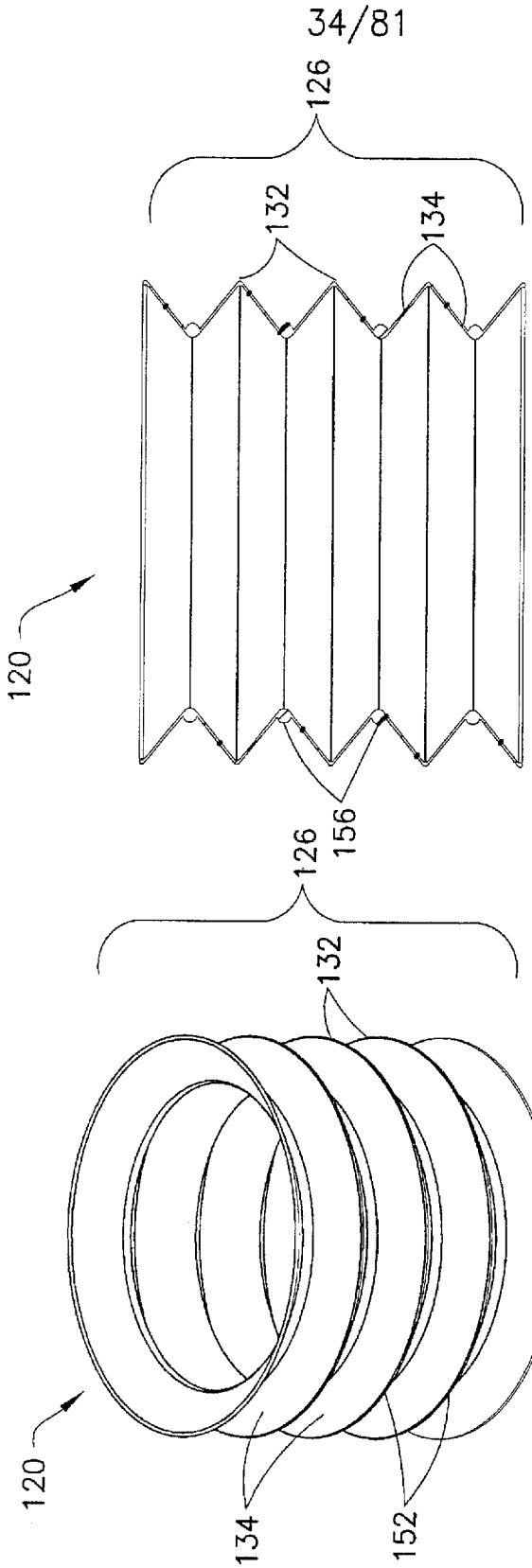

FIG.22D

FIG.22C

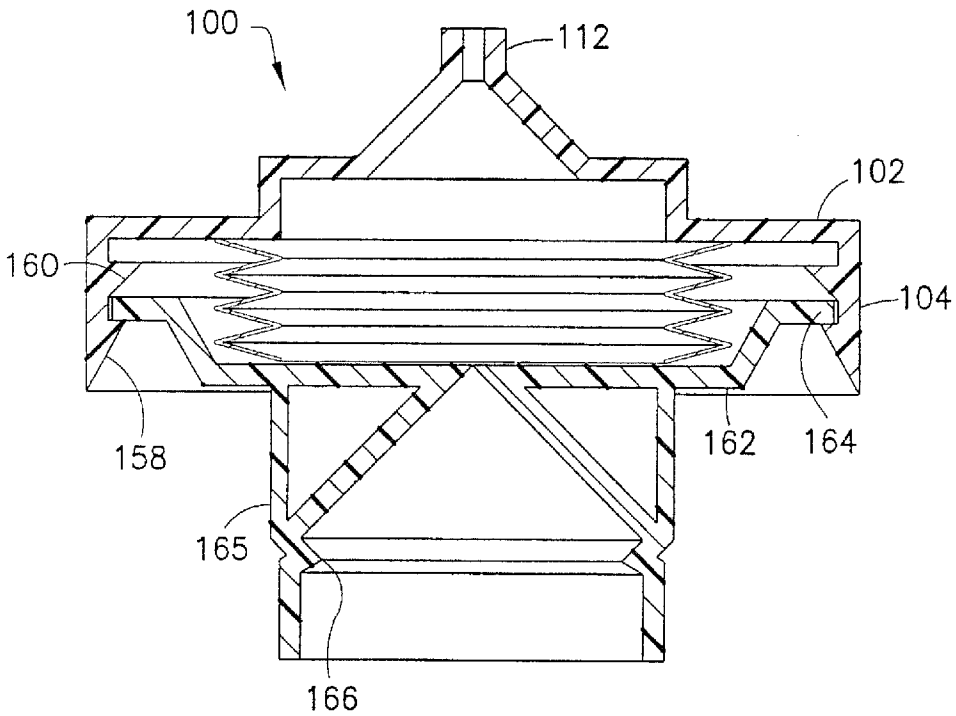

FIG.23A

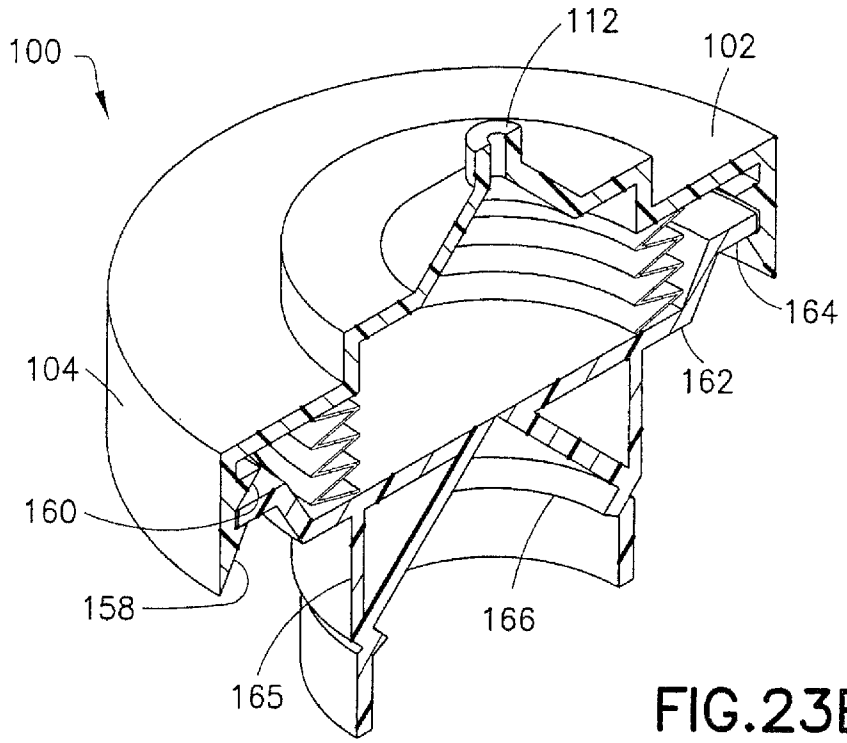

FIG.23B

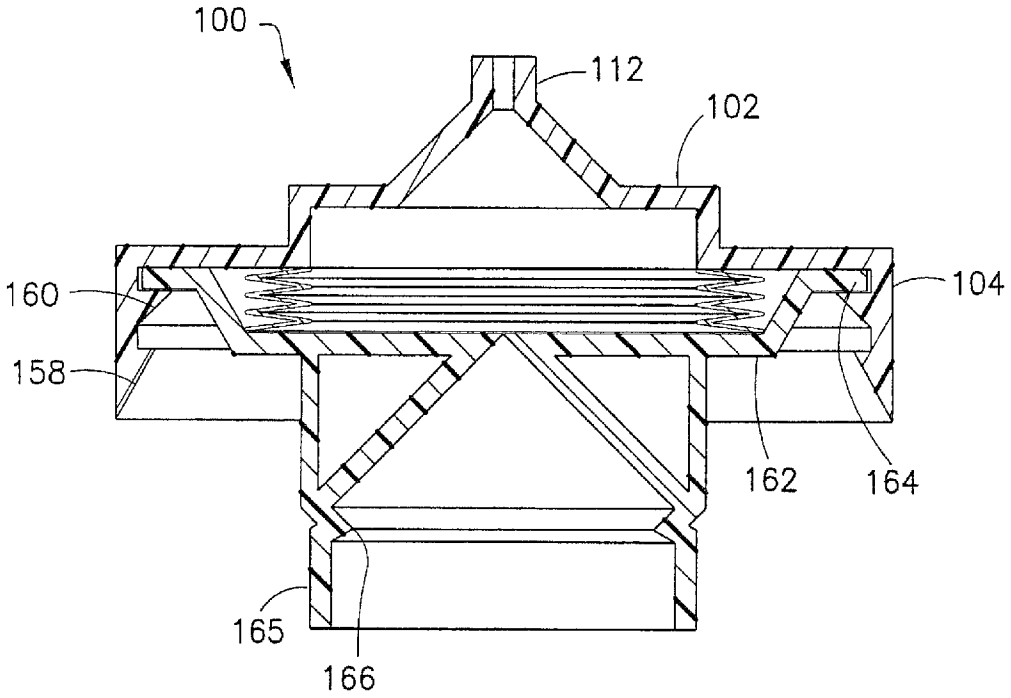

FIG.23C

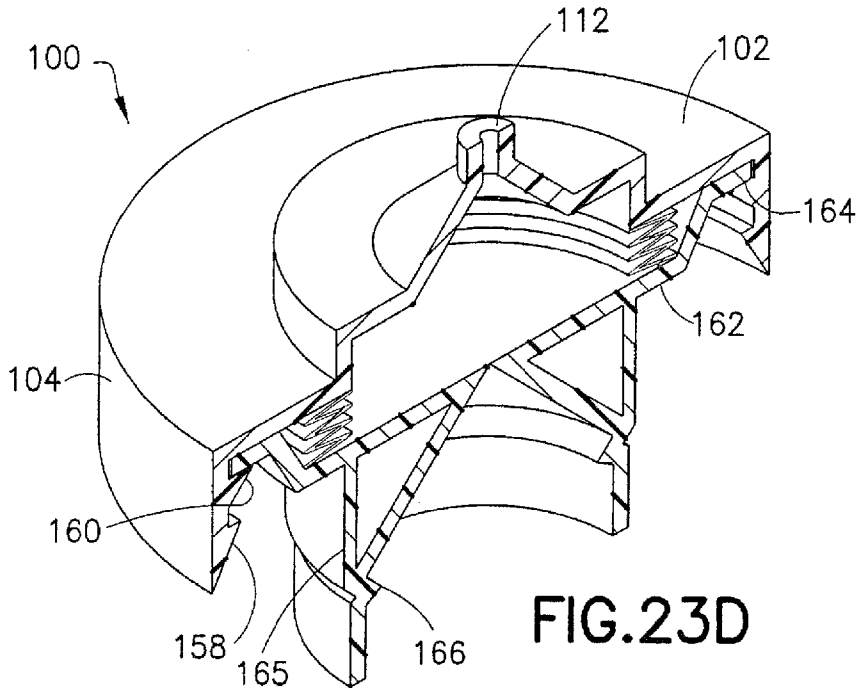

FIG.23D

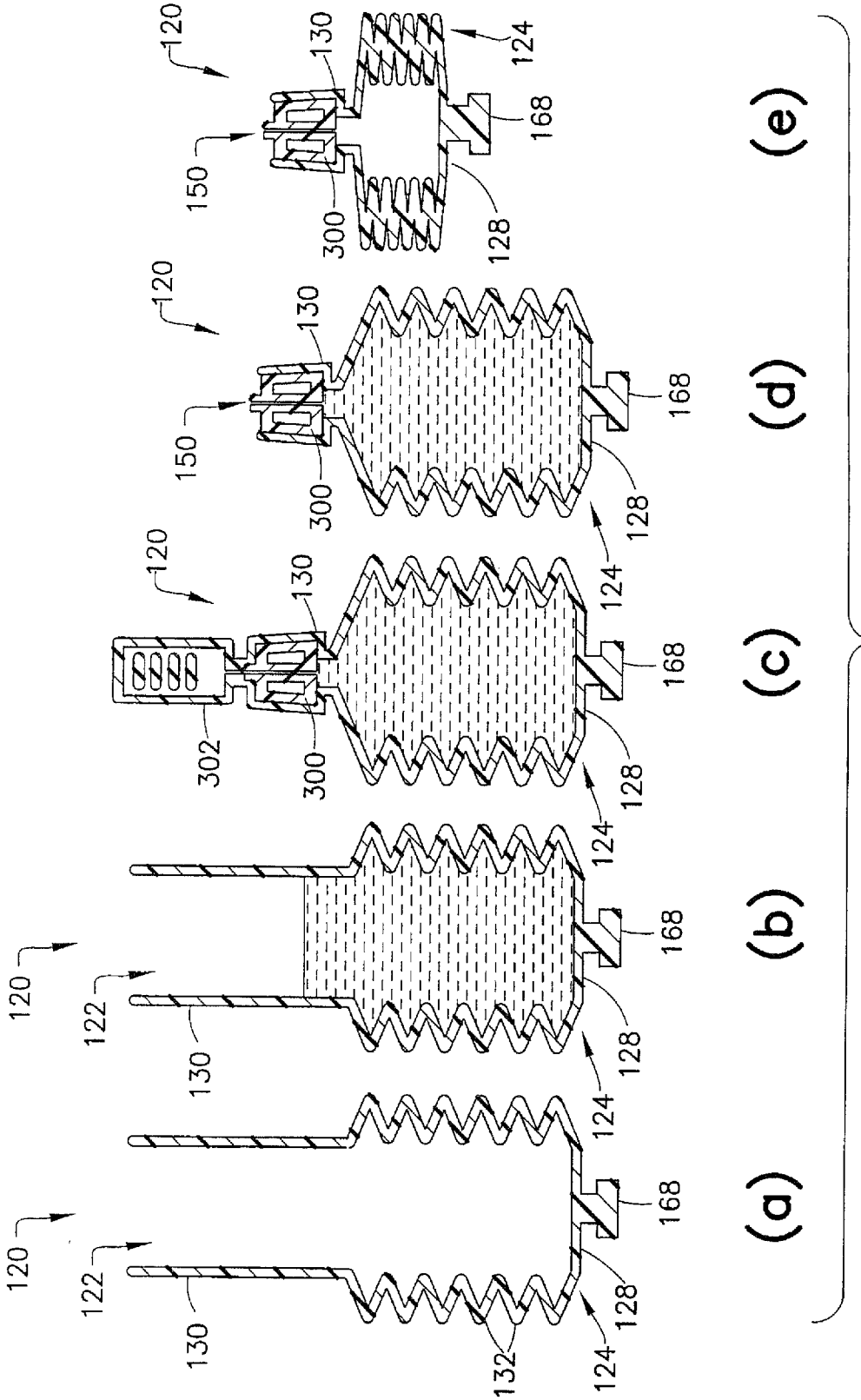

FIG.24

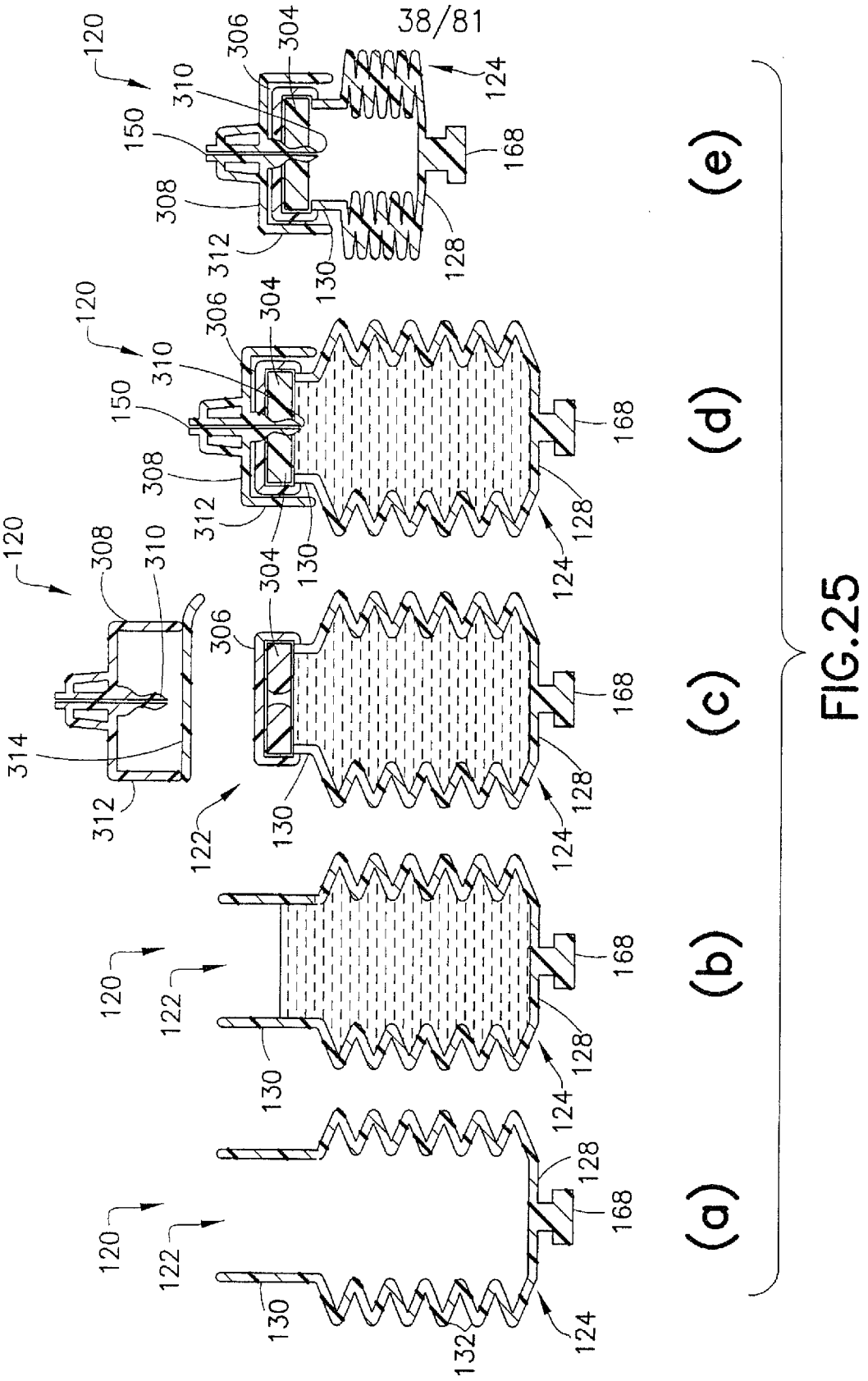

FIG.25

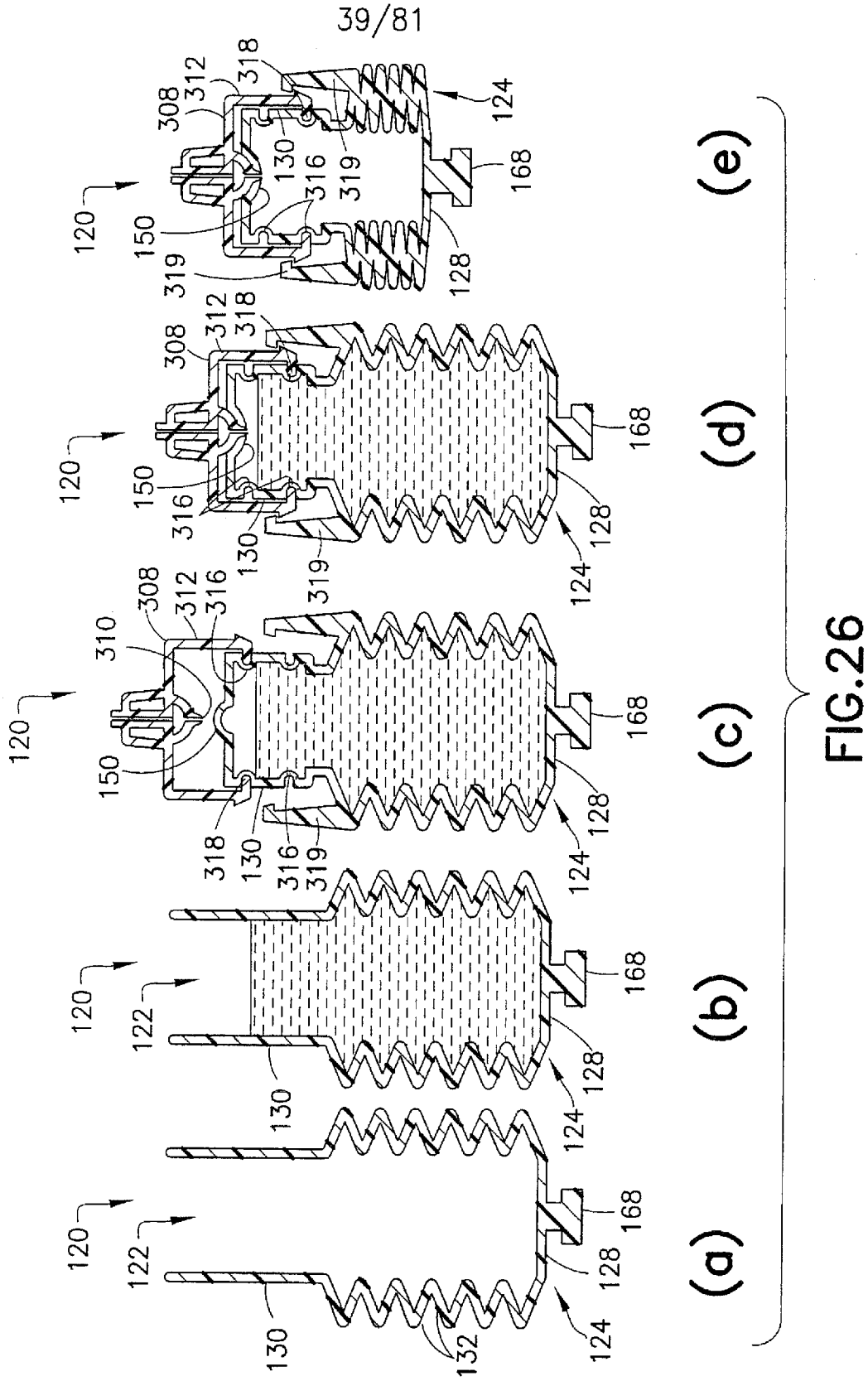

FIG.26

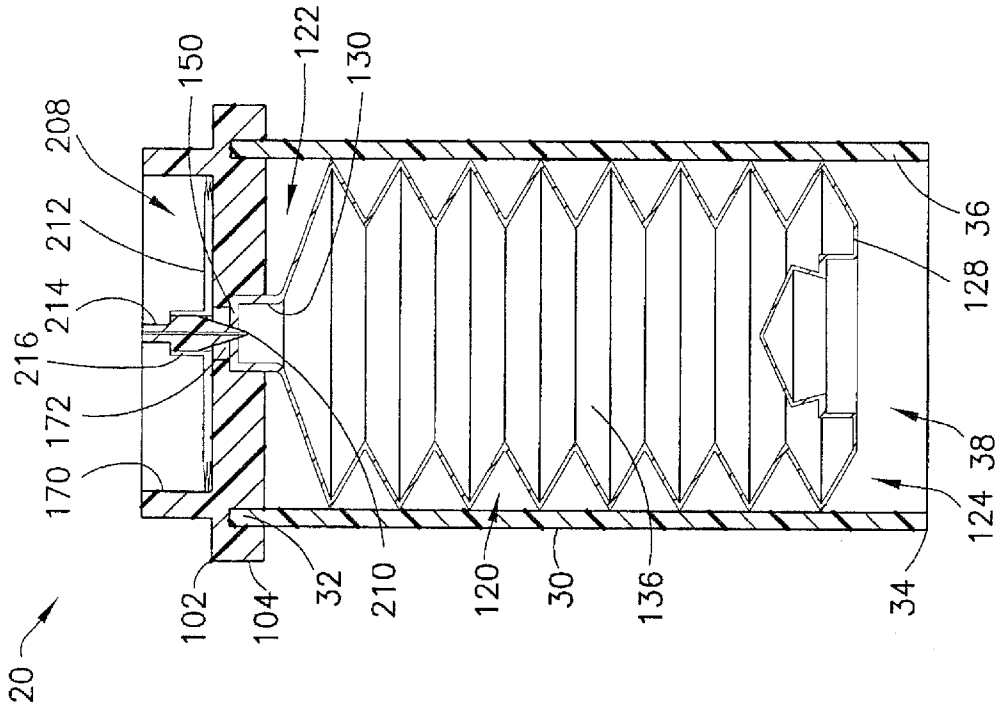

FIG.27B

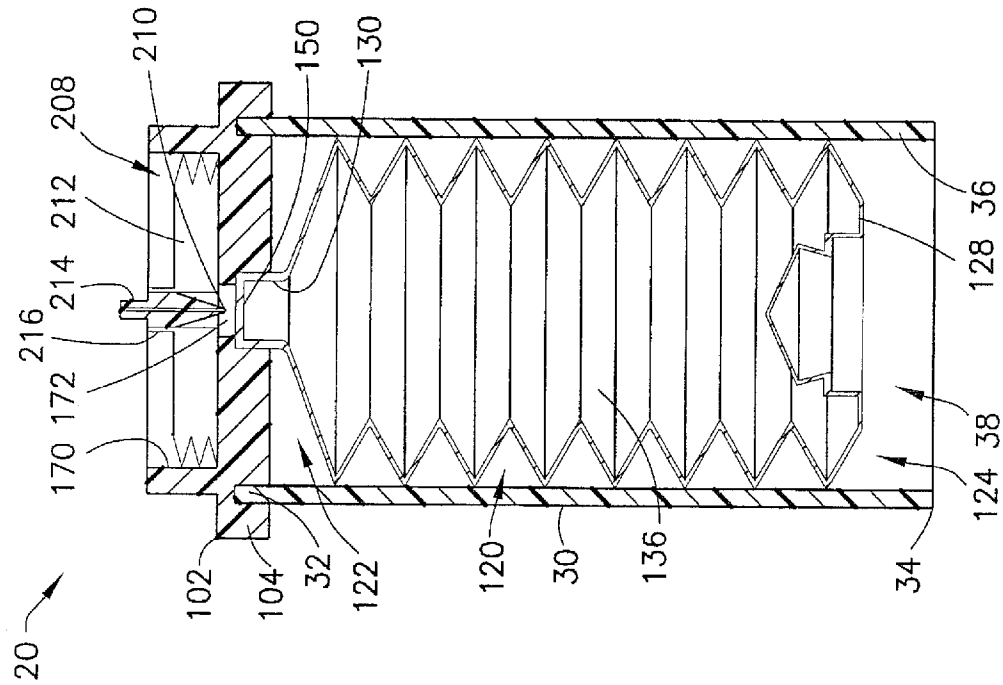

FIG.27A

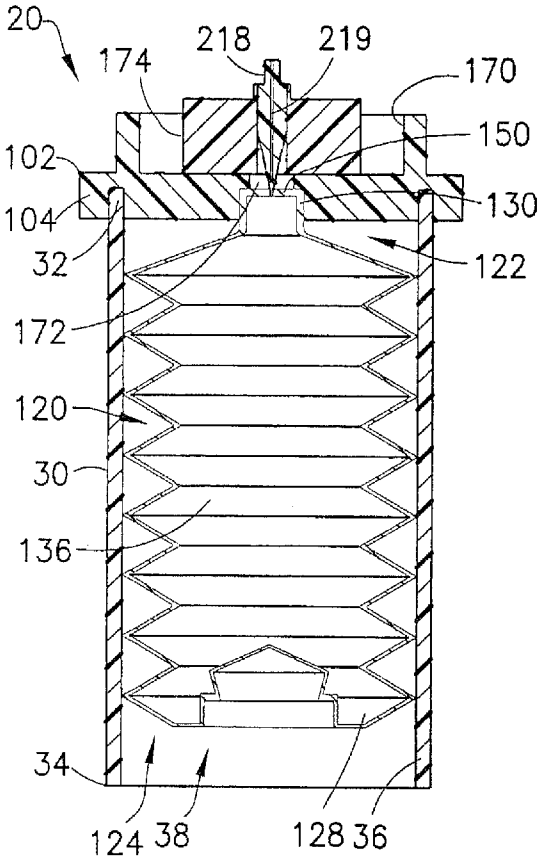

FIG.28A

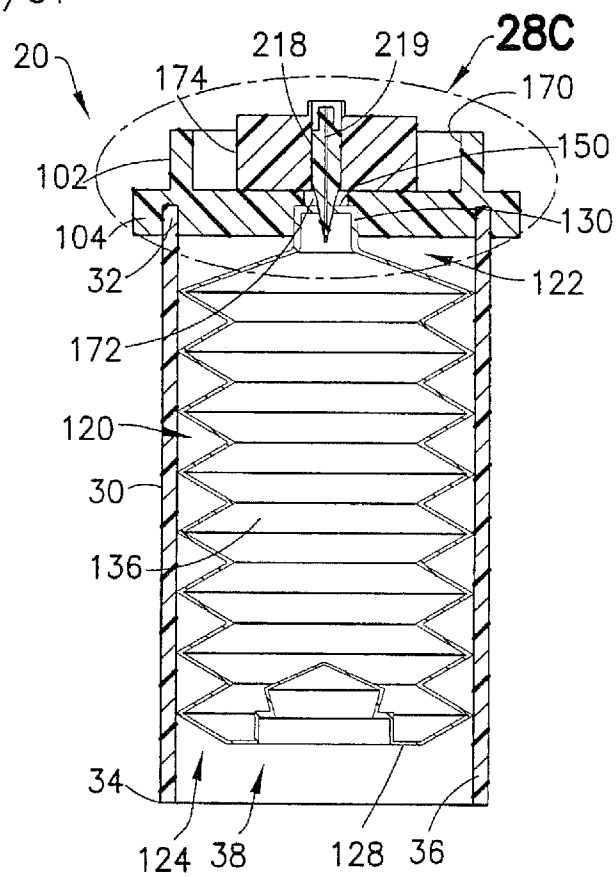

FIG.28B

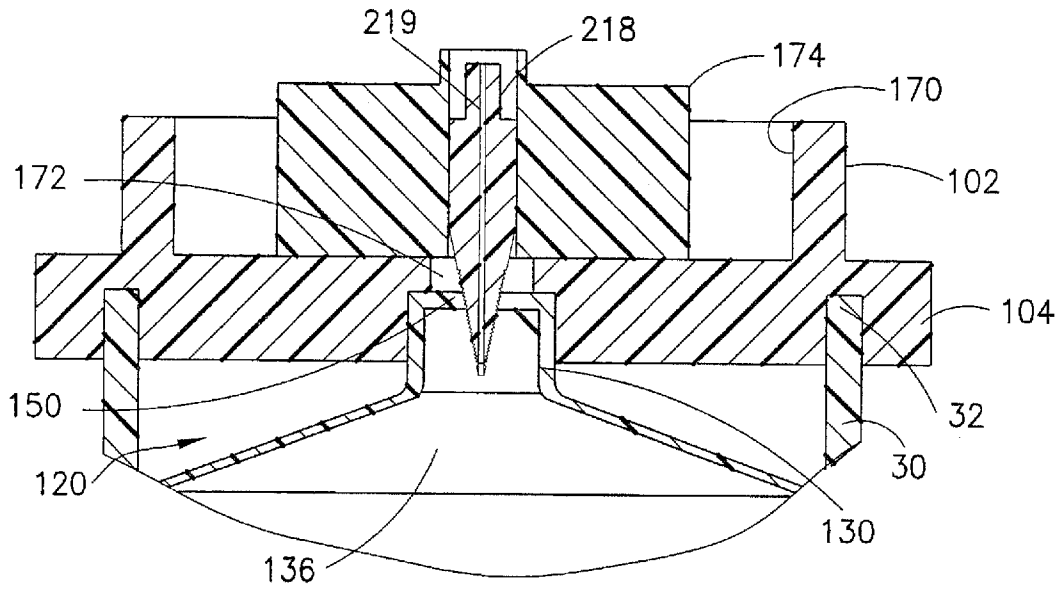

FIG.28C

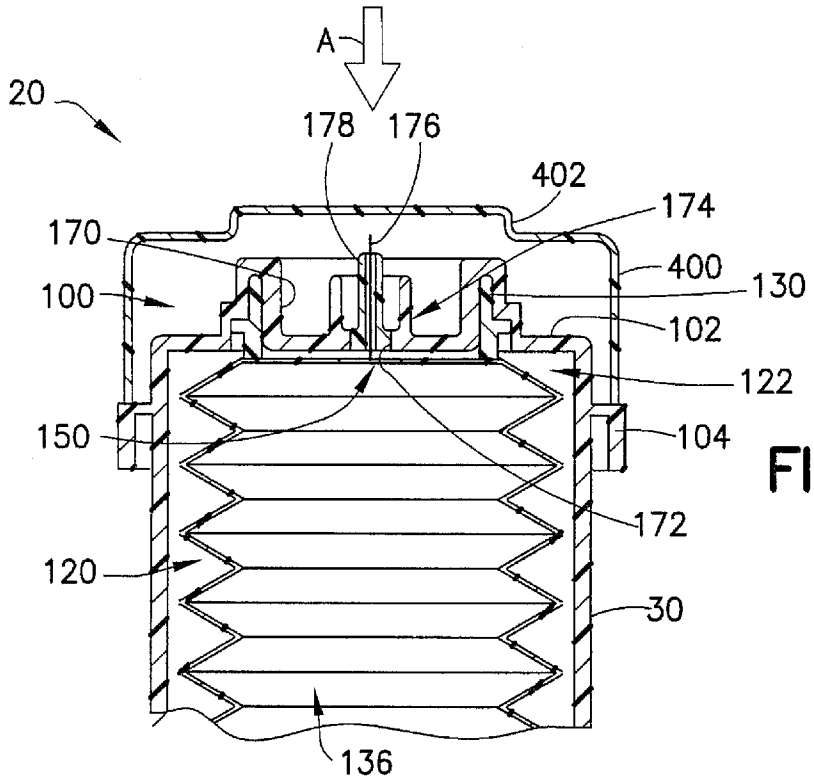

FIG.29

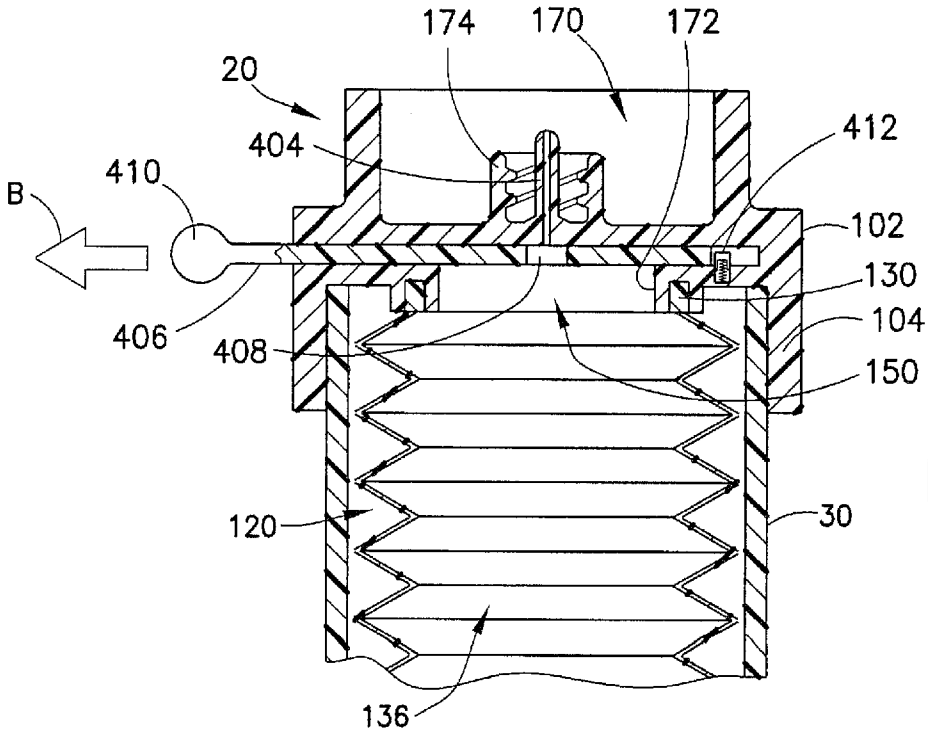

FIG.30A

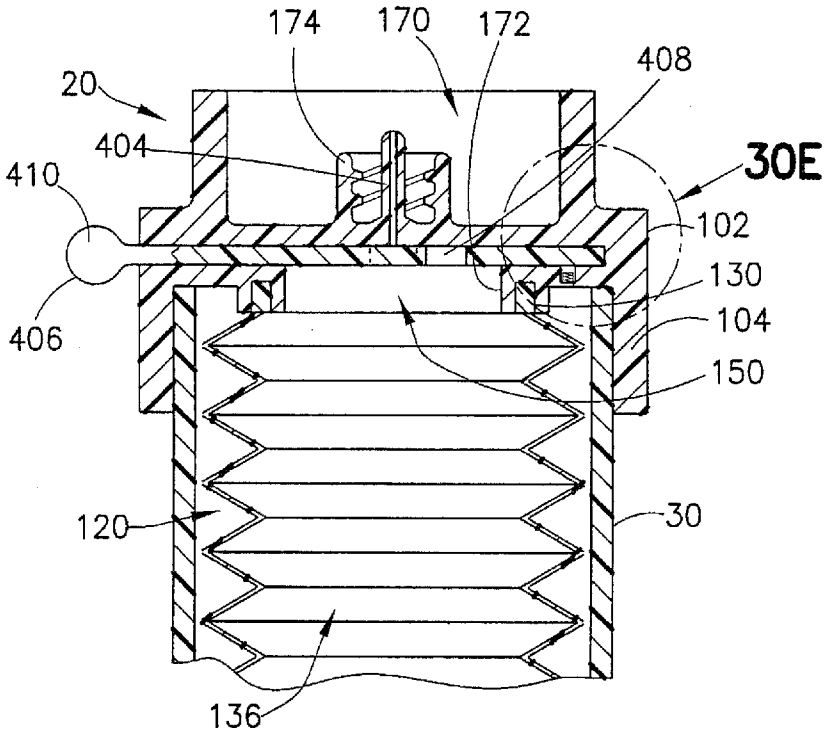

FIG.30B

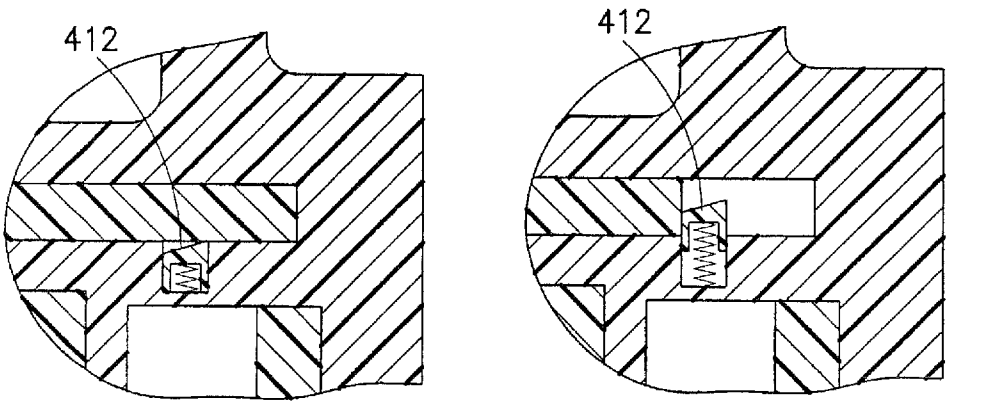

FIG.30E

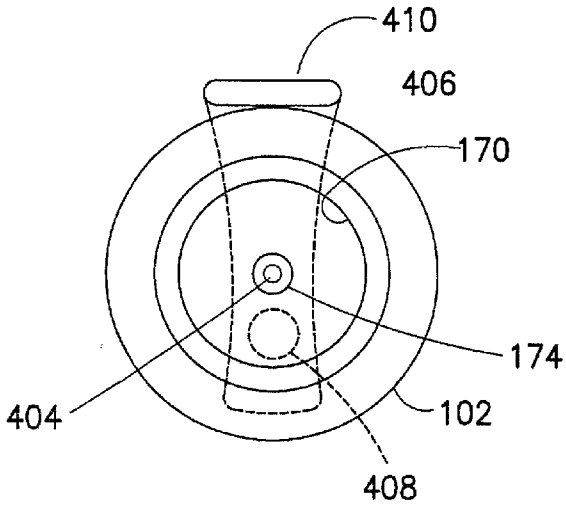

FIG.30C

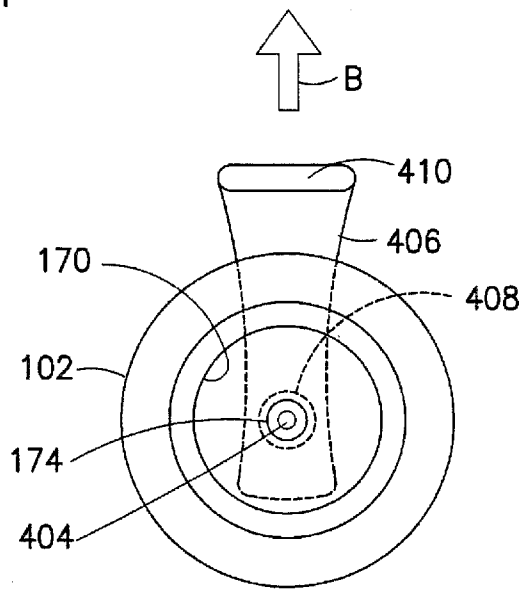

FIG.30D

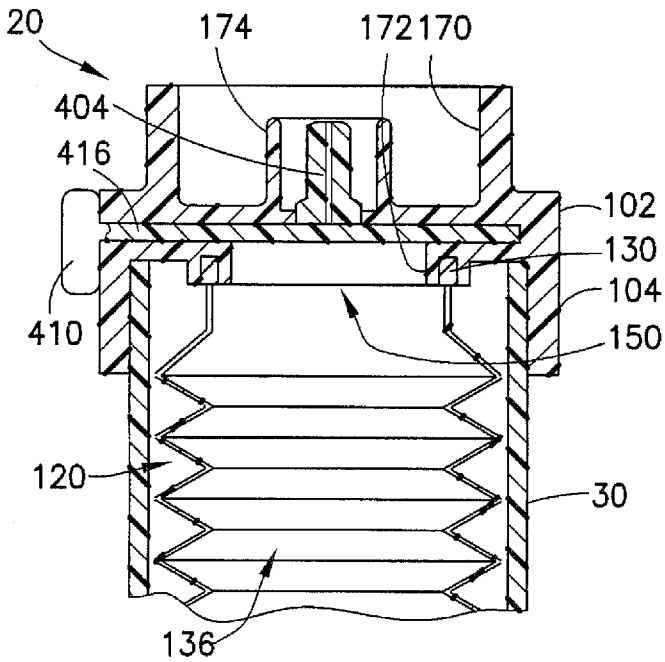

FIG.31A

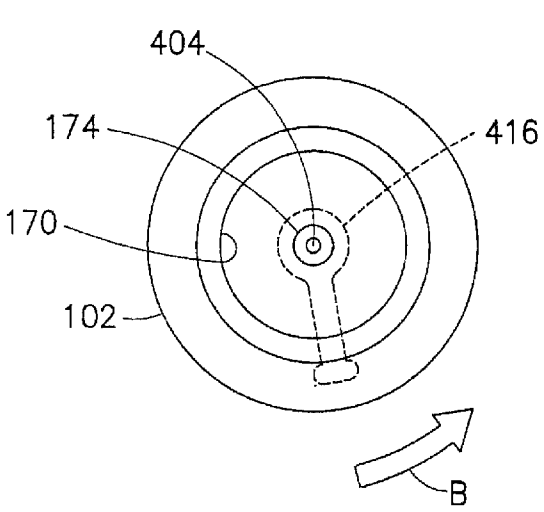

FIG.31B

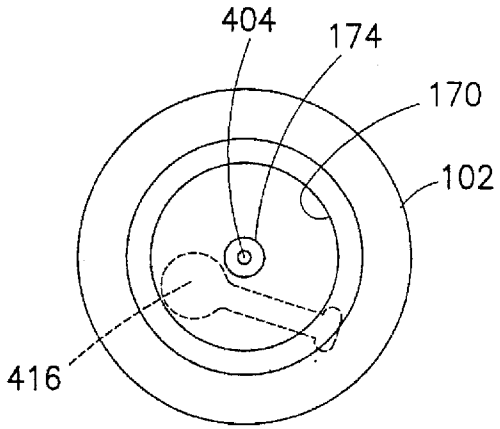

FIG.31C

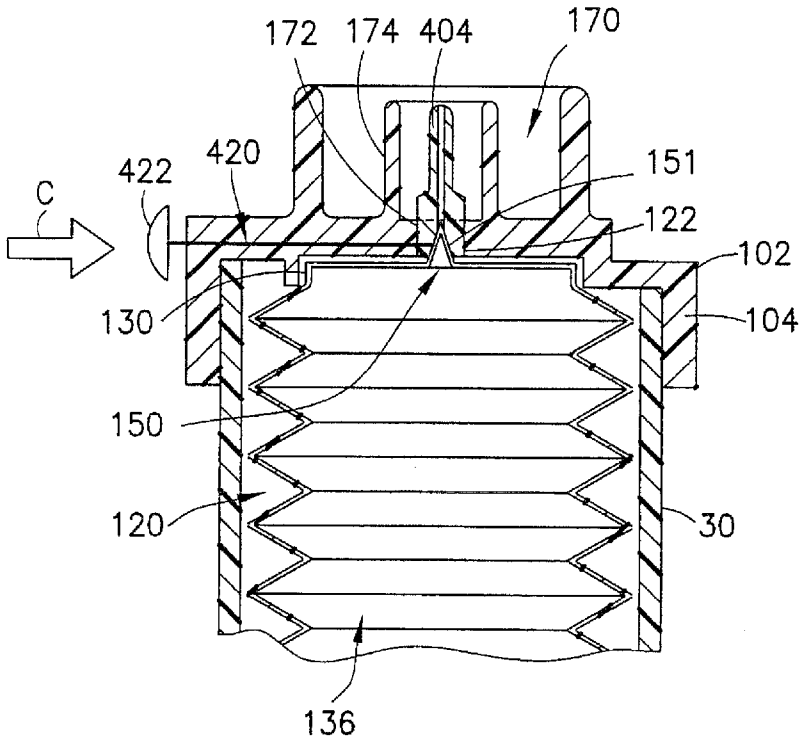

FIG.32

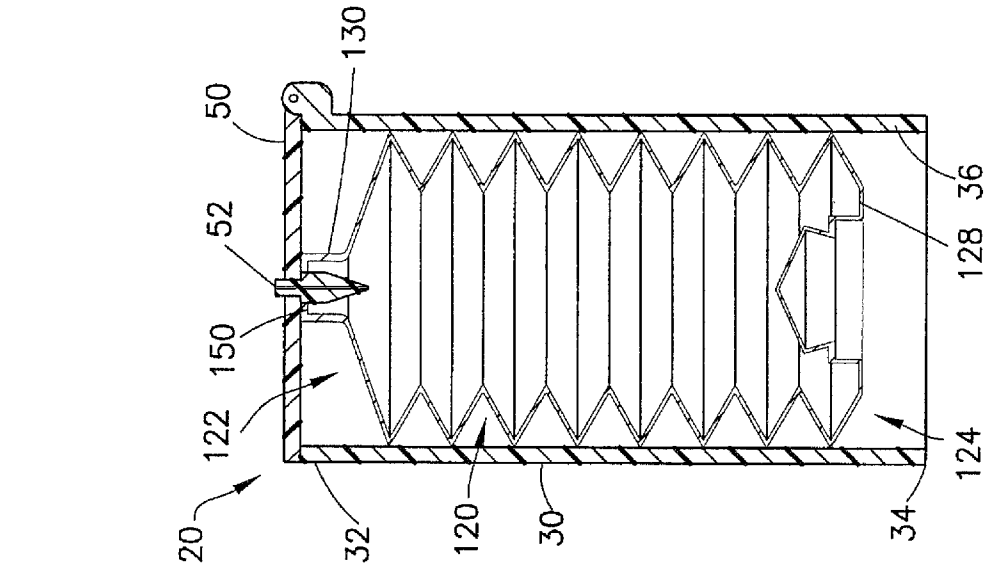

FIG.33B

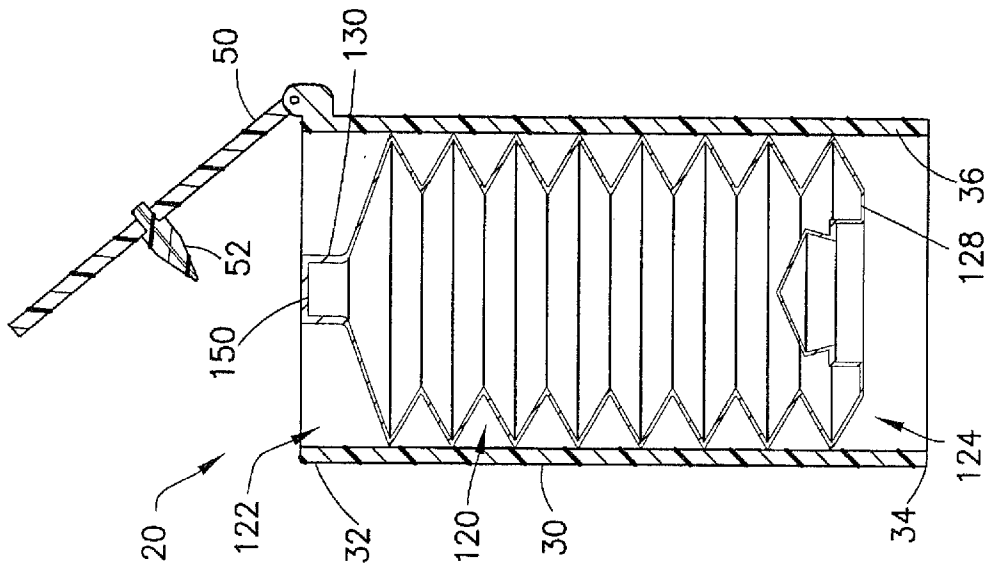

FIG.33A

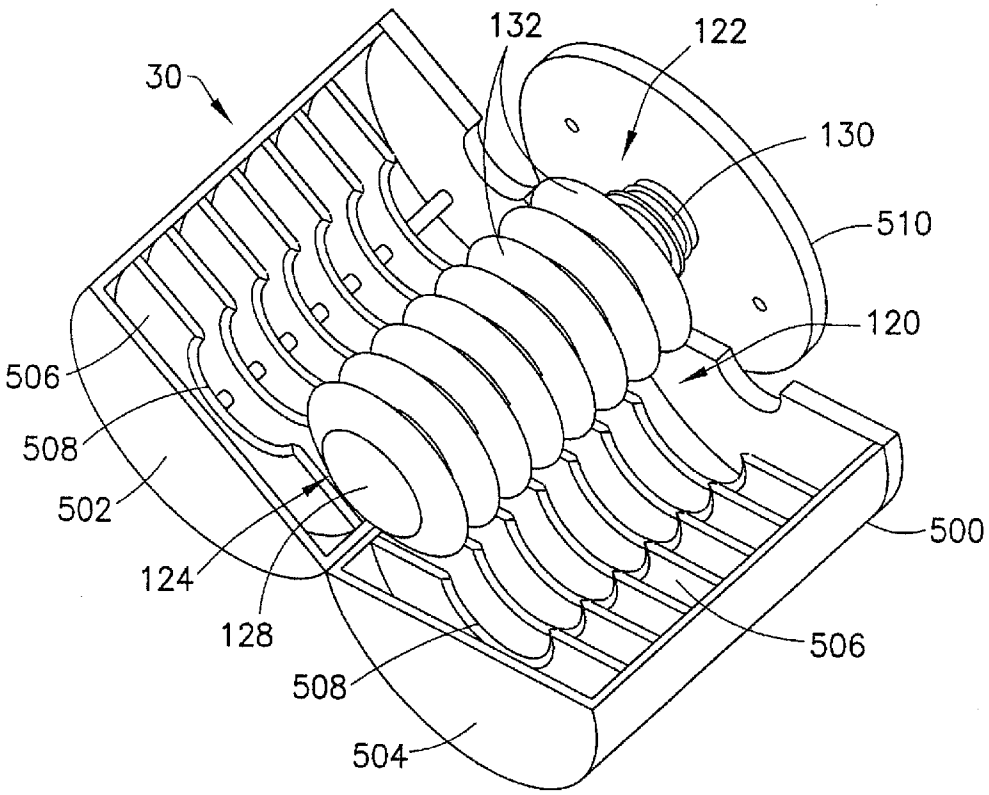

FIG.34

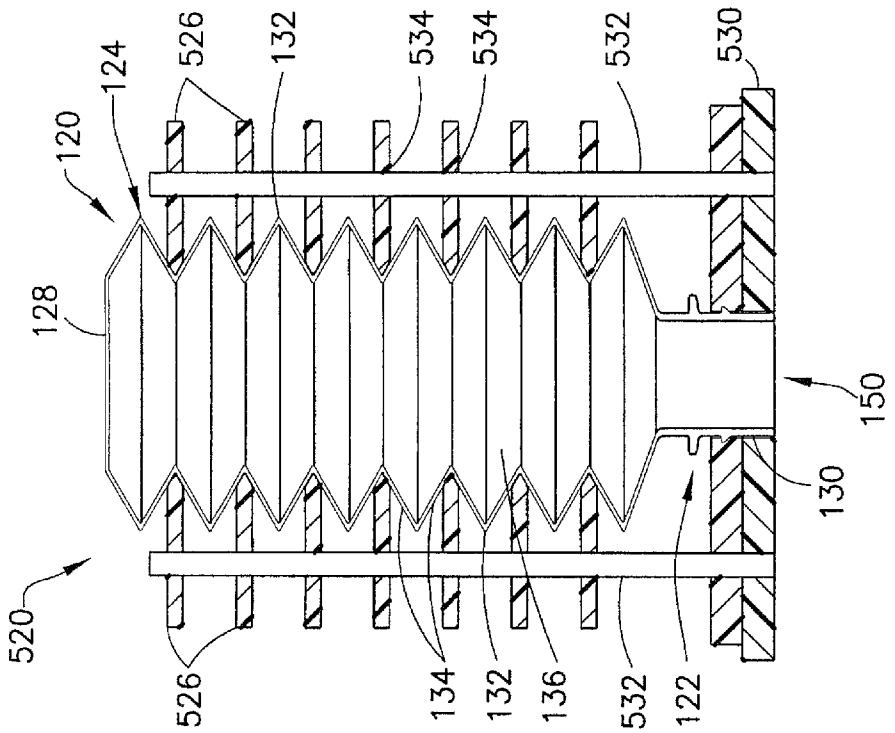

FIG.35B

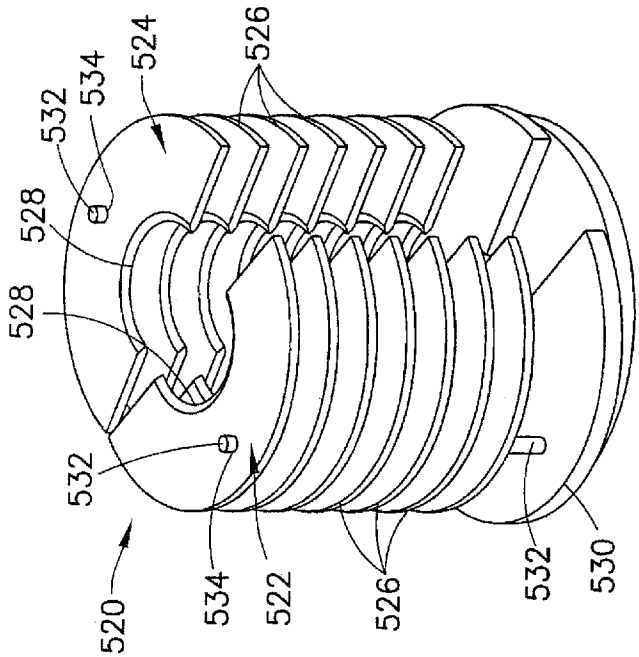

FIG.35A

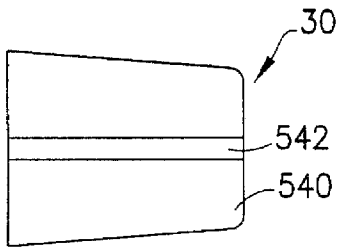

FIG.36A

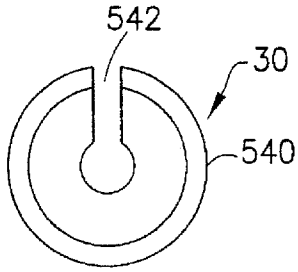

FIG.36B

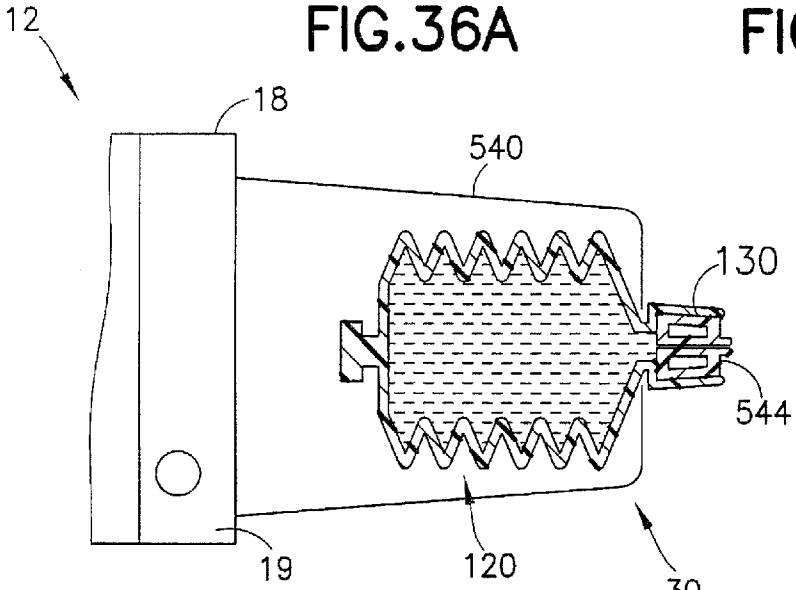

FIG.36C

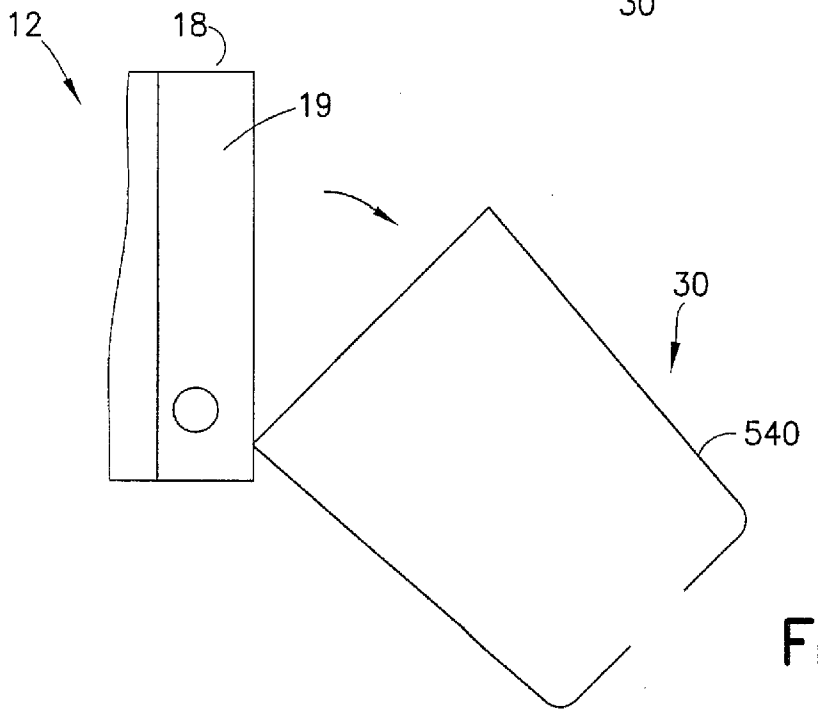

FIG.36D

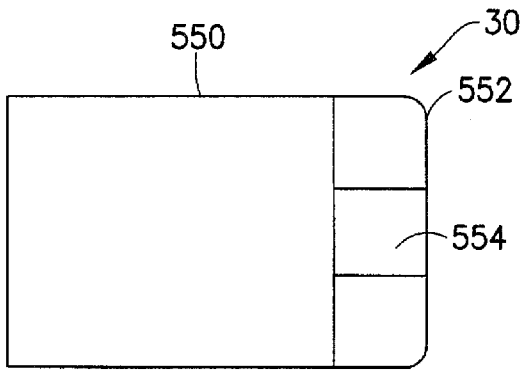

FIG.37A

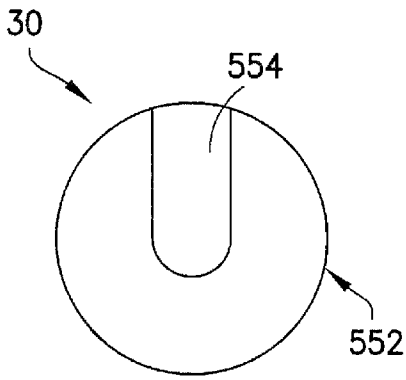

FIG.37B

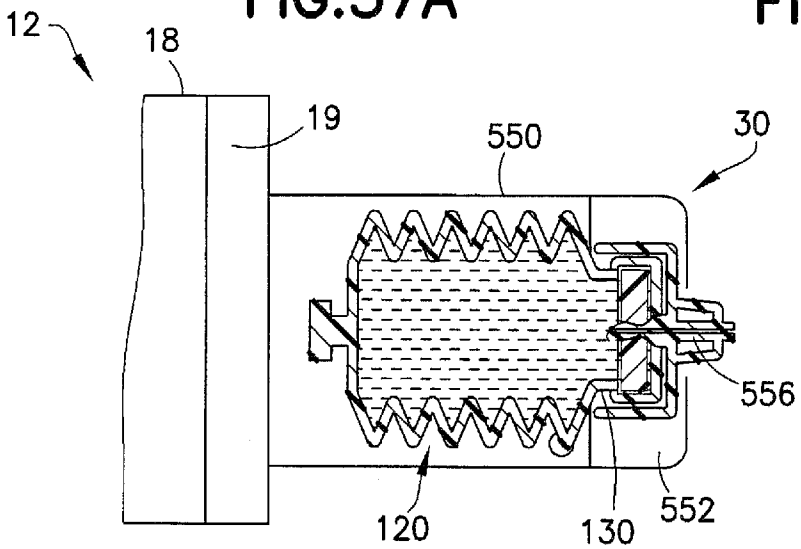

FIG.37C

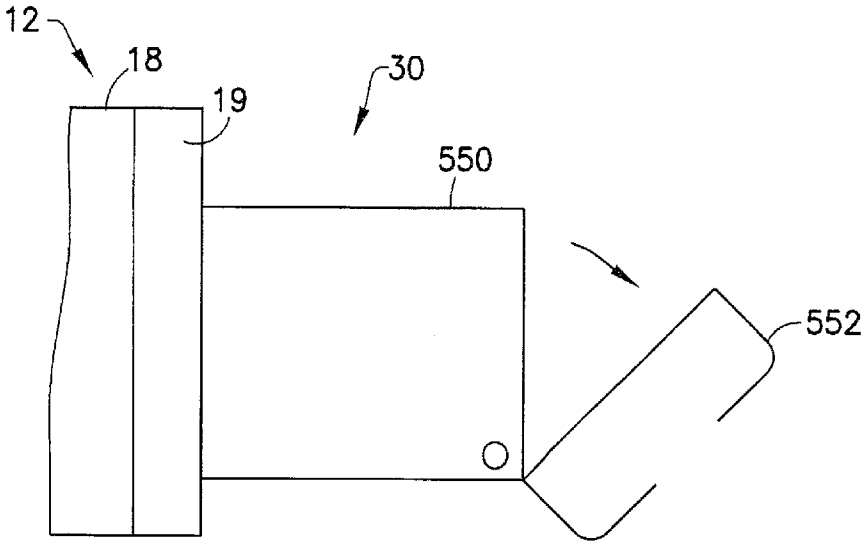

FIG.37D

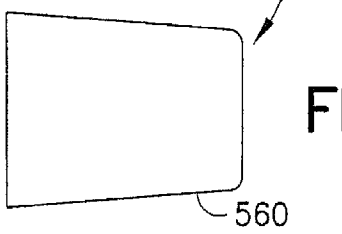

FIG.38A

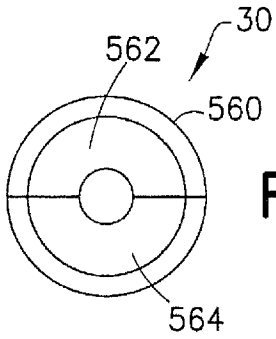

FIG.38B

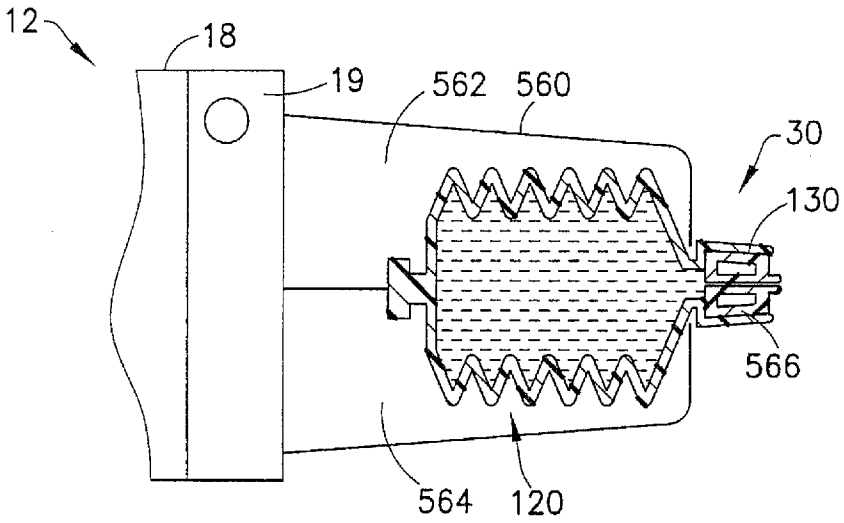

FIG.38C

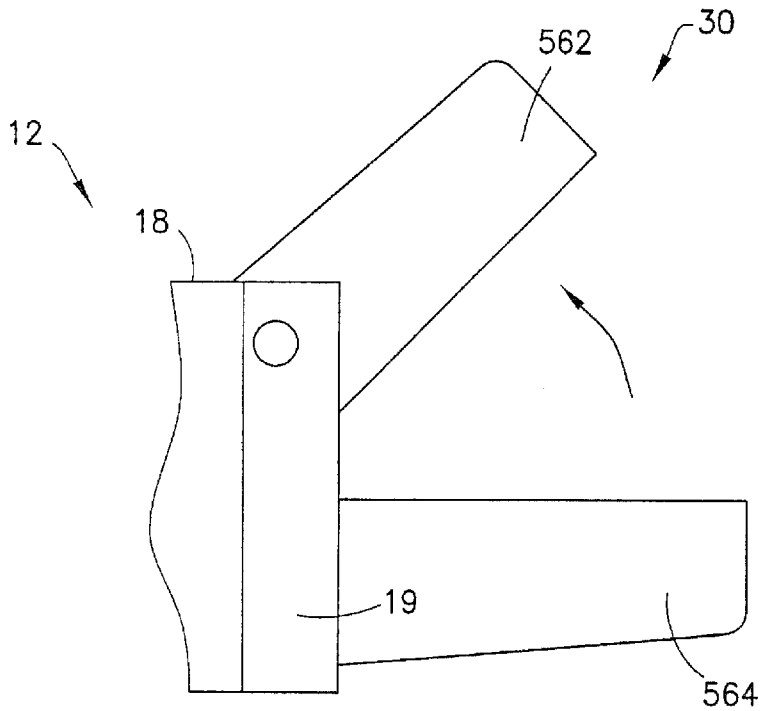

FIG.38D

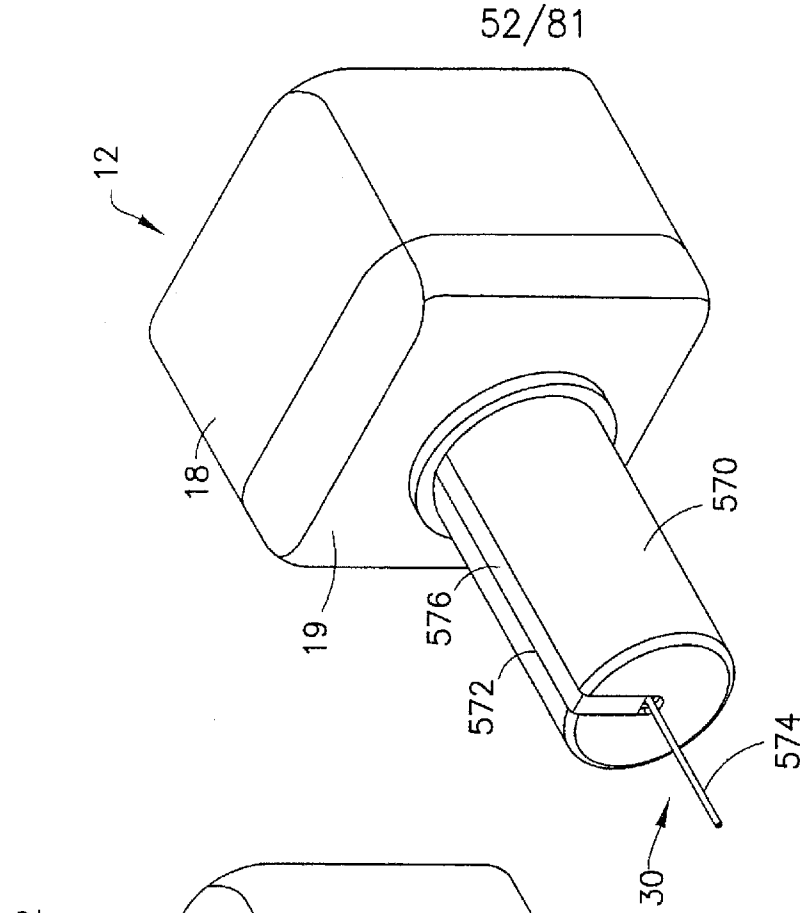

FIG.39B

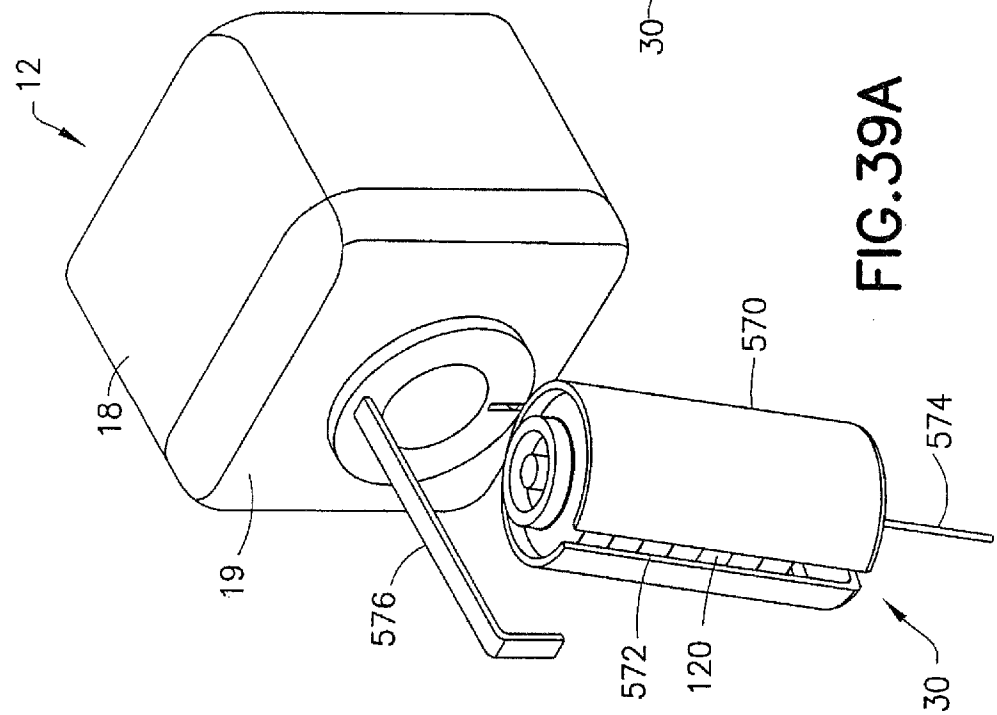

FIG.39A

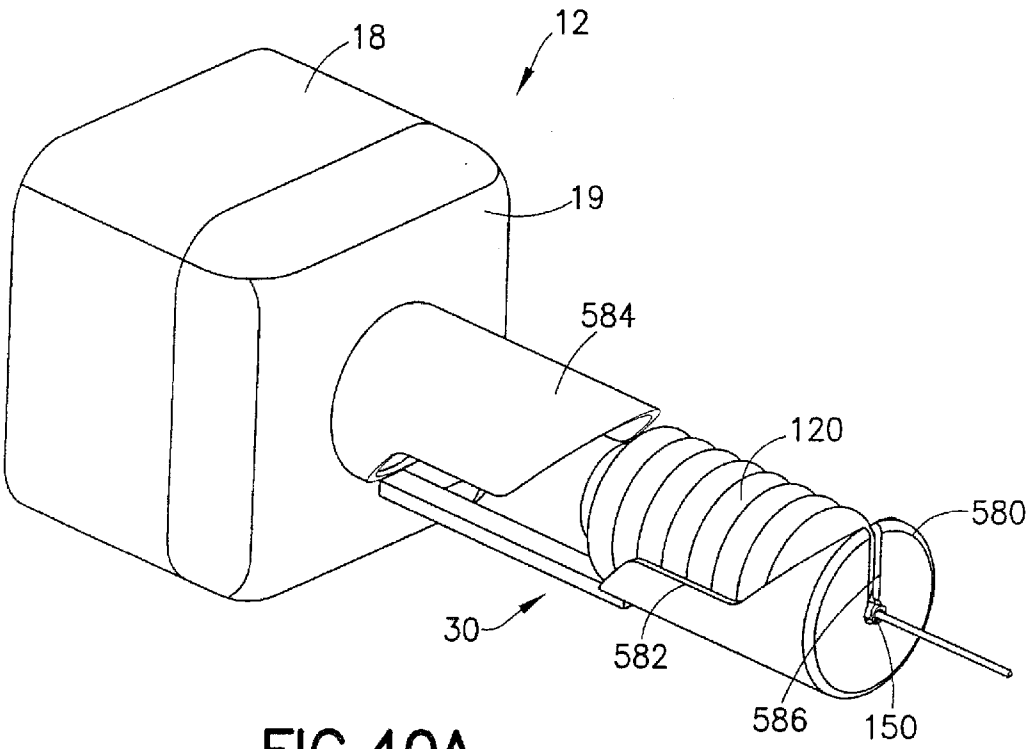

FIG.40A

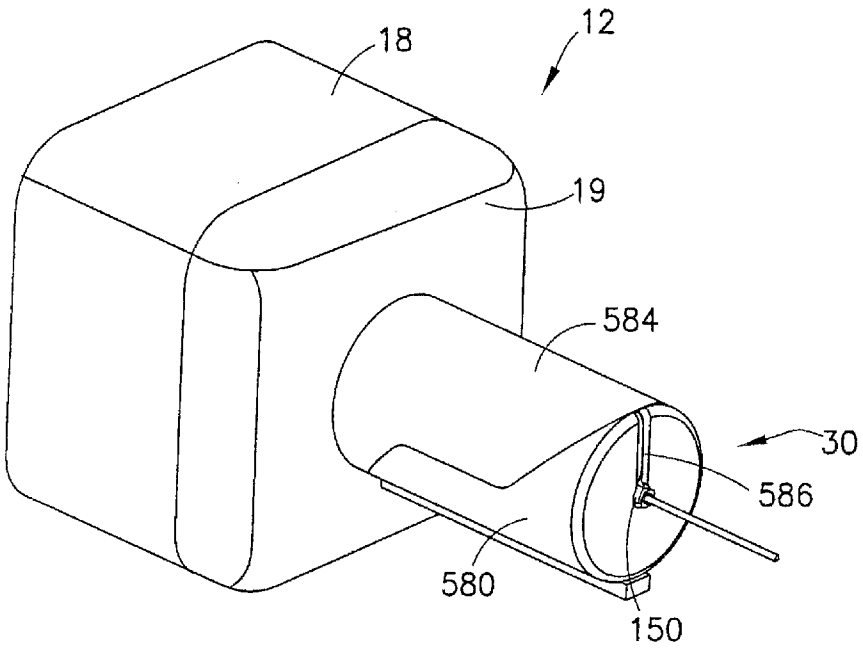

FIG.40B

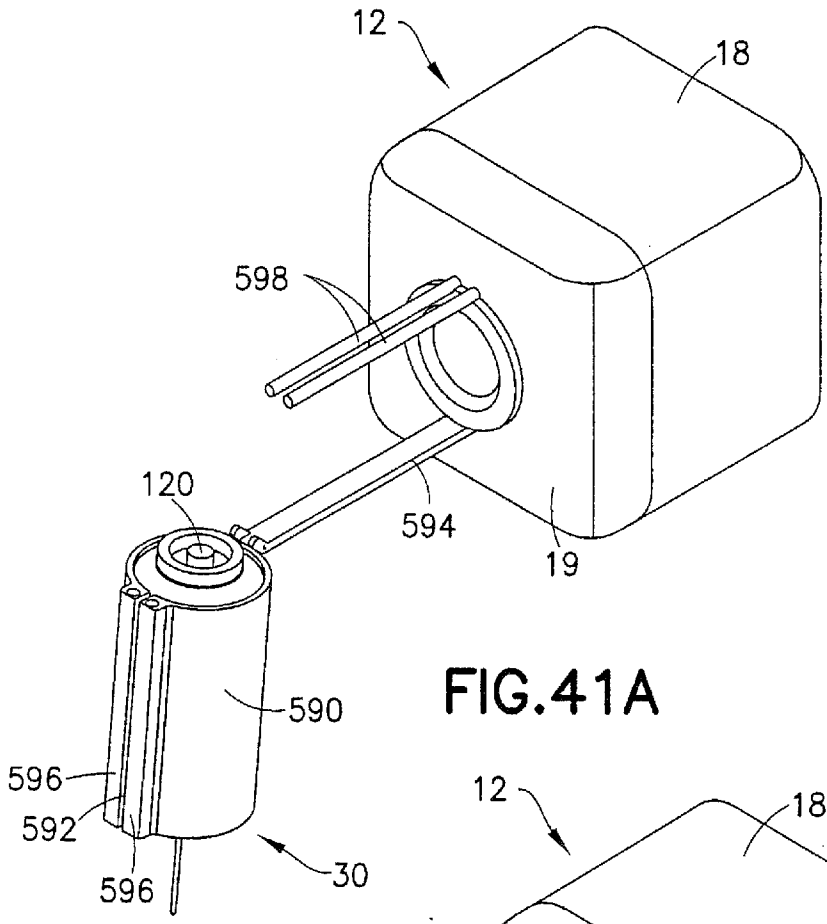

FIG.41A

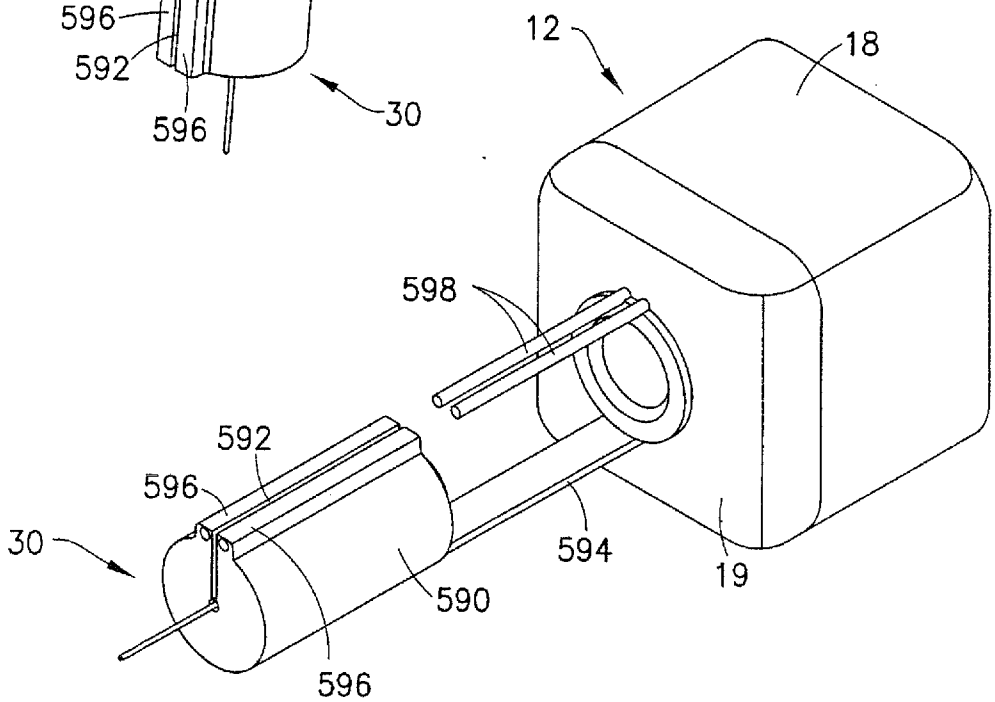

FIG.41B

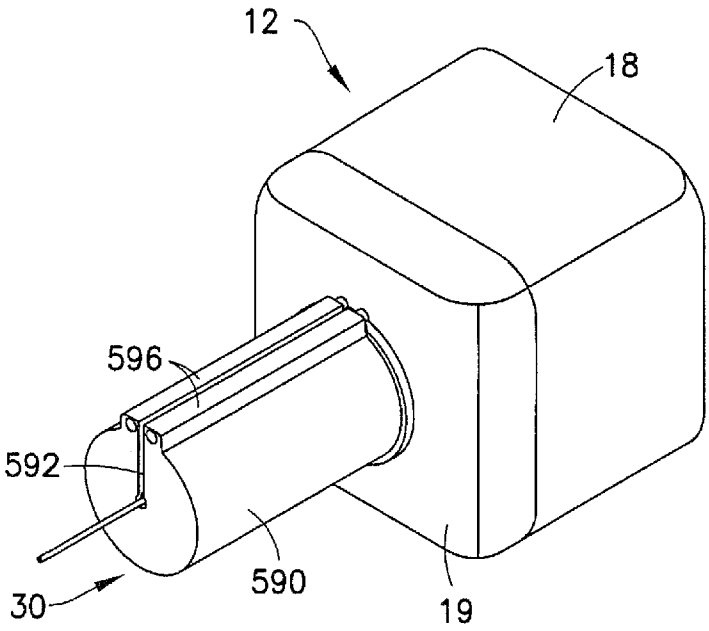

FIG.41C

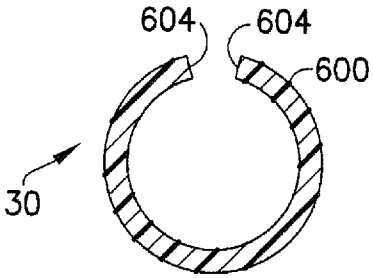

FIG.42B

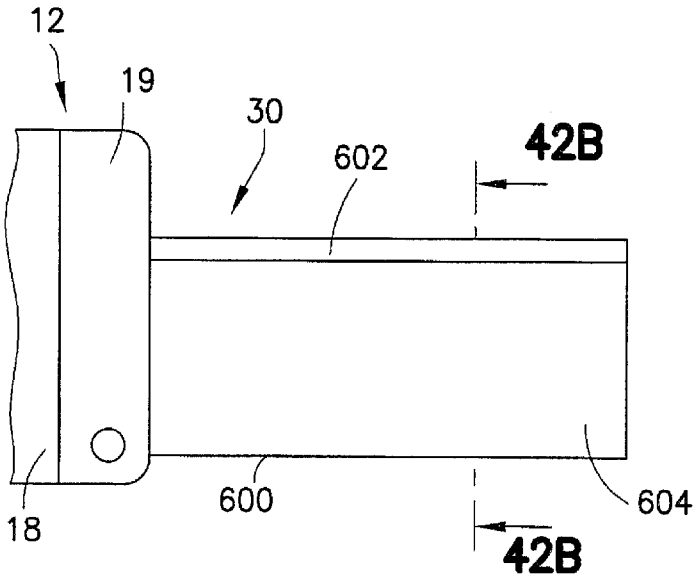

FIG42A

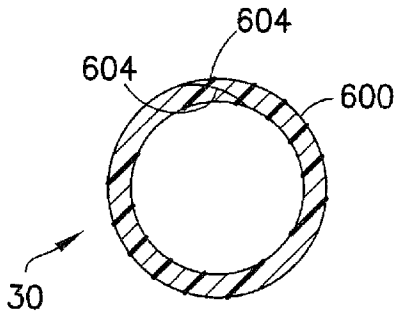

FIG.42C

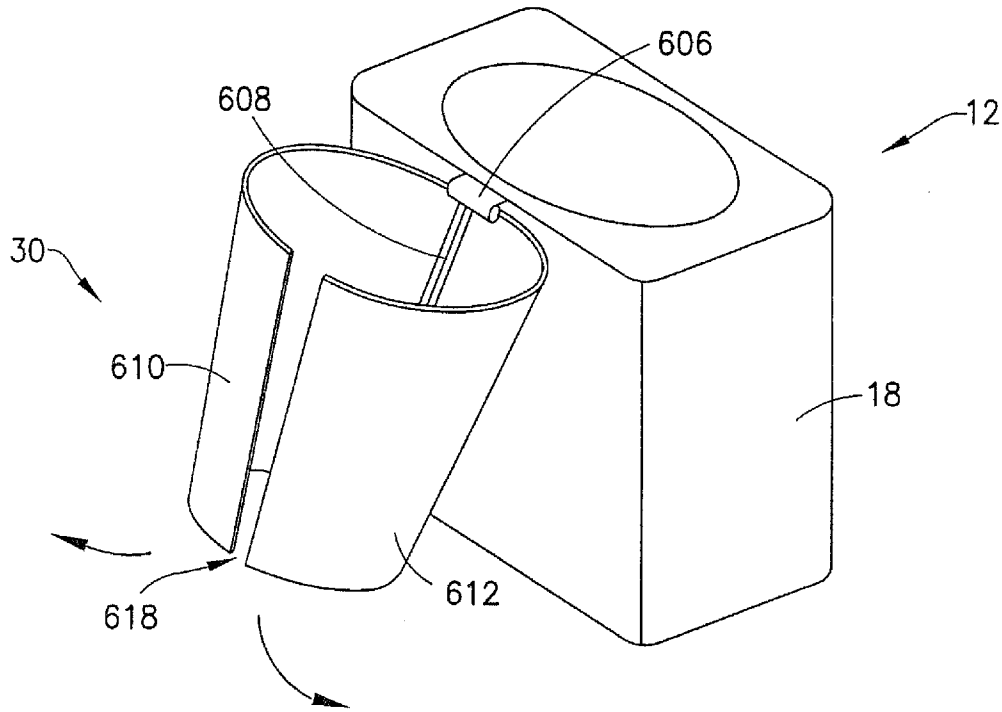

FIG.43A

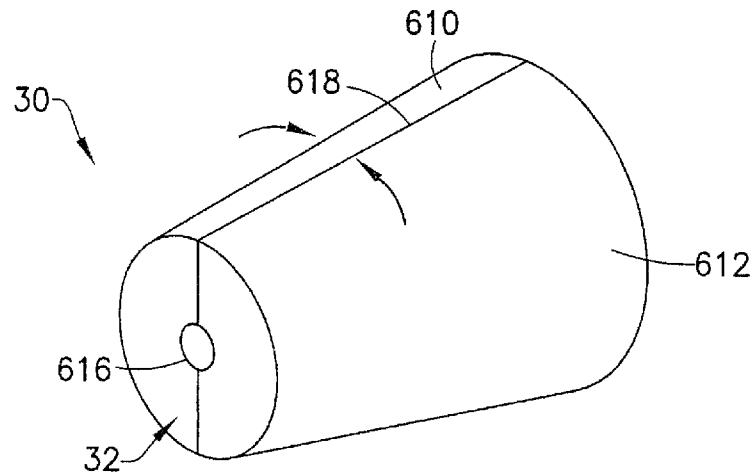

FIG.43B

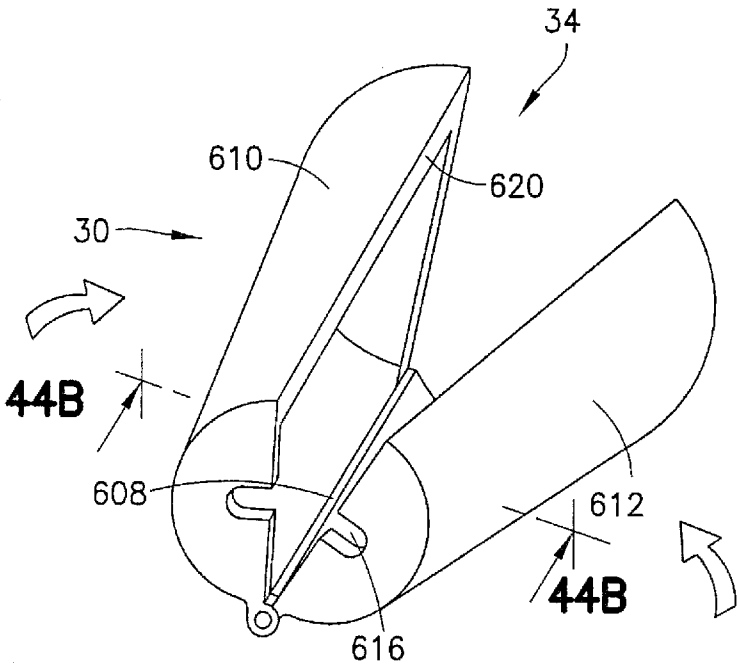

FIG.44A

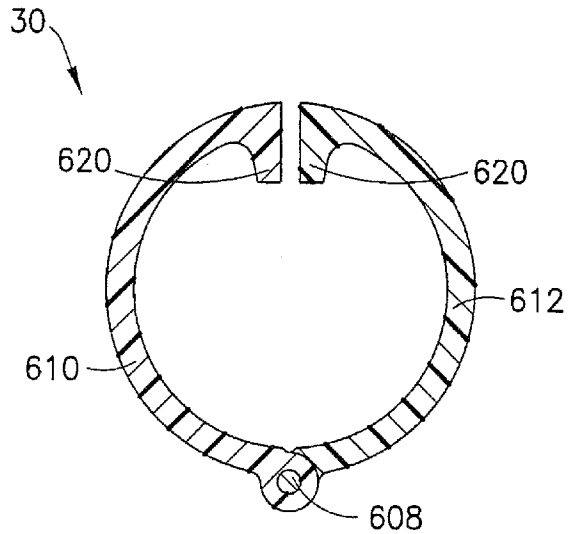

FIG.44B

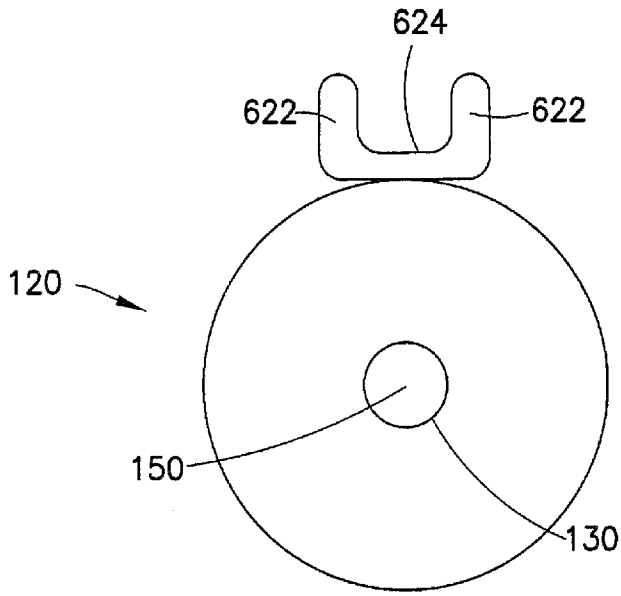

FIG.44C

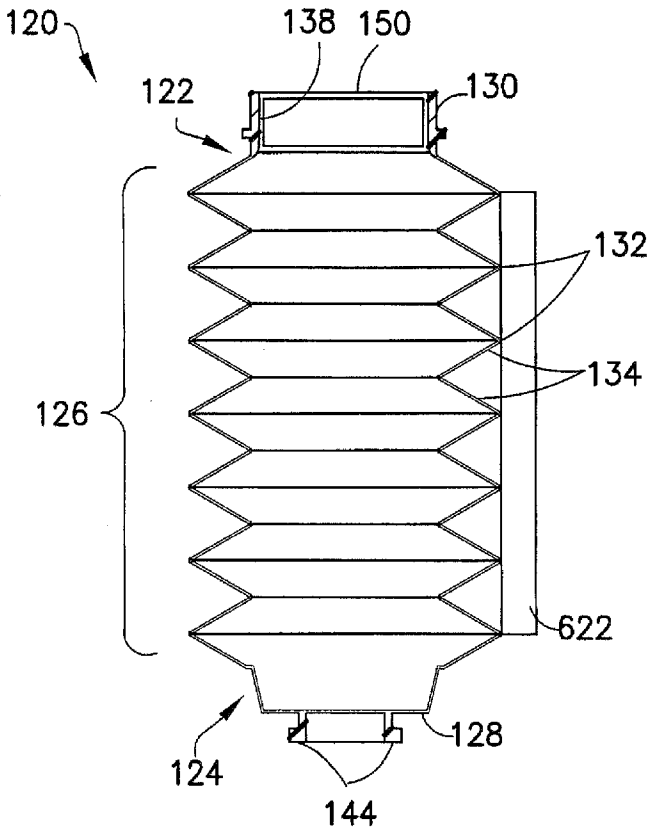

FIG.44D

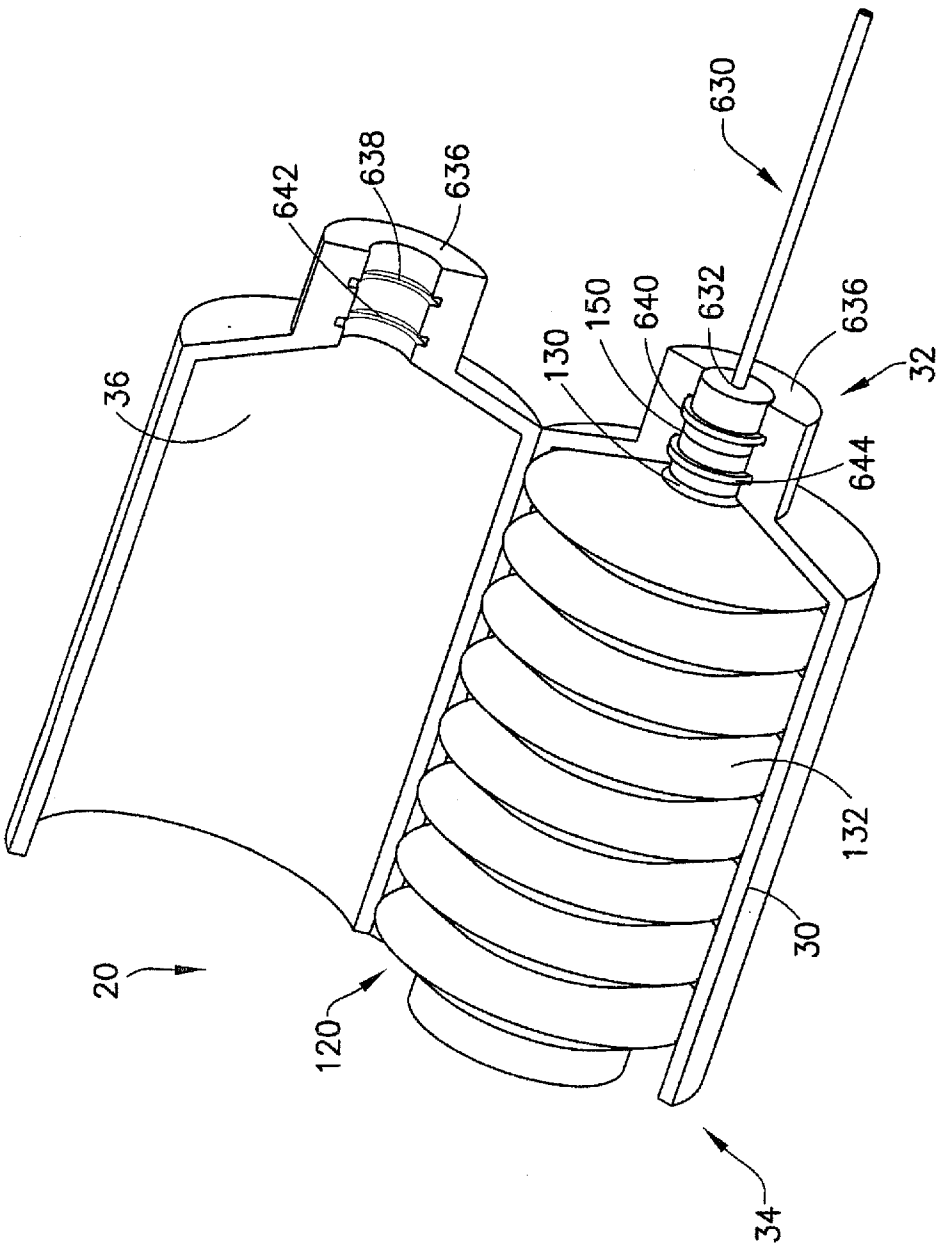

FIG.45

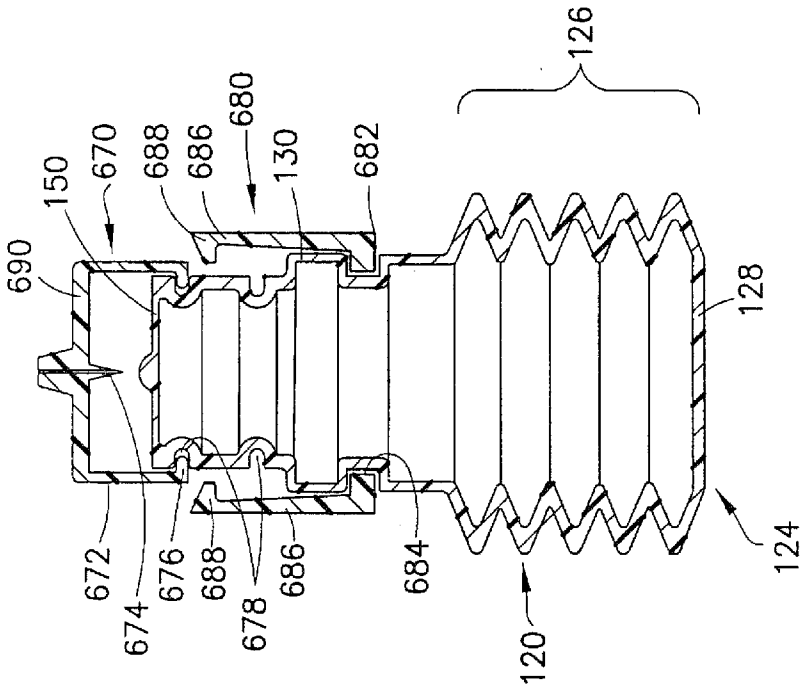
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FIG.47

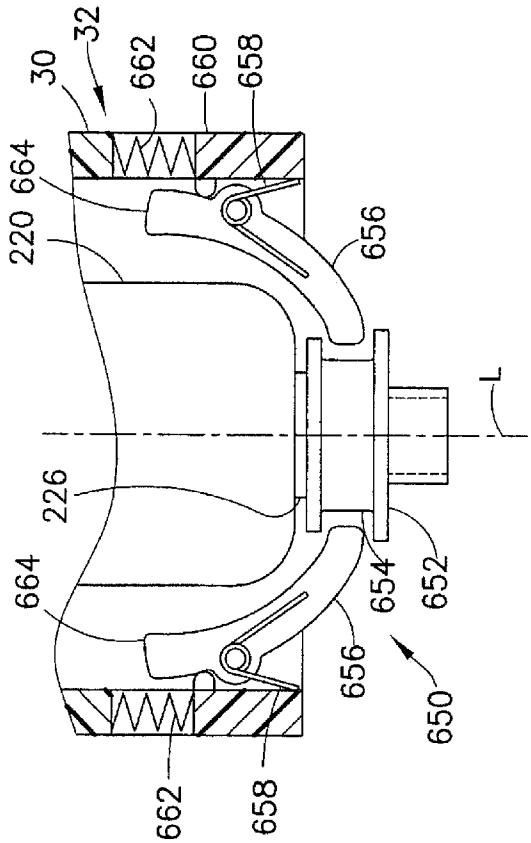
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FIG.46

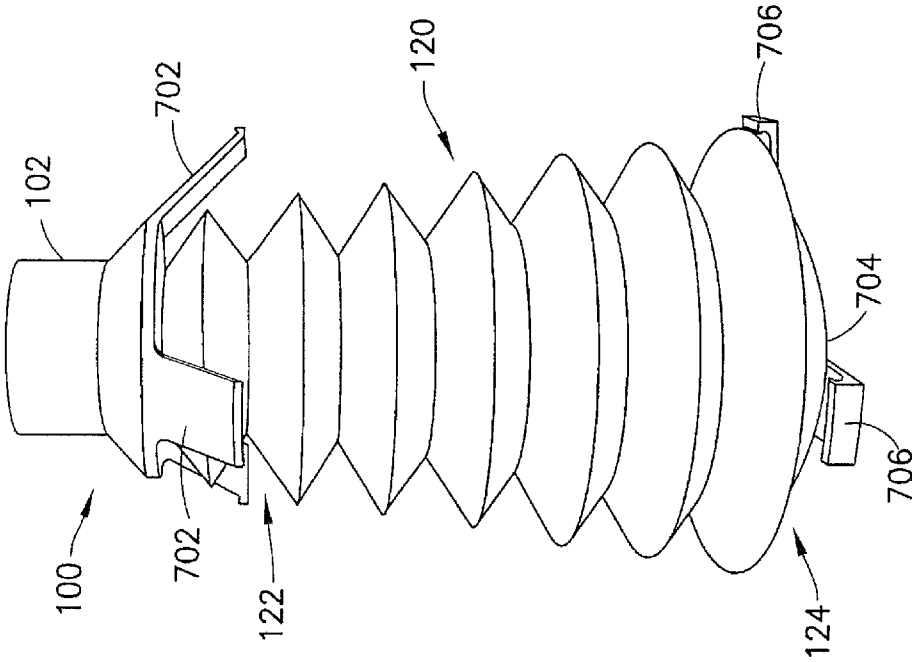

FIG.48B

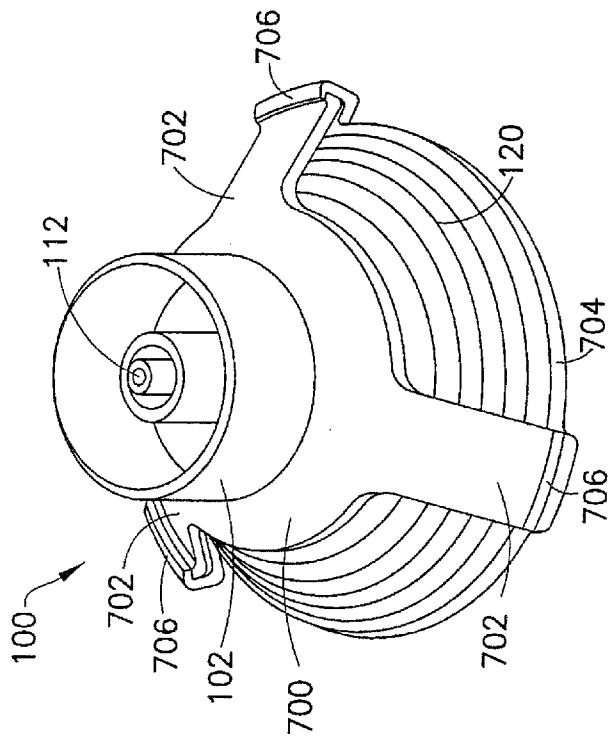

FIG.48A

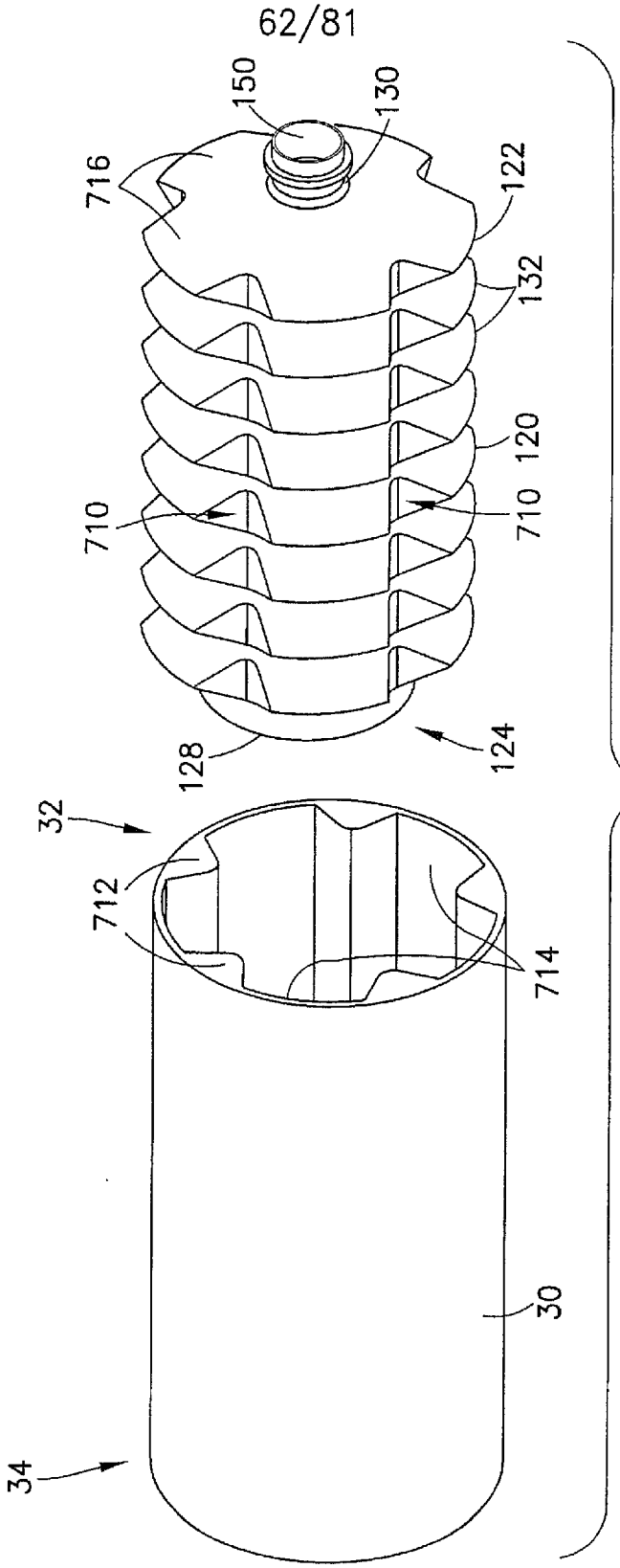

FIG.49A

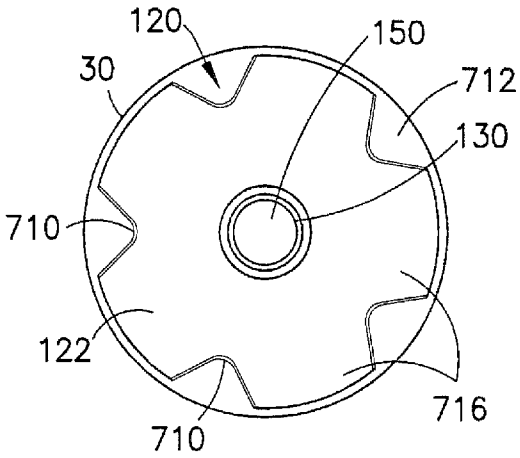

FIG.49B

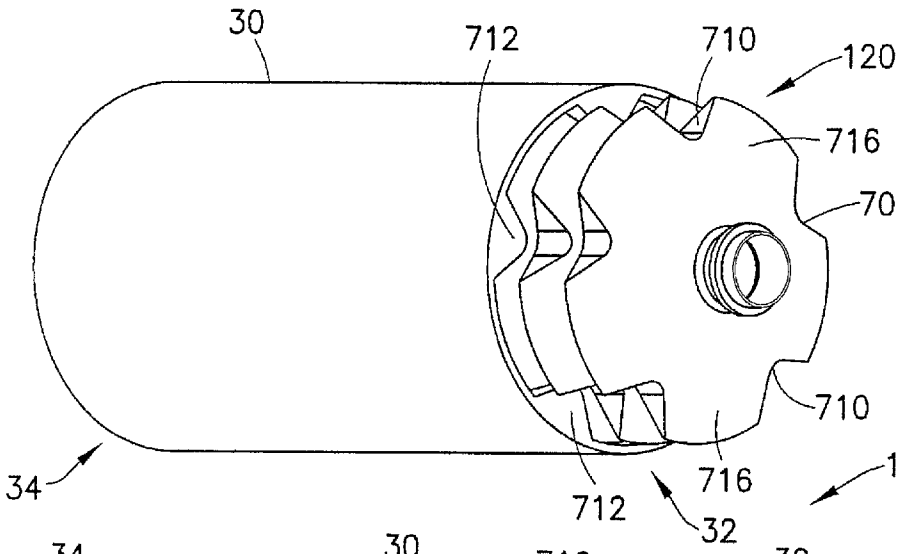

FIG.49C

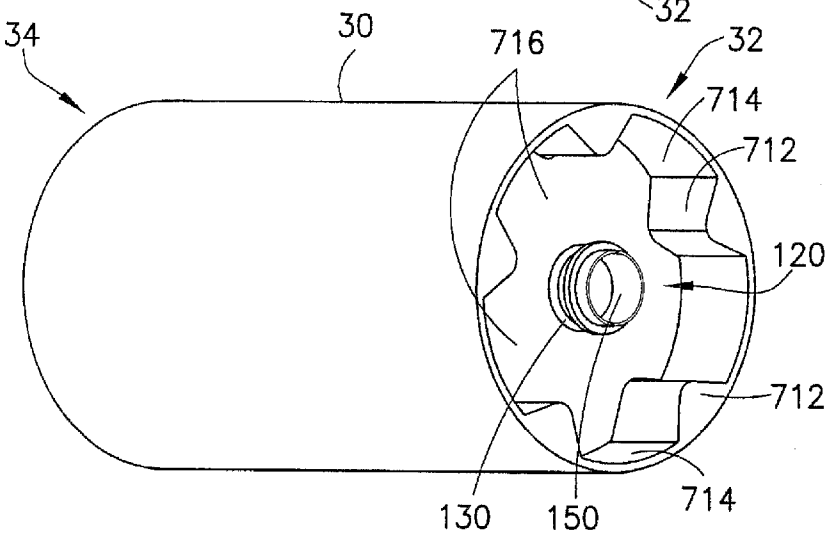

FIG.49D

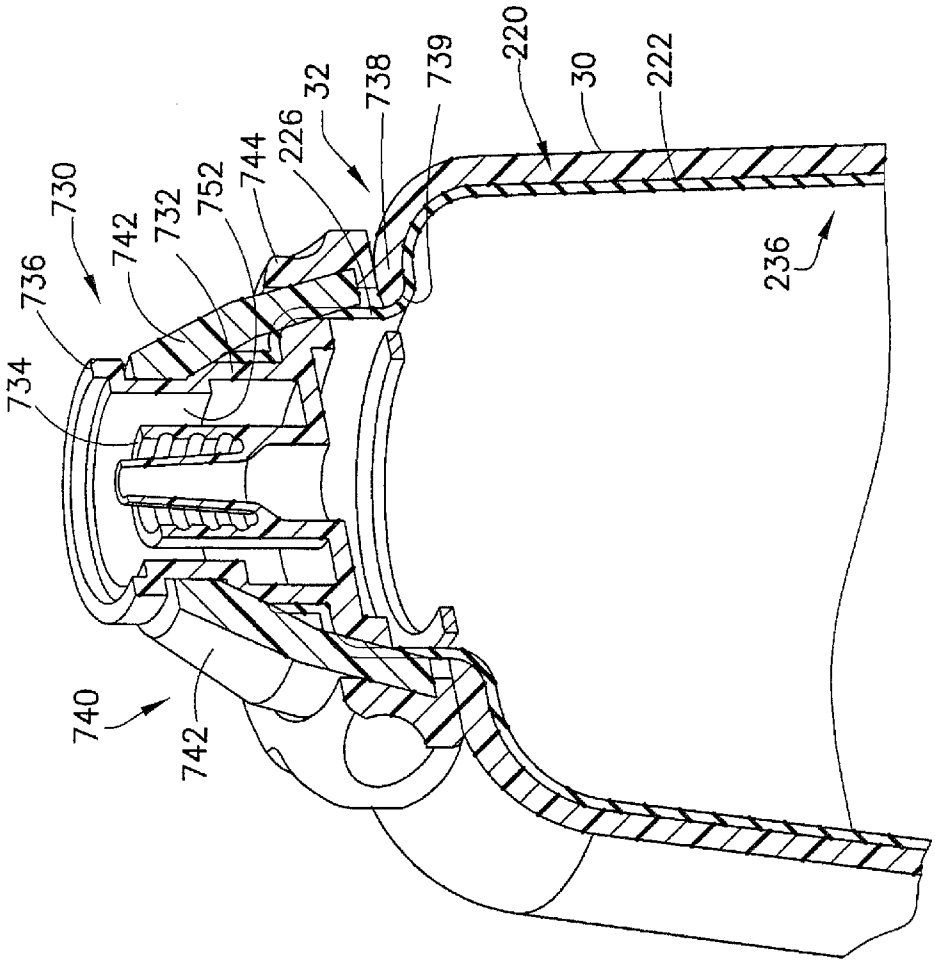

FIG.51A

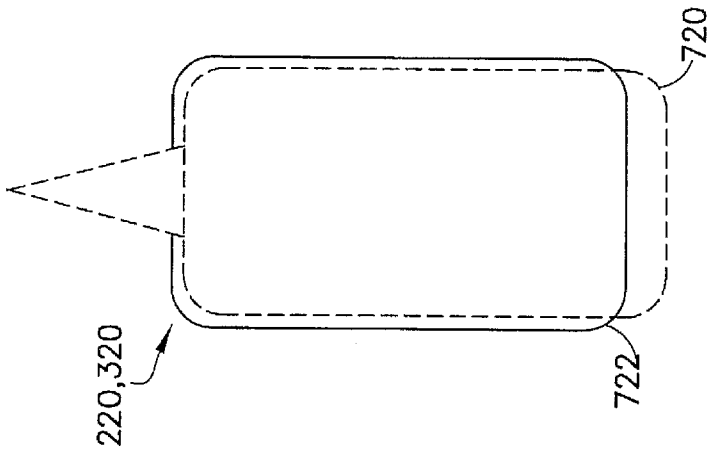

FIG.50

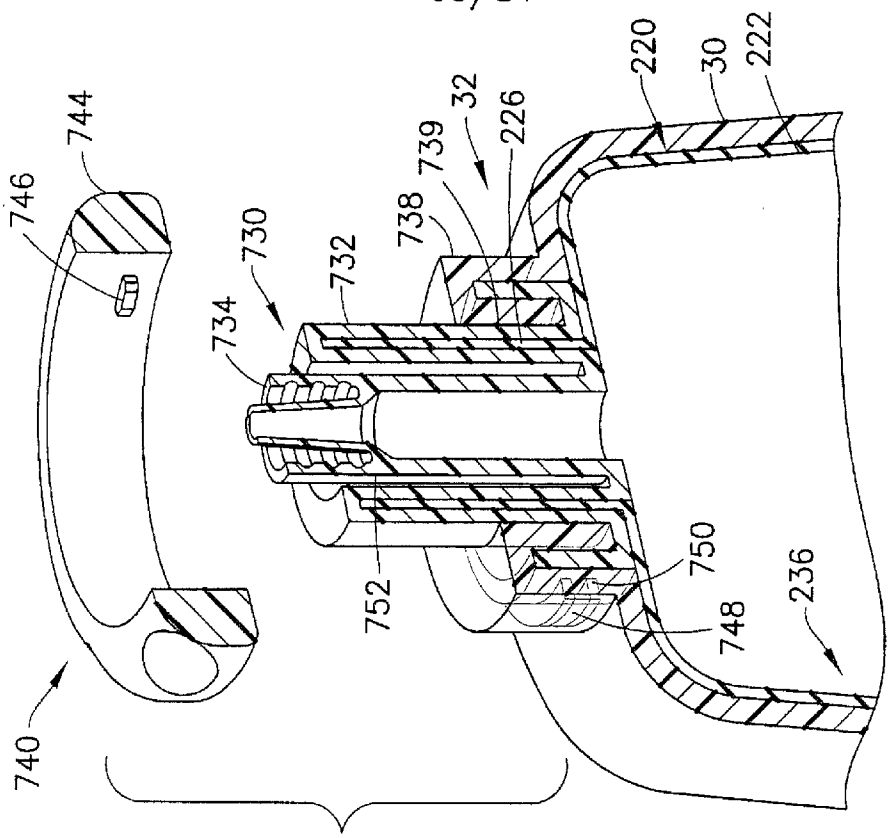

FIG.51C

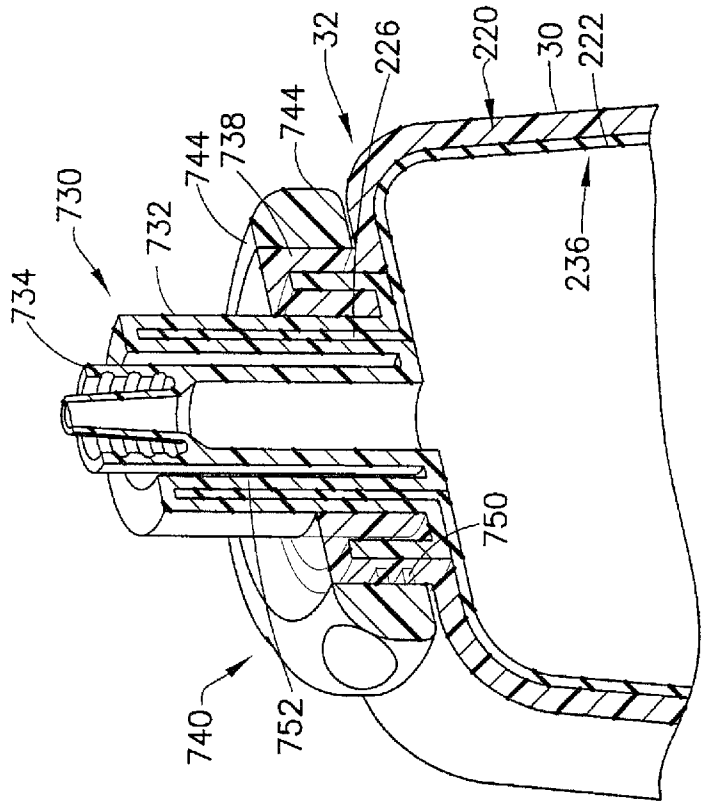

FIG.51B

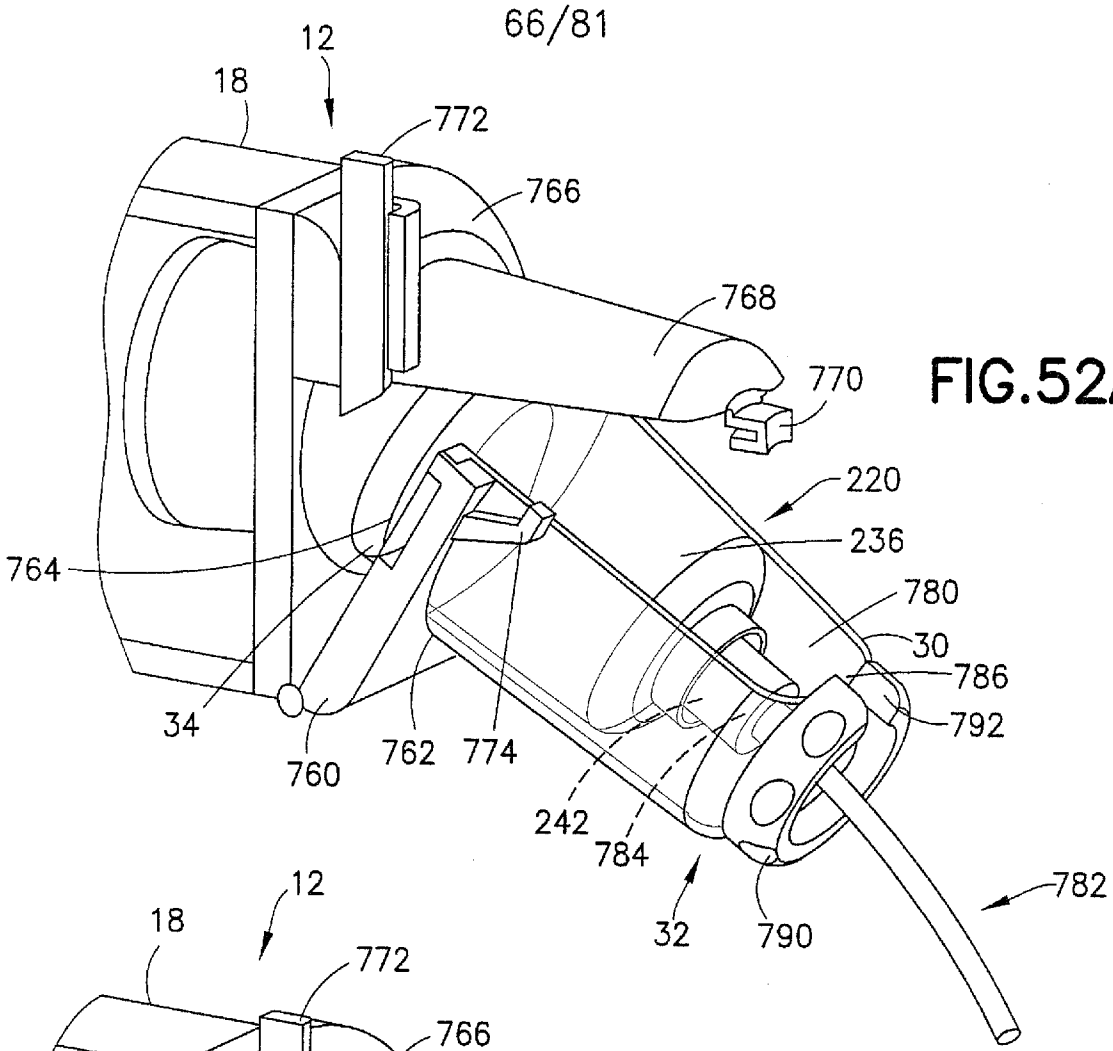

FIG.52A

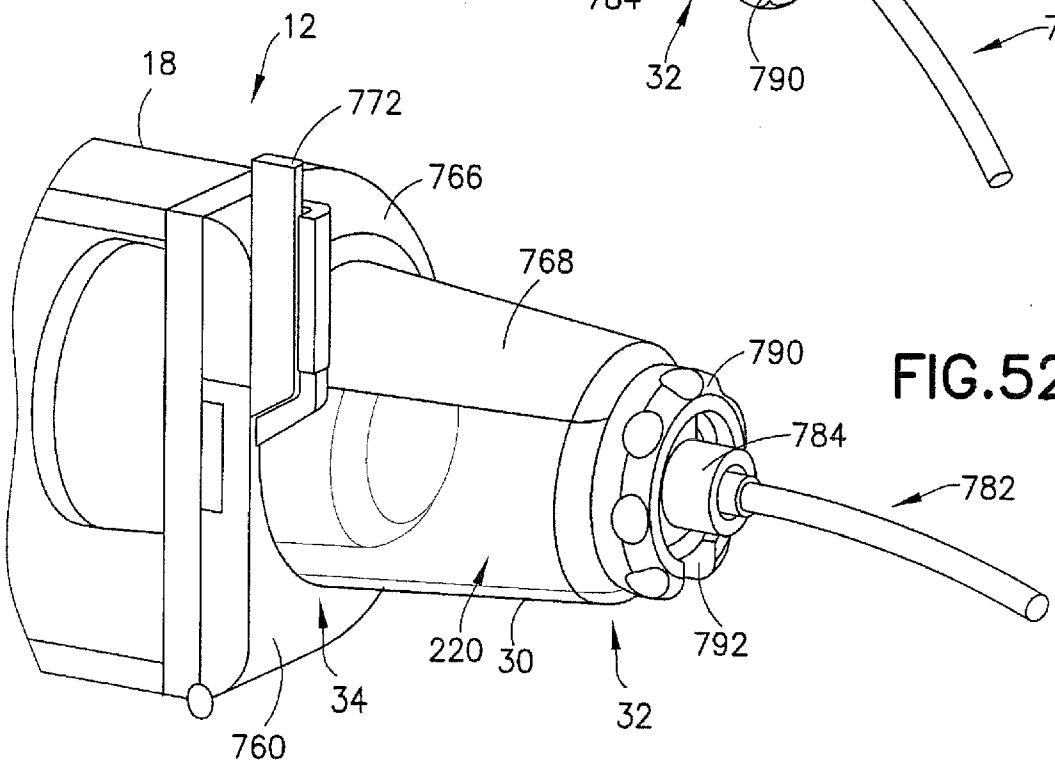

FIG.52B

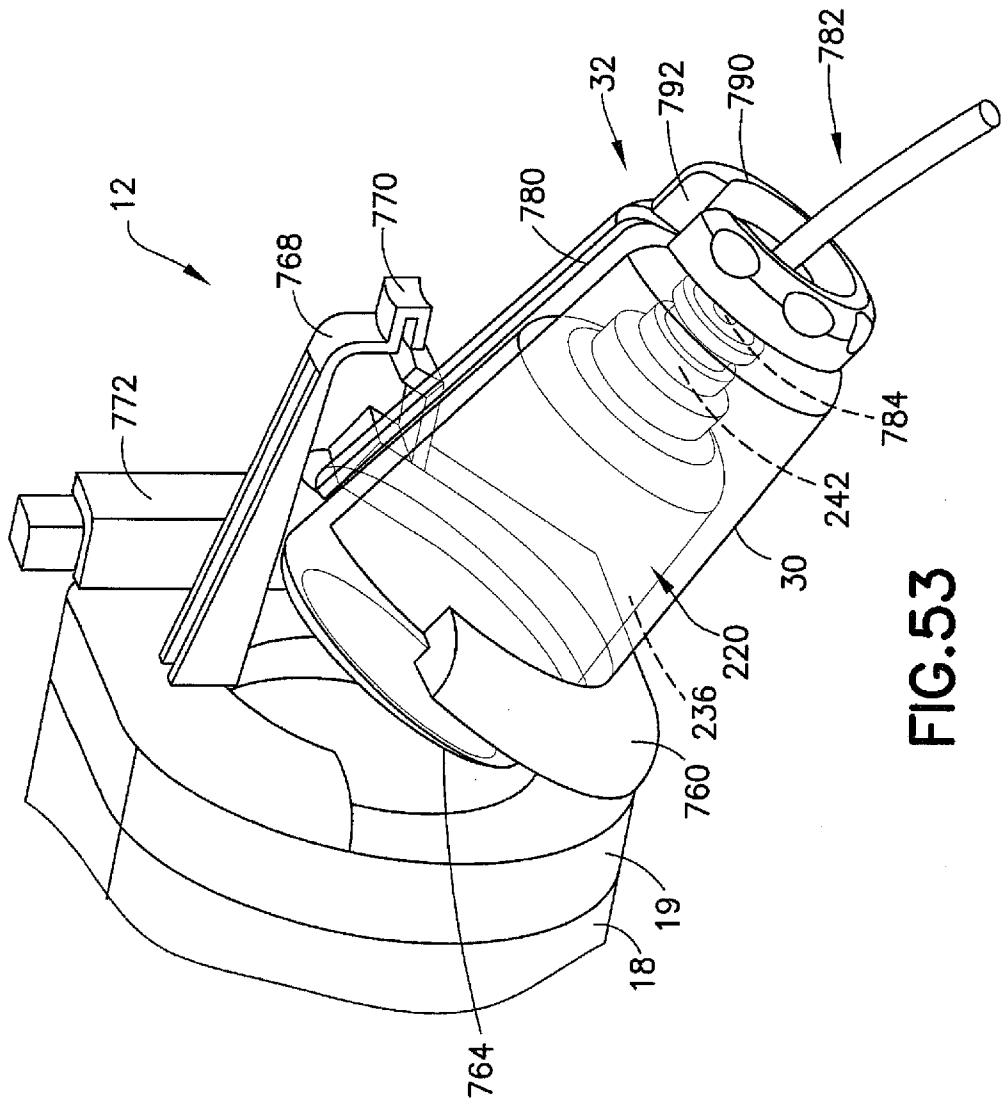

FIG.53

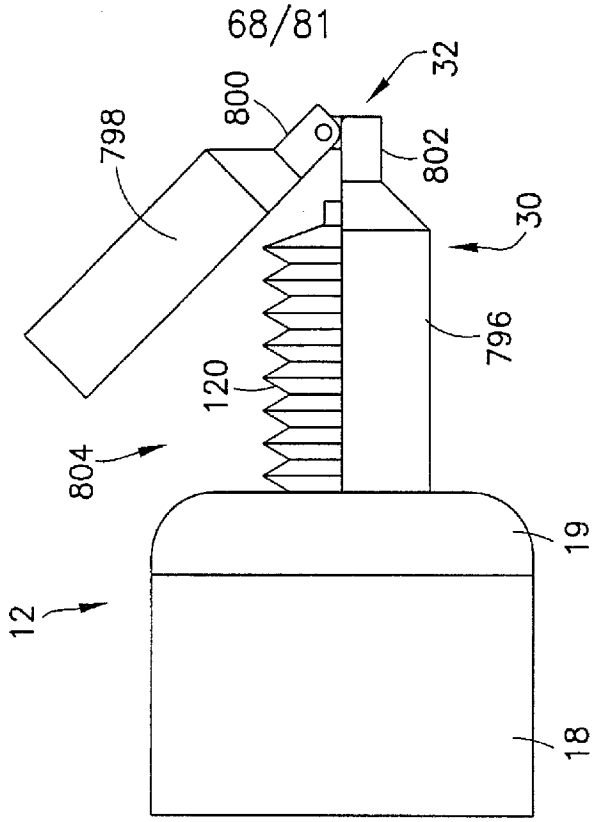

FIG.54B

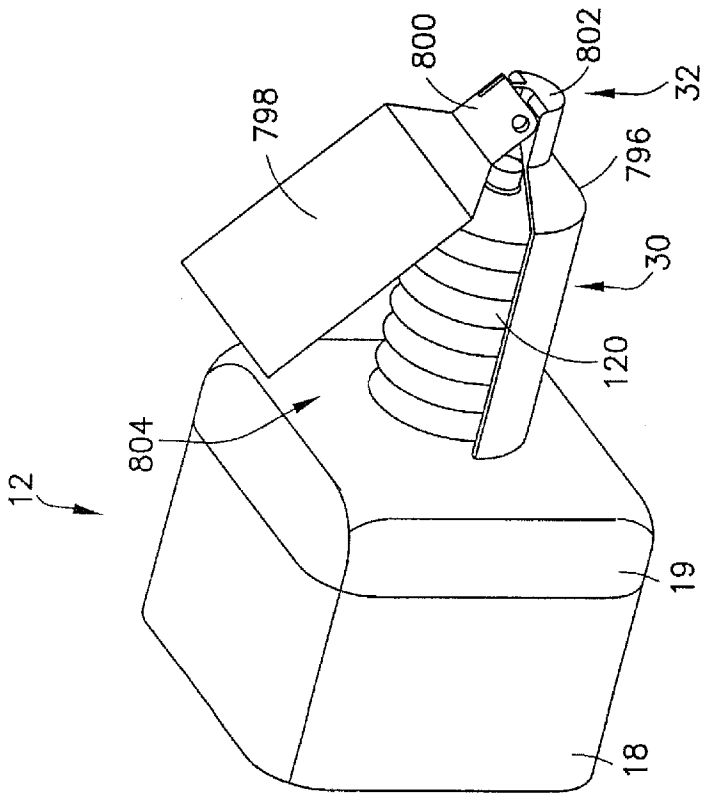

FIG.54A

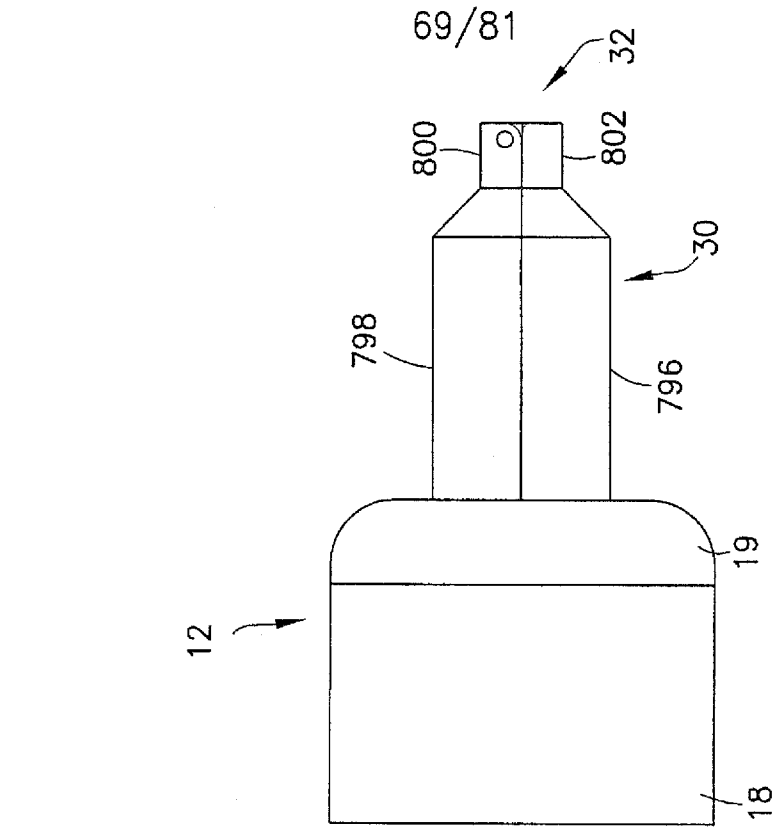

FIG.54D

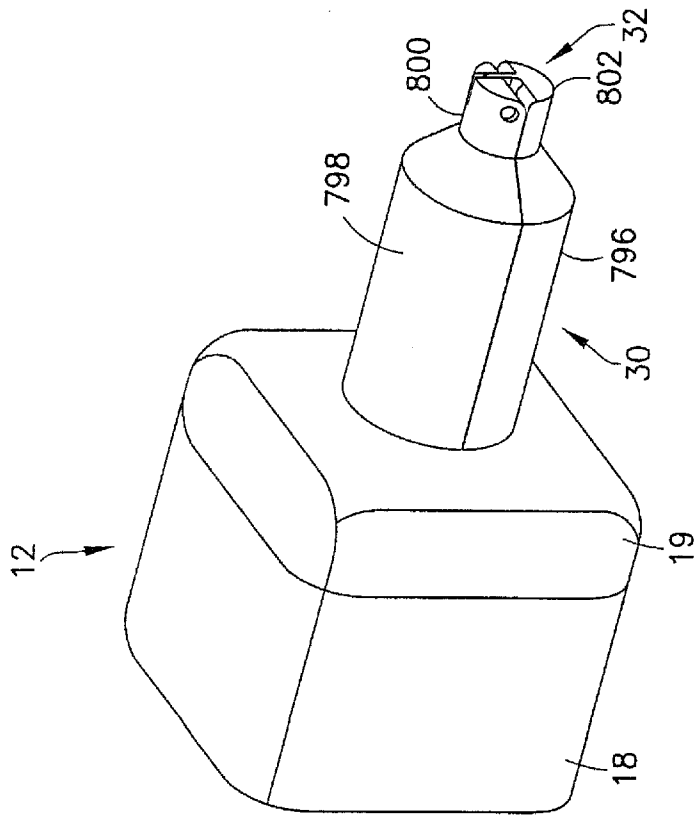

FIG.54C

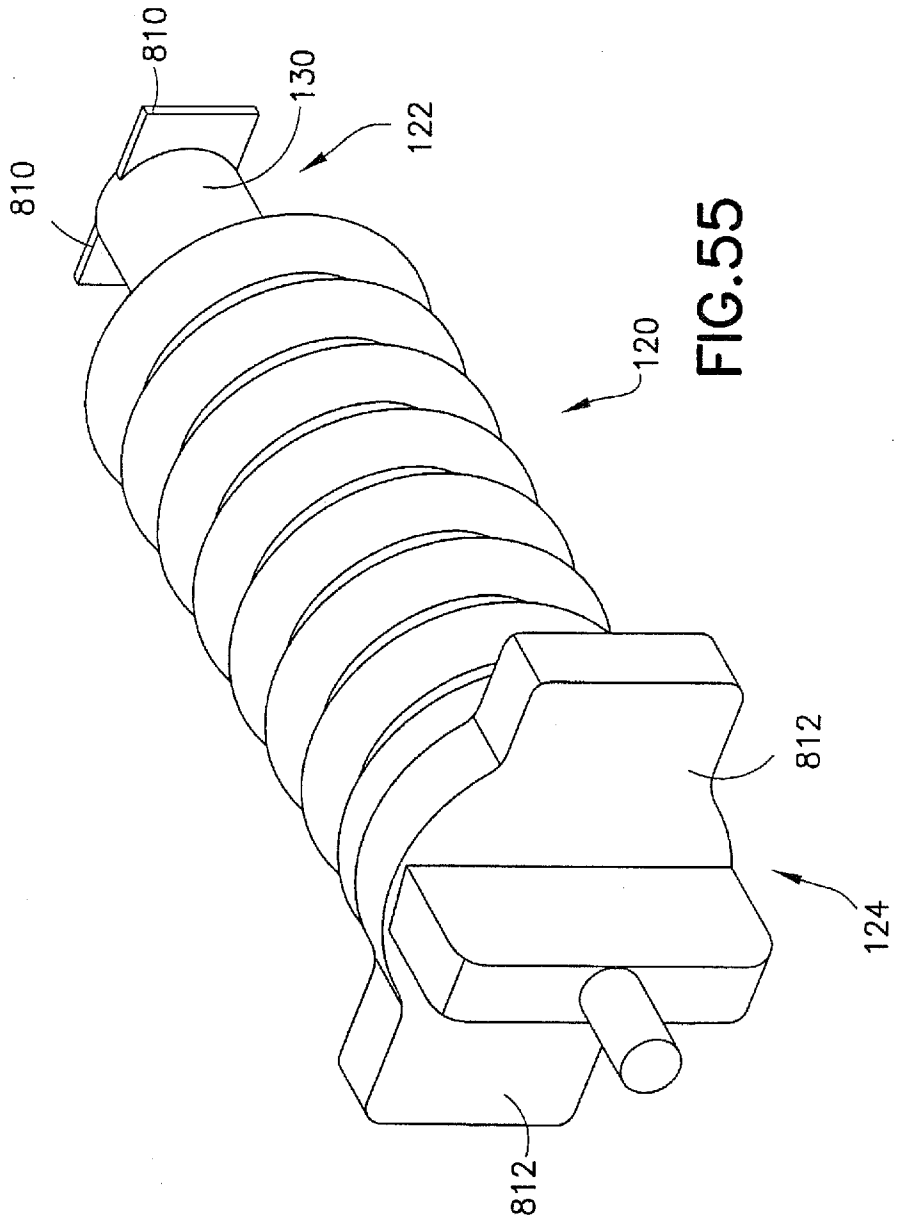

FIG.55

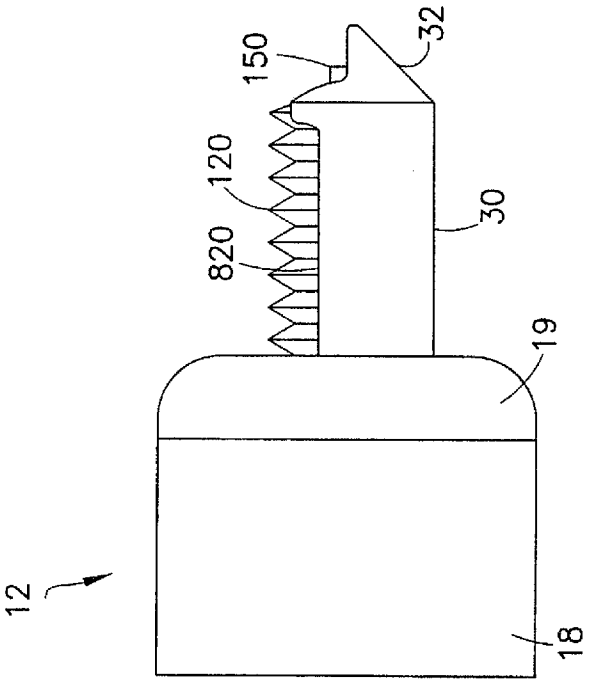

FIG.56B

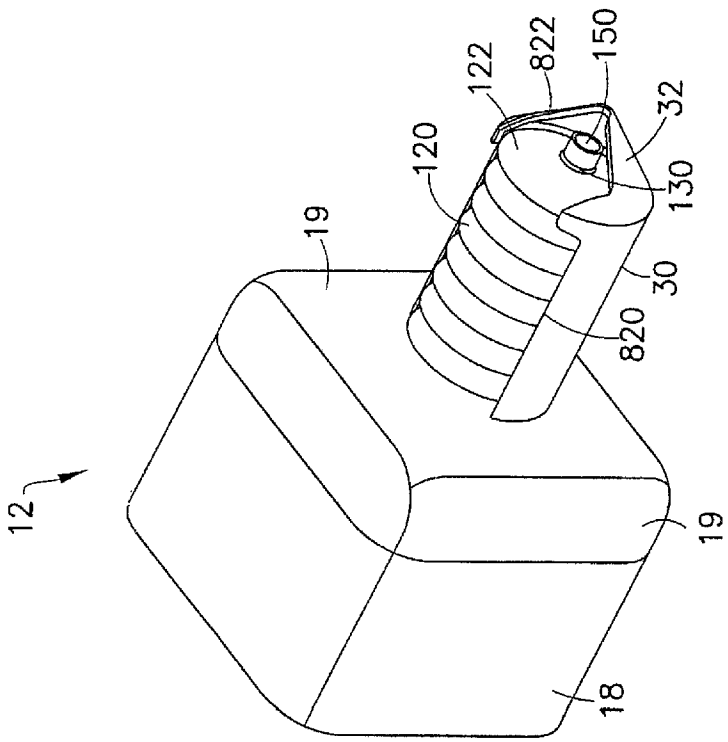

FIG.56A

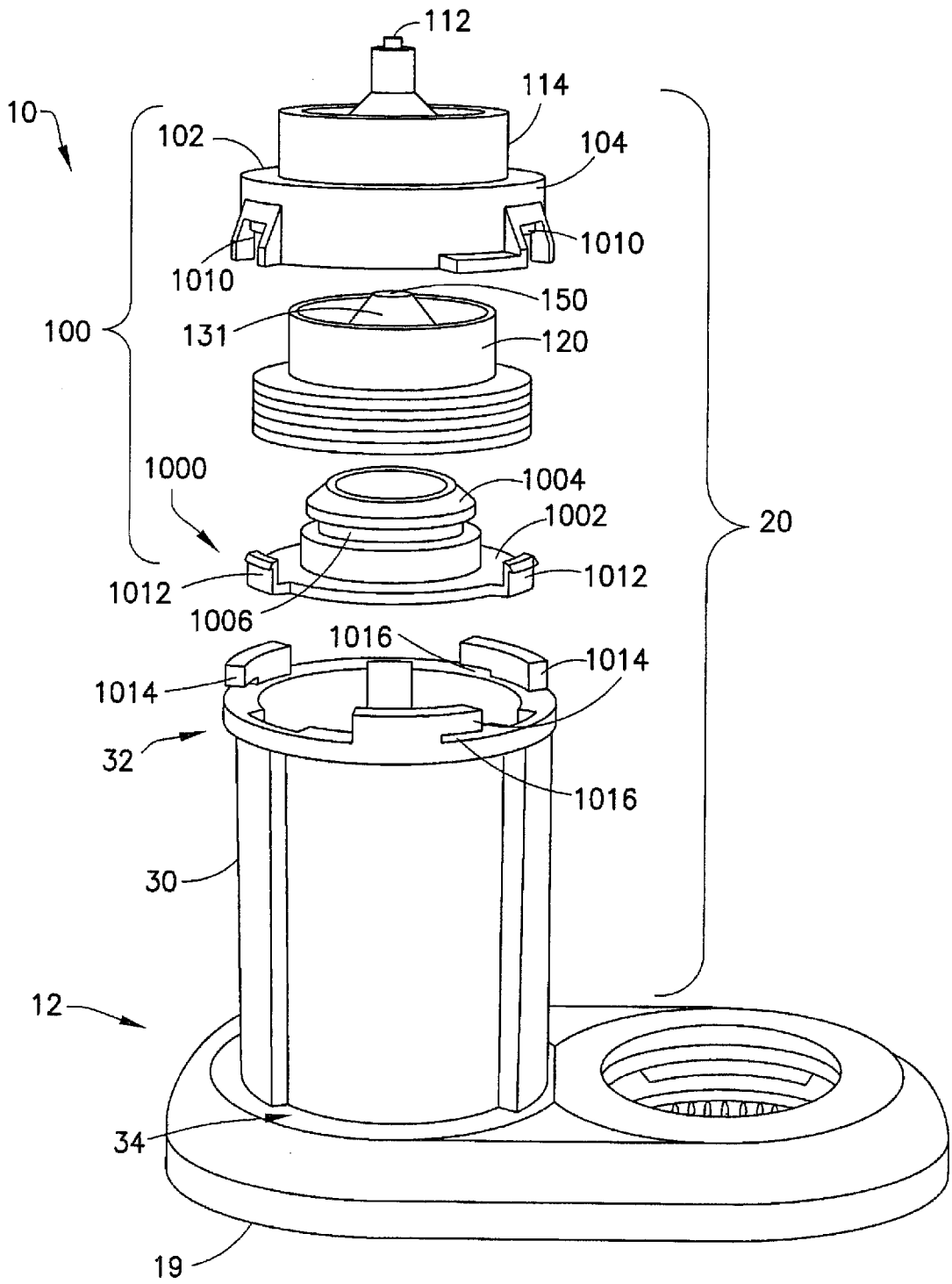
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FIG.57

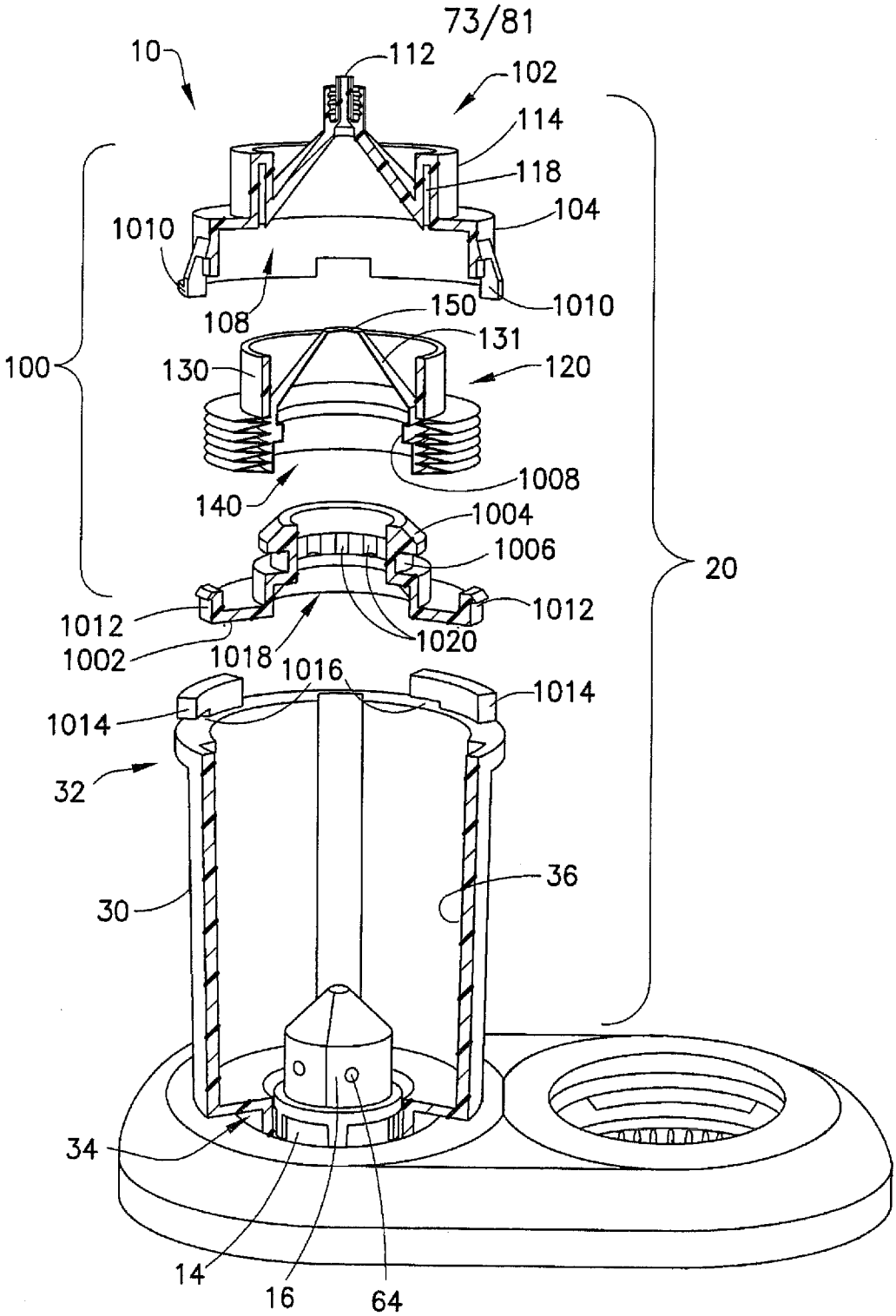
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FIG.58

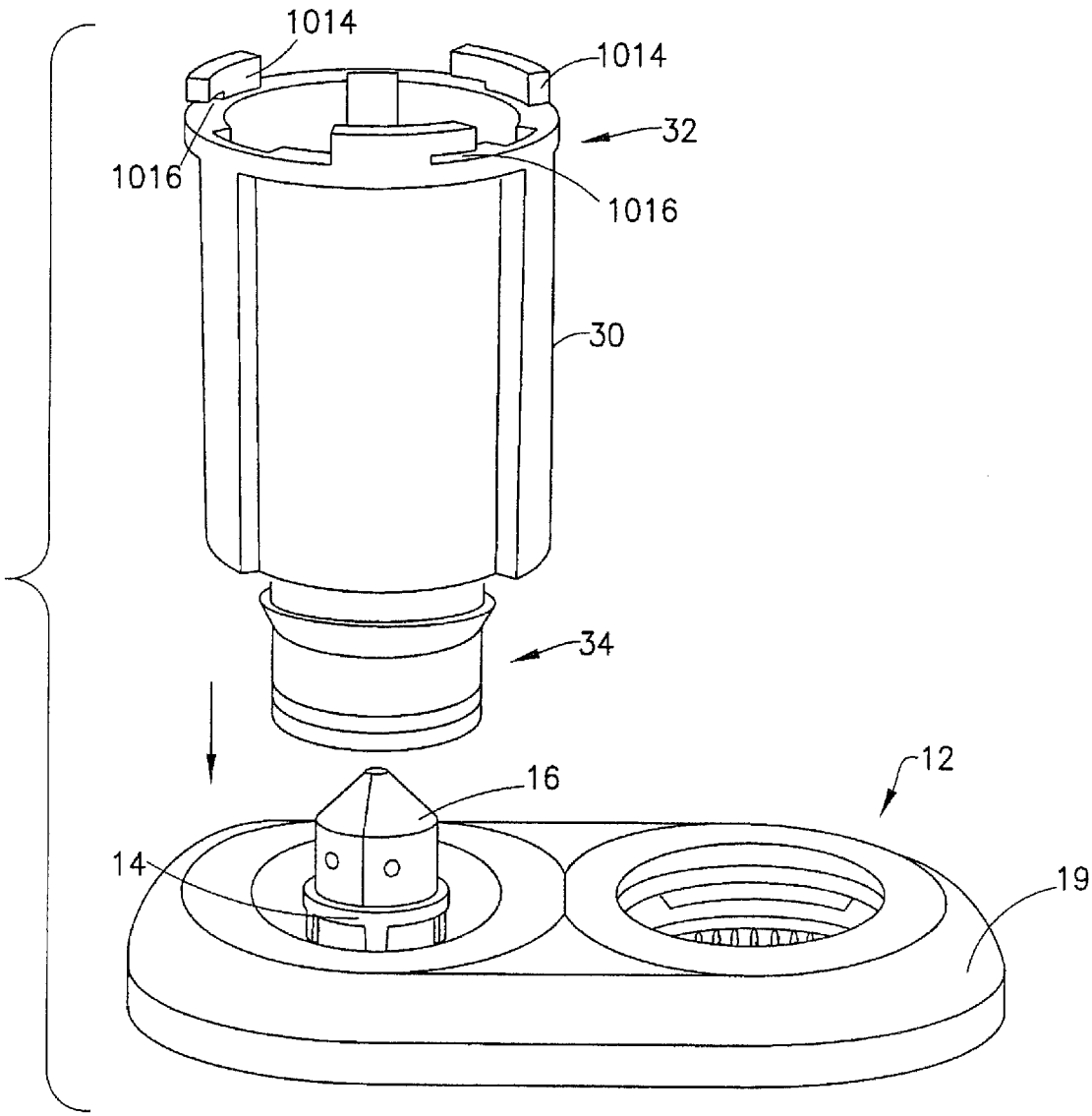

FIG.59

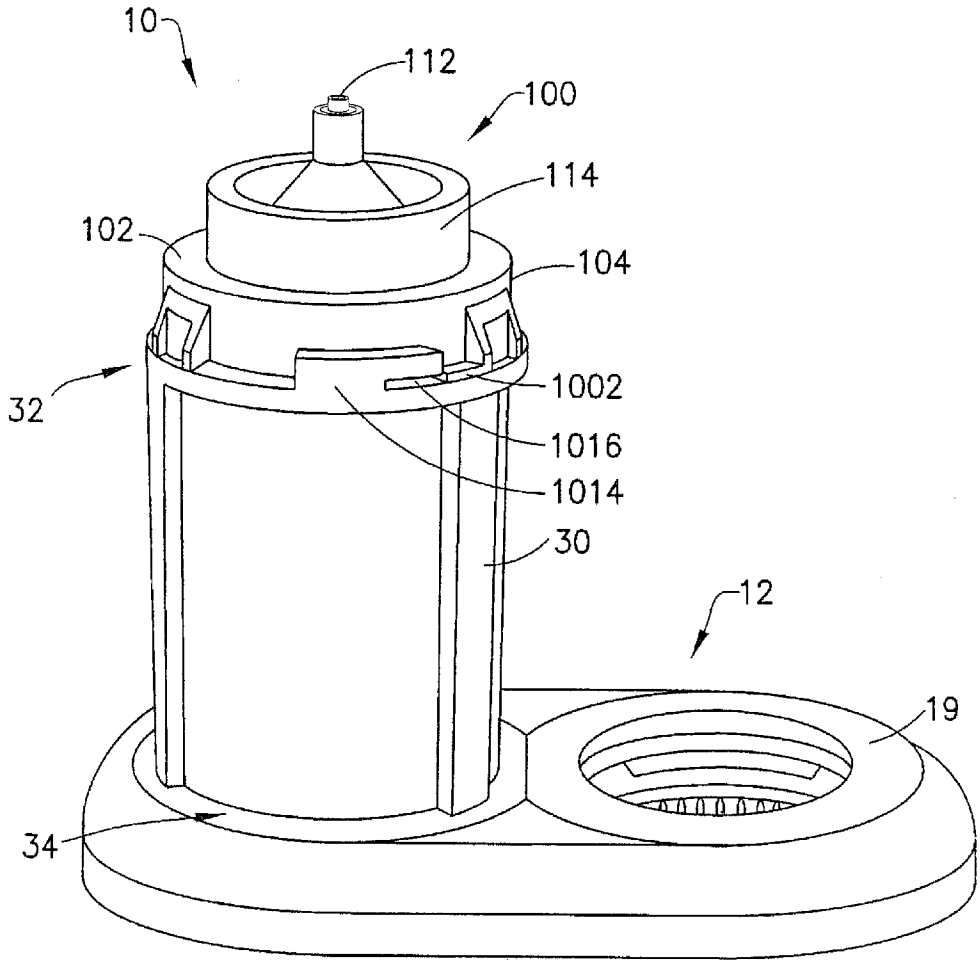

FIG.60

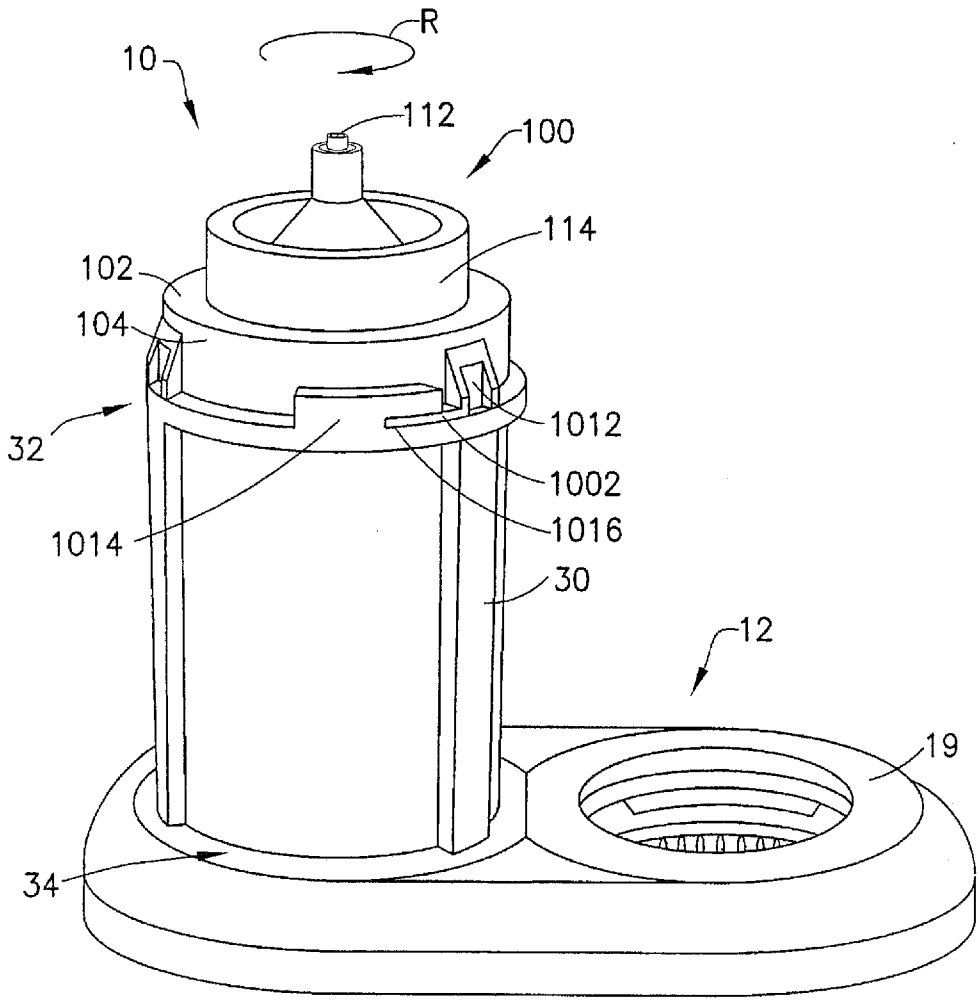

FIG.61

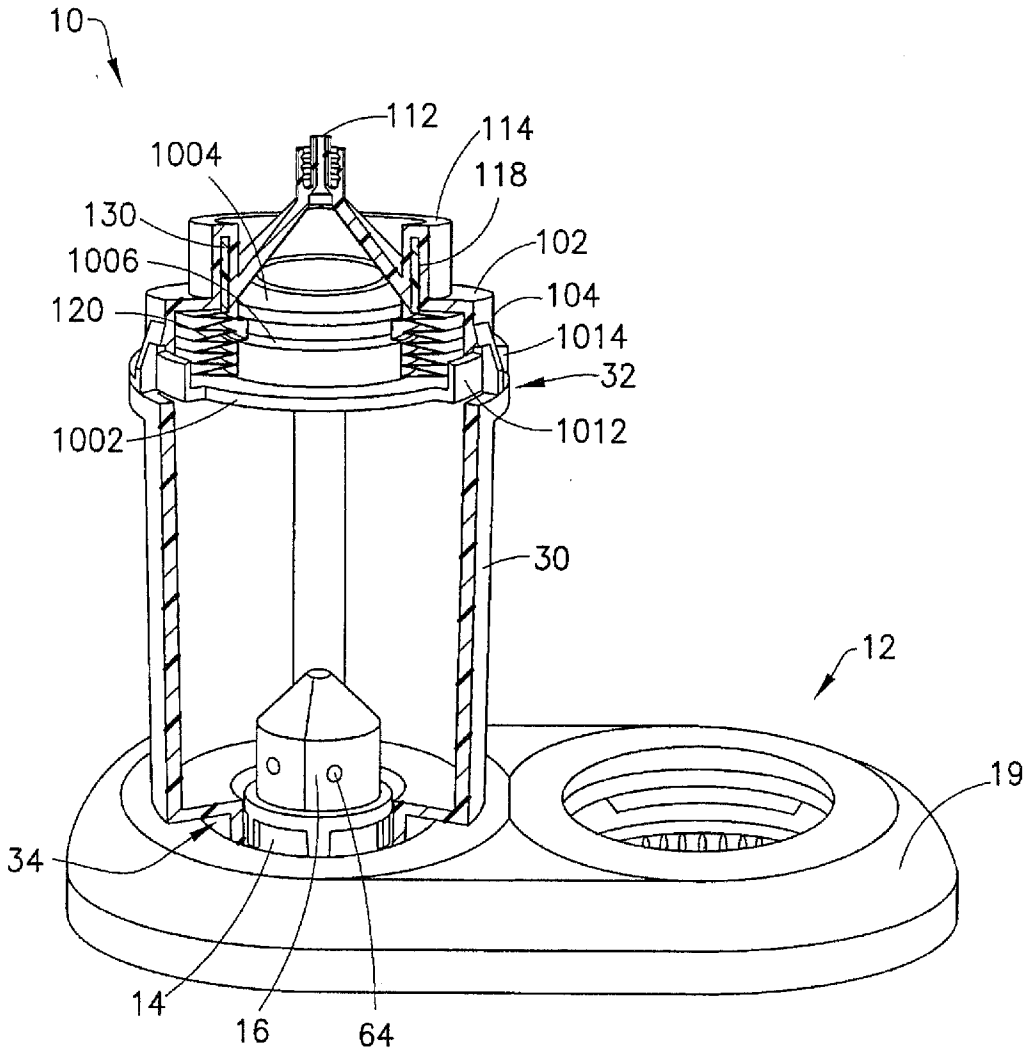
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FIG.62

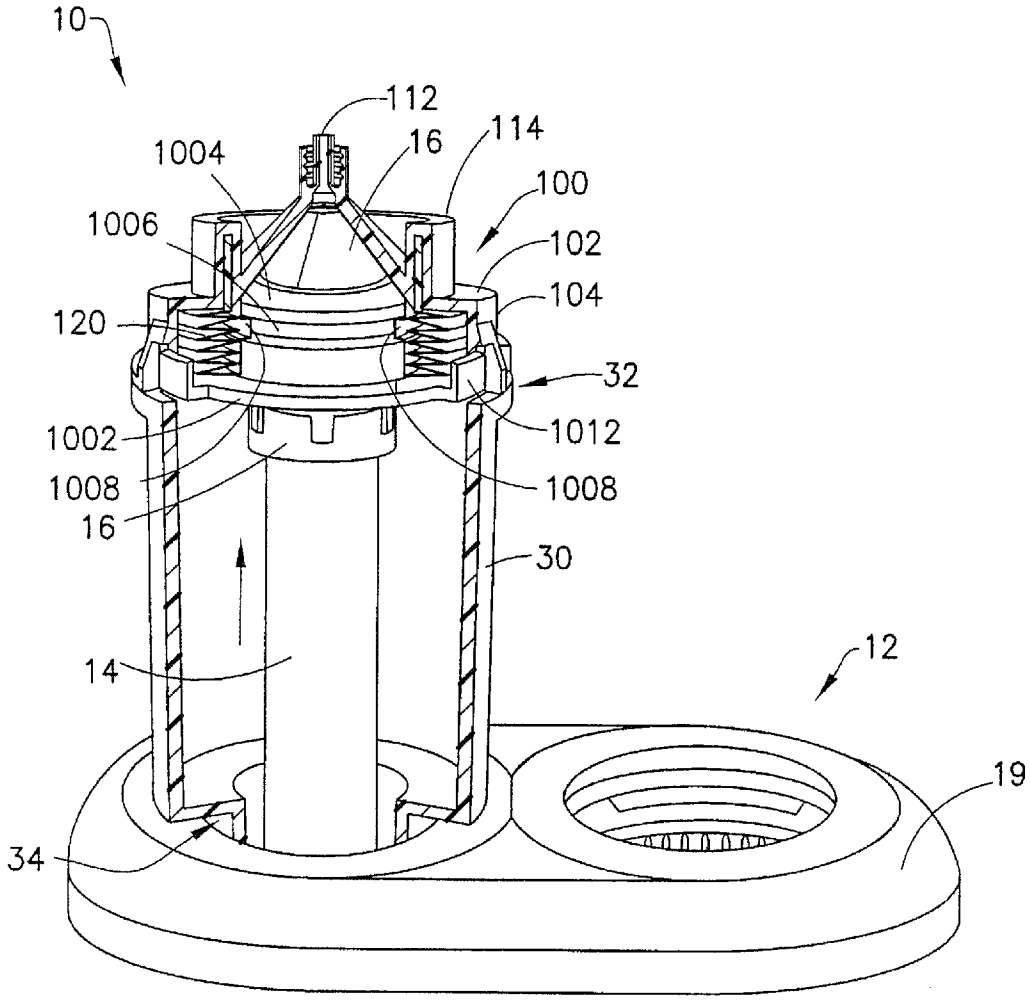
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FIG.63

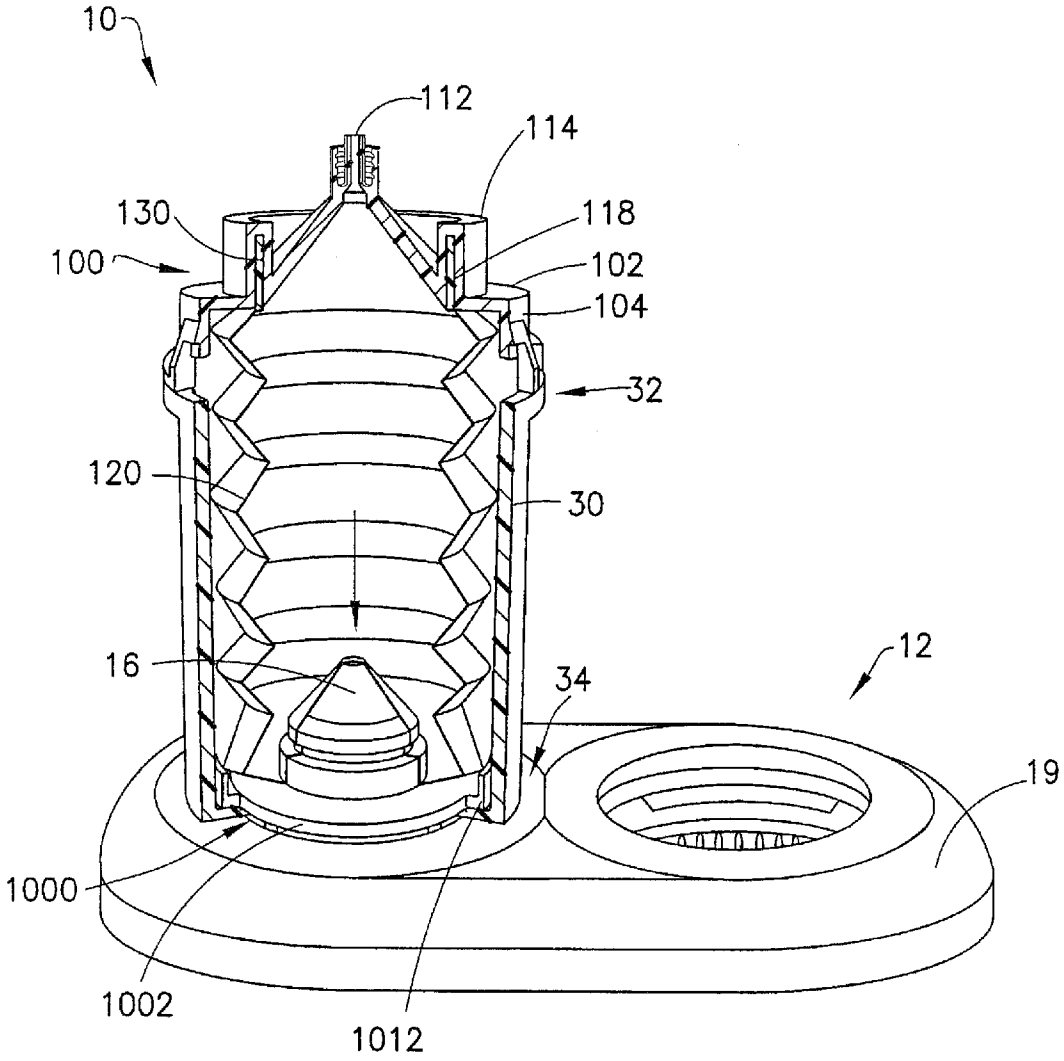
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FIG.64

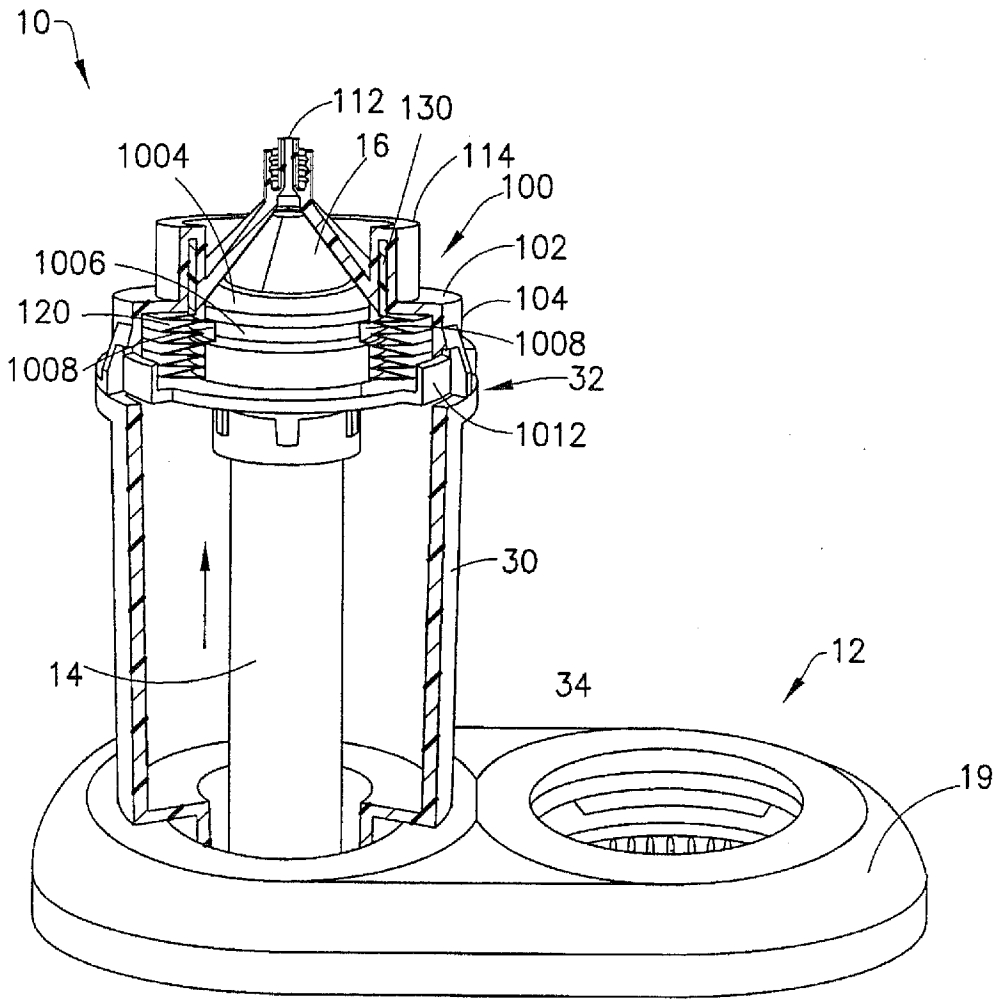
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FIG.65

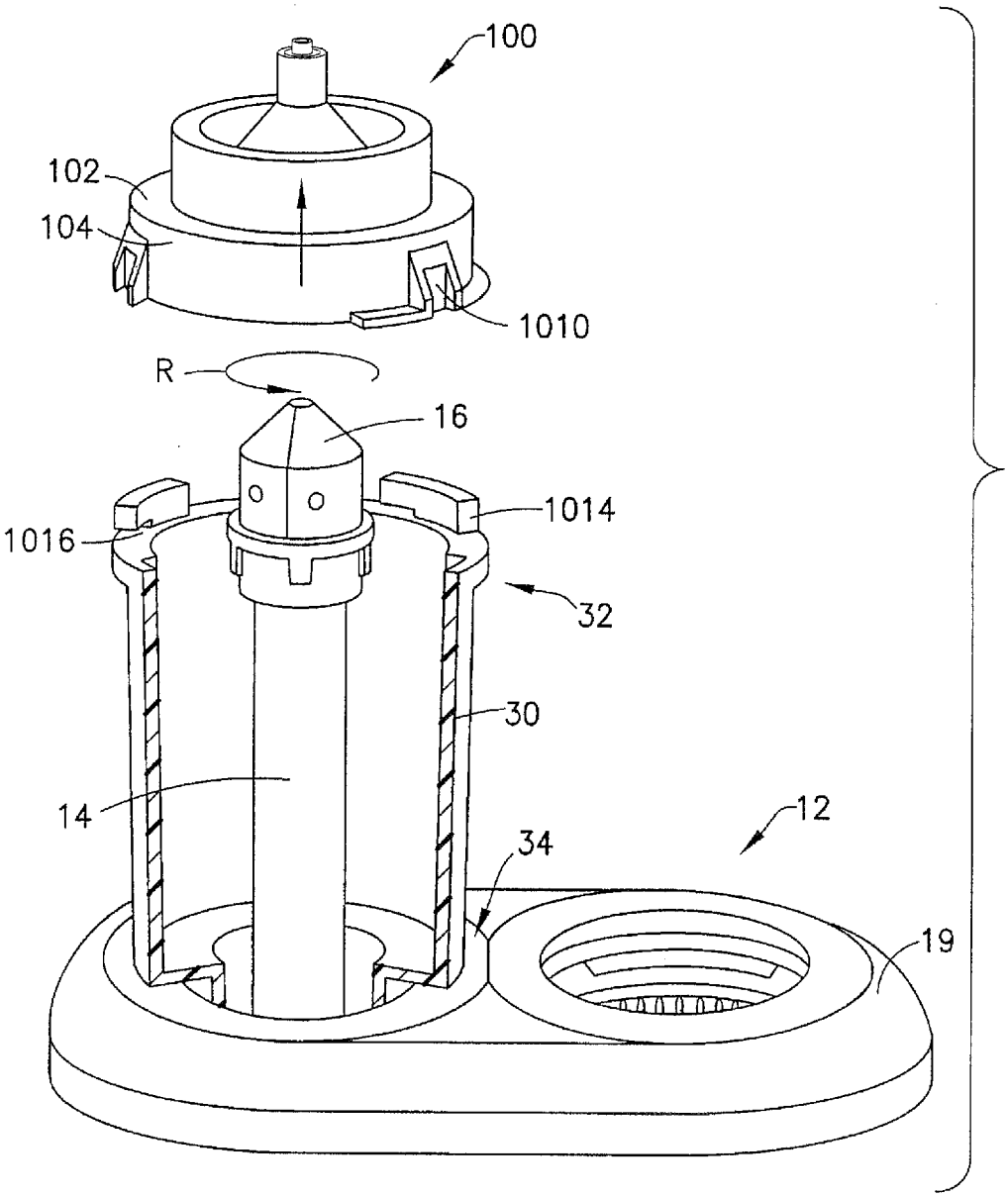

FIG.66

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/035884

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/178 (2013.01)
USPC - 604/216
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61J 1/00, 1/06; A61M 5/178, 5/24, 5/31; B65D 1/09, 5/36, 21/08, 90/00, 90/02 (2013.01)
USPC - 206/528; 215/11.3, 379, 382, 900; 604/212, 216, 217

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61J 1/067; A61M 5/24, 5/2425, 5/282 (2013.01)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 7,011,650 B2 (ROSOFF et al) 14 March 2006 (14.03.2006) entire document	1-5, 9-13, 19-23
Y	DE 298 18 399 U1 (PAPST) 24 February 2000 (24.02.2000) entire document	1-5, 9-13, 19-23
Y	US 2011/0218499 A1 (CAHEN) 08 September 2011 (08.09.2011) entire document	4, 12, 22
Y	US 5,300,031 A (NEER et al) 05 April 1994 (05.04.1994) entire document	9-13, 19-23
A	US 6,485,471 B1 (ZIVITZ et al) 26 November 2002 (26.11.2002) entire document	1-28
A	US 6,319,235 B1 (YOSHINO) 20 November 2001 (20.11.2001) entire document	1-28

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search	Date of mailing of the international search report
11 June 2013	28 JUN 2013
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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