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(54) Title: APPARATUS FOR APPLYING AN ENDOTHERMIC VAPOR TO SKIN AS AN ANESTHETIC

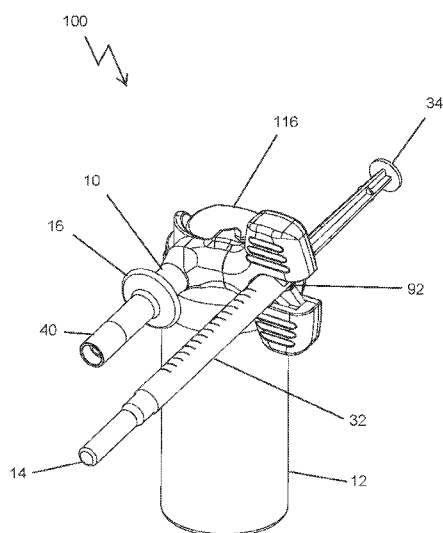


FIG. 1

(57) Abstract: The present device provides a method and an apparatus for applying a vaporized endothermic gas to a skin surface to provide numbing of the application site for injection with a syringe. The device includes a container or canister containing an endothermic gas that rapidly absorbs heat when released to the atmosphere. A depressible actuating member or trigger propels the gas or vapor through an outlet nozzle that is constructed to break the liquid into a vapor that can be projected as a stream of vapor along a delivery axis that intersects a delivery axis of the syringe needle; therefore, the gas or vapor can be successively delivered to an injection site with minimal repositioning of the device.

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APPARATUS FOR APPLYING AN ENDOTHERMIC VAPOR TO SKIN AS AN ANESTHETIC

FIELD OF THE INVENTION

Generally, the invention relates to an apparatus for applying an endothermic gas
5 to tissue to provide an anesthetic to an injection site prior to an injection to minimize the
pain associated with conventional injection techniques. In particular, the apparatus
comprises a receptacle for a liquefied endothermic gas and system for converting the
liquefied endothermic gas to a vapor for application to the skin.

BACKGROUND

10 Syringes are employed millions of times daily all over the world to inject
medicines into people, as well as animals. Many times, injections are made in areas of
the body that are somewhat less sensitive to pain. Other locations of the body where
injections are contemplated are significantly more sensitive to pain, and the patient feels a
pinching sensation that may be quite painful as the syringe needle is inserted beneath the
15 skin. Such areas include, for example, gums and areas of the face, such as the forehead,
as well as the lips. To minimize the pain that results when the injection needle
penetrates, for example, a patient's gums, the dental practitioner will often apply a topical
agent to the injection site using a cotton swab. Because the deadening agent is only
applied topically, it is not effective, as it does not cross the skin/mucosal membranes and
20 misleads the patient into a false expectation of a painless injection. As a result, injecting
an anesthetic often causes significant pain at the injection site. In other cases, such as
diabetics, patients may be required to self-medicate on a daily basis. The repeated
injections often create sensitive areas where injections are painful to the patient. This
pain may cause patients to delay or omit medication to avoid the pain associated
25 therewith. Current devices, even those to the present inventor, that utilize cold sprays to
numb the injection site suffer from applying the numbing agent as a liquid pressurized
spray. The liquid spray fails to optimally atomize for proper cooling of the skin. The
vaporization of the liquid is slowed, and thus the cooling effect is reduced for a given
amount of spray applied.

SUMMARY

There is currently a need for a means of minimizing the pain associated with an injection. The present invention addresses this need by providing a syringe having a liquid compressed gas canister securely attached. The device includes an endothermic gas compressed to a liquid form. When the liquid endothermic material is released, it is converted to a vapor that can be directionally guided to the injection point to rapidly absorb heat when released to the atmosphere. The endothermic vapor is applied to the injection site prior to an injection to minimize the pain associated with conventional injection techniques. Furthermore, the vapor also blanches the mucosa almost instantly, allowing a practitioner to readily identify the pretreated injection site so that the needle is not inserted into an unanesthetized area.

Embodiments of the invention are also directed to an apparatus comprising a syringe which is removably attached to a cold spray module for converting the liquefied gas to a vapor by impingement. The cold spray module is secured to a compressed gas assembly which holds the liquefied endothermic gas. The apparatus comprises an actuating member which acts to dispense the contents of a container or canister containing the anesthetic composition. The cold spray module includes an actuating member for the controlled release of the liquefied endothermic gas for conversion to a vapor.

Embodiments of the invention are further directed to a liquefied endothermic gas canister assembly for attachment to the present device. The canister assembly includes a dispensing valve that is secured to a locking collar. The combination of the dispensing valve and the locking collar prevent other types of pressurized canisters from being secured to the dispensing valve for the present device, thereby reducing or preventing the present device from being used with unknown gaseous materials. The combination also prevents the gas cylinders from being refilled with the wrong compressed gas.

Other aspects are described *infra*.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of the cold spray module with the gas cylinder and syringe installed and ready for use;

Figure 2 is a perspective view of the cold spray module with the gas cylinder assembly and the syringe detached;

Figure 3 is a partially exploded view illustrating the gas cylinder assembly with storage cap and cold spray module ready for connection;

Figure 4 is a perspective view of one embodiment of the cold spray module connected to the gas cylinder assembly;

Figure 5 is a perspective view of the embodiment illustrated in Figure 4;

Figure 6A is a perspective view illustrating connection of the cold spray module to a gas release valve securable to the gas cylinder;

Figure 6B is a perspective view illustrating connection of the cold spray module to a gas release valve securable to the gas cylinder;

Figure 6C is a perspective view illustrating connection of the cold spray module to a gas release valve securable to the gas cylinder;

Figure 6D is a perspective view illustrating connection of the cold spray module to a gas release valve securable to the gas cylinder;

Figure 6E is a perspective view illustrating connection of the cold spray module to a gas release valve securable to the gas cylinder;

Figure 7A is a front view of the gas cylinder assembly;

Figure 7B is a side view of the gas cylinder assembly of Figure 7A;

Figure 7C is a section view taken along lines 7C-7C of Figure 7B;

Figure 7D is an enlarged partial section view taken along lines 7D-7D of Figure 7C illustrating the locking ring for providing a tamper resistant gas cylinder assembly;

Figure 7E is a top view of the gas cylinder assembly of Figure 7A;

Figure 7F is a partially exploded view illustrating the lock ring of the gas cylinder assembly;

Figure 7G is a partial perspective view of the gas cylinder assembly of Figure 7A;

Figure 8 is an exploded view of the gas cylinder assembly illustrated in Figures 7A-7G;

Figure 9 is an alternative embodiment of the gas cylinder assembly constructed without the locking ring;

Figure 10A is a top left perspective view of the preferred embodiment of the actuator for the gas cylinder assembly;

5 Figure 10B is a bottom rear perspective view of the actuator of Figure 10A;

Figure 10C is a front view of the actuator shown in Figure 10A;

Figure 10D is a section view taken along lines 10D-10D of Figure 10C;

Figure 10E is a left side view of the actuator of Figure 10A;

Figure 10F is a section view taken along lines 10F-10F of Figure 10E;

10 Figure 10G is a bottom view of the actuator of Figure 10A;

Figure 10H is a section view taken along lines 10H-10H of Figure 10G;

Figure 10I is a rear view of the actuator of Figure 10A;

Figure 10J is a top view of the actuator of Figure 10A;

Figure 10K is a section view taken along lines 10K-10K of Figure 10J;

15 Figure 11A is a perspective view of a cover cap assembly for the gas cylinder assembly;

Figure 11B is a front view of the cover cap assembly shown in Figure 11A;

Figure 11C is a right side view of the cover cap assembly shown in Figure 11A;

Figure 11D is a top view of the cover cap assembly shown in Figure 11A;

20 Figure 11E is a bottom view of the cover cap assembly shown in Figure 11A;

Figure 11F is a section view taken along lines 11F-11F of Figure 11B;

Figure 11G is a partial section view taken along lines 11G-11G of Figure 11F;

Figure 12A is a perspective top front view of one embodiment of the actuator of the present invention;

25 Figure 12B is a top rear view of the actuator illustrated in Figure 12A;

Figure 12C is a front view of the actuator illustrated in Figure 12A;

Figure 12D is a right side view of the actuator illustrated in Figure 12A;

Figure 12E is a bottom view of the actuator illustrated in Figure 12A;

Figure 12F is a top view of the actuator illustrated in Figure 12A;

30 Figure 12G is a left side view of the actuator illustrated in Figure 12A;

Figure 12H is a section view taken along lines 12H-12H of Figure 12C;

Figure 12I is a front view taken along lines 12I-12I of Figure 12D;

Figure 12J is a partial view taken along lines 12J-12J of Figure 12F;

Figure 13A is a top perspective view of the locking ring;

Figure 13B is a top view of the locking ring of Figure 13A;

5 Figure 13C is a section view taken along lines 13C-13C of Figure 13B;

Figure 14A is a partial perspective view illustrating one embodiment of the cold spray module;

Figure 14B is an exploded view of the portions of the cold spray module of Figure 14A;

10 Figure 14C is a section view taken along the longitudinal centerline, illustrating the cold spray module secured to a gas cylinder assembly;

Figure 15 is a section view of one embodiment of the cold spray assembly secured to a gas cylinder assembly;

Figure 16 is an exploded view of the cold spray assembly of Figure 15;

15 Figure 17A is a perspective view of the cold spray assembly;

Figure 17B is an exploded view of the cold spray assembly of Figure 17A;

Figure 18A is a front left perspective view of the cold spray housing;

Figure 18B is a rear right perspective view of the cold spray housing;

Figure 18C is a rear plan view of the cold spray housing;

20 Figure 18D is a bottom view of the cold spray housing;

Figure 18E is a right side view of the cold spray housing;

Figure 18F is a front view of the cold spray housing;

Figure 18G is a top view of the cold spray housing;

Figure 18H is a partial section view taken along lines 18H-18H of Figure 18C;

25 Figure 18I is a section view taken along lines 18I-18I of Figure 18D;

Figure 18J is a partial section view taken along lines 18J-18J of Figure 18I;

Figure 19A is a front left perspective view of one embodiment of the cold spray housing;

30 Figure 19B is a rear right perspective view of the cold spray housing of Figure 19A;

Figure 19C is a rear right perspective view of the cold spray housing of Figure 19A;

Figure 19D is a front view of the cold spray housing of Figure 19A;

Figure 19E is a bottom view of the cold spray housing of Figure 19A;

5 Figure 19F is a left side view of the cold spray housing of Figure 19A;

Figure 19G is a rear view of the cold spray housing of Figure 19A;

Figure 19H is a section view taken along lines 19H-19H of Figure 19D;

Figure 19I is a partial section view taken along lines 19I-19I of Figure 19G;

Figure 19J is a right side view of the cold spray housing of Figure 19A;

10 Figure 19K is a section view taken along lines 19K-19K of Figure 19J;

Figure 19L is a partial section view taken along lines 19L-19L of Figure 19D;

Figure 20A is a rear perspective view of a rear plate for the cold spray assembly;

Figure 20B is a front perspective view of the rear plate of Figure 20A;

Figure 20C is a rear view of the rear plate of Figure 20A;

15 Figure 20D is a left side view of the rear plate of Figure 20A;

Figure 20E is a top view of the rear plate of Figure 20A;

Figure 20F is a bottom view of the rear plate of Figure 20A;

Figure 20G is a front view of the rear plate of Figure 20A;

Figure 20H is a section view taken along lines 20H-20H of Figure 20C;

20 Figure 20I is a section view taken along lines 20I-20I of Figure 20G;

Figure 21A is a front perspective view of one embodiment of the rear plate member;

Figure 21B is a rear perspective view of the rear plate of Figure 21A;

Figure 21C is a front view of the rear plate of Figure 21A;

25 Figure 21D is a rear view of the rear plate of Figure 21A;

Figure 21E is a left side view of the rear plate of Figure 21A;

Figure 21F is a right side view of the rear plate of Figure 21A;

Figure 21G is a bottom view of the rear plate of Figure 21A;

Figure 21H is a top view of the rear plate of Figure 21A;

30 Figure 21I is a partial section view taken along lines 21I-21I of Figure 21D;

Figure 22A is a perspective view of a clamp block of the cold spray module;

Figure 22B is a side view of the clamp block of Figure 22A;

Figure 22C is a rear view of the clamp block of Figure 22A;

Figure 22D is a side view of the clamp block of Figure 22A;

5 Figure 22E is a section view of the clamp block of Figure 22A taken along lines 22E-22E of Figure 22D;

Figure 23A is a perspective view of a clamp block spring suitable for use with the present device;

Figure 23B is a side view of the clamp block spring of Figure 23A;

Figure 23C is an end view of the clamp block spring of Figure 23C;

10 Figure 24A is a perspective view of one embodiment of the core tube of the cold spray module;

Figure 24B is a side view of the core tube of Figure 24A;

Figure 24C is a front view of the core tube of Figure 24A

Figure 24D is a section view taken along lines 24D-24D of Figure 24C;

15 Figure 25A is a front perspective view of one embodiment of a core tube of the cold spray module;

Figure 25B is a rear perspective view of the core tube of Figure 25A;

Figure 25C is a top view of the core tube of Figure 25A;

Figure 25D is a side view of the core tube of Figure 25A;

20 Figure 25E is a front view of the core tube of Figure 25A;

Figure 25F is a rear view of the core tube of Figure 25A;

Figure 25G is a section view taken along lines 25G-25G of Figure 25D;

Figure 25H is a section view taken along lines 25H-25H of Figure 25C;

Figure 26A is a perspective view of the nozzle body for the cold spray module;

25 Figure 26B is a side view of the nozzle body of Figure 26A;

Figure 26C is a front view of the nozzle body of Figure 26A;

Figure 26D is a section view taken along lines 26D-26D of Figure 26C;

Figure 27A is a front perspective view of the supply tube for the cold spray module;

30 Figure 27B is a side view of the supply tube of Figure 27A;

Figure 27C is an end view of the supply tube of Figure 27A;

Figure 28A is a rear perspective view of a breakup nozzle for the cold spray module;

Figure 28B is a rear view of the breakup nozzle of Figure 28A;

Figure 28C is a front view of the breakup nozzle of Figure 28A;

5 Figure 28D is a section view taken along lines 28D-28D of Figure 28B;

Figure 29A is a front perspective view of a breakup nozzle for the cold spray module;

Figure 29B is a rear perspective view of the breakup nozzle of Figure 29A;

Figure 29C is a side view of the breakup nozzle of Figure 29A;

10 Figure 29D is a side view of the breakup nozzle of Figure 29A;

Figure 29E is a front view of the breakup nozzle of Figure 29A;

Figure 29F is a rear view of the breakup nozzle of Figure 29A;

Figure 29G is a section view of the breakup nozzle of Figure 29A taken along lines 29G-29G of Figure 29C;

15 Figure 30A is a front right perspective view of a breakup nozzle suitable for use with the present invention;

Figure 30B is a rear perspective view of the breakup nozzle of Figure 30A;

Figure 30C is a side view of the breakup nozzle of Figure 30A;

Figure 30D is a front view of the breakup nozzle of Figure 30A;

20 Figure 30E is a rear view of the breakup nozzle of Figure 30A;

Figure 30F is a section view of the breakup nozzle of Figure 30A taken along lines 30F-30F of Figure 30E;

Figure 31 is a perspective view of an embodiment having a flange retention member for attachment of the syringe;

25 Figure 32 is a perspective view of an embodiment having a flange retention member for attachment of the syringe;

Figure 33A is a perspective view illustrating the flange retainer;

Figure 33B is a perspective view illustrating the flange retainer;

30 Figure 34 is a perspective view of the attachment of the cold spray module to the gas cylinder;

Figure 35A is a perspective view of the cold spray module with flange retention;

Figure 35B is an exploded perspective view of the embodiment illustrated in Figure 35A;

Figure 36 is a front perspective view of the embodiment illustrated in Figure 35A;
and

5 Figure 37 is a front perspective view of the embodiment illustrated in Figure 35A.

DETAILED DESCRIPTION

It is to be understood that while a certain form of the invention is illustrated, it is not to be limited to the specific form or arrangement herein described and shown. It will be apparent to those skilled in the art that various changes may be made without departing from the scope of the invention and the invention is not to be considered limited to what is shown and described in the specification and any drawings/figures included herein.

Referring to Figures 1-31, embodiments of the present invention relate to a method and apparatus of applying an anesthetic in the form of a vaporized endothermic gas. The endothermic vapor applicator 100 is attachable to a syringe to provide the endothermic vapor along a trajectory that aligns with the puncture point of the syringe needle. This construction allows the user to align the device once for the skin or epidermis, dermis numbing provided by the endothermic gas vapor as it cools the skin to be followed by the injection without the need for repositioning the device. The endothermic vapor applicator 100 includes a cold spray module 10, a canister assembly 12, and a syringe 14. The cold spray module 10 includes a cold spray module housing 16, a core tube 18, a breakup nozzle 20 and a syringe barrel securing assembly 90. The canister assembly 12 includes a canister 26, a valve assembly 28, and a locking ring 30. The syringe 14 includes a barrel 32, a plunger 34, a barrel tip 36 and a needle 38.

Referring generally to the Figures, and more specifically to Figs. 1-5, 31-34 and 37, the endothermic vapor applicator 100 is illustrated as an assembly. In general, the cold spray module 10 is constructed and arranged for removable attachment to the canister assembly 12, as well as removably attached to the syringe 14 to connect the assemblies together in a manner that allows the cold vapor to be controllably sprayed and the syringe 14 to be positioned for operation of the cold spray and the syringe 14 with one hand. In this manner, the endothermic vapor applicator 100 can be aimed at a desired injection site and the endothermic gas released, for example, with the thumb. The thumb can then be repositioned to the plunger 34 of the syringe 14 for the injection. The endothermic vapor creates a blanched area on the skin, which is visible to insert the needle 38 of the syringe 14 into the numbed area. The ergonomic construction of the endothermic vapor applicator 100 allows both operations to occur without repositioning

of the hand with respect to the cold spray module 10 and canister assembly 12 or visa-versa. Thus, the nozzle 20 is constructed and arranged to cause the endothermic vapor to be directed as a stream to intersect with a delivery axis of the needle 38 connected to the syringe 14 when the syringe 14 is attached to the cold spray module 100.

5 Referring generally to the Figures, and more specifically to Figs. 1-6E, 14A-23C, and 31-37, the cold spray module 10 is illustrated. The cold spray module 10 generally connects the syringe 14 and the canister assembly 12, and maintains the positioning of each assembly with respect to the other. In addition, the cold spray module 10 routes the liquefied endothermic gas from the canister assembly 12 to the desired area of the skin, 10 breaking the liquid into a stream of vapor as it passes through the cold spray module 10. The cold spray module 10 includes a cold spray housing 16, a syringe barrel securing assembly 90, a core tube 18, and a breakup nozzle 20. The housing 16 is constructed generally as a tubular portion 40 having the syringe barrel securing assembly 90 depending therefrom, also forming a pair of finger grips 42. In some embodiments, a 15 positioning anchor 44 extends from the area between the tubular portion 40 and the syringe barrel securing assembly 90 to snap onto the top rim 46 of the valve assembly 28 to prevent rotation and linear translation between the canister assembly 12 and the cold spray module 10. Secondary finger grips 48 may be integrally formed to the tubular portion 40 to provide versatility to gripping the endothermic vapor applicator 100. The 20 internal bore 50 of the tubular portion 40 is generally a smooth, consistent or slightly tapered bore and may contain one or more internal flanges 52 for maintaining the position of the core tube 18 and breakup nozzle 20 within the bore. Thus, the core tube 18 seen in Figs. 14A-16, and 24A-27C is inserted into the internal bore 50 of the tubular portion 40. The core tube 18 receives the liquefied endothermic gas from the canister assembly 12 and provides a pathway for the liquid to travel to a position where the liquid endothermic 25 gas is directed to impinge at an angle upon a breakup surface 54 of the breakup nozzle 20 to convert the liquid to a vapor. The vapor is thus expanded to cause it to escape through the orifice under pressure to create a stream of endothermic vapor the user can direct at a skin surface.

30 Referring generally to the Figures, and more specifically to Figs. 14A-16, 24A-27C, and 35A-35B, various embodiments of the core tube 18 are illustrated. In general,

the core tube 18 is constructed and arranged to be in fluid communication with the canister assembly 12 to transfer the compressed liquid endothermic gas from the canister 26 and direct the liquid into the breakup surface 54 of the breakup nozzle 20. Thus, the core tube 18 may be provided in various forms to provide the same or similar functions.

5 Figures 15 and 16 illustrate an embodiment of the core tube 18 that includes an elongated body 58 sized to fit snugly into the tubular portion 40 of the cold spray module 10. A first end 60 of the core tube 18 is constructed to fit snugly into a discharge tube 62 of the canister valve 28, and a second end 72 is constructed to fit snugly into an inside bore 68 of the breakup nozzle 20. The snug fitment between the components allows the side

10 surface 64 of the core tube 18 to include a U-shaped channel 70, whereby an internal surface 66 of the discharge tube 62, the internal bore 50 of the tubular portion 40 of the housing 16, and the inside bore 68 of the breakup nozzle 20 all form a closing surface for the U-shaped channel 70 to form a passage for the liquefied endothermic gas. It should be noted that the U-shaped channel 70 is positioned off center of the core tube 18,

15 terminating in an annular groove 78 which directs the liquefied gas at a breakup surface 54 of the breakup nozzle 20. In this manner, the liquefied gas is required to impact the breakup surface 54 and travel across it at an angle to reach the orifice 56 of the nozzle 20. Figs. 14A-14C, 26A-26D and 27A-27C illustrate an alternative embodiment of the core tube 18. In this embodiment, the first end 60 of the tube is a metal or polymeric tubing

20 74. An outer surface of the tubing 74 is constructed and arranged to cooperate with an inner surface 66 of the discharge tube 62. A centrally positioned conduit 80 extends from the distal end 82 of the tubing 74 to a discharge port 84. In a preferred embodiment, the discharge port 84 directs the liquefied gas against the breakup surface 54 of the nozzle 20 at an angle to break up the liquid into a vapor as it passes over the breakup surface 54. In

25 at least one embodiment, the discharge port 84 is constructed by positioning a pair of offset flat panels 86 with a U-shaped notch 88 positioned in a central portion of the forward most flat panel. The offset positioning of the two panels 86 causes the liquid to exit the central conduit 80 at an angle with respect to the longitudinal centerline of the core tube 18. In some embodiments, see Fig. 14C, a tapered sleeve 76 may be

30 overmolded or press-fit onto an outer surface of the tubing 74 to provide a snug fit to the inner surface 66 of the discharge tube 62 of the canister assembly 12. It should be noted

that the term “snug” does not require a liquid or air tight seal, so long as the preponderance of the liquid is transferred through the core tube 18 to the breakup nozzle 20.

Referring generally to the Figures, and more specifically to Figs. 1-6E, and 17A-23C, wherein the cold spray module 10 includes a syringe barrel securing assembly 90; the syringe barrel securing assembly 90 including at least two opposing spring loaded clamping members 92 configured for securing the syringe barrel 14 to the cold spray module 10. The cold spray module 10 is preferably configured to include a housing 94 having a first upper portion and a second lower portion formed to include channels or slots 96 sized and shaped to hold and allow the two opposing spring loaded clamping members 92 to slide therein. Springs 98 may be placed into pockets 102 positioned in the ends of the clamping members 92 to bias the clamping members to a closed or clamping position. While coil springs are illustrated, it should be noted that other biasing members, such as elastomeric, rubber or torsion members, may be utilized without departing from the scope of the invention. A cap member 104 is secured to the cold spray housing 94 with spring clips 106. The spring clips 106 are constructed and arranged to flex when inserted into blind apertures 108 (Fig. 16) as they slide past a catch member 110 (Fig. 18I) to interlock and prevent the removal of the cap member 104. Alignment pins 112 may be used in conjunction with the spring clips 106 to align the cap member 104 to the cold spray housing 94 to provide a more precise alignment between the two components. The alignment pins 112 may also be used without the spring clips 106 by providing a press fit into the blind apertures 108.

Referring generally to the Figures, and more specifically to Figs. 7A-13C, embodiments of the canister assembly 12 are illustrated. The canister assembly 12 includes a metal canister 26 having a valve assembly 28 crimped and sealed to cover an open end of the canister to create a sealed pressure canister. In general, the canister assembly 12 is constructed and arranged to contain the liquefied endothermic gas sufficiently pressurized to maintain the liquid state of the gas until released from the canister 26. The valve assembly 28 includes a dispenser tube 114 extending outwardly therefrom for connection to the cold spray module 10 through a discharge tube 62 secured to a discharge actuator 116. The discharge actuator 116 is constructed and

arranged to operate by depressing the dispenser tube 114 in the valve assembly 28, which allows the liquefied endothermic gas to flow through the valve assembly 28 and through the discharge tube 62. In at least one embodiment, a locking ring 30 is placed below the valve assembly crimp utilized to attach the valve assembly to the cannister. The locking
5 ring 30 is laser or radio frequency welded 118 to the discharge actuator 116 to prevent removal of the discharge actuator 116 from the canister 26. This construction prevents unwanted refilling of the canister 26, which may allow contaminants or incorrect liquids into the system. Removal of the discharge actuator 116 requires destruction of the locking ring 30 as an obvious indicator of refilling or tampering of the canister 26. A cap
10 120 is constructed and arranged to cooperate with the discharge actuator 116 to prevent inadvertent operation thereof. Examples of endothermic liquefied gasses that can be used include, but should not be limited to, 1,1,1,3,3 Pentafluoropropane CAS-No.: 460-73-1 at greater than 90% of the mixture combined with 1,1,1,2 Tetrafluoroethane CAS-No.: 811-97-2 making up the remaining portion. Alternatively, SOLSTICE® Propellant: HFO-
15 1234ze(E) or SOLSTICE® Enhance: HFO-1233zd(E) mixed with 10% or less of PERIDEX™ chlorhexidine gluconate 0.12% may be utilized. The chlorhexidine gluconate is formed from 1,1¹ hexamethylene bis [5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Peridex is a near-neutral
20 solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconic acid. It should be noted that other combinations of liquefied endothermic gasses and materials, such as antibacterials, may be combined with the endothermic gasses to reduce the possibility of frostbite, while still reducing the temperature of the skin to the level necessary to reduce the pain of the injection.

25 Figs. 10A-10K illustrate an alternative embodiment of the discharge actuator 117. This embodiment is constructed to function the same as the discharge actuator labeled 116, with the exception of snap locks 122 formed into the skirt 124. The snap locks 122 snap over the crimped valve assembly 28 to hold the discharge actuator 117 in position; the snap locks 122 include a ramping surface 126 that allows the skirt 124 to expand as it
30 passes over the valve assembly 28. Removal of the discharge actuator 117 from the crimped valve assembly 28 will thus require destruction of the discharge actuator 117.

Figs. 11A-11G illustrate a cap member 120 suitable for use with the discharge actuator 116, 117. The cap member 120 includes a depending lip 128 which depends from the cover plate 130. The depending lip 128 includes a snap flange 132 constructed and arranged to snap over the outer diameter of the discharge actuator 116, 117 to hold the cap 120 in position to prevent inadvertent actuation of the discharge actuator 116, 117. The cap 120 is removable and replaceable to the discharge actuator 116, 117.

Referring generally to the Figures, and more specifically to Figs. 28A-30F, various embodiments of breakup nozzles 20 are illustrated. The breakup nozzle 20 includes a rear breakup surface 54, and a front surface 55 including the nozzle orifice 56.

The rear breakup surface 54 includes at least one shearing corner 134, and more preferably a plurality of shearing corners 134. In general, the shearing corners 134 are sharp corners constructed from two adjoining planar surfaces 136, one of the planar surfaces 136 aligned parallel with respect to the longitudinal centerline of the core tube 18, and one of the planar surfaces 136 arranged perpendicular to the core tube 18. In this manner, the liquefied endothermic gas directed at the rear breakup surface 54 impinges the rear surface 54 adjacent the nozzle orifice 56, wherein the liquid breaks up and expands to exit the orifice 56 as a vapor with velocity. In a most preferred embodiment, the at least one shearing corner 134 is a sharp corner constructed from three adjoining planar surfaces 136, constructing a U-shaped breaker channel 138, two of the planar surfaces 136 aligned parallel with respect to the longitudinal centerline of the core tube 18, and one of the planar surfaces 136 arranged perpendicular to the longitudinal centerline of the core tube 18. In another embodiment, the rear surface 54 of the breakup nozzle 20 includes four of the U-shaped breaker channels 138. The breaker channels 138 may be arranged at right angles with respect to each other, breaking the rear surface into four quadrants. The core tube 18 is constructed and arranged to direct the liquefied endothermic gas at the rear breakup surface 54 at an acute angle with respect to the longitudinal centerline of the core tube 18 to break the liquefied endothermic gas into a vapor which is directed at a skin surface to decrease the temperature of the skin suitably to cause numbness of the skin. Because of its physical properties, the heat-absorbing endothermic vapor constricts blood flow at the injection site, and temporary numbing occurs. The endothermic vapor stops the propagation of the painful nerve stimuli, and

the patient feels the tactile, or pressure, as opposed to the pain sensation. According to the Gate theory, the pressure nerve fibers supersede the painful nerve fibers so that the mechanical contraction of the muscles blocks the transmission of pain perception. The use of the endothermic vapor also temporarily distracts the patient by creating a noise that
5 diverts the patient's attention away from any potential or anticipated pain. Finally, because the endothermic vapor blanches the mucosa, a readily-visible target is created for insertion of the needle to assure that the deadened area is not bypassed. When the practitioner observes that the injection site mucosa has been blanched, the site is effectively deadened and a painless, concomitant injection is possible. The practitioner
10 can then quickly inject the injection site by inserting the injection needle 38 and depressing the plunger 34. Because of the positioning of the vapor outlet nozzle 20 with respect to the needle 38, the dispersal of the vapor and subsequent injection of anesthetic can be accomplished almost concurrently, and with no pain to the patient.

Referring generally to the Figures, and more specifically to Figs. 31-37, an
15 embodiment of the present device that includes a slide-in syringe retainer 140 is illustrated. The slide-in syringe retainer 140 includes a front wall 142 and a rear wall 144 having a gap therebetween to receive the opposing grips 39 of a syringe 14. The front wall 142 and rear wall 144 are formed or secured together and divided in a central portion to form two spring fingers 146. The opposing grips 39 are slid between the front wall
20 142 and the rear wall 144. The diameter of the syringe barrel 32 causes the spring fingers 146 to move slightly apart to snap over the syringe barrel 32. The spring pressure created by the spring fingers 146 retains the syringe barrel snugly to the cold spray module housing 16, while the opposing grips 39 positioned between the front and rear walls 142, 144 prevent rotation of the syringe 14 perpendicular to the longitudinal axis of the
25 syringe during operation of the syringe 14.

One skilled in the art will readily appreciate that the present invention is well adapted to carry out the objectives and obtain the ends and advantages mentioned, as well as those inherent therein. The embodiments, methods, procedures and techniques described herein are presently representative of the preferred embodiments, are intended
30 to be exemplary, and are not intended as limitations on the scope. Changes therein and other uses will occur to those skilled in the art which are encompassed within the spirit of

the invention and are defined by the scope of the appended claims. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. Indeed, various modifications of the described modes for carrying
5 out the invention which are obvious to those skilled in the art are intended to be within the scope of the following claims.

CLAIMS

What is claimed is:

Claim 1. An endothermic vapor applicator attachable to a syringe comprising:

a cold spray module configured to be removably attached to the barrel portion of a syringe, said cold spray module including a body, said body including a core tube for directing a an endothermic liquid stream to impinge against a breaker surface for breaking the liquid stream into an endothermic vapor before the endothermic vapor is directed through a nozzle, the nozzle constructed and arranged to cause the endothermic vapor to be directed as a stream to intersect with a delivery axis of a needle connected to the syringe when the syringe is attached to the cold spray module;

a canister containing a liquefied endothermic gas, the canister fluidly connected through a connection to the cold spray module so that the liquefied endothermic gas is in fluid communication with the core tube.

Claim 2. The endothermic vapor applicator according to Claim 1 wherein the cold spray module includes a syringe barrel securing assembly, the syringe barrel securing assembly including at least two members configured for securing said syringe barrel to the cold spray module.

Claim 3. The endothermic vapor applicator according to Claim 2 wherein the at least two members configured for securing said syringe barrel in place includes two opposing spring loaded clamping members.

Claim 4. The endothermic vapor applicator according to Claim 2 wherein the syringe barrel securing device includes a housing having a first upper portion and a second lower portion.

Claim 5. The endothermic vapor applicator according to Claim 4 wherein the first upper portion comprises channels or slots sized and shaped to hold and allow said two opposing spring loaded clamping members to slide therein.

Claim 6. The endothermic vapor applicator according to Claim 1 wherein the canister is a metal canister having a valve assembly crimped and sealed within an open end of said canister to create a sealed pressure canister, said valve assembly including a dispenser tube extending outwardly therefrom for connection to the cold spray module.

Claim 7. The endothermic vapor applicator according to Claim 6 wherein the valve is finger operable to release the liquefied endothermic gas.

Claim 8. The endothermic vapor applicator according to Claim 1 wherein the breaker surface is a rear surface of the nozzle, the liquefied endothermic gas directed at the rear surface to impinge the rear surface adjacent a nozzle orifice, wherein the vaporized breaks up and expands to exit the orifice with velocity.

Claim 9. The endothermic vapor applicator according to Claim 8 wherein the rear surface of the nozzle includes at least one shearing corner.

Claim 10. The endothermic vapor applicator according to Claim 9 wherein the rear surface of the nozzle includes a plurality of shearing corners.

Claim 11. The endothermic vapor applicator according to Claim 9 wherein the at least one shearing corner is a sharp corner constructed from two adjoining planar surfaces, one of the planar surfaces aligned parallel with respect to the longitudinal centerline of the core tube, and one of the planar surfaces arranged perpendicular to the core tube.

Claim 12. The endothermic vapor applicator according to Claim 9 wherein the at least one shearing corner is a pair of sharp corners constructed from three adjoining planar surfaces, constructing a U-shaped channel, two of the planar surfaces aligned parallel with respect to the longitudinal centerline of the core tube, and one of the planar surfaces arranged perpendicular to the core tube.

Claim 13. The endothermic vapor applicator according to Claim 12 wherein the rear surface of the nozzle includes four of the U-shaped channels.

Claim 14. The endothermic vapor applicator according to Claim 13 wherein the four U-shaped channels are arranged at right angles with respect to each other, breaking the rear surface into four quadrants.

Claim 15. The endothermic vapor applicator according to Claim 8 wherein the core tube is constructed and arranged to direct the liquefied endothermic gas at the rear breakup surface of the nozzle at an acute angle with respect to the longitudinal centerline of the core tube.

Claim 16. The endothermic vapor applicator according to Claim 1 wherein said liquefied endothermic gas decreases the temperature of skin to cause numbness.

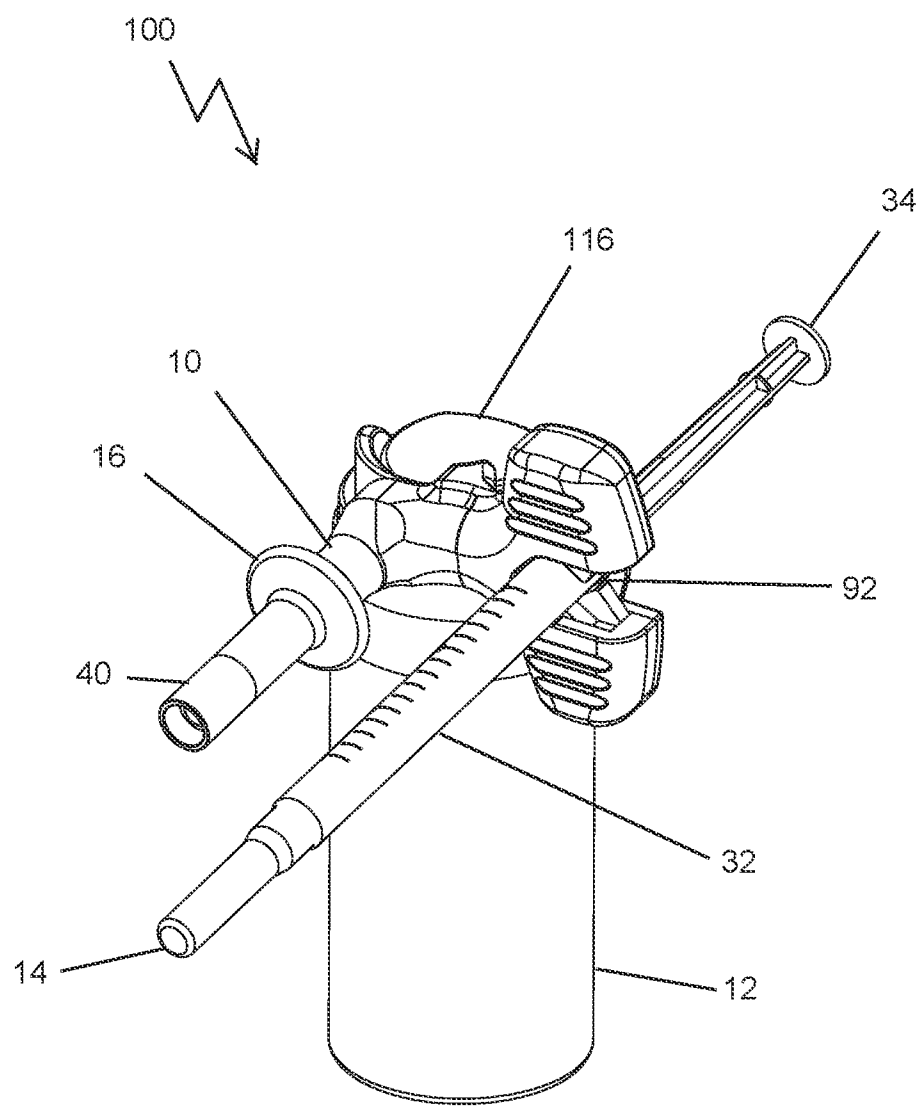


FIG. 1

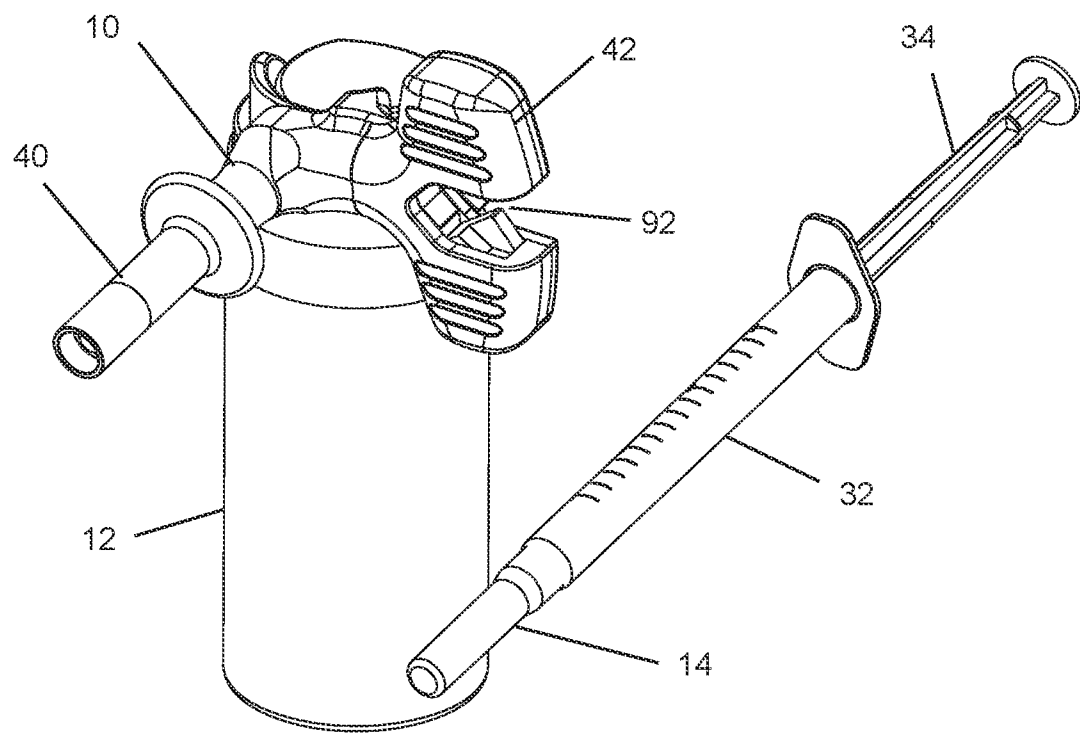


FIG. 2

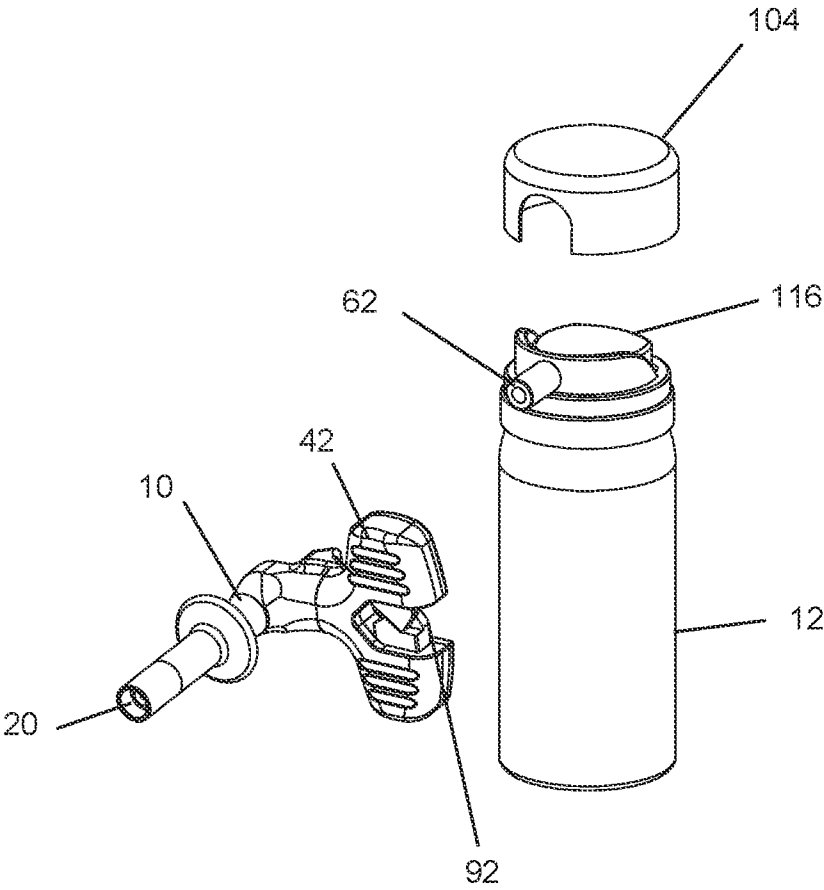


FIG. 3

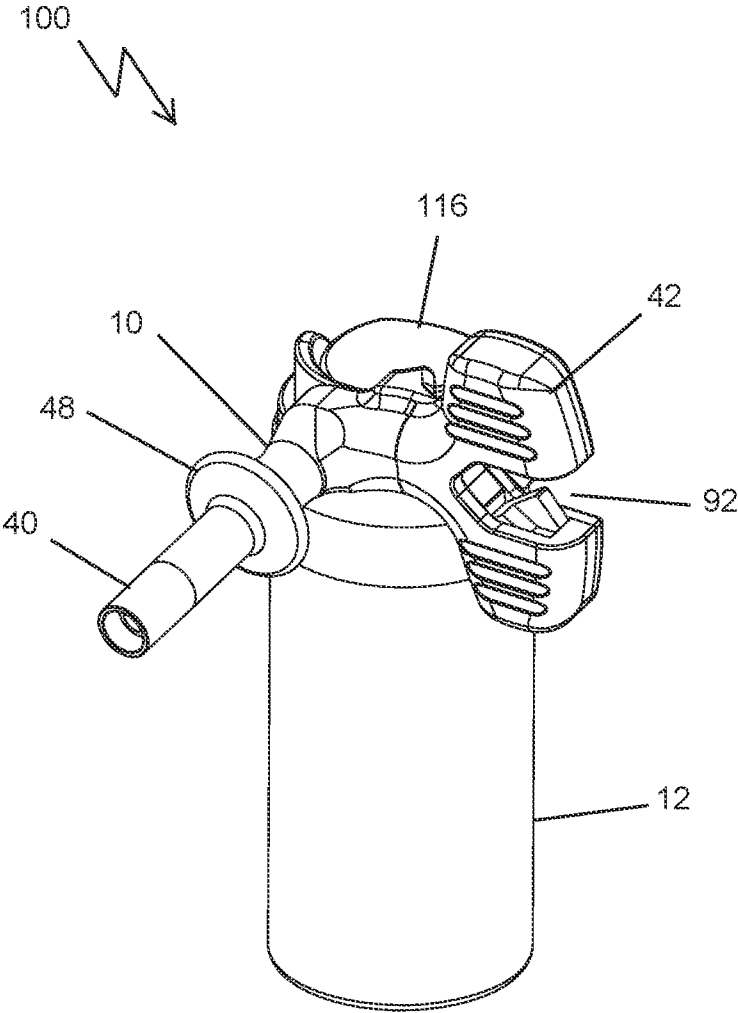


FIG. 4

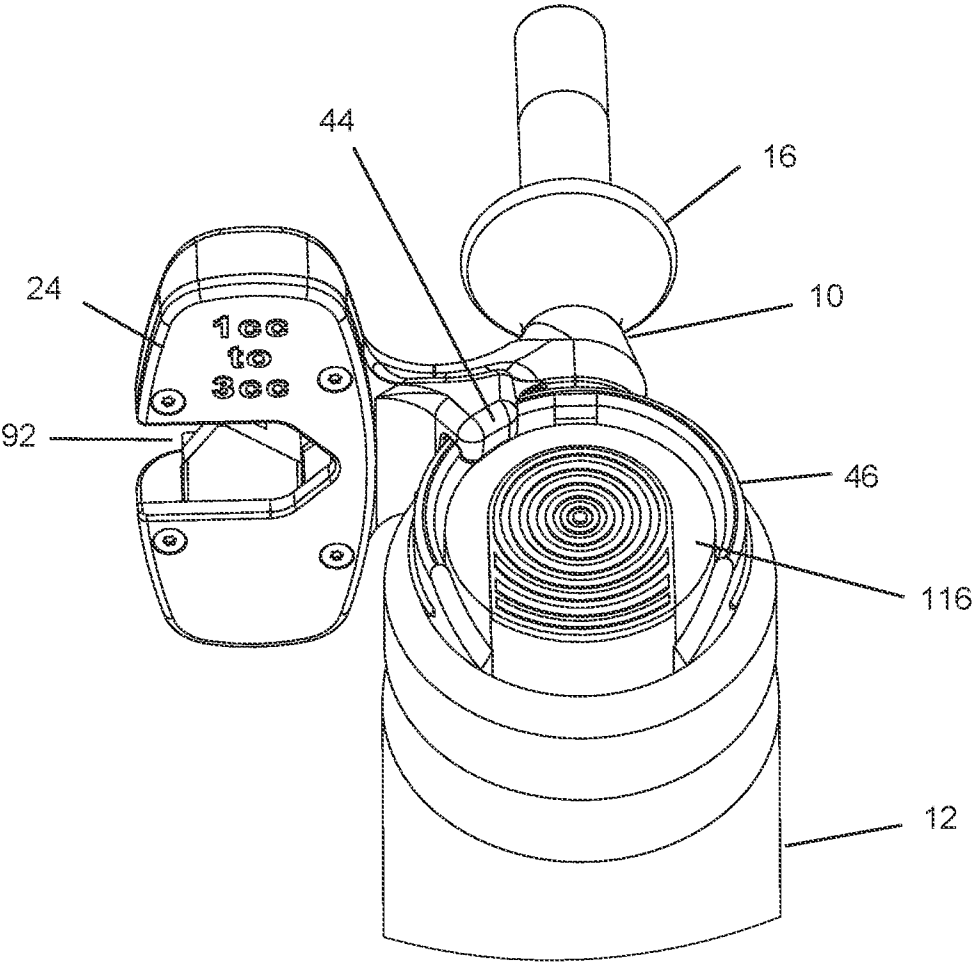


FIG. 5

FIG. 6A

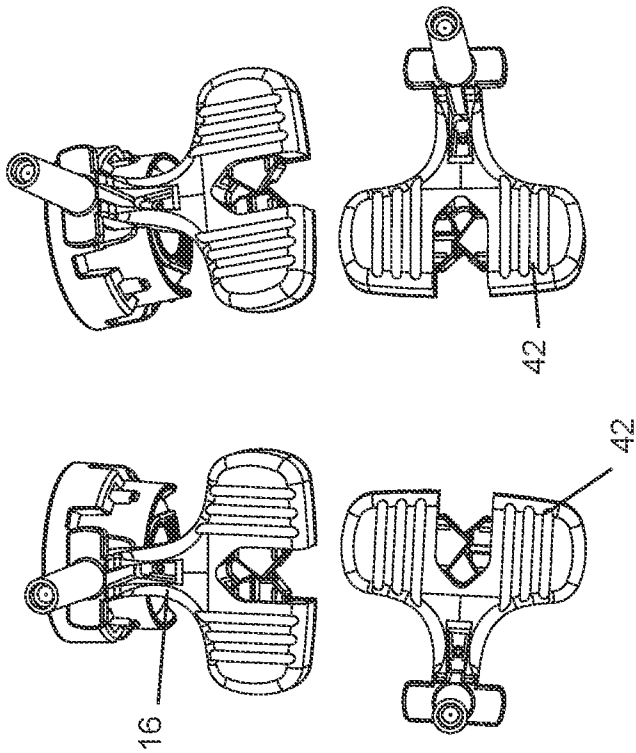


FIG. 6B

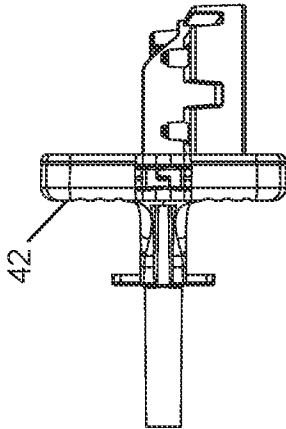
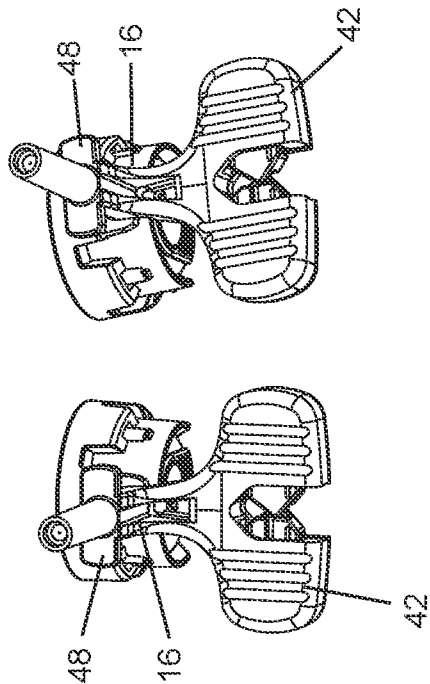


FIG. 6C

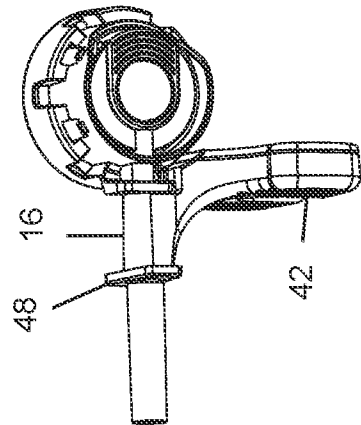


FIG. 6D

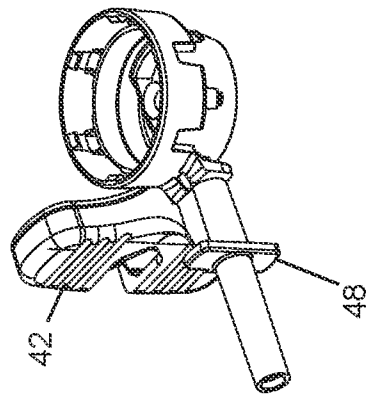


FIG. 6E

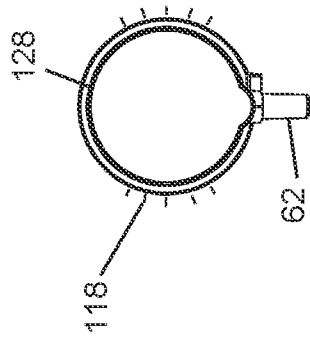


FIG. 7E

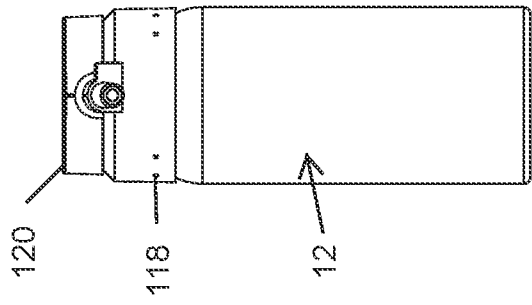


FIG. 7A

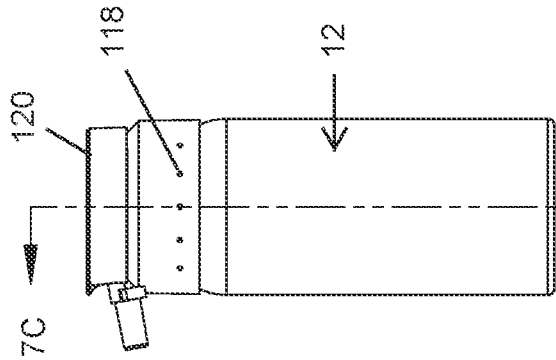
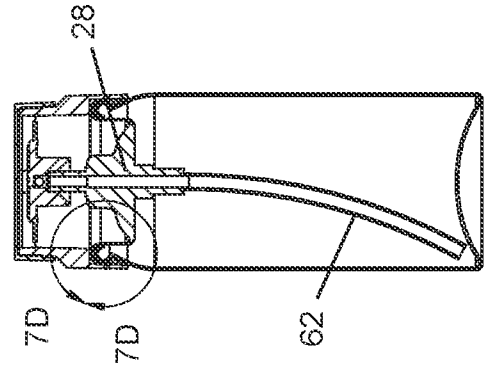
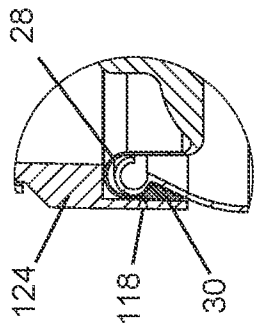


FIG. 7B



SECTION

FIG. 7C



DETAIL

FIG. 7D

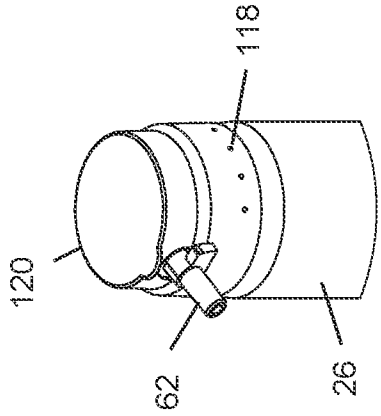


FIG. 7G

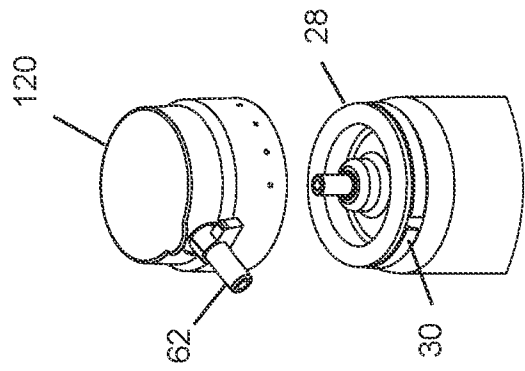


FIG. 7F

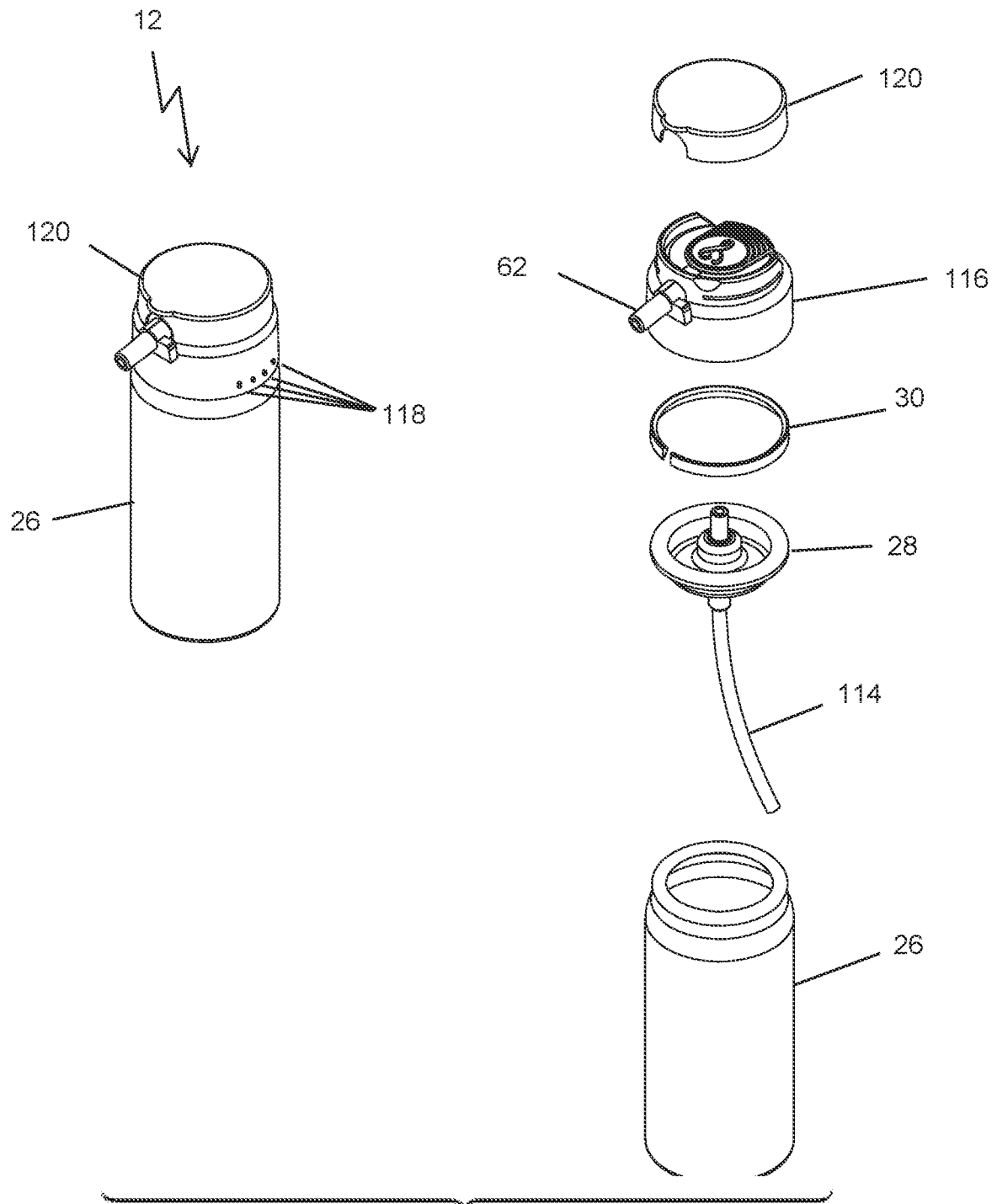


FIG. 8

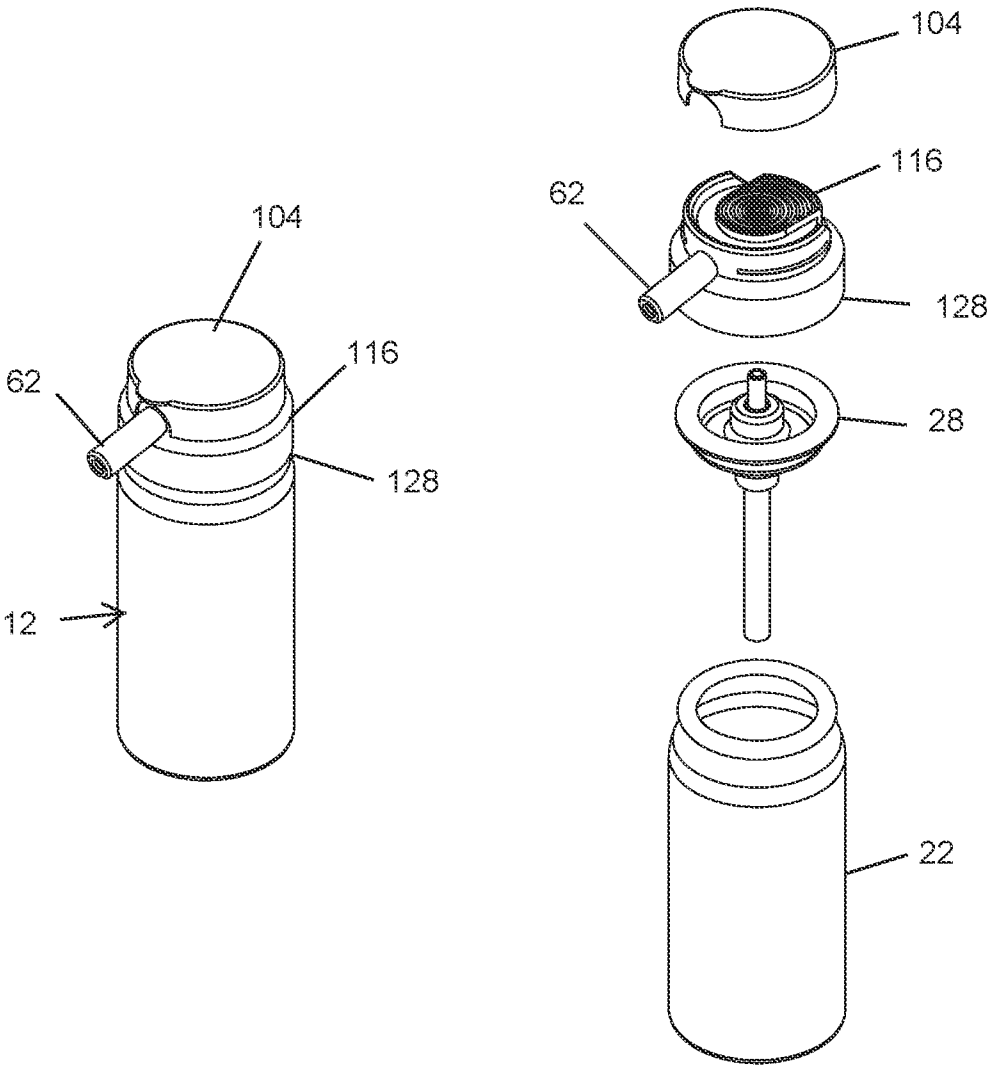


FIG. 9

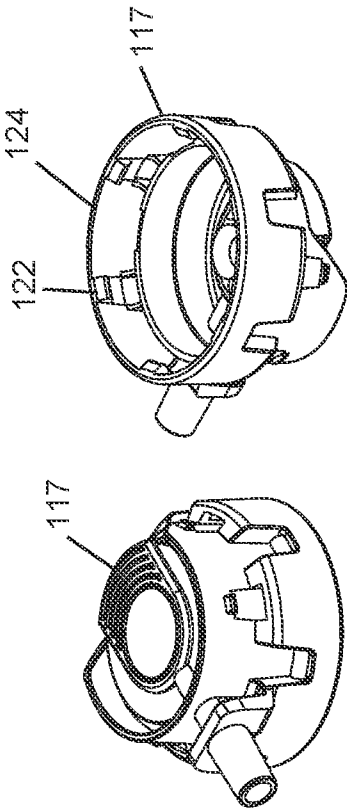


FIG. 10B

FIG. 10A

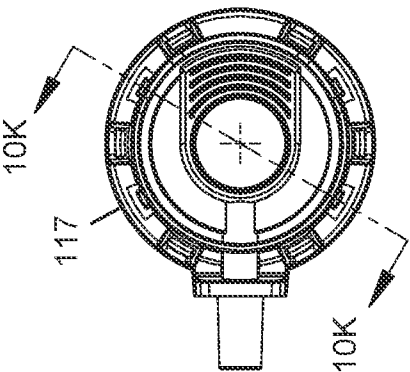
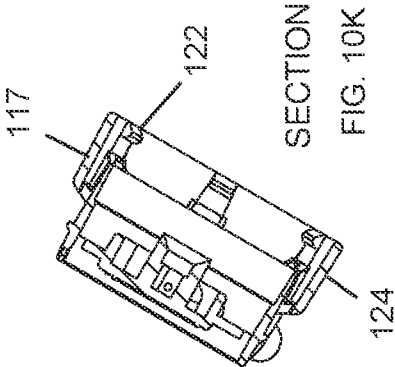


FIG. 10J



SECTION
FIG. 10K

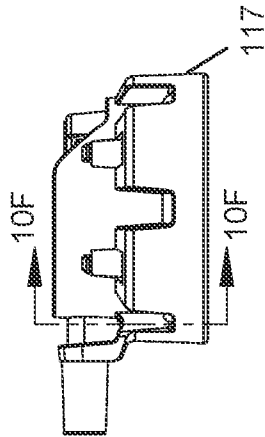


FIG. 10E

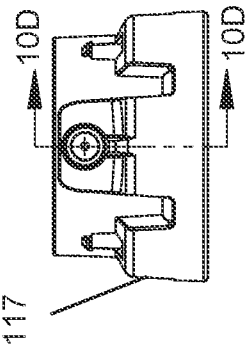


FIG. 10C

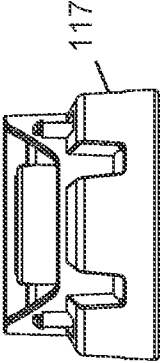
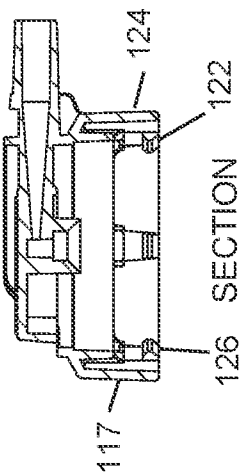


FIG. 10I



SECTION
FIG. 10D

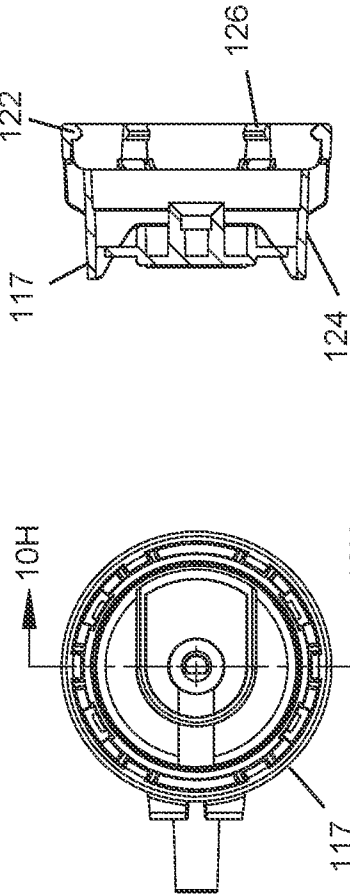
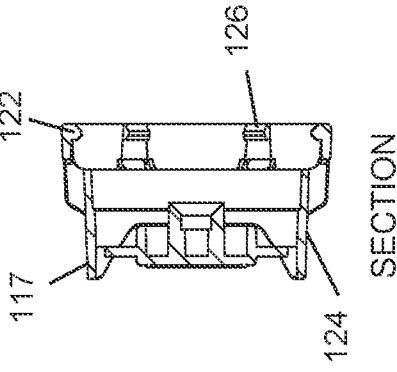
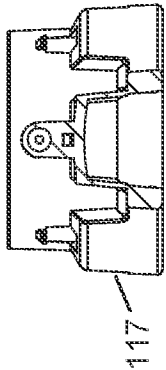


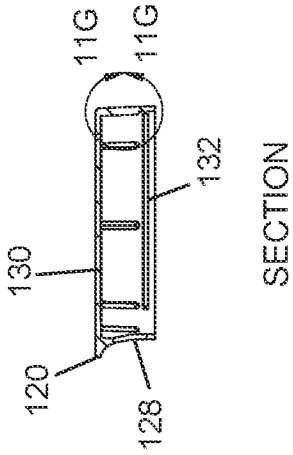
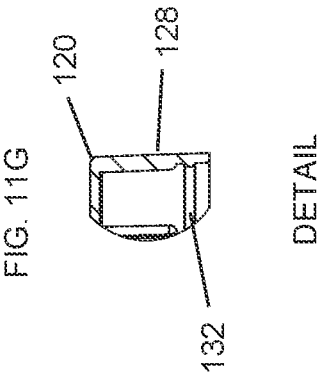
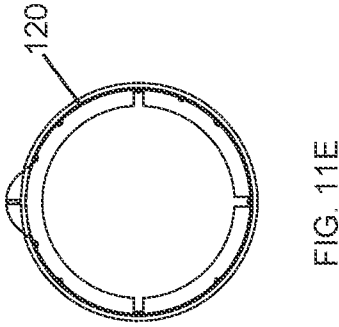
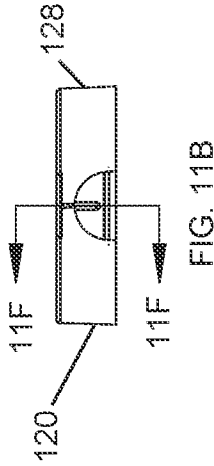
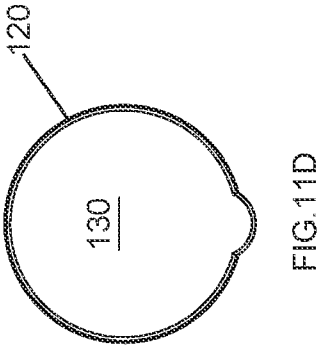
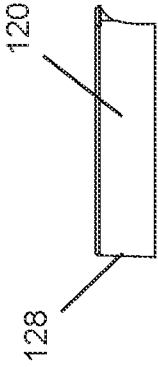
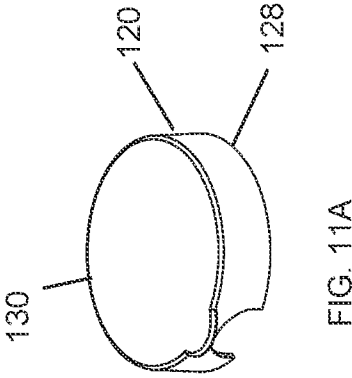
FIG. 10H



SECTION
FIG. 10H



SECTION
FIG. 10F



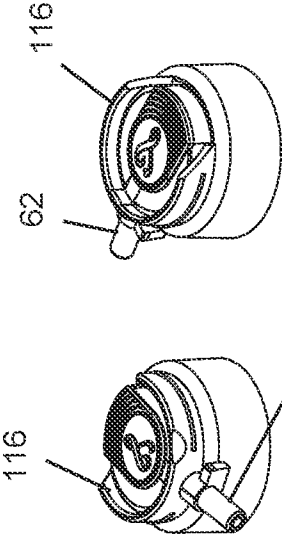
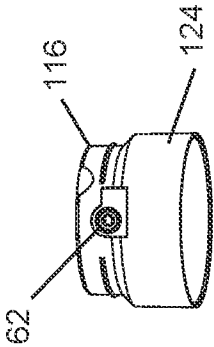


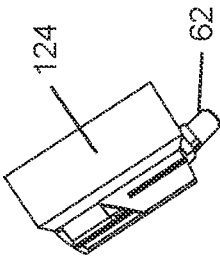
FIG. 12A

FIG. 12B



VIEW

FIG. 12I



VIEW

FIG. 12J

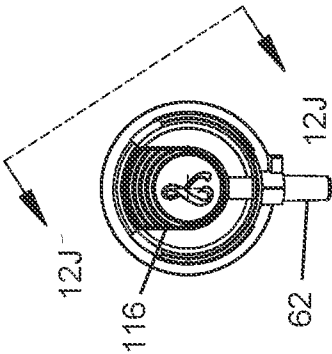


FIG. 12F

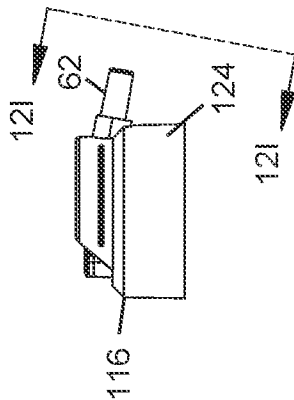


FIG. 12D

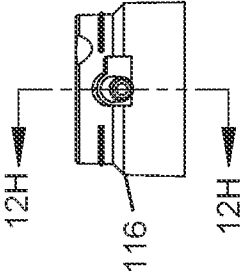


FIG. 12C

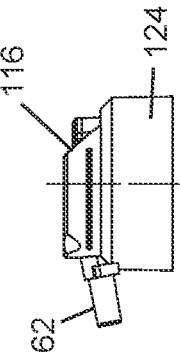
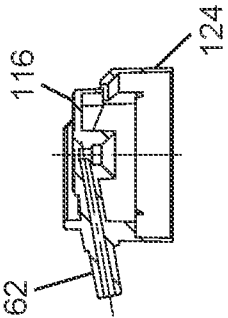


FIG. 12G



SECTION

FIG. 12H

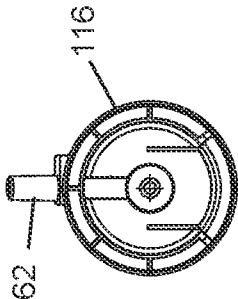


FIG. 12E

FIG. 13A

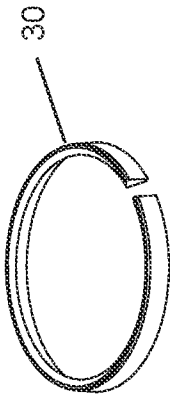


FIG. 13C

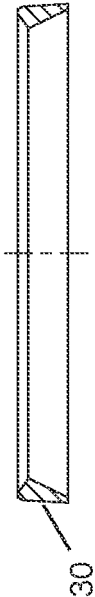
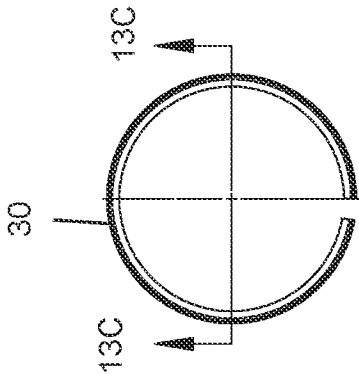
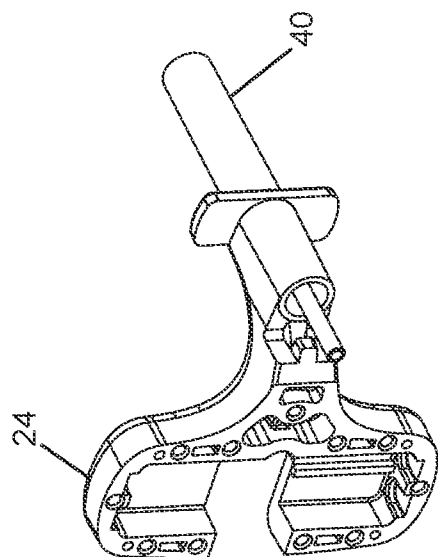
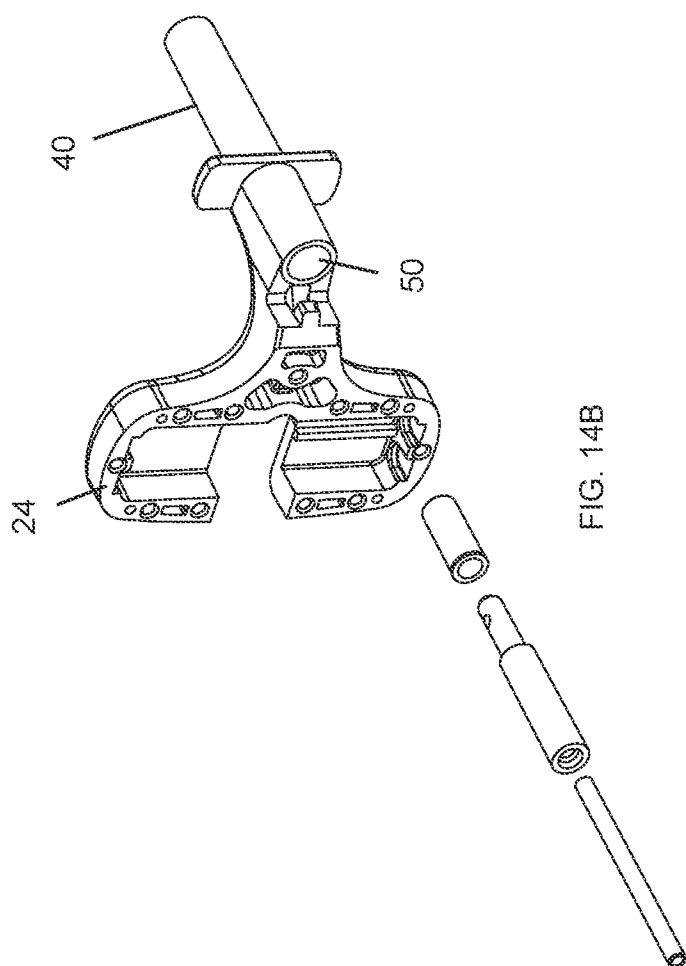


FIG. 13B





14A
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G.
m
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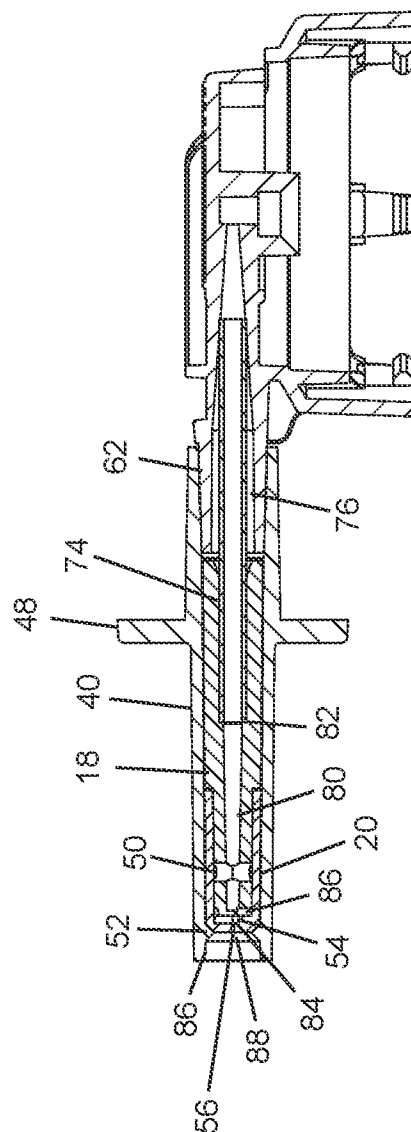


FIG. 14C

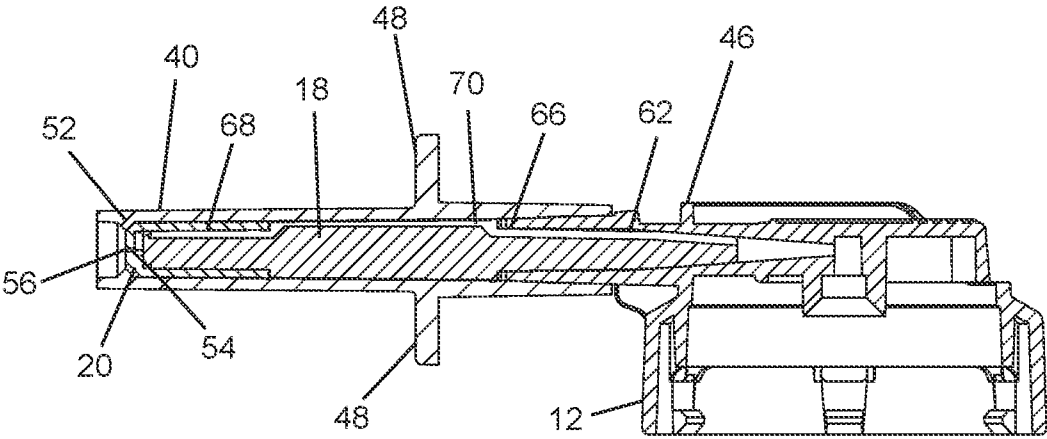


FIG. 15

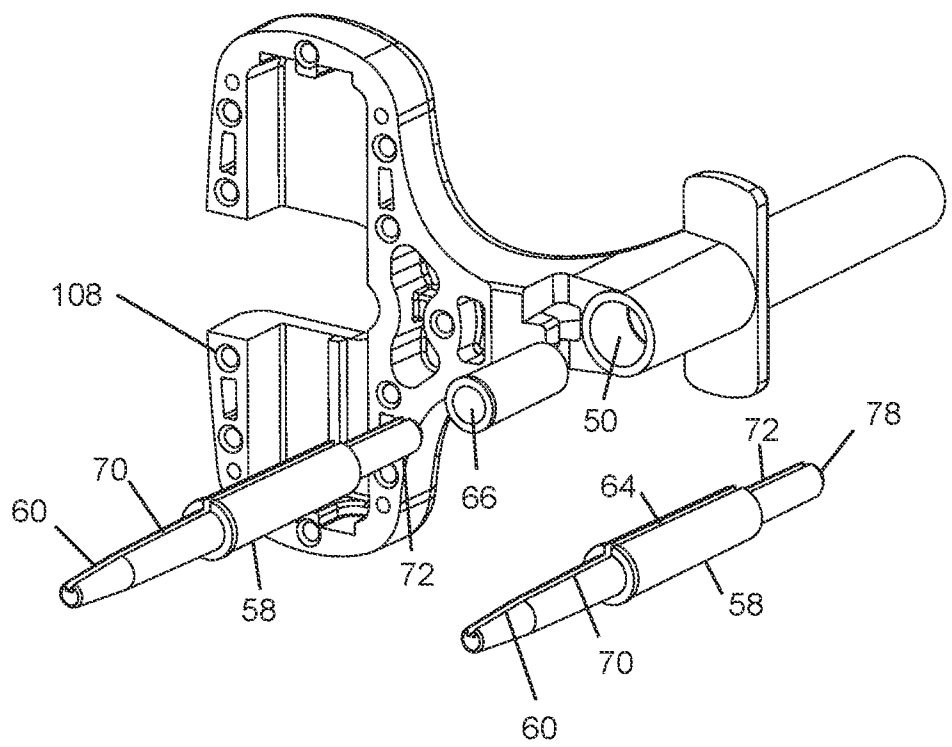


FIG. 16

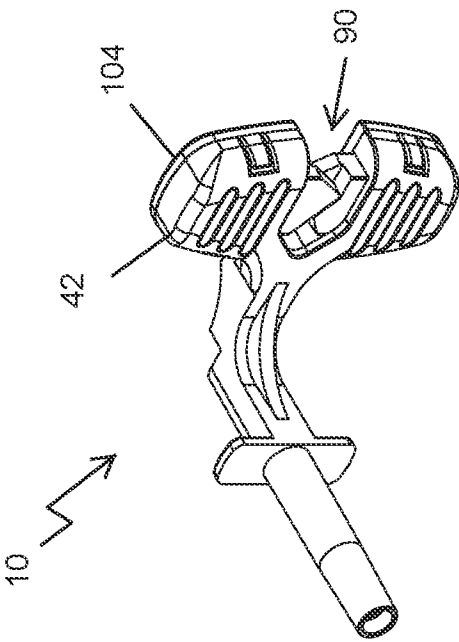


FIG. 17A

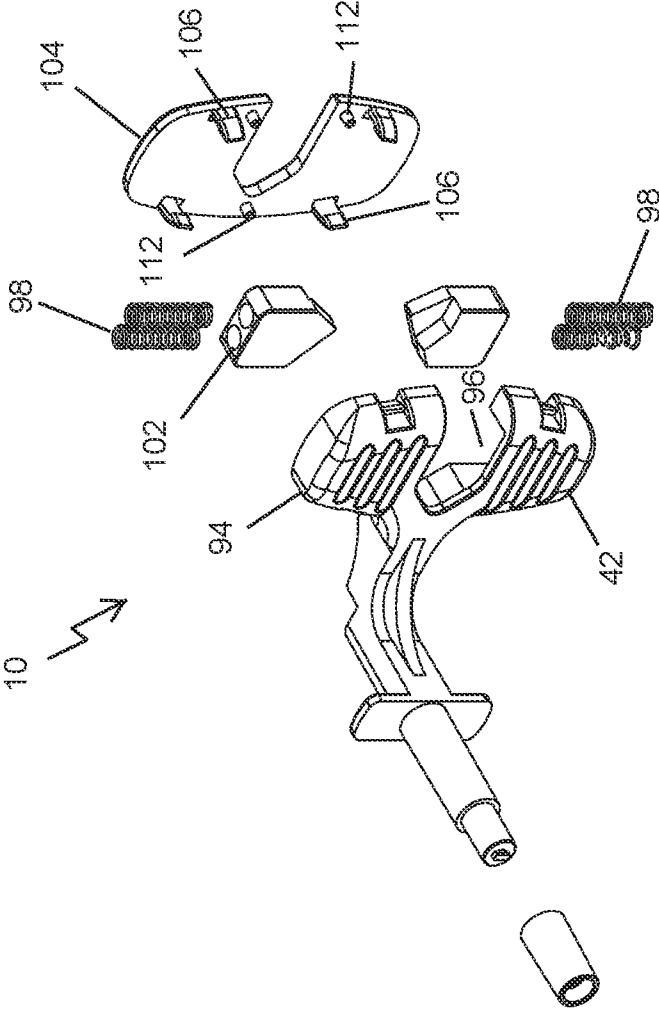


FIG. 17B

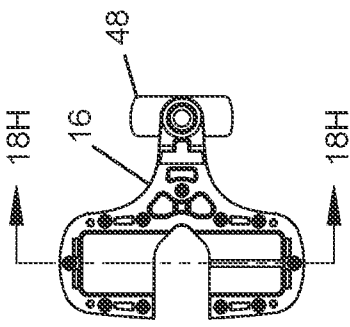
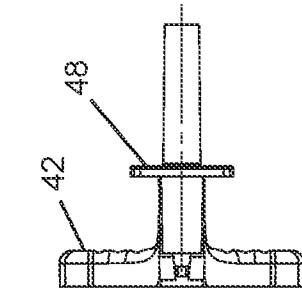
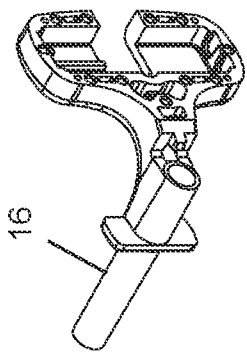
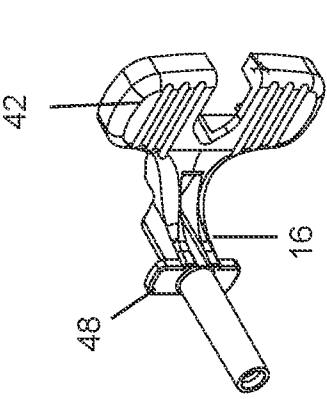


FIG. 18E

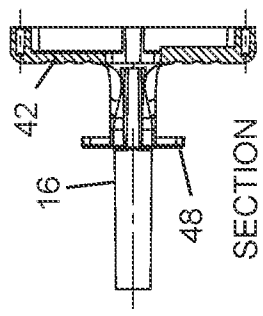


FIG. 18G

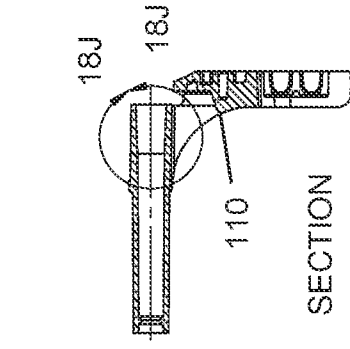


FIG. 18I

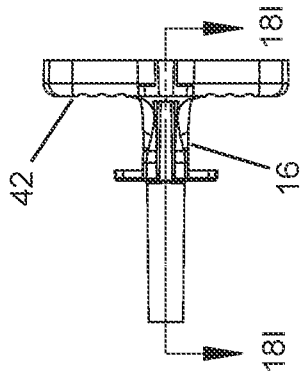


FIG. 18K

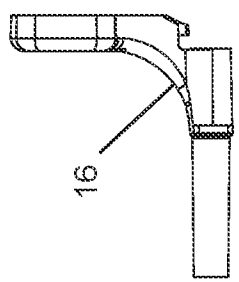


FIG. 18M

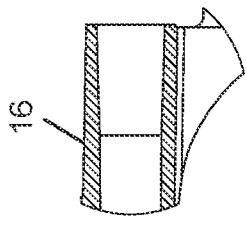


FIG. 18O

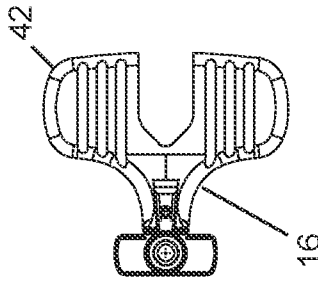


FIG. 18Q



FIG. 18S



FIG. 18U



FIG. 18W



FIG. 18Y

FIG. 18AA

FIG. 18AC

FIG. 18AE

FIG. 18AG

FIG. 18AI

FIG. 18AK

FIG. 18AM

FIG. 18AO

FIG. 18AQ

FIG. 18AS

FIG. 18AU

FIG. 18AW

FIG. 18AY

FIG. 18BA

FIG. 18BC

FIG. 18BE

FIG. 18BG

FIG. 18BI

FIG. 18BK

FIG. 18BM

FIG. 18BO

FIG. 18BQ

FIG. 18BS

FIG. 18BU

FIG. 18BW

FIG. 18BY

FIG. 18CA

FIG. 18CC

FIG. 18CE

FIG. 18CG

FIG. 18CI

FIG. 18CK

FIG. 18CM

FIG. 18CO

FIG. 18CQ

FIG. 18CS

FIG. 18CU

FIG. 18CW

FIG. 18CY

FIG. 18DA

FIG. 18DC

FIG. 18DE

FIG. 18DF

FIG. 18DG

FIG. 18DH

FIG. 18DI

FIG. 18DJ

FIG. 18DK

FIG. 18DL

FIG. 18DM

FIG. 18DN

FIG. 18DO

FIG. 18DP

FIG. 18DQ

FIG. 18DR

FIG. 18DS

FIG. 18DT

FIG. 18DU

FIG. 18DV

FIG. 18DW

FIG. 18DX

FIG. 18DY

FIG. 18DZ

FIG. 18EA

FIG. 18EB

FIG. 18EC

FIG. 18ED

FIG. 18EE

FIG. 18EF

FIG. 18EG

FIG. 18EH

FIG. 18EI

FIG. 18EJ

FIG. 18EK

FIG. 18EL

FIG. 18EM

FIG. 18EN

FIG. 18EO

FIG. 18EP

FIG. 18EQ

FIG. 18ER

FIG. 18ES

FIG. 18ET

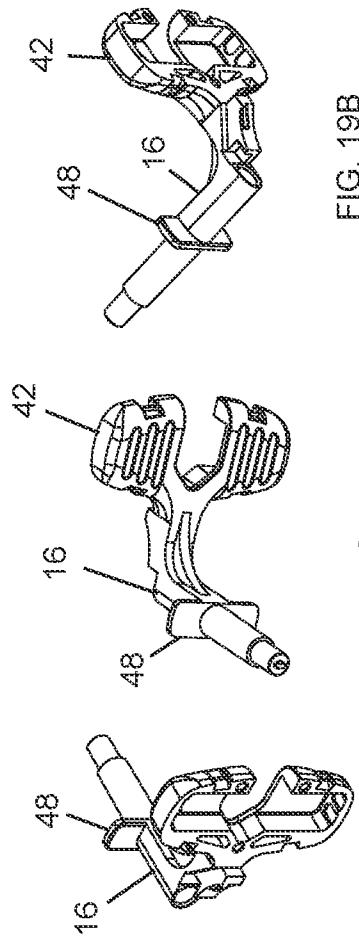


FIG. 19A

FIG. 19B

FIG. 19C

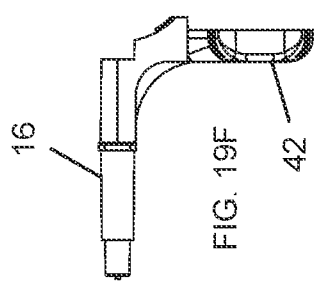


FIG. 19F

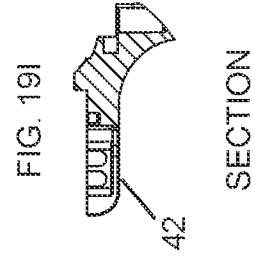


FIG. 19I

SECTION

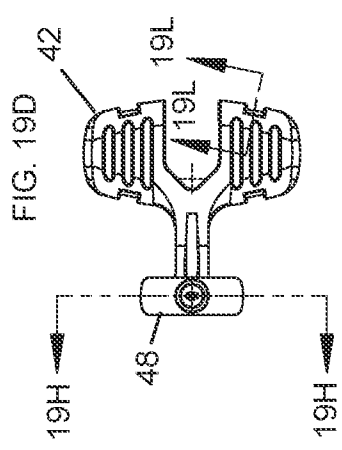


FIG. 19D

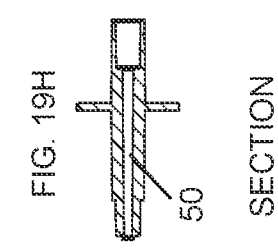


FIG. 19H

SECTION

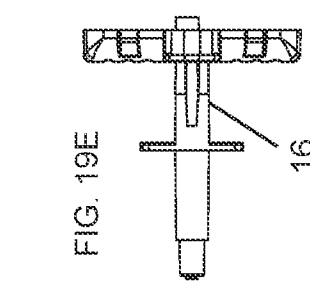


FIG. 19E

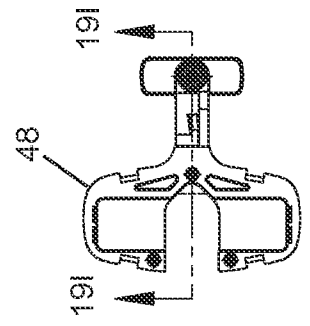


FIG. 19G

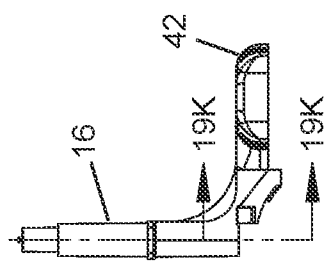


FIG. 19J

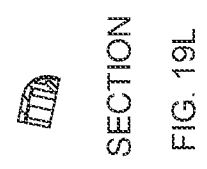


FIG. 19L

SECTION

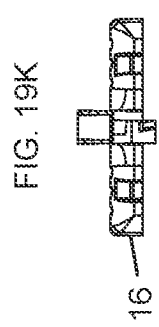


FIG. 19K

SECTION

FIG. 20A

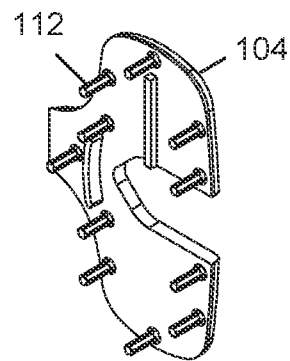
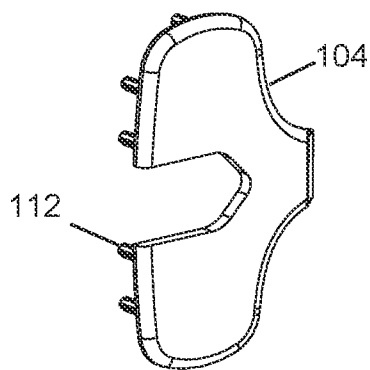


FIG. 20B

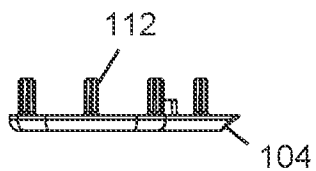


FIG. 20D

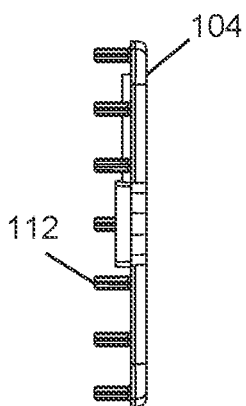


FIG. 20F

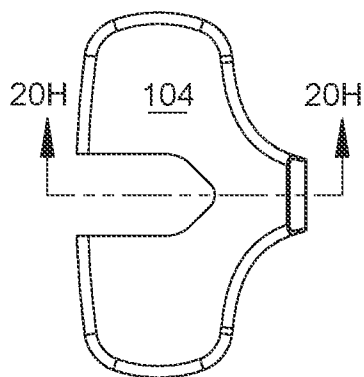


FIG. 20C

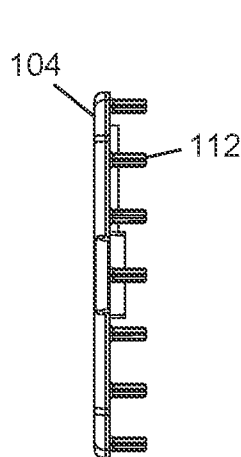


FIG. 20E

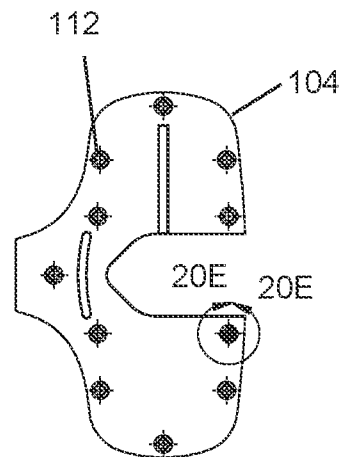
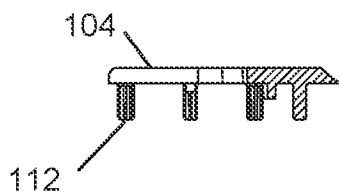
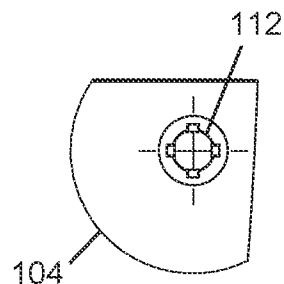


FIG. 20G



SECTION
FIG. 20H



DETAIL
FIG. 20I

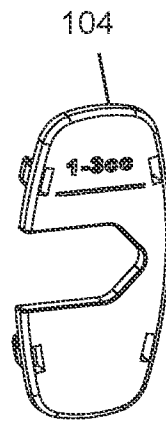


FIG. 21B

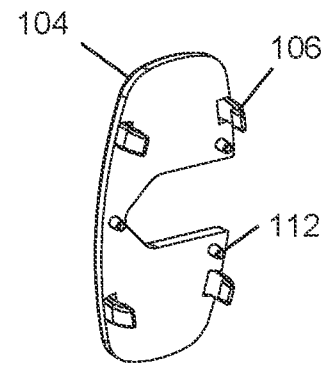


FIG. 21A

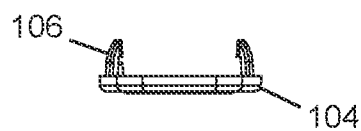


FIG. 21E

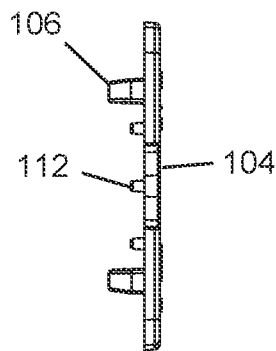


FIG. 21G

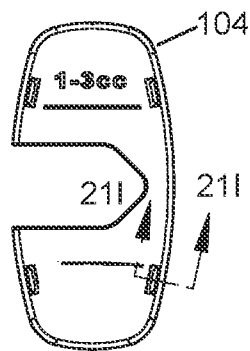


FIG. 21D

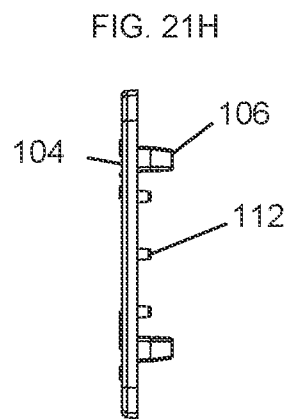


FIG. 21H

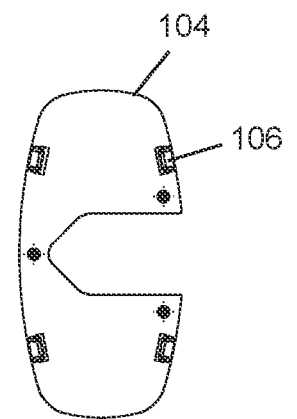
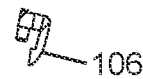


FIG. 21C



SECTION

FIG. 21I

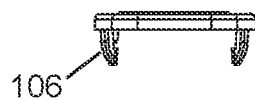


FIG. 21F

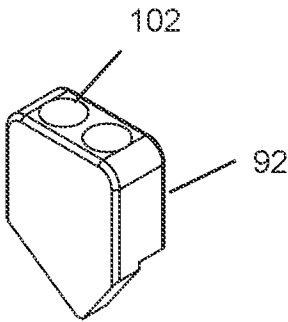


FIG. 22A

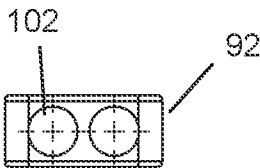


FIG. 22C

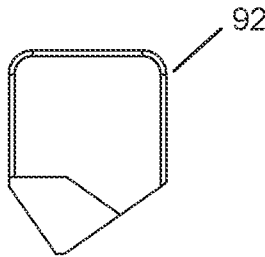


FIG. 22B

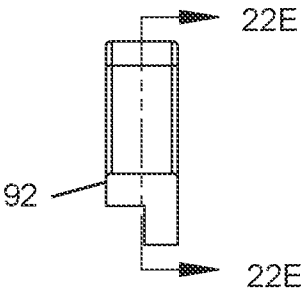
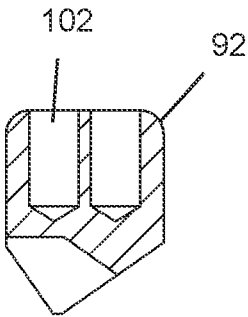


FIG. 22D



SECTION
FIG. 22E

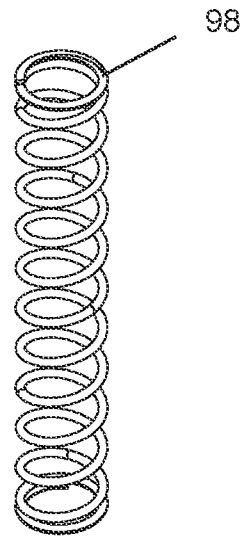


FIG. 23A

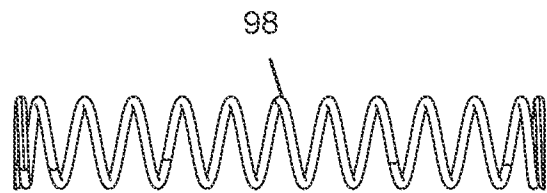


FIG. 23B

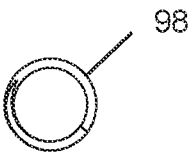


FIG. 23C

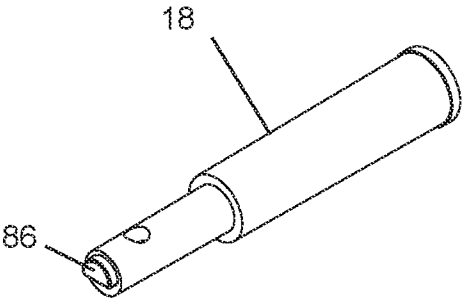


FIG. 24A

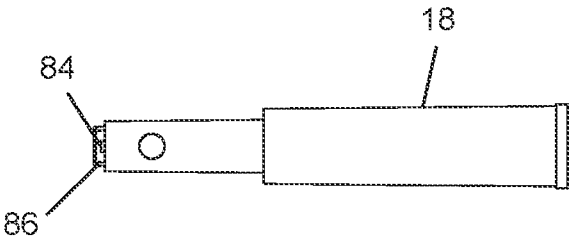


FIG. 24B

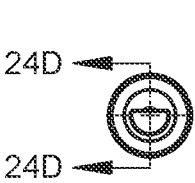
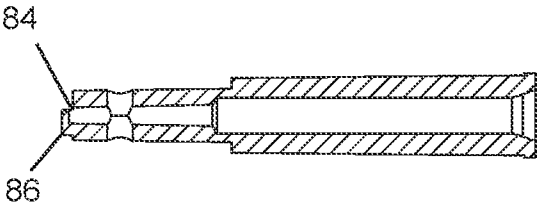


FIG. 24C



SECTION

FIG. 24D

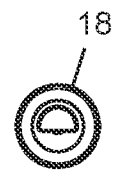
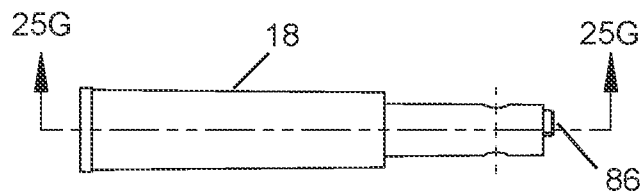
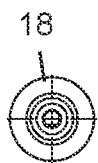
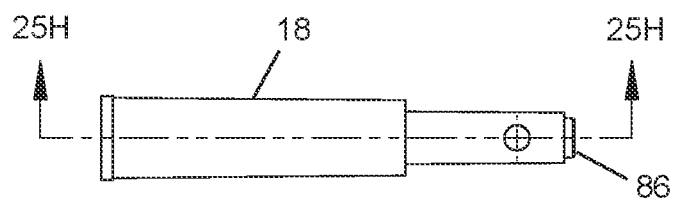
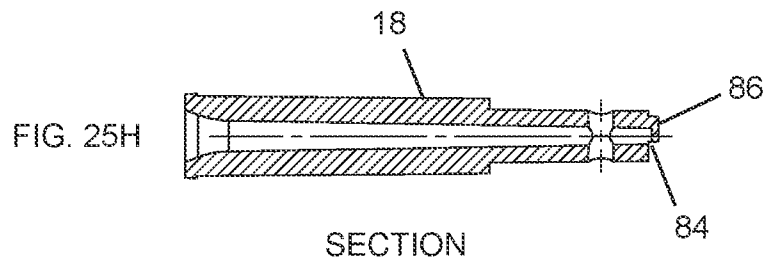
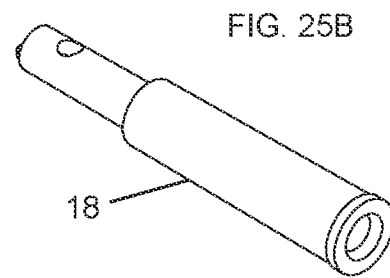
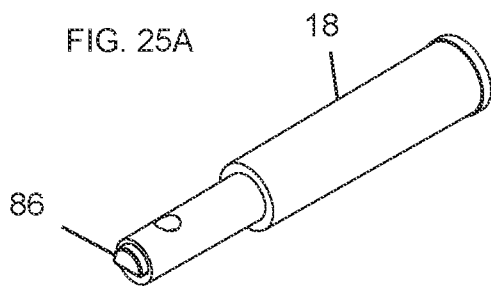
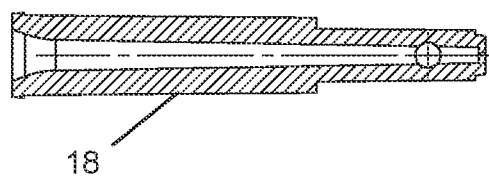


FIG. 25F

FIG. 25E



SECTION

FIG. 25G

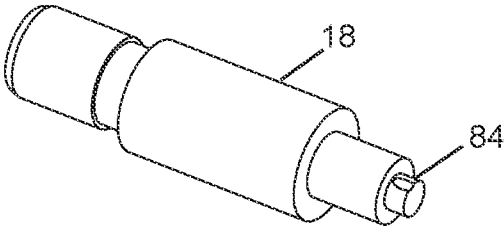


FIG. 26A

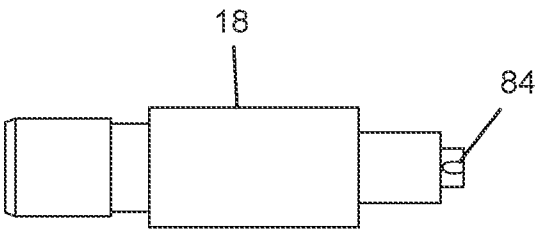


FIG. 26B

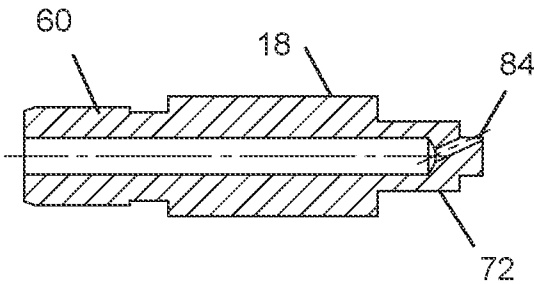


FIG. 26D

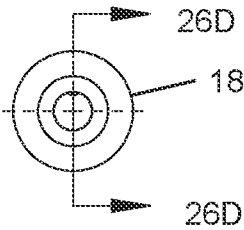


FIG. 26C

SECTION

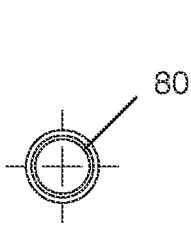
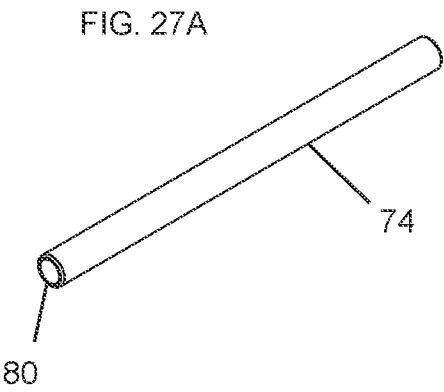


FIG. 27C

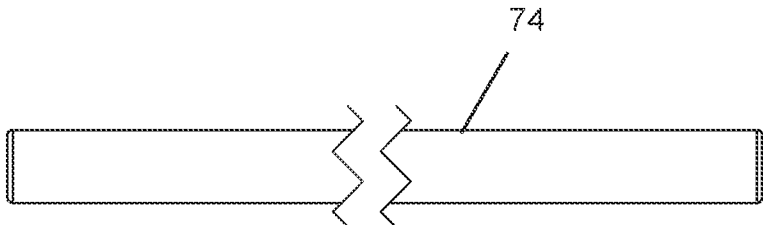


FIG. 27B

FIG. 28A

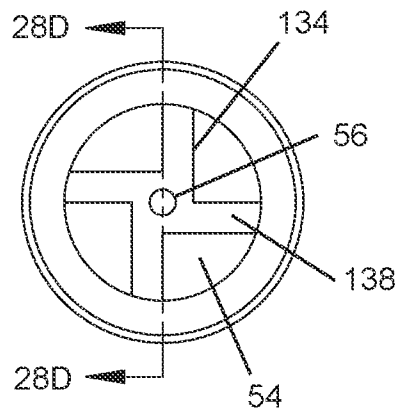
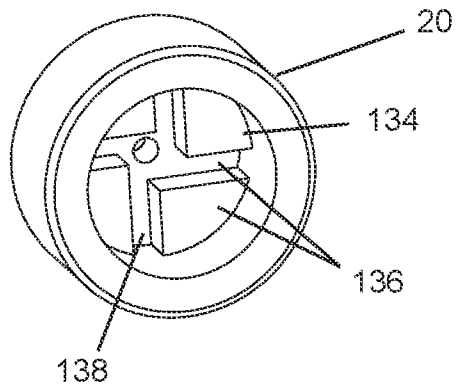
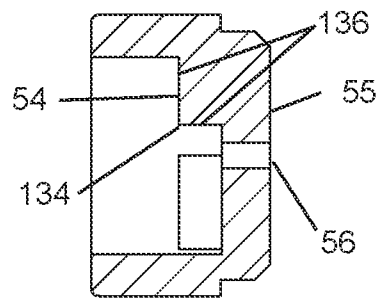


FIG. 28B



SECTION

FIG. 28D

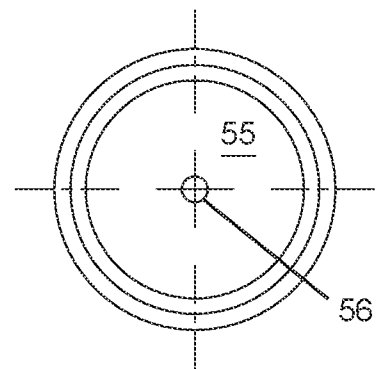


FIG. 28C

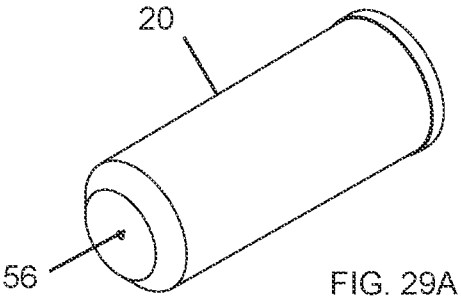
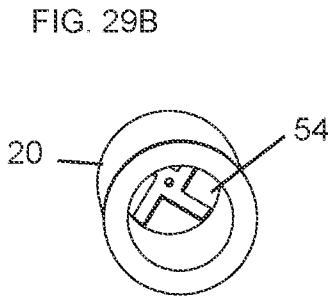


FIG. 29A

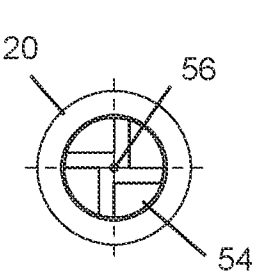
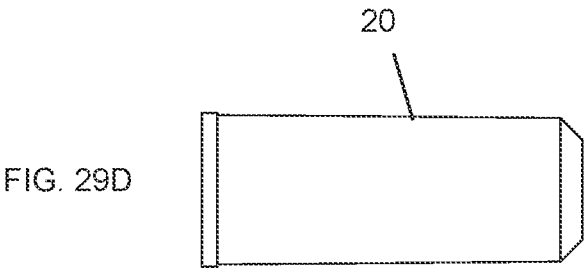


FIG. 29F

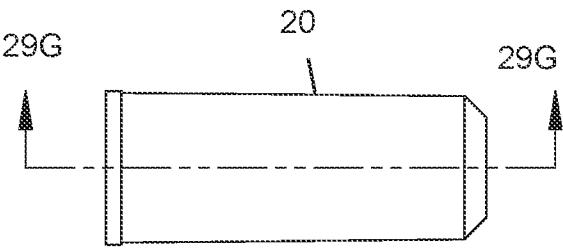


FIG. 29C

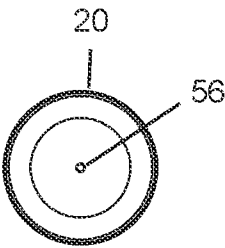
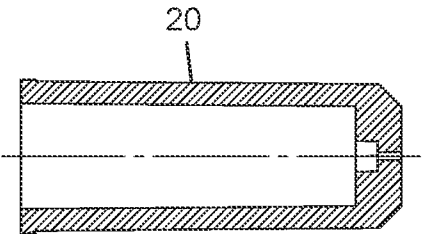


FIG. 29E



SECTION

FIG. 29G

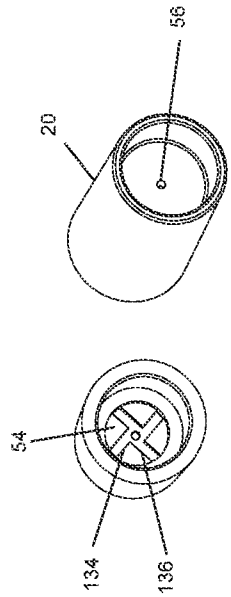


FIG. 30A

FIG. 30B

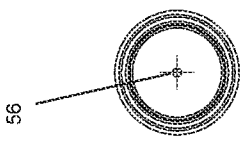


FIG. 30D

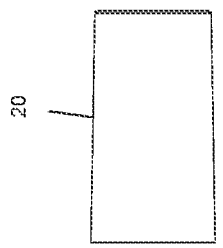


FIG. 30C

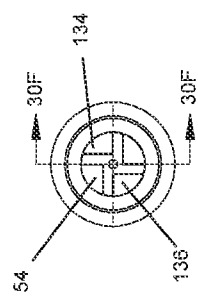
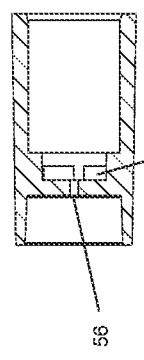


FIG. 30E



SECTION

FIG. 30F

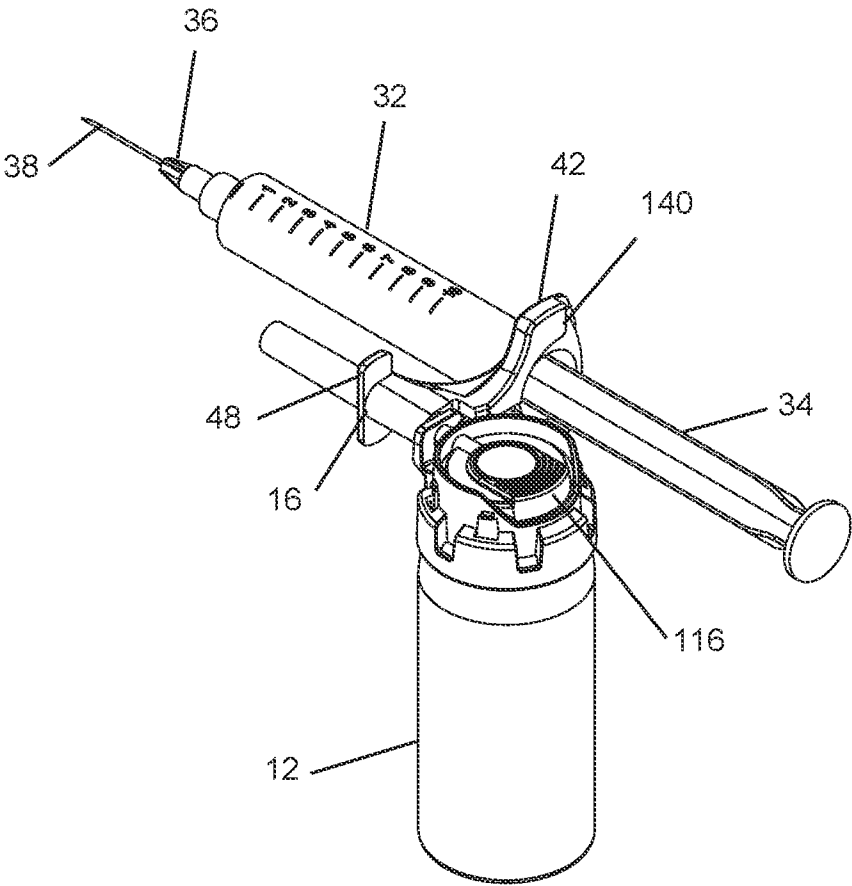


FIG. 31

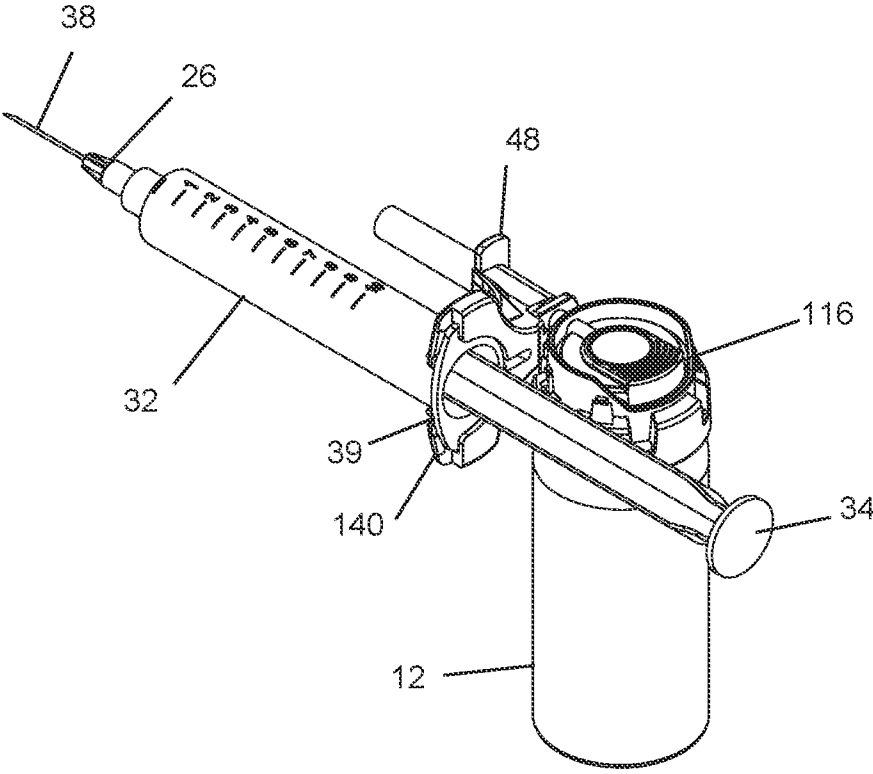
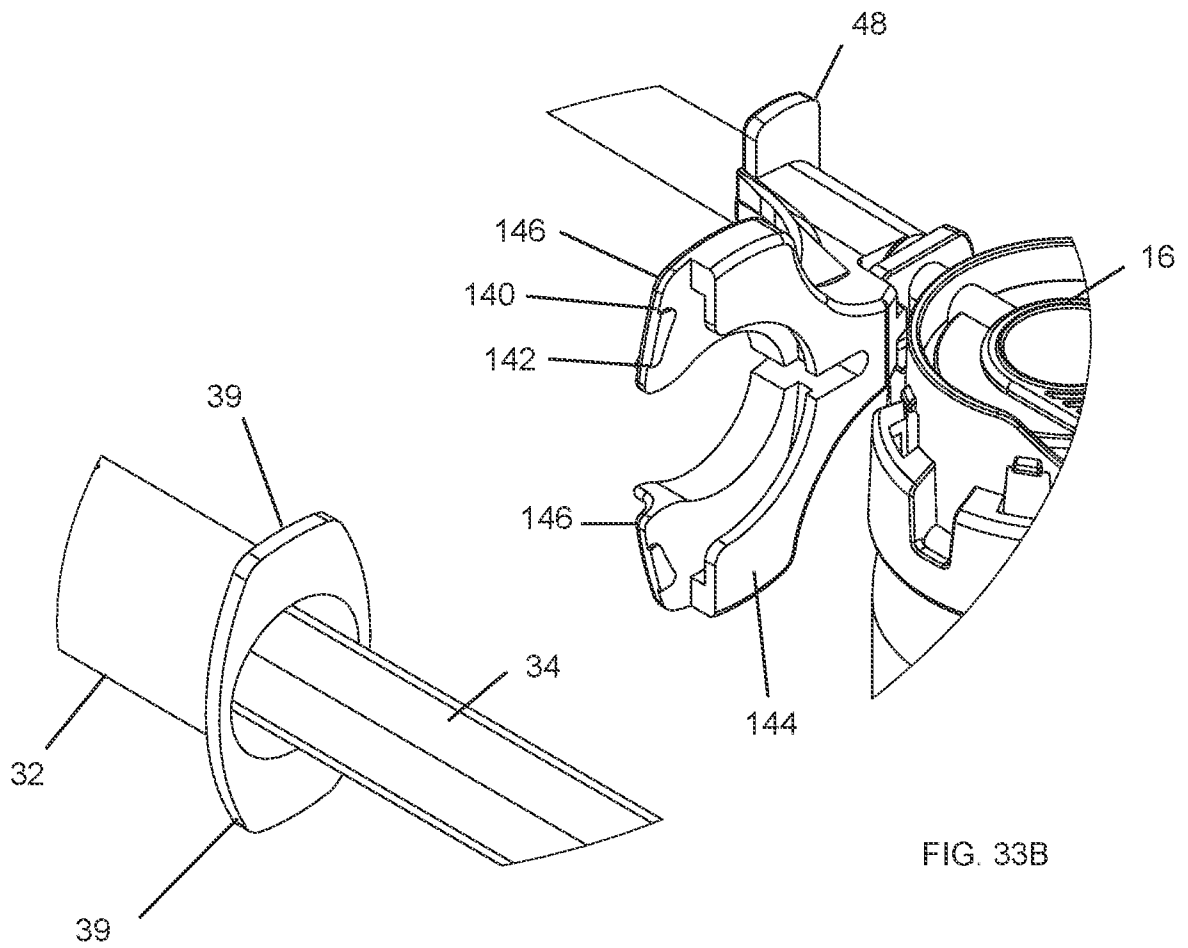
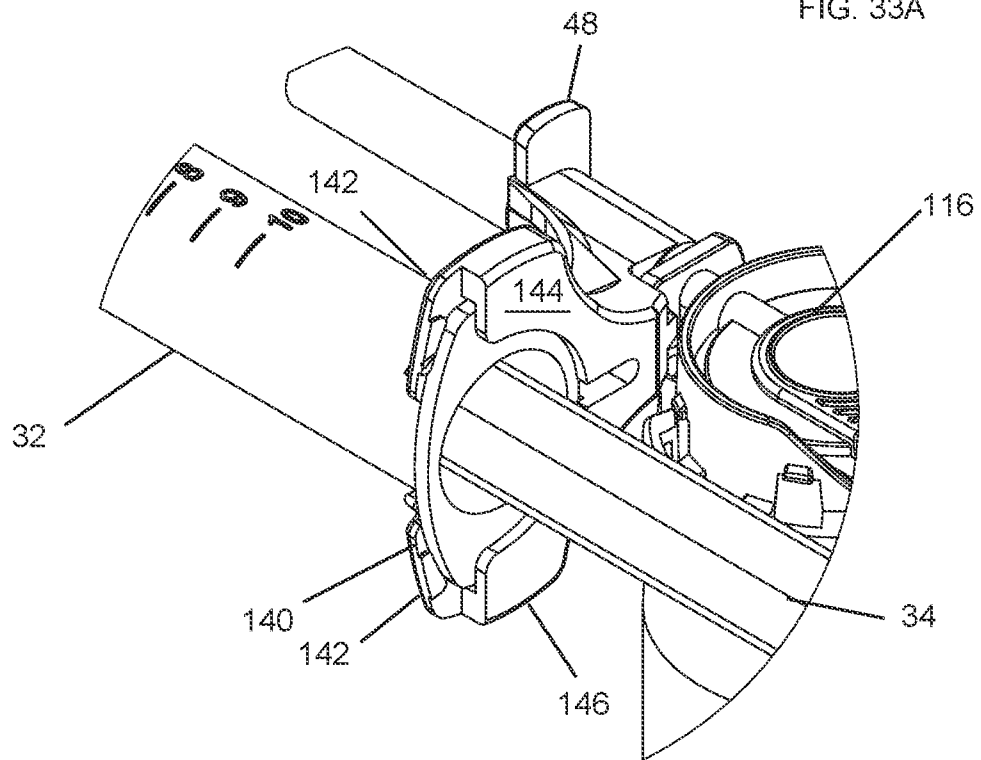


FIG. 32

FIG. 33A



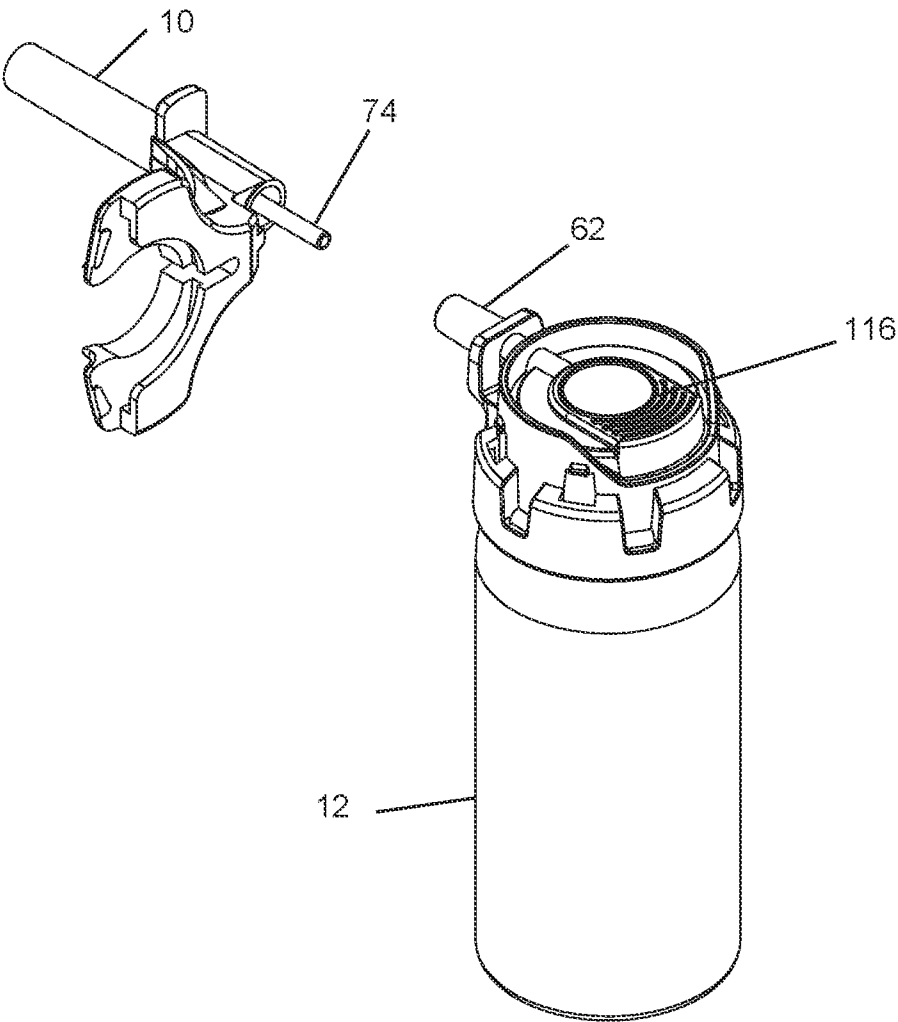


FIG. 34

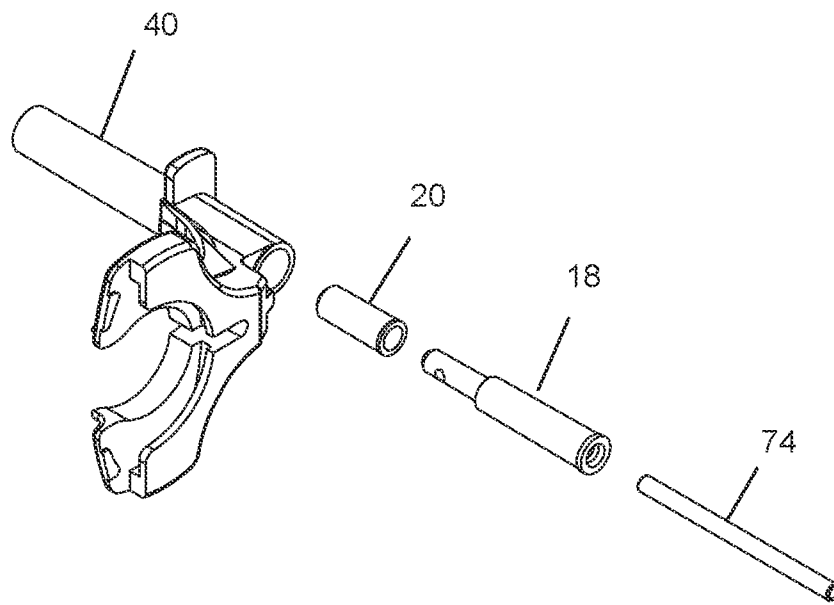
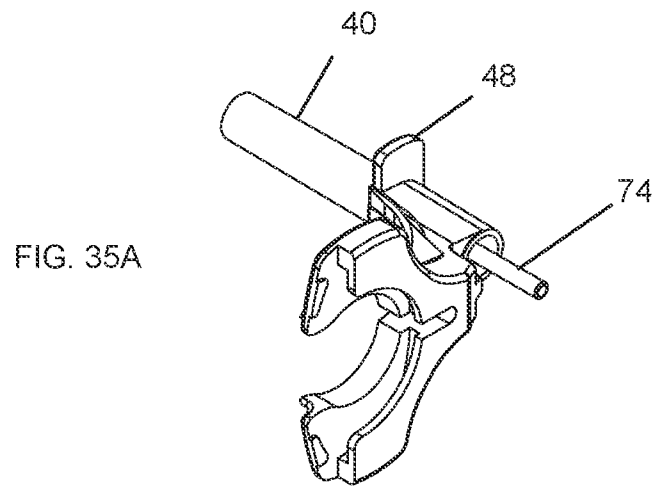


FIG. 35B

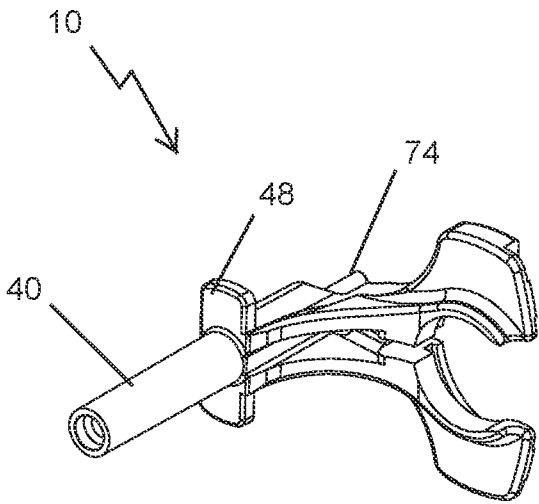


FIG. 36

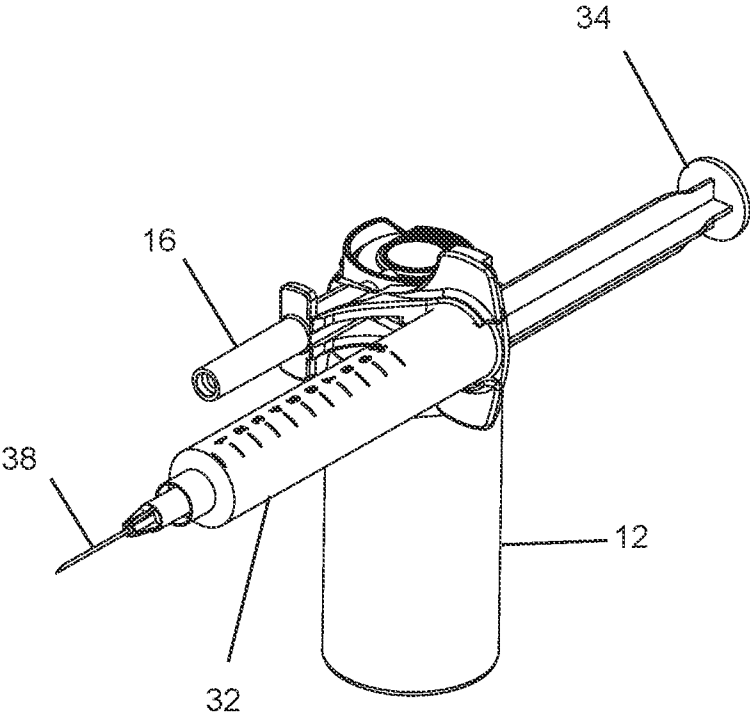


FIG. 37

International application No
PCT/US2022/080577

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2022/080577

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 1 436 855 A (REYNAUD MARC) 29 April 1966 (1966-04-29) figures 1,2 -----	1-16
A	US 5 341 993 A (HABER TERRY M [US] ET AL) 30 August 1994 (1994-08-30) figures 5,6,7 -----	1-16

INTERNATIONAL SEARCH REPORT

Information on patent family members

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