

Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

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All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the Add button.					Add	
Title of Invention		MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES				
Attorney Docket Number (if applicable)		031312-06399				
Correspondence Address						
Direct all correspondence to (select one):						
☒ The address corresponding to Customer Number			☐ Firm or Individual Name			
Customer Number			90259			

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.	
☒ No.	
☐ Yes, the name of the U.S. Government agency and the Government contract number are:	

Entity Status

Applicant claims small entity status under 37 CFR 1.27

- ☐ Yes, applicant qualifies for small entity status under 37 CFR 1.27
- ☒ No

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Signature

Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Walter M. Egbert, III/			Date (YYYY-MM-DD)	2010-05-17
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This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in handling the provisional application.**

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**MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING
MEDICAL DEVICES**

BACKGROUND OF THE INVENTION

[0001] Diabetes Mellitus is an incurable chronic disease in which the body does not produce or properly utilize insulin. Insulin is a hormone produced by the pancreas that regulates blood sugar (glucose). In particular, when blood sugar levels rise, *e.g.*, after a meal, insulin lowers the blood sugar levels by facilitating blood glucose to move from the blood into the body cells. Thus, when the pancreas does not produce sufficient insulin (a condition known as Type 1 Diabetes) or does not properly utilize insulin (a condition known as Type 2 Diabetes), the blood glucose remains in the blood, resulting in hyperglycemia or abnormally high blood sugar levels.

[0002] The fluctuations in blood glucose levels in people suffering from diabetes cause long-term, serious complications. Some of these complications include blindness, kidney failure, and nerve damage. Additionally, it is known that diabetes is a factor in accelerating cardiovascular diseases such as atherosclerosis (hardening of the arteries), leading to stroke, coronary heart disease, and other diseases. Accordingly, one important and universal strategy in managing diabetes is to control blood glucose levels.

[0003] One way to manage blood glucose levels is testing and monitoring blood glucose levels by using conventional *in vitro* techniques, such as drawing blood samples, applying the blood to a test strip, and determining the blood glucose level using colorimetric, electrochemical, or photometric test meters. Another more recent technique for monitoring blood glucose levels is by using an *in vivo* glucose-monitoring system, that continuously and/or automatically tests glucose, such as, for example, the FreeStyle Navigator® Continuous Glucose Monitoring

System, manufactured by Abbott Diabetes Care, Inc. Unlike conventional blood glucose meters, continuous analyte-monitoring systems employ a sensor at least a portion of which is positioned in a subject, which detects and monitors blood glucose levels. Prior to each use of a new sensor, the user self-inserts at least a portion of the sensor under his/her skin. An inserter assembly may be employed to insert the sensor in the body of the user. In this manner, an introducer sharp, while engaged to the sensor, pierces an opening into the skin of the user, releases the sensor, and is removed from the body of the user. Accordingly, there exists a need for an easy-to-use, simple, insertion assembly that is reliable, minimizes pain, and is easy to use.

SUMMARY

[0004] Sensors for detecting a physical parameter of a subject are disclosed herein. In some embodiments, a sensor is used to determine a level of analyte, such as, *e.g.*, glucose. Devices are disclosed for inserting a sensor into a subject, *e.g.*, at least partially beneath the skin of a subject. Sensor assemblies that include a medical device, such as a sensor and/or an infusion device, and a device to position at least a portion of the medical device are provided, as well as methods of positioning at least a portion of a medical device such as a sensor (*e.g.*, a glucose sensor) and/or an infusion device, and methods of using a positioned medical device, *e.g.*, methods for analyte testing are disclosed herein.

[0005] Sensor assembly embodiments include a housing adapted to adhere to the skin of a subject; an analyte sensor coupled or coupleable to the housing; and an insertion sharp having a longitudinal body including a longitudinal opening to receive at least a portion of the sensor.

[0006] In certain embodiments, the sensor includes a body having a proximal section and a distal section, and the distal section may be longitudinally (or otherwise) aligned with the

proximal section. Some sensor embodiments may include an intermediate section. An intermediate section, if present, may or may not be laterally displaced from at least the distal member, and a gap may be defined between the laterally displaced intermediate section and a portion of the distal section. A second gap may be defined in the sensor between the proximal section and the laterally displaced intermediate section. The proximal section of the sensor may have a substantially curved profile. A proximal section and a distal section of a given sensor may or may not be in axial alignment with respect to each other.

[0007] In some embodiments, the distal section of the sensor body is received in the longitudinally defined opening of the insertion sharp. A gap may be defined between the distal section and the laterally displaced intermediate section, which allows the distal section, in some embodiments a substantial portion – including the entirety of the distal section – to be received in the longitudinal opening of the insertion needle. The intermediate section and the proximal section may be proximate the distal section received in the insertion needle.

[0008] In some embodiments, the proximal section of the sensor may be disposed in a horizontal plane, and the distal section of the sensor body may be disposed in a vertical plane, at least during a sensing operation. In some embodiments, the sensor is configured for insertion in a soft tissue of a user. In some embodiments, the sensor is a glucose sensor.

[0009] Embodiments include sensor assemblies which include a sensor including a portion for operative contact with a fluid of the subject; a housing defining a distal surface adapted for attachment to the skin of a subject and housing a circuit coupled to sensor for performing a function with the sensor. In some embodiments, the sensor is integrated with the circuit within the housing to define an on-body device such as a single-unit on-body device. In some

embodiments, a switch is provided at least partially disposed in the housing and having a member defining a first position which protrudes from the distal surface of the mount and a second position which is recessed in the mount, the member configured to activate the circuit when in the second position.

[0010] In some embodiments, the member is biased in the first position. The member may include an elongated member disposed in an opening in the mount. In some embodiments, the member is moved from the first position to the second position when the mount contacts the skin of the subject. In some embodiments, an adhesive layer is disposed on the skin of the subject, and wherein the member is moved from the first position to the second position when the mount contacts the adhesive layer.

[0011] In some embodiments, the switch activates the circuit upon the member reaching the second position. In some embodiments, the switch activates the circuit as long as the member is maintained in the second position. In some embodiments, the sensor is a glucose sensor.

[0012] In some embodiments, the circuit applies a potential to the sensor. In some embodiments, the circuit applies a current to the sensor.

[0013] Embodiments include apparatuses for inserting medical devices at least partially through the skin of a subject. An insertion apparatus may include a sheath defining a distal surface for placement on the skin of the subject; a device support movable between a proximal and distal position, and adapted to support a medical device; a sharp support movable between a proximal position and a distal position, and adapted to support a sharp extending through a portion of the device support; a handle movable between a proximal position and distal position relative to the sheath and adapted to urge the device support and the sharp support from a

proximal to a distal position and defining guides for slidable engagement with the sharp support and the device support and a driver for biasing the handle towards the proximal position.

[0014] In some embodiments, the user attaches the inserter to the skin, pressing on the sheath to secure the device adhesively to the skin. The handle is pressed distally urging the device and sharp support into the skin and at the same time energizes the driver element. Once the handle is bottomed out and the medical device placed with respect to the skin, the user releases pressure on the handle. The driver element retracts the device and sharp support, while the device is left coupled to the skin (either mechanically or adhesively). The sharp is retracted from the skin, and the inserter device can be removed.

[0015] In variations of the above embodiment, the driver includes a compression member such as a compression spring. The handle is at least partially disposed within the sheath or is at least partially disposed surrounding the sheath. The sharp support may be permanently fixed to the handle. The device support may be permanently affixed to the handle.

[0016] In some embodiments, a stop portion for retaining the device support in the distal position is included. In some embodiments, the device support is coupled to the sharp support until the device support reaches a distal position.

[0017] In some embodiments, the device support is uncoupled from the sharp support when the device support reaches the distal position. In some embodiments, a retention member is provided to couple the sharp support to the sheath when the sharp support is disposed in the proximal position.

[0018] In some embodiments, the medical device is an analyte sensor. In some embodiments, the medical device is a glucose sensor. In some embodiments, the medical device is an infusion set.

[0019] In certain embodiments, apparatuses for inserting a medical device at least partially through the skin of a subject are provided which include a sheath defining a distal surface for placement on the skin of the subject; a handle movable between a proximal position and distal position; a device support for supporting the medical device and defining an aperture therethrough, the device support coupled to the handle; a sharp support for supporting a sharp extending through said aperture and coupled to the device support; and driver for biasing the sharp support towards the proximal position.

[0020] In some embodiments, the driver includes a compression spring. In some embodiments, the handle is at least partially disposed surrounding the sheath.

[0021] In some embodiments, a stop portion for retaining the device support in the distal position is included. In some embodiments, the device support is coupled to the handle until the device support reaches a distal position. In some embodiments, the device support is uncoupled from the sharp support when the device support reaches the distal position.

[0022] In some embodiments, a second assembly interfaces with the insertion devices or first subassembly. The second assembly automates the insertion segment motion of the described inserter. The second assembly may include a housing configured for removable attachment to the first subassembly, a handle configured for longitudinal movement with respect to the housing, an actuator configured for longitudinal movement with respect to the housing, a release member either located on the actuator or handle which is actuated upon the handle reaching a

predetermined position, a driver element coupled between the handle and the actuator, energized upon distal movement of the handle, which drives the actuator distally once the release member is actuated, and a second driver which is also energized upon distal movement of the handle, that applies a proximal force on the handle that returns the handle to a proximal position after pressure is relieved from the handle post insertion. The second driver, coupled through the handle, also provides a proximal force to return the actuator to its proximal position where the release member is reengaged.

[0023] In some embodiments, the first driver includes a compression spring, or a torsion spring.

[0024] In some embodiments, the handle is at least partially disposed surrounding the sheath. In some embodiments, a retention member for retaining the device support in the distal position is provided. The device support may be coupled to the handle until the device support reaches a distal position.

[0025] In some embodiments, the first subassembly is configured for a single use. In some embodiments, the second subassembly is configured for multiple uses.

[0026] Embodiments of analyte sensors are provided which include a body having a proximal section and a distal section. The distal section may be longitudinally aligned with the proximal section. An intermediate section may be included between the proximal and distal sections, and in some embodiments the intermediate section is laterally displaced from at least the distal member. A gap may be defined between the laterally displaced intermediate section and a portion of the distal section.

[0027] In some embodiments, the proximal end is received within a needle seat to create an anchor region to allow the sensor body to slide into an opening defined in the insertion sharp but prevent the sensor body from inadvertently slipping out of the insertion needle. In some embodiments, a width of the distal section of the sensor body is sized to fit within the opening of the insertion sharp. In certain embodiments, the opening in the sharp has a diameter of about 20 to about 26 gauge, *e.g.*, 21 gauge to about 25 gauge, where in certain embodiments the sharp is 21 gauge or 23 gauge or 25 gauge. Such sharp may be used with a sensor having a width or diameter – at least the portion that is carried by the sharp – of about .20 mm to about .80 mm, *e.g.*, about .25 mm to about .60 mm, where in some embodiments the width or diameter of at least a portion of a sensor is .27 mm or .33 mm or .58 mm.

[0028] In some embodiments, the intermediate member includes a plane-altering portion. The plane-altering portion allows the proximal section of the sensor body to be in a plane different than the distal section of the sensor body. In some embodiments, the proximal section and the distal section are in planes substantially perpendicular to each other, *e.g.*, the area may define an angle of about 120° to about 60°, *e.g.*, about 90°.

[0029] In some embodiments, the proximal section has a curved portion.

[0030] In some embodiments, the sensor body includes conductive material disposed in or on a surface thereto to define one or more electrodes. The sensor body may include conductive material defining traces disposed in or on a surface of the sensor body. The traces are in communication with the one or more electrodes. The traces may be disposed in or on at least one surface of the proximal section of the sensor body. The one or more electrodes may be disposed on the distal section of the sensor body. At least one of the traces or electrodes may

include a metal or carbon material such as gold, platinum, titanium, and carbon. At least one of the traces or electrodes may be formed by ablation of material. The ablation may include laser ablation. In some embodiments, the sensor is a wire.

[0031] In some embodiments, the sensor includes a sensing layer. The sensing layer may include an enzyme. The sensing layer may include an electron transfer agent. The electron transfer agent may be a redox mediator. In some embodiments, the electron transfer agent includes osmium transition metal complexes and one or more ligands. The electron transfer agent may be configured to transfer electrons directly between the analyte and the working electrode. The electron transfer agent may be configured to transfer electrons indirectly between the analyte and the working electrode.

[0032] In some embodiments, the sensing layer includes a redox polymer. The redox polymer may include osmium. The sensing layer may include a catalyst. The catalyst may include an enzyme. The catalyst may act as an electron transfer agent. In some embodiments, the enzyme includes glucose oxidase. In some embodiments, the enzyme includes glucose dehydrogenase.

[0033] In some embodiments, the sensing layer is configured such that the reaction of glucose in the presence of an enzyme forms hydrogen peroxide, and glucose level may be correlated to the level of hydrogen peroxide. In some embodiments, the sensor is a subcutaneous sensor.

[0034] These and other features, objects, and advantages of the disclosed subject matter will become apparent to those persons skilled in the art upon reading the detailed description as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] A detailed description of various aspects, features, and embodiments of the subject matter described herein is provided with reference to the accompanying drawings, which are briefly described below. The drawings are illustrative and are not necessarily drawn to scale, with some components and features being exaggerated for clarity. The drawings illustrate various aspects and features of the present subject matter and may illustrate one or more embodiment(s) or example(s) of the present subject matter in whole or in part.

[0036] **FIGURE 1** is a schematic view of the system in accordance with one embodiment of the disclosed subject matter;

[0037] **FIGURE 2** is a view, in partial cross section, of an electrochemical sensor in accordance with one embodiment of the disclosed subject matter;

[0038] **FIGURE 3** is a view, in partial cross-section, of an electrochemical sensor in accordance with another embodiment of the disclosed subject matter;

[0039] **FIGURE 4** is a view of the electrochemical sensor of FIGURE 3 in a folded configuration in accordance with the disclosed subject matter;

[0040] **FIGURE 5A** is a view of an electrochemical sensor in accordance with a further embodiment of the disclosed subject matter;

[0041] **FIGURE 5B** is a view of the electrochemical sensor of FIGURE 5 in a folded configuration in accordance with the disclosed subject matter;

[0042] **FIGURES 6A-6B** are views of an electrochemical sensor in accordance with a further embodiment of the disclosed subject matter;

[0043] **FIGURE 7** is a perspective view of an on-body unit in accordance with one embodiment of the disclosed subject matter;

[0044] **FIGURE 8** is a perspective view in partial cross-section of an on-body unit of FIGURE 7 in accordance with the disclosed subject matter;

[0045] **FIGURE 9** is a schematic view of the system in accordance with one embodiment of the disclosed subject matter;

[0046] **FIGURE 10** is a sectional, perspective view of another embodiment of an inserter in accordance with the disclosed subject matter;

[0047] **FIGURES 11-12** are perspective views of components of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0048] **FIGURE 13** is a sectional, perspective view of a component of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0049] **FIGURES 14-15** are perspective views of components of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0050] **FIGURE 16** is a sectional view of the component of FIGURE 15 in accordance with the disclosed subject matter;

[0051] **FIGURES 17-18** are schematic views of a needle hub in accordance with one embodiment of the disclosed subject matter;

[0052] **FIGURE 19** is a distal end view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0053] **FIGURE 20** is a side view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0054] **FIGURE 21** is a side view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0055] **FIGURE 21A** is a perspective view with parts separated of an inserter in accordance with one embodiment of the disclosed subject matter;

[0056] **FIGURE 21B** is a schematic view of an alternate embodiment for forming a sharp to be used in an inserter in accordance with one embodiment of the disclosed subject matter;

[0057] **FIGURE 22** is a perspective view of an inserter in accordance with one embodiment of the disclosed subject matter;

[0058] **FIGURE 23** is a perspective view with parts separated of an inserter in accordance with one embodiment of the disclosed subject matter;

[0059] **FIGURE 24** is an enlarged sectional view with parts separated of an inserter in accordance with one embodiment of the disclosed subject matter;

[0060] **FIGURES 25-27** are perspective views of components of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0061] **FIGURES 28-29** are sectional views of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0062] **FIGURES 30-31** are sectional views of components of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0063] **FIGURE 31A** is a sectional view of components of the inserter of FIGURE 10 shown separated from the on-body unit in accordance with the disclosed subject matter.

[0064] **FIGURES 32-33** illustrate, by schematic, a power supply switch mechanism including conductive plug of the on-body integrated sensor and sensor electronics assembly in accordance with embodiments of the disclosed subject matter;

[0065] **FIGURE 34** is a perspective view of an embodiment of an inserter in accordance with one embodiment of the disclosed subject matter;

[0066] **FIGURES 35-36** are perspective views of the inserter of FIGURE 34 in accordance with the disclosed subject matter;

[0067] **FIGURES 37-39** are sectional, perspective views of the inserter of FIGURE 34 in accordance with the disclosed subject matter;

[0068] **FIGURES 40-41** are perspective views of the inserter of FIGURE 34 in accordance with the disclosed subject matter;

[0069] **FIGURES 42-43** are perspective views of another embodiment of an inserter in accordance with the disclosed subject matter;

[0070] **FIGURES 44-49** are perspective views of components of the inserter of FIGURE 42 in accordance with the disclosed subject matter;

[0071] **FIGURE 50** is a sectional view of the inserter of FIGURE 42 in accordance with the disclosed subject matter;

[0072] **FIGURE 51** is a sectional, perspective view of the inserter of Figure 42 in accordance with the disclosed subject matter;

[0073] **FIGURE 52** is a perspective view of the inserter of FIGURE 42 in accordance with the disclosed subject matter;

[0074] **FIGURES 53-54** are sectional, perspective views of the inserter of FIGURE 42 in accordance with the disclosed subject matter;

[0075] **FIGURES 55-56** are perspective views of the inserter of FIGURE 42 in accordance with the disclosed subject matter;

[0076] **FIGURES 57-58** are perspective views of another embodiment of an inserter in accordance with the disclosed subject matter;

[0077] **FIGURES 59-63** are perspective views of components of the inserter of FIGURE 57 in accordance with the disclosed subject matter;

[0078] **FIGURE 64** is a sectional views of the inserter of FIGURE 57 in accordance with the disclosed subject matter;

[0079] **FIGURES 65-67** are sectional, perspective views of the inserter of Figure 57 in accordance with the disclosed subject matter;

[0080] **FIGURE 68** is a perspective view of another embodiment of an inserter In accordance with the disclosed subject matter;

[0081] **FIGURE 69** is a side view of the inserter of FIGURE 68 in accordance with the disclosed subject matter;

[0082] **FIGURES 70-71** are cross-sectional views of the inserter of FIGURE 68 in accordance with the disclosed subject matter;

[0083] **FIGURE 72** is a cross-sectional view of another inserter in accordance with the disclosed subject matter;

[0084] **FIGURE 72A** is an exploded perspective view of the inserter of FIGURE 72 in accordance with the disclosed subject matter;

[0085] **FIGURES 72B-I** are perspective views of the inserter of FIGURE 72 showing the assembly of various components in accordance with the disclosed subject matter;

[0086] **FIGURES 72J-N** are cross-sectional views of the inserter of FIGURE 72 in accordance with the disclosed subject matter;

[0087] **FIGURE 72O** illustrates a process for utilizing a sterilized versions of the inserter of FIGURE 72 in accordance with the disclosed subject matter;

[0088] **FIGURE 72P** illustrates an alternate process for utilizing a sterilized versions of the inserter of FIGURE 72 in accordance with the disclosed subject matter;

[0089] **FIGURE 73** is a perspective view of another inserter in accordance with the disclosed subject matter;

[0090] **FIGURE 73A** is a perspective view of a component of the inserter of FIGURE 73 in accordance with the disclosed subject matter;

[0091] **FIGURE 73B** is a cross-sectional view of a component of the inserter of FIGURE 73 in accordance with the disclosed subject matter;

[0092] **FIGURES 73C-G** are perspective views of a components of the inserter of FIGURE 73 in accordance with the disclosed subject matter;

[0093] **FIGURES 73H-N** are cross-sectional views of the inserter of FIGURE 73 in accordance with the disclosed subject matter;

[0094] **FIGURE 73O** illustrates a process for utilizing a sterilized versions of the inserter of FIGURE 72 in accordance with the disclosed subject matter;

[0095] **FIGURE 74** is a perspective view of another inserter in accordance with the disclosed subject matter;

[0096] **FIGURES 74A-74C** are perspective views of various components of the inserter of FIGURE 74;

[0097] **FIGURE 74D** is a partial cross-section view of a component of the inserter FIGURE 74;

[0098] **FIGURE 74E-74F** are perspective views of various components of the inserter of FIGURE 74;

[0099] **FIGURES 75A-75C** depict different subassemblies of the components of the inserter of FIGURE 74;

[00100] **FIGURES 75D-75E** are cross-sectional views of a subassembly of the components of the inserter of FIGURE 74;

[00101] **FIGURES 76A-76C** depict the steps used to actuate the inserter of FIGURE 74;

[00102] **FIGURES 77-78** are perspective views of an inserter in accordance with another embodiment of the disclosed subject matter;

[00103] **FIGURES 79-80** are perspective views of the inserter of the embodiment of FIGURE 77 in combination with the inserter of FIGURE 68 in accordance with another embodiment of the disclosed subject matter;

[00104] **FIGURES 81-83** are side views of the inserter of the embodiment of FIGURE 77 in combination with the inserter of FIGURE 68 in accordance with another embodiment of the disclosed subject matter;

[00105] **FIGURES 84-85** are perspective views of an inserter in accordance with another embodiment of the disclosed subject matter;

[00106] **FIGURES 86-87** are perspective views of the inserter of the embodiment of FIGURE 84 in combination with the inserter of FIGURE 68 in accordance with another embodiment of the disclosed subject matter;

[00107] **FIGURES 88-90** are side views of the inserter of the embodiment of FIGURE 84 in combination with the inserter of FIGURE 68 in accordance with another embodiment of the disclosed subject matter;

[00108] **FIGURES 91-92** are perspective views of an inserter in accordance with another embodiment of the disclosed subject matter;

[00109] **FIGURES 92A-92J** are views of the inserter of FIGURES 91-92 showing the inserter actuation process;

[00110] **FIGURE 93** is a perspective view of an inserter in accordance with the disclosed subject matter;

[00111] **FIGURES 93A-93E** are cross-sectional views of the inserter of FIGURE 93 in accordance with the disclosed subject matter;

[00112] **FIGURES 93F-93H** are perspective views of components of the inserter of FIGURE 93 in accordance with the disclosed subject matter;

[00113] **FIGURE 94** is a perspective view of an inserter in accordance with the disclosed subject matter;

[00114] **FIGURE 94A** is a perspective view with parts separated of the inserter of FIGURE 94 in accordance with the disclosed subject matter;

[00115] **FIGURES 94B-94I** are cross-sectional views of the inserter of FIGURE 94 in accordance with the disclosed subject matter;

[00116] **FIGURE 95** is a perspective view of an inserter assembly in accordance with the disclosed subject matter;

[00117] **FIGURE 96** is a perspective view of a component of an inserter assembly of FIGURE 95 in accordance with the disclosed subject matter;

[00118] **FIGURE 97** is a perspective view of a component of an analyte measurement system in accordance with the disclosed subject matter;

[00119] **FIGURE 98** is a perspective view with parts separated of the inserter assembly of FIGURE 95 in accordance with the disclosed subject matter;

[00120] **FIGURE 99** is a cross-sectional view of the inserter assembly of FIGURE 95 in accordance with the disclosed subject matter;

[00121] **FIGURE 100** is a side view of a portion of an inserter assembly in accordance with the disclosed subject matter;

[00122] **FIGURE 101** is a top view of an analyte sensor in accordance with the disclosed subject matter;

[00123] **FIGURES 102-103** are perspective views of a portion of an inserter assembly in accordance with the disclosed subject matter;

[00124] **FIGURES 104-114** are views of analyte sensors in accordance with the disclosed subject matter;

[00125] **FIGURES 115-116** are cross-sectional views of an inserter assembly in accordance with the disclosed subject matter;

[00126] **FIGURES 117-118** are cross-sectional views of another inserter assembly in accordance with the disclosed subject matter;

[00127] **FIGURES 119-120** are cross-sectional views of a further inserter assembly in accordance with the disclosed subject matter;

[00128] **FIGURES 121-122** are views of a portion of an inserter assembly in accordance with the disclosed subject matter;

[00129] **FIGURE 123** is a cross-sectional view of a portion of an inserter assembly in accordance with the disclosed subject matter;

[00130] **FIGURES 124-125** are perspective views of a portion of an inserter assembly in accordance with the disclosed subject matter;

[00131] **FIGURES 126-129** are side views of various inserter assemblies in accordance with the disclosed subject matter;

[00132] **FIGURES 130-135** are views of a sharp and sharp carrier in accordance with the disclosed subject matter;

[00133] **FIGURE 136** is a perspective view of a portion of an inserter assembly in accordance with the disclosed subject matter;

[00134] **FIGURES 137-140** are perspective views illustrating the operation of an inserter assembly in accordance with the disclosed subject matter;

[00135] **FIGURE 141** is a side view of an inserter assembly in accordance with the disclosed subject matter;

[00136] **FIGURES 142-144** are cross-sectional views of an inserter assembly in accordance with the disclosed subject matter;

[00137] **FIGURE 145** is a perspective view with parts separated of an embodiment of a sharp/sensor cartridge in accordance with the disclosed subject matter;

[00138] **FIGURE 146** is a perspective view of the cartridge of FIGURE 145 in a first stage of deployment in accordance with the disclosed subject matter;

[00139] **FIGURE 147** is a cross-sectional view of the cartridge of FIGURE 145 in a neutral state in accordance with the disclosed subject matter;

[00140] **FIGURE 148** is a perspective view of the cartridge of FIGURE 145 in a neutral state in accordance with the disclosed subject matter;

[00141] **FIGURE 149** is a cross-sectional view of the cartridge of FIGURE 145 in a first stage of deployment in accordance with the disclosed subject matter;

[00142] **FIGURE 150** is a perspective view of the cartridge of FIGURE 145 in a second stage of deployment in accordance with the disclosed subject matter;

[00143] **FIGURE 151** is a cross-sectional view of the cartridge of FIGURE 145 in a second stage of deployment in accordance with the disclosed subject matter;

[00144] **FIGURE 152** is a perspective view of the cartridge of FIGURE 145 in a third stage of deployment in accordance with the disclosed subject matter;

[00145] **FIGURE 153** is a cross-sectional view of the cartridge of FIGURE 145 in a third stage of deployment in accordance with the disclosed subject matter;

[00146] **FIGURE 154** is a perspective view with parts separated of another embodiment of a sharp/sensor cartridge in accordance with the disclosed subject matter;

[00147] **FIGURE 155** is a perspective view of the cartridge of FIGURE 154 in a neutral state in accordance with the disclosed subject matter;

[00148] **FIGURE 156** is a cross-sectional view of the cartridge of FIGURE 154 in a neutral state in accordance with the disclosed subject matter;

[00149] **FIGURE 157** is a perspective view of the cartridge of FIGURE 154 in a second stage of deployment in accordance with the disclosed subject matter;

[00150] **FIGURE 158** is a cross-sectional view of the cartridge of FIGURE 154 in a second stage of deployment in accordance with the disclosed subject matter;

[00151] **FIGURE 159** is a perspective view of the cartridge of FIGURE 154 in a third stage of deployment in accordance with the disclosed subject matter; and

[00152] **FIGURE 160** is a cross-sectional view of the cartridge of FIGURE 154 in a third stage of deployment in accordance with the disclosed subject matter.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[00153] A detailed description of the disclosure is provided herein. It should be understood, in connection with the following description, that the subject matter is not limited to particular embodiments described, as the particular embodiments of the subject matter may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the disclosed subject matter will be limited only by the appended claims.

[00154] Where a range of values is provided, it is understood that each intervening value between the upper and lower limit of that range, and any other stated or intervening value in that stated range, is encompassed within the disclosed subject matter. Every range stated is also intended to specifically disclose each and every “subrange” of the stated range. That is, each and every range smaller than the outside range specified by the outside upper and outside lower limits given for a range, whose upper and lower limits are within the range from said outside lower limit to said outside upper limit (unless the context clearly dictates otherwise), is also to be understood as encompassed within the disclosed subject matter, subject to any specifically

excluded range or limit within the stated range. Where a range is stated by specifying one or both of an upper and lower limit, ranges excluding either or both of those stated limits, or including one or both of them, are also encompassed within the disclosed subject matter, regardless of whether or not words such as “from,” “to,” “through,” or “including” are or are not used in describing the range.

[00155] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosed subject matter belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosed subject matter, this disclosure may specifically mention certain exemplary methods and materials.

[00156] All publications mentioned in this disclosure are, unless otherwise specified, incorporated by reference herein for all purposes, including without limitation to disclose and describe the methods and/or materials in connection with which the publications are cited.

[00157] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present disclosed subject matter is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates, which may need to be independently confirmed.

[00158] As used herein and in the appended claims, the singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise.

[00159] Nothing contained in the Abstract or the Summary should be understood as limiting the scope of the disclosure. The Abstract and the Summary are provided for bibliographic and convenience purposes and due to their formats and purposes should not be considered comprehensive.

[00160] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present disclosed subject matter. Any recited method can be carried out in the order of events recited, or in any other order which is logically possible. Reference to a singular item includes the possibility that there are plural of the same item present. When two or more items (for example, elements or processes) are referenced by an alternative “or,” this indicates that either could be present separately or any combination of them could be present together except where the presence of one necessarily excludes the other or others.

System Overview

[00161] Embodiments include analyte monitors that are provided in small, lightweight, battery-powered and electronically-controlled systems. Such systems may be configured to detect physical parameters of subjects, such as signals indicative of *in vivo* analyte levels using an electrochemical sensor, and collect such signals, with or without processing. The electrochemical sensors may employ any suitable measurement technique, *e.g.*, may detect current, may employ potentiometry, etc. Techniques may include, but are not limited to amperometry, coulometry, voltammetry. In some embodiments, sensing systems may be optical,

colorimetric, and the like. In some embodiments, the portion of the system that performs this initial processing may be configured to provide the raw or at least initially processed data to another unit for further collection and/or processing. Such provision of data may be effected, for example, by a wired connection, such as an electrical, or by a wireless connection, such as an IR or RF connection.

[00162] Certain embodiments of analyte-monitoring systems for *in vivo* measurement employ a sensor that measures analyte levels in interstitial fluids at least partially under the surface of the subject's skin. A sensor in such a system may operate as an electrochemical cell. Such a sensor may use any of a variety of electrode configurations, such as a three-electrode configuration (*e.g.*, with “working,” “reference,” and “counter” electrodes) driven by a controlled potential (potentiostat) analog circuit; a two-electrode system configuration (*e.g.*, with only working and counter electrodes or a working electrode and a counter/reference electrode), which may be self-biasing and/or self-powered; and/or other configurations (see, *e.g.*, U.S. Patent Application Serial No. 12/393,921, the disclosure of which is incorporated by reference herein for all purposes). In some embodiments, the sensor may be positioned within a blood vessel.

[00163] In certain systems, the analyte sensor is in communication with a sensor control unit. As used in this disclosure, an on-body unit sometimes refers to such a combination of an analyte sensor with such a sensor control unit. The on-body unit may include a housing in which the sensor control unit electronics and at least a portion of the sensor are received.

[00164] Certain embodiments are modular. The on-body unit may be separately provided as a physically distinct assembly from a monitor unit, *e.g.*, which displays or otherwise indicates analyte levels to a user. The on-body unit may be configured to provide the analyte levels

detected by the sensor and/or other information (such as temperature, sensor life, etc.) over a communication link to the monitor unit. The monitor unit, in some embodiments, may include, *e.g.*, a mobile telephone device, an *in vitro* glucose meter, a personal digital assistant, or other consumer electronics such as MP3 device, camera, radio, personal computer, etc., or other communication-enabled data-processing device.

[00165] The monitor unit may perform a variety of functions such as but not limited to data storage and/or processing and/or analysis and/or communication, etc., on the received analyte data to generate information pertaining to the monitored analyte levels and/or process the other information. The monitor unit may incorporate a display screen, which can be used, for example, to display measured analyte levels, and/or an audio component such as a speaker to audibly provide information to a user, and/or a vibration device to provide tactile feedback to a user. It is also useful for a user of an analyte-monitoring system to be able to see trend indications (including the magnitude and direction of any ongoing trend, *e.g.*, the rate of change of an analyte or other parameter, and the amount of time a subject is above and/or below a threshold, such as a hypoglycemic and/or hyperglycemic threshold, etc.); such data may be displayed either numerically, or by a visual indicator such as an arrow that may vary in visual attributes, like size, shape, color, animation, or direction. The monitor unit may further be adapted to receive information from or about an *in vitro* analyte test strip, which may be manually or automatically entered into the monitor unit. In some embodiments a monitor unit may incorporate an *in vitro* analyte test strip port and related electronics in order to be able to make discrete (*e.g.*, blood glucose) measurements using an *in vitro* test strip (see, *e.g.*, U.S. Patent No. 6,175,752, the disclosure of which is incorporated by reference herein for all purposes).

[00166] The modularity of these systems may vary where one or more components may be constructed to be single use and one or more may be constructed to be re-useable. In some embodiments the sensor is designed to be attachable and detachable from the sensor control unit (and the on-body unit may be reusable), *e.g.*, so that one or more of the components may be reused one or more times, while in other embodiments, the sensor and sensor control unit may be provided as an integrated, undetachable package, which may be designed to be disposable after use, *i.e.*, not re-used.

[00167] FIGURE 1 shows one embodiment of an analyte measurement system 10. In such a system, a data-processing unit or sensor control unit 12 may interact with an analyte sensor 14 to obtain signals representative of analyte levels. Sensor control unit 12 may further include communications circuitry with associated electronics (not shown). In some embodiments, the sensor control unit 12 and at least a portion of a sensor are configured to be maintained “on the body” of the subject, in the substantially same position on the body of the subject, for a period of time that may include hours, days, weeks, or a month or more. Accordingly, the sensor control unit 12 and sensor 14 may be referred to collectively herein as an on-body unit 16. A monitor unit 18 may also be provided. In the embodiment shown, sensor control unit 12 and monitor unit 18 communicate *via* connection 20 (in this embodiment, a wireless radio frequency (RF) connection). Communication may occur, *e.g.*, *via* RF communication, infrared communication, Bluetooth communication, Zigbee communication, 802.1x communication, or WiFi communication, etc. In some embodiments, the communication may include a radio frequency of 433 MHz, 13.56 MHz, or the like. In some embodiments, communication between sensor control unit 12 and monitor unit 18 may include radio frequency identification (RFID) techniques, and may be active RFID or passive RFID, where in some embodiments passive

RFID technology and the respective system components include the necessary components therefor. For example, in certain embodiments, the on-body unit 16 and the monitor unit 18 may be configured to communicate using RFID communication protocol, wherein the on-body unit 16 may be configured to communicate or provide analyte-related signals to the monitor unit 18 based on the presence or reception of at least one signal from the monitor unit 18. That is, in certain embodiments, the monitor unit 18 may be configured to provide or radiate RF power signals, and when the on-body unit 16 is positioned within the radiated or provided RF signal range radiated from the monitor unit 18, the on-body unit 16 in certain embodiments is configured to provide one or more signals associated with the monitored analyte level received from the analyte sensor 14 to the monitor unit 18. For example, in one embodiment, the monitor unit may include a backscatter RFID reader configured to transmit an RF field such that when the on-body unit is within the transmitted RF field, an antenna is tuned and in turn provides a reflected or response signal (for example, a backscatter signal) to the monitor unit. The reflected or response signal may include sampled analyte level data from the analyte sensor. Additional exemplary details for various embodiments can be found in, *e.g.*, U.S. Patent Application Serial No. 12/698,124 filed February 1, 2010, the disclosure of which is incorporated by reference herein for all purposes.

[00168] In some embodiments, a secondary monitor unit 22 may be provided. A data-processing terminal 24 may also be included, *e.g.*, for providing further processing or review of analyte data. In some embodiments, the secondary monitor unit 22 may include similar components and/or functionalities as the monitor unit 18, or alternatively, include more or less functionalities or components compared to the monitor unit 18 to, for example, analyze, process, store, and/or communicate data from the analyte sensor 14 and/or monitor unit 18.

[00169] In some embodiments, system 10 may be a continuous analyte monitor (*e.g.*, a continuous glucose-monitoring system or CGM), and accordingly operate in a mode in which the communications *via* connection 20 has sufficient range to support a flow of data from on-body unit 16 to monitor unit 18. In some embodiments, the data flow in a CGM system is automatically provided by the on-body unit 16 to the monitor unit 18. For example, no user intervention may be required for the on-body unit 16 to send the data to the monitor unit 18, *e.g.*, it may be continually and/or automatically broadcasted. In some embodiments, the on-body unit 16 provides signal relating to analyte level to the monitor unit 18 automatically and periodically. For example, one or more signals may be provided, *e.g.*, automatically sent, on a schedule, *e.g.*, once every 250ms, once a second, once a minute, etc. That is, in certain embodiments, the on-body unit 16 may be configured and/or programmed to communicate or transmit the data acquired from the analyte sensor 14 based on a predetermined schedule, and continue to broadcast or transmit signals related to the real time monitored analyte levels based on the predetermined schedule. In such embodiments, the monitor unit 18 may be configured to receive and/or anticipate and acquire the transmitted signals from the on-body unit 16 based on the predetermined schedule, for example, for further processing, such as display, storing, analysis, and/or further data communication.

[00170] In some embodiments, one or more signals may be provided to the monitor unit 18 upon the occurrence of, or impending occurrence of, an event, *e.g.*, a hyperglycemic event or a hypoglycemic event, etc. In some embodiments, the one or more signals may be provided to the monitor unit 18 on an adaptive schedule. For example, the schedule for automatically communicating the one or more signals may be adjusted by machine learning techniques (*e.g.*, supervised learning techniques, unsupervised learning techniques, data mining, etc.) according to

parameters received by the sensor control unit 12 and/or monitor unit 18, such as, *e.g.*, analyte values and trends, activity levels, meal times, etc.). In some embodiments, sensor control unit 12 may further include local memory in which it may record “logged data” or buffered data collected over a period of time and provide some or all of the accumulated data to monitor unit 18 from time-to-time. Or, a separate data-logging unit may be provided to acquire periodically provided data from sensor control unit 12. Data transmission in a CGM system may be one-way communication, *e.g.*, the on-body unit 16 provides data to the monitor unit 18 without receiving signals from the monitor unit 18. In some embodiments, two-way communication is provided between the on-body unit 16 and the monitor unit 18, using, for example, one or more transceivers or other bi-directional communication components. Such two-way communication may be achieved in certain embodiments independently. That is, in certain embodiments, certain data communication from the on-body unit 16 may be independent of the data received from the monitor unit 18. In other embodiments, certain data communication from the on-body unit 16 may be in response or responsive to the data, signal, request, or one or more commands received from the monitor unit 18.

[00171] In some embodiments, one or more signals may be provided to the monitor unit 18 from the on-body unit on user demand. According to such embodiments, the monitor unit 18 requests data from the on-body unit 16. Accordingly, embodiments include systems in which data is transferred from the on-body unit to the monitor unit only when the monitor unit invokes data from the on-body unit.

[00172] The data transfer request may be provided in several ways. For example, in some embodiments, one or both of the on-body unit 16 and monitor unit 18 may include a mechanical

switch activatable by a user or activated upon some other action or event, the activation of which initiates the transfer of signal from the on-body unit 16 to the monitor unit 18. A mechanical switch may be provided which is activatable by the user to cause power to be turned on to the on-body system, *e.g.*, to electronic components that control the sensor.

[00173] In some embodiments, the monitor unit 18 is placed in close proximity (*e.g.*, within a range of about one to about ten inches or less in certain embodiments) with the communications electronics of the on-body unit to cause initiation of data transfer from the on-body unit to the monitor unit, either over a wired connection, or wirelessly by various means, including, for example, various RF-carried encodings and protocols and IR links.

[00174] In some embodiments, a signal relating to analyte level is instantaneously generated by the analyte sensor 14 upon receipt of the request, and provided to the monitor unit 18 as requested.

[00175] In other embodiments, a signal relating to analyte level is obtained according to a schedule, *e.g.*, once every 250ms, once a second, once a minute, etc., and at least temporarily stored. Upon receipt of the data transfer request at the on-body unit 16 from the monitor unit 18, analyte-related information is provided to the monitor unit 18 from the on-body unit 16. In some cases, analyte-related information provided to the monitor unit 18 is or at least includes the most recent analyte signal(s).

[00176] In further embodiments, additional data is provided to the monitor unit 18 on demand. For example, analyte trend data may be provided. Such trend data may include two or more analyte data points to indicate that analyte levels are rising, falling, or stable. Analyte trend data

may include data from longer periods of time, such as, *e.g.*, several minutes, several hours, several days, or several weeks.

[00177] Further details regarding on-demand systems are disclosed in U.S. Patent Publication Nos. 2009/0018425 A1, published January 15, 2009; 2009/0054749 A1, published February 26, 2009; 2009/0257911 A1, published October 15, 2009, 2009/0281406 A1, published November 12, 2009; 2009/0294277 A1, published December 3, 2009; 2008/0058625 A1, published March 6, 2008; 2008/0064937 A1, published March 13, 2008; 2008/0071157 A1, published March 20, 2008; 2008/0071158 A1, published March 20, 2008; 2008/0179187 A1, published July 31, 2008; 2008/0319295 A1, published December 25, 2008; 2008/0319296 A1, published December 25, 2008; 2007/0149873 A1, published June 28, 2007; 2007/0149875 A1, published June 28, 2007; 2009/0321277 A1, published December 31, 2009; 2010/0030052 A1, published February 4, 2010; and pending U.S. Patent Application Nos. 12/211,014, filed September 15, 2008; 12/242,780, filed September 30, 2008; 12/393,921, filed February 27, 2009; 12/495,709, filed June 30, 2009; 12/495,712, filed June 30, 2009; 12/495,730, filed June 30, 2009; 12/544,061, filed August 19, 2009; 12/625,185, filed November 24, 2009; 12/625,208, filed November 24, 2009; 12/625,524, filed November 24, 2009; 12/625,525, filed November 24, 2009; 12/625,528, filed November 24, 2009; 12/624,767, filed November 24, 2009; 12/628,177, filed November 30, 2009; 12/628,198, filed November 30, 2009; 12/628,201, filed November 30, 2009; 12/628,203, filed November 30, 2009; 12/628,210, filed November 30, 2009; 12/698,129, filed February 1, 2010; 12/698,124, filed February 1, 2010; 12/714,439, filed February 26, 2010; 61/163,006, filed March 24, 2009; 61/227,967, filed July 23, 2009; 61/238,159, filed August 29, 2009; 61/238,483, filed August 31, 2009; 61/238,494, filed August 31, 2009; 61/238,581, filed August 31, 2009; 61/247,508, filed September 30, 2009; 61/247,514, filed September 30, 2009;

61/247,516, filed September 30, 2009; 61/247,519, filed September 30, 2009; 61/249,535, filed October 7, 2009; 61/256,925, filed October 30, 2009; 61/291,326, filed December 31, 2009; 61/299,924, filed January 29, 2010; 61/297,625, filed January 22, 2010; 61/297,615, filed January 22, 2010, each of which is incorporated by reference herein for all purposes.

The Sensor

[00178] The analyte sensor 14 of the analyte measurement system 10 may be used to monitor levels of a wide variety of analytes. Analytes that may be monitored include, for example, acetylcholine, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (*e.g.*, CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid-stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (*e.g.*, gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be monitored. One or more analyte may be monitored by a given sensor.

[00179] In one embodiment of the present disclosure, sensor 14 is physically positioned in or on the body of a user whose analyte level is being monitored. Sensor 14 may be configured to continuously sample the analyte level of the user and convert the sampled analyte level, *e.g.*, glucose concentration into a corresponding data signal, *e.g.*, a current or voltage, for input into sensor control unit electronics. Alternatively, sensor 14 may be configured to sample analyte levels on demand. The sensor control unit electronics may amplify, filter, average, and/or otherwise process signal provided by the sensor.

[00180] The sensor may take on a number of forms. For example, the sensor may include a flexible or rigid substrate. In some embodiments, the sensor may be a wire. In some embodiments, the sensor may include two or three or more electrodes.

[00181] An embodiment of the sensor 14 is illustrated in FIGURE 2. The shape(s) described herein are exemplary only. Other sensor shapes are contemplated. In some embodiments, sensor 14 includes a substrate which is a dielectric, *e.g.*, a polymer or plastic material, such as polyester or polyamide. In this embodiment, the sensor is constructed so that a portion is positionable beneath skin and a portion is above skin. Accordingly, sensor 14 includes an insertion or internal portion 30 and an external or electrical contact portion 32. The contact portion 32 typically includes several conductive contacts 36, 38, and 40 (herein shown as three contacts) for connection to other electronics, *e.g.*, at the sensor control unit 12. The contacts provided in this embodiment are for a working electrode, a reference electrode, and a counter electrode. In some embodiments, two or more working electrodes are provided. The operative portions of these electrodes, that is, working electrode, reference electrode, and counter electrode (not individually shown), are provided at the insertion portion, *e.g.*, at the distal end of insertion portion 30, *e.g.*, portion 34. In some embodiments, one or more electrodes may be external to the body, *e.g.*, an external counter electrode. The contact and operative portions of the electrodes are connected by circuit traces 42, 44, and 46 running on the surface of the substrate. In some embodiments, the traces are provided in channels, or may be embedded within the substrate, or may traverse different sides of the substrate. The conductive contacts, conductive traces, and electrodes are fabricated from conductive material, such as platinum, palladium, gold, carbon, or the like. More than one material may be used for a given sensor. Further details of sensors are described,

e.g., in U.S. Patent Nos. 6,175,572 and 6,103,033, which are incorporated by reference herein for all purposes.

[00182] Sensor 14 may include a proximal retention portion 48. In some embodiments, the insertion portion 30 and the proximal retention portion 48 are substantially longitudinally aligned. The insertion portion 30 and the proximal retention portion 48 are sized and configured to be positioned with a sharp for installation into the skin of a subject, as described herein. In use, the sensor 14 may be configured to bend (*e.g.*, along the line B) and therefore be positioned in two substantially perpendicular, intersecting planes.

[00183] As illustrated in FIGURE 3, sensor 14' is substantially identical to sensor 14, with many of the differences illustrated in FIGURE 3 and noted herein. Sensor 14' further includes additional features useful for connecting to, *e.g.*, mounting to or in or on, a housing associated with the sensor control unit 12. For example, sensor 14' includes a laterally displaced portion (or sensor tab) 50' and a connector portion, shown in this embodiments as a longitudinal displaced portion 52' which provides a path for electrical connections, *e.g.*, the conductive traces, between the proximal and distal portions of the sensor. Sensor 14' is further provided with a notch or cut-out 54' between the proximal retention portion 48' and the longitudinal displaced portion 52'. Such configuration facilitates the sensor 14' to bend (*e.g.*, along the line indicated by line B) and therefore be positioned in two substantially perpendicular, intersecting planes, as illustrated in FIGURE 4. As will be described below, the sensor tab 50' can be encased in the portion of the body of the sensor control unit 12 to aid in securing and positioning the sensor 14'. Proximal retention portion 48' maintains its longitudinal alignment with insertion portion 30 for positioning within an insertion sharp.

[00184] FIGURES 5A and 5B illustrate a further embodiment of a sensor 14'' in accordance with the disclosure. Sensor 14'' is substantially identical to sensor 14 and 14', with certain exemplary differences illustrated in FIGURE 4 and noted herein. For example, sensor 14'' includes a contact portion 32' which defines a fan-like configuration having a curved edge. The contact portion 32'' typically includes several conductive contacts 36'', 38'', and 40'' (herein shown as three contacts) for connection to other electronics, *e.g.*, at the sensor control unit 12. The contacts provided in this embodiment are for a working electrode, a reference electrode, and a counter electrode. In some embodiments, two or more working electrodes are provided. The operative portions of these electrodes, that is, working electrode, reference electrode, and counter electrode (not individually shown), are provided at the insertion portion, *e.g.*, at the distal end of insertion portion 30'', *e.g.*, portion 34''. The contact and operative portions of the electrodes are connected by circuit traces 42'', 44'', and 46'' running on the surface of substrate, provided in channels, embedded within the substrate, or traversing different sides of the substrate, substantially as described in connection with FIGURES 2 and 3. Sensor 14'' defines a sensor flag indentation 56 '' which also serves to assist in retaining the sensor 14'' in a vertical orientation, as will be described below, and provides a discrete location for mating with a feature of the sensor control unit 12, *e.g.*, the bottom surface of a printed circuit board. Sensor 14'' is likewise capable of bending along axis B, as illustrated in FIGURE 5B. In any of the embodiments of the sensor described herein, the distance between insertion portion 30 to retention portion 48 may be, *e.g.*, about 5 mm, or about 10 mm, or about 15 mm, or about 20 mm.

[00185] FIGURE 6A illustrates a further embodiment of a sensor 14''' in accordance with the disclosure. Sensor 14''' is substantially identical to sensor 14, 14' and 14'', with certain

exemplary differences illustrated in FIGURE 6A and noted herein. For example, sensor 14''' includes a contact portion 32'''. The contact portion 32''' typically includes several conductive contacts 36'', 38'', and 40''' (herein shown as three contacts) for connection to other electronics, *e.g.*, at the sensor control unit 12. The contacts provided in this embodiment are for a working electrode, a reference electrode, and a counter electrode. In some embodiments, two or more working electrodes are provided. The operative portions of these electrodes, that is, working electrode, reference electrode, and counter electrode (not individually shown), are provided at the insertion portion, *e.g.*, at the distal end of insertion portion 30'', *e.g.*, portion 34'''. As shown, contact portion 32''', proximal retention portion 48''' and the distal portion 30''' of sensor 14''' are linearly aligned with respect to one another. The contact and operative portions of the electrodes may be connected by circuit traces running on the surface of the substrate. In some embodiments, the circuit traces may be embedded within the substrate, or traversing different sides of the substrate.. Sensor 14''' is likewise capable of bending along axis B, as illustrated in FIGURE 6B. In FIGURE 6B, contacts 36'', 38'', and 40''' are not visible, because they are located on the underside of contact portion 32''' and thus not shown in this view. It is understood that sensor 14''' may be positioned such that when the sensor is placed in contact with surrounding circuitry the contacts are downwardly positioned to engage circuitry below the contact portion 32''' or, in some embodiments, the contacts are upwardly directed to engage circuitry positioned above the contact portion 32'''. In any of the embodiments of the sensor described herein, the distance between insertion portion 30 to retention portion 48 may be, *e.g.*, about 5 mm, or about 10 mm, or about 15 mm, or about 20 mm.

[00186] Embodiments of analyte sensors have been described herein to operate electrochemically, through an arrangement of electrodes having chemical sensing layers applied

thereto, by generating an electrical current proportional to the volume of a redox reaction of the analyte (and indicative of analyte concentration), catalyzed by an analyte-specific oxidizing enzyme. Embodiments exist in which the number of electrodes provided to bring about and detect the level of these reactions is two, three, or a greater number. However, other types of sensors may be employed as described herein.

[00187] A portion of sensor 14 (which collectively refers to sensors 14', 14'', and 14''' herein) may be situated above the surface of the skin, with a distal portion 30 penetrating through the skin and into the subcutaneous space in contact with the user's biofluid, such as interstitial fluid. Further details regarding the electrochemistry of sensor 14 is provided in U.S. Patent Nos. 5,264,104; 5,356,786; 5,262,035; 5,320,725; and 6,990,366, each of which is incorporated by reference herein for all purposes.

[00188] In some embodiments, the sensor is implantable into a subject's body for a usage period (*e.g.*, a minute or more, at least one day or more, about one to about 30 days or even longer, about three to about ten days, about three to about seven days, or in some embodiments, longer periods of up to several weeks) to contact and monitor an analyte present in a biological fluid. In this regard, the sensor can be disposed in a subject at a variety of sites (*e.g.*, abdomen, upper arm, thigh, etc.), including intramuscularly, transcutaneously, intravascularly, or in a body cavity.

[00189] In some embodiments, sensor 14 is employed by insertion and/or implantation into a user's body for some usage period. In such embodiments, the substrate may be formed from a relatively flexible material.

[00190] While the embodiments illustrated in FIGURES 2-6 have three electrodes, other embodiments can include a fewer or greater number of electrodes. For example, a two-electrode sensor can be utilized. The sensor 14 may be externally-powered and allow a current to pass proportional to the amount of analyte present. Alternatively, the sensor 14 itself may act as a current source in some embodiments. In some two-electrode embodiments, the sensor may be self-biasing and there may be no need for a reference electrode. An exemplary self-powered, two-electrode sensor is described in U.S. Patent Application Serial No. 12/393,921, filed February 26, 2009, and entitled "Self-Powered Analyte Sensor," which is hereby incorporated by reference herein for all purposes. The level of current provided by a self-powered sensor may be low, for example, on the order of nanoamperes, in certain embodiments.

On Body Unit

[00191] An exemplary configuration for a sensor 14 (and sensors 14' 14", and 14''') and sensor control unit 12 (*e.g.*, collectively, on-body unit 16) is illustrated in FIGURES 7-8. Sensor control unit 12, including its associated electronics 80, are housed in housing 122. Sensor housing 122 may be provided with a substantially circular configuration, or other shape. Sensor housing 122 has a reduced height (*i.e.*, "Z"-dimension) to provide a low profile when sitting on the skin of the subject. In some embodiments, the height is about 3 mm to about 25 mm, *e.g.*, may be about 4 mm, about 5 mm, about 10 mm, or about 15 mm. In certain embodiments, the sensor housing 122 may have a variable height such that it may have at least one portion that has a height that differs from at least one other portion. For example, electronics 80 may include one or more of, *e.g.*, an analog interface for connecting to the sensor 14, a processor, which may include, *e.g.*, an ASIC 91, antenna 94, power supply 82 to power the sensor and/or

communications components, and capacitors 93. In some embodiments, power supply 82 provides a current or voltage to the analyte sensor only. In some embodiments, power supply 82 also powers a communications circuit for providing signal to the monitor unit 18. Power supply 82 may be used to charge capacitors 93 for such periodic signal communication. A serial communication section may be provided. A temperature sensor, such as a thermistor that detects skin temperature, sensor temperature, and/or ambient temperature may be included to provide compensation to the analyte signal. An RF communication circuit is provided to communicate with the monitor unit 18. (See, FIGURES 1 or 9.) A data storage unit may be provided to store analyte data over a period of time, which in some embodiments may be a short term of time, *e.g.*, several hours or minutes, or over a longer term, *e.g.*, several days or weeks. Additional optional electronics include a serial communication section, a leakage detection circuit, or user input, *e.g.*, a switch to activate/deactivate some or all functions of the device. Many of the components may be combined together and/or their function provided by common components. Furthermore, certain components may be eliminated entirely. For example, a power supply may be omitted if power is provided by inductive coupling.

[00192] In some embodiments, a portion of sensor 14 is disposed on or within housing 122, *e.g.*, in a bent configuration, as illustrated in certain embodiments herein, *e.g.*, in FIGURES 4, 6, and 6B. In some embodiments, a portion of the contact portion of the sensor may be located on an outer surface of the sensor housing 122. The contact portion 32 of sensor 14 may be oriented in a substantially horizontal configuration (*e.g.*, substantially parallel to the skin surface to which it is attached), and secured to a printed circuit board of the sensor control unit 12. The insertion portion 30 of the sensor 14 may extend in a substantially downwardly vertical orientation for placement in the skin of the subject. In some embodiments, the insertion portion 30 is provided

with a substantially sharpened and/or pointed configuration to facilitate piercing of the skin. See, *e.g.*, U.S. Patent Application Serial No. 61/238,159 filed August 29, 2009, which is incorporated by reference herein for all purposes. It is understood that sensor 14 may be disposed in other configurations, *e.g.*, in an entirely substantially vertical configuration, etc. As a further example, the insertion portion 30 may be disposed at an oblique angle, *e.g.*, between about 0° and about 90° with respect to the skin surface.

[00193] Adhesive pad 118 is illustrated in FIGURE 8 to attach sensor housing 122 to the skin of the subject. In some embodiments, adhesive pad 118 is used instead of a separate mount. Adhesive pad 118 may include adhesive on both distal (upper) and proximal (lower) surfaces, such that adhesive pad is attached or attachable to both sensor housing 122 and the skin of the subject. In some embodiments, adhesive pad 118 may be first attached to the skin of the subject with the adhesive on the distal surface thereof. Subsequently, the housing 122 is adhered to the proximal surface of the adhesive pad 118. In other embodiments, proximal surface of adhesive pad 118 is first attached to sensor housing 122, and subsequently, the distal surface of adhesive pad 118 is then attached to the skin of the subject.

[00194] As illustrated in FIGURE 9, the on-body unit 16 communicates with the monitor unit 18. Such communication may be one-way communication, *e.g.*, from the on-body unit 16 to the monitor unit 18. In some embodiments, the communication may be two-way, *e.g.*, both from the on-body unit 16 to the monitor unit 18 and from the monitor unit 18 to the on-body unit 16. Communication between the on-body unit 16 and monitor unit 18 may be achieved using one or more radio frequency communication protocols, inductive coupling, magnetic coupling, direct wired connection, infrared data communication protocol, and the like as described herein.

Insertion Assembly

[00195] Insertion assemblies are provided, which are used to install a medical device to the subject. In some embodiments, an insertion assembly includes an inserter and the medical device itself. The inserter can be configured to insert various medical devices into the subject, such as for example, an analyte sensor, an infusion set, or a cannula. In some embodiments, the inserter can be configured to install a combination of such devices, *e.g.*, a combined sensor/infusion set, etc., at the same or different times or locations. For example, in certain embodiments a given inserter can be configured to install a first device and a second device at different times. In this regard, the inserter can be reusable. For example, an inserter may be modifiable to be used with more than one medical device, to include more than one type of medical device, *e.g.*, by attaching an adapter and/or removing detaching a portion of an inserter. The inserter can install the medical device in, under, or through the skin of the subject, or place the medical device on the surface of the skin. The medical device can include features or structures, *e.g.*, barbs, tabs, adhesive, etc., to maintain the device in position with respect to the skin after insertion. The inserter device may also be used as a lancet, *e.g.*, to pierce the skin without inserting or installing a medical device.

[00196] In some embodiments, an insertion assembly includes an inserter, a medical device, such as an analyte sensor, and a mount for supporting the medical device at least partially in or on the skin of the subject. In some embodiments, the mount is a support structure, plate and/or member which is attached, adhered, or otherwise secured to the skin of the subject. The mount may be inserted simultaneously with the medical device by the inserter. In other embodiments, the mount is installed after or before installation of the medical device. A mount may be applied

by the inserter or separately. The mount may include features or structures (*e.g.*, adhesive, guides, barbs, tabs, etc.) to maintain the sensor in position with respect to the skin after insertion and/or maintain the sensor in relative position with respect to the sensor control unit. In some embodiments, an adhesive pad or strip is used to secure the medical device, *e.g.*, the sensor and/or the sensor control unit, and no mount is used.

[00197] In some embodiments, an insertion assembly includes an inserter, an analyte sensor, a mount, and a power supply. The mount and power supply may be inserted simultaneously with the analyte sensor by the inserter. In other embodiments, the mount and battery are installed after or before installation of the analyte sensor. In such case the mount and/or power supply may be applied by the inserter or separately. The power supply may be used to provide a current or a potential to the sensor and/or to provide power for communication of one or more signals to the monitor unit.

[00198] In some embodiments, an insertion assembly includes an inserter, a medical device such as an analyte sensor, a mount, and a sensor control unit. The mount and sensor control unit may be deployed and/or installed simultaneously with the analyte sensor by the inserter. In other embodiments, the mount and sensor control unit are installed after or before installation of the analyte sensor. For example, the mount and the analyte sensor may be installed by the inserter, and the sensor control unit may be subsequently installed. In other embodiments, the mount is installed, followed by insertion of the analyte sensor by the inserter, and further followed by installation of the sensor control unit. In other embodiments, the mount and sensor control unit are installed first, and the analyte sensor is subsequently installed.

[00199] In some embodiments, electronics of the sensor control unit provide a voltage or current to the analyte sensor. In some embodiments, the electronics processes signals provided by the analyte sensor. In further embodiments, the electronics may include communication functionality for providing signal relating to signal provided by the analyte sensor to a further component, such as, *e.g.*, a monitor unit, a computer, or other component. In some embodiments, communications circuitry, such as RFID antenna or communications circuitry, is provided. The power supply may be used to power some or all of these functions. In some embodiments, power is provided from the monitor unit, *e.g.*, via inductive coupling.

[00200] An inserter can include a plurality of different components. For example, an inserter may include one or more components for advancing a sharp towards the skin of the subject. The sensor and sensor control unit and/or mounting structure may be supported by a support structure, such as a carriage. A driver may be provided for advancing the sharp and/or the analyte sensor/support structure. In some embodiments, the actuator is directly or indirectly coupled to the sharp and/or support structure, such that manual force and speed applied by the user to the actuator is transferred to the sharp and/or support structure. In some embodiments, the applied force drives the sharp and/or support structure between a retracted position and an advanced position. In some embodiments, the sensor and sensor control unit and/or mounting structure is maintained in a retracted position prior to installation by contacting projections extending inwardly from a sheath. In accordance with this embodiment, the sensor and sensor control unit and/or mounting structure are temporarily maintained operatively between the support structure and the projections disposed on the interior wall of the sheath.

[00201] An inserter can also include one or more components for retracting the sharp, while allowing the analyte sensor and optional mount and/or electronics to remain on the subject. The components for retracting the sharp can include a retractor. It is understood that the retractor and the actuator may be the same structure or include some common components. In some embodiments, the retractor is directly or indirectly coupled to the sharp such that the manual force applied by the user is transferred from the retractor to the sharp to retract the sharp from the skin. In other embodiments, a drive assembly may be provided to retract the sharp. For example, the drive assembly may include a spring, motor, hydraulic piston, etc., to retract the sharp away from the skin of the subject. The drive assembly may also include a linear drive component.

[00202] In some embodiments, the retractor withdraws the sharp upon actuation by the user. In such cases, the user actuates the retractor when it is desired to withdraw the sharp. For example, the retractor may include a release switch. Upon activation of the release switch, the drive assembly, *e.g.*, the spring or other driver, retracts the sharp from the skin. In other embodiments, the retractor and the actuator include common components. After activating the actuator to advance the sharp and the analyte sensor, the user releases the actuator, which allows the drive assembly to withdraw the sharp from the skin.

[00203] In some embodiments, the retractor withdraws the sharp without further user interaction after actuation of insertion. For example, the inserter may include features or components which automatically retract the sharp upon advancement of the sharp and support structure by a predetermined amount. Inserter devices, in which no further action by the user is

required to initiate withdrawal of the sharp after insertion, are referred to herein as having “automatic” withdrawal of the sharp.

Insertor Devices

[00204] An inserter 100 in accordance with an exemplary embodiment is illustrated in FIGURE 10. In some embodiments, inserter 100 has a maximum diameter of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 100 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 100 has a volume of about 35 cm³ to about 110 cm³, *e.g.*, about 40 cm³, about 41 cm³, about 50 cm³, about 60 cm³, about 61 cm³, about 62 cm³, about 69 cm³, about 70 cm³, about 79 cm³, about 90 cm³, about 106 cm³, etc. Inserter 100 includes a handle 102 and a removable distal cap 104. The cap 104 may maintain a sterile, contaminant-free environment for the medical device and sharp housed therein. As illustrated in FIGURES 10-13, distal cap 104 is detachably secured to handle 102, *e.g.*, by use of one or more mating members, *e.g.*, threads 110 and 111, or hooks, tape, magnets, adhesive, friction-fit, snap-fit, and the like. Inserter 100 includes a base 142 which defines a distal surface 112, which may be a substantially planar surface as shown in this embodiment, for placement on the skin S of a subject, and in other embodiments may be a curved or inclined surface, *e.g.*, a concave or convex surface. Inserter 100 may be utilized to advance a medical device into the skin of the subject, *e.g.*, an analyte sensor, and infusion set, etc., as described herein. In some embodiments, handle 102 is advanced relative to base 142 in order to advance the medical device into the skin of the patient, as will be described in greater detail herein.

[00205] The components of inserter 100 are illustrated in FIGURES 11-27. As illustrated in FIGURE 11, handle 102 includes a contact surface 114 for contact by a user to depress to advance the sensor housing 122 (as illustrated in FIGURE 10) and sensor 14 towards the skin of the subject. Threads 110 are provided on handle 102 (as illustrated in FIGURE 11) for attachment to cap 104 *via* threads 111 (as illustrated in FIGURES 12-13). Cap 104 can include a receptacle, such as an upwardly extending sleeve 125 to assist holding sensor housing 122 fixed in position. The distal portion of cap 104 includes a recess 115 for retaining a desiccant 190 therein. In some embodiments, a silica gel or molecular sieves may be used. Such material can be in granular form (pellets) or pressed into tablets, or otherwise. In some embodiments, silica gel tablets are used. Embodiments may include desiccant and/or packaging as described in U.S. Patent Application Serial No. 12/714,439, which is incorporated by reference herein for all purposes.

[00206] Cap 104 may be provided with one or more apertures 117, which allows for passage of air to the desiccant 190 to remove moisture from the interior of the inserter 100. Cap 104 may include a stop such as an annular ridge 113, which engages the distal edge portion 116 of handle 102. In some embodiments, a stop such as annular ridge 113 prevents distal movement of handle 102 (as well as sensor housing 122) when cap 104 is attached to handle 102.

[00207] Base 142, as illustrated in FIGURES 10 and 14, includes a distal sheath portion 192, which shields sharp 124 and sensor housing 122 prior to deployment and a distal rim 112 having a substantially planar surface configuration to rest on the subject's skin S. Base 142 also includes side walls 191, which along with inner rail 128 defines a recess for retraction spring 146. Base 142 provides a spring retention portion 148, as illustrated in FIGURE 29.

[00208] Support member or shuttle 134, as illustrated in FIGURES 15-16, supports needle hub 136, from which sharp 124 extends longitudinally within the inserter 100. In some embodiments, the sharp is supported at an oblique angle, *e.g.*, between and including about 0° (parallel to the skin) and about 90° (normal to the skin) with respect to the skin surface. Needle hub 136 can be secured to shuttle 134 *via* interlocking snaps or tabs, an O-ring configuration, adhesive, insert-molding, or other techniques known in the art. Alternatively, needle hub 136 may be integrally molded with shuttle 134. In some embodiments, sharp 124 is a solid needle. In some embodiments, sharp 124 is provided with a substantially cylindrical configuration defining an interior bore, *e.g.*, a rigid cylindrical member or a hypodermic-style needle.

[00209] Needle hub 136 is further illustrated in FIGURES 17-18. Needle hub 136 supports sharp 124, having a sharpened distal portion 160. In some embodiments, as discussed herein, a longitudinal wall opening or gap 162 is provided in at least a portion of the wall of the sharp 124. The length N of the gap 162 is selected to be commensurate with the length of the insertion portion 30 through to the proximal retention portion 48 of the sensor, and in certain embodiments may be about 3 mm to about 50 mm, *e.g.*, about 5 mm, or about 10 mm, or about 15 mm, or about 20 mm. The length L of the sharp 124 may be about 3 mm to about 50 mm, *e.g.*, 5mm or more, or about 10 mm, or about 20 mm, or about 30 mm, or about 50 mm, and is selected based upon the length of the insertion portion 30 of a sensor and the desired depth of the insertion portion 30 of the sensor 14. In some embodiments, the distance or spacing between the two edges of the gap is about 0.2mm to about 0.5mm, *e.g.*, about 0.22mm, about 0.25mm, etc.

[00210] The distal portion 160 of sharp 124 is illustrated in greater detail in FIGURES 19-21. As illustrated in FIGURE 19, sharp 124 has a substantially “C”- or “U”-shaped profile in this

embodiment, but may have other configurations, *e.g.*, substantially “V”-shaped. A longitudinal gap 162 is provided in the wall of the sharp 124. FIGURE 20 illustrates distal portion 160 is provided with an angled tip. In some embodiments, the angled tip may be provided with a first angled tip portion 164 and a second steep-angled tip portion 166. The exemplary configuration, which includes multiple edges and faces, provides a sharp point to reduce penetration force, trauma, and bleeding for the subject. The distal section of the sensor body has a width sized to fit within the notch 162 of the insertion sharp 124 having a diameter less than about 20 to about 26 gauge, *e.g.*, 21 gauge to about 25 gauge, where in certain embodiments the sharp is 21 gauge or 23 gauge or 25 gauge. Such sharp may be used with a sensor having a width or diameter - - at least the portion that is carried by the sharp - - of about .20 mm to about .80 mm, *e.g.*, about .25 mm to about .60 mm, where in some embodiments the width or diameter of at least a portion of a sensor is .27 mm or .33 mm or .58 mm. In some embodiments, sharp 124 is fabricated from a sheet of metal and folded into a substantially “V” or “U” or “C” configuration in cross-section. Various technologies can be used to manufacture a folded sheet of metal to form sharp 124. For example, etched-sheet metal technology can be used to form the sharp 124. In this manner, the sharp can be formed having a very sharp edge so that penetration through the skin during insertion is less painful. In other embodiments, a progressive die technology may be utilized to form a complex sheet-metal shape that has a sharp edge as depicted in FIGURE 21A. In some embodiments, the sharp 124 can be molded with a plastic cap so that the sharp can be handled during the inserter assembly process. Further, the die cut sharp may be molded with plastic to reinforce the “V,” “U,” or “C” shaped sheet metal configuration. In other embodiments, a laser-cut sharp can be formed. In this manner, the laser can be used to form the wall opening or gap 162 and first-angled tip portion 164 and a second, steep-angled tip portion 166.

[00211] In another embodiment, sharp 224 may be formed from a standard hypodermic needle utilizing the method depicted in FIGURE 21B. First, the hypodermic needle (having a circular cross-section) is cut to the desired length for sharp 224. Next, the hypodermic needle is compressed so that its cross-section is permanently deformed from a circular shape to an oval shape. The tip of the hypodermic needle is then ground to a bevel to produce a sharp point to reduce the required penetration force, as previously discussed. Finally, the top section of the needle is removed by appropriate techniques (e.g., grinding, electropolish, etc.). The resulting sharp 224 has a “U”-shaped configuration and provides ample space for the insertion of sensor 14. In some embodiments, the tip-grinding step and the compression step may be carried out in reversed order.

[00212] Due to the compression step, a user may initially start with a larger diameter hypodermic needle so that the finished sharp 224 will have similar dimensions to the previously described sharps.

[00213] FIGURES 22-23 illustrate the position of sensor housing 122 with respect to the needle hub 136 and sharp 124. The sensor housing 122 can be configured to hold at least a portion of sensor 14 and sensor control unit 12. As illustrated in FIGURE 22, the sharp 124 extends through an aperture 168 in the sensor housing 122. Thus, in some embodiments, the sharp 124 is uncoupled to sensor housing 122. The distal portion of sensor 14 is positioned with the sharp 124. As further illustrated in FIGURE 23, electronics 80 of the sensor control unit 12 (e.g., a printed circuit board containing electronics components of the on-body unit 16) and sensor hub 123 are positioned within sensor housing 122. Sensor 14 may include a positioning structure, or slit 127 which receives a positioning member, such as tab 129 of sensor hub 123. A

power supply 82, such as a battery, *e.g.*, a single use disposable battery, or rechargeable battery, is provided. The power supply 82 is used to provide potential or current to the sensor in some embodiments. In embodiments where a passive communications protocol such as passive RFID is used, no power supply is provided for the communications. Such power is provided by the monitor unit 18. In some embodiments where the sensor control unit is used to transmit one or more signals, one or more power supplies may be used to provide power for such communications circuitry. In some embodiments, the active operational life of the battery may exceed the active operational life of the sensor 14.

[00214] FIGURE 24 illustrates in cross-section the orientation of the sensor housing 122 with respect to the sharp 124 of inserter 100. As discussed herein, sensor 14 is disposed in a substantially bent configuration in some embodiments, such that a portion of the sensor, *e.g.*, the insertion portion 30 and the proximal retention portion 48, are substantially vertical (*e.g.*, substantially aligned with the longitudinal axis of the inserter 100 and substantially perpendicular to the skin surface) and the contact portion 32 (shown in profile) is oriented in a substantially horizontal configuration, and in electrical contact with the data-processing unit electronics, such as circuit 80. The sensor tab 50 can be encased in the plastic of the sensor housing 122 (*e.g.*, “overmolded”) and secured in place. The notch 56 provides further stability to the sensor 14, *e.g.*, by allowing the sensor tab 50 to be encased by the material of the sensor housing 122, and further provides a means for vertically orienting the sensor 14 during mounting, *e.g.*, by allowing vertical positioning of the notch 56 with respect to a vertical landmark of the sensor housing 122.

[00215] The sensor 14, mounted with the sensor housing 122, can be disposed within a recess of the carriage 130 such as a concave recess in the carriage 130. Alternatively, the sensor 14,

mounted with the sensor housing 122 can be disposed between the support structure and one or more projections extending from the wall of the sheath. In yet another alternative, the sensor 14 mounted with the sensor housing 122 can be held in position by a releasable friction fit coupling to the sharp 124. In this manner, the carriage need not have a recess within which the sensor mounted with the sensor housing is disposed. In the initial configuration of the inserter 100 (see, *e.g.*, FIGURE 22) the sharp 124 extends through a longitudinal aperture 168 formed in a carriage 130. In some embodiments, the aperture 168 is appropriately sized, such that neither the sharp 124 nor needle hub 136 is in contact with the carriage 130. Accordingly, the needle hub 136 (and sharp 124) on the one hand, and the carriage 130 and the sensor housing 122, on the other hand, move simultaneously but independently from one another. In other embodiments, a friction fit may be provided between the aperture and the sharp.

[00216] The insertion portion 30 and proximal retention portion 48 of the sensor 14 are disposed within a longitudinal bore 162 within the sharp 124 (See, *e.g.*, FIGURE 19). The proximal retention portion 48 is disposed within the longitudinal bore of the sharp 124 and provides additional stability to the mounting of the sensor 14 within the sharp 124. The longitudinal wall gap or opening 162 of sharp 124 is aligned with the sensor 14, such that the tab 50 and the contact portion 32 extend laterally outward from the sharp 124.

[00217] With continued reference to FIGURES 15 and 16, shuttle 134 includes wings 182 and resilient distally extending fingers 184. Inner rail 128 is illustrated in FIGURE 25. As illustrated in FIGURE 26, shuttle 134 is sized and configured for longitudinal movement within inner rail 128. Wings 182 of shuttle 134 are configured for longitudinal movement within axial notches 188 of inner rail 128. When fingers 184 of shuttle 134 are disposed in their normally biased

outward position, fingers 184 engage the lower surface 194 of inner rail 128. In the configuration illustrated in FIGURE 26, shuttle 134 is locked with respect to inner rail 128. As will be discussed herein, fingers 184 may be biased radially inward to allow upward movement of shuttle 134 relative to inner rail 128.

[00218] As illustrated in FIGURE 10, inner rail 128 includes an upper surface 186 for engagement with handle 102. In some embodiments, surface 186 is adhered or otherwise fixed to handle 102.

[00219] The relationship of inner rail 128, shuttle 134 and base 142 is illustrated in FIGURE 27. In an initial configuration, inner rail 128 and shuttle 134 are in a locked relationship by engagement of wings 182 and fingers 184. Inner rail 128 and shuttle 134 are axially movable within base 142. Spring 146, which is secured between spring retention portion 148 of base 142 and wings 182 of shuttle 134 biases the inner rail 128 and shuttle 134 in a proximal (upward) direction.

[00220] Inserter 100 is illustrated in section in FIGURES 28-29 prior to use in a sensor predeployment position. Cap 104 is attached to the distal portion of inserter 100, *e.g.*, *via* inter-engagement of threads 110 and 111.

[00221] As illustrated in FIGURE 28, the inserter 100 includes an initial configuration in which the handle 102 is disposed in a proximal position with respect to the base 142. In such configuration, the sharp 124 is disposed in a configuration spaced apart from an aperture of the adhesive layer 118.

[00222] As illustrated in FIGURE 30, inner rail 128 includes a carriage 130. In a sensor insertion position, the handle 102 is depressed downward (arrow D) against the bias of spring 146, the inner rail 128 moves downwardly with the carriage 130 and the sensor housing 122. Shuttle 134 supports needle hub 136, from which sharp 124 extends longitudinally within the inserter 100. Initially, shuttle 134 is coupled to inner rail 128 *via* inter-engagement of fingers 184 of shuttle 134 with distal surface 194 of inner rail 128, and both shuttle 134 and inner rail 128 move distally together as a unit.

[00223] As the sharp 124 is urged distally towards the subject's skin (FIGURE 30), it carries the sensor insertion portion 30 of sensor 14 into the subcutaneous portion of the subject's skin S and into contact with the interstitial fluid. As carriage 130 reaches a distal position, the distal surface of the sensor housing 122 engages the upper surface of adhesive pad 118, thereby becoming adhered to the skin surface S of the subject.

[00224] In some embodiments, components are provided which allow the shuttle to be disengaged from the handle 102. For example, flanges 170 on base 142 engage fingers 184 of shuttle 134. Fingers 184 are pivoted or bend inwards by contact with flanges 170 (as indicated by arrows F).

[00225] As illustrated in FIGURE 31, such pivoting of fingers 184 causes fingers 184 to become disengaged from distal edge 194 of inner rail 128. Shuttle 134 is thereby disengaged from inner rail 128. Disengagement of the shuttle 134 from the inner rail 128 permits the spring 146 decompress and to expand, thereby advancing the shuttle 134 to a proximal or retracted position, and withdrawing the sharp 124 from the sensor housing 122, withdrawing from its position around sensor 14, and receding from skin S of the subject, while leaving the sensor 14 in

the skin and the on body unit 16 attached to the skin surface by adhesive pad 118. Once the sharp has been withdrawn from the subject, it is no longer accessible from the distal portion of the inserter 100, which prevents accidental needle sticks. When the carriage 130 reaches the distal position in which flanges 170 engage fingers 184 of needle shuttle 134, needle shuttle 134 withdraws sharp 124 automatically without further input from the user.

[00226] As illustrated in FIGURE 31A, the inserter 100 may be removed from the skin S of the subject, leaving the on-body unit 16 installed on the subject, e.g., lower surface of housing 122 adhered to the skin S via adhesive pad 118 and sensor 14 at least partially inserted in the skin and in contact with the interstitial fluid.

[00227] Prior to activation of the on-body unit 16 which includes the integrated sensor 14 and sensor control unit 12 for use, there may be a period of time from the manufacturing that the assembly 16 may be in a “sleep” or “idle” mode. With a power supply such as a battery integrated within the assembly, for reasons including cost optimization and prolonging shelf life, some embodiments of the present disclosure include optional systems that are activated merely by positioning the sensor 14 and on-body unit 16 on a skin surface as described above, *i.e.*, no additional action may be required of the user other than applying a force to sensor housing 122. As such, insertion of the sensor 14 and/or mounting of the sensor housing 122 causes activation of the electronics 80. In certain embodiments, activation switch configurations are included which may be configured to be triggered, for example, by the insertion device activation, thereby turning on the integrated sensor and sensor electronics assembly into an active mode.

[00228] As illustrated in FIGURE 29, inserter 100 may be provided with a switch 185, which provides automatic activation of the electronics 80 of the sensor control unit 12. In some

embodiments, the switch 185 is a longitudinally slidable member or plunger extending distally from or otherwise disposed on the distal surface of the sensor housing 122. When the sensor housing is advanced proximally, it engages the adhesive pad 118, or alternatively the skin surface of the subject. Upon such engagement, the switch 185 is moved axially (proximally) with respect to the housing 122. When the sensor housing 122 is in approximation with the adhesive pad 118 and/or the skin of the subject, the plunger switch 185 is in the proximal position (not shown). Such axial movement may be used to activate the sensor electronics 80. In some embodiments, a switch 185 is spring biased. Accordingly, as long as the sensor housing 122 is maintained in a fixed relationship with the adhesive pad 118 against the bias, electronic activation is maintained in such embodiments. If the sensor housing 122 is removed from the adhesive or the skin, the switch 185 moves with the bias, and the electronics are deactivated. In other embodiments, the switch 185 provides a one-time activation of the electronics. In such cases, once the electronics are activated, the sensor housing 122 is not required to remain in contact with the adhesive or the skin in order to maintain activation.

[00229] As illustrated in FIGURES 32-33, embodiments of a power supply switch mechanism include conductive plugs of the on-body unit 16 in accordance with the present disclosure. FIGURES 32-33 illustrate enlarged sectional views of sensor housing 122. As shown, the sensor electronics assembly circuit board 860 may be provided with a physical gap 858 that breaks the electrical circuit between the power supply (*e.g.*, battery) and the other circuitry of the sensor electronics assembly.

[00230] In one embodiment, when the predetermined force is applied on the insertion device 100 as discussed above, a conductive portion 852 provided within the housing 122 of the sensor

electronics may be moved in a direction as shown by arrow 854 such that electrical contact is established in the physical gap 858 on the circuit board, by for example, the conductive portion 852 coming into physical contact with the conductive portions of the circuit board 860. In this manner, in one embodiment, the electrical path from the power supply and the remaining circuitry on the circuit board of the sensor electronics is completed, thereby powering the sensor electronics.

[00231] By way of another example, referring to FIGURE 33, the conductive portions 860 of the circuit board are provided on the board itself, and the conductive plug 856, for example, when pushed into the cavity 858, establishes electrical contact between the conductive portions 860 of the circuit board.

[00232] In one embodiment, as discussed above, the actuation of the insertion device 100 to position the sensor 14 and sensor electronics assembly triggers the switch mechanism shown in FIGURES 32-33 by also moving the conductive portion 852 or the conductive plug 856 in the direction complimentary to the direction of the introducer movement, and thereby switching on the sensor electronics. Within the scope of the present disclosure, the activation of the sensor electronics by moving the conductive portion 852 or the conductive plug 856 may include a separate procedure, where, after positioning the sensor and the sensor electronics assembly on the skin surface, a predetermined force is applied on the housing of the integrated sensor 14 and sensor electronics assembly such that the desired movement of the conductive portion 852 or the conductive plug 856 may be achieved. Further embodiments of the insertion devices are described in U.S. Patent Application Serial Nos. 61/149,639, filed February 3, 2009, and No. 12/698,129, filed February 1, 2010, which are incorporated by reference herein in their entirety.

[00233] An inserter 200 in accordance with another exemplary embodiment is illustrated in FIGURE 34. In some embodiments, inserter 200 has a maximum diameter, of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 200 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 200 has a volume of about 35 cm³ to about 110 cm³, *e.g.*, about 40 cm³, about 41 cm³, about 50 cm³, about 60 cm³, about 61 cm³, about 62 cm³, about 69 cm³, about 70 cm³, about 79 cm³, about 90 cm³, about 106 cm³, etc.

[00234] With reference to FIGURE 34, inserter 200 includes a housing 202 and a removable distal cap 204 for maintaining a sterile environment for the medical device and sharp housed therein. Housing 202 and distal cap 204 may be fabricated from any suitable materials such as metal, plastic, etc. In some embodiments cap 204 may be fabricated from a polymer or plastic material. Also provided is a removable proximal cover 206, which, among other things, prevents accidental deployment of the inserter 200. In some embodiments, proximal cover 206 is a sheet of material such as a foil sheet or the like secured to the upper surface of housing 202 using an adhesive, and may include a tab 208 to assist removal of the cover 206. Proximal cover 206 may also be a plastic sheet or member that forms a seal with housing 202. In some embodiments, proximal cover 206 may include a pull tab or a perforated section for easy removal.

[00235] As illustrated in FIGURE 35, proximal cover 206 and distal cap 204 are shown removed from inserter 200. Distal cap 204 is secured to housing 202, *e.g.*, by use of threads 210. In some embodiments, distal cap 204 is secured by a friction fit, snap fit, a bayonet mount, an adhesive, etc. Housing 202 includes a distal surface 212 for placement on the skin of a subject.

Insertor 200 includes an actuator 214 to advance a medical device into the skin of the subject. In some embodiments, actuator 214 is disposed within an opening 216 in housing 202 and can be longitudinally moveable within housing 202.

[00236] The distal portion of inserter 200 is illustrated in FIGURE 36. In some embodiments, an adhesive pad 218, having adhesive material 218 on both faces, is provided across the distal portion 212 of the housing 202. A central aperture 220 may be provided in adhesive pad 218. As will be described in greater detail herein, inserter 200 supports a medical device, such as an analyte sensor housing 122 (not shown) and a sharp 224. In some embodiments, sensor housing 122, includes an analyte sensor 14 and a sensor control unit 12. During insertion, sharp 224 passes through aperture 220 and into the skin of the subject carrying at least the sensor with it.

[00237] FIGURE 37 illustrates inserter 200 in cross-section, in an initial configuration prior to use, after removal of the distal cap 204. Actuator 214 may be cylindrical in shape (or other shape as appropriate) and, including an upper contact surface 226, capable of being depressed by a user and/or a mechanism, as described herein. Actuator 214 may further include side walls 228 extending downwardly from upper surface 226, and which engage or otherwise contact the upper surface of carriage 230. Carriage 230 provides a support for holding the medical device, such as sensor housing 122 of on-body unit 16, prior to and during installation. In some embodiments, carriage 230 includes a distal portion 232, which may be configured to form a substantially concave recess 232a as shown in this embodiment, for supporting the medical device therein. In some embodiments, the sensor housing 122 is supported within the recess 232a of carriage 230 in a snap-fit or other relationship. In some embodiments, carriage 230 does not include a recess.

In such embodiments, carriage may include one or more projections which contact and/or advance the sensor housing 122.

[00238] In FIGURE 38 the longitudinal axis L of the inserter 200 is illustrated. Extending distally from the upper surface 226 of actuator 214 and substantially parallel to the longitudinal axis is a support member 234, which may have an elongated configuration. Support member 234 supports needle hub 236, from which sharp 224 extends longitudinally within the inserter 200. In some embodiments, the sharp 224 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface. Needle hub 236 can be secured to support member 234 via an interlocking O-ring configuration, adhesive, or other techniques known in the art. Support member 234 can be omitted and needle hub 236 can be secured to the actuator 214 directly in some embodiments.

[00239] In some embodiments, sharp 224 is a solid needle. In some embodiments, sharp 224 is provided with a substantially cylindrical configuration defining an interior bore, *e.g.*, a rigid cylindrical member or a hypodermic-style needle. Sharp 224 may also be provided with an elongated longitudinal opening or gap in the wall of the sharp 224 (see, sharp 224 in FIGURES 22-24). In some embodiments, sharp 224 is fabricated from a sheet of metal, and folded into a substantially “V” or “U” or “C” configuration in cross-section to define the longitudinal recess.

[00240] The sensor 14, mounted with the sensor housing 122, is carried by the carriage, *e.g.*, disposed within the concave recess 232a in the carriage 230, as described hereinabove (see, *e.g.*, FIGURES 22-24). In the initial configuration of the inserter 200 (see, *e.g.*, FIGURE 37), the sharp 224 extends through a longitudinal aperture 268 formed in the carriage 230. In some embodiments, the aperture 268 is appropriately sized, such that neither the sharp 224 nor needle

hub 236 is in contact with the carriage 230. In other words, in some embodiments a clearance may be provided between the surfaces of the carriage and the sharp and needle hub. In some cases, sharp 224 is capable of substantial lateral movement or “play” with respect to aperture 268. Accordingly, the needle hub 236 (and sharp 224) on the one hand, and the carriage 230 and the sensor housing 122, on the other hand, can move simultaneously but independently from one another.

[00241] Referring back to FIGURE 23, the insertion portion 30 and proximal retention portion 48 of the sensor 14 are disposed within a longitudinal bore of the sharp 224. The proximal retention portion 48 is disposed within the longitudinal bore of the sharp 224 and provides additional stability to the disposition of the sensor 14 within longitudinal bore of the sharp 224. The longitudinal wall gap of sharp 224 is aligned with the sensor 14, such that the tab 50 and the contact portion 32 extend laterally outward from the sharp 224.

[00242] With continued reference to FIGURE 37, an optional sheath 242 is positioned within housing 202, having an annular configuration and including a circumferential recess 244 in which a retraction spring 246 is positioned. The distal portion of spring 246 contacts a spring retention portion 248 in sheath 242. The proximal portion of spring 246 contacts one or more tabs 250 extending laterally outwardly from actuator 214. In the initial configuration, the spring 246 may be in a semi-compressed state, *i.e.*, not fully compressed, nor fully extended. It is understood that sheath 242 may be omitted from inserter 200, and a recess, such as recess 244, provided within housing 202. Similarly, recess 244 may be omitted entirely, and spring 246 or other actuator may be disposed between stops in housing 202.

[00243] Depression of the actuator 214 causes distal longitudinal movement of the carriage 230 and sharp 224, from a proximal position to a distal position. During such downward, distal movement, spring 246 is further compressed between spring retention portion 248 and flanges 250.

[00244] As illustrated in FIGURE 38, depression of the actuator 214 advances the inserter 200 from an initial configuration to a deployed configuration. Depression of the contact surface 226 moves the actuator side walls 228 and the tabs 250 downwardly distally against the bias of spring 246. Contact of the side wall 228 of the actuator 214 with the upper surface of the carriage 230 during depression of the actuator 214 imposes a downward force and consequential distal movement of the carriage 230. As the sharp 224 is urged distally, it carries the sensor insertion portion 30 into the subcutaneous portion of the subject's skin S.

[00245] As illustrated in FIGURE 37, flanges 270 are disposed in the inner wall of sheath 242. When carriage 230 reaches a distal position, as shown in FIGURE 38, the flanges 270 engage the proximal (upper) surface of the carriage 230, and thereby inhibit proximal movement of the carriage 230 (see also FIGURE 41). The distal (lower) surface of the sensor housing 122 engages the upper surface of adhesive pad 218, thereby becoming adhered to the skin surface S of the subject. As the flanges 270 engage the carriage 230, the flanges 270 also engage fingers 274 disposed on the proximal face of the carriage 230. Fingers 274 are pivoted inwards by flanges 270. Such pivoting of fingers 274 causes fingers 274 to become disengaged from retention tab 250 on actuator 214. Spring 246 is thereby permitted to decompress and expand, and thereby provide an upward force on actuator 214. If the user or some apparatus provides no downward force, or minimal downward force to overcome the bias of spring 246, the actuator

214, along with needle hub 236 and sharp 224 move proximally, withdrawing the sharp 224 from the skin S of the subject.

[00246] As shown in FIGURES 39 and 40, the actuator 214 and coupled sharp 224 is permitted to advance to a more proximal position than at the initial configuration illustrated in FIGURES 35 and 37. Thus the sharp 224 retracts from a distal position to a proximal position after installation of the on-body unit and insertion of at least a portion of the sensor. As illustrated in FIGURE 41, the carriage 230 is maintained in a distal position, but the sharp 224 has been withdrawn from the subject and is no longer accessible from the distal portion of the inserter 200, which prevents accidental needle sticks.

[00247] A further embodiment of an inserter is illustrated in FIGURES 42-56 and designated inserter 300. In some embodiments, inserter 300 has a maximum diameter of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 300 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 300 has a volume of about 35 cm³ to about 110 cm³, *e.g.*, about 40 cm³, about 41 cm³, about 50 cm³, about 60 cm³, about 61 cm³, about 62 cm³, about 69 cm³, about 70 cm³, about 79 cm³, about 90 cm³, about 106 cm³, etc.

[00248] As illustrated in FIGURE 42-43, inserter 300 includes, *e.g.*, a handle 302, a sheath 342, and a removable distal cap 304 for maintaining a sterile environment for the medical device and sharp housed therein. FIGURE 43 illustrates that distal cap 304 is removed from handle 302. Distal cap 304 is secured to handle 302 by one of a number of securement means, *e.g.*, by use of threads 310. Sheath 342 defines a distal surface 312 for placement on the skin of a

subject. Inserter 300 may be utilized to advance a medical device into the skin of the subject. In some embodiments, handle 302 is advanced relative to sheath 342 in order to advance the medical device into the skin of the patient.

[00249] The components of inserter 300 are illustrated in FIGURES 44-49. As illustrated in FIGURE 44, handle 302 may include threads 310 for attachment of cap 304 via threads 311 (as illustrated in FIGURE 46). It is understood that other securement techniques, such as a snap-fit or friction-fit may be used to secure cap 304. Cap 304 may include a receptacle 325 for positioning of the sharp 324. Sheath 342, as illustrated in FIGURE 45, includes longitudinal notches 382.

[00250] Projections 386 on carriage 330, as illustrated in FIGURE 47, are configured to engage sheath to secure carriage 330 within the inserter 300, thereby preventing release of the carriage from the inserter. Notches 384 allow for the free travel of projections 386. The bottom of the notches acts as the retention portion that prevents the carriage 330 from falling out of the inserter 300. Projections 375 engage with the triangular latch features 370 of the sheath 342 as illustrated in FIGURES 51 and 53.

[00251] Carriage 330 also is provided with fingers 374 which engage a shoulder wall 376 of handle 302 (as illustrated in FIGURE 51), as will be described in greater detail herein.

[00252] Inserter 300 also includes a spring retention component 348, as illustrated in FIGURE 48. Spring retention component 348 defines an upper surface 349, which engages spring 346 (as illustrated in FIGURE 51). Spring retention component 348 also includes locking towers 351, which engage flanges 328 of needle carrier 334 to prevent accidental deployment of the sharp 324 after use of the inserter 300 is completed.

[00253] Inserter 300 is illustrated in cross-section in FIGURE 50 prior to use. Cap 304 is attached to the distal portion of inserter 300, via securement means, such as inter-engagement of threads 310 and 311. Cap 304 includes a desiccant tablet 390; a seal, such as a foil seal 392; and a Tyvek® layer 394, which allows breathability between the desiccant tablet 390 and the interior of the inserter 300.

[00254] As illustrated in FIGURE 51, the inserter 300 includes an initial configuration in which the handle 302 is disposed in a proximal position with respect to the sheath 342. In such configuration, the sharp 324 is disposed in a configuration spaced apart from the aperture 320 of the adhesive layer 318. The distal portion of inserter 300 is illustrated in FIGURE 52.

[00255] With continued reference to FIGURE 51, the longitudinal axis L of the inserter 300 is illustrated. Extending distally from the upper surface of handle 302 is an inner wall portion 326 and intermediate wall portion 374. Support member 334 extends from wall portion 326 and supports needle hub 336, from which sharp 324 extends longitudinally within the inserter 300. In some embodiments, the sharp is supported at an oblique angle, *e.g.*, between 0° and 90° with respect to the skin surface.

[00256] Sheath 342 is positioned within handle 302, having an annular configuration in which a retraction spring 346 is positioned. The distal portion of spring 346 contacts a surface 349 of spring retention component 348. The proximal portion of spring 346 contacts the inner surface 350 of handle 302. In the initial configuration, the spring 346 is in an extended or semi-extended configuration.

[00257] FIGURE 53 illustrates inserter 300 in cross-section, during insertion. Depression of handle 302 with respect to sheath 342 against the bias of spring 346 causes distal longitudinal

movement of the carriage 330 and sharp 324, from a proximal position towards a distal position. During such downward, distal movement, spring 346 is compressed between surface 349 of spring retention component 348 and surface 350 of handle 302. As the sharp 324 is urged distally, it carries the sensor insertion portion 30 of sensor 14 into the subcutaneous portion of the subject's skin S.

[00258] As carriage 330 reaches a distal position, the distal surface of the sensor housing 122 engages the upper surface of adhesive pad 318, thereby becoming adhered to the skin surface S of the subject. Also, flange 370 engages fingers 374 disposed on the carriage 330. Fingers 374 are pivoted outwards by flanges 370 in direction T. Such pivoting of fingers 374 causes fingers 374 to become disengaged from slots 376 in intermediate housing walls 374. Carriage 330 is thereby disengaged from handle 302 and needle carrier 334.

[00259] As illustrated in FIGURE 54, handle 302, along with needle hub 336 and sharp 324 are permitted to move proximally, while the sheath 342 and sensor housing 122 remain adjacent to the skin of the subject. If the user or some apparatus provides no downward force, or minimal downward force to the handle 302 to overcome the bias of spring 346, spring 346 is permitted to expand, thereby withdrawing the sharp 324 from the skin S of the subject.

[00260] Upon reaching the proximal position, flanges 328 on needle carrier 334 engage locking towers 351 of needle floor component 348. The inter-engagement of flanges 328 and locking towers 351 prevents inadvertent deployment of sharp 324 after installation of the medical device.

[00261] As shown in FIGURES 55 and 56, the carriage 330 is maintained in a distal position, but the sharp 324 has been withdrawn from the subject and is no longer accessible from the distal portion of the inserter 300, which prevents accidental needle sticks.

[00262] A further embodiment of an inserter is illustrated in FIGURES 57-67, and designated inserter 400. In some embodiments, inserter 400 has a maximum diameter of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 400 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 400 has a volume of about 35 cm³ to about 110 cm³, *e.g.*, about 40 cm³, about 41 cm³, about 50 cm³, about 60 cm³, about 61 cm³, about 62 cm³, about 69 cm³, about 70 cm³, about 79 cm³, about 90 cm³, about 106 cm³, etc.

[00263] Inserter 400 generally includes, *e.g.*, a handle 402, sheath 442, and a removable distal cap 404 for maintaining a sterile environment for the medical device and sharp housed therein. As illustrated in FIGURE 58, distal cap 404 is shown removed from handle 402. Distal cap 404 is detachably secured to handle 402, *e.g.*, by use of threads 410. Sheath 442 includes a distal surface 412 for placement on the skin of a subject. Inserter 400 may be utilized to advance a medical device into the skin of the subject. In some embodiments, handle 402 is advanced relative to sheath 442 in order to advance the medical device distally and into the skin of the patient.

[00264] The components of inserter 400 are illustrated in FIGURES 59-63. As illustrated in FIGURE 59, handle 402 includes threads 410 for attachment of cap 404 via threads 411 (as illustrated in FIGURE 61). Cap 404 may include a receptacle 425 for positioning of the sharp

424. Sheath 442, as illustrated in FIGURE 60, includes longitudinal notches 482. Projections 486 on carriage 430, as illustrated in FIGURE 62, are configured to engage sheath 442 to secure carriage 430 within inserter 400, thereby preventing release of the carriage from the inserter. Sheath 442 also includes notches 484 which receive projection 475 of carriage 430. Notches 484 allow for the free travel of projections 486. The bottom of the notches acts as the retention portion that prevents the carriage 430 from falling out of the inserter 400. Projections 475 engage with the latch features 470 of the sheath 442 as illustrated in FIGURES 66 and 67. Carriage 430 also is provided with fingers 474 which engages a shoulder wall 476 of needle carrier 436, as illustrated in FIGURES 65-66, and as will be described in greater detail herein.

[00265] Sheath 442 also includes a spring retention portion 448, provided at the distal end of circumferential notch 496, as illustrated in FIGURES 60, 64 and 65. Needle carrier 434, as illustrated in FIGURE 63, includes wings 450, which provide an upper engagement surface for spring 446. Wings 450 also include recesses 451 including a shoulder 476 for engagement with fingers 474 of carriage 430.

[00266] Inserter 400 is illustrated in cross-section in FIGURE 64 in a state prior to use and prior to removal of cap 404, which is shown attached to the distal portion of handle 402, via inter-engagement of threads 410 and 411. Cap 404 includes a desiccant tablet 490, a seal such as a foil seal 492, and a Tyvek® layer 494, which allows breathability between the desiccant tablet 490 and the interior of the inserter 400.

[00267] As illustrated in FIGURE 65, the inserter 400 is shown in an initial configuration in which handle 402 is disposed in a proximal position with respect to the sheath 442. In such configuration, the sharp 424 is disposed in a configuration spaced apart from the aperture 420 of

the adhesive layer 418. The longitudinal axis L of the inserter 400 is illustrated. Extending distally from the upper surface of handle 402 is inner wall 475. The distal end portions of wall 475 provide a downward force on the carriage 430 upon depression of the handle 402 by a user. Alternatively, instead of handle having a distally extending inner wall, the carriage can include one or more upwardly extending walls or projections (not shown). The one or more upwardly extending inner walls or projections can have a length sufficient to either contact the upper surface of 402 or, alternatively, contact corresponding downwardly extending inner walls of the handle 402. In this manner, depression of handle 402 by a user provides a downward force on the one or more upwardly extending walls or projections of the carriage to advance the carriage (and on-body unit) distally to an installation and insertion position. In one embodiment a downwardly extending wall of the handle 402 and a corresponding upwardly extending wall of the carriage are aligned such that depression of the handle 402 by a user allows the upwardly extending wall and the downwardly extending wall to make direct contact, thereby permitting the carriage 430 and on-body unit to advance distally. In such embodiment, the downwardly extending inner wall of the handle has a distal end that is disposed proximally of the proximal most end of sheath 442.

[00268] Needle carrier 434 can be axially moveable within handle 402. Needle carrier 434 supports needle hub 436, from which sharp 424 extends longitudinally within inserter 400. In some embodiments, sharp 424 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface. Initially, needle carrier 434 is coupled to carriage 430 via inter-engagement of fingers 474 of carriage 430 with shoulder 476 of needle carrier 434. Spring 446 is disposed between spring retention portion 448 of sheath 442 and wings 450 (FIGURE 63) of needle carrier 434. Initially, spring 446 is in an expanded or semi-

expanded state while handle 402 is disposed proximally from sheath 442. In another exemplary embodiment, needle carrier 434 can be secured to handle 402, for example, secured to downwardly extending inner wall 475. In this manner, needle carrier and carriage 430 are longitudinally moveable with respect to sheath 442. In this regard, needle carrier 434 includes one or more apertures to receive one or more downwardly extending inner walls 475 of handle 402. In some embodiments, neither the needle carrier 434 nor the carriage 430 are in slidable contact with sheath 442, *e.g.*, spaced apart from sheath 442, during longitudinal movement of the needle carrier 434 and/or carriage 430.

[00269] FIGURE 66 illustrates inserter 400 in cross-section, during insertion. Depression of handle 402 with respect to sheath 442, against the bias of spring 446, causes distal longitudinal movement of the carriage 430 and needle carrier 434, from a proximal position towards a distal position. During such downward proximal movement, spring 446 is compressed between spring retention portion 448 and wings 450 (FIGURE 63) of needle carrier 434. As the sharp 424 is urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIGURE 23) into the subcutaneous portion of the subject's skin S.

[00270] As carriage 430 reaches a distal position, the distal surface of the sensor housing 122 engages the upper surface of adhesive pad 418, thereby becoming adhered to the skin surface S of the subject. Flange 470 engages fingers 474 disposed on the carriage 430. Fingers 474 are pivoted outwards by flanges 470 in direction T. Such pivoting of fingers 474 causes fingers 474 to become disengaged from shoulder 476 of needle carrier 434. Needle carrier 434 is thereby disengaged from carriage 430.

[00271] As illustrated in FIGURE 67, disengagement of the needle carrier 434 from the carriage 430 permits the spring 446 to expand, thereby advancing the needle carrier 434 to a proximal position and withdrawing the sharp 424 from the skin S of the subject while leaving the sensor 14 in the skin. Once the sharp 424 has been withdrawn from the subject, it is no longer accessible from the distal portion of the inserter 400 and unable to make contact by accident with the subject's skin because it is positioned at a proximal position within the carrier handle 402.

[00272] A further embodiment of an inserter is illustrated in FIGURES 68-71 and designated inserter 500. In some embodiments, inserter 500 has a maximum diameter of about 30 mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 500 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 500 has a volume of about 35 cm³ to about 110 cm³, *e.g.*, about 40 cm³, about 41 cm³, about 50 cm³, about 60 cm³, about 61 cm³, about 62 cm³, about 69 cm³, about 70 cm³, about 79 cm³, about 90 cm³, about 106 cm³, etc.

[00273] Inserter 500 includes, *e.g.*, a bellows portion 502, a sheath 542, and a removable distal cap 504 for maintaining a sterile environment for the medical device and sharp housed therein. As illustrated in FIGURE 69, distal cap 504 is shown removed from sheath 542. Sheath 542 defines a distal surface 512 for placement on the skin of a subject. Inserter 500 may be utilized to advance a medical device into the skin of the subject. In some embodiments, bellows portion 502 is compressed in order to advance the medical device into the skin of the subject. Bellows portion 502 includes a series of concentric folds, including raised portions 516 and folded portions 518.

[00274] Inserter 500 is illustrated in cross-section in FIGURE 70 prior to use and prior to removal of cap 504, which is attached to sheath 542 via inter-engagement of threads 510 on sheath and threads 511 on cap 504. Cap 504 includes a desiccant tablet 590. Cap 504 may further include a receptacle for maintaining the position of the sharp 524 within the sheath 542 prior to use.

[00275] As illustrated in FIGURE 70, the inserter 500 includes an initial configuration in which the bellows portion 502 is disposed in a relaxed, extended position. In such configuration, the sharp 524 is disposed in a position spaced apart from the aperture 520 of the adhesive layer 518. The proximal end portion of the housing includes a button or actuator portion 514. Extending distally from the actuator portion 514 are side walls 528 and needle hub 536. Downward force on the actuator portion 514 causes a downward force on the needle hub 536 and on the carriage 530 (through coupling to side walls 528). Carriage 530 includes a recess 532 for reception of the sensor housing 122 therein. Sharp 524 extends longitudinally from needle hub 536 within the inserter 500. In some embodiments, the sharp is supported at an oblique angle, *e.g.*, between including about 0° and 90° with respect to the skin surface.

[00276] FIGURE 71 illustrates inserter 500 in cross-section, during insertion. Depression of bellows portion 502 with respect to sheath 542 against the bias of spring 546 causes distal longitudinal movement of the carriage 530 and sharp 524 from a proximal position toward a distal position. During such downward, proximal movement, spring 546 is compressed between an upper (proximal) portion adjacent to actuator 514 and a lower (distal) portion adjacent to sheath 542. As the sharp 524 is urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIGURE 23) into the subcutaneous portion of the subject's skin S.

[00277] By removing downward force on the actuator portion 514, the bias of spring 546 provides an upward (proximal) force, which permits sharp 524 to withdraw from the skin S of the subject. Once the sharp 524 has been withdrawn from the subject, it is no longer accessible from the distal portion of the inserter 500, and unable to make contact by accident with the subject's skin.

[00278] An inserter 2400 in accordance with another exemplary embodiment is illustrated in FIGURE 72. In some embodiments, inserter 2400 has a maximum diameter, of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 2400 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 2400 has a volume of about 35 cm³ to about 110 cm³, *e.g.*, about 40 cm³, about 41 cm³, about 50 cm³, about 60 cm³, about 61 cm³, about 62 cm³, about 69 cm³, about 70 cm³, about 79 cm³, about 90 cm³, about 106 cm³, etc.

[00279] With reference to FIGURE 72, inserter 2400 includes a housing 2402 and a removable distal cap 2412 for maintaining a sterile environment for the medical device and sharp housed therein. Housing 2402 and distal cap 2412 may be fabricated from any suitable materials such as metal, plastic, etc. In some embodiments, cap 2412 may be fabricated from a polymer or plastic material.

[00280] An exploded view of the components of inserter 2400 is illustrated in FIGURE 72A. As shown, inserter 2400 generally comprises plunger 2405, spring 2406, housing 2402, sharp 2404, sensor housing 122, sharp holder 2408, adhesive patch 218, and cap 2412 when fully assembled.

[00281] A more detailed view of sharp holder 2408 is shown in FIGURE 72B. Needle holder 2408 retains sharp 2404 in a fixed position with respect to itself within inserter 2400, thereby allowing it to safely penetrate a subject's skin during later use.

[00282] To assemble inserter 2400, sharp 2404 is inserted through an opening in sensor housing 122 as shown in FIGURE 72C. Needle holder 2408 prevents sharp 2404 from being fully inserted through sensor housing 122. In some embodiments, sensor housing 122 includes an analyte sensor 14 and a sensor control unit 12.

[00283] Next, plunger 2405, spring 2406, and housing 2402 are assembled as shown in FIGURES 72D-72F. Plunger 2405 contains a spring retention member which is inserted through the center of spring 2406. Lip 2414 of plunger 2405 engages inner wall 2416 of housing 2402 when assembled (FIGURE 72). This causes spring 2406 to be contained between lip 2418 of housing member 2402 and the bottom surface 2424 of plunger 2405. The resulting sub-assembly of inserter 2400 shown in allows plunger 2405 to move between a proximal position, with spring 2406 fully extended, and a distal position, wherein bottom surface 2424 engages wall 2426 of housing 2402.

[00284] The sensor housing assembly shown in FIGURE 72C is then inserted into the inserter sub-assembly shown in FIGURES 72D-72F. As shown in FIGURE 72F, sensor housing 122 is inserted into housing 2402 with the tip of sharp 2404 pointing away from plunger 2405. The resulting assembly is depicted in FIGURE 72G. As shown in FIGURE 72, grooves on sharp holder 2408 engage tabs 2422 on plunger 2405.

[00285] Finally, adhesive patch 218 is placed over the opening of housing 2402 and cap 2412 is friction fit over housing 2402 as shown in FIGURE 72H. The fully assembled inserter 2400 is

depicted in FIGURE 72I. In some embodiments, adhesive pad 218 has an adhesive material on both faces. A central aperture 220 may be provided in adhesive pad 218 to allow sharp 2404 to be deployed into the skin of a subject. During insertion, sharp 2404 passes through aperture 220 and into the skin of the subject carrying at least the sensor with it.

[00286] FIGURE 72J illustrates inserter 2400 in cross-section, in an initial configuration prior to use, after removal of the distal cap 2412. As shown, sharp 2404 extends longitudinally within the inserter 2400. In some embodiments, sharp 2404 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface.

[00287] In some embodiments, sharp 2404 is a solid needle. In some embodiments, sharp 2404 is provided with a substantially cylindrical configuration defining an interior bore, *e.g.*, a rigid cylindrical member or a hypodermic-style needle. Sharp 2404 may also be provided with an elongated longitudinal opening or gap in the wall of the sharp 2404. In some embodiments, sharp 2404 is fabricated from a sheet of metal, and folded into a substantially “V” or “U” or “C” configuration in cross-section to define the longitudinal recess.

[00288] Depression of plunger 2405 causes distal longitudinal movement of sensor housing 122 and sharp 2404, from a proximal position to a distal position. During such downward, distal movement, spring 246 is further compressed between lip 2418 and bottom surface 2424. Lip 2414 is pushed outward by sensor housing 122 and the friction between sensor housing 122 and lip 2414 of the housing hold the sensor housing 122 up against plunger 2405.

[00289] As illustrated in FIGURE 72K, depression of plunger 2405 advances the inserter 2400 from an initial configuration to a deployed configuration. Contact of plunger 2405 and sharp holder 2408 during depression of plunger 2405 imposes a downward force and

consequential distal movement of sharp 2405.the carriage 230. As the sharp 2404 is urged distally, it carries the sensor insertion portion 30 into the subcutaneous portion of the subject's skin S.

[00290] When plunger 2505 reaches a distal position, as shown in FIGURE 72L, bottom surface 2424 engages wall 2426 and prevents further downward movement. The distal (lower) surface of sensor housing 122 engages the upper surface of adhesive pad 218, thereby becoming adhered to the skin surface S of the subject.

[00291] As the subject or some apparatus removes force from pusher 2405, spring 2406 urges pusher 2405 toward its proximal position as shown in FIGURE 72M, leaving sensor housing 122 adhered to the skin surface S of the subject. Tabs 2424 provide additional force on sensor housing 122 to assist holding it to adhesive patch 218 while the sharp 2404 is withdrawn through sensor housing 122. Eventually, the upward force exerted by spring 2406 returns inserter 2400 to its initial configuration as illustrated in FIGURE 72N.

[00292] In some embodiments, inserter 2400 may be distributed in a sterilized package 2480 as depicted in FIGURE 72O. To use inserter 2400 in this configuration, a user would first clean the insertion site on the skin with alcohol. The subject would then remove inserter 2400 from sterilized package 2480 as shown in step 1. Next a subject would place the inserter on the insertion site and push down on inserter 2400 until sensor housing 122 is adhered to the subject's skin as shown in steps 2-3. Finally, the subject would remove inserter 2400 from the insertion site and dispose of the inserter.

[00293] In another embodiment, the sterilized inserter 2500 shown in FIGURE 72O may be utilized with driver apparatus 3900 (FIGURES 93-93H) as shown in FIGURE 72P. In this

manner, insertion of sensor housing unit is semi-automated which may deliver a more consistent user experience and reduce the risk of user error. Additionally, because inserter 2500 is already sterilized, utilizing the method depicted in FIGURE 72P also reduces the risk of possible infection.

[00294] A further embodiment of an inserter is illustrated in FIGURES 73-73N, and designated inserter 2500. In some embodiments, inserter 2500 has a maximum diameter of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.25 mm, about 52 mm, etc. In some embodiments, inserter 2500 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50.25 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 2500 has a volume of about 35 cm³ to about 110 cm³, *e.g.*, about 40 cm³, about 41 cm³, about 50 cm³, about 60 cm³, about 61 cm³, about 62 cm³, about 69 cm³, about 70 cm³, about 79 cm³, about 90 cm³, about 106 cm³, etc.

[00295] Inserter 2500 generally includes, *e.g.*, a handle 2502, sheath 2512, and a removable distal cap 2504 for maintaining a sterile environment for the medical device and sharp housed therein (FIGURE 73). As illustrated in FIGURES 73A-73B, handle 2502 is shown removed from distal cap 2504. Distal cap 2504 is detachably secured to handle 2502, *e.g.*, by use of threads 2506. It is understood that cap may be secured using snap-fit or press-fit configuration. Inserter 2500 may be utilized to advance a medical device into the skin of the subject. In some embodiments, handle 2502 is advanced relative to sheath 2512 in order to advance the medical device distally and into the skin of the patient.

[00296] Handle 2502 further includes needle carrier guides 2508 which allow the needle carrier 2514 to slidingly move relative to distal cap 2504. Detent 2507 prevents sheath 2512

from moving towards a “firing position” until a minimum force is applied. Location feature 2510 allows for the proper positioning of distal cap 2508 and carriage 2516 when engaged.

[00297] Further components of inserter 2500 are illustrated in FIGURES 73C-73G. Sheath 2512, as illustrated in FIGURES 73C, may include longitudinal notches 2518 which snap into detents 2507. Retention members, such as ribs 2520, pinch spring arms 2522 located on carriage 2516 to prevent sensor housing 122 from falling out of inserter 2500 when sheath 2512 is in the extended position. Ribs 2520 do not extend to the bottom of sheath 2512, thus allowing carriage 2516 to release sensor housing 122 when it has traveled to the bottom of sheath 2512 during insertion. Interfering structure, such as locking beam 2524, prevents inserter 2500 from being used again once needle carrier 2514 passes the locking beam (FIGURE 73N). Specifically, locking feature 2526 of needle carrier 2526 engages with locking beam 2524 to prevent further use of inserter 2500.

[00298] Needle carrier 2514 is illustrated in greater detail in FIGURES 73D-73E. In some embodiments, needle carrier 2514 includes guides, such as rail guides 2528, which interface with rail guides 2508, thereby allowing needle carrier 2514 to slidingly move relative to handle 2502. Notches 2527 are provided in sheath 2512 which has a larger dimension than the wings 2550 of needle carrier 2514, such that the needle carrier 2514 does not contact sheath 2512 during longitudinal movement of needle carrier 2514. Needle carrier 2514 also comprises detents 2530 which interface with the upper edge of the spring when inserter 2500 is fully assembled (see FIGURES 73H-73N). In some embodiments, needle carrier 2514 comprises an attachment feature 2532 capable of accommodating a custom needle hub or attachment. Rails 2534, located

on the inner perimeter of needle carrier 2514, slidably engage with slots 2536 located on carriage 2516.

[00299] Carriage 2516 is illustrated in greater detail in FIGURES 73F-73G. As shown, carriage 2516 may comprise latches 2538 which connect it to needle carrier 2514 by locking with latches 2540. Spring hook 2542 allows for support for retaining sensor housing 122 when the inserter has not been fired and allows for release of sensor housing 122 when it has been attached to the skin of the user.

[00300] Inserter 2500 is illustrated in cross-section in FIGURE 73H in a state prior to use in which handle 2502 is disposed in a proximal position with respect to the sheath 2512. In such configuration, the sharp 2550 is disposed in a configuration spaced apart from the aperture 420 of the adhesive layer (not shown). The longitudinal axis L of the inserter 2500 is illustrated. The upper surface of spring 2544 is retained in inserter 2500 by detents 2530 located on needle carrier 2514. The bottom surface of spring 2544 is retained by retention tab 2546 located on sheath 2512. In some embodiments, sheath 2512 may additionally comprise retention member 2548 to help retain the position of spring 2544 against the walls of sheath 2512 during insertion. Initially, spring 2544 is in an expanded or semi-expanded state while handle 2502 is disposed proximally from sheath 2512.

[00301] Extending distally from the upper surface of handle 2502 is inner wall 2552. The distal end portions of wall 2552 provide a downward force on needle carrier 2514 upon depression of handle 2502 by a user. Alternatively, instead of handle 2502 having a distally extending inner wall 2552, needle carrier 2514 can include one or more upwardly extending walls or projections (not shown). The one or more upwardly extending inner walls or projections

can have a length sufficient to either contact the upper surface of handle 2502 or, alternatively, contact corresponding downwardly extending inner walls of handle 2502. In this manner, depression of handle 2502 by a user provides a downward force on the one or more upwardly extending walls or projections of needle carrier 2514 to advance carriage 2516 (and sensor housing 122) distally to an installation and insertion position. In one embodiment, a downwardly extending wall of the handle 2502 and a corresponding upwardly extending wall of needle carrier 2514 are aligned such that depression of the handle 2502 by a user allows the upwardly extending wall and the downwardly extending wall to make direct contact, thereby permitting the carriage 2516 and on-body unit to advance distally. In such embodiment, the downwardly extending inner wall of the handle has a distal end that is disposed proximally of the proximal most end of sheath 2512.

[00302] Sharp 2550 extends longitudinally from needle carrier 2514 within inserter 2500. In some embodiments, sharp 2550 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface.

[00303] FIGURE 73I illustrates inserter 2500 in cross-section after a user applies an initial downward force to button 2502. In some embodiments, a predetermined minimum force must be used so that longitudinal notches 2518 advance past detent 2507.

[00304] After detent 2507 has been overcome, further depression of handle 2502 with respect to sheath 2512, against the bias of spring 2544, causes distal longitudinal movement of the carriage 2516 and needle carrier 2514, from a proximal position towards a distal position as shown in FIGURE 73J. During such downward proximal movement, spring 2544 is compressed between detents 2530 and retention tab 2546. As sharp 2550 is further urged distally, it carries

the sensor insertion portion 30 of sensor 14 (FIGURE 23) into the subcutaneous portion of the subject's skin S.

[00305] As carriage 2516 reaches a distal position as shown in FIGURE 73J, the distal surface of the sensor housing 122 engages the upper surface of adhesive pad (not shown), thereby becoming adhered to the skin surface S of the subject. Latch 2538 engages the upper surface of retention tab 2546 as shown in FIGURES 73K. As a result, the top portion of latch 2538 is pivoted outward in direction T. Such pivoting of latch 2538 causes needle carrier to become disengaged from carriage 2516.

[00306] As illustrated in FIGURE 73L, disengagement of the needle carrier 2514 from the carriage 2516 permits spring 2544 to expand, thereby advancing the needle carrier 2514 to a proximal position and withdrawing the sharp 2550 from the skin S of the subject while leaving the sensor housing 122 attached to the skin. As the sharp is withdrawn (FIGURE 73M), locking beam 2524 advances past locking beam 2526 because of the upward force exerted on needle carrier 2514 by spring 2544.

[00307] Referring now to FIGURE 73N, once the sharp 2550 has been withdrawn from the subject, button 2500 cannot be pressed again because any downward movement will be blocked by the interaction of locking beam 2524 and locking feature 2526.

[00308] In some embodiments, inserter 2500 may come in a sterilized package which is capable of a one-time use as shown in FIGURE 73O. To use inserter 2500 in this manner, a user would first sterilize the insertion site on the skin with alcohol. The subject would then twist off cap 2504 as shown in step 1. Next a subject would place the inserter on the sterilized insertion site and push down on inserter 2500 until sensor housing 122 is adhered to the subject's skin as

shown in steps 2-3. Finally, the subject would remove inserter 2500 from the insertion site and dispose of the inserter. In this manner, the inserter 2500 itself serves as its own sterilized packaging.

[00309] Referring to FIGURES 74-76C, in another exemplary embodiment, inserter 2600 generally includes: actuator button 2602 (FIGURE 74A), shuttle 2604 (FIGURE 74B), inserter sharp 2610 with skin piercing edge 2612 (FIGURE 74B), retraction spring 2608 (FIGURE 74C), sensor 2614 (FIGURE 74D), housing 2616 (FIGURE 74E), and base 2618 (FIGURE 74F). It is understood that inserter 2600 may include additional or fewer components than described herein. The assembly of the different components of inserter 2600 is depicted in FIGURES 75A-75C. As shown in FIGURE 75A, actuator button is adapted to be slidably inserted through an opening in shuttle 2604 where it locks into position. Further, as shown in FIGURE 75B, retraction spring 2608 is adapted to be inserted into a second opening on the opposite side of shuttle 2604. Additionally, in this view, sensor 2614 has been attached to inserter sharp 2610. Any number of the aforementioned sensor connection methods can be utilized in conjunction with inserter 2600. For example, inserter sharp 2610 may be provided with rails and dimples, as previously described, in order to retain sensor 2614, the inserter sharp 2610 having a diameter of about 20 to about 26 gauge, *e.g.*, 21 gauge to about 25 gauge, where in certain embodiment's the sharp is 21 gauge or 23 gauge or 25 gauge. Such sharp may be used with a sensor having a width or diameter—at least the portion that is carried by the sharp—of about .20 mm to about .80 mm, *e.g.*, about .25 mm to about .60 mm, where in some embodiments the width or diameter of at least a portion of a sensor is .27 mm or .33 mm or .58 mm.

[00310] FIGURE 75C depicts a cross-sectional view of the assemblage of FIGURE 75B after inserter 2600 has been fully assembled (joining housing 2616 to base 2618). As depicted, retraction spring 2608 is surrounded by guides 2622 on its sides and by shuttle 2604 and base 2618 when inserter 2600 is assembled. Additionally, shuttle 2604 is adapted to slidably move on rails (not shown) within housing 2616, thereby allowing it to move in a linear direction when actuator button 2602 is depressed.

[00311] FIGURES 76A-76C illustrate the steps utilized to deploy sensor 2614 using inserter 2600. FIGURE 76A depicts inserter 2600 in a first configuration. The upward force exerted by retraction spring 2608 on shuttle 2604 (and consequently actuator button 2602) keeps inserter 2600 in its cocked position in the first configuration. As actuator button 2602 is pressed by a user against the bias of retraction spring 2608, it exerts a downward force on shuttle 2604 and retraction spring 2608. Introducer sharp 2610, on which sensor 2614 is mounted, is consequently driven downward and into the skin of the subject (*e.g.*, to a second configuration). Skin piercing edge 2612 pierces the skin of the subject and allows sensor 2614 to be properly inserted, as shown in FIGURE 76B.

[00312] As the force is removed from actuator button 2602, retraction spring 2608 exerts an upward force on shuttle 2604, thereby causing introducer sharp 2610 to return proximally to its original position inside of housing 2616 (*e.g.*, to the first configuration). Sensor 2614 remains implanted in the patient's skin, as shown in FIGURE 76C.

[00313] Embodiments of driver apparatuses for actuation of inserters 100, 200, 300, 400, and 500 discussed herein are provided. The driver apparatuses are modular subassemblies for coupling with any of the inserters. The driver apparatuses may be used with one or more of the

inserters described herein, or may be used with other inserters. Of course, the inserters described herein need not include a driver apparatus. A driver apparatus and an inserter may be removable from each other or may be provided to be fixed together and therefore constructed not to be separated from each other. In some embodiments the driver apparatus is attached to the inserter by a snap-fit or a frictional fit. In some embodiments, the inserter is fully functional to install an electrochemical sensor in a subject without the use of the driver apparatus.

[00314] The driver apparatuses provide a consistently repeatable / reproducible actuation force to assist in the installation of the medical device with an inserter such as the inserters described herein. In some embodiments, a driver apparatus includes a spring-biased element to provide force for the advancement of the sharp and/or sensor housing. In some embodiments, the driver apparatuses are reusable apparatuses, capable of being used multiple times, whereas inserters 100, 200, 300, 400, and 500 may be disposable devices, *e.g.*, capable of being used only once. In other embodiments, both the driver apparatus and the inserter are reusable, both the driver apparatus and the inserter are disposable, and/or the driver apparatus is disposable, and the inserter is reusable.

[00315] An exemplary driver apparatus is illustrated in FIGURES 77-83 and designated driver apparatus 3600.

[00316] Driver apparatus 3600 includes a housing 3602 for positioning with respect to an inserter. A loading element 3604 —longitudinally movable with respect to housing 3602—is provided. In some embodiments, driver apparatus 3600 is provided with an actuator , *e.g.*, rotating cam 3606 which provides automatic actuation of an inserter. In use, arming button 3620 is pressed (in direction of arrow E) to connect rack 3610 with pinion 3612 (FIGURE 77). As

illustrated in FIGURE 77, once arming button 3620 is pressed, loading element 3604 is depressed downwardly (direction of arrow D) to rotate cam 3606 in a first direction F against the bias of torsion spring 3614. Firing button 3618 maintains the spring in the loaded position until pressed.

[00317] As illustrated in FIGURE 79, the driver apparatus 3600 is positioned with respect to an inserter 500. Although inserter 500 is illustrated in FIGURES 79-83, it is understood that any one of inserters 100, 200, 300, 400, or 500 may be used with driver apparatus 3600. Since driver apparatus 3600 and the appropriate inserter may be modular, the dimensions of the housing 3602 and the location and shape of cam 3606 are selected to interact with the dimensions of the inserter. For example, the housing 3602 may be designed for snap-fit or friction-fit cooperation with the sheath 542 of inserter 500.

[00318] As illustrated in FIGURE 80, cap 504 of inserter 500 is removed, thereby allowing placement of adhesive 518 (not shown) on the skin of the subject. To insert sharp 524 (not shown), release button 3618 may be depressed (arrow H).

[00319] FIGURES 81-83 illustrate the sequence of motions of the driver apparatus 3600 to drive sharp 524 into the skin of the patient. As illustrated in FIGURE 81, upon depressing release button 3618, torsion spring 3614 is released thereby driving rotation of cam 3606 in the direction J with the bias of the torsion spring. Cam 3606 includes a surface including a protrusion 3607. As illustrated in FIGURE 82, further rotation of cam 3606 causes protrusion 3607 to engage actuator button 514 of inserter 500. Consequently, bellows 502 and spring 546 are compressed, and needle hub 536 and carriage 530 are advanced distally. (Not shown in FIGURES 81-83. See, e.g., FIGURE 70.) Sharp 524 is driven into the skin of the subject and

sensor housing 122 is adhered to the adhesive 518 (not shown). Further unwinding of the torsion spring causes the cam 3606 to further rotate, which results in protrusion 3607 being spaced from the actuator button 514, as illustrated in FIGURE 83. As a result, the spring bias of retraction spring 546 (not shown) returns bellows 502 to its expanded configuration, and retracts the sharp 524 from the skin of the subject.

[00320] Another exemplary driver apparatus for actuation of inserters, *e.g.*, the inserters 100, 200, 300, 400, and 500, discussed herein, is illustrated in FIGURES 84-90 and designated driver apparatus 3700. In some embodiments, driver apparatus 3700 is a reusable apparatus, whereas inserters 100, 200, 300, 400, and 500 may be disposable devices. Driver apparatus 3700 is substantially identical to driver apparatus 3600, with the substantial differences noted herein and indicated in the accompanying figures.

[00321] As illustrated in FIGURES 84 and 85, driver apparatus 3700 includes a housing 3702 for positioning with respect to an inserter. A loading element 3704— longitudinally movable with respect to an upper housing 3705—is provided. In some embodiments, actuator 3706 is a reciprocal element that provides automatic actuation of an inserter. In use, loading element 3704 is advanced laterally (direction of arrow K) along a track 3710 against the normal bias of a drive spring 3714. Upon loading of the drive spring 3714, a locking mechanism 3718 maintains the loading of spring 3714.

[00322] As illustrated in FIGURE 86, the driver apparatus 3700 is positioned with respect to an inserter 500. Although inserter 500 is illustrated in FIGURES 86-90, it is understood that any of inserters 100, 200, 300, 400, 500, 900, etc., may be used with driver apparatus 3700. As illustrated in FIGURE 87, cap 504 of inserter 500 is removed, thereby allowing placement of

adhesive 518 (not shown) on the skin of the subject. To insert the sharp 524 (not shown), release button 3718 may be depressed (arrow L).

[00323] FIGURES 88-90 illustrate the sequence of motions of the driver apparatus 3700 to drive the sharp 524 into the skin of the patient. As illustrated in FIGURES 88-90, upon depressing release button 3718, drive spring 3714 is released, thereby driving sliding member 3707 in the direction M with the bias of the spring 3714. Sliding member 3707 is restrained to lateral motion due its positioning in track 3710. Similarly, actuator 3706 is restrained to longitudinal motion due to its positioning in track 3709. Sliding member 3707 is coupled to actuator 3706 by a crank member 3720, which is pivotally connected to one end to sliding member 3707 and at the other end to actuator 3706. As illustrated in FIGURE 89, further lateral movement of sliding member 3707 causes the actuator 3706 to advance distally and to engage the actuator button 514 of inserter 500. Consequently, bellows 502 is compressed and needle hub 536 and carriage 530 are advanced distally, thereby driving sharp 524 into the skin of the subject and adhering sensor housing 122 to the adhesive 518 (not shown. See, *e.g.*, FIG 70, 518, 546). Further lateral movement of sliding member 3707 causes the actuator 3706 to advance proximally, as illustrated in FIGURE 90. As a result, the spring bias of retraction spring 546 (Not shown. See, *e.g.*, FIGURE 70) returns bellows 502 to its expanded configuration, and retracts the sharp 524 from the skin of the subject.

[00324] A driver apparatus for actuation of inserters , *e.g.*, inserters 100, 200, 300, 400, and 500, discussed herein, is illustrated in FIGURES 91-92J and designated driver apparatus 3800. In some embodiments, driver apparatus 3800 is a reusable apparatus, whereas inserters 100, 200, 300, 400, and 500 may be disposable devices. Driver apparatus 3800 is substantially identical to

actuators 3600 and 3700, with the substantial differences noted herein and indicated in the accompanying figures.

[00325] As illustrated in FIGURES 91 and 92, driver apparatus 3800 includes a housing 3802 for positioning with respect to an inserter. A loading element 3804 is provided which is longitudinally movable with respect to housing 3802. Depression of the loading element causes a rotor 3808 to rotate against the bias of a torsion spring (not shown). A locking element (not shown) maintains the loading of the torsion spring.

[00326] As illustrated in FIGURES 91 and 92, the driver apparatus 3800 is positioned with respect to inserter 100. Although inserter 100 is illustrated in FIGURE 91, it is understood that any of inserters 100, 200, 300, 400, 500, 900, etc., may be used with driver apparatus 3800. As illustrated in FIGURES 11-12, cap 104 of inserter 100 is removed, thereby allowing placement of adhesive 118 (not shown) on the skin of the subject. To insert the sharp 124 (not shown), loading element 3804 may be depressed.

[00327] Upon depressing loading element 3804, the torsion spring is released, thereby driving the actuator 3806 in the longitudinal direction with the bias of the spring. Actuator 3806 is advanced distally and engages the actuator button 114 of inserter 100. Consequently, needle hub 136 and carriage 130 are advanced distally, thereby driving sharp 124 into the skin of the subject and adhering sensor housing 122 to adhesive 118 (not shown). The actuator 3806 is subsequently advanced proximally. As a result, the spring bias of retraction spring 146 (not shown) retracts sharp 124 from the skin of the subject.

[00328] An enhanced view of the actuation of driver apparatus 3800 is depicted in FIGURES 92A-92J. As depicted in FIGURE 92A, driver apparatus 3800 includes trigger 3810, cam 3808,

arming button 3812, torsion spring 3814, shaft 3816, pawl 3818, actuator 3806, and return spring 3820. To arm driver apparatus 3800, loading element 3804 is pressed causing arming button 3812 to be pushed down, winding shaft 3816 and thus torsion spring 3814 (FIGURE 92B). Pawl 3818 locks shaft 3816 into place (FIGURE 92C). After a user depresses loading element 3804, arming button 3812 returns to its original position while shaft 3816 is held in place by pawl 3818 (FIGURE 92D).

[00329] In order to actuate driver apparatus 3800, a user again pushes loading element 3804. This causes trigger 3810 to move in a downward motion causing cam 3808 to be released. In some embodiments, loading element 3804 is used to alternately depress arming button 3812 and trigger 3810. Cam 3808 is then driven forward by torsion spring 3814 (FIGURE 92E). In some embodiments, a first loading element is used to depress arming button 3812, and a second loading element is used to depress trigger 3810 (not shown).

[00330] As cam 3808 rotates, it pushes down on actuator 3806, which in turn pushes down on actuator button 114 of inserter 100 (FIGURES 92F-92G). At the end of the stroke, there is a slight dwell. This allows the sensor body to be held and pressed on to the adhesive skin patch (FIGURE 92H). After a full rotation, cam 3808 is stopped by trigger 3810 as shown in FIGURE 92I. Return spring 3820 pushes actuator 3806 back up, releasing pressure on inserter 100. When trigger 3810 is released by the user, cam 3808 continues to rotate until it is in the home position, thereby allowing driver apparatus 3800 to be used again (FIGURE 92J).

[00331] An exemplary driver apparatus is illustrated in FIGURES 93-93H and designated driver apparatus 3900.

[00332] Driver apparatus 3900 includes a housing 3902 for positioning with respect to an inserter. A release button 3904—longitudinally movable with respect to housing 3902—is provided. The force exerted by return spring 3904 allows release button 3904 to be moved between a proximal and distal position, as shown in FIGURES 93A-93D.

[00333] As illustrated in FIGURE 93, the driver apparatus 3900 is positioned with respect to an inserter 2400. Although inserter 2400 is illustrated in FIGURES 72-72P, it is understood that any one of inserters 100, 200, 300, 400, or 500 may be used with driver apparatus 3900. Since driver apparatus 3900 and the appropriate inserter may be modular, the dimensions of the housing 3902 and the location and shape of release button 3904 are selected to interact with the dimensions of the inserter. For example, the housing 3902 may be designed for snap-fit or friction-fit cooperation with the sheath 2402 of inserter 2400.

[00334] FIGURES 93A-93D illustrate the sequence of motions of the driver apparatus 3900 to drive sharp 2404 into the skin of the patient. FIGURE 93A illustrates driver apparatus 3900 before firing. As shown, driver apparatus 3900 comprises housing 3902, release button 3904, return spring 3906, driver spring 3908, and plunger 3910. Three-dimensional perspective views of housing 3902, plunger 3910, release button 3904, are depicted in FIGURES 93F-93H, respectively. Release button 3904 comprise tabs 3912 which engage lip 3914 on housing 3902 which prevent the upward force of return spring 3906 from disengaging release button 3904 and housing 3902 (see FIGURE 93E). Release button 3904 also comprises protrusion 3918.

[00335] Plunger 3910 comprises tabs 3916 which confine plunger 3910 to housing 3902. Driver spring 3908 is disposed between the bottom of release button 3904 and the top of plunger

3910. Alternatively, the driver spring 3908 could be around the post shown of plunger 3910 and compressed by the cylinder of button 3904.

[00336] As illustrated in FIGURE 93B, upon depressing release button 3904 towards housing 3902, return spring 3906 and drive spring 3908 become compressed. Concurrently, protrusion 3918 causes tab 3916 to become disengaged from housing 3902. This allows drive spring 3908 to advance plunger 3910 towards inserter 3900 as shown in FIGURE 93C. Sharp 2404 is driven into the skin of the subject and sensor housing 122 is adhered to adhesive pad 118.

[00337] As the user releases pressure on the button 3904, the return spring 3906 pushes it back to its initial position. As the button 3904 returns, the arms of the button pull the arms of the plunger 3910 back to its initial position, automatically re-engaging the tabs 3916 with the housing 3902 (FIGURE 93D).

[00338] An exemplary driver apparatus is illustrated in FIGURES 94-94K and designated driver apparatus 4000.

[00339] Driver apparatus 4000 includes a housing 4004 for positioning with respect to an inserter. An outer button 4002—longitudinally movable with respect to housing 4004—is provided. The force exerted by a return spring (not shown) located between housing 4004 and outer button 4002 allows outer button 3904 to be moved between a proximal and distal position, as shown in FIGURES 94C-94K.

[00340] As illustrated in FIGURE 94, the driver apparatus 4000 is positioned with respect to an inserter 2400. Although inserter 2400 is illustrated in FIGURES 73-73N, it is understood that any one of inserters 100, 200, 300, 400, or 500 may be used with driver apparatus 4000. Since

driver apparatus 4000 and the appropriate inserter may be modular, the dimensions of the housing 4004 and the location and shape of cam release button 3904 are selected to interact with the dimensions of the inserter. For example, the housing 4004 may be designed for snap-fit or friction-fit cooperation with the sheath of inserter 2400.

[00341] FIGURE 94A illustrates an exploded view of the components of driver apparatus 4000. As shown, driver apparatus 4000 comprises outer button 4002, return spring 4006, inner button 4008, housing 4004, drive spring 4010, and pusher 4012. The assembled driver apparatus 4000 is shown in FIGURE 94B, wherein some components are partially transparent for clarity.

[00342] FIGURES 94C-94I illustrate the sequence of motions of the driver apparatus 4000 to drive sharp 2404 into the skin of the user. FIGURE 94C illustrates driver apparatus 4000 before firing. When assembled, return spring 4006 is encapsulated between outer button 4002 and housing 4004. Similarly, drive spring 4010 is encapsulated between the bottom of inner button 4008 and surface 4020 located on plunger 4012.

[00343] Outer button 4002 comprises guides 4013 which lock inner button 4008 in position using tabs 4022. Inner button 4008 comprises rails 4015 which allow outer button 4002 to move with respect to housing 4004.

[00344] Plunger 4012 comprises tabs 4014 which allow it to be fit into and retained within inner button 4008. Furthermore, plunger 4012 comprises arms 4016 having appendages 4018 with openings that engage ledge 4017 on housing 4004.

[00345] To actuate driver apparatus 4000, a user pushes down on outer button 4002 in the direction of the user's skin causing return spring 4006 and driver spring 4010 to become

compressed as illustrated in FIGURE 94E. Eventually, tabs 4019 located on inner button 4008 cause appendages 4018 to be pushed off ledge 4017 as shown in FIGURE 94E.

[00346] The displacement of tabs 4018 allows drive spring 4010 to drive plunger 4012 towards plunger 2405 of inserter 2400 as shown in FIGURE 94F. Eventually, sharp 2404 is driven into the skin of the user and sensor housing 122 is adhered to the user as shown in FIGURE 94G. If there is no inserter 2400 present, the plunger eventually stops its forward motion when the plunger arms engage ledge 4017 or when tabs 4014 engage inner button 4008.

[00347] To remove sharp 2404 from the user's skin, the user must remove pressure from outer button 4002 which allows return spring 4006 to exert upward pressure on outer housing 4002 as shown in FIGURE 94H. The guides 4013 pull up the inner button through rails 4015. Inner button 4008 pulls up plunger 4012 by tabs 4014. The pusher 4008 is pulled up far enough to re-engage tabs 4018 on ledge 4017. This makes the inserter instantly ready to be re-used with no addition user steps. Concurrently, the return spring located in inserter 2400 retracts sharp 2404 from the user's skin. Return spring 4006 eventually returns driver apparatus 4000 to its original configuration, as shown in FIGURE 94I.

[00348] In another aspect of the disclosed subject matter, an inserter assembly, as illustrated in FIGURE 95, is provided which is useful for installing a medical device, such as an analyte sensor, in the skin of a subject. Inserter assembly 4300 may include an inserter, a medical device, such as an analyte sensor, and a mount for positioning the medical device at least partially in or on the skin of the subject. In some embodiments, the mount is a support structure, plate and/or member which is attached, adhered, or otherwise secured to the skin of the subject. The mount may be inserted simultaneously with the medical device by the inserter. In other embodiments, the

mount is installed after or before installation of the medical device. A mount may be applied by the inserter or separately. The mount may include features or structures (*e.g.*, adhesive, guides, barbs, tabs, etc.) to maintain the sensor in position with respect to the skin after insertion and/or maintain the sensor in relative position with respect to the sensor control unit.

[00349] Inserter assembly 4300 is useful for analyte measurement systems, *e.g.*, glucose measurement systems which include an on-body unit that may be assembled on the skin of the subject. For example, the on-body unit may include a sensor and a sensor control unit. The sensor is typically installed in the patient. Subsequently, the sensor control unit is installed and coupled to the sensor. In other embodiments, the sensor control unit is installed at the patient first, followed by installation of the sensor, which is then coupled to the sensor control unit. In yet other embodiments, the sensor and sensor control unit are simultaneously installed and coupled. An optional mount may or may not be used to position the sensor and/or the sensor control unit.

[00350] Generally, the inserter assembly 4300 is useful to install a sensor in the skin of a subject. A sensor (not shown) may be preloaded within inserter 4310 prior to installation. After preparing an insertion site on the skin of a subject, the user removes an upper liner 4316 and lower liner 4318 from mount 4312 to expose the bottom surface and a portion of the top surface of an adhesive tape located on the bottom surface of the mount 4312. Mount 4312, with inserter 4310 attached, is then applied to the subject's skin at the insertion site. In some embodiments, the mount 4312 is first attached, and then the inserter is coupled to or positioned within and/or adjacent to the mount 4312. The inserter includes an actuator button 4324 to be depressed causing inserter 4310 to fire, thereby inserting a sensor into the user's skin. As will be described herein, certain embodiments install the sensor with a predetermined velocity and force upon actuation. In some embodiments of the

disclosed subject matter, the inserter includes a safety member to impede actuation of the inserter as described below.

[00351] In some embodiments, the sensor 4314 remains positioned at the mount 4312 by one or more positioning techniques. For example, as illustrated in FIGURE 96, sensor 4314 has a surface 4356 that extends orthogonally from main surface 4346. Surface 4356 may include an adhesive portion that contacts the subject's skin 4328 or the mount 4312. In some embodiments, the raised end stop 4444 of mount 4312 is provided with a raised bead or bump which is received in an aperture in sensor 4314. Following insertion of the sensor 4314 into the skin, the user may remove the inserter 4310 from mount 4312, *e.g.*, by pressing release tabs 4326 on opposite sides of inserter 4310 and lifting inserter 4310 away from mount 4312. In some embodiments, the inserter 4310 is retained by other techniques, *e.g.*, a friction-fit or a snap-fit with the mount 4312.

[00352] Once inserter 4310 is removed from mount 4312, a sensor control unit 4330 can be positioned into place with respect to the mount 4312. The circuitry of sensor control unit 4330 makes electrical contact with the contacts on sensor 4314 after sensor control unit 4330 is seated on mount 4312. For example, as shown in FIGURE 97, seal 4332 has an exterior wall for surrounding electrical contacts on sensor 4314 (not shown in FIGURE 97), and interior walls for isolating electrical contacts from each other. In some embodiments, rails on sensor control unit 4330 are slidable within corresponding rails or grooves 4434 on mount 4312.

[00353] In some embodiments, initialization and synchronization procedures are completed, and then electrochemical measurements from sensor 4314 can be provided from sensor control unit 4330 to a monitor unit, such as, *e.g.*, portable monitor unit 4332, shown in FIGURE 97. Sensor control unit 4330 and monitor unit 4332 communicate *via* connection 20 (in this embodiment, a wireless

radio frequency (RF) connection). Communication may occur, *e.g.*, *via* RF communication, infrared communication, Bluetooth communication, Zigbee communication, 802.1x communication, or WiFi communication, etc. In some embodiments, the communication may include a radio frequency of 433 MHz, 13.56 MHz, or the like. In some embodiments, communication between sensor control unit 4330 and monitor unit 4332 may include radio frequency identification (RFID) techniques, and may be active RFID or passive RFID, where in some embodiments passive RFID technology and the respective system components include the necessary components therefor. For example, in one embodiment, the monitor unit may include a backscatter RFID reader configured to transmit an RF field such that when the sensor control unit is within the transmitted RF field, an antenna is tuned and in turn provides a reflected or response signal (for example, a backscatter signal) to the monitor unit. The reflected or response signal may include sampled analyte level data from the analyte sensor. Additional exemplary details for various embodiments can be found in, *e.g.*, U.S. Patent Application Serial No. 12/698,124 filed February 1, 2010, the disclosure of which is incorporated by reference herein for all purposes.

[00354] Sensor 4314, mount 4312 and sensor control unit 4330 can remain in place on the subject for a predetermined maximum period of time that may include hours, days, weeks, or a month or more. These components are then removed so that sensor 4314 and mount 4312 can be properly discarded in some embodiments. The entire procedure above can then be repeated with a new inserter 4310, sensor 4314 and mount 4312, reusing sensor control unit 330 and monitor unit 332. In other embodiments, inserter 4310 is reusable.

[00355] Referring to FIGURE 98, the inserter assembly 4300 according to one embodiment can be assembled as shown from the following components: housing 4334, actuator button 4324, drive

spring 4336, shuttle 4338, introducer sharp 4340, sensor 4314, retraction spring 4342, inserter base 4344, upper liner 4316, adhesive mount 4312, adhesive tape 4320, and lower liner 4318.

[00356] In some embodiments, sensor main surface 4346 is slidably mounted between U-shaped rails 4348 of introducer sharp 4340. In addition to the holding members disposed on the introducer, as described above, retention techniques are provided in certain embodiments to retain the sensor 4314 in position on sharp 4340 during storage of the inserter 4300 and/or during insertion of the sensor 4314 into the subject's skin. For example, a sensor dimple (not shown) is provided which engages an introducer dimple (also not shown). Introducer sharp 4340 can be mounted to face 4354 of shuttle 4338, such as with adhesive, heat stake or ultrasonic weld.

[00357] In some embodiments, shuttle 4338 can be slidably and non-rotatably constrained on base 4344 by arcuate guides 4360. The shuttle can be generally formed by an outer ring 4362 and an inner cup-shaped post 4364 connected by two bridges 4366. Bridges 4366 can be configured to slide between the two slots 4368 formed between guides 4360 and allow shuttle 4338 to travel along guides 4360 without rotating. In some embodiments, a retraction spring 4342 is provided, which can be captivated at its outer circumference by guides 4360, at its bottom by the floor 4370 of base 4344, at its top by bridges 4366, and at its inner circumference by the outer surface of shuttle post 4364. In some embodiments, a drive spring is provided for advancing the sensor 4314 and the sharp 4340 into the skin of the subject. For example, drive spring 4336 is captivated at its bottom and outer circumference by the inside surface of shuttle post 4364, at its top by the ceiling 4372 inside actuator button 4324, and at its inner circumference by stem 4374 depending from ceiling 4372. In some embodiments, a drive spring is omitted from the inserter assembly. In such case, for example, sensor 4314 and sharp 4340 are distally advanced by manual force applied by a user.

[00358] When drive spring 4336 is compressed between actuator button 4324 and shuttle 4338 it can urge shuttle 4338 towards base 4344. When retraction spring 4342 is compressed between shuttle 4338 and base 4344, it urges shuttle 4338 towards actuator button 4324.

[00359] When sensor 4314, introducer 4340, shuttle 4338, retraction spring 4342, drive spring 4336 and actuator button 4324 are assembled between base 4344 and housing 4334 as shown in FIGURES 98-99 and described above, housing 4334 is snapped into place on base 4344. Base 4344 is held onto housing 4334 by upper base barbs 4390 that engage upper openings 4392 in housing 4334, and lower base barbs 4394 that engage lower openings 4396 in housing 4334. Further details regarding the construction and operation of inserter 4300 is provided in U.S. Patent No. 7,381,184 which is incorporated by reference herein in its entirety for all purposes.

[00360] In some embodiments, retention techniques and/or structures are provided to assist in supporting the sensor 4314 with respect to the sharp 4340 during storage and insertion. As illustrated in FIGURES 100-114, retention mechanisms are provided which are located on the sensor and/or the sharp.

[00361] FIGURES 100-101 illustrate a sensor 4514 which is provided with one or two laterally extending tabs 4560. Tabs 4560 engage the rails 4548 of the sharp 4540 for retention. In some embodiments, a radiused edge on the ears allow them to be formed in two punch operations, *e.g.*, a hole punch and a straight cut. A gap between left hard-stop 4549 and the top of sensor 4514 produces, during firing, a moment that biases the sensor tip into the sharp channel. During deployment, the sensor deflects to disengage the sharp.

[00362] FIGURES 102-103 illustrate an inserter having a sensor retention mechanism in accordance with a further embodiment of the subject disclosure. Sharp 4640 is provided with a clip

4660 that engages a retention window 4662 at the top of sensor 4614 to provide retention of sensor 4614 in sharp 4640, and vertical registration. Two drive blocks 4659 and 4661 on carrier 4654 traverse sharp 4640 to engage the top edge of sensor 4614. There is a gap between the left drive block 4659 and the top edge of sensor 4614. Right drive block 4661 is in contact with the top edge of sensor 4614. During insertion, the upward drive force of the skin on sensor 4614 produces a clockwise rotational moment on sensor 4614 that biases sharp 4614 into the sharp channel.

[00363] The clip feature 4660 and the window 4662 can be moved to the left to bias the tip of the sensor 4614 into the channel during shipping. During deployment, the sensor 4614 and the clip 4662 deflect to transfer the sensor 4614 to the mount 4312.

[00364] FIGURE 104 illustrates a further embodiment of a sensor retention technique. In particular, sensor 4714 is provided with a retention member 4760, which extends from the contact portion 4732 of the sensor 4714. Retention member 4760 is resiliently biased in the position as shown. When the sensor 4714 is inserted within the sharp (not shown), the retention member engages the inner portion of rails (not shown) of the sharp, and provides a retention force to the sensor 4714.

[00365] FIGURE 105 illustrates another embodiment of a sensor retention technique. Sensor 4814 is provided with a dimple 4860 which is thermally formed. As shown in FIGURE 106, a raised bump 4864 on the sharp 4840 frictionally contacts thermally formed dimple 4860 in order to provide retention force to the sensor 4814. In some embodiments, raised bump is formed using heat. In another embodiment, a raised bump is formed on the sensor and the dimple is formed on the sharp.

[00366] FIGURES 107-108 illustrate an aperture 4960 which is formed in the contact portion of the sensor 4914. A raised bump or tab 4962 is provided on the sharp 4940. The interaction of the tab

4962 within the aperture 4960 of the sensor 4914 assists in retaining the sensor 4914 within the inserter.

[00367] FIGURES 109-110 illustrate a technique for retention of the sensor 5014 which is similar to the techniques illustrated in FIGURES 105-108. For example, a raised bump 5062 is provided on sharp 5040 which engages the contact portion 5032 of the sensor 5014. In such configuration, the raised bump 5062 creates a bias force against the contact portion 5032. Such force acts as a frictional force to assist retention of the sensor 5014 within the sharp 5040.

[00368] FIGURES 111 and 112 illustrate sensors having retention members which engage a raised post or button on the sharp. FIGURE 111 illustrates that contact portion 5132 of sensor 5114 includes a pair of “pincer fingers” 5160 having a substantially arcuate configuration which surround and engage a post 5162 provided on the sharp. Similarly, FIGURE 112 illustrates sensor 5214 having a pair of proximally extending arms 5260, which engage a post 5262 on the sharp.

[00369] FIGURE 113 illustrates a sensor 5314 having a laterally extending arm 5360 which defines a channel 5364 between the arm 5360 and the contact portion 5332 of the sensor 5314. As illustrated in the figure, a post 5360 may be positioned within the channel 5364, and provides frictional resistance to maintain the sensor 5314 within the sharp.

[00370] FIGURE 114 illustrates a sensor 5414 having a proximally extending arm 5460 which defines a channel 5362 between the arm 5460 and the contact portion 5432 of the sensor 5414. As illustrated in the figure, a tab 5364 is provided on the arm 5460 and is received within a gap provided in the rails of the sharp. This interaction of the tab 5364 with the gap provides frictional resistance to maintain the sensor 5414 within the sharp.

[00371] FIGURES 115-116 refer to sensor retention techniques which include a retention member which provides a frictional force substantially normal (perpendicular) to the surface of the sensor. FIGURES 115 and 116 illustrate a retention member which is provided within the housing 5534 of the inserter 5510. For example, the retention member 5560 may extend distally from the housing 5534 and includes a laterally extending tab 5562 which contacts the sensor 5563 and provides a frictional force to assist retention of the sensor within the sharp 5540.

[00372] FIGURES 117 and 118 illustrate a retention member which is provided with the base 5644 of the inserter 5610. For example, retention member may include a cantilever 5660 which extends proximally from base 5644 of the inserter 5610. Cantilever 5660 may include a laterally extending member 5662 which contacts the sensor 5661 and provides a frictional force to assist retention of the sensor within the sharp 5640. When the carrier 5666 bottoms down, the cantilever 5660 ceases contact and release of the sensor occurs.

[00373] FIGURES 119 and 120 illustrate a resilient or elastomeric member which is disposed within the housing 5734 of the inserter 5710. For example, elastomeric member 5760 is manufactured from TPE and presses against the sensor and the resulting friction keeps the sensor in place. The TPE material creates a higher friction with respect to the sensor, and therefore requires less pressure to produce the sensor holding force. When the inserter 5710 is actuated, the frictional forces are directed upward keeping the sensor inside the sharp. When the carrier bottoms down, the contact with the friction rib ceases and the sensor releases to the mount. In some embodiments, the elastomeric member 5760, or rib, is produced with a second-shot injection molded process or press-fit into housing 5734.

[00374] FIGURES 121 and 122 refer to retention member which provide a frictional force in a substantially coplanar direction to the surface of the sensor. FIGURE 121 illustrates a retention

member or cantilever 5860 which is biased against the side edge of the contact portion 5832 of the sensor 5814. In some embodiments, cantilever 5860 is provided on the carrier or sharp (not shown). FIGURE 122 illustrates a sensor retention technique which includes a retention member, or cantilever 5960 which is biased against the sensor, as described in FIGURE 121. Cantilever 5960 includes a laterally extending portion which is at least partially received in an optionally provided notch 5964 in sensor 5914. In addition, a second retention member, or retention spring 5990, is provided which is biased to engage the front surface of the sensor. In some embodiments, retention spring 5990 is partially received in cut-out 5994 (or a slot) to capture the sensor.

[00375] In some embodiments, an inserter assembly is provided which includes a reusable inserter apparatus. Repeated uses of the inserter include the use of a removable and exchangeable sensor and sharp which may be coupled to the inserter during deployment of the sensor, and in which the sharp is removed and discarded after deployment.

[00376] FIGURES 123-125 illustrate a system of sharp/sensor packs 6002 which contain a plurality of sensor/sharp combinations 6006. As illustrated in FIGURES 123 and 125, a support is provided which includes a plurality of trays 6004 which are useful for containing the sensor/sharp configuration 6006, and well as a desiccant 6010 which is contained in a chamber 6008. A well 6012 is provided on one side of the tray 6004 to accommodate the sensor sharp for installation into a patient. A cover, such as a foil lid 6014 is applied to the top of the support to maintain the sterility of the sensor/sharp combination until installation in a subject. FIGURE 124 is a perspective view which illustrates an exemplary configuration of pack 6002. The foil lid 6014 for each of trays 6004 may include a tab 6016 to facilitate removal of the lid from the tray 6004. (FIGURES 124, 125).

[00377] FIGURES 126-129 illustrate a plurality of reusable inserters which are useful in combination with the sharp/sensor packs 6002 described herein. FIGURE 126 illustrates an inserter

6030 which includes a body portion 6032, a loading or cocking structure 6036, and an actuator button 6040 for deploying the sensor into the skin of the subject. The advancement structure of inserter 6030 may include a cocking structure which is pulled to arm, *e.g.*, by withdrawing the cocking structure 6036 from the housing 6032; which is pushed to arm, *e.g.*, by depressing the cocking structure 6036 into the housing 6032; or which is rotated to arm, *e.g.*, by rotating the cocking structure 6036 in a rotational movement parallel to the longitudinal axis of the inserter 6030, or perpendicular to the longitudinal axis of the inserter 6030. The driving mechanism of inserter 6030 is substantially similar to the driving mechanisms as disclosed in U.S. Patent Publication 2008/0082166, U.S. Patent No. 6,197,040, or U.S. Patent No. 4,976,724, which are incorporated by reference in their entirety herein for all purposes.

[00378] To insert the sharp/sensor combination into the inserter 6030, the foil lid is removed from sharp/sensor pack 6002. The distal end portion 6034 of the inserter 6030 is positioned within the walls 6004 of the tray 6002, as indicated in the direction of arrow E. The distal end portion 6034 comes to rest on the upper surface of desiccant chamber 6008, such that the insertion sharp remains exposed.

[00379] FIGURE 127 illustrates an inserter 6130 substantially identical to the inserter 6030 described herein. Inserter 6130 is used in connection with sharp/sensor trays 6102. Trays 6102 include a desiccant chamber 6108 which is located in the center portion of the tray 6102. Accordingly, a channel 6112 surrounds the periphery of desiccant chamber 6108. When the inserter 6130 is applied to the sharp/sensor tray 6102, the distal end portion 6134 can be positioned within the channel 6112. As illustrated in FIGURE 127, this configuration allows the sensor and sharp to be completely housed within the inserter 6130.

[00380] FIGURE 128 illustrates an inserter 6230 substantially identical to the inserters 6030 and 6130 described herein, with the differences noted herein and illustrated in the figures. Inserter 6230 may be used in connection with sharp/sensor trays 6204. The tray 6204 and inserter 6230 are sized and configured such that tray 6204 is capable of being positioned entirely within the distal end portion 6234 of inserter 6230. One or more support struts 6220 are provided adjacent the distal end portion 6234 to stabilize the inserter with respect to any surface on which the inserter 6230 and trays 6204 are placed for the insertion step. Support struts 6220 may also secure inserter 6230 to an adhesive mount (not shown) during insertion.

[00381] FIGURE 129 illustrates an inserter 6330 which is substantially identical to the inserters 6030, 6130, and 6230 described herein, with the differences noted herein and illustrated in the figures. Inserter 6330 may be used in connection with sharp/sensor tray 6304. In some embodiment, tray 6304 includes a distally projecting handle portion 6340 which may be grasped by the user to facilitate insertion of the sharp/sensor into the inserter.

[00382] FIGURES 130-131 illustrate an exemplary sharp/sensor combination for use with inserters 6030, 6130, 6230, and 6330 described herein. Sharp 6440 includes side rails 6448 for sliding reception of a sensor therein. A locking tab 6450 is also provided on the proximal portion of the sharp and includes cut-out portion 6452 for interlocking with the carrier of the inserter 6030 (or 6130, 6230, or 6330). As illustrated in FIGURES 134A-134B and 171 carrier 6466 includes reception structure for mating reception with the sharp 6440. For example, carrier 6466 may include a pair of walls 6478 providing a channel 6480 in which said sharp 6440 may be positioned. Walls 6478 are provided with cutout portions 6482 for reception of undercut portion 6452 in locking tab 6450. A pair of securement members 6484 are movably mounted on the carrier 6466. For example, members 6484 are biased via a spring 6486 towards a center portion of the carrier 6466. As

illustrated in FIGURE 134B, securement members 6484 may be moved outwardly against the spring bias to allow for the insertion of the locking tab 6450 into the cutout portion 6482 of the carrier. Securement member 6484 is subsequently released and returns to a position to engage the undercut portion 6452 to prevent accidental removal of the sharp and sensor from the inserter (FIGURE 135). It is understood that coupling of the sharp and carrier may be provided by alternative techniques such as frictional fit, snap-fit, bayonet mounts, magnetic coupling, etc.

[00383] FIGURES 136-140 illustrate a further embodiment of the subject disclosure that is reusable, and useful with the sharp/sensor packs discussed herein. FIGURE 136 illustrates a sensor pack 6504 which is similar to the sensor packs 6200 described herein. Sharp/sensor pack 6504 also includes one or more reinforcing ribs 6574 to prevent accidental deformation of the pack 6504 when the sensor is being inserted into the inserter.

[00384] As illustrated in FIGURE 137, inserter 6530 is provided which is substantially similar to inserters 6030, 6130, 6230, and 6330 described herein, with the differences noted herein or illustrated in the figures. Inserter 6530 includes a carrier (not shown) for coupling with a sharp/sensor combination. As illustrated in the figure, inserter 6530 is lowered onto sharp/sensor pack 6504 in order to couple the sharp 6506 with the carrier. As illustrated in FIGURE 138, inserter 6530 which now contains the sharp/sensor 6506 is positioned over the mount 6512. Mount 6512 may include an adhesive for securement to the skin of the subject. Inserter 6530 includes a locking structure 6526 which allows for temporary engagement of the inserter 6530 with the mount 6512.

[00385] As illustrated in FIGURE 139, the sensor is deployed by depressing actuation button 6532 on the inserter 6530 to advance the sensor into the skin by use of an internal drive mechanism, such as, e.g., a spring. It is understood that the above-described process may alternatively be carried

out by using an inserter which allows the user to provide a manual distal force for deployment of the sensor.

[00386] Following installation of the sensor, inserter 6530 is decoupled from the mount, *e.g.*, by depressing locking buttons 6526 on inserter 6530. Once the inserter 6530 is separated from the mount, the user may remove and discard the sharp. In some embodiments, inserter 6530 includes a sliding lever 6540 which allows for removal of the sharp. It is understood that disengagement of the sharp from carrier may be executed in one of several ways, *e.g.*, sliding switch allows securement member (discussed herein) to slide outwardly and allow disengagement of the contact portions 6483 of the securement members 6484 from the undercut portions 6452 of locking tab 6450.

[00387] FIGURE 141 illustrates an inserter 6630 and engagement structure for mounting on mount 6612. Inserter 6630 includes a body portion 6640 which is configured to advance a sharp/sensor cartridge into the skin S of a subject along longitudinal axis LON. The longitudinal axis LON may be substantially perpendicular to the skin surface. In some embodiments, axis LON forms an acute angle with the skin surface. Mount 6612 and inserter 6630 are each provided with complementary locking structures 6662 on the mount 6612 and 6664 on the inserter. Inserter is advanced laterally (direction LAT) over mount 6612. Inserter 6630 may be locked in place by pivoting locking structure 6632 about pivot 6626. Following such pivoting action, the engagement portion 6666 of locking structure 6632 is received in recess 6668 in mount 6612. Securement of the inserter to the mount is further provided by insertion of the sharp/sensor cartridge 6650 between the inserter 6630 and the mount 6612. For example, cartridge 6650 includes raised tabs 6654 which are slidable within complementary grooves 6652 provided on the inserter 6630 and mount 6612. Insertion of the cartridge is carried out in a direction perpendicular to the direction in which the inserter is attached to the mount, *e.g.*, a direction perpendicular to the plane of the figure.

[00388] FIGURES. 142-144 illustrate another embodiment of an inserter in accordance with the disclosed subject matter. Inserter 6730 is useful for advancing a medical device, such as an analyte sensor, into the skin of a subject. Inserter 6730 includes a hammer member 6760 which accumulates advancement energy to provide a more rapid and powerful advancement stroke. As illustrated in FIGURE 142, hammer member 6760 is initially positioned somewhat askew with respect to the longitudinal axis of the device. As the alignment trigger 6734 is advanced distally, alignment sleeves 6736 gradually pivot the hammer member 6760 into a longitudinal configuration. As the hammer member 6760 is being pivoted into position, the advancement spring continues to be compressed. With reference to FIGURE 143, the hammer member 6760 is pivoted into alignment with the central bore of the inserter 6730. Consequently, the tension of advancement spring 6742 is immediately released, which permits rapid distal movement of the hammer member 6760. Hammer member 6760 contacts carrier 6744, which in turn contacts sharp/sensor combination 6712 to provide distal movement.

[00389] As illustrated in FIGURE 144, a ledge or lateral member 6726 is provided with the internal bore of the inserter. As the hammer member 6760 advances distally, the distal surface of the hammer member contacts the ledge 6726. Interengagement of the hammer member 6760 and the ledge 6726 inhibits further distal travel of the hammer member 6760.

[00390] FIGURE 145 illustrates an exemplary embodiment of a simplified unit, or cartridge 6800, which holds certain components for sterility and subsequent interaction with the subject. In some embodiments, the components include the sharp 6840, the housing 6860, the sensor 6814. The cartridge 6800 may be used in connection with any of the inserters 6030, 6130, 6230, 6330, 6530 and/or 6730 described herein. In some embodiments, the cartridge includes a housing and a lid which contain the sharp and sensor therein. In some embodiments, a resilient member or other

cantilever structure is used to maintain the alignment of the sharp and sensor within the cartridge. Interaction of the cartridge with the inserter advances the sensor and sharp such that the sensor is installed at the subject.

[00391] As illustrated in FIGURES 146-147, the sharp 6840 and sensor 6814 may sit in a recessed portion of the disposable cartridge 6800. A spring finger or cantilever 6876 on the housing lid maintains a load on the sharp 6840 and sensor 6814 to keep it depressed in the cavity. Attachment for a lid to the base of the cartridge housing 6860 is not shown in the figure above, but methods such as snaps, heat stake, or ultrasonic welding may be used to join the two housings in assembly. The sensor 6814 is contained within the sharp 6840, laterally by the two rounded ends 6848 of the sharp, and in the orthogonal lateral direction (in relation to the views shown above), by two bent tabs 6849 on the sharp 6840 and the cartridge housing base cavity. The sharp is held in its lateral position by not only the cavity, but also by the raised pyramid feature 6878 shown on the housing base 6870. In the figure above, the locating pyramid sits in the opening 6882 created from the bent tab in the sharp. The engagement features to locate/attach/engage the cartridge to the inserter portion of the device are not shown in the figures above, but may include such features as illustrated in FIGURES 130-135 above.

[00392] As illustrated in FIGURES 148 and 149, when the cartridge 6800 is loaded onto the reusable inserter part of the device, the sharp is raised out of its cavity by stationary elements built onto the inserter (not shown). Features from the reusable portion of the inserter enter through the two shorter slots 6864 shown FIGURE 145. These features will remain stationary throughout the sensor delivery action of the inserter device.

[00393] In the longer middle slot 6866, a stepped feature from the inserter, mates with the opening on the sharp (shown as two holes 6864 in the figure above). The stepped portion of the

feature provides a force on the back portion of the sharp to keep it raised against the force of the sprung cantilever 6876 on the housing. This feature of the inserter will move in relation to the cartridge and provide the drive and retraction movement for the sharp through insertion and delivery of the sensor. In some embodiments, the force is transmitted through driving pins which are part of the movable portion of the inserter device. The driving pins protrude through holes 6864. In case of minor misalignment of the driving pins (not shown) ribs on the cartridge housing lid will constrain the sharp from tilting up.

[00394] Once the sharp and sensor are raised from the cavity portion of the cartridge, they are no longer constrained by the recessed cavity portion of the housing base and the pyramid feature maintaining the sharp position. The sharp is held in its raised position by the stationary and stepped drive feature of the inserter, balanced with the force of the cantilever finger on the lid housing. The sensor is kept in place by being pinched against the cantilever finger on the housing lid. The sharp is constrained in its retracted position by the mated drive feature of the inserter.

[00395] As the inserter is actuated, the mated inserter drive feature drives the sharp downward as it moves through the longer slot shown in the figure above (see, FIGURES 150-151 and 152). The driven sharp slides along the stationary ribs of the inserter, ribbed features built into the cartridge housing, and the housing lid cantilever finger. The friction force of the cantilever keeps the sensor up against the 'drive block' bends in the sharp sheet metal to assure the tail is not exposed from the sharp channel during insertion. In some embodiments, the 'drive block' features are longitudinal constraints either built into the sharp or the carrier which constrain the sensor from proximal movement with respect to the sharp. In another embodiment, the drive block features are protrusions on the carrier or bends on the sharp which push the sensor as the sharp is propelled distally.

[00396] The sensor is kept from popping over the drive block features by the stationary ribs built into the housing lid. As the cantilever slides over the top edge of the sensor, the retention force is relieved from the sensor, and it can be captured onto the mount portion of the device with relatively little force. Alternately, if geometry permits, and the finger is positioned appropriately, the pinching of the cantilever on the sharp may provide enough resistance on the return motion of the sharp to keep the sensor in its inserted position even without a capture device on the mount. The inserter drive feature then retracts the sharp, leaving the sensor in place on the mount portion (that is attached to the skin) of the device.

[00397] The cartridge can be removed from the inserter. As the cartridge is removed, the force from the housing lid cantilever presses the sharp back into the recess on the cartridge base housing. The base housing is removed and can be discarded.

[00398] Another embodiment of the cartridge is illustrated in FIGURES 154-160. As illustrated in FIGURE 154, the sharp 6940 and sensor 6914 in this design sit on ribs 6972 and 6974 and on insertion plane to which the sharp 6940 will be driven and retracted by the inserter into the skin. The sharp and sensor are held in place by a central cantilever feature 6976 built onto the cartridge lid housing 6970. This cantilever 6976 has geometry such that a vertical portion of the end of the cantilever is butted against the sharp 6940 and sensor 6914.

[00399] As illustrated in FIGURES 155 and 156, the cartridge 6900 is loaded onto the inserter, in which a stationary feature on the inserter raises the cartridge cantilever so that the ramped portion of the cantilever end feature is now in line with the insertion plane of the sharp. Also, the driving element of the inserter fits through the slot opening on the sharp. In the embodiment described herein, a step is not required on the driving element on this design.

[00400] As the sharp is driven downward (see, FIGURES 157-158), the cantilever arm 6976 is pushed up, keeping the sensor in position against the sharp 6940. Stationary ribs on the housing lid assure that the sharp 6940 maintains its insertion plane during insertion, and also assures that the pinching force of the cantilever does not cause the sensor to hop the drive block elements integrated into the sharp. (The stationary ribs keep the sensor flat against the sharp through the insertion motion.)

[00401] As illustrated in FIGURES 159-160, the sensor 6914 is captured at the bottom of its motion on the mount, as discussed hereinabove. The drive elements on the inserter retract the sharp 6940 back to its starting position. The cantilever arm 6976 falls back in place. The cartridge 6900 is removed from the inserter and can be discarded.

[00402] It is understood that the subject matter described herein is not limited to particular embodiments described, as such may, of course, vary. It is also understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present subject matter is limited only by the appended claims.

[00403] Additional detailed description of embodiments of the disclosed subject matter is provided in but not limited to: U.S. Patent No. 7,381,184; U.S. Patent No. 7,299,082; U.S. Patent No. 7,167,818; U.S. Patent No. 7,041,468; U.S. Patent No. 6,942,518; U.S. Patent No. 6,893,545; U.S. Patent No. 6,881,551; U.S. Patent No. 6,773,671; U.S. Patent No. 6,764,581; U.S. Patent No. 6,749,740; U.S. Patent No. 6,746,582; U.S. Patent No. 6,736,957; U.S. Patent No. 6,730,200; U.S. Patent No. 6,676,816; U.S. Patent No. 6,618,934; U.S. Patent No. 6,616,819; U.S. Patent No. 6,600,997; U.S. Patent No. 6,592,745; U.S. Patent No. 6,591,125; U.S. Patent No. 6,560,471; U.S. Patent No. 6,540,891; U.S. Patent No. 6,514,718; U.S. Patent

No. 6,514,460; U.S. Patent No. 6,503,381; U.S. Patent No. 6,461,496; U.S. Patent No. 6,377,894; U.S. Patent No. 6,338,790; U.S. Patent No. 6,299,757; U.S. Patent No. 6,284,478; U.S. Patent No. 6,270,455; U.S. Patent No. 6,175,752; U.S. Patent No. 6,161,095; U.S. Patent No. 6,144,837; U.S. Patent No. 6,143,164; U.S. Patent No. 6,134,461; U.S. Patent No. 6,121,009; U.S. Patent No. 6,120,676; U.S. Patent No. 6,071,391; U.S. Patent No. 5,918,603; U.S. Patent No. 5,899,855; U.S. Patent No. 5,822,715; U.S. Patent No. 5,820,551; U.S. Patent No. 5,628,890; U.S. Patent No. 5,601,435; U.S. Patent No. 5,593,852; U.S. Patent No. 5,509,410; U.S. Patent No. 5,320,715; U.S. Patent No. 5,264,014; U.S. Patent No. 5,262,305; U.S. Patent No. 5,262,035; U.S. Patent No. 4,711,245; U.S. Patent No. 4,545,382; U.S. Patent Publication No. 2004/0186365, published September 23, 2004; U.S. Patent Application No. 61/238,646, filed August 31, 2009; U.S. Patent Application No. 12/698,129, filed February 1, 2010; U.S. Patent Application No. 61/317,243, filed March 24, 2010; and International Application No. PCT/US10/22860, filed February 22, 2010, the disclosures of each of which is incorporated by reference herein for all purposes.

CLAIMS

WHAT IS CLAIMED IS:

1. An apparatus for inserting a medical device into the skin of a subject, which comprises:
a sheath defining a distal surface for placement on the skin of the subject;
a device support movable between a proximal and distal position, and adapted to support the medical device;
a sharp support movable between a proximal and a distal position, and adapted to support a sharp extending through a portion of said device support;
a handle movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from a proximal to a distal position to insert the sharp into the skin of the subject and defining guides for slidable engagement with the sharp support and the device support; and
a driver for biasing the handle towards the proximal position.
2. The apparatus of claim 1, wherein the driver comprises a compression spring.
3. The apparatus of claim 1, wherein the handle is at least partially disposed within the sheath.
4. The apparatus of claim 1, wherein the handle is at least partially disposed surrounding the sheath.
5. The apparatus of claim 1, further comprising a retention member for retaining the device support in the proximal position.

6. The apparatus of claim 5, wherein the retention member comprises a stop portion.
7. The apparatus of claim 1, wherein the medical device is an analyte sensor.
8. The apparatus of claim 1, wherein the medical device is a glucose sensor.
9. The apparatus of claim 1, wherein the medical device is an infusion set.
10. An apparatus for inserting a medical device through the skin of a subject, which comprises:
 - a first subassembly comprising
 - a sheath defining a distal surface for placement on the skin of the subject;
 - a handle movable between a proximal position and distal position;
 - a device support for supporting the medical device and movable between a proximal and distal position with respect to the sheath in response to distal movement of the handle;
 - a sharp support for supporting a sharp and movable between a proximal and distal position with respect to the sheath in response to distal movement of the handle ; and
 - a first driver for biasing the sharp support towards the proximal position; and
 - a second subassembly comprising
 - a housing configured for removable attachment to the first subassembly
 - an actuator configured for distal movement with respect to the housing and a release member actuated upon the actuator reaching predetermined position; and

a second driver for advancing the handle towards the distal position, wherein the biasing member is released upon actuation of the release member.

11. The apparatus of claim 10, wherein the second driver comprises a compression spring.
12. The apparatus of claim 10, wherein the first driver comprises a compression spring.
13. The apparatus of claim 10, wherein the handle is at least partially disposed surrounding the sheath.
14. The apparatus of claim 10, further comprising a retention member for retaining the device support in the distal position.
15. The apparatus of claim 10, wherein the device support is coupled to the handle until the device support reaches a distal position.
16. The apparatus of claim 10 wherein the device support is uncoupled from the sharp support when the device support reaches the distal position.
17. The apparatus of claim 10, further comprising a second driver for biasing the device support towards the distal position.
18. The apparatus of claim 10, wherein the medical device is an analyte sensor.
19. The apparatus of claim 10, wherein the medical device is a glucose sensor.
20. The apparatus of claim 10, wherein the medical device is an infusion set.
21. The apparatus of claim 10, wherein the housing is configured for friction-fit attachment to the first subassembly.

22. The apparatus of claim 10, wherein the first subassembly is configured for a single use.
23. The apparatus of claim 10, wherein the second subassembly is configured for multiple uses.
24. The apparatus of claim 10, wherein the second driver contacts the handle.
25. The apparatus of claim 10, wherein the handle is movable between a proximal position and distal position; the device support is movable between a proximal and distal position with respect to the sheath in response to distal movement of the handle; the sharp support is movable between a proximal and distal position with respect to the sheath in response to distal movement of the handle ; and the first driver is capable of biasing the sharp support towards the proximal position when the second subassembly is removed from the first subassembly.
26. The apparatus of claim 10, wherein the second subassembly is attached to the first subassembly by a frictional fit.
27. The apparatus of claim 10, wherein the second subassembly is attached to the first subassembly by a snap fit.
28. An apparatus for inserting a medical device through the skin of a subject, which comprises:
- a housing defining a cantilever member;
 - a sharp movable within the housing from a retracted position to a partially exposed position; and
 - an electrochemical sensor releasably coupled to the sharp for movement with the sharp, and for subsequent insertion in the skin of a subject;

wherein the cantilever member resiliently contacts at least one of the sharp and the sensor.

29. The apparatus of claim 24, wherein the housing comprises a distal opening for release of the electrochemical sensor therefrom.

30. An apparatus for inserting a medical device through the skin of a subject, which comprises:

a housing defining a longitudinal cavity therein and a interference member extending into the cavity;

a biasing member;

a driver member coupled to the biasing member for movement from a proximal position to a distal position and further configured for movement between a misaligned configuration in which the driver member is impeded from distal movement by the interference member and an aligned configuration in which the driver member is not impeded from distal movement by the interference member; and

an actuator having an alignment surface for moving the driver member from the misaligned configuration to the aligned configuration.

31. The apparatus of claim 30, wherein the actuator is movable from a proximal position to a distal position.

32. The apparatus of claim 30, wherein distal movement of the actuator compresses the first biasing member.

33. The apparatus of claim 30, wherein the first position of the driver member is at an oblique angle with respect to the longitudinal cavity.

34. The apparatus of claim 30, wherein the second position of the driver member comprises a configuration substantially aligned with the longitudinal cavity.

ABSTRACT

An apparatus for insertion of a medical device in the skin of a subject is provided, as well as methods of inserting and using medical devices.

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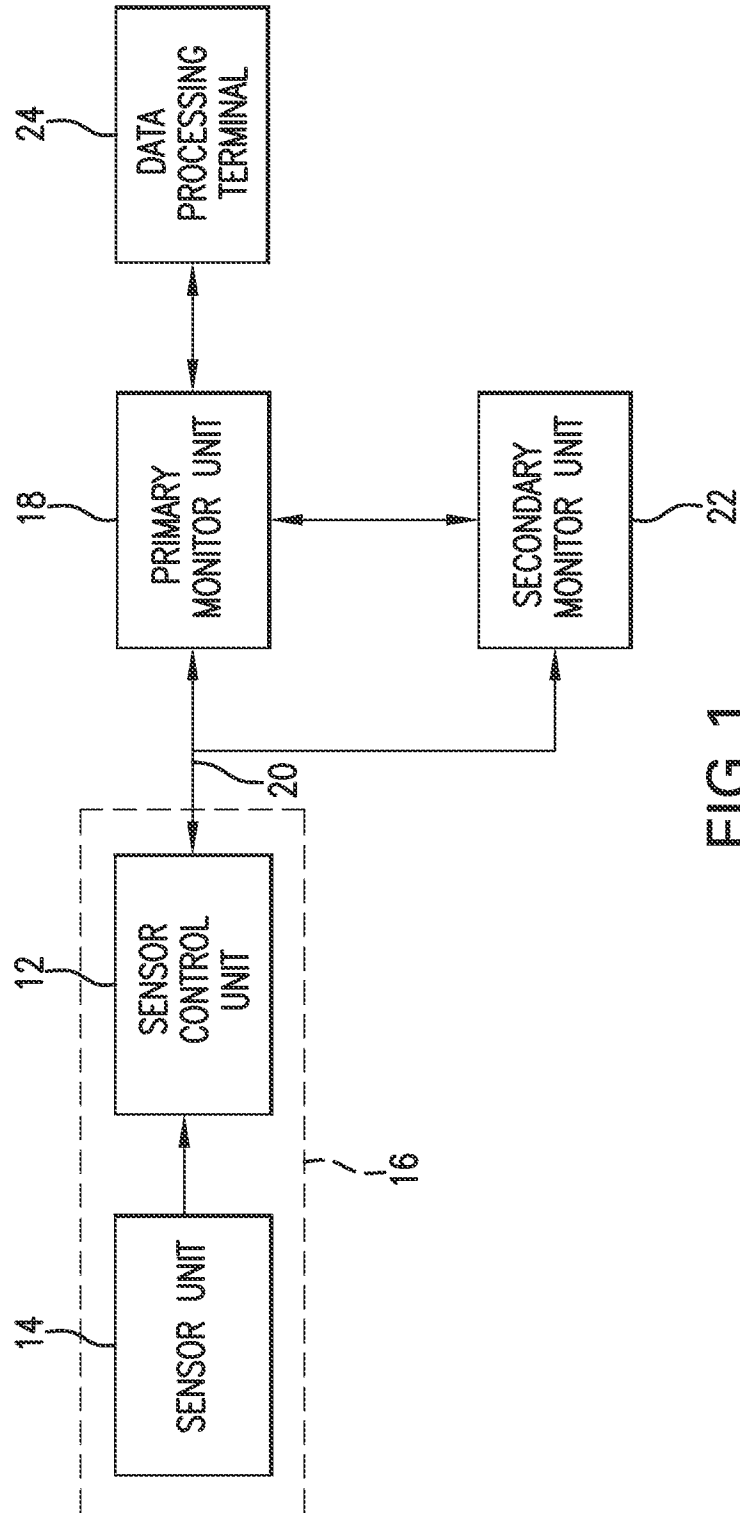


FIG.1

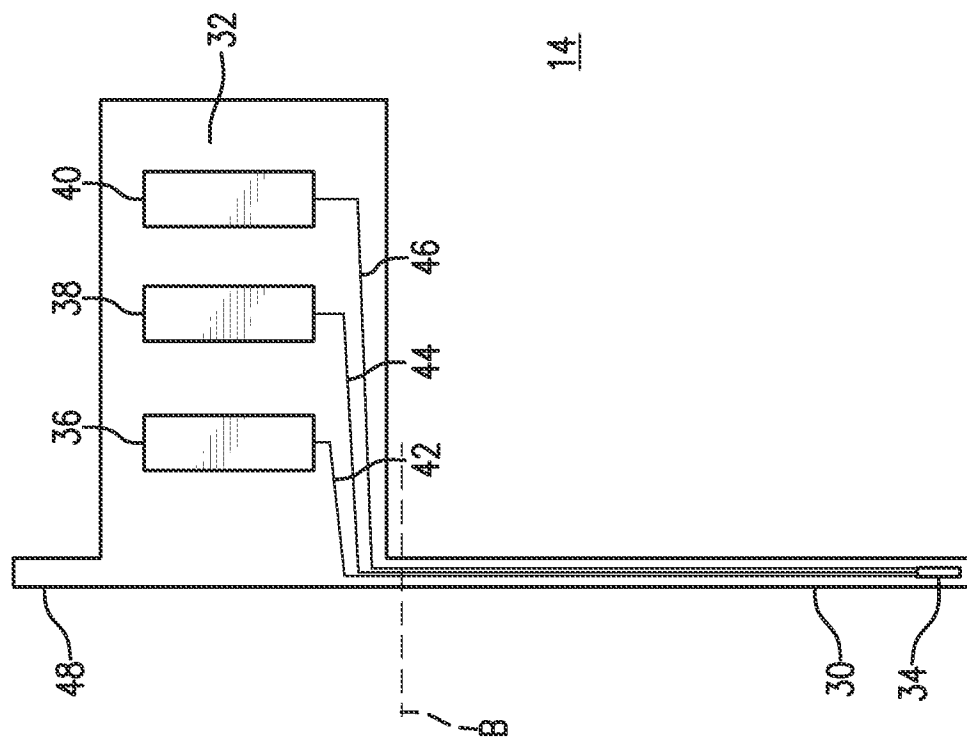


FIG. 2

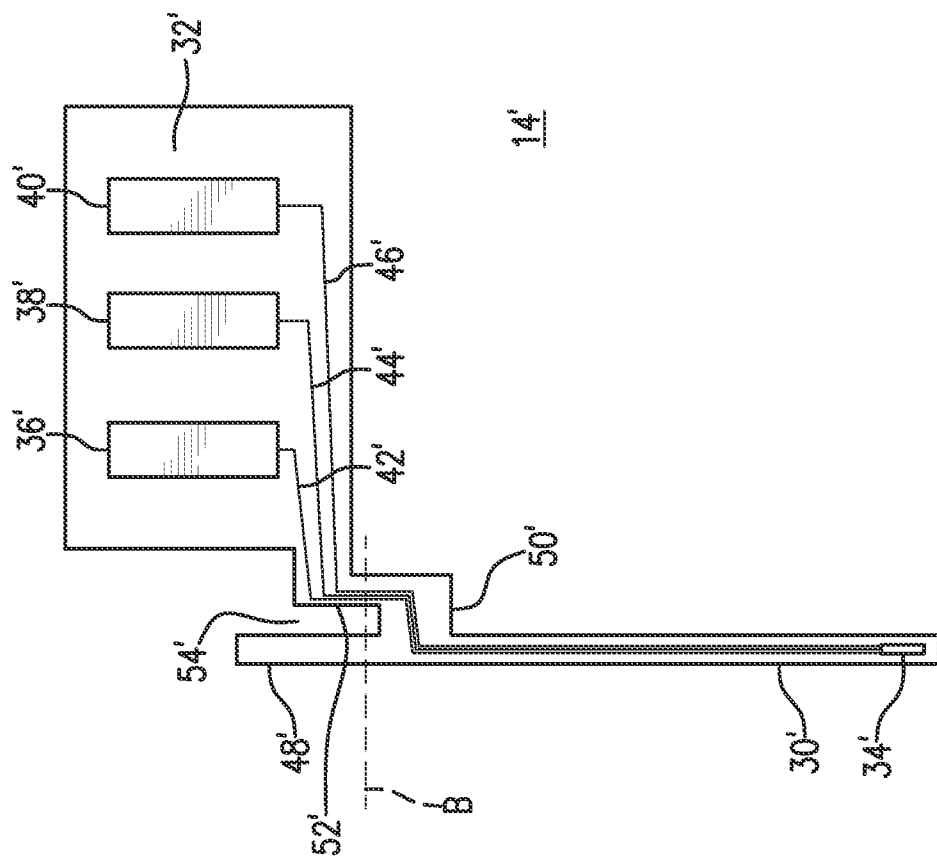
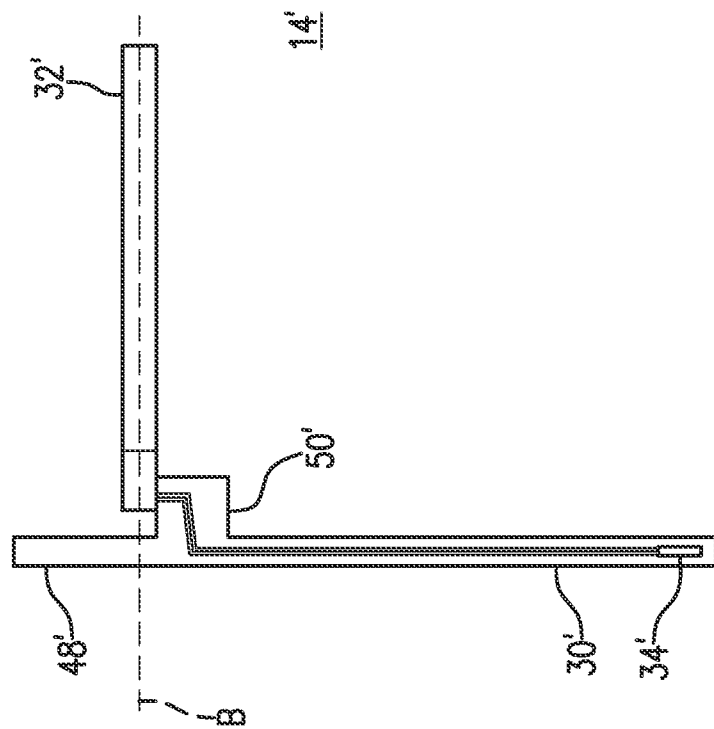


FIG. 3



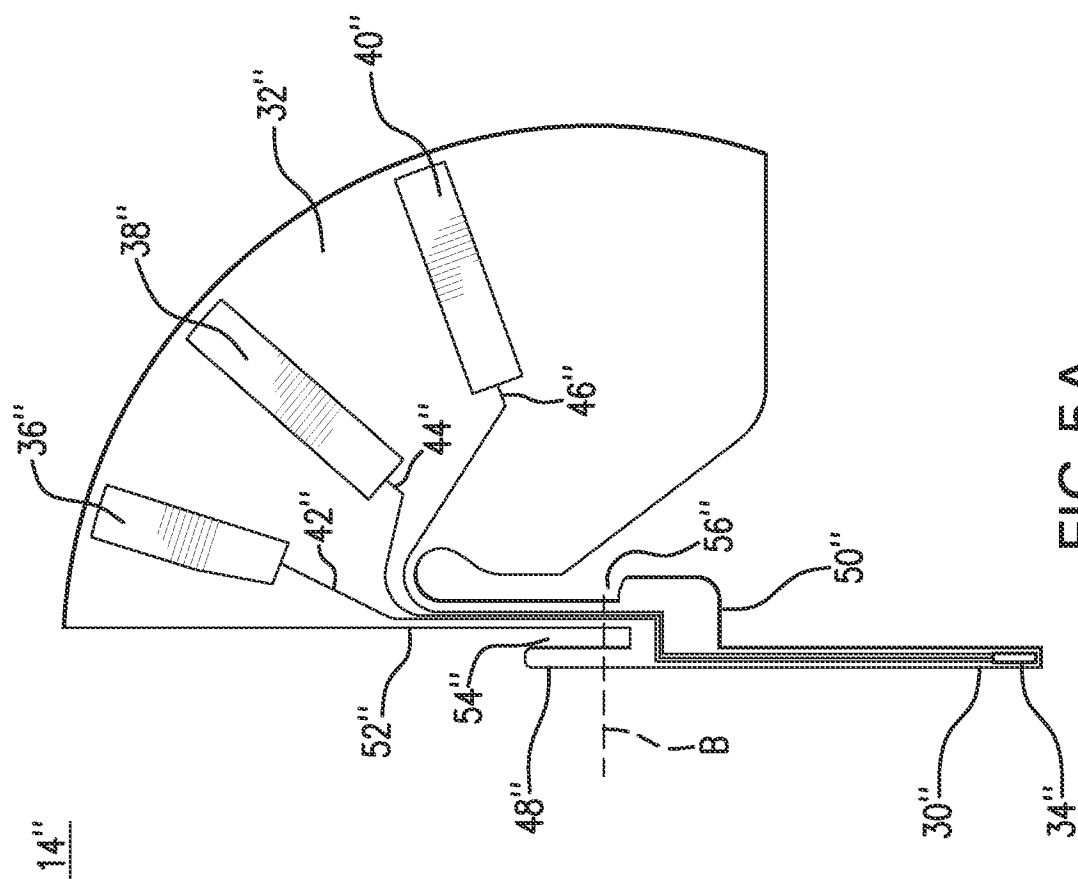
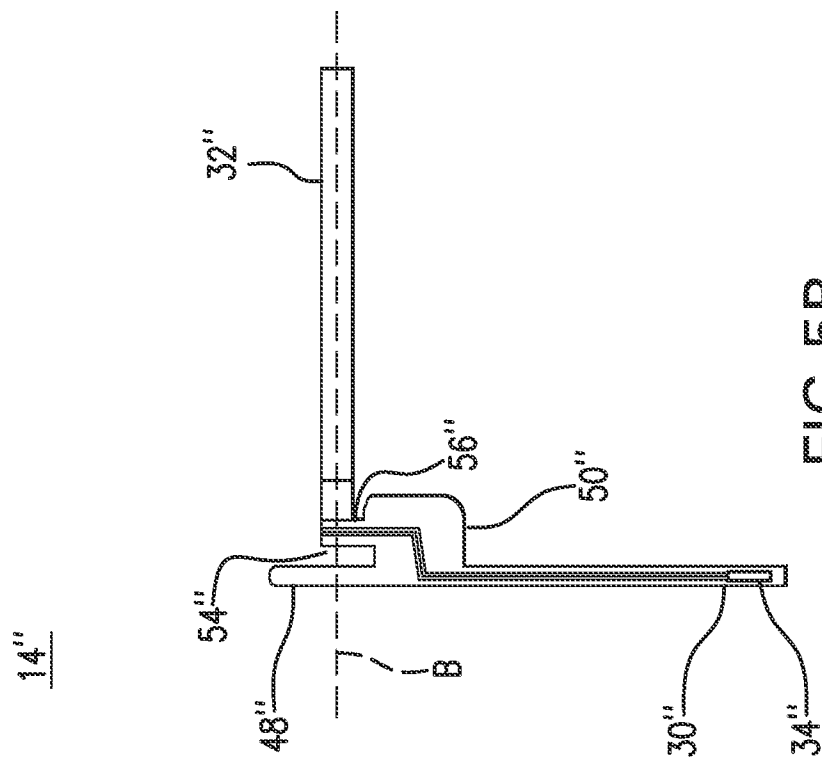


FIG. 5A



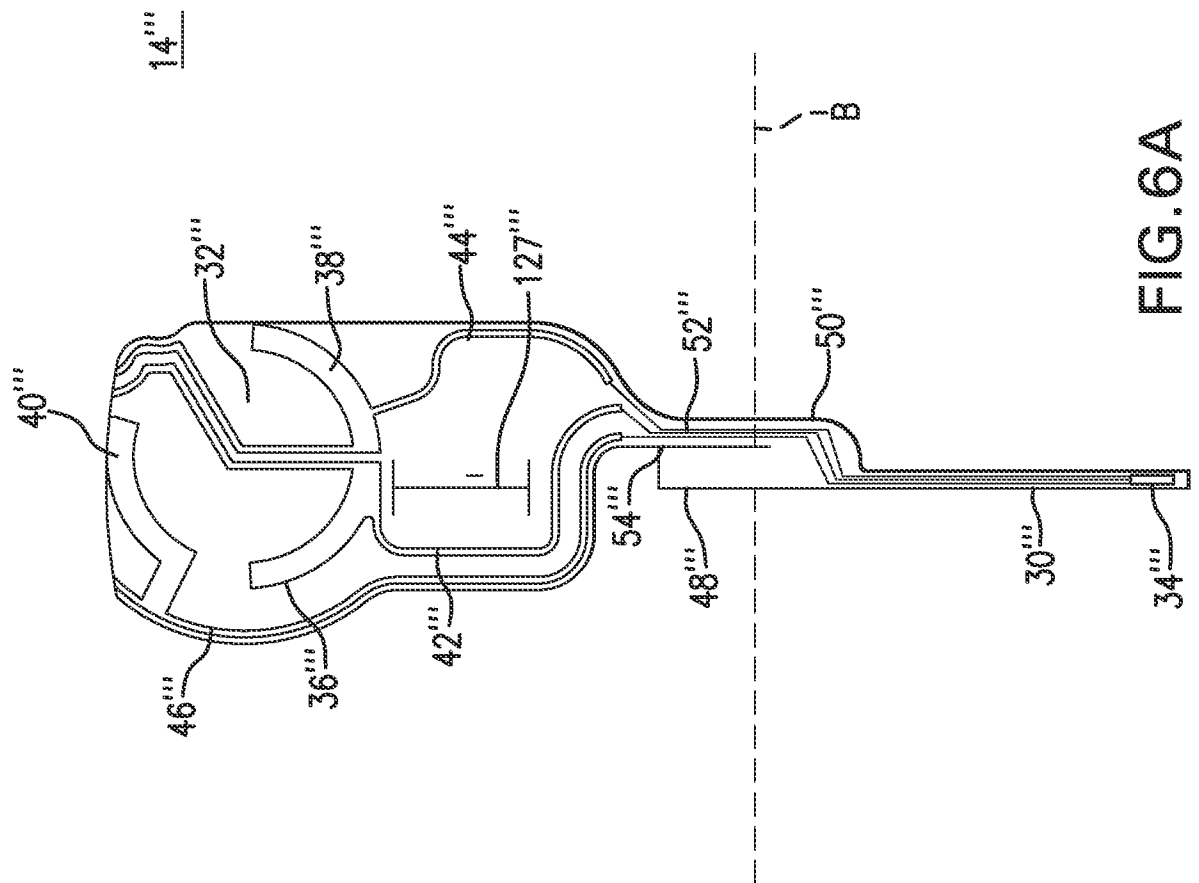


FIG. 6A

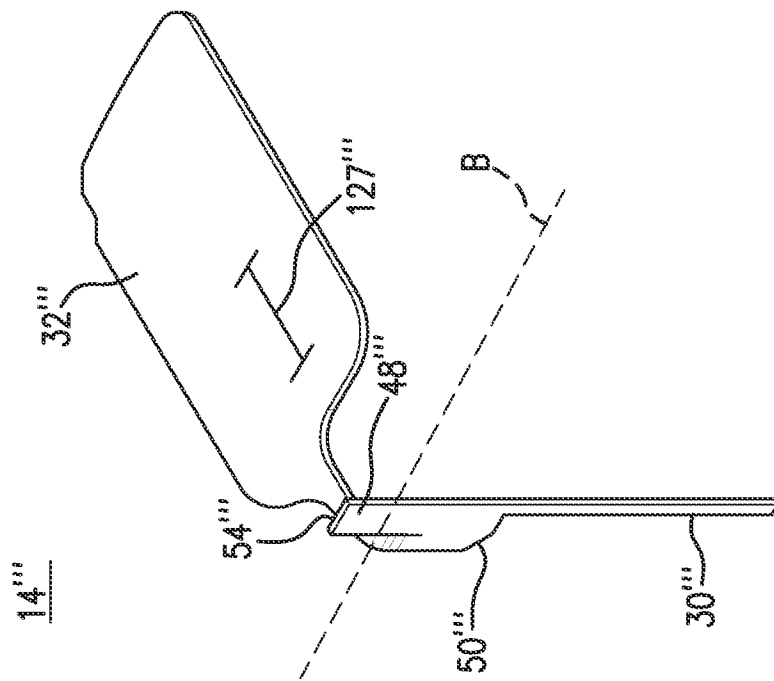


FIG. 6B

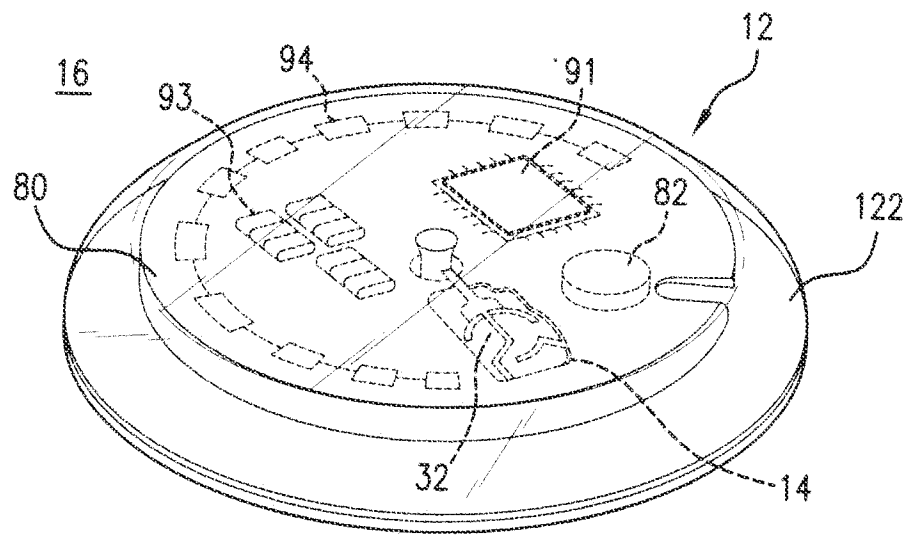


FIG. 7

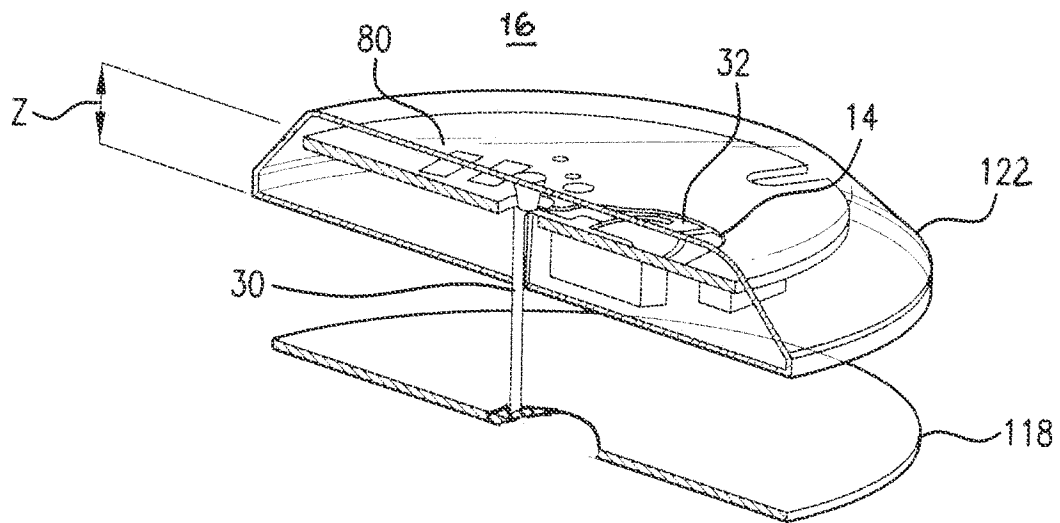


FIG. 8

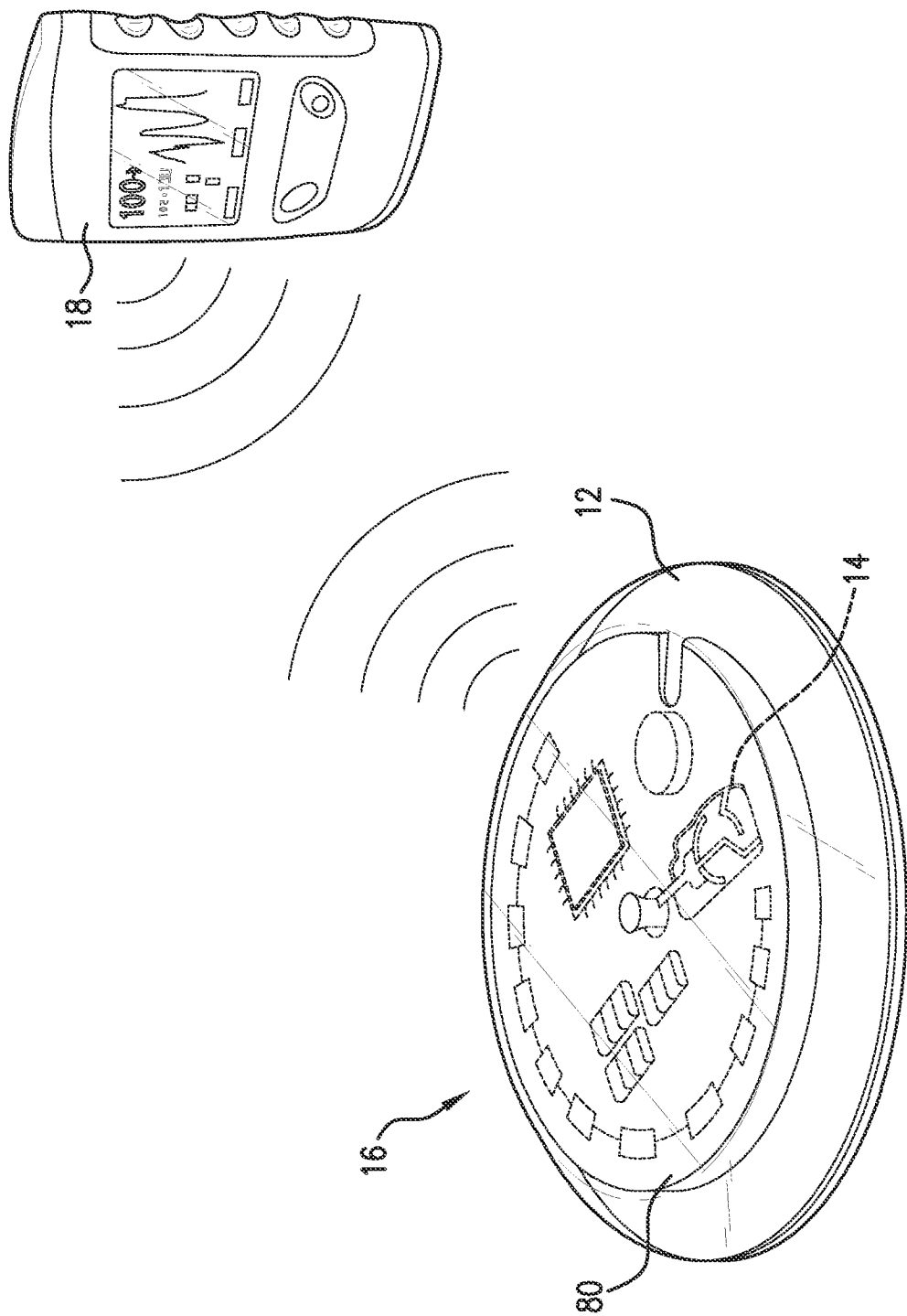


FIG. 9

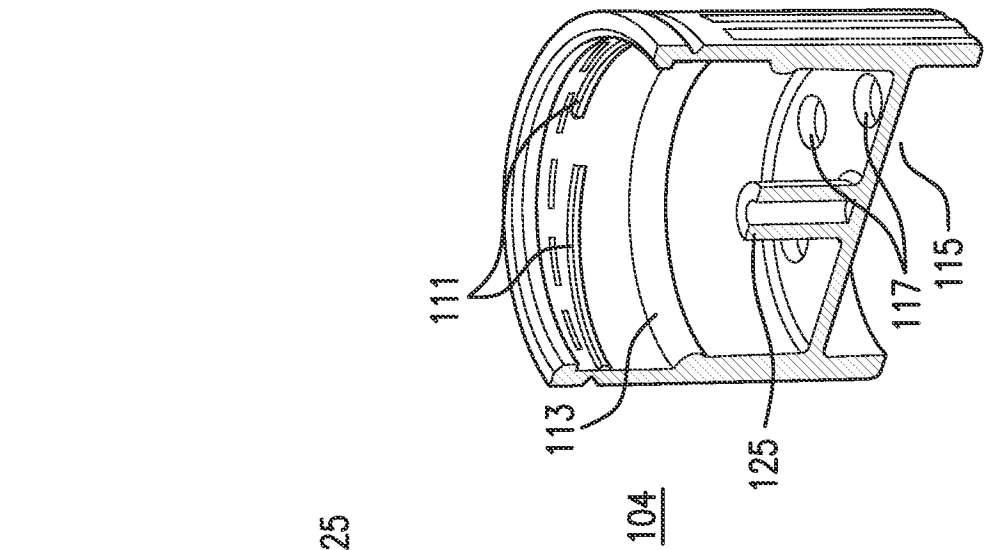


FIG.11

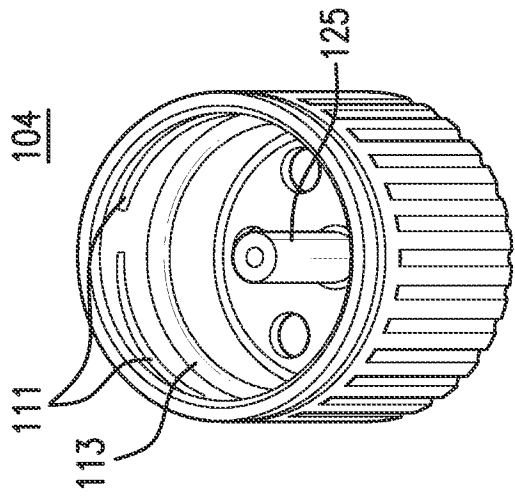


FIG.12

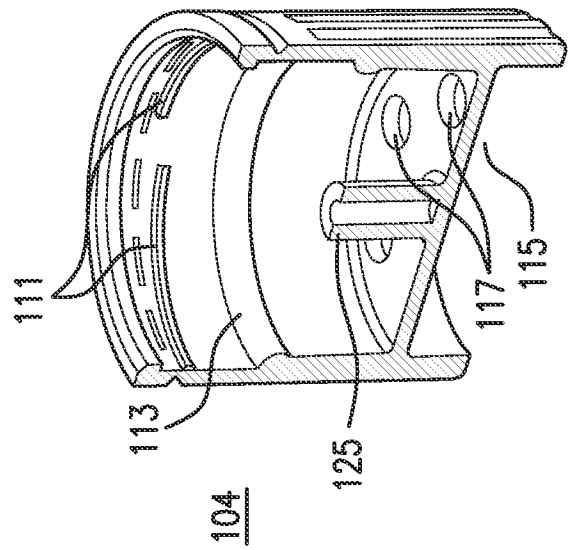


FIG.13

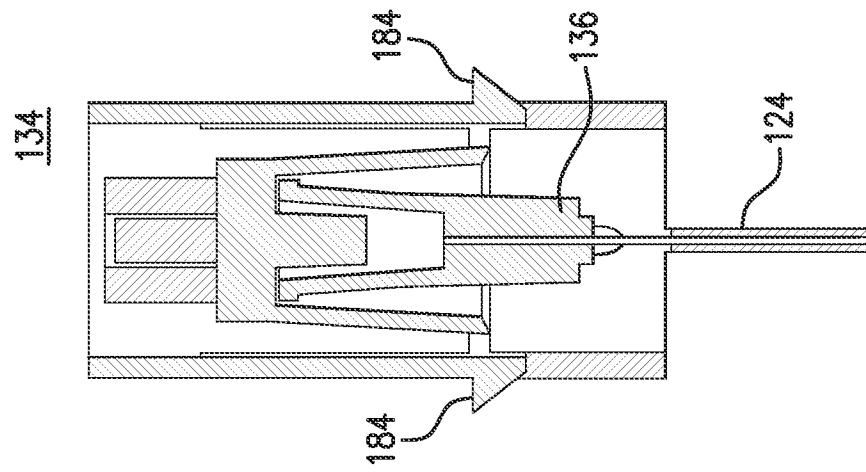


FIG.16

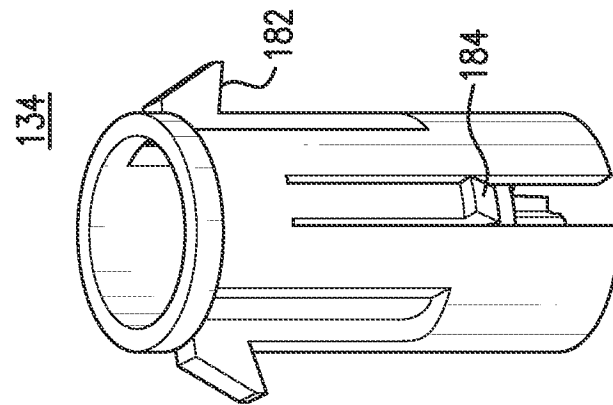


FIG.15

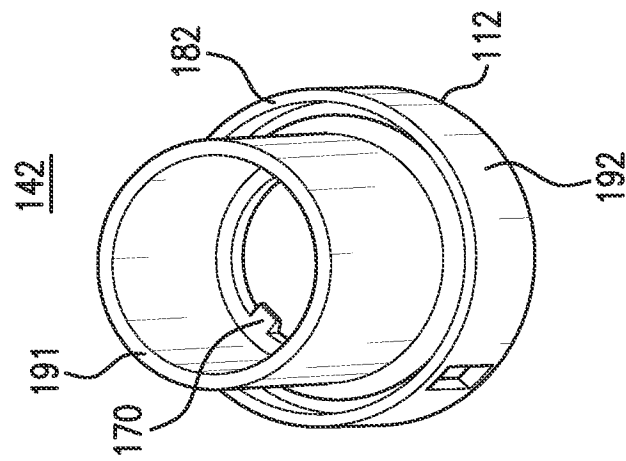


FIG.14

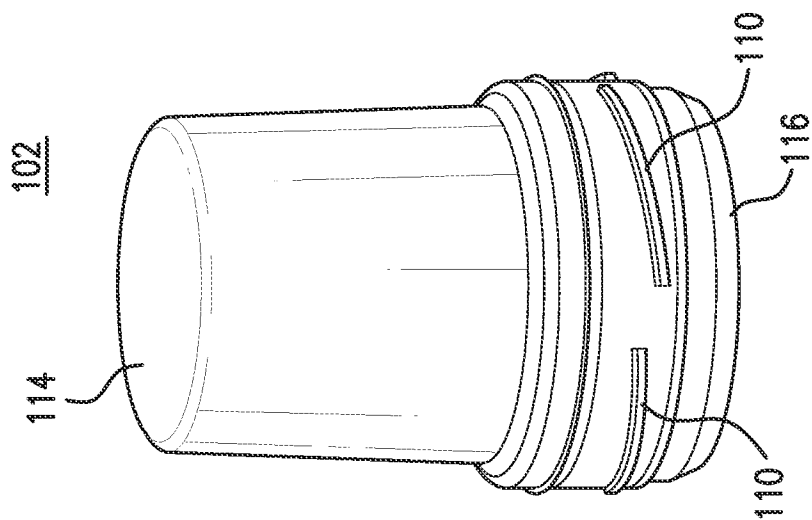


FIG. 11

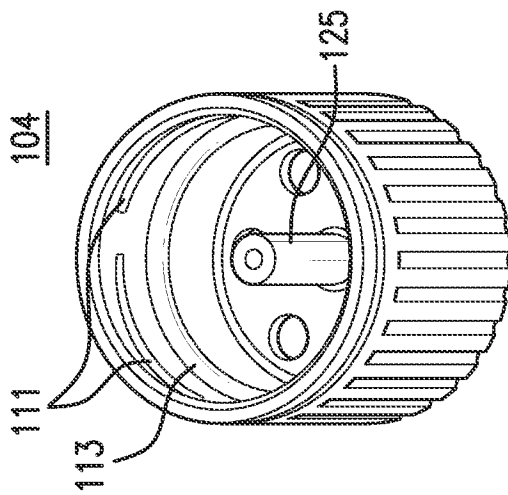


FIG. 12

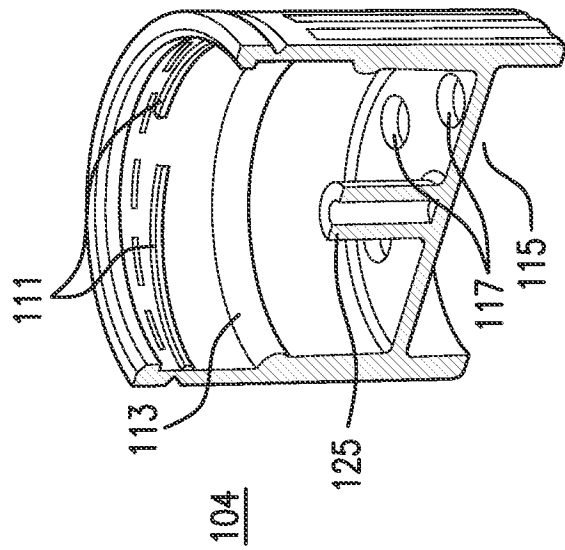


FIG. 13

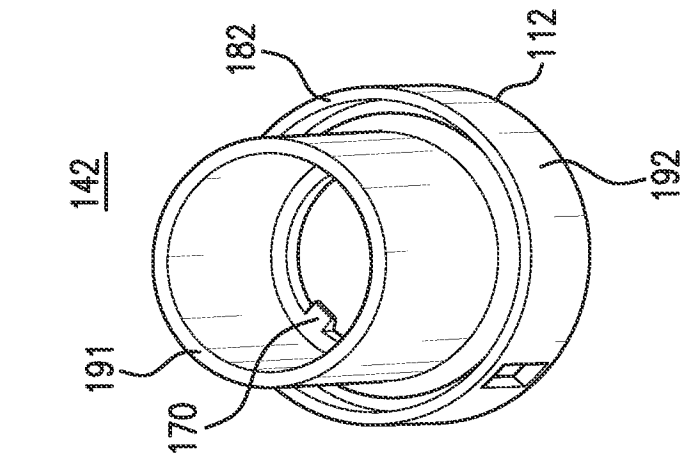


FIG. 14

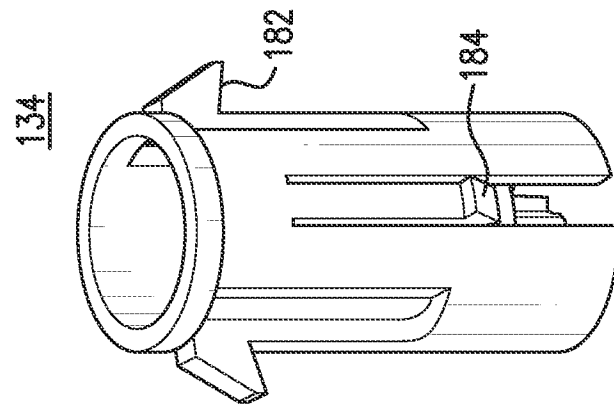


FIG. 15

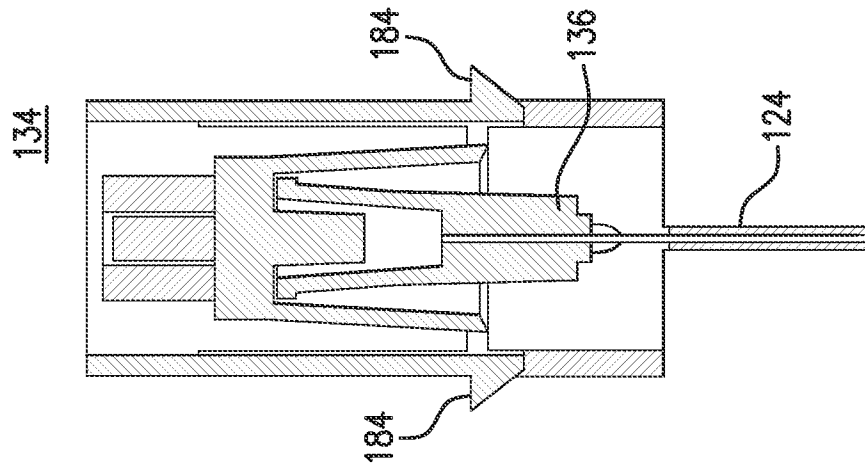


FIG. 16

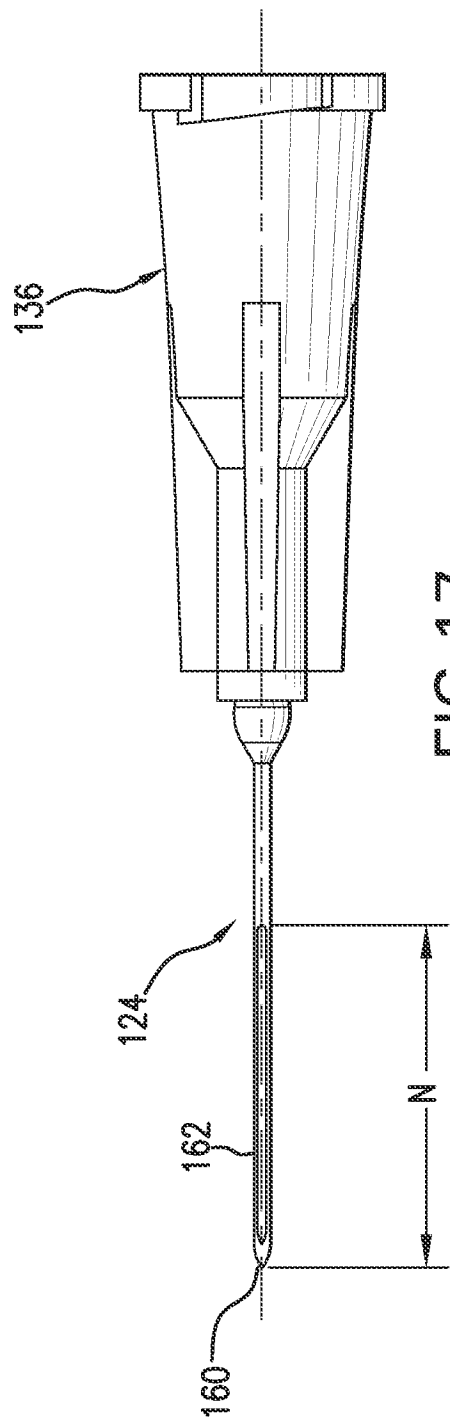


FIG. 17

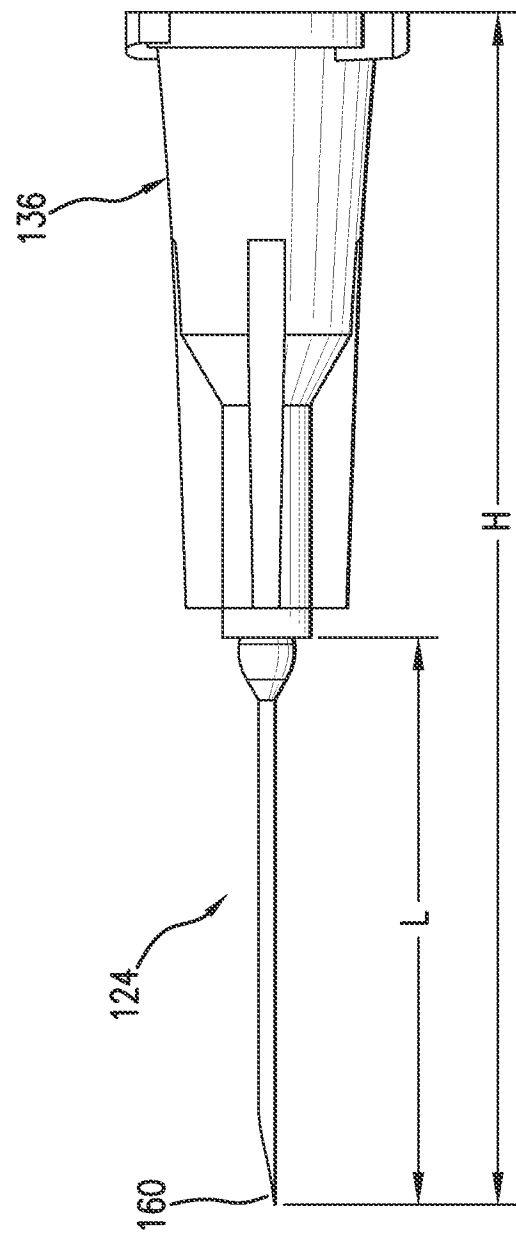


FIG. 18

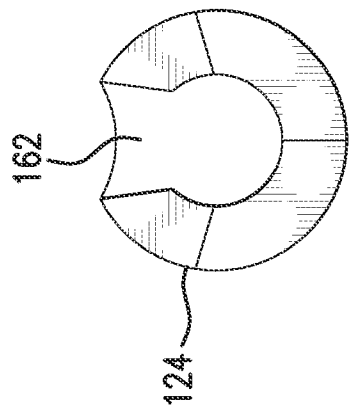


FIG. 19

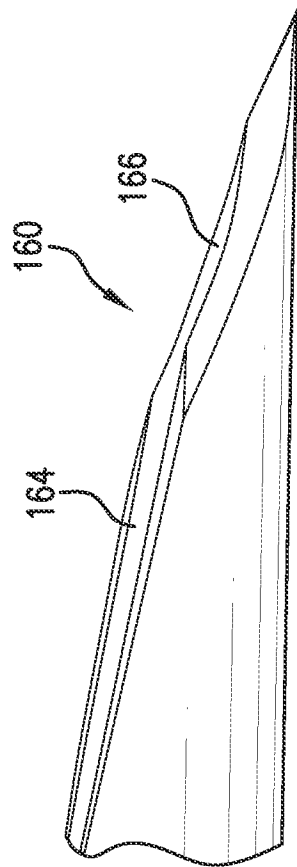


FIG. 20

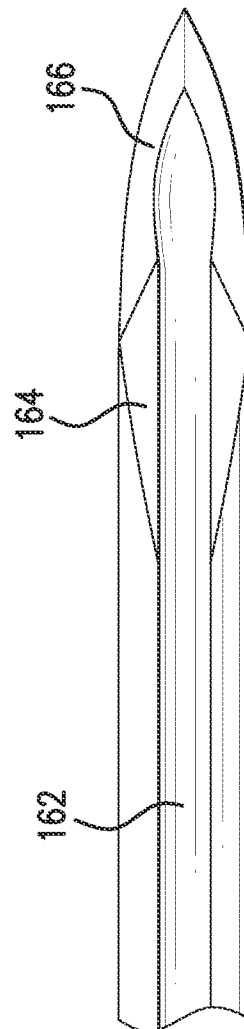


FIG. 21

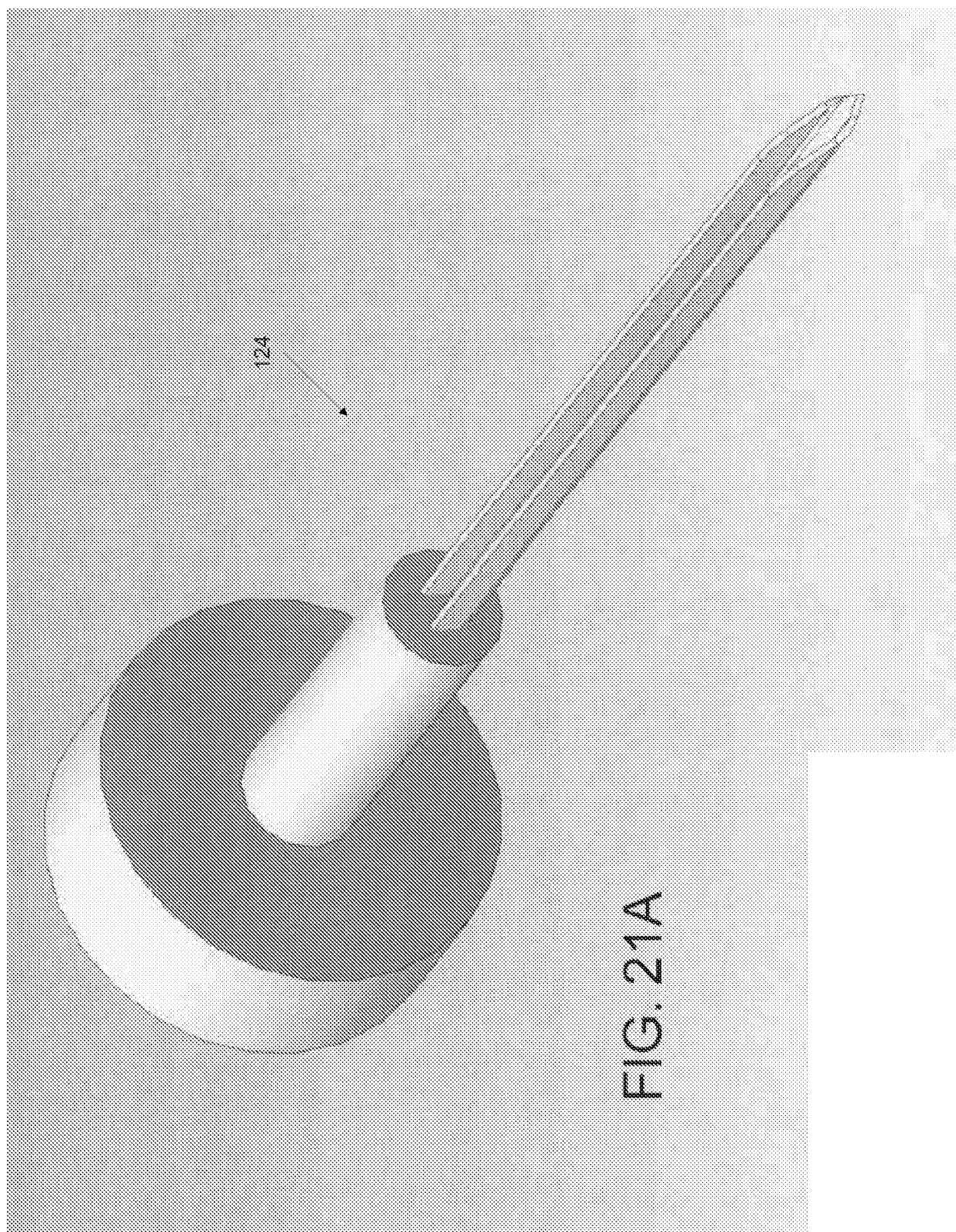
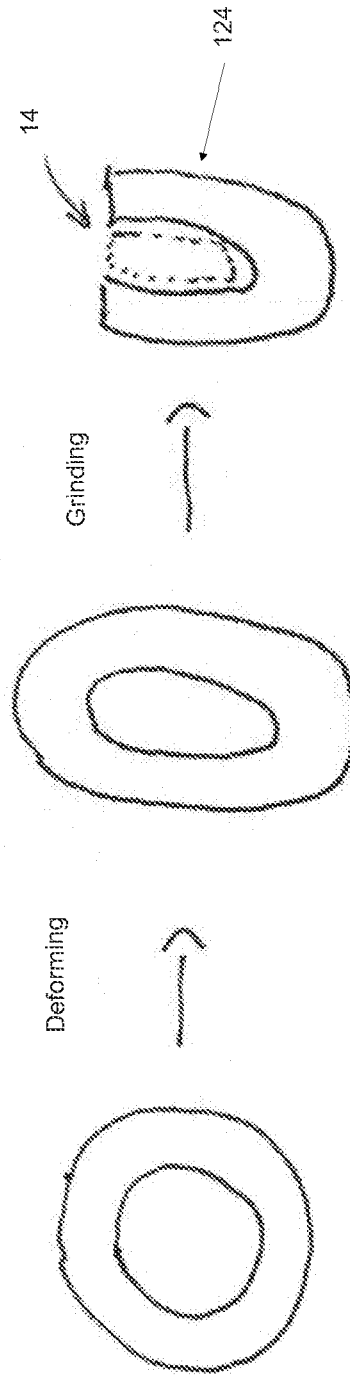


FIG. 21A

FIG. 21B



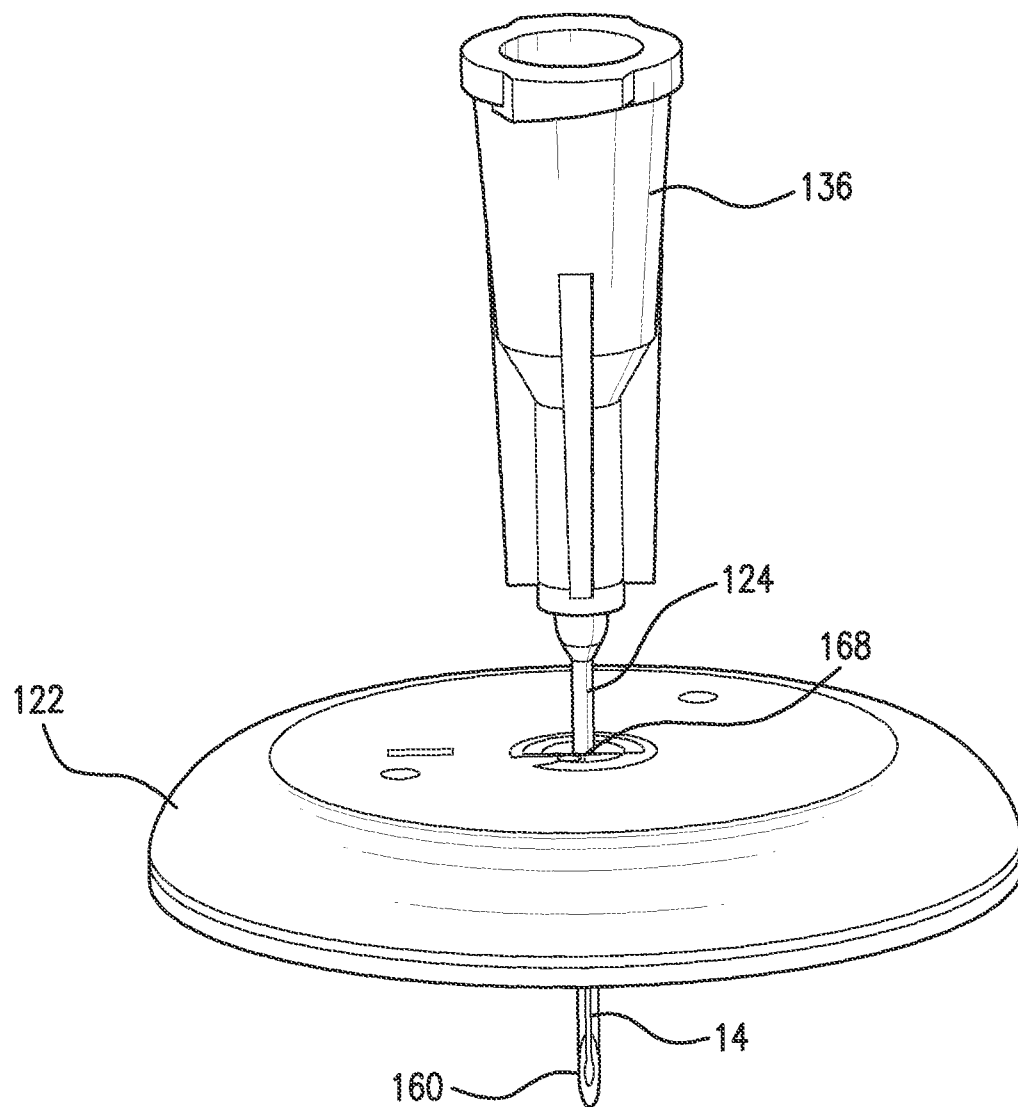


FIG.22

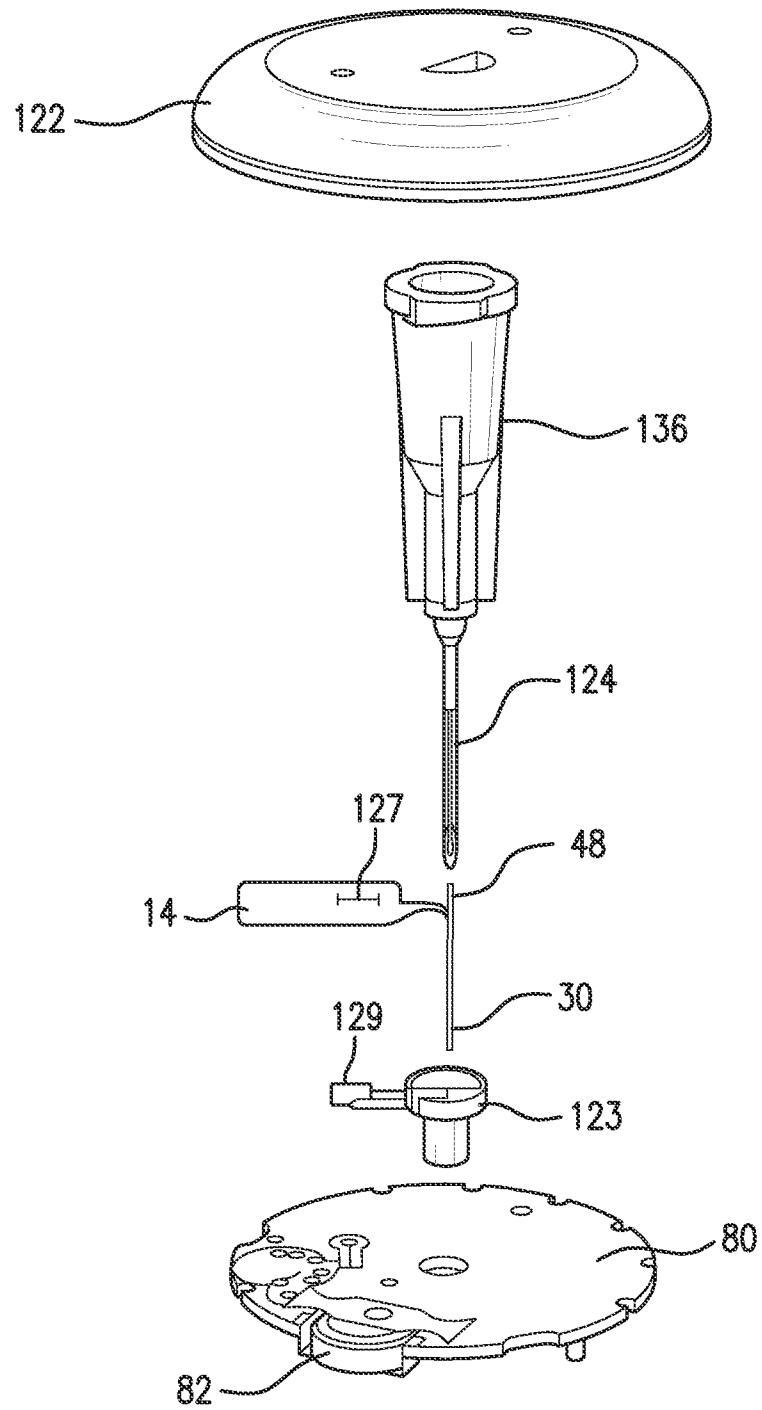


FIG.23

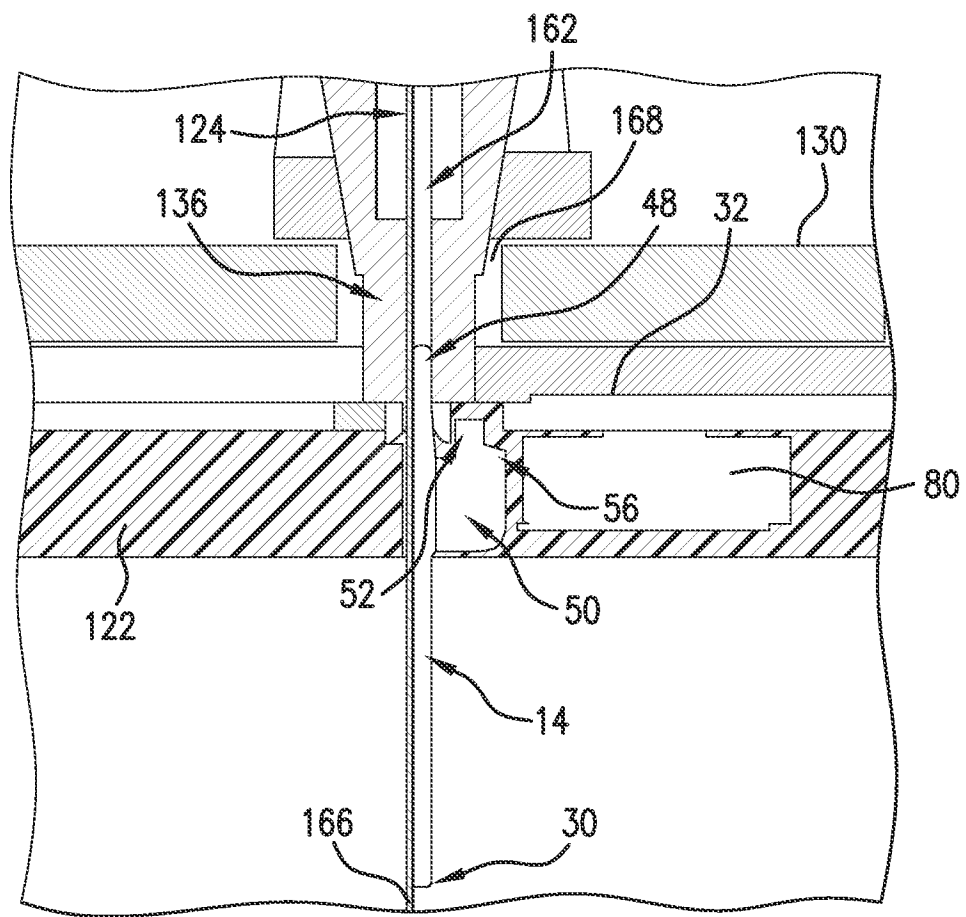


FIG. 24

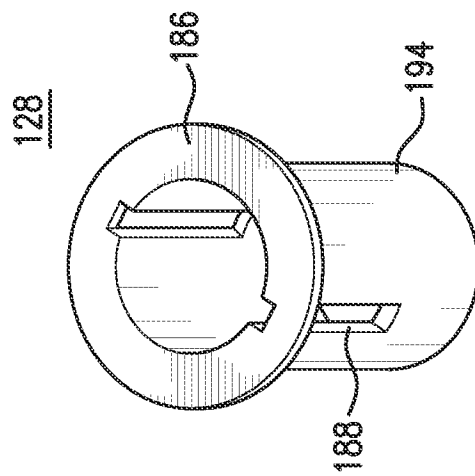


FIG. 25

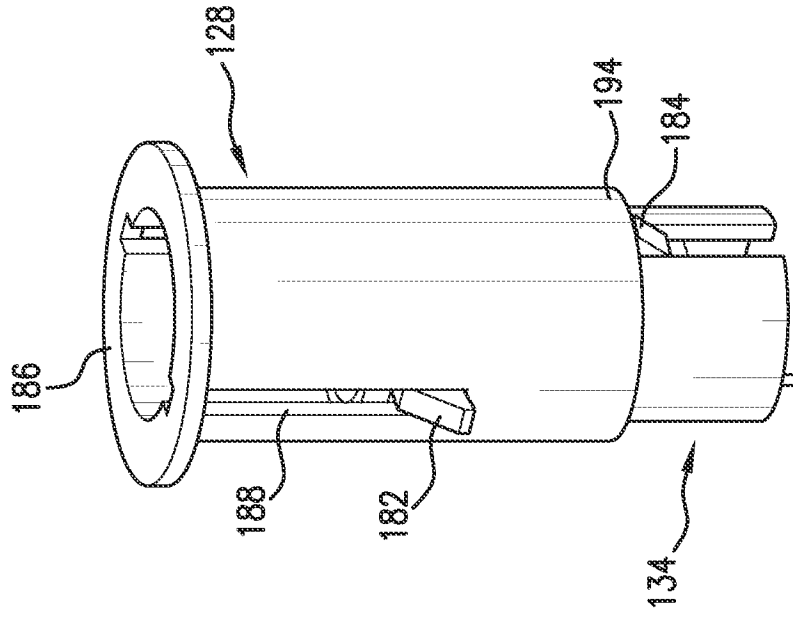


FIG. 26

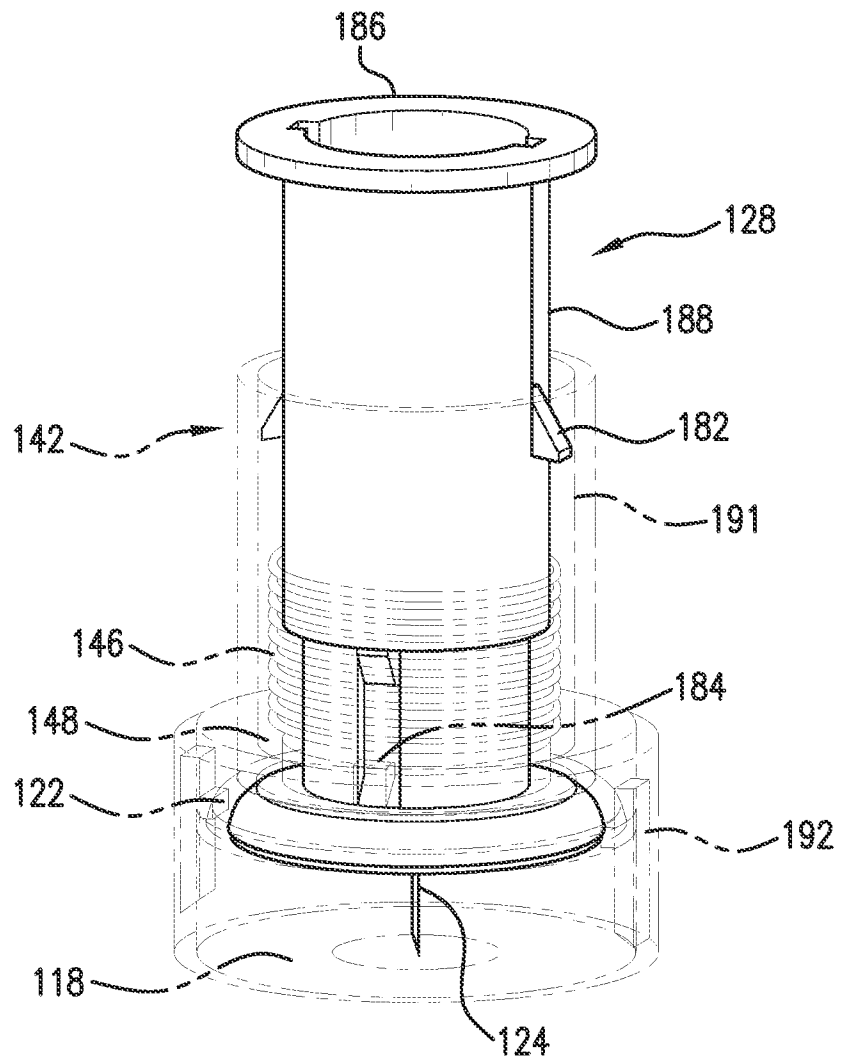


FIG. 27

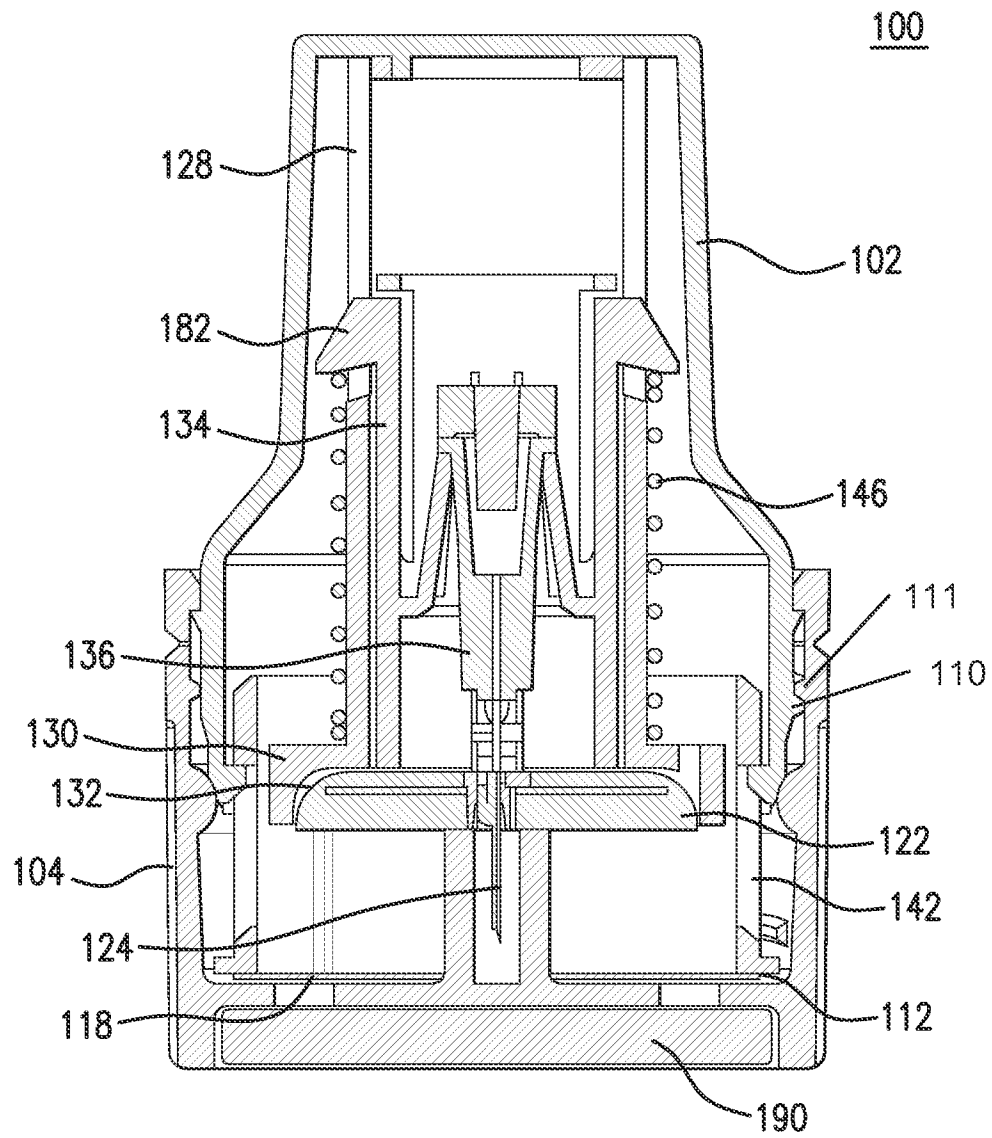


FIG.28

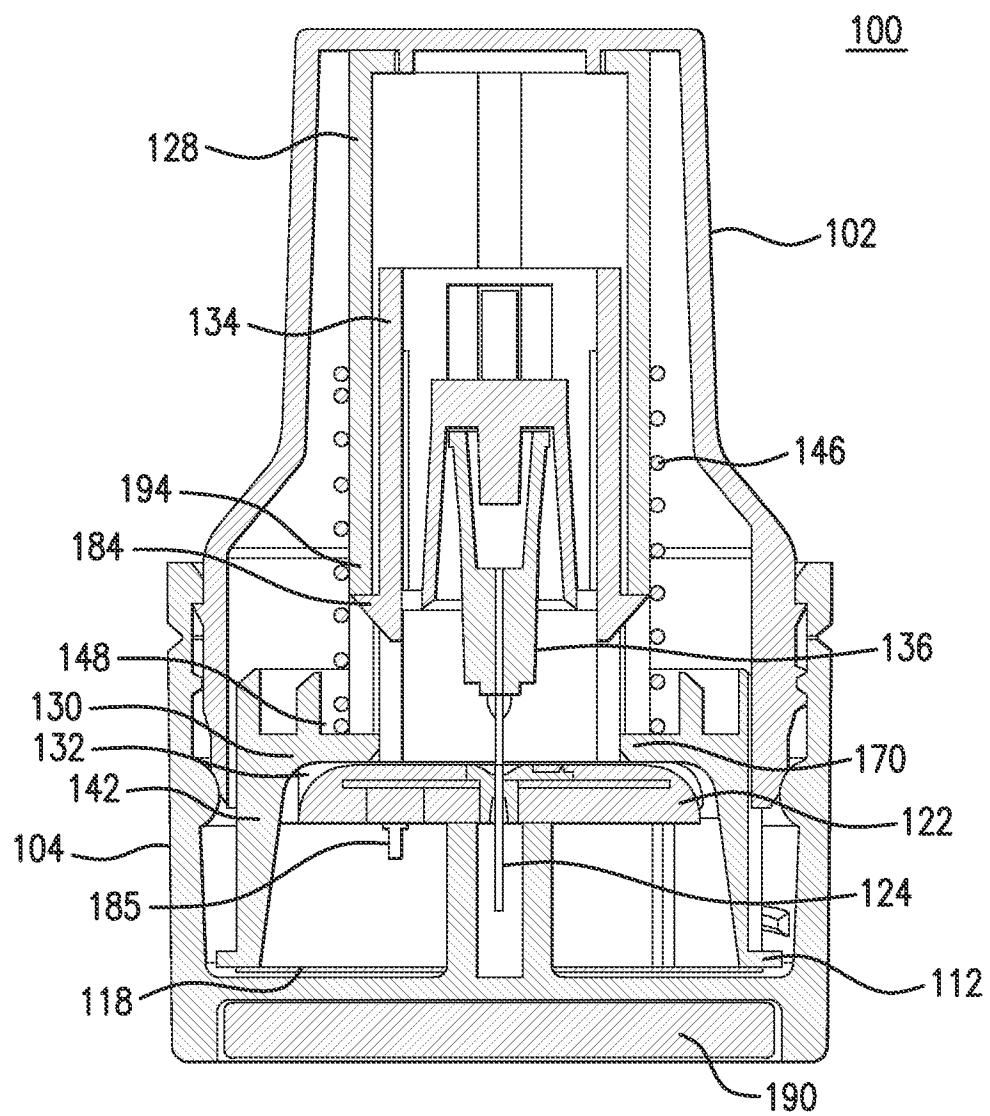
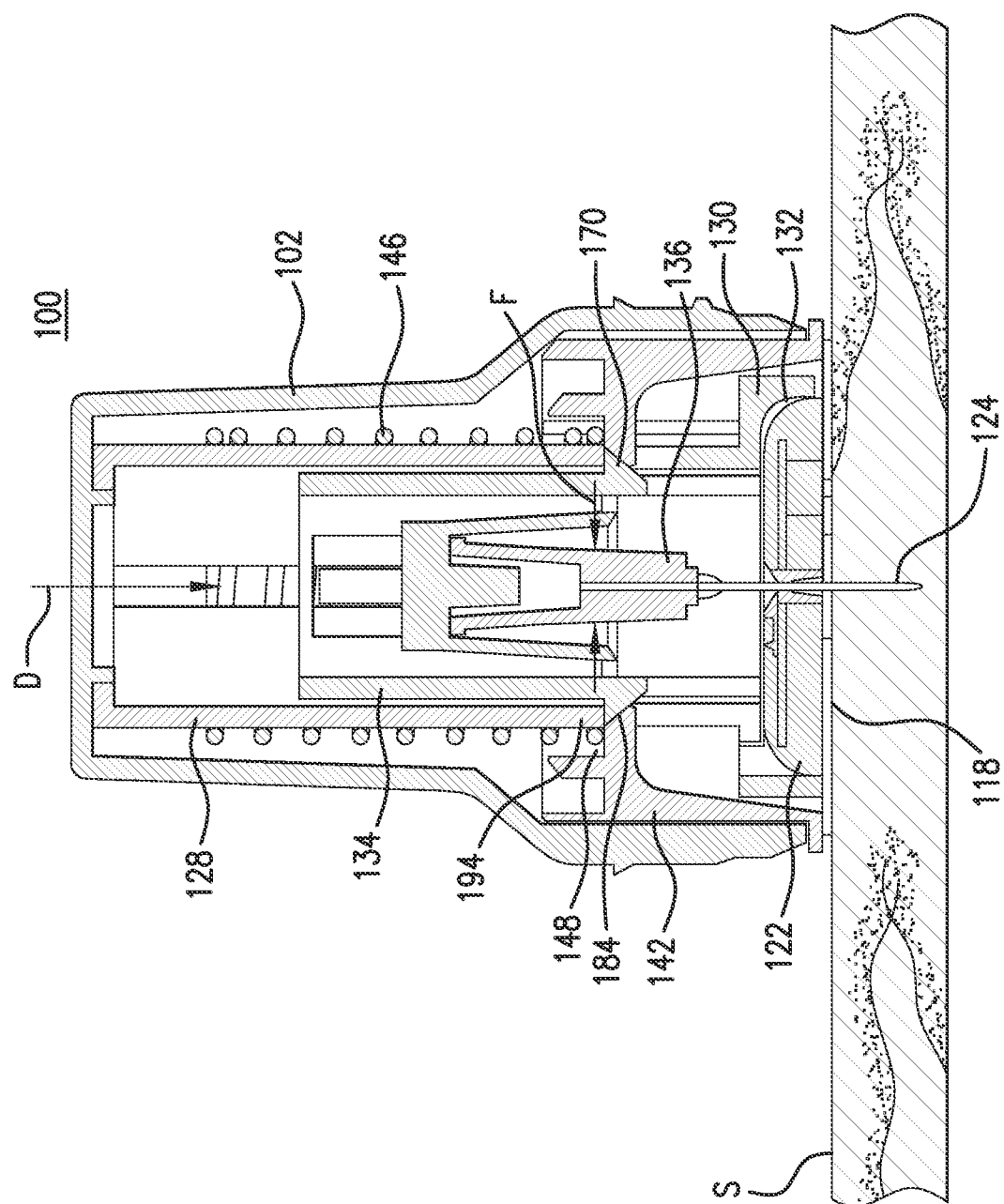


FIG.29



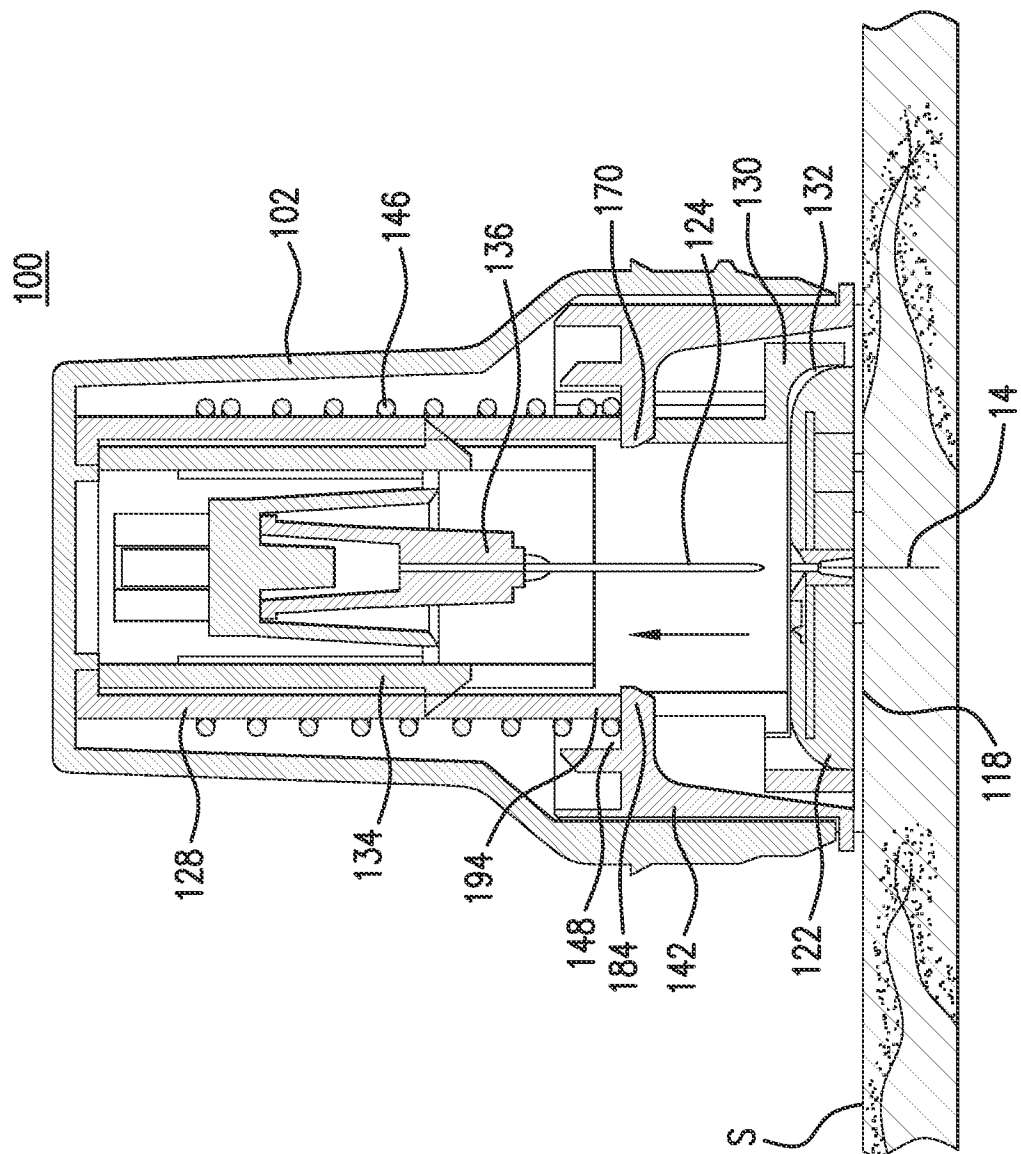


FIG. 31

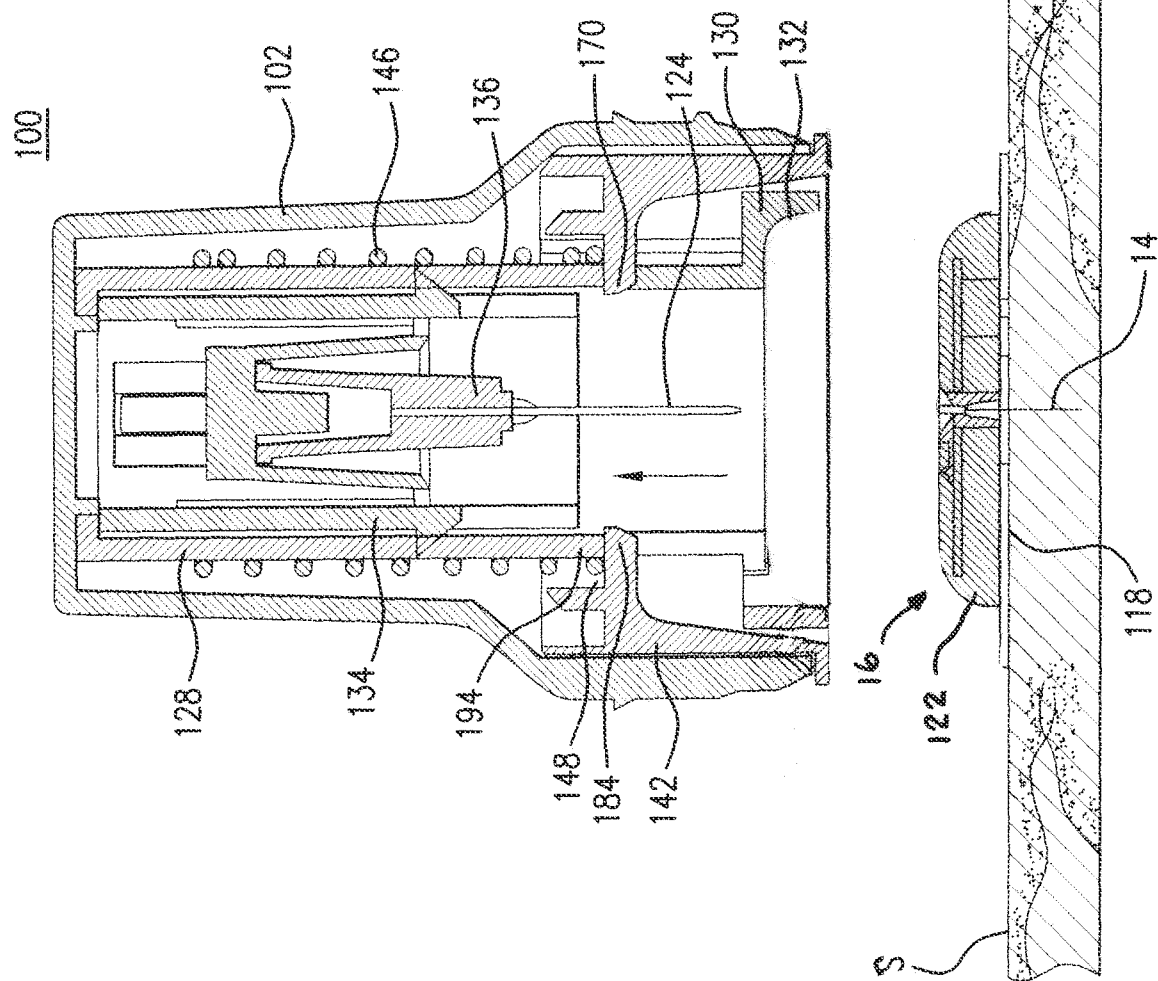


FIG. 31A

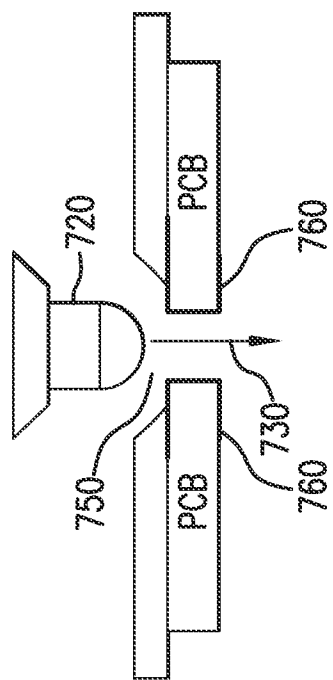


FIG. 32

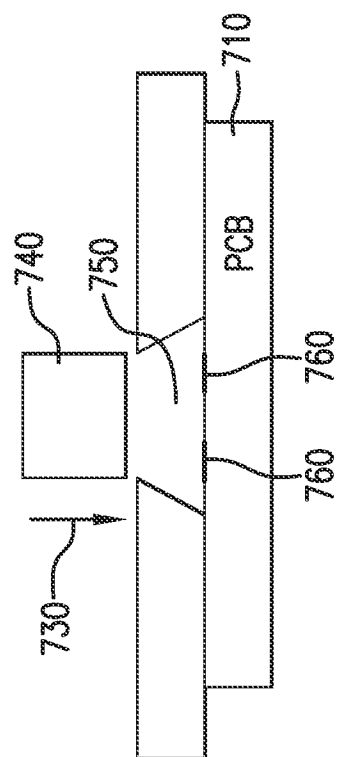


FIG. 33

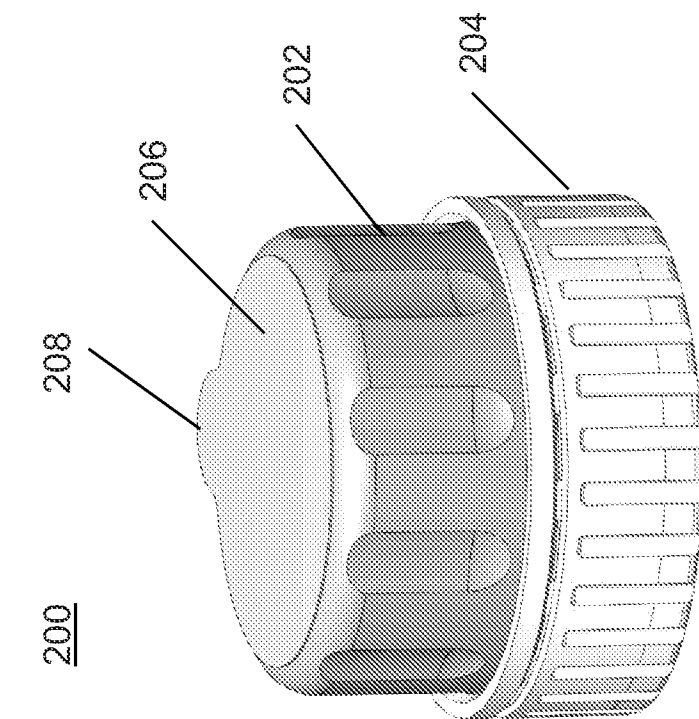


FIGURE 34

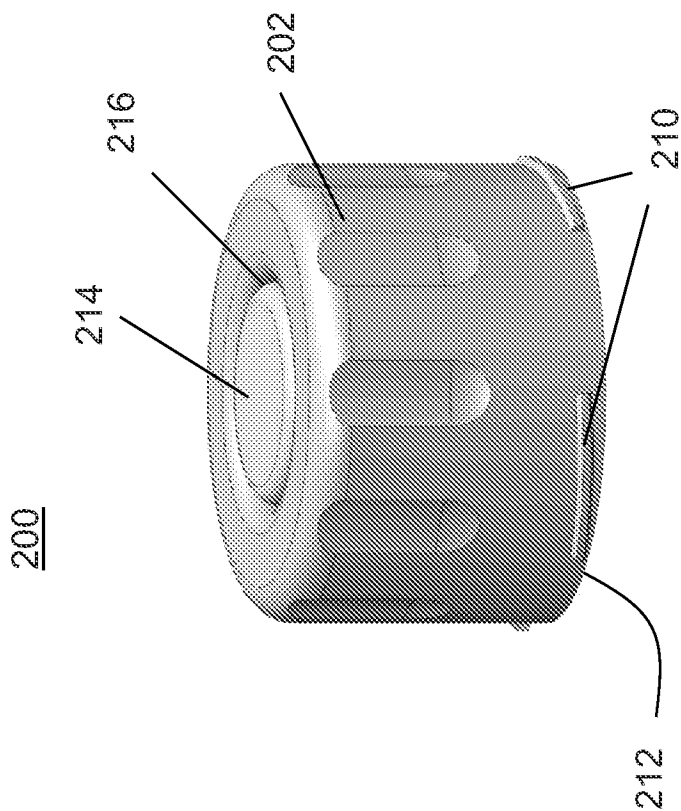


FIGURE 35

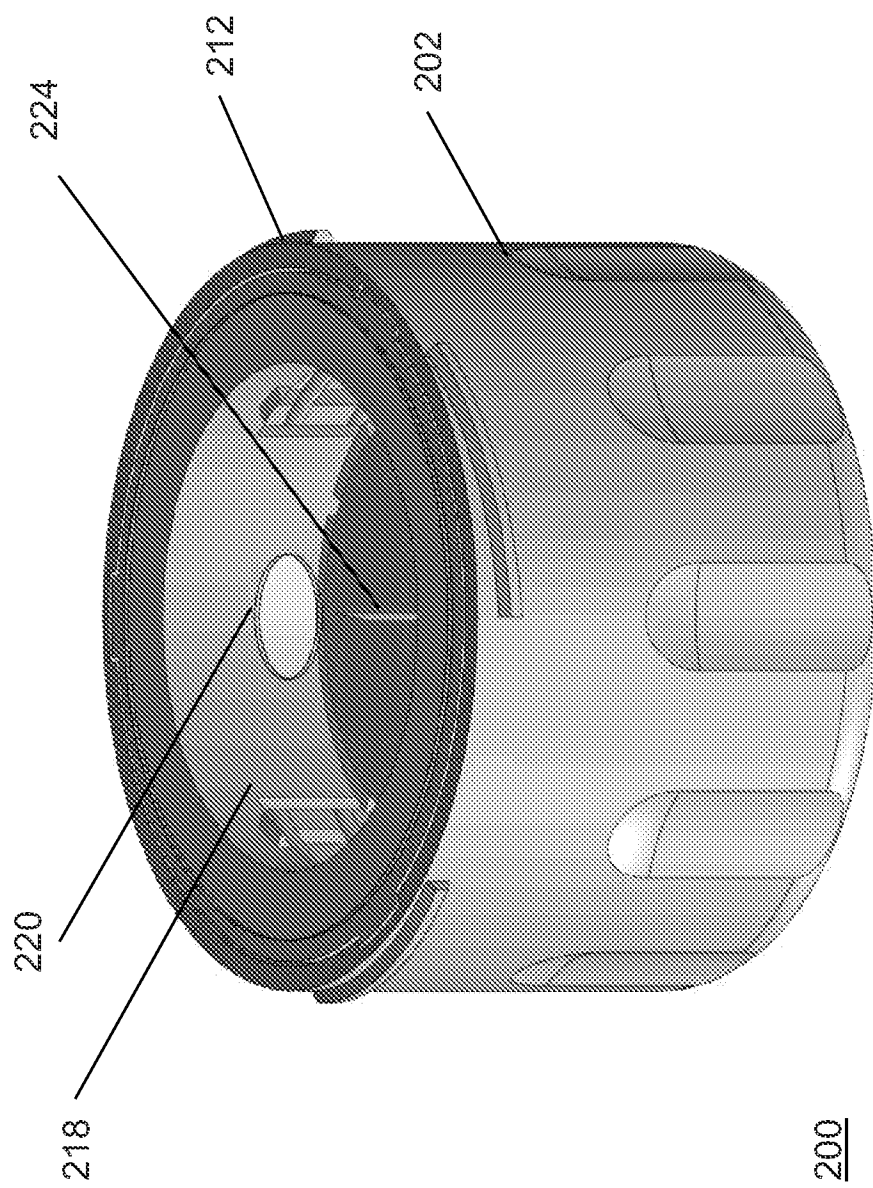


FIGURE 36

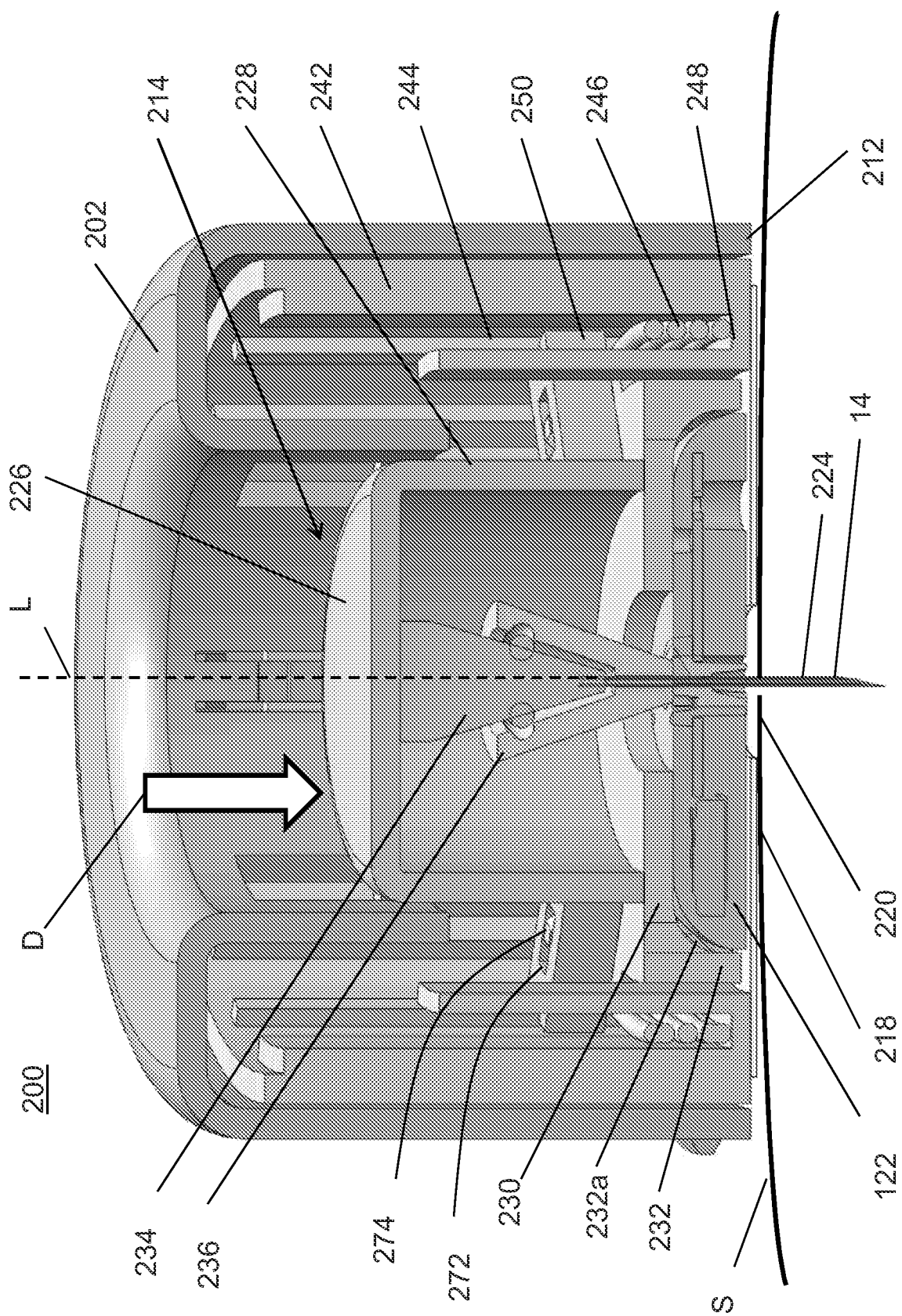


FIGURE 38

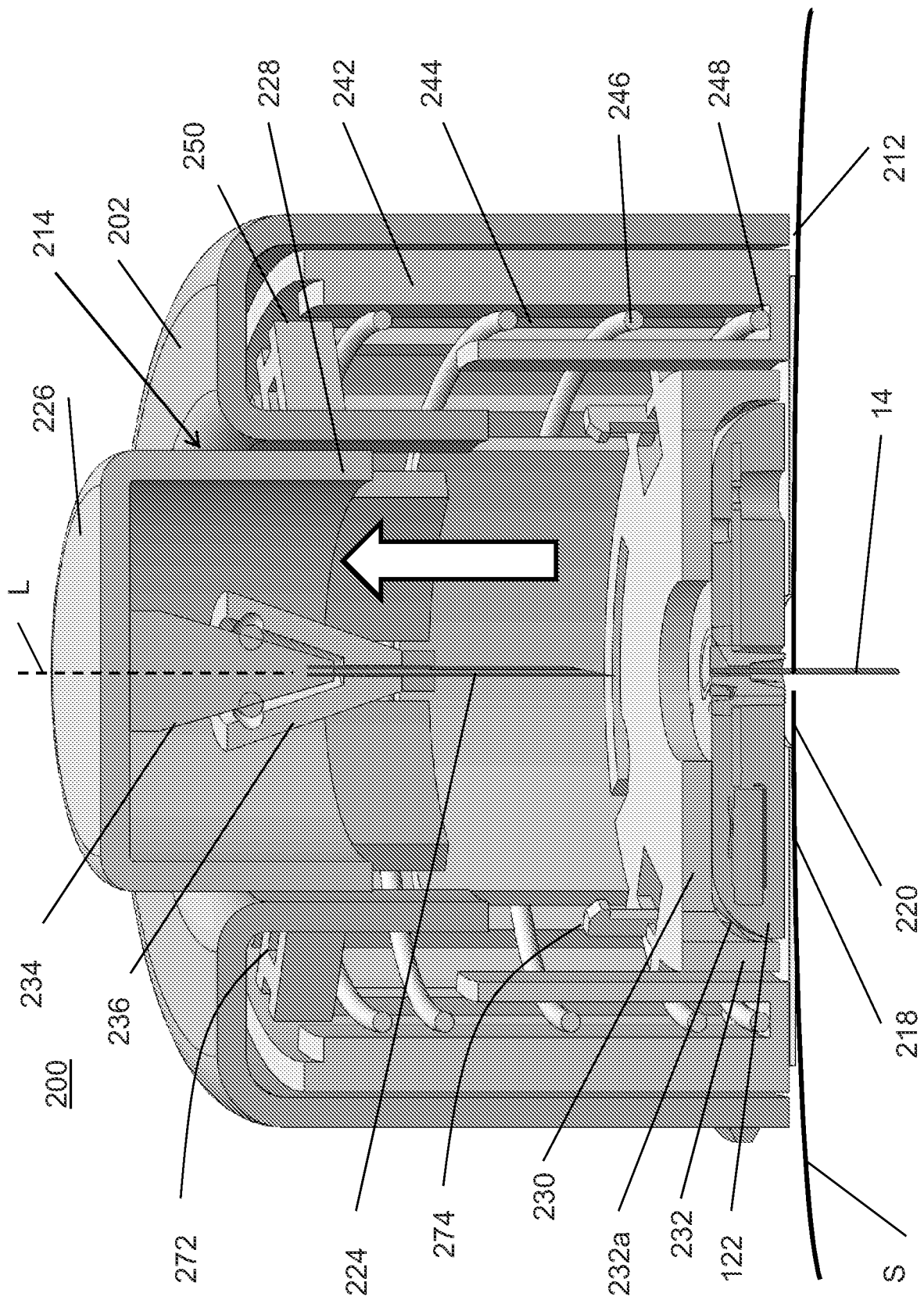


FIGURE 39

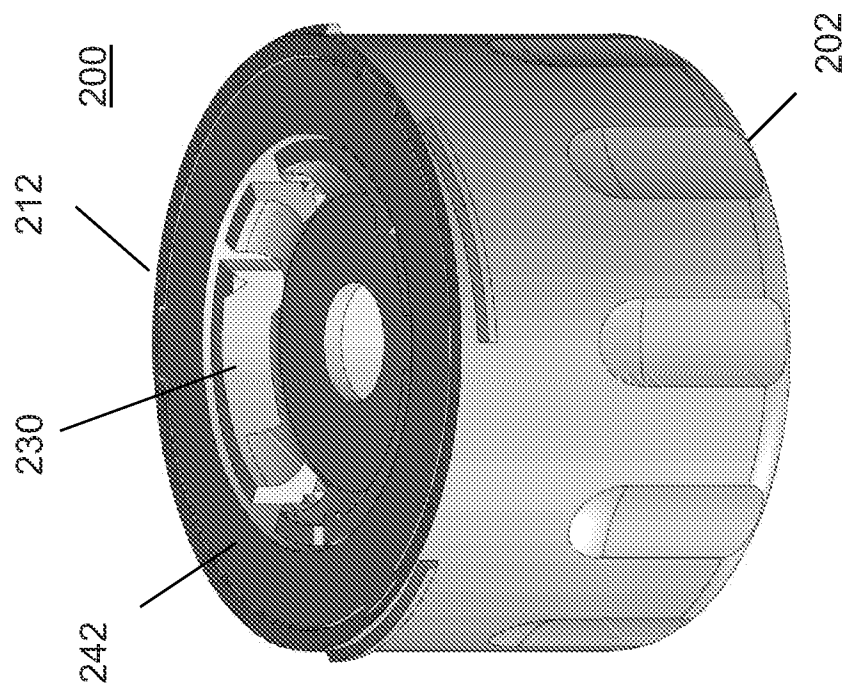


FIGURE 41

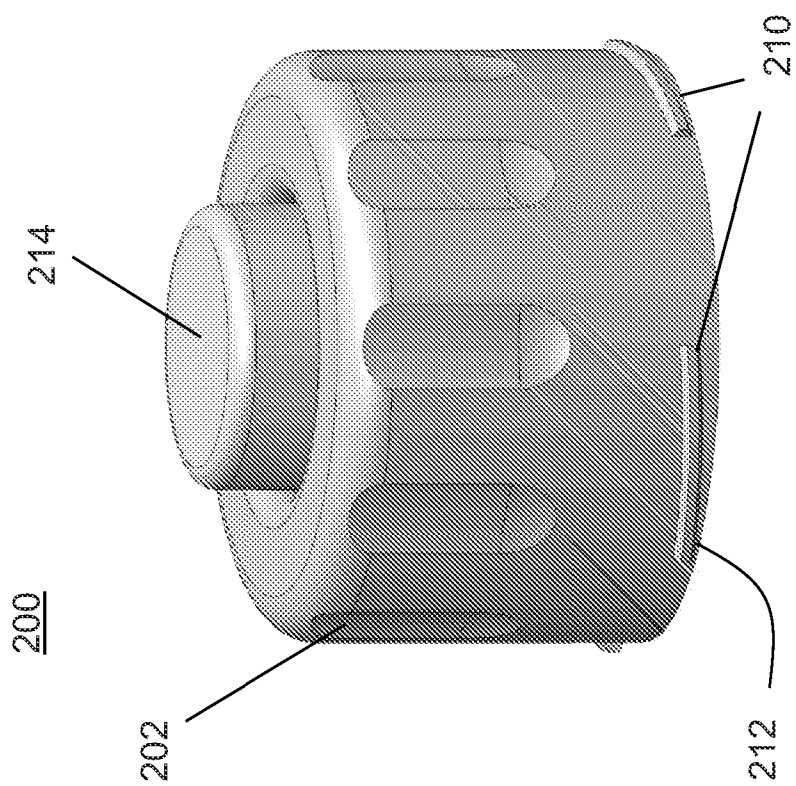


FIGURE 40

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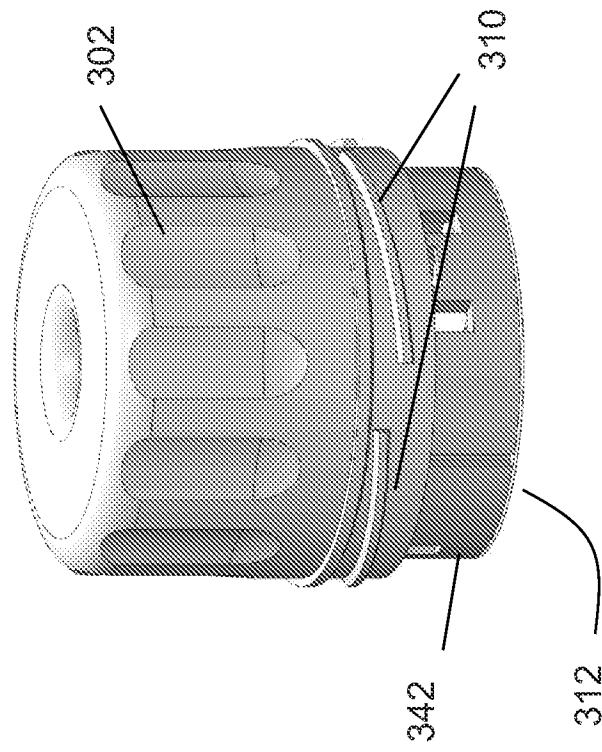


FIGURE 43

300

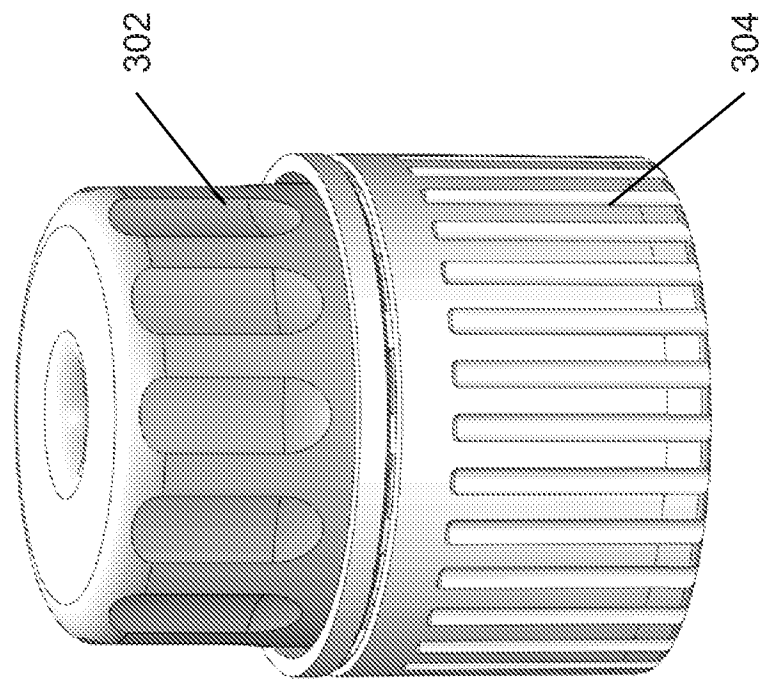


FIGURE 42

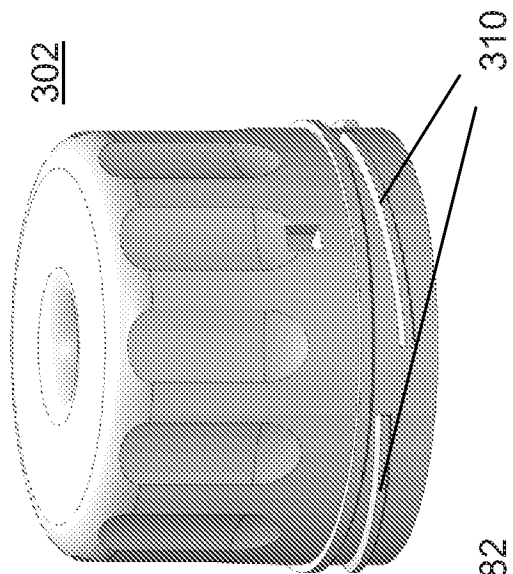


FIGURE 44

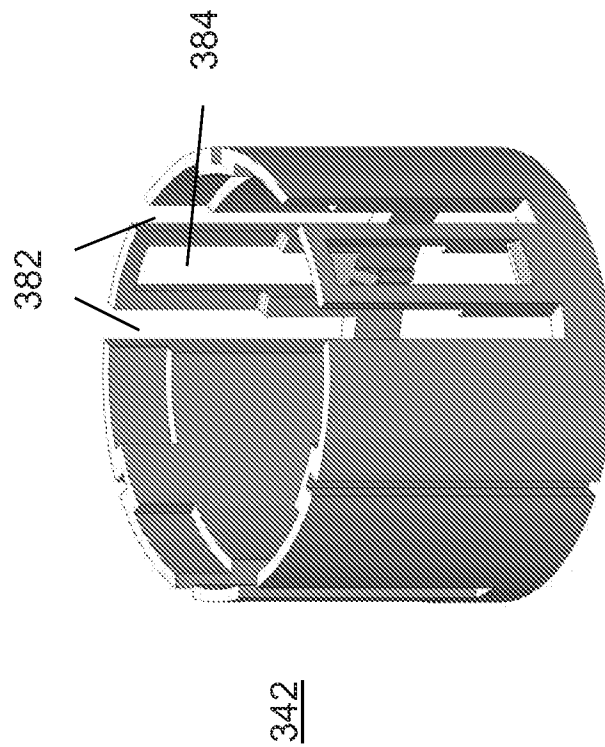


FIGURE 45

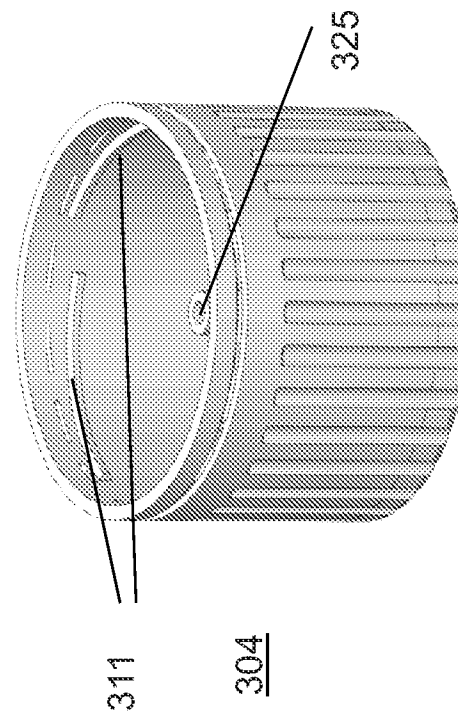
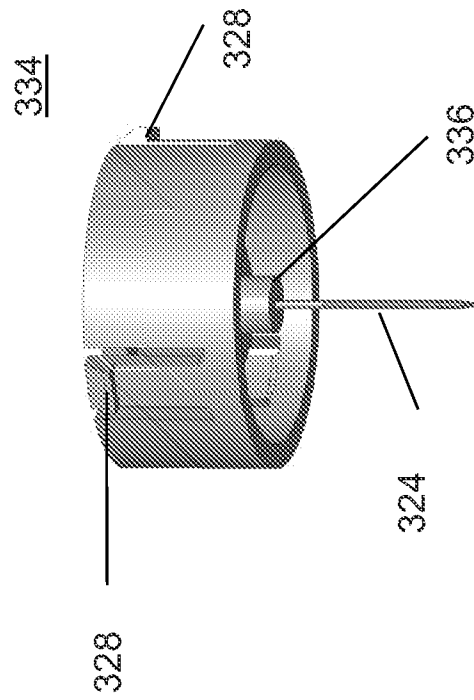
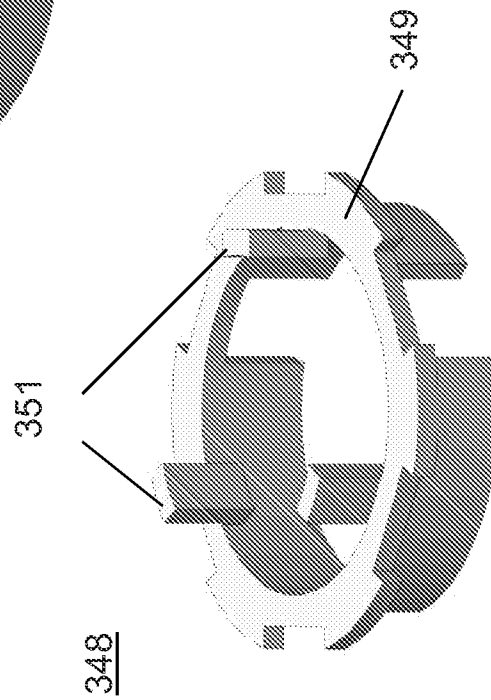
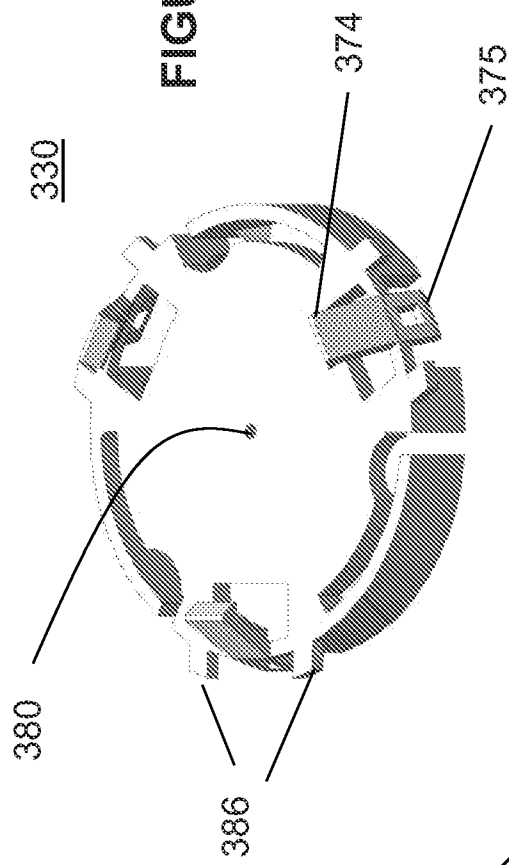


FIGURE 46



300

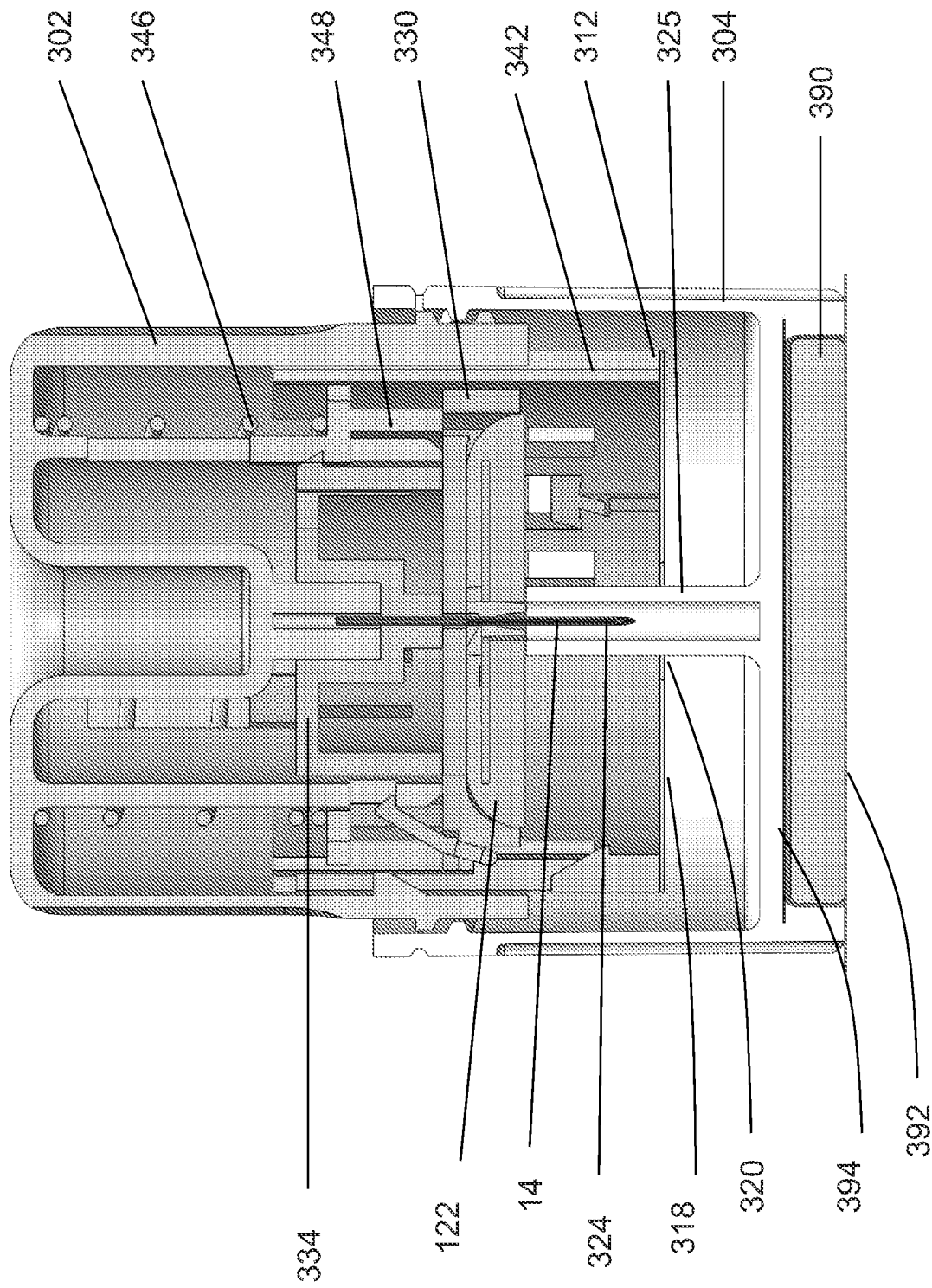


FIGURE 50

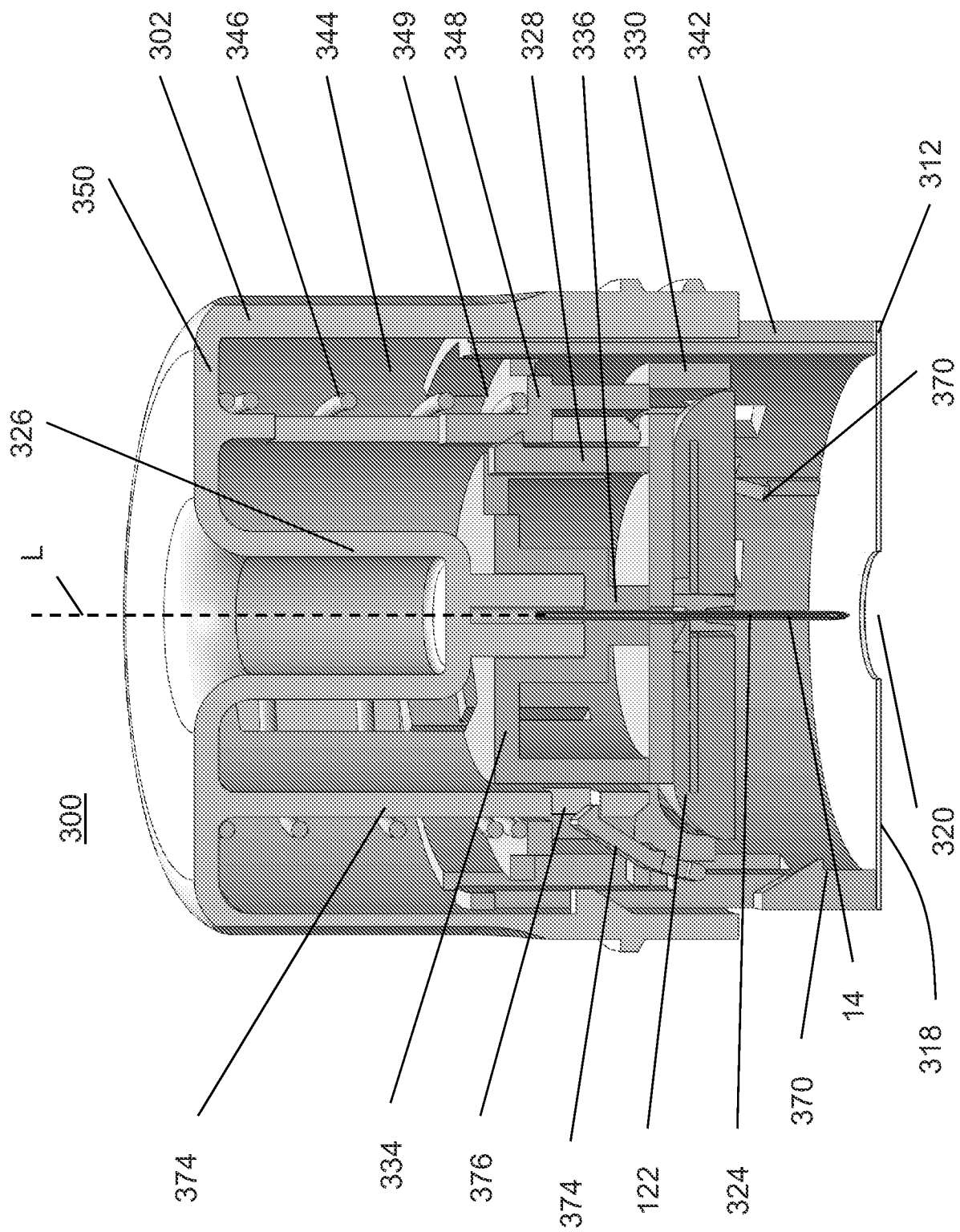


FIGURE 51

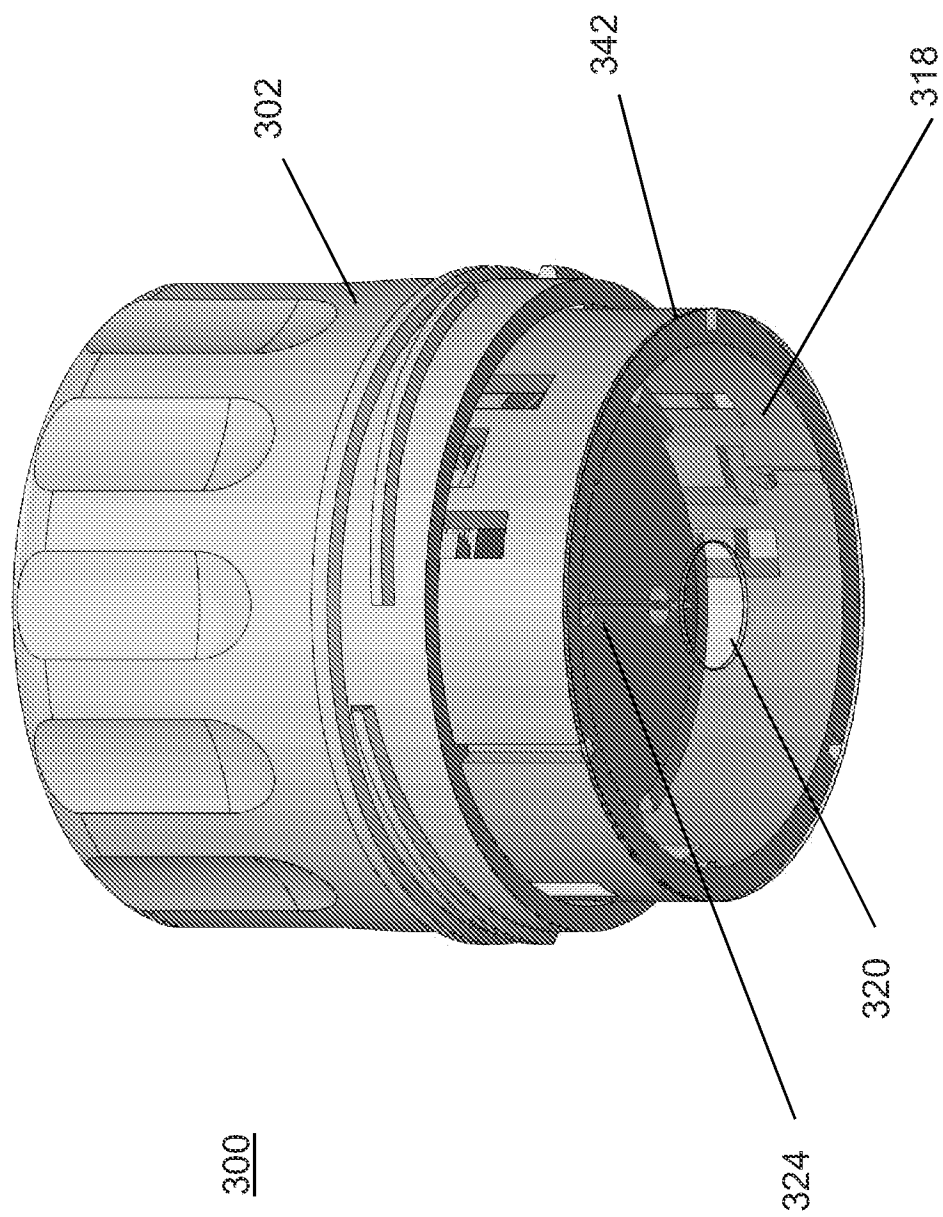


FIGURE 52

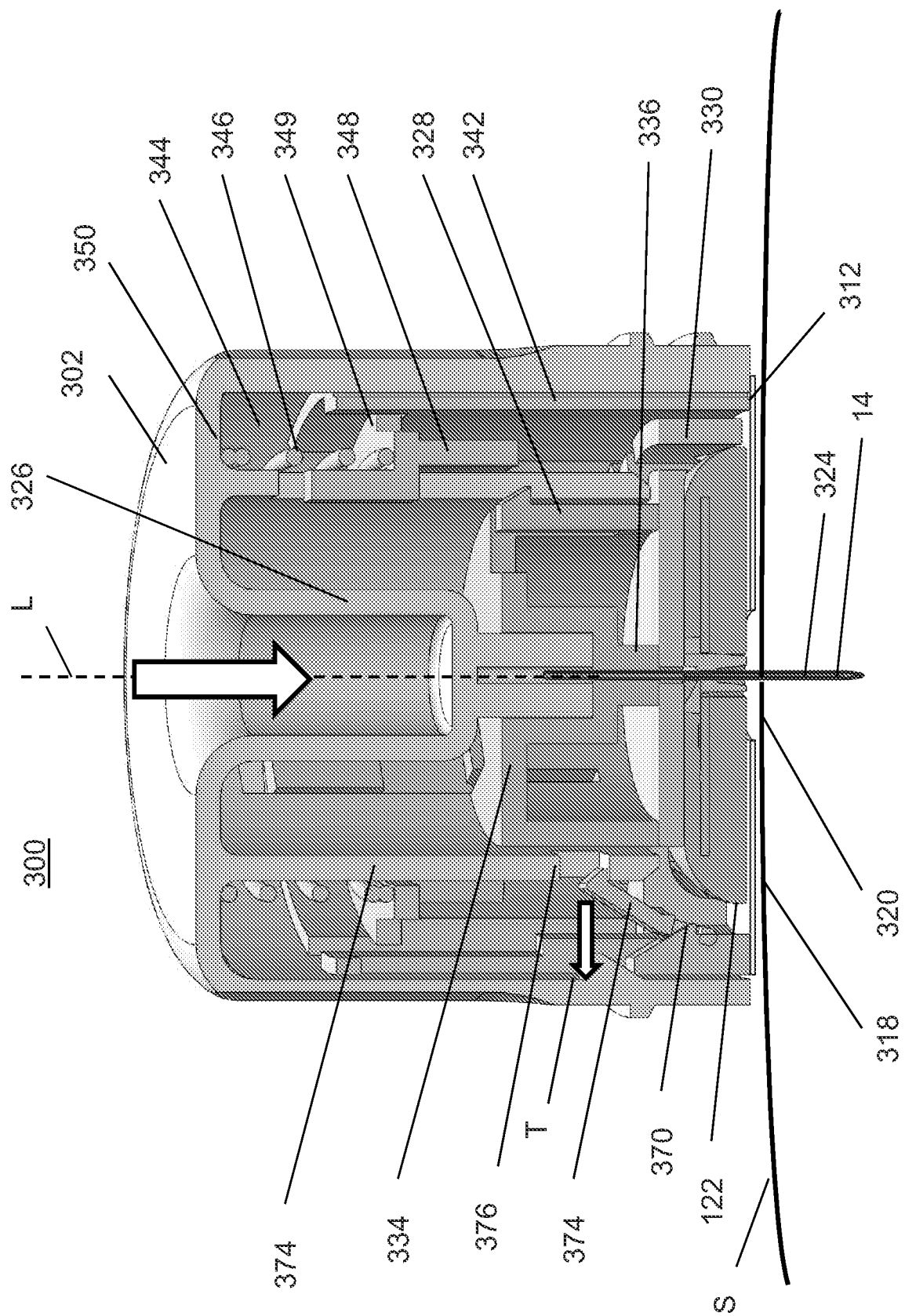


FIGURE 53

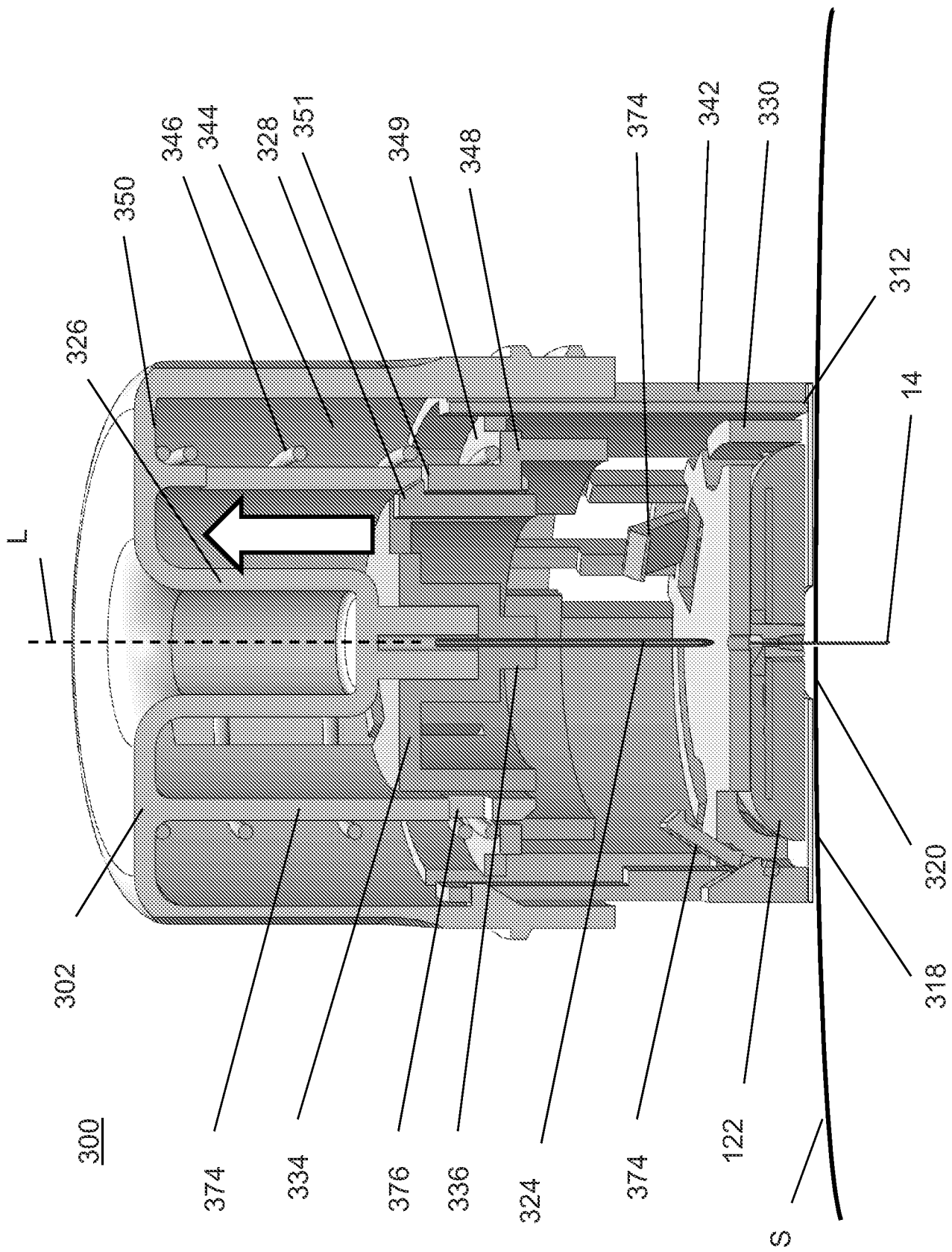
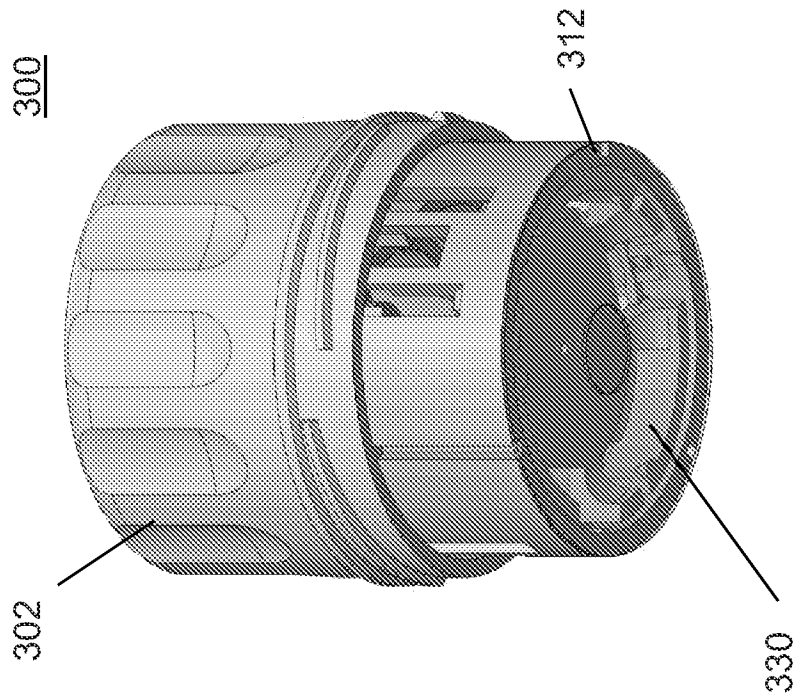
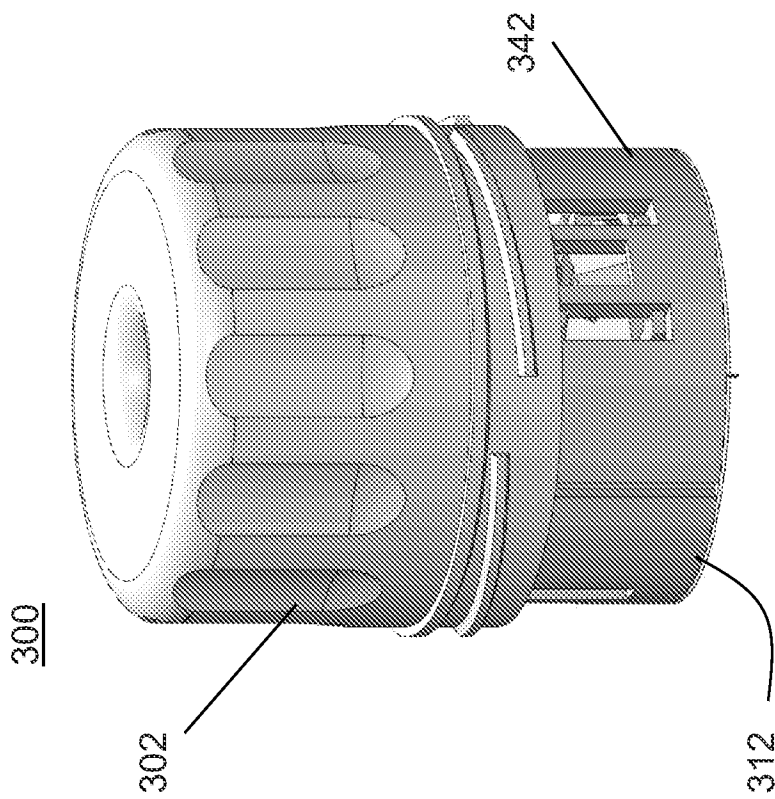


FIGURE 54



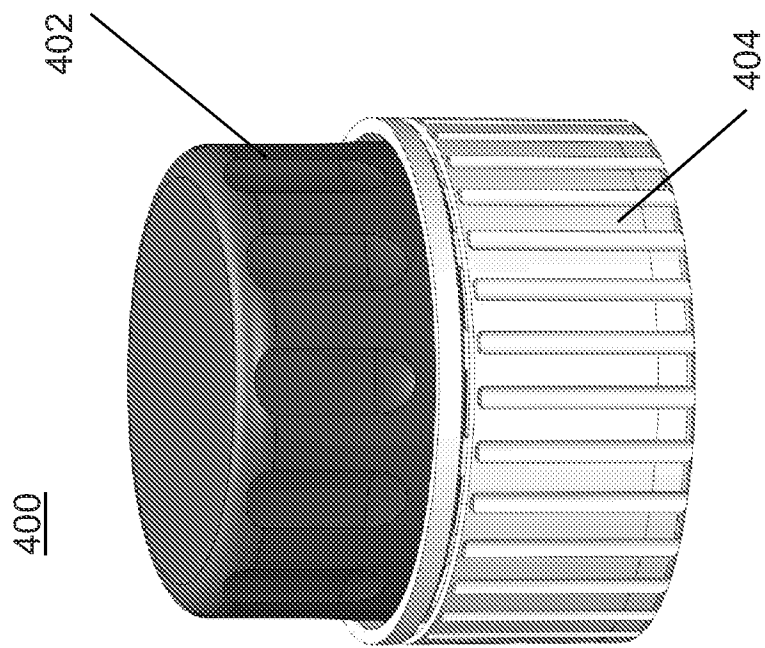


FIGURE 57

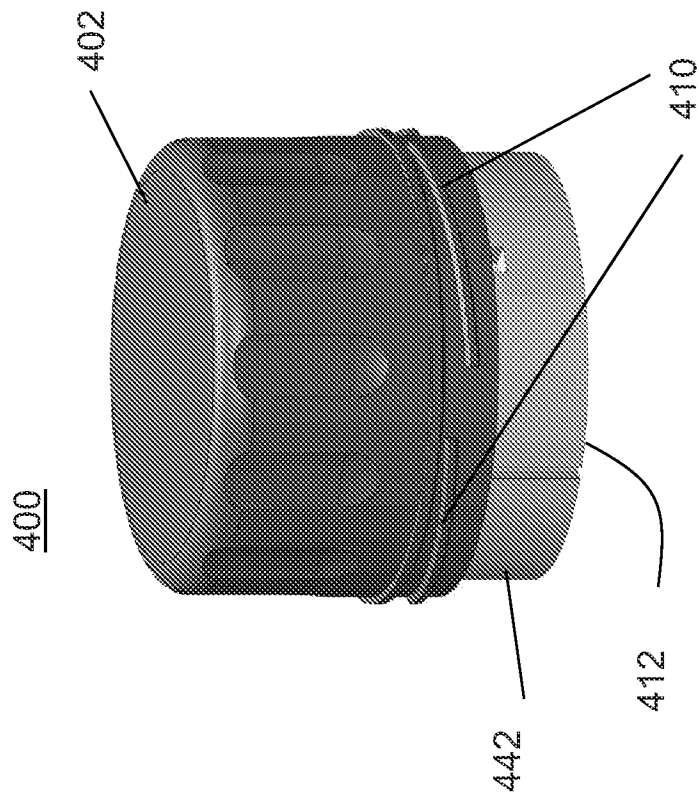


FIGURE 58

402

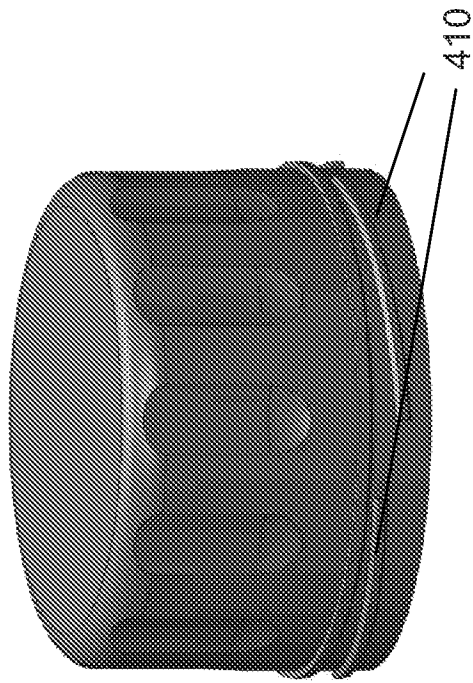


FIGURE 59

496

442

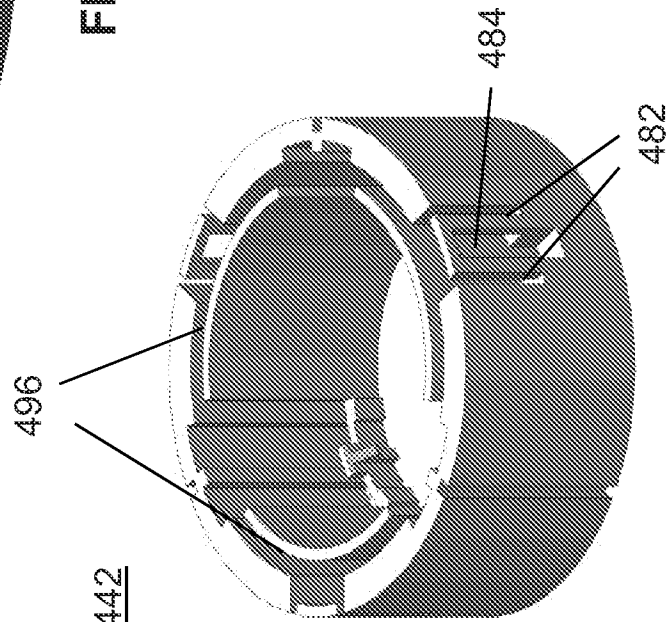


FIGURE 60

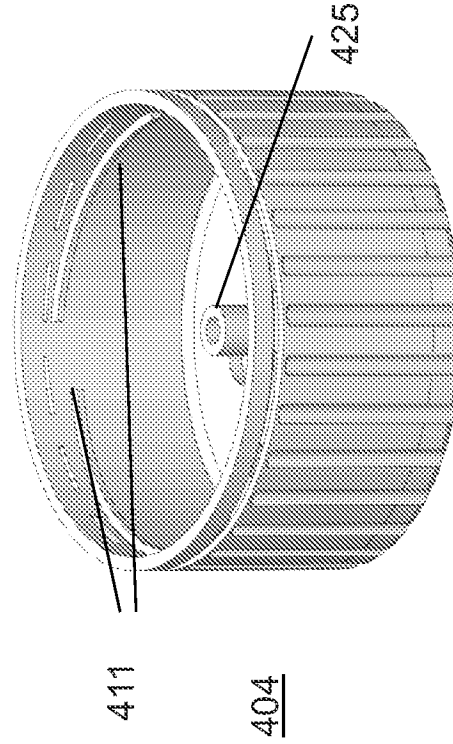


FIGURE 61

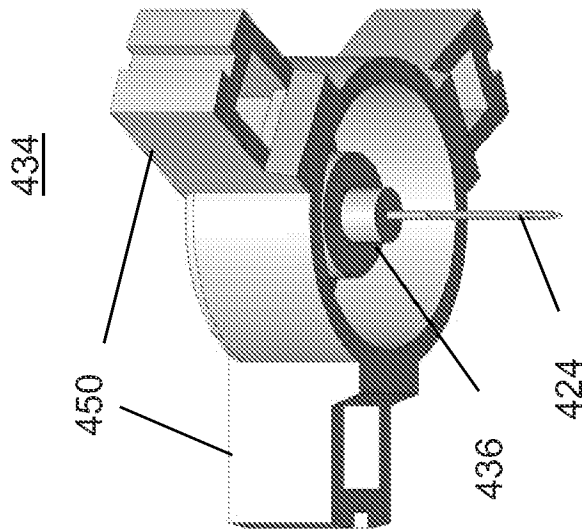


FIGURE 63

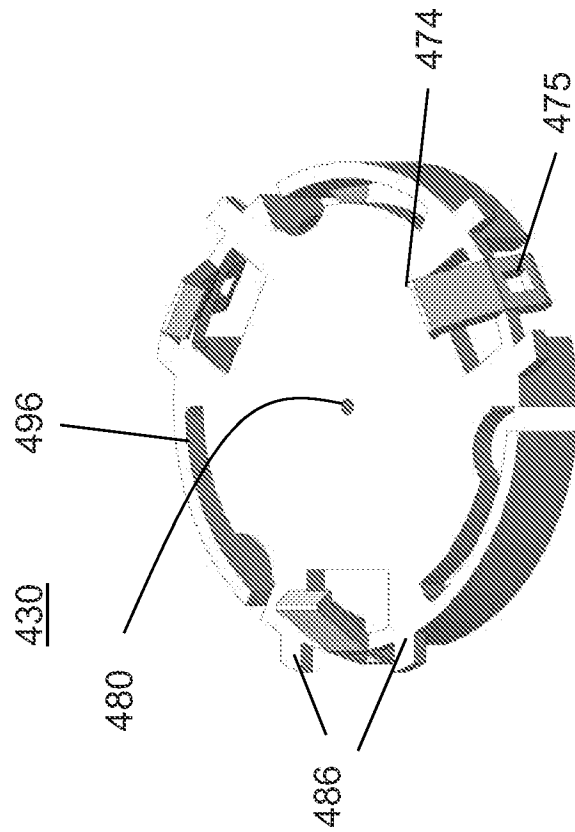


FIGURE 62

400

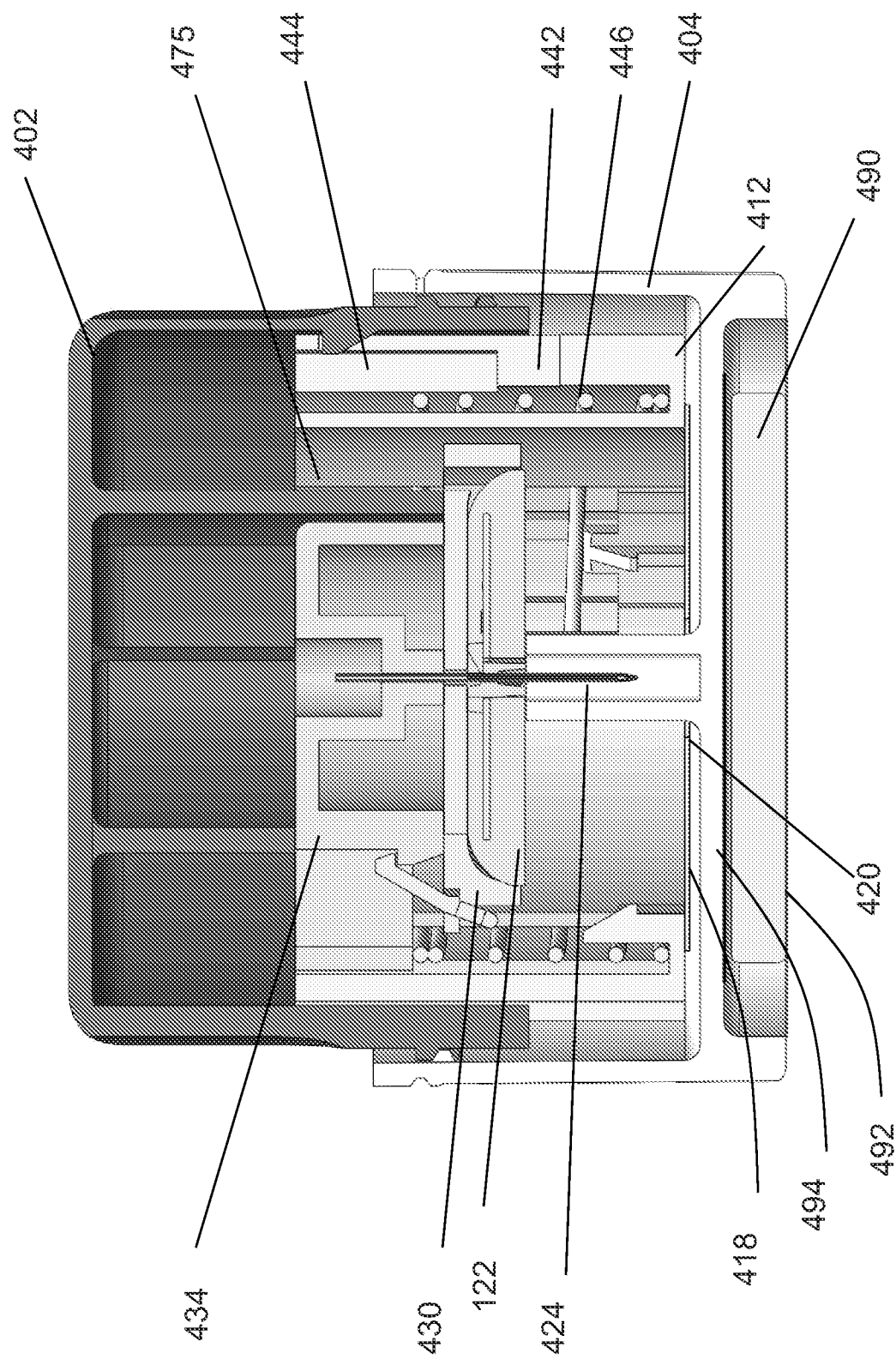


FIGURE 64

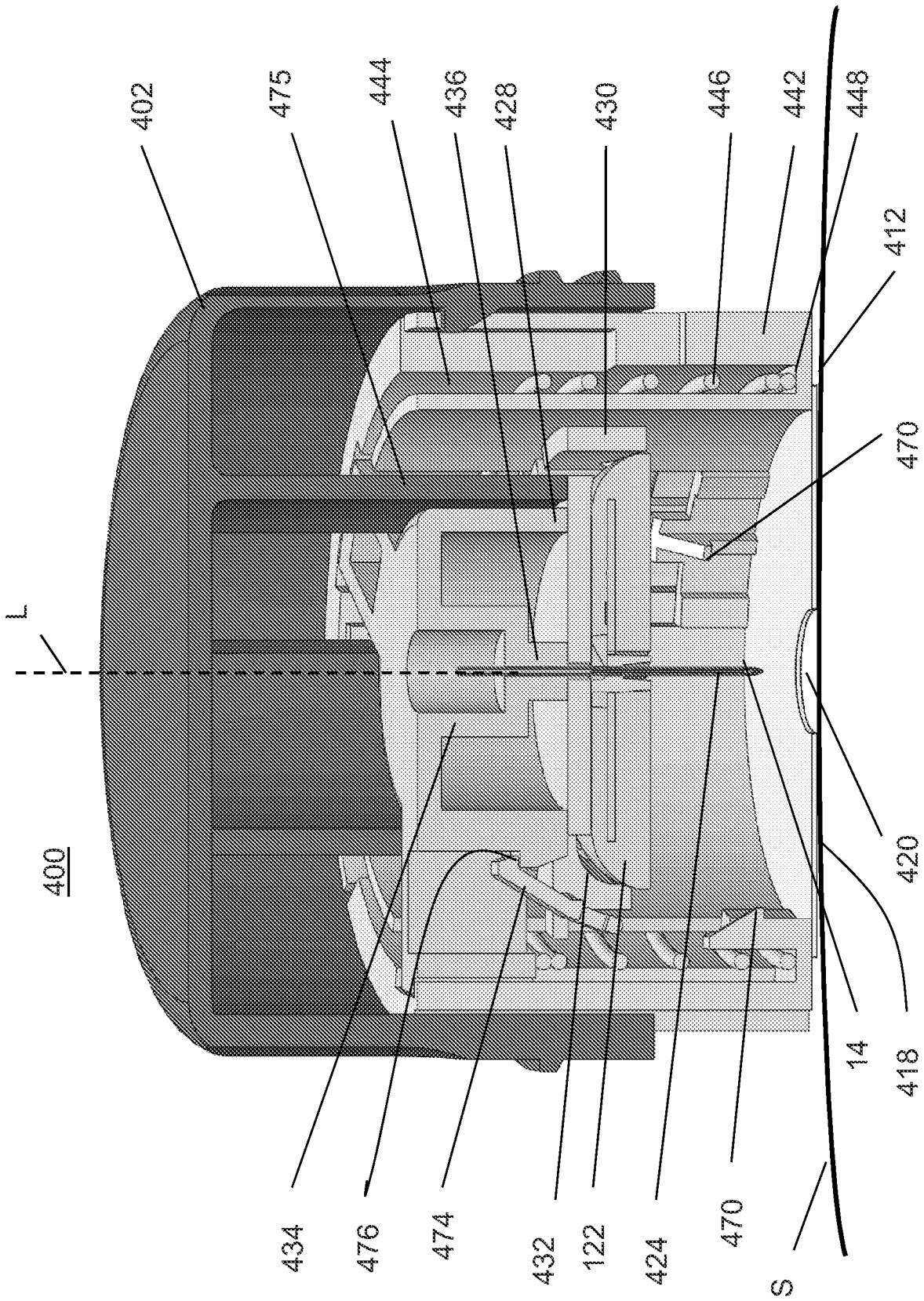


FIGURE 65

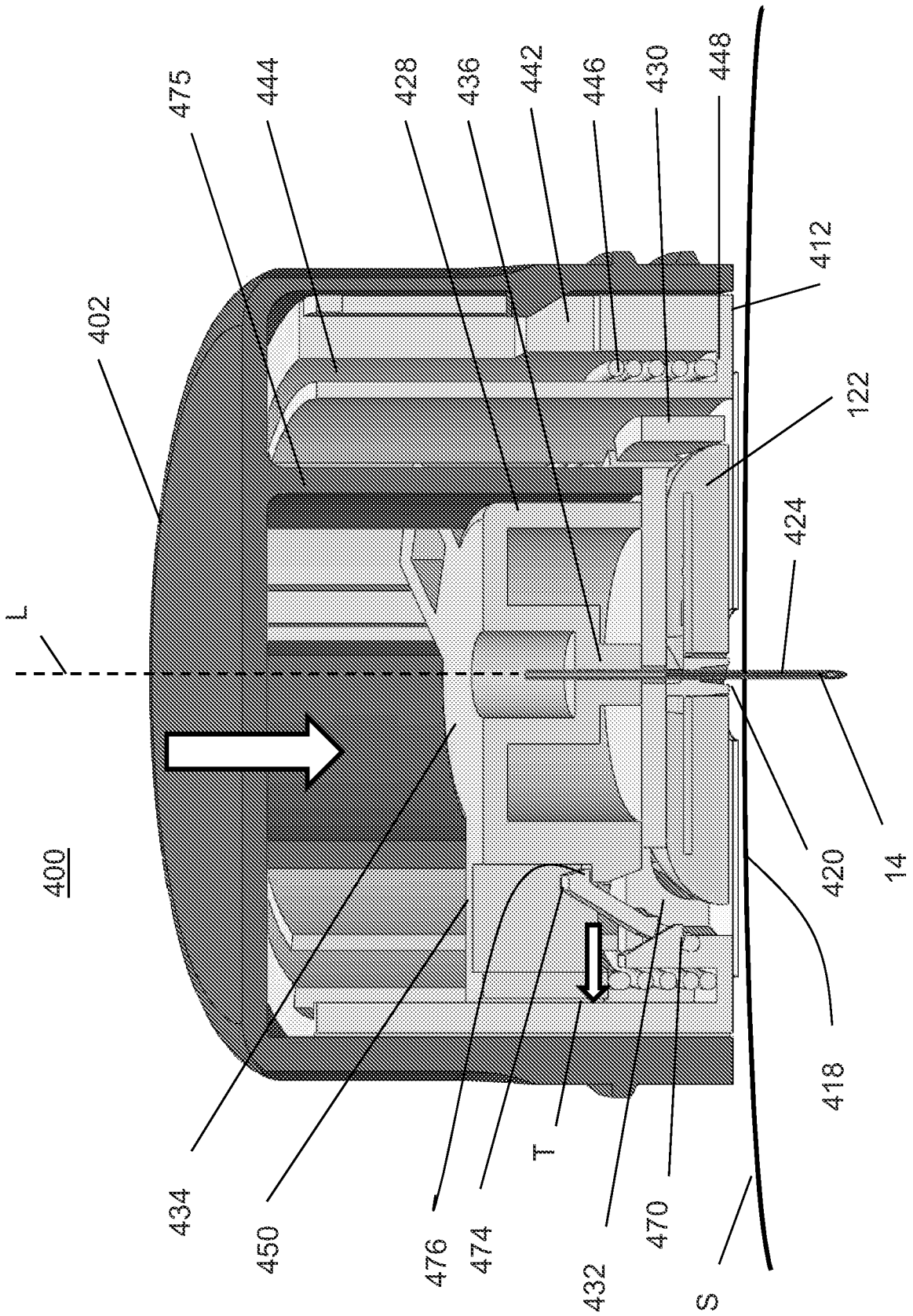


FIGURE 66

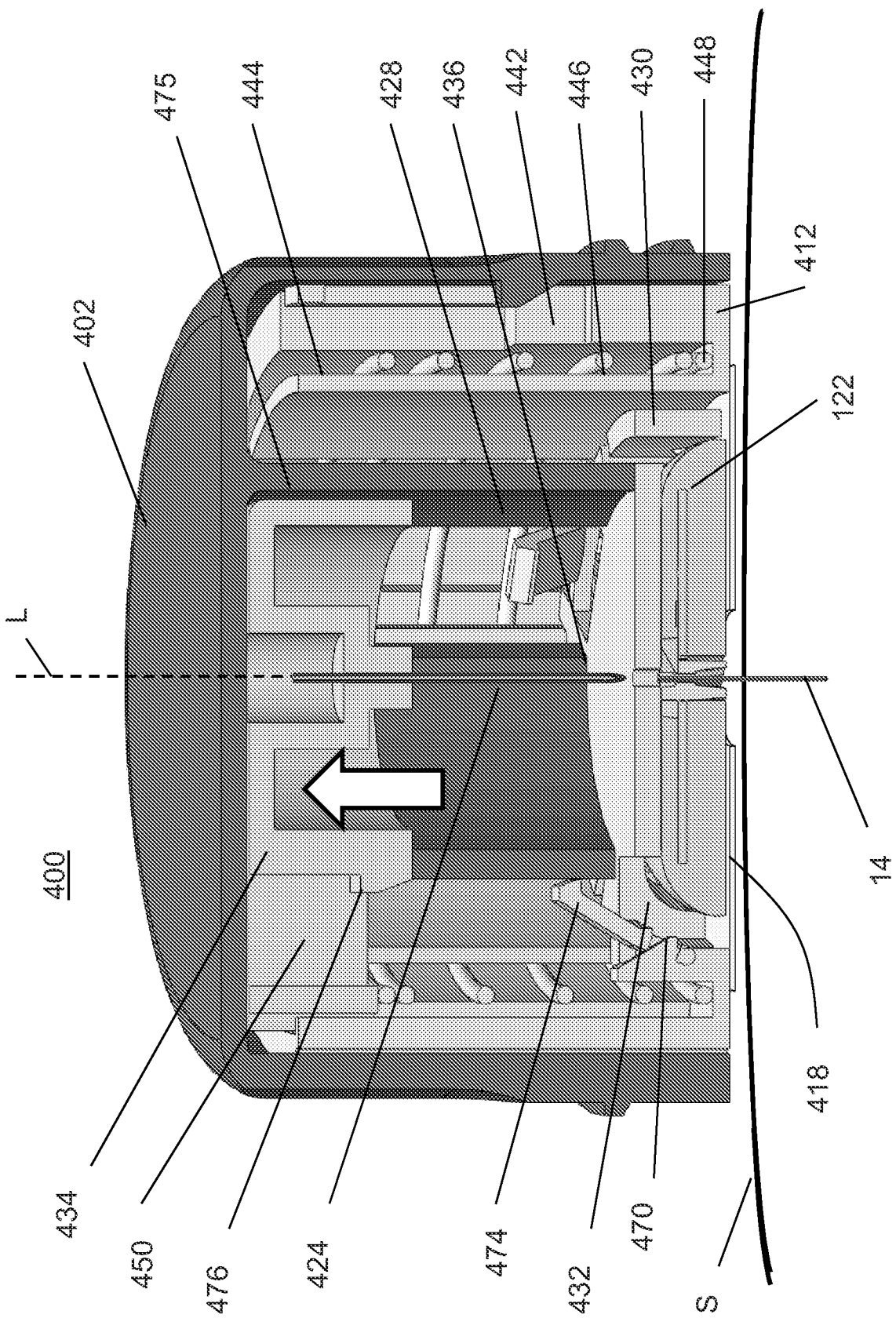


FIGURE 67

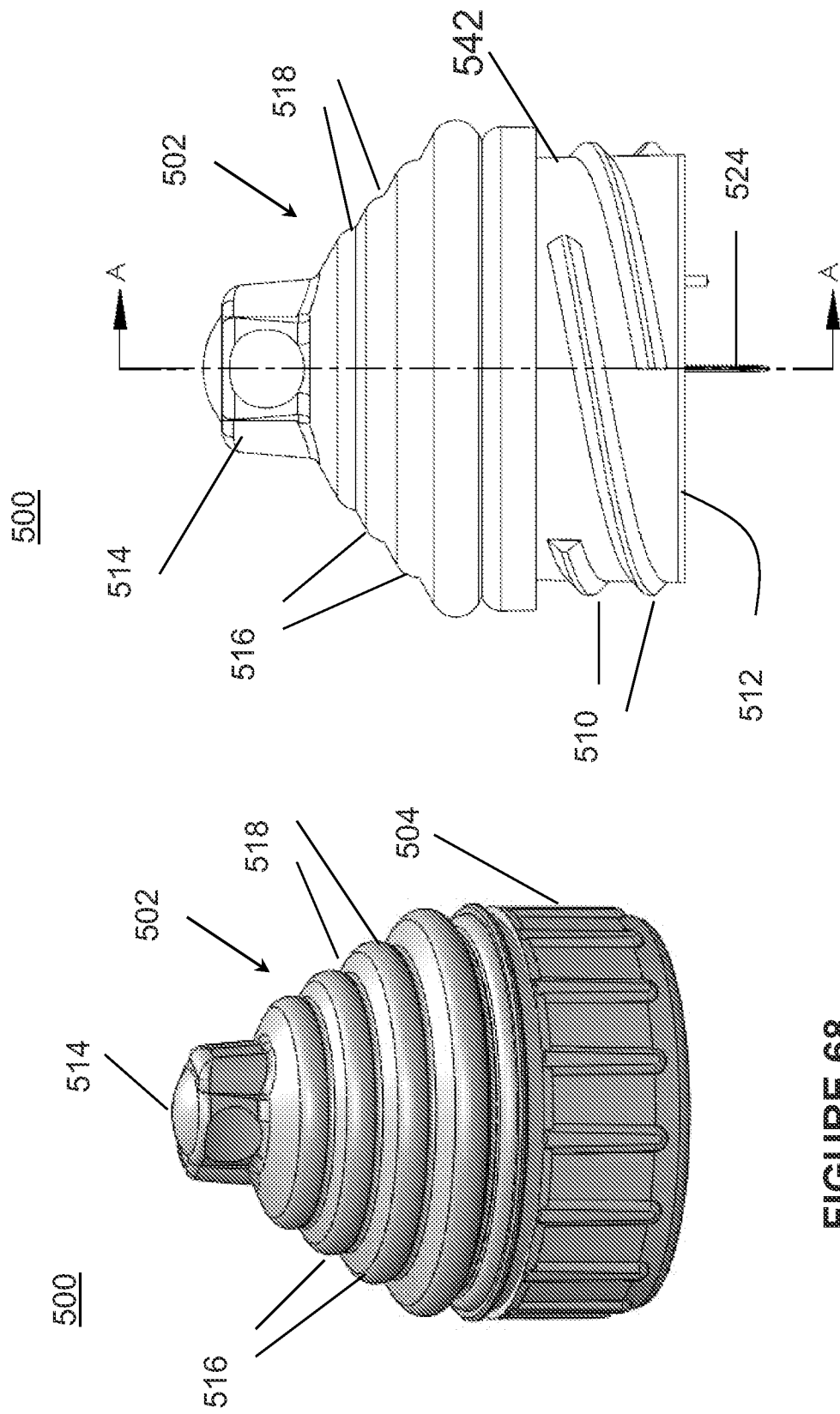


FIGURE 69

FIGURE 68

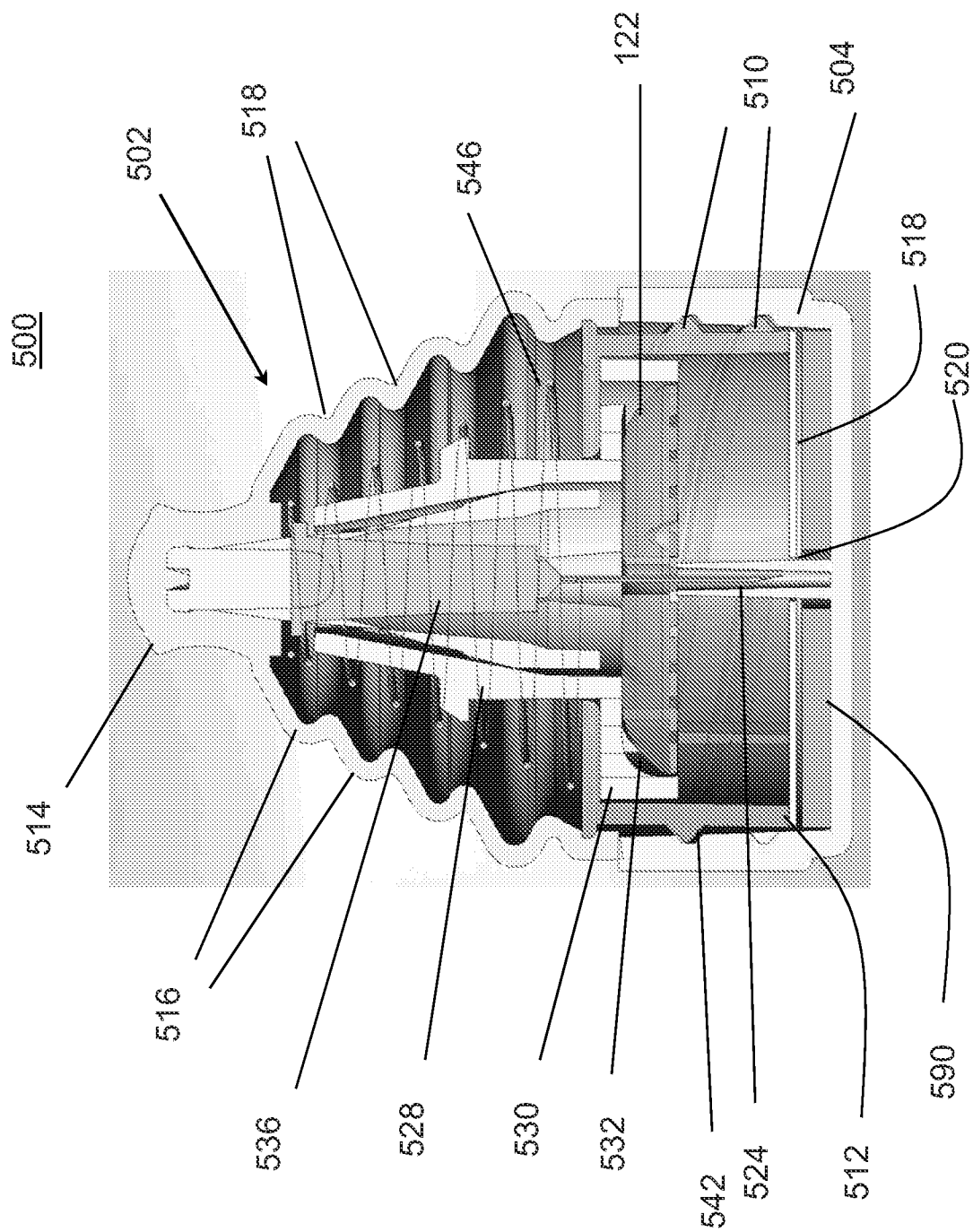


FIGURE 70

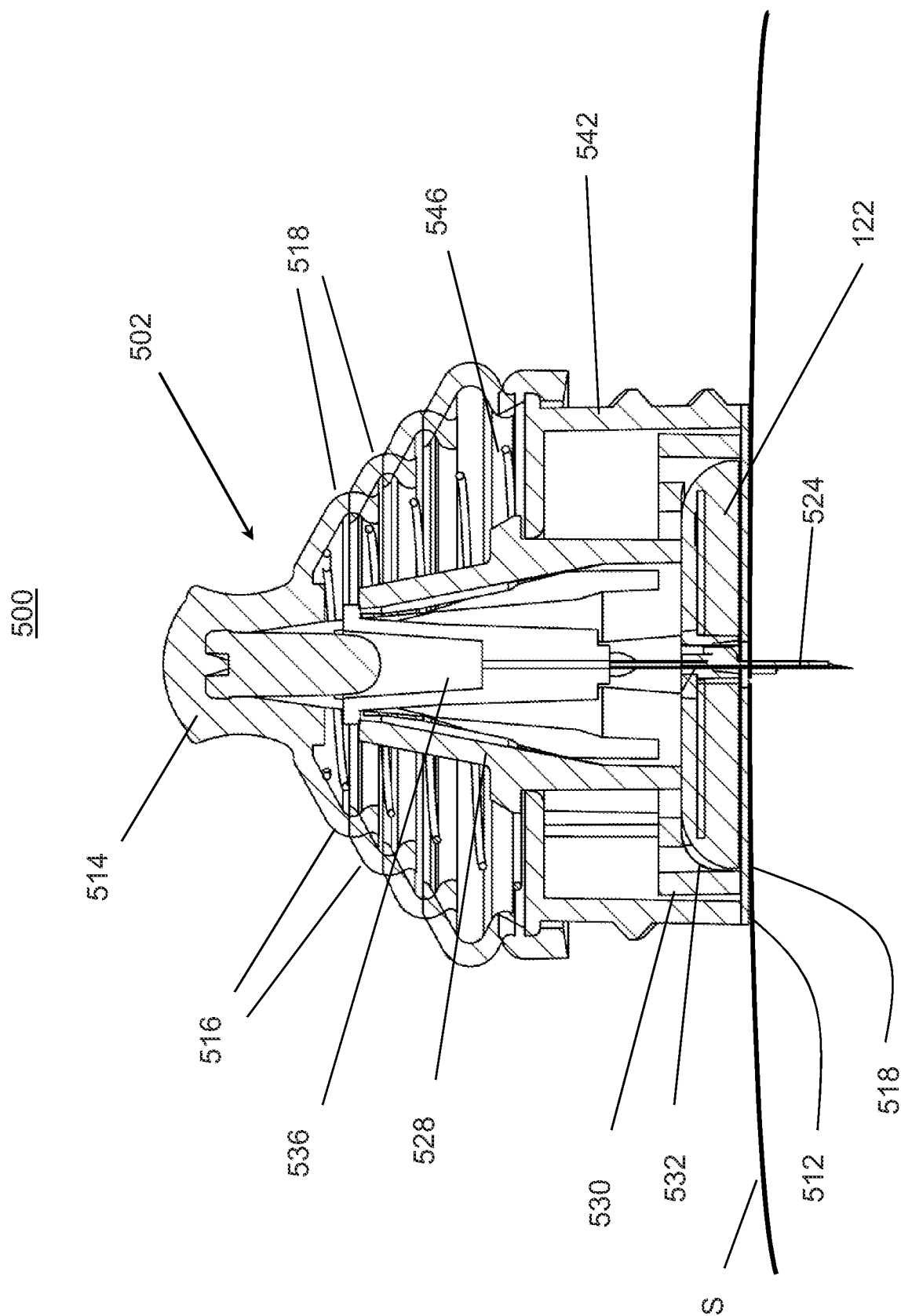


FIGURE 71

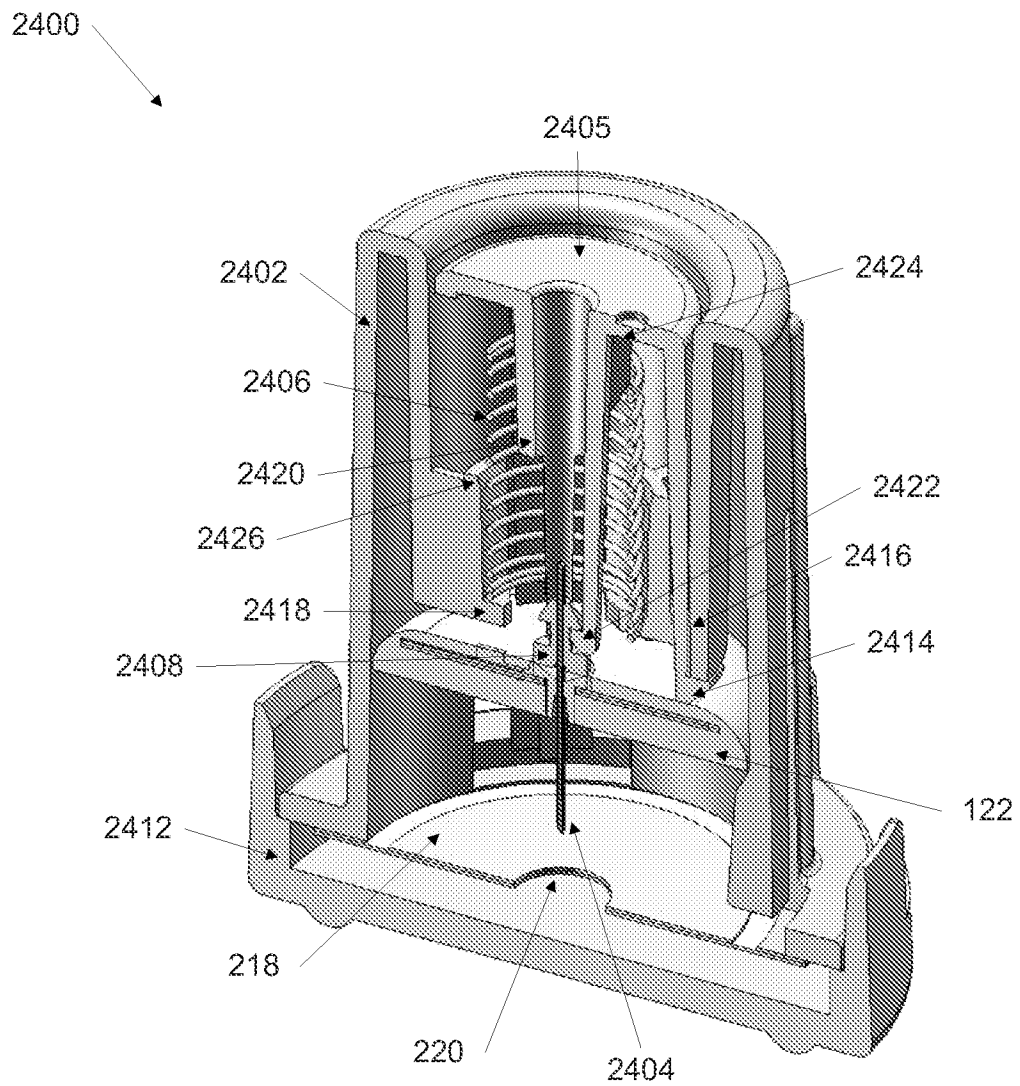


FIG. 72

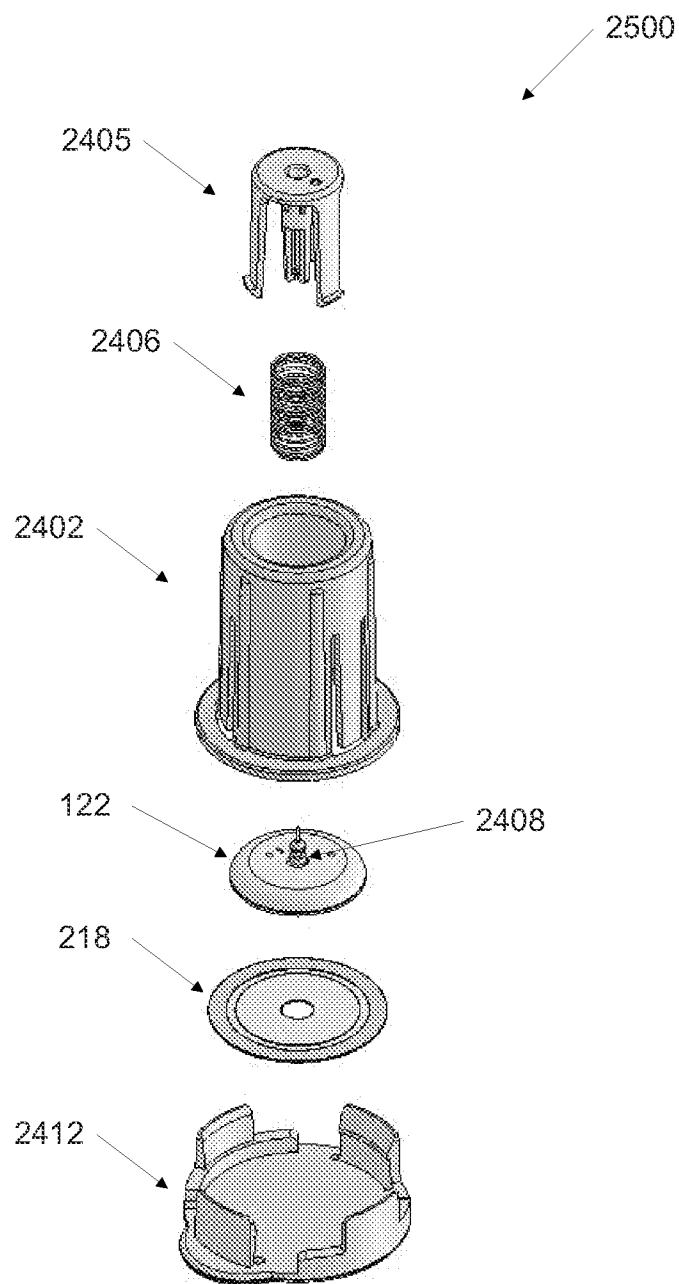


FIG. 72A

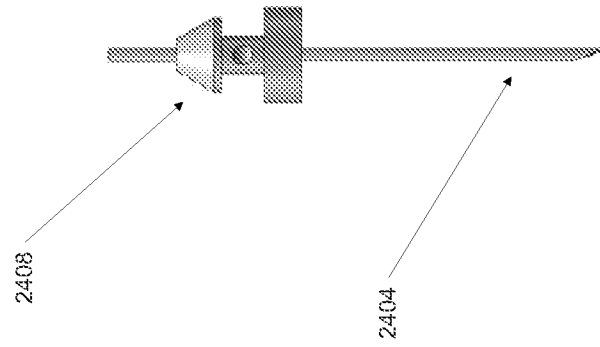


FIG. 72B

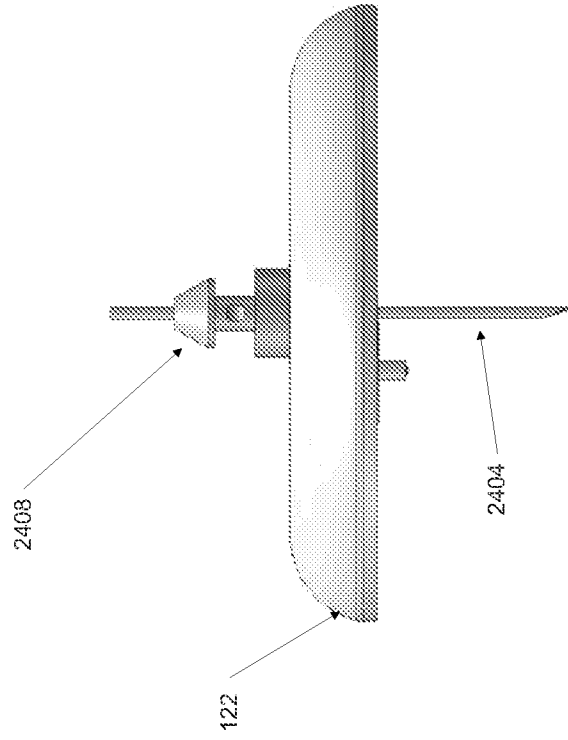


FIG. 72C

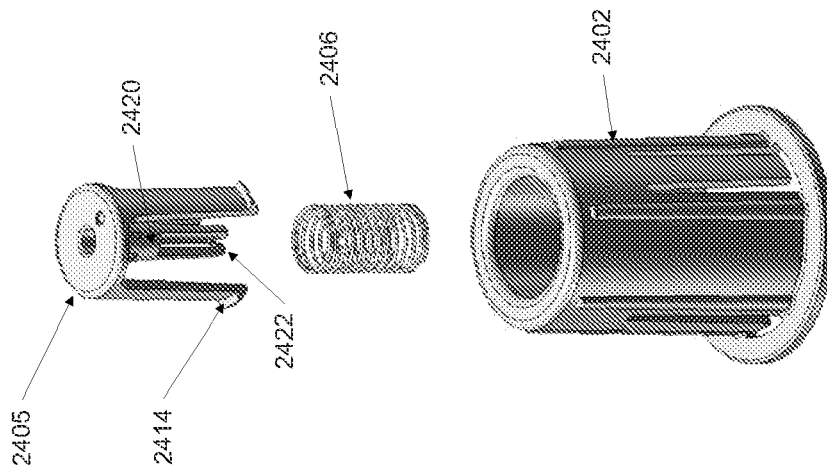


FIG. 72D

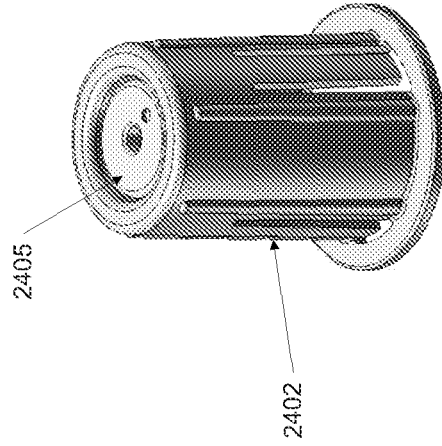


FIG. 72E

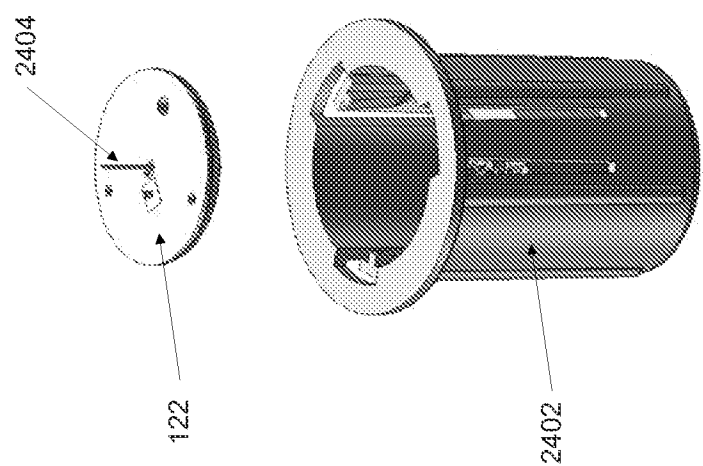


FIG. 72F

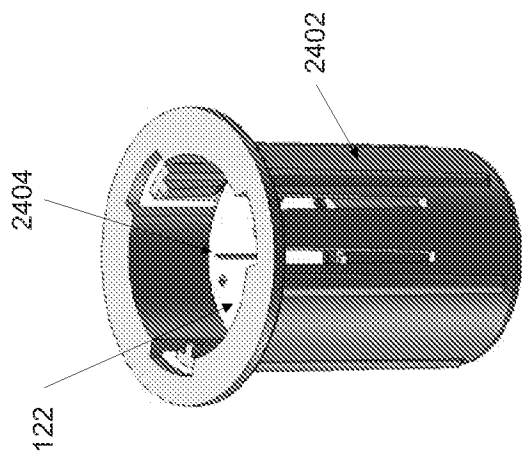


FIG. 72G

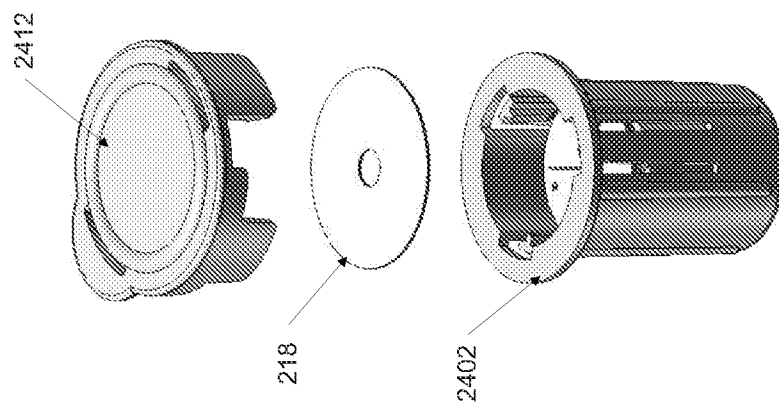


FIG. 72H

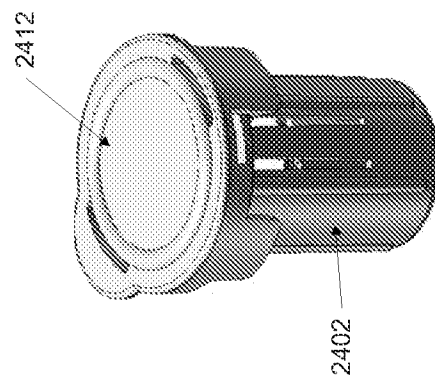


FIG. 72I

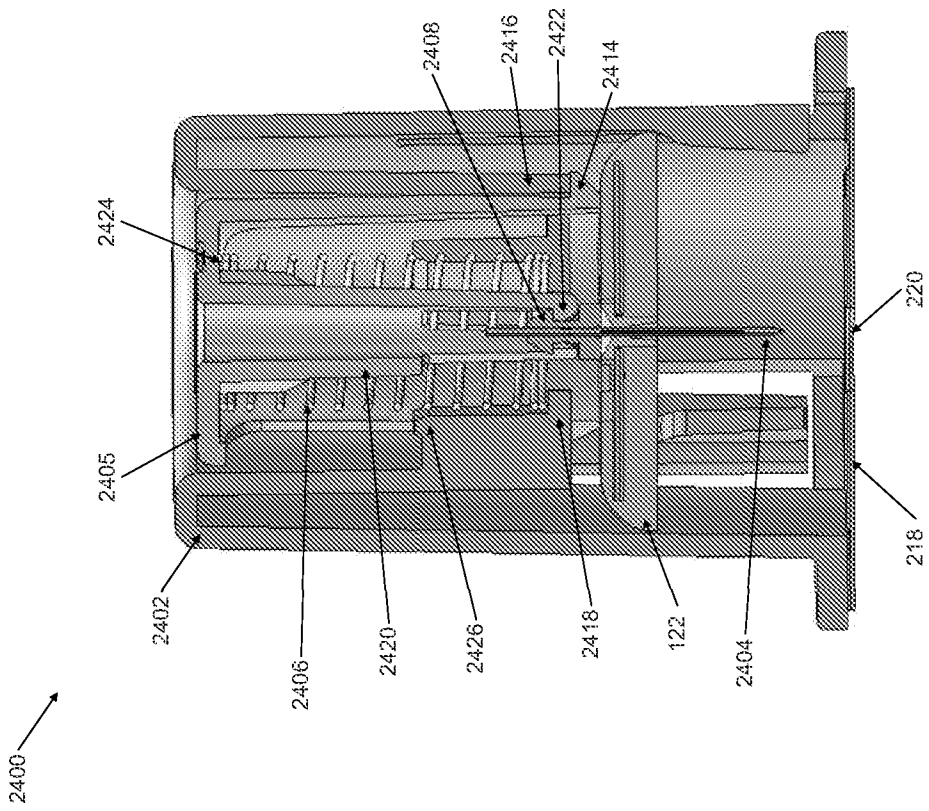


FIG. 72J

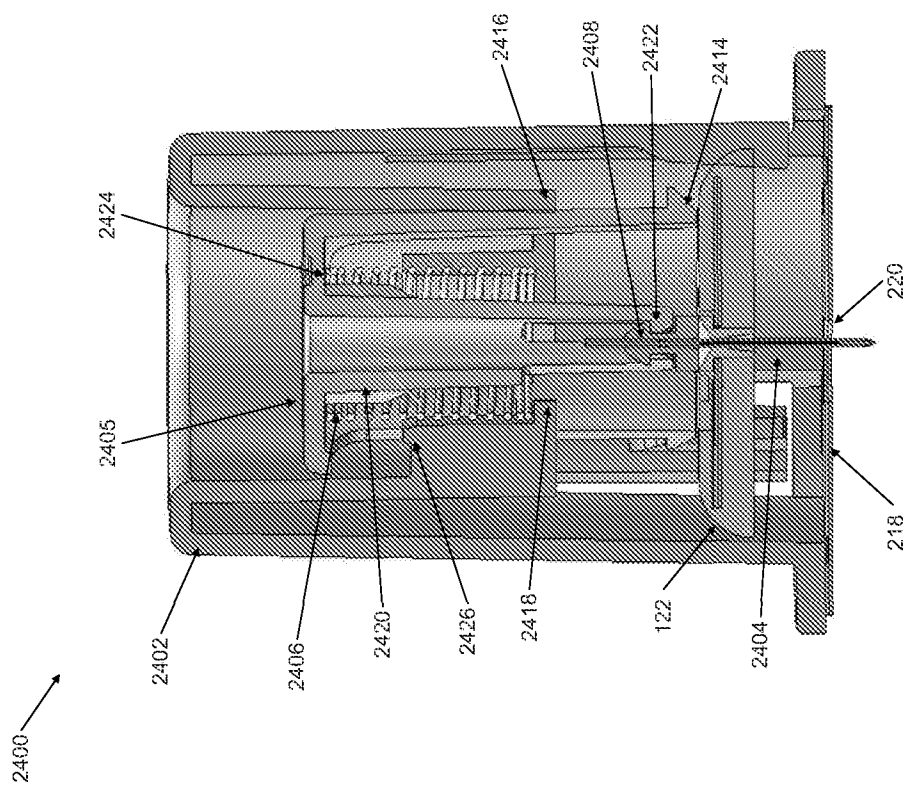


FIG. 72K

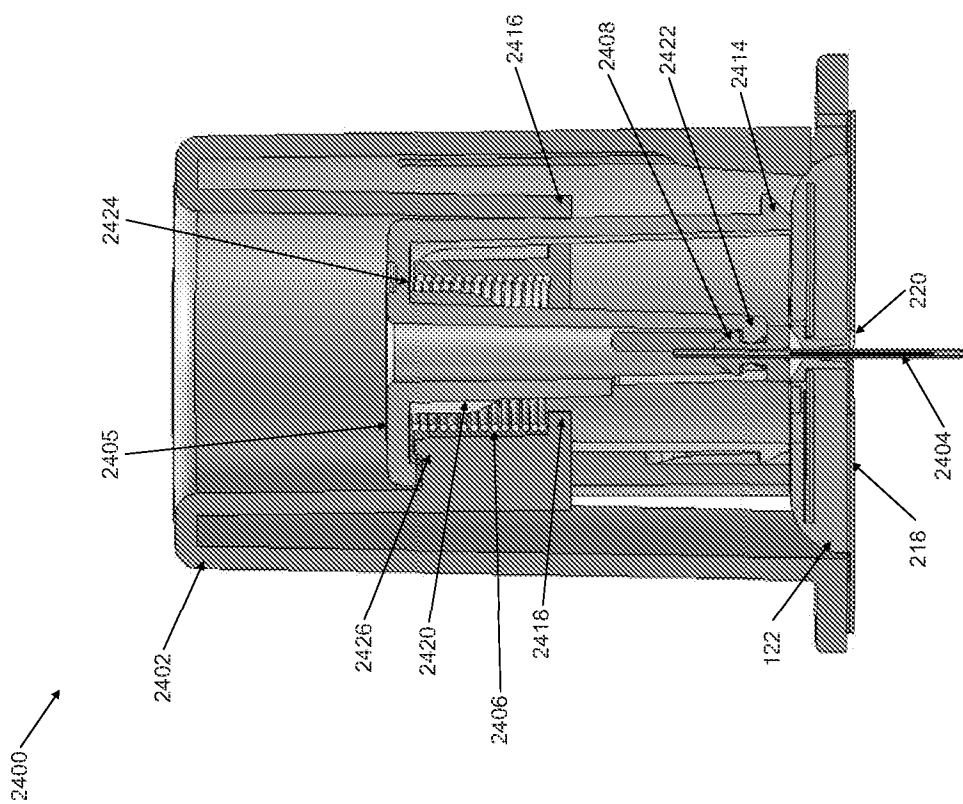


FIG. 72L

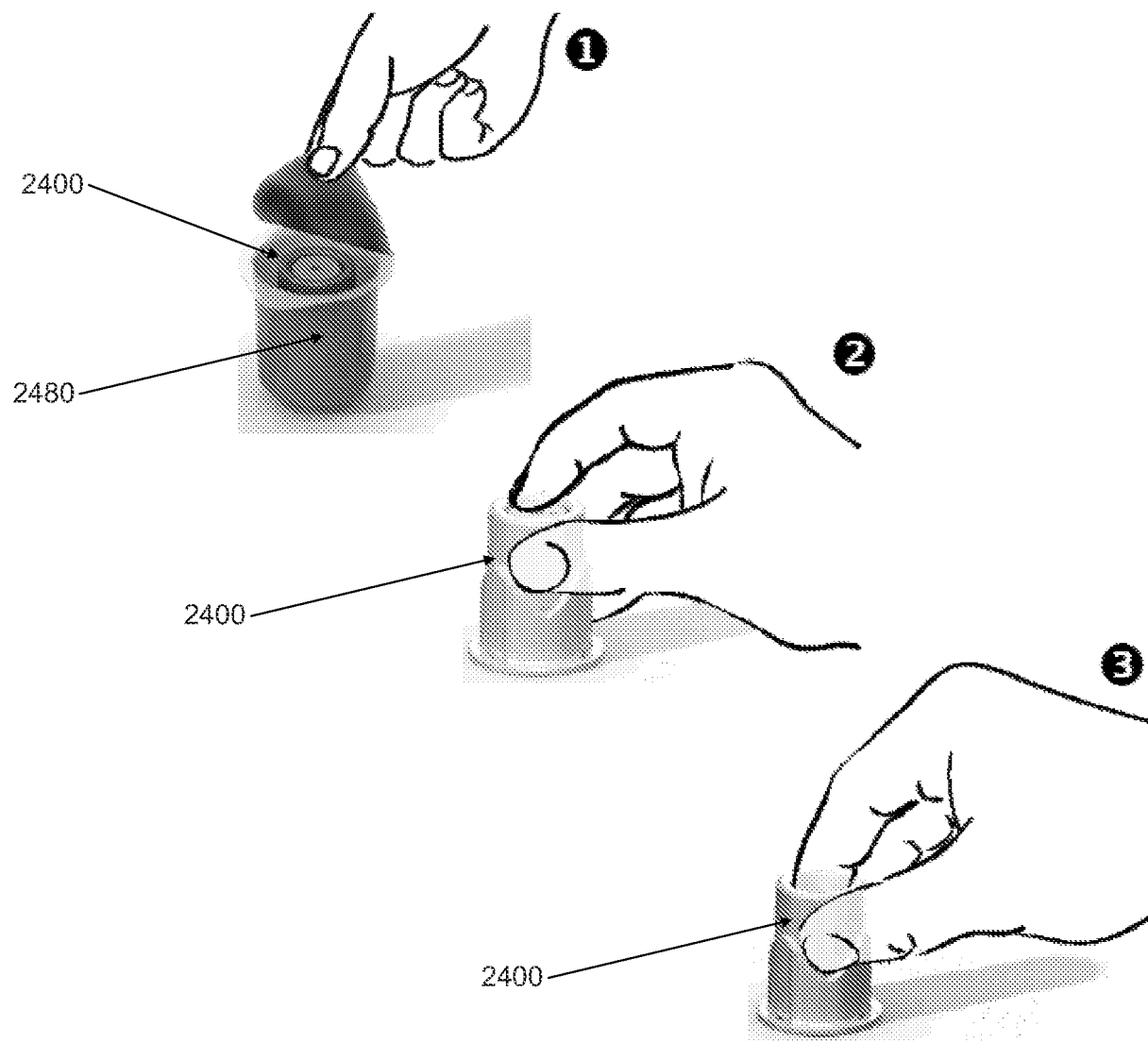


FIG. 720

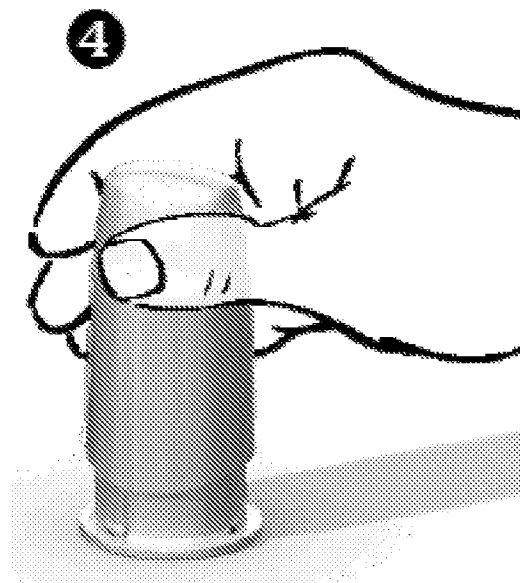
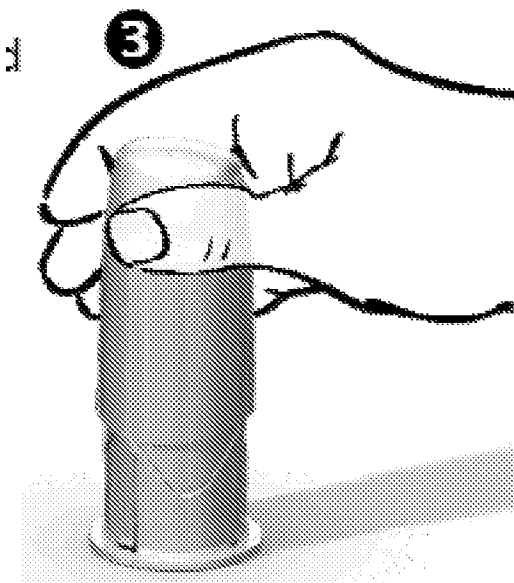
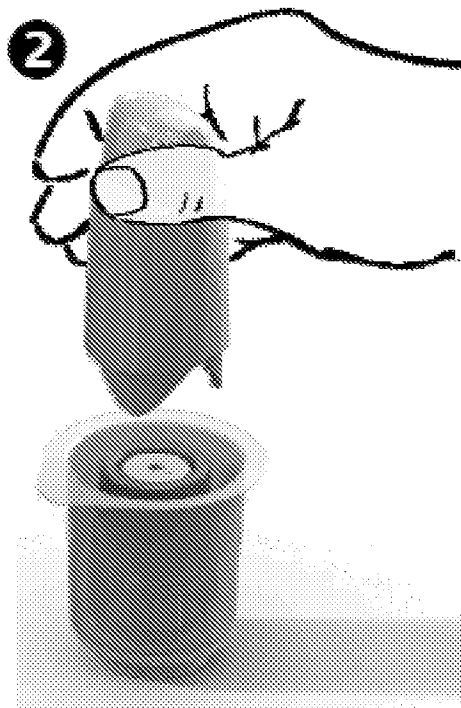
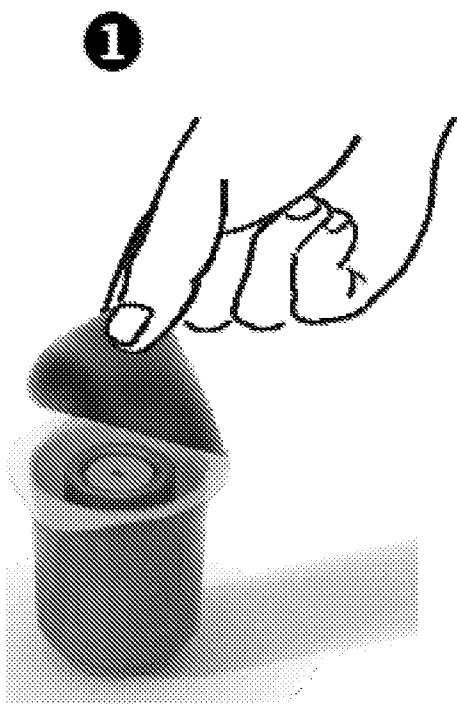


FIG. 72P

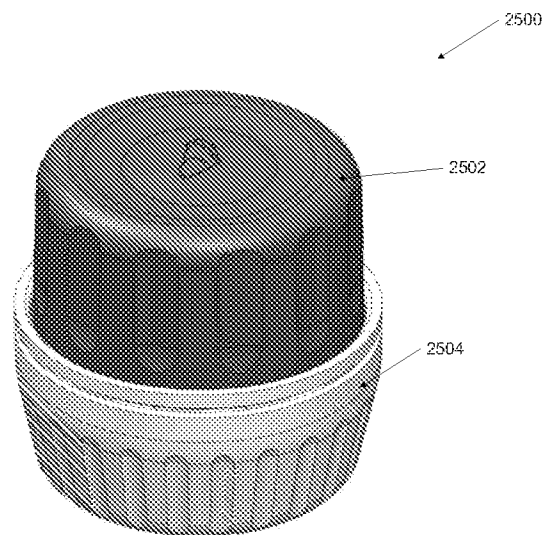


FIG. 73

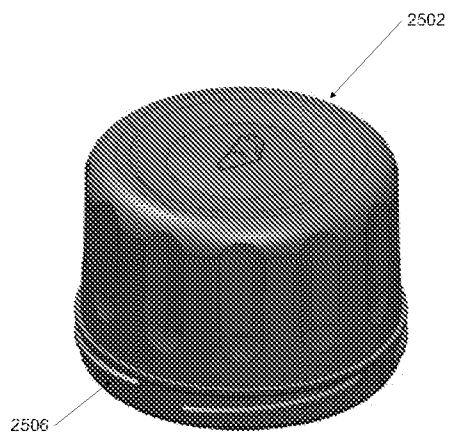


FIG. 73A

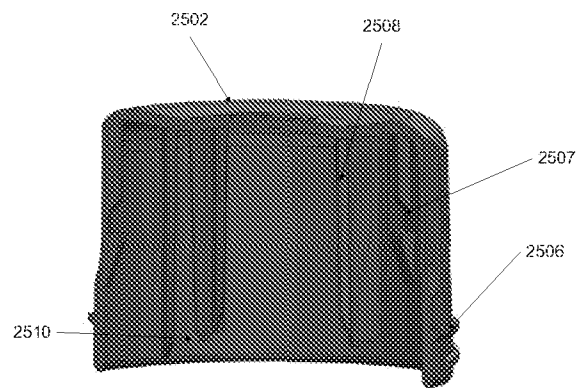
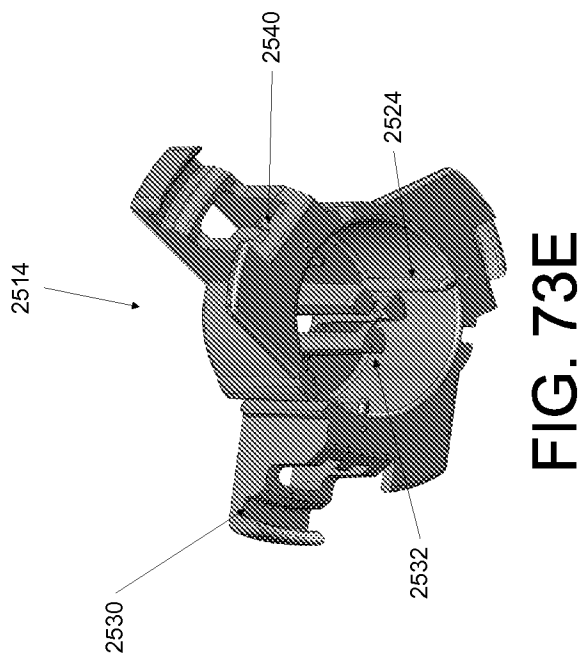
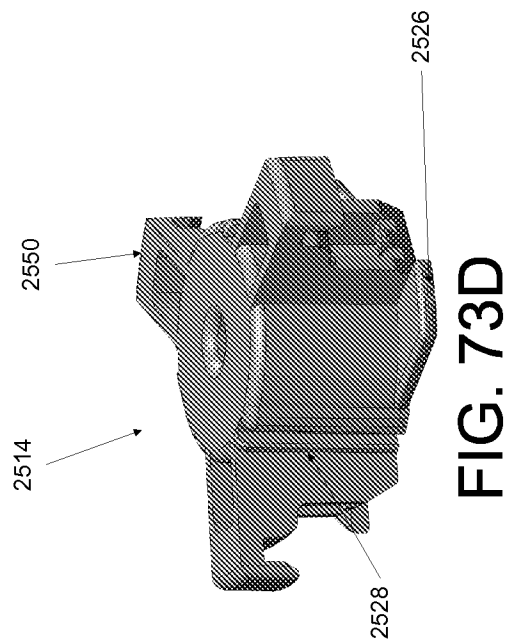
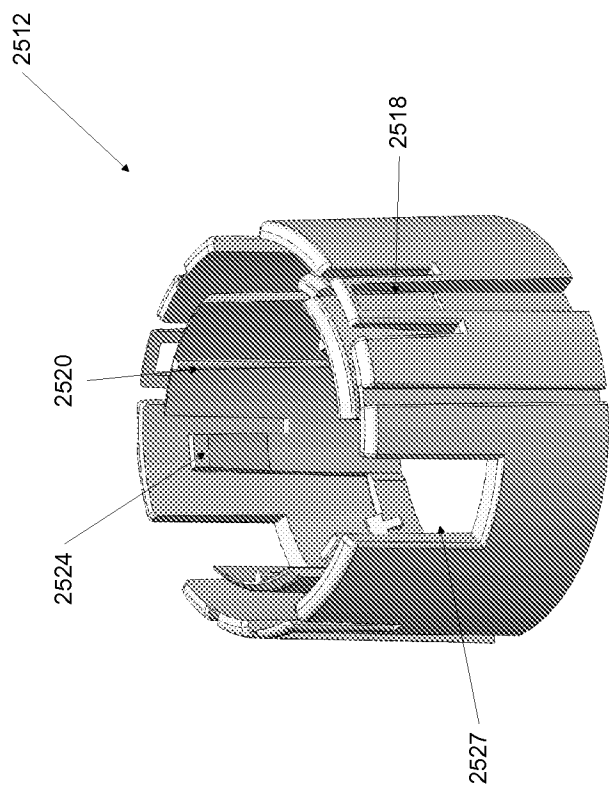
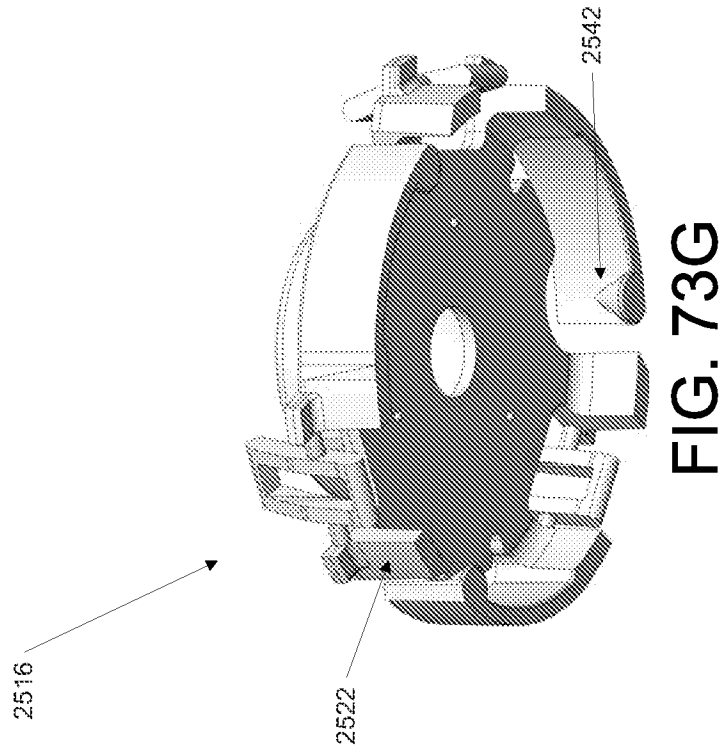
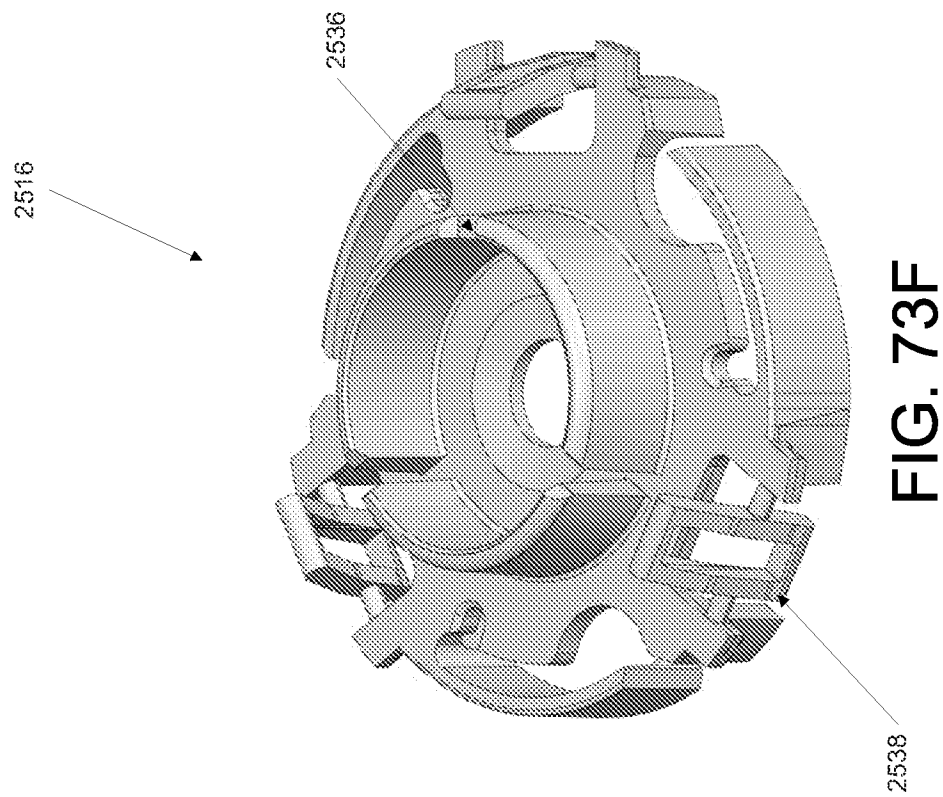


FIG. 73B







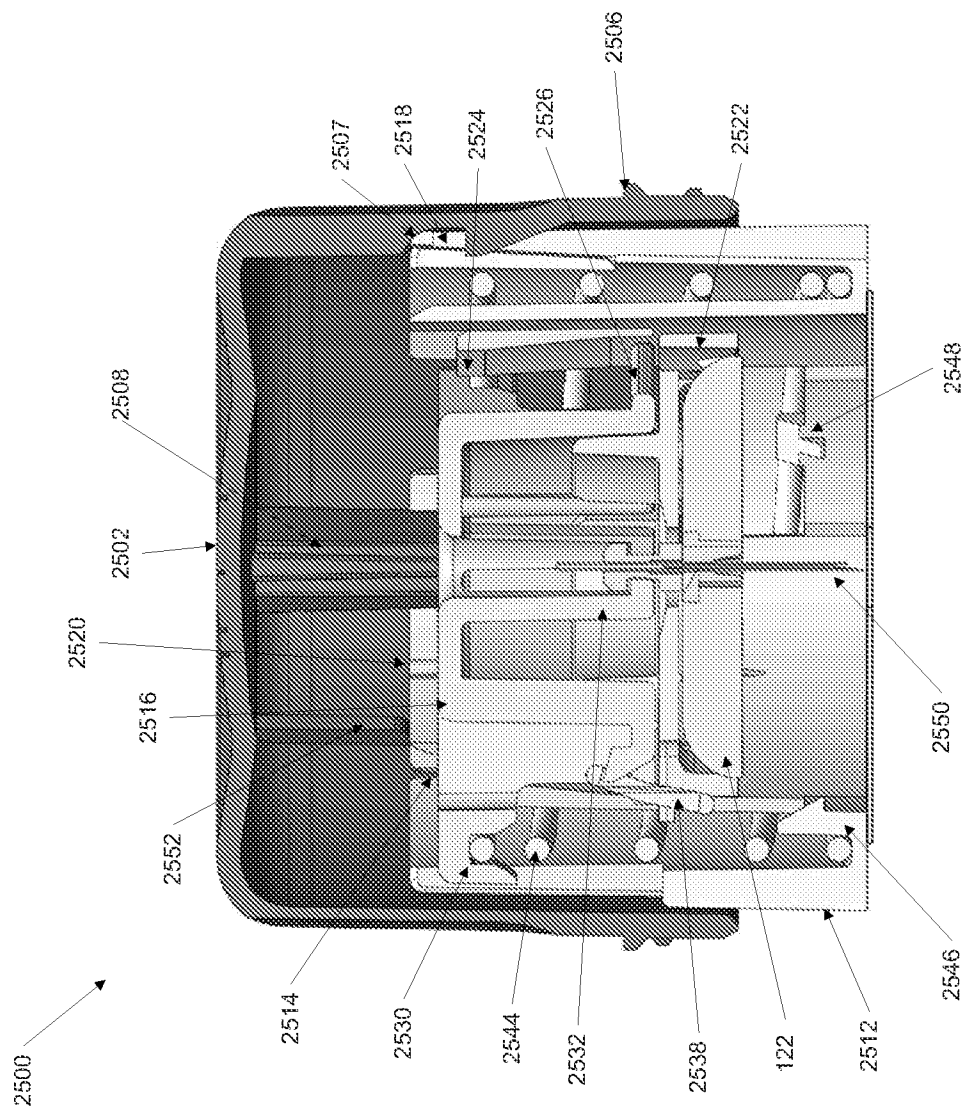


FIG. 73I

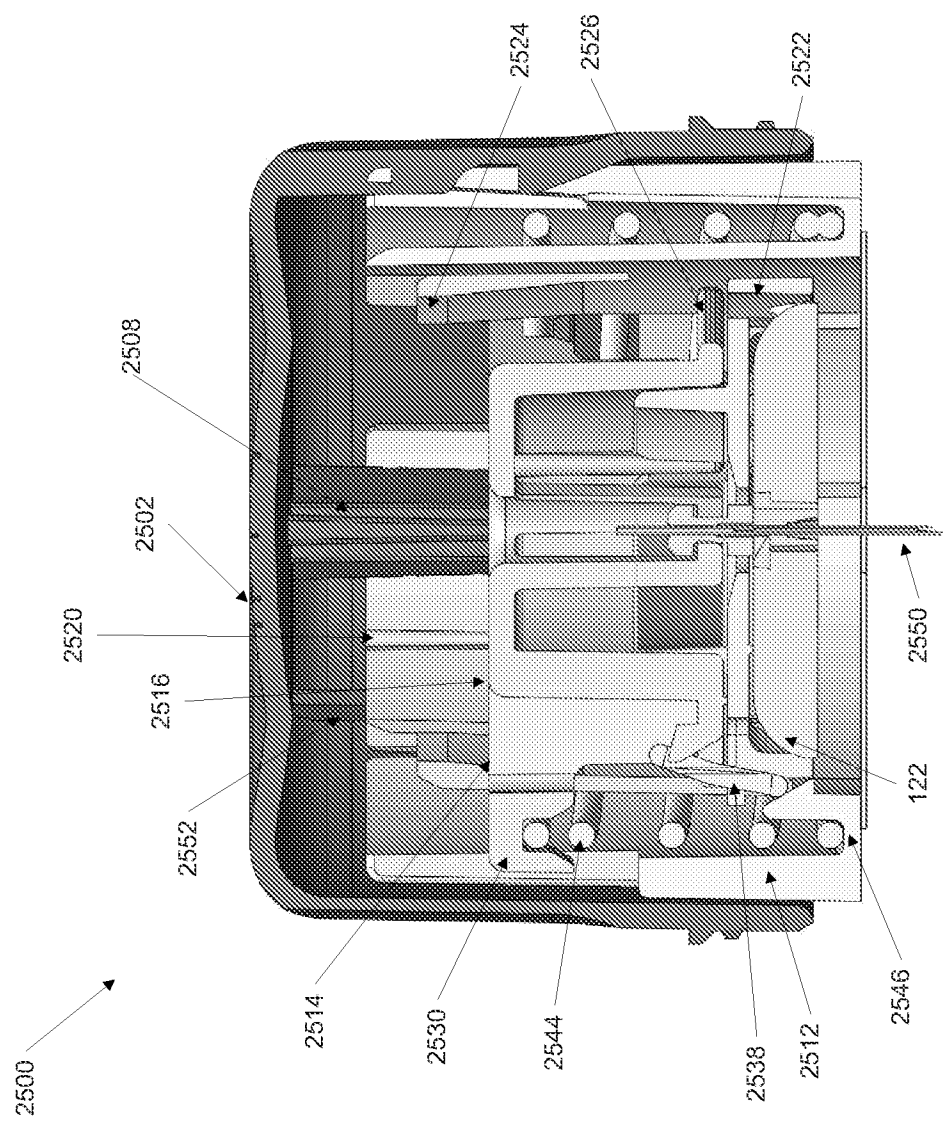


FIG. 73J

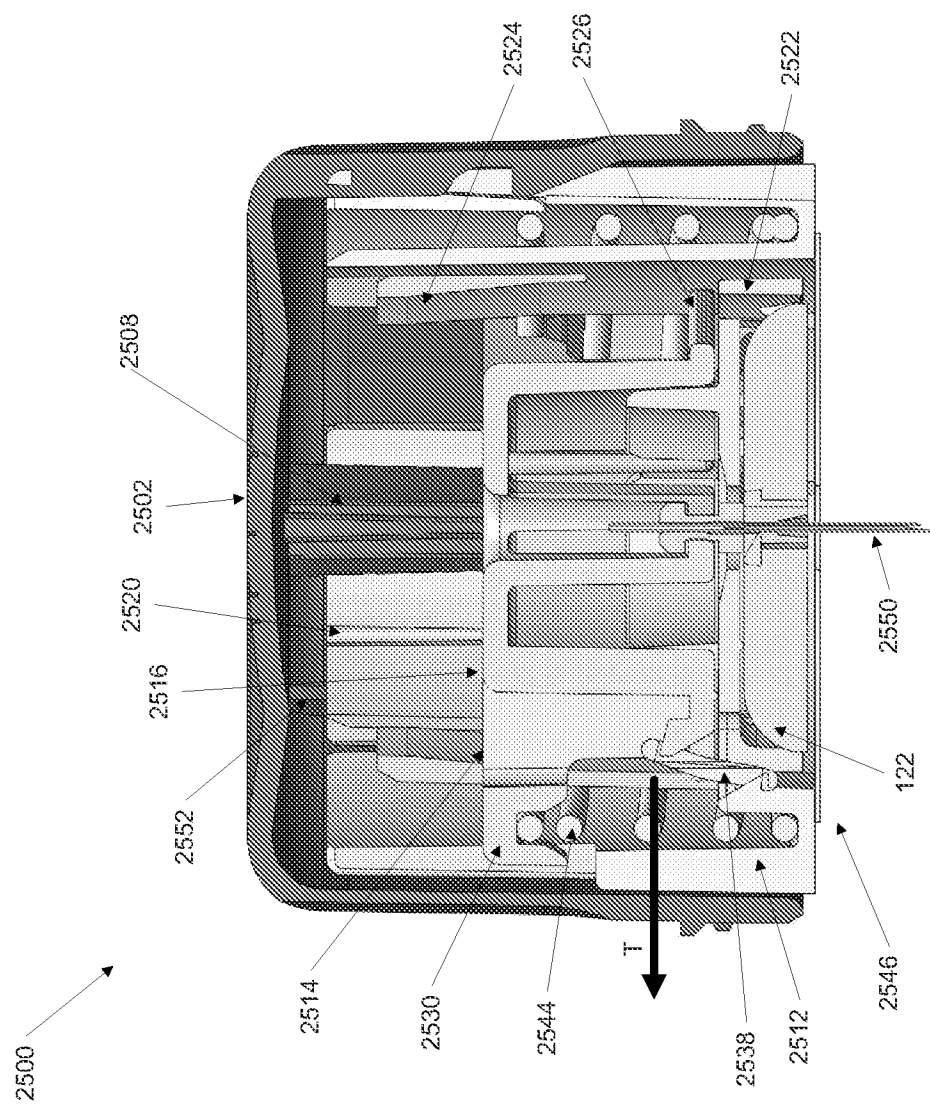


FIG. 73K

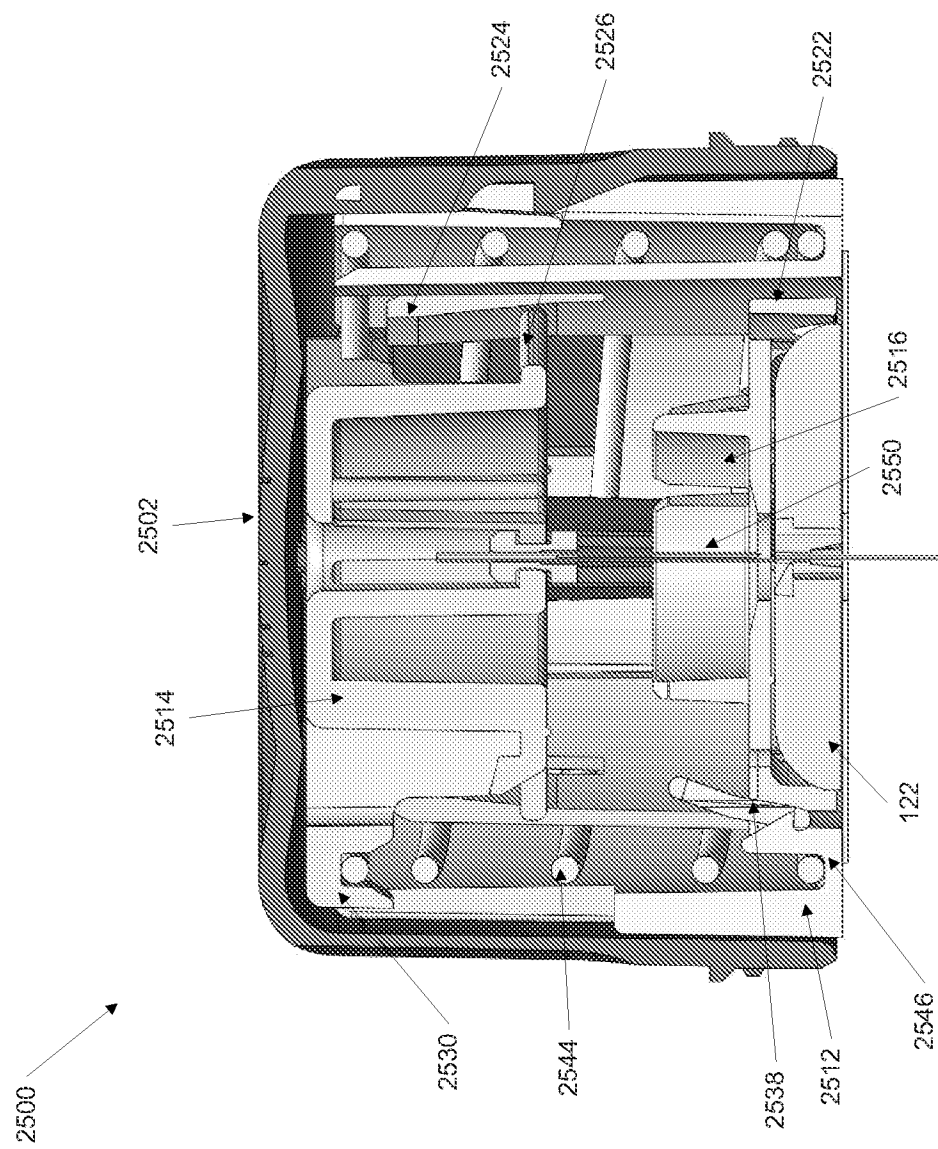


FIG. 73L

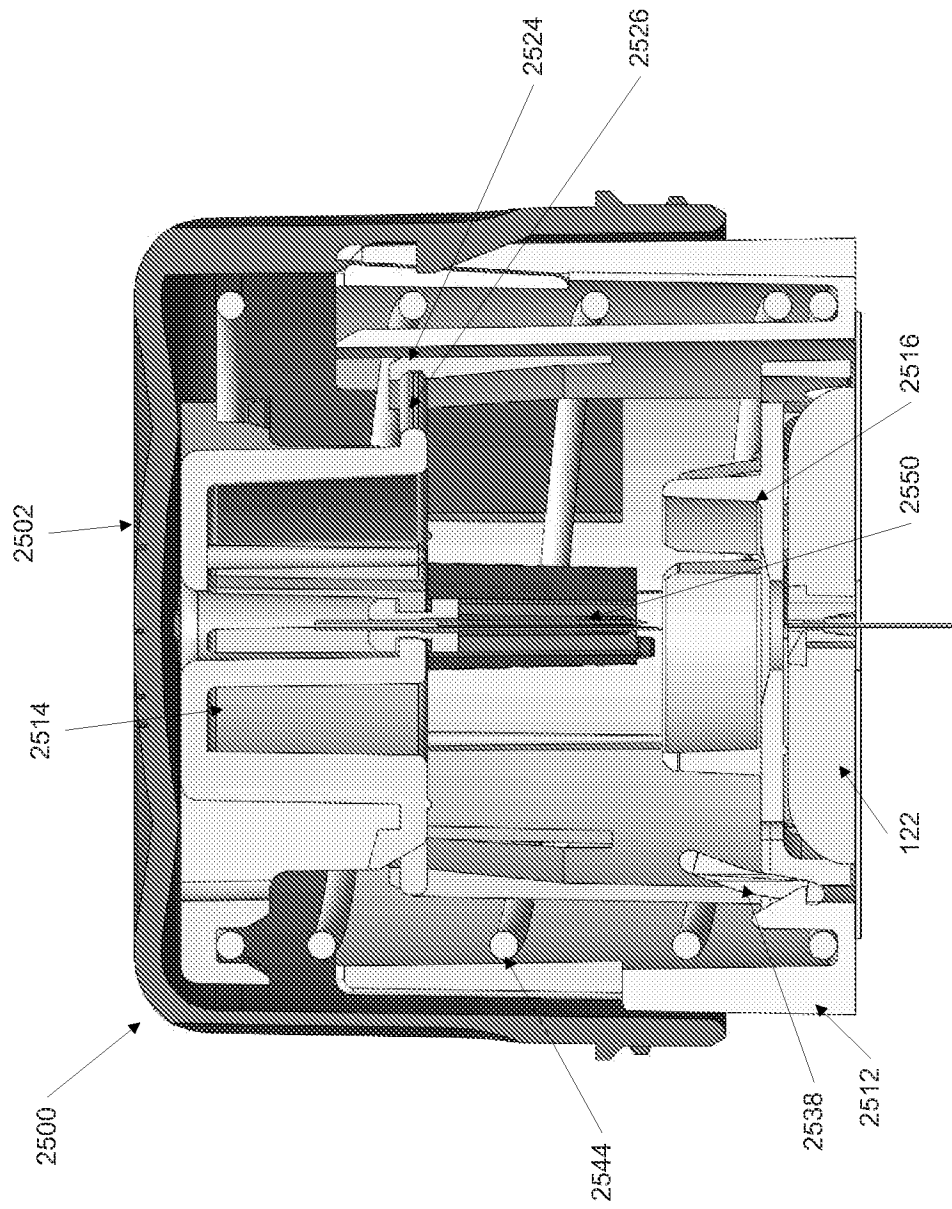


FIG. 73M

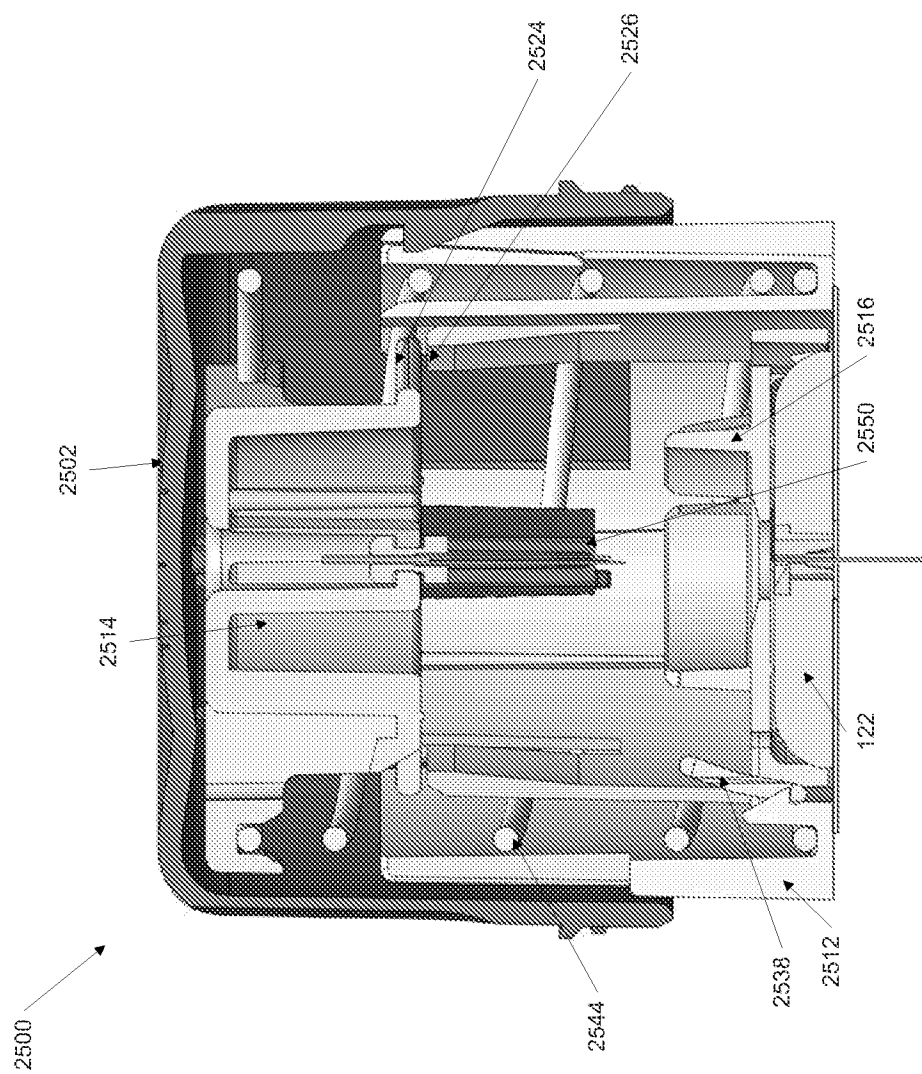


FIG. 73N

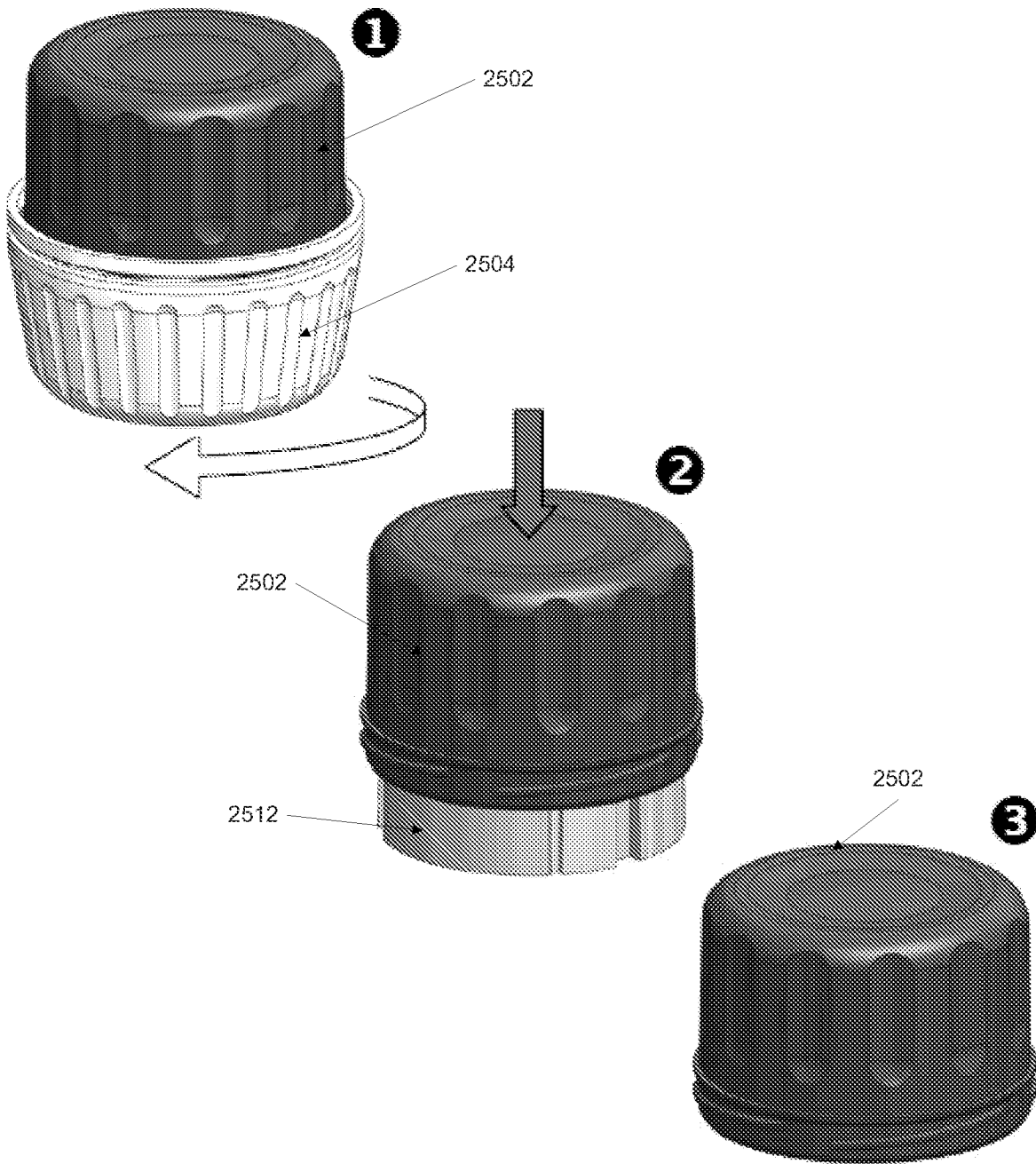


FIG. 730

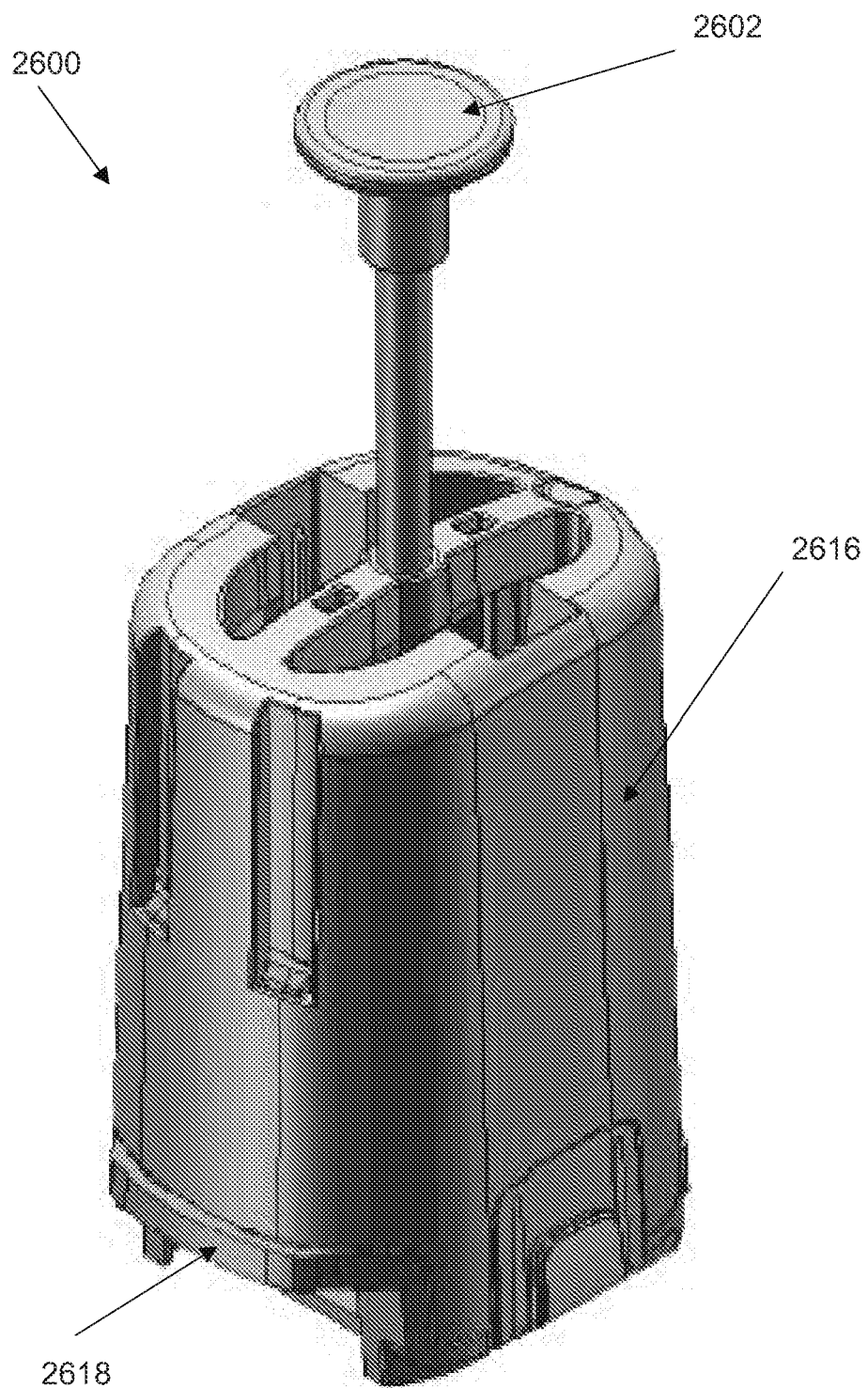


FIG. 74

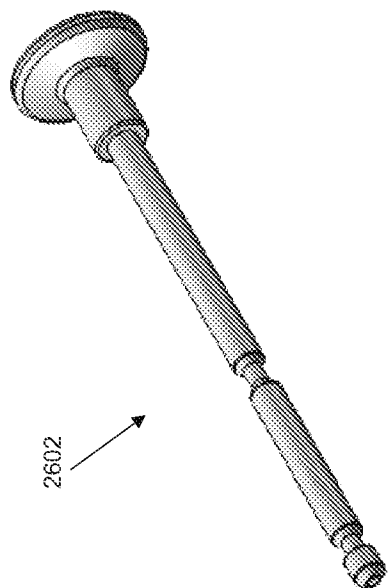


FIG. 74A

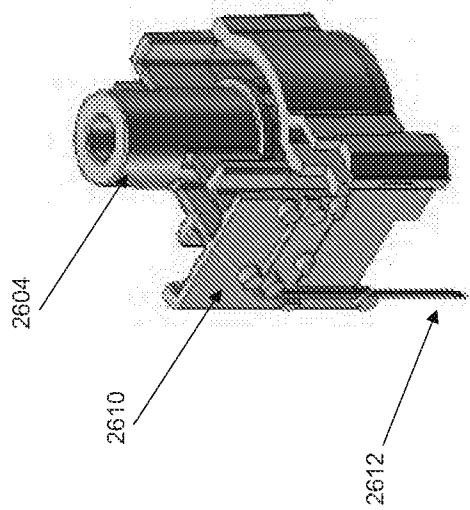


FIG. 74B

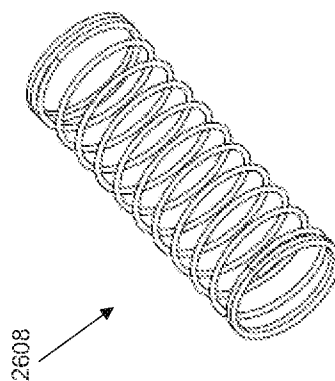


FIG. 74C

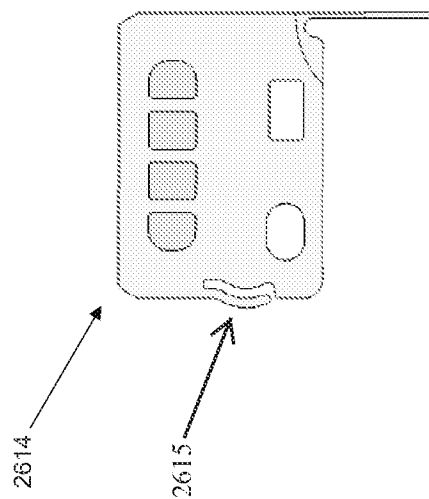


FIG. 74D

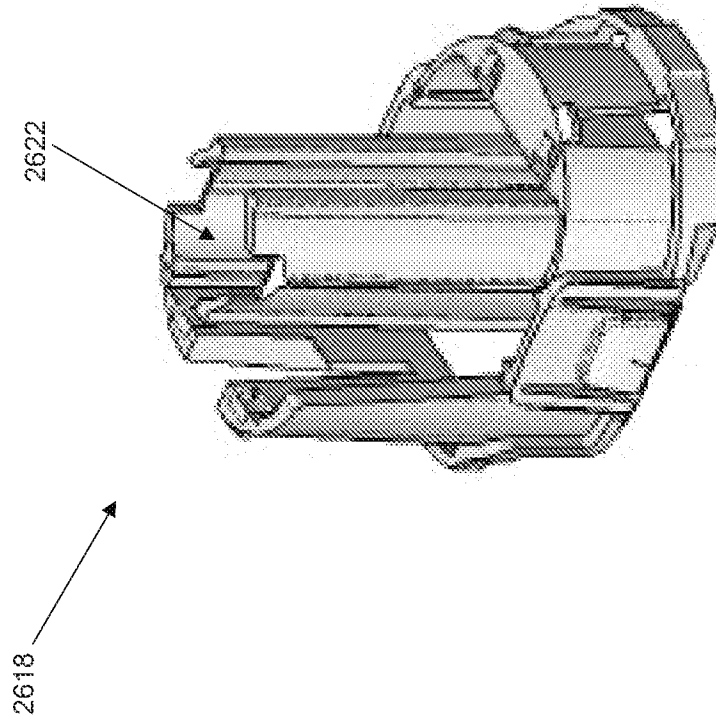


FIG. 74F

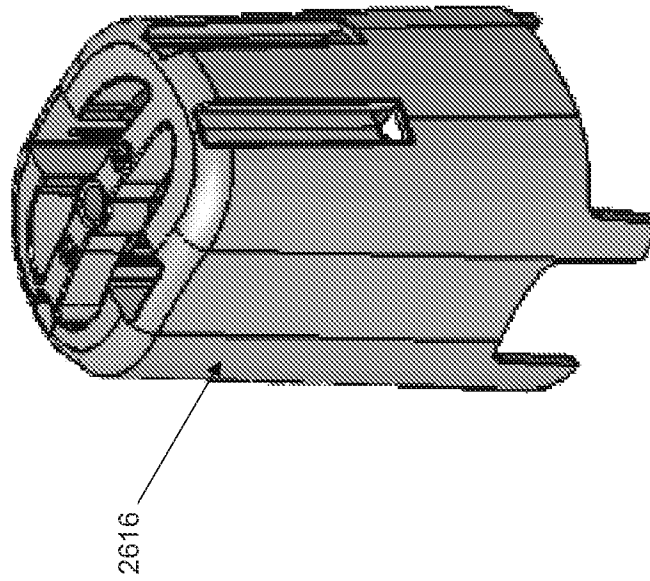


FIG. 74E

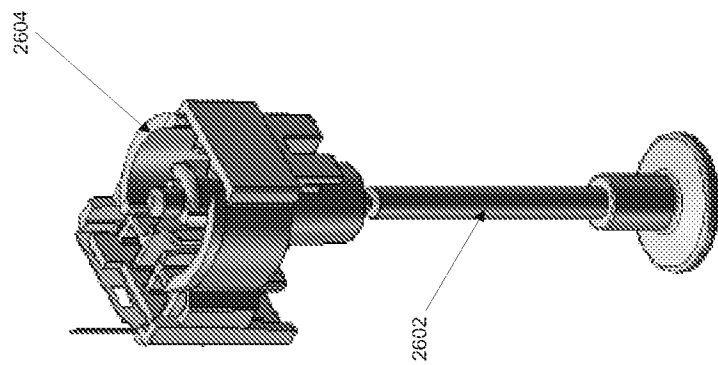


FIG. 75A

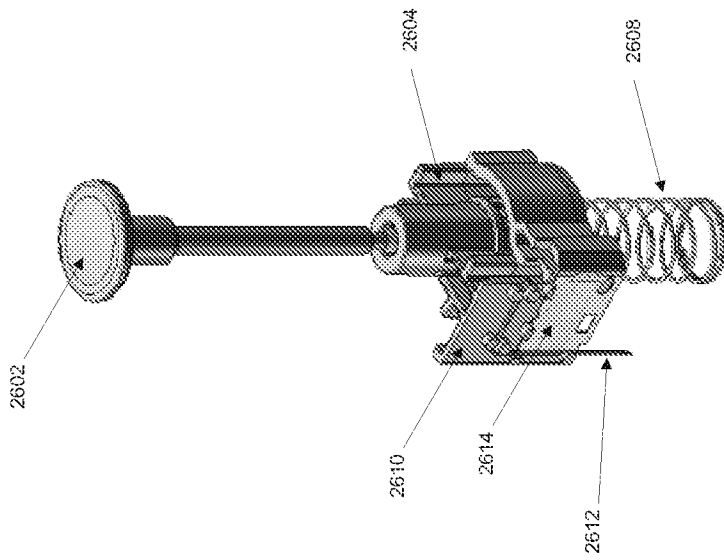


FIG. 75B

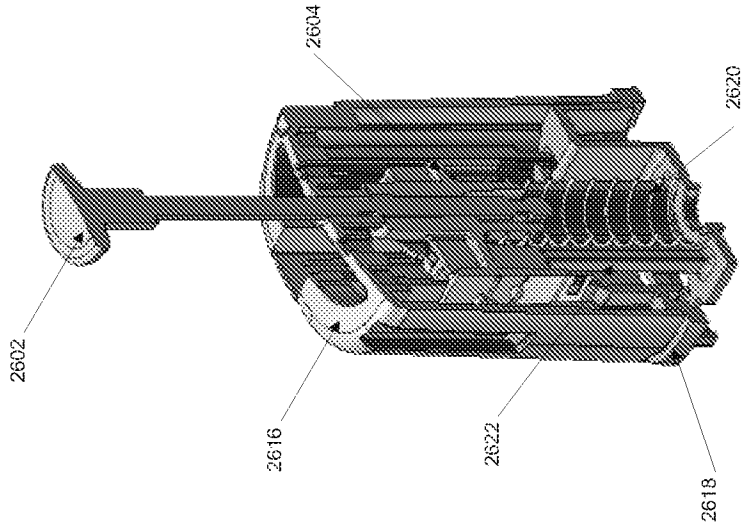


FIG. 75C

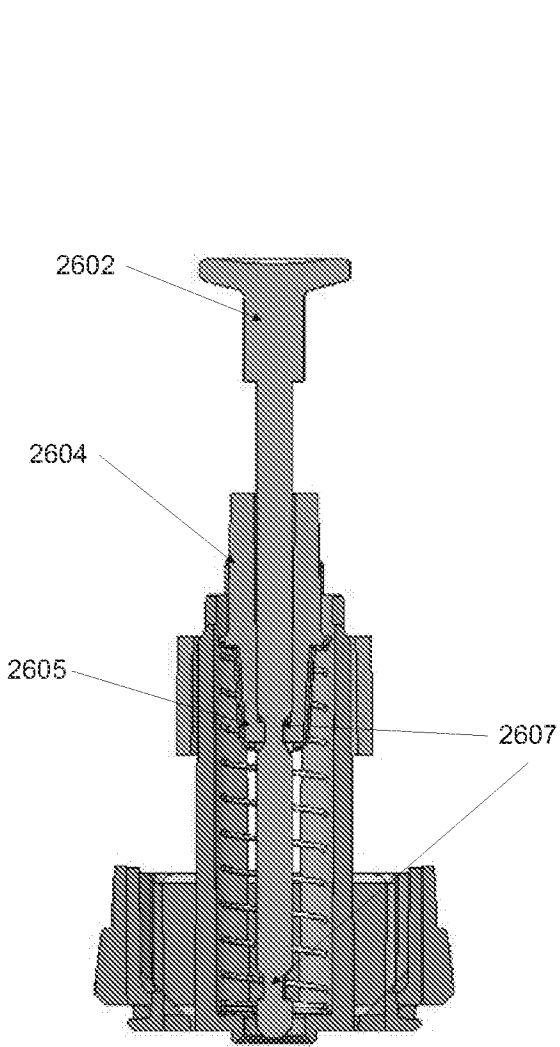


FIG. 75D

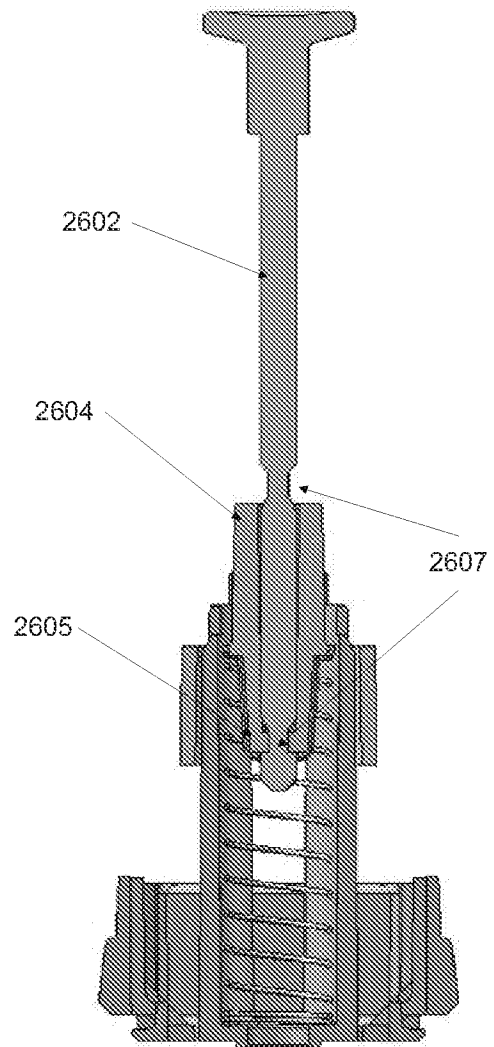


FIG. 75E

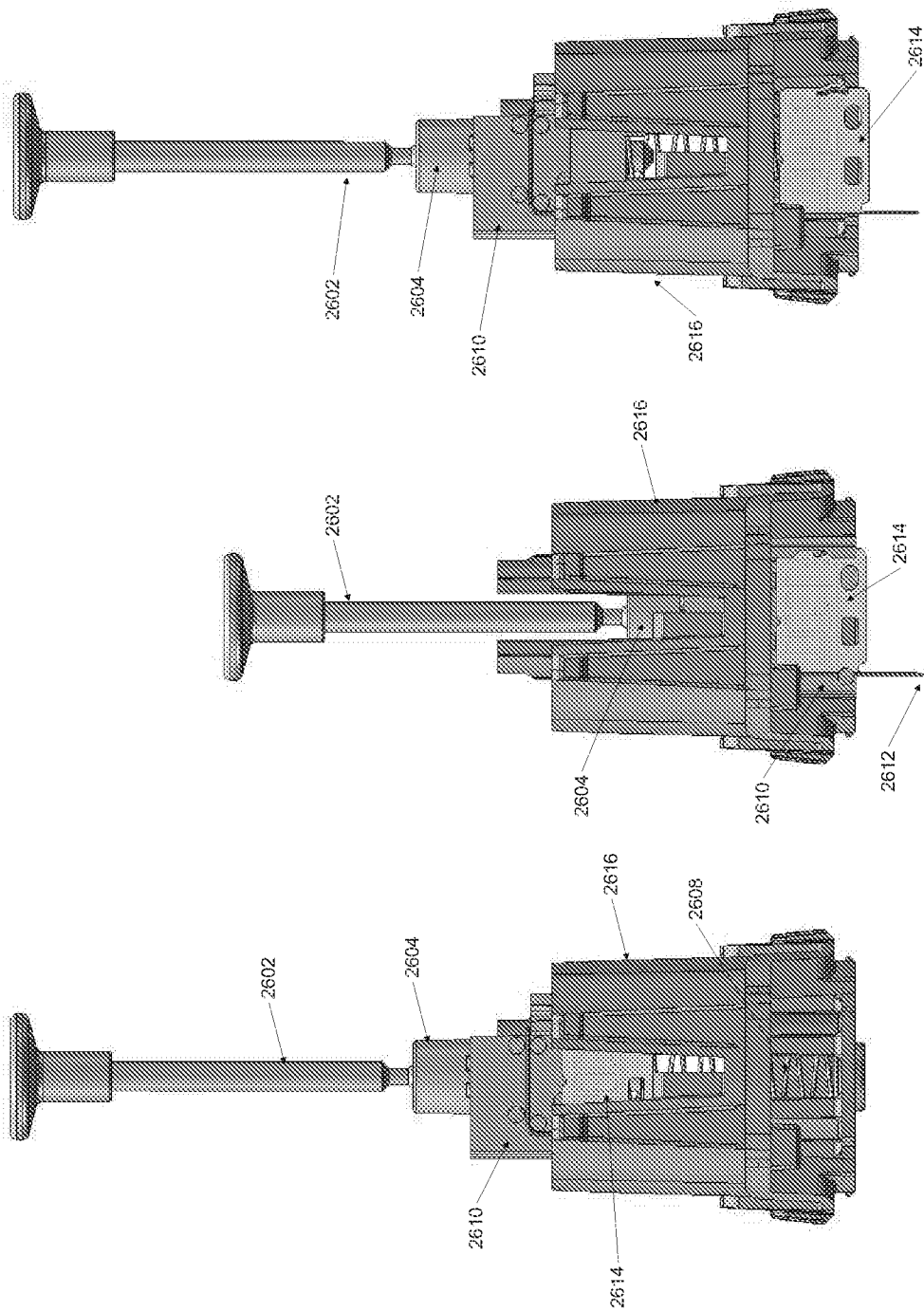


FIG. 76C

FIG. 76B

FIG. 76A

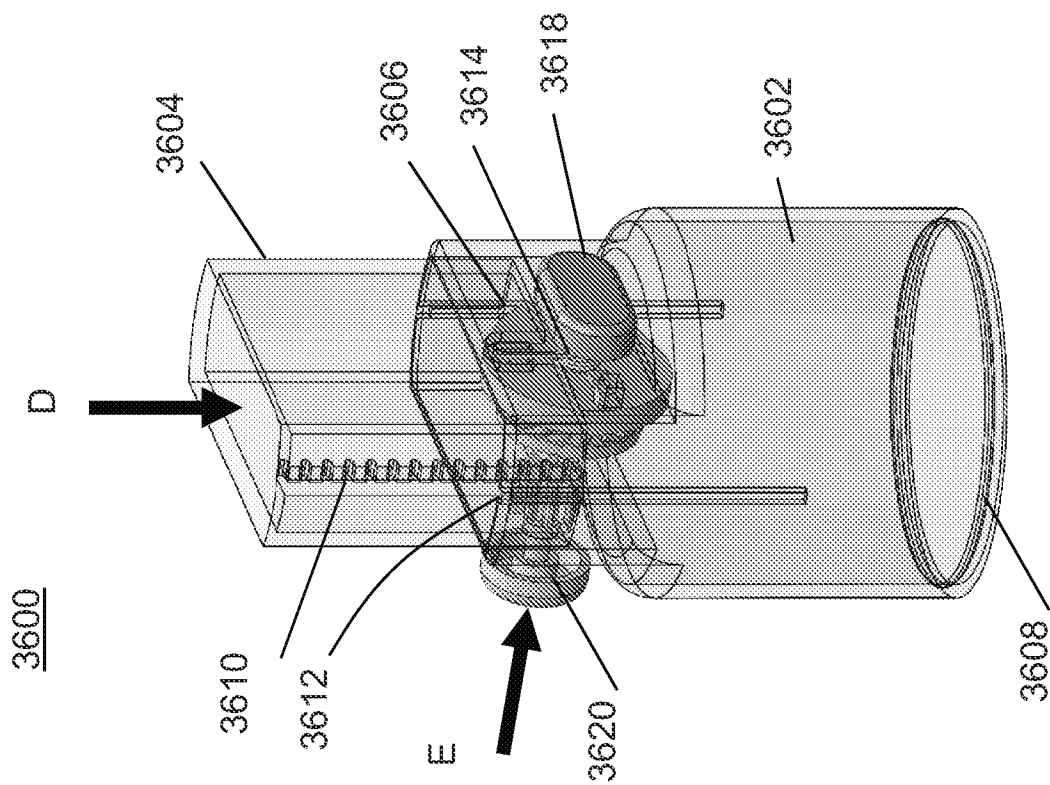


FIG. 77

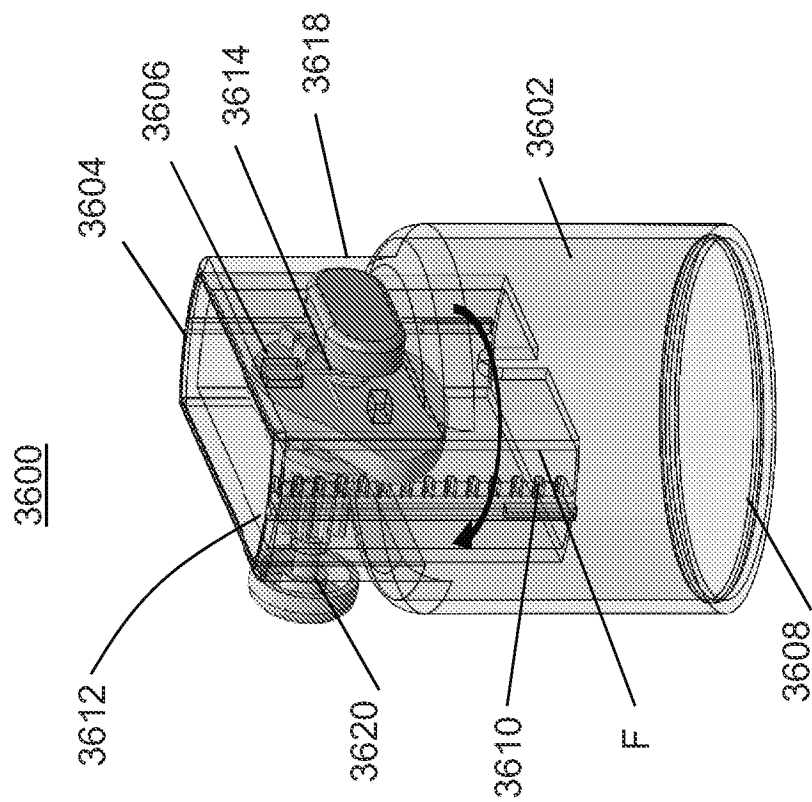


FIG. 78

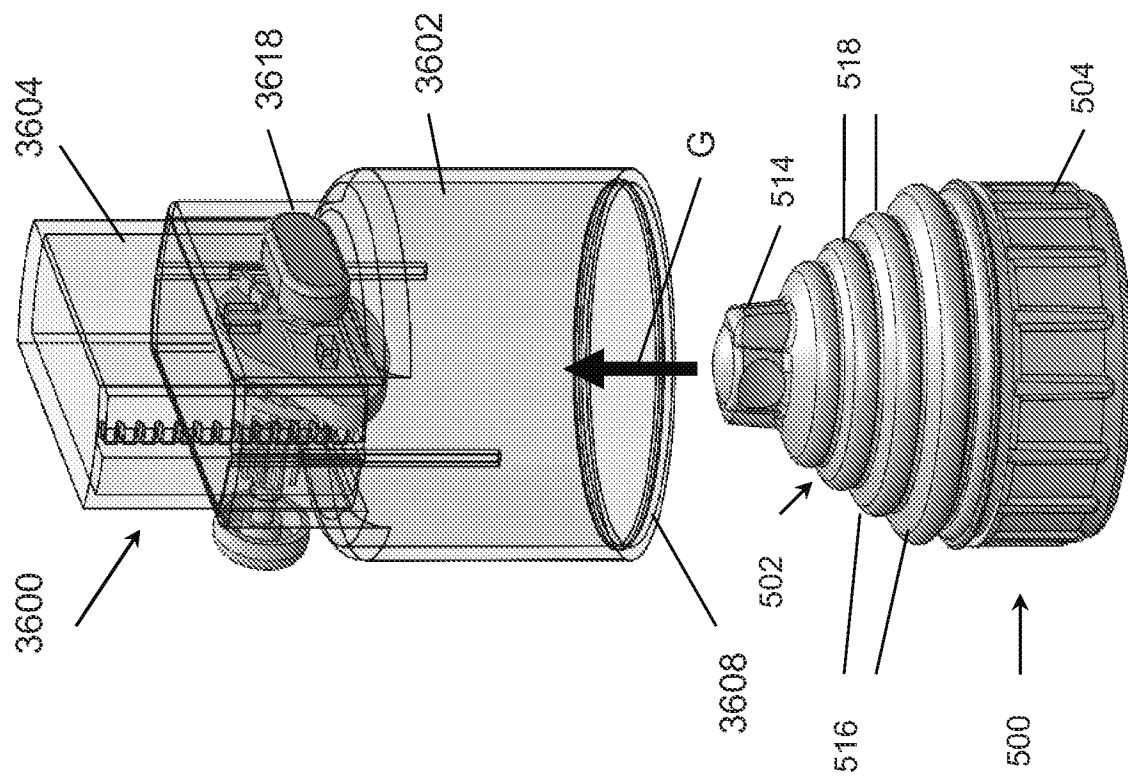


FIG. 79

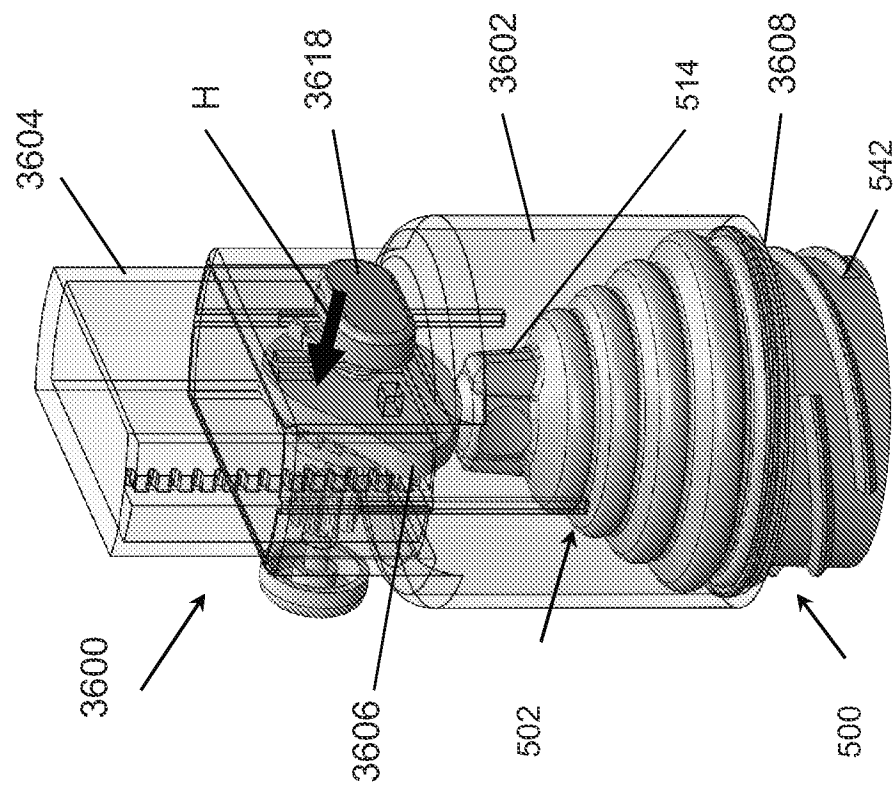


FIG. 80

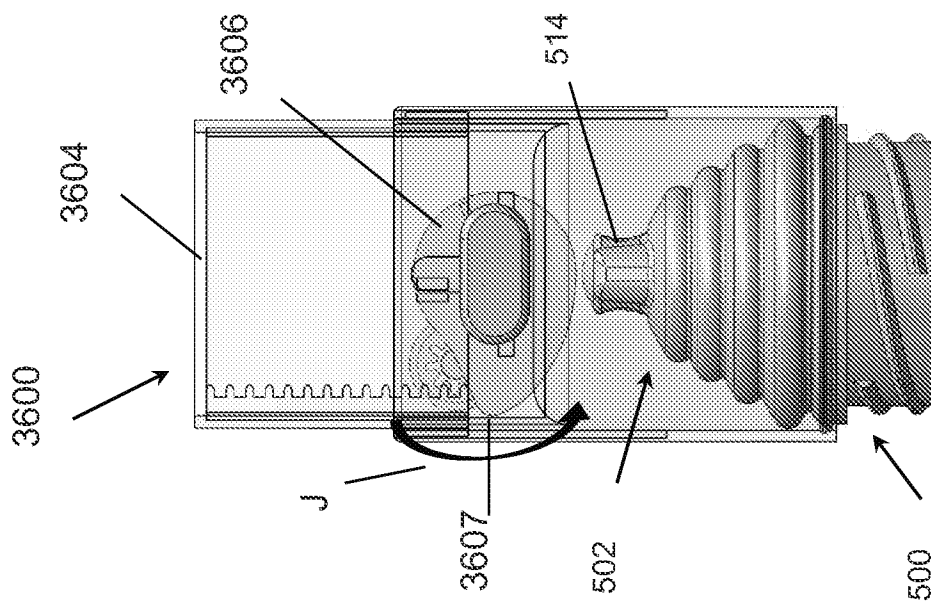


FIG. 81

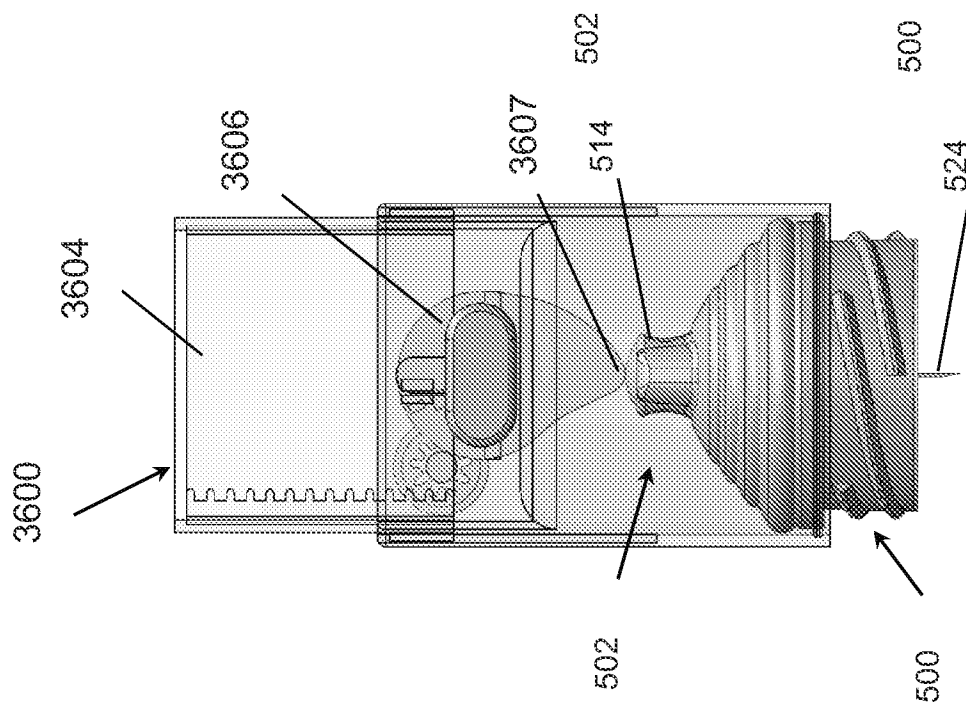


FIG. 82

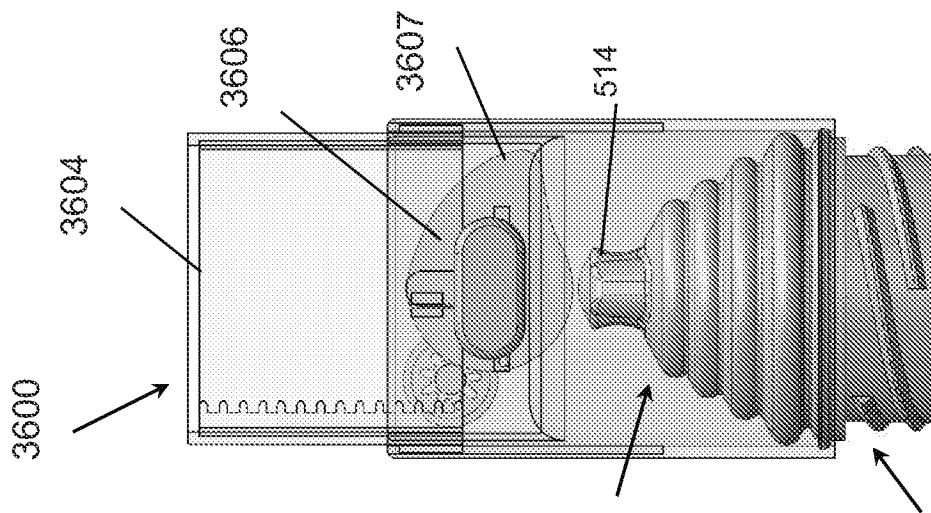


FIG. 83

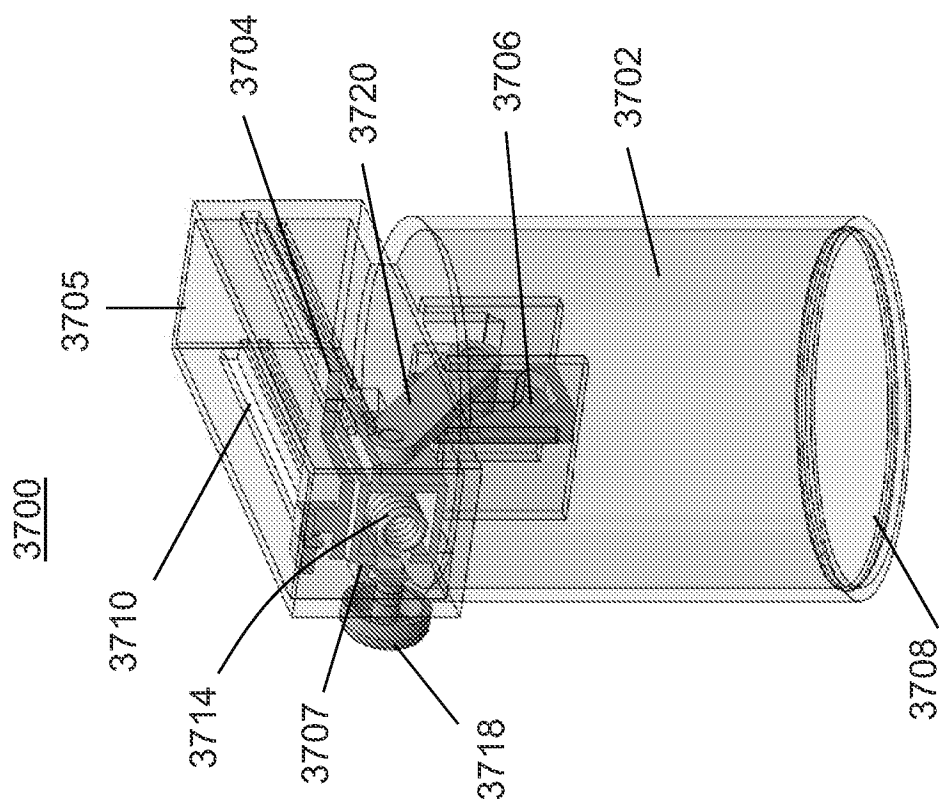


FIG. 85

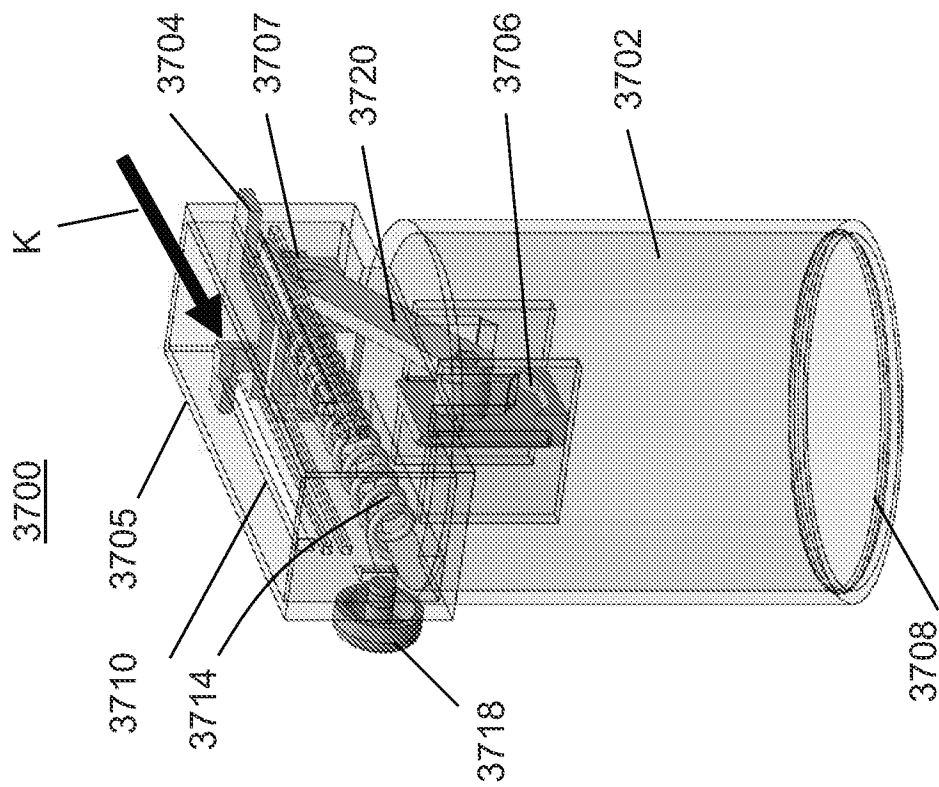


FIG. 84

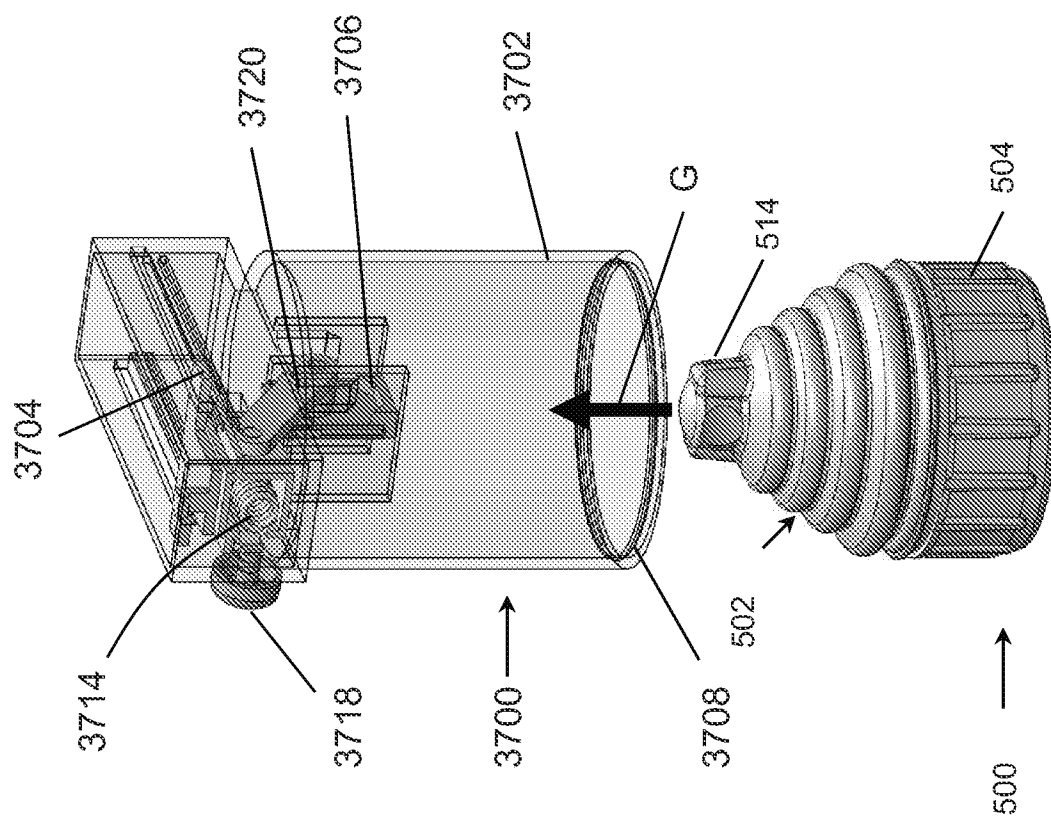


FIG. 86

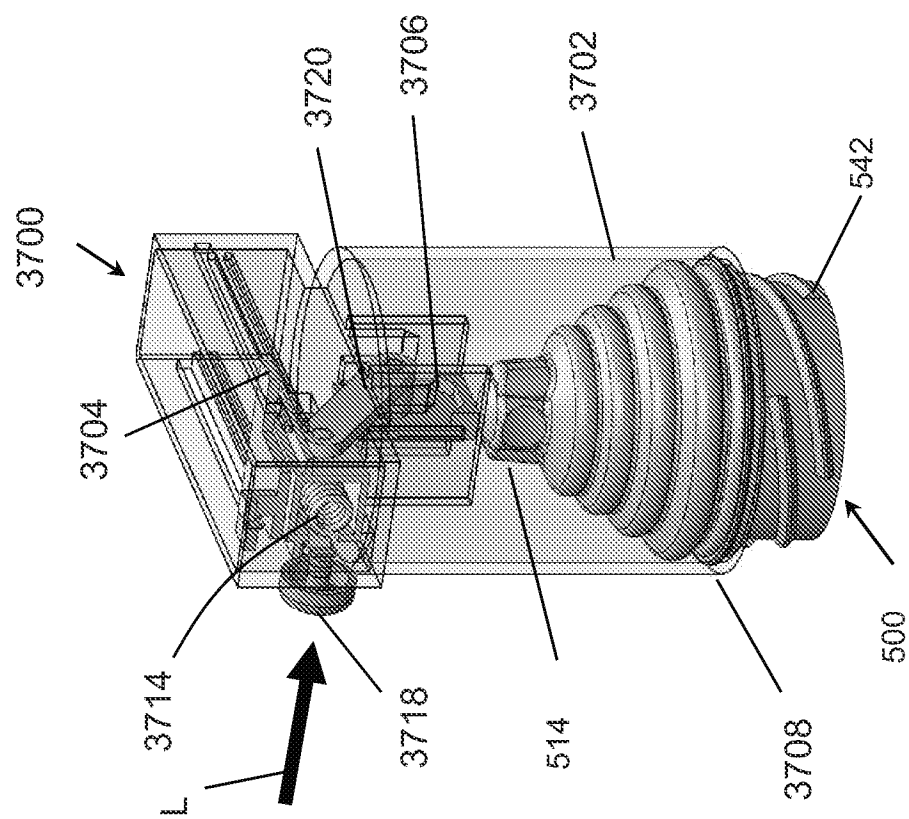


FIG. 87

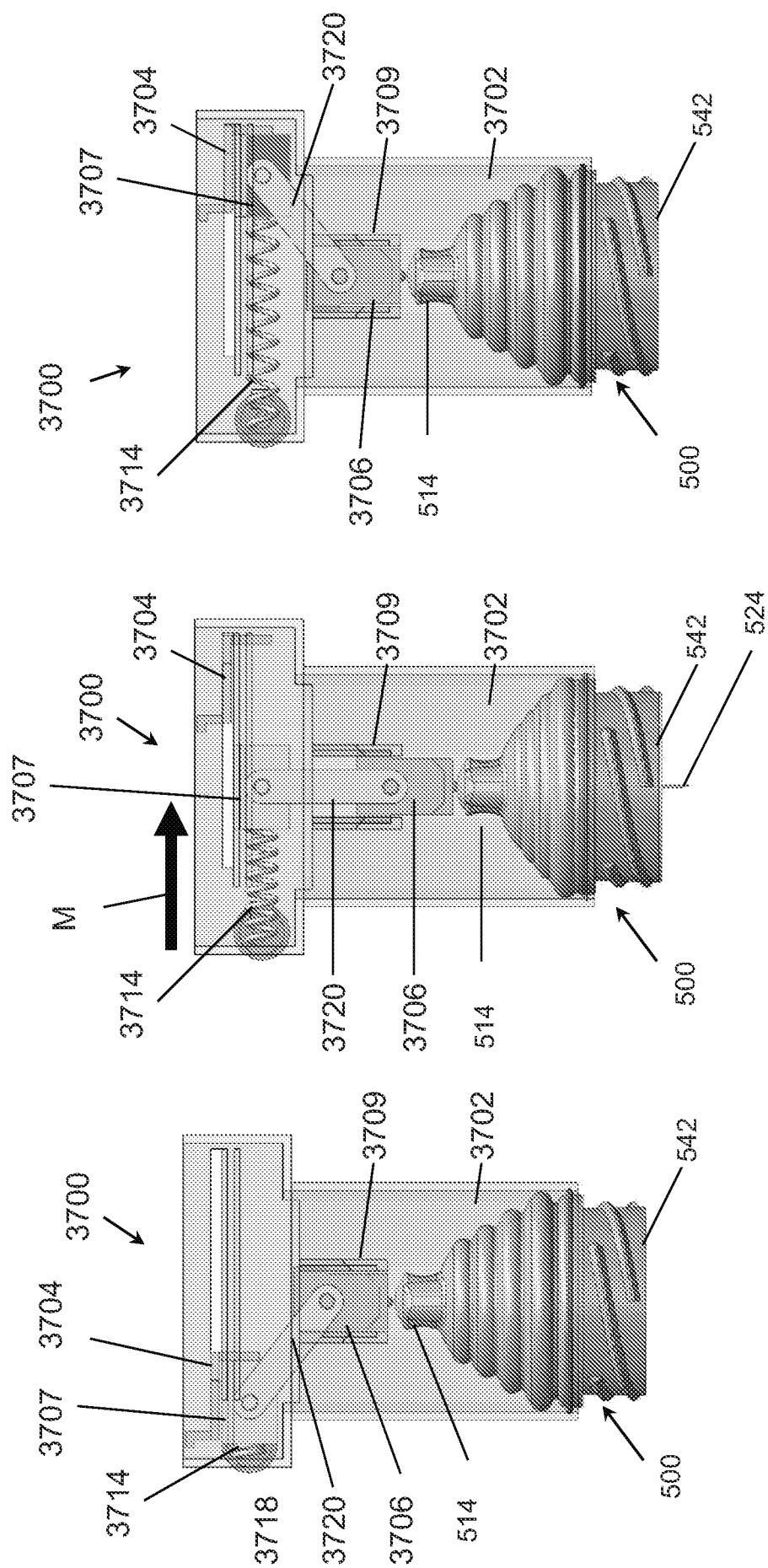


FIG. 90

FIG. 89

FIG. 88

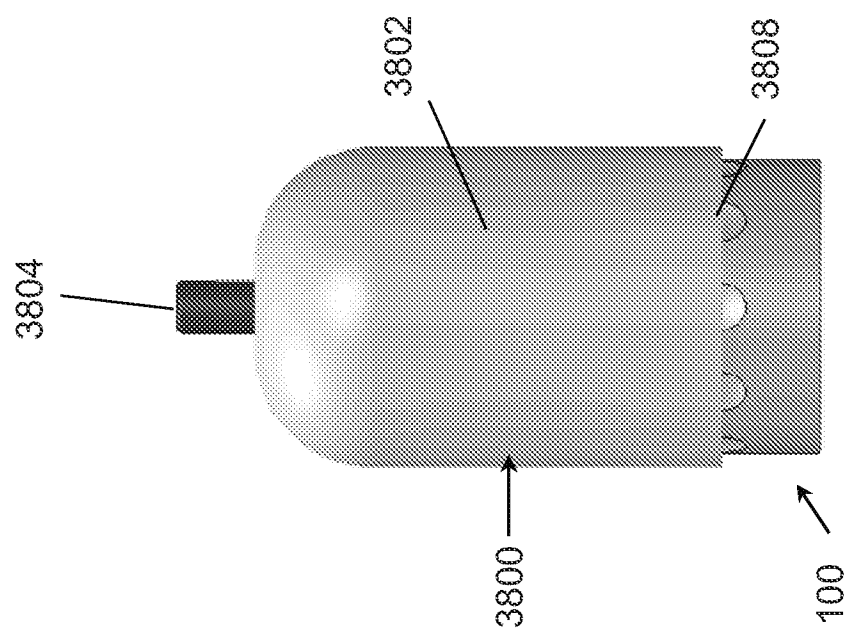


FIG. 91

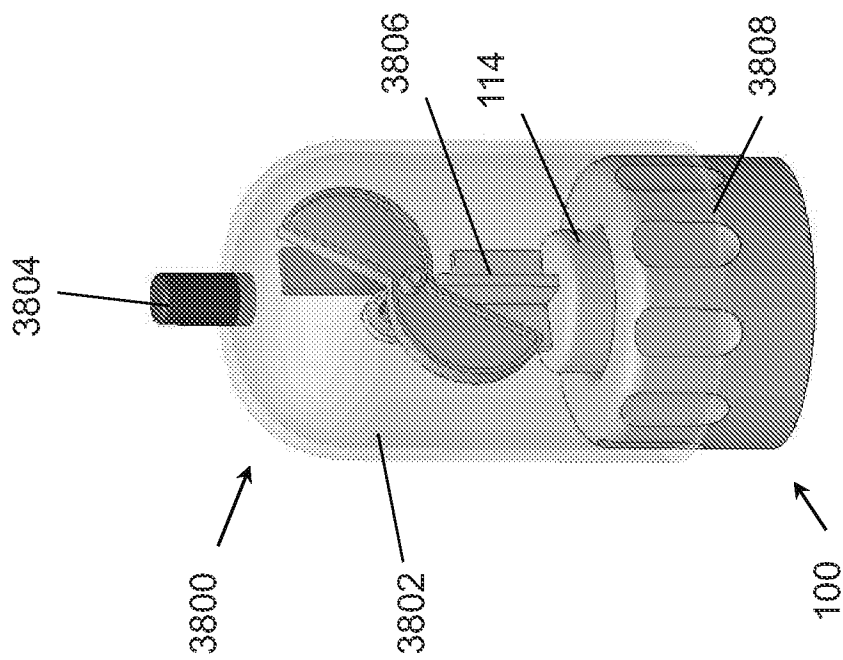


FIG. 92

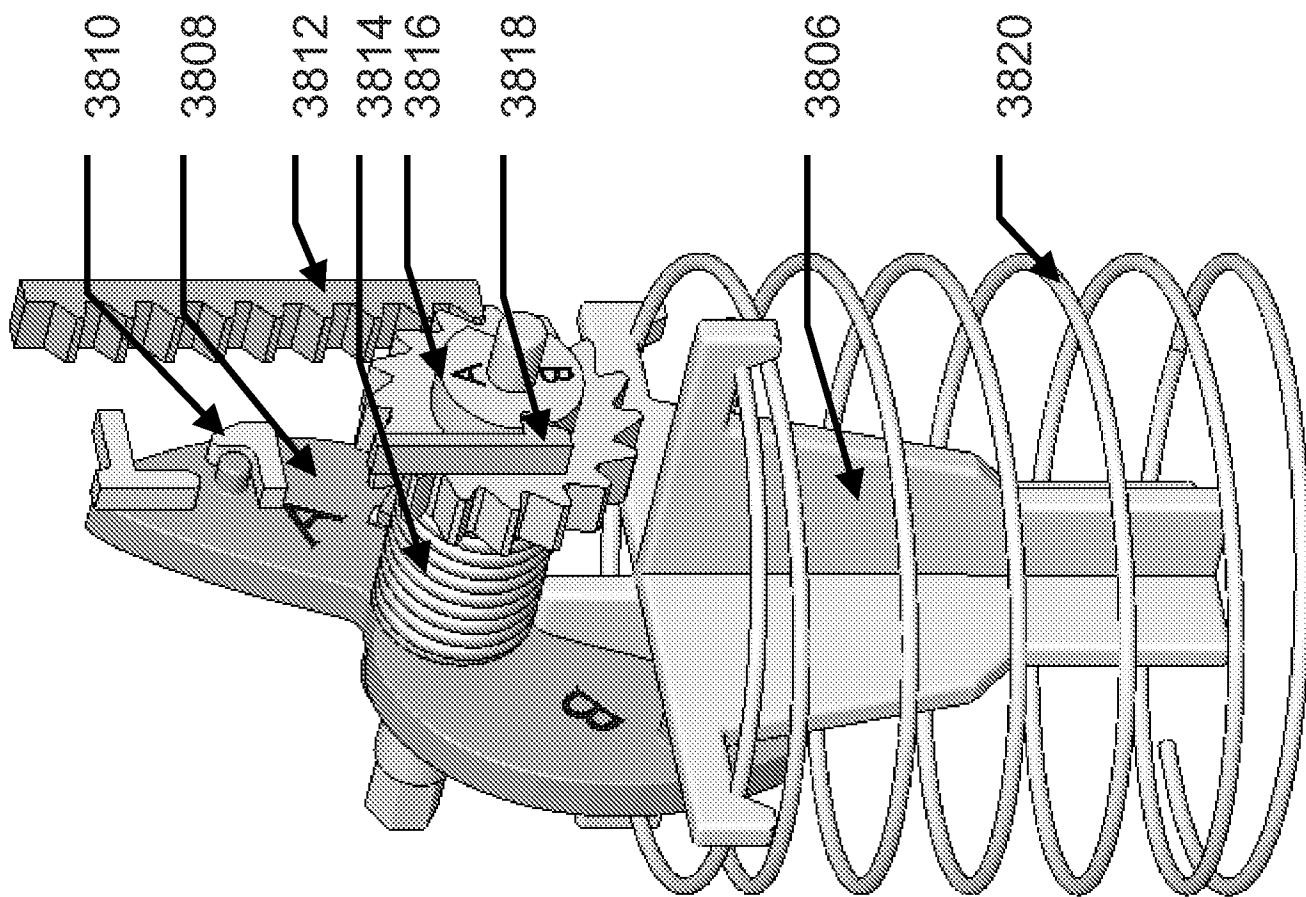


FIGURE 92A

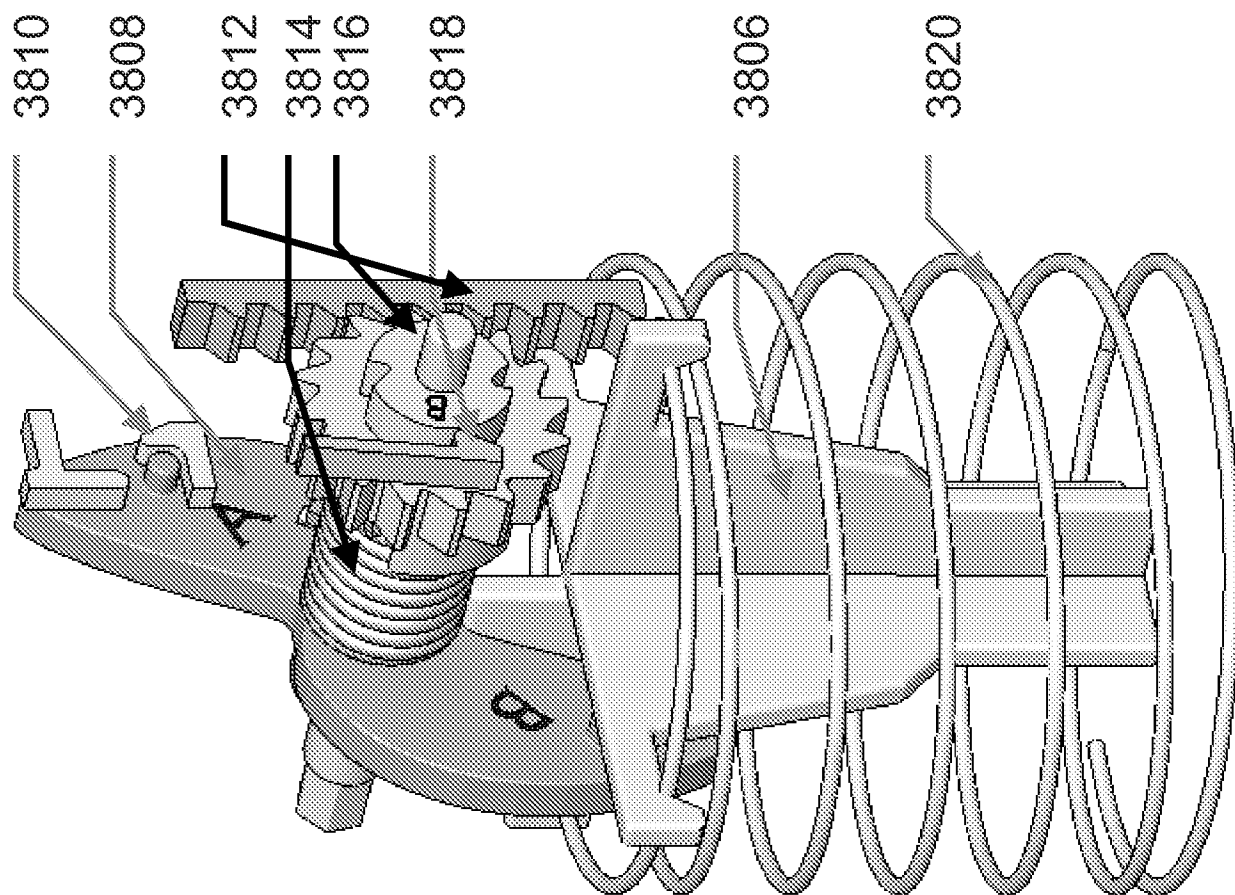


FIGURE 92B

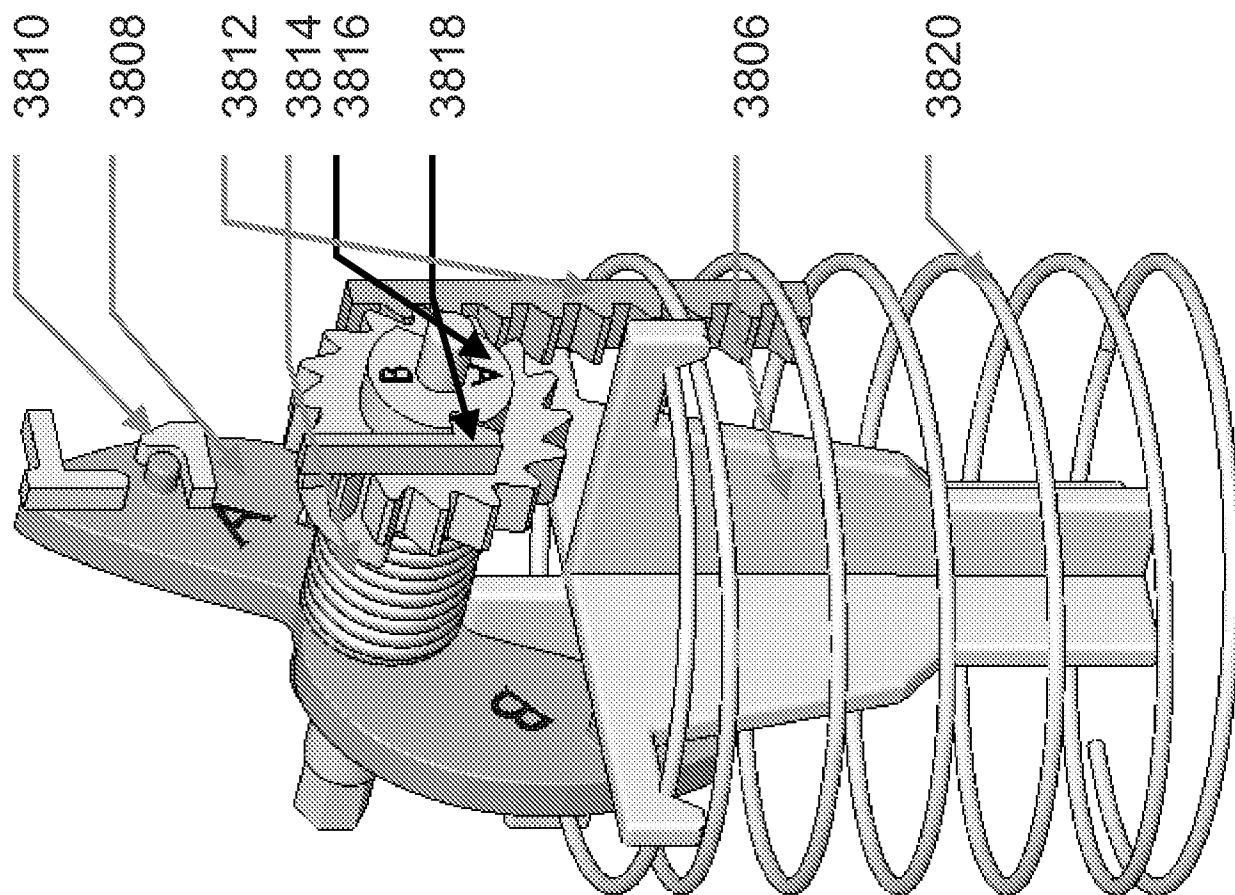


FIGURE 92C

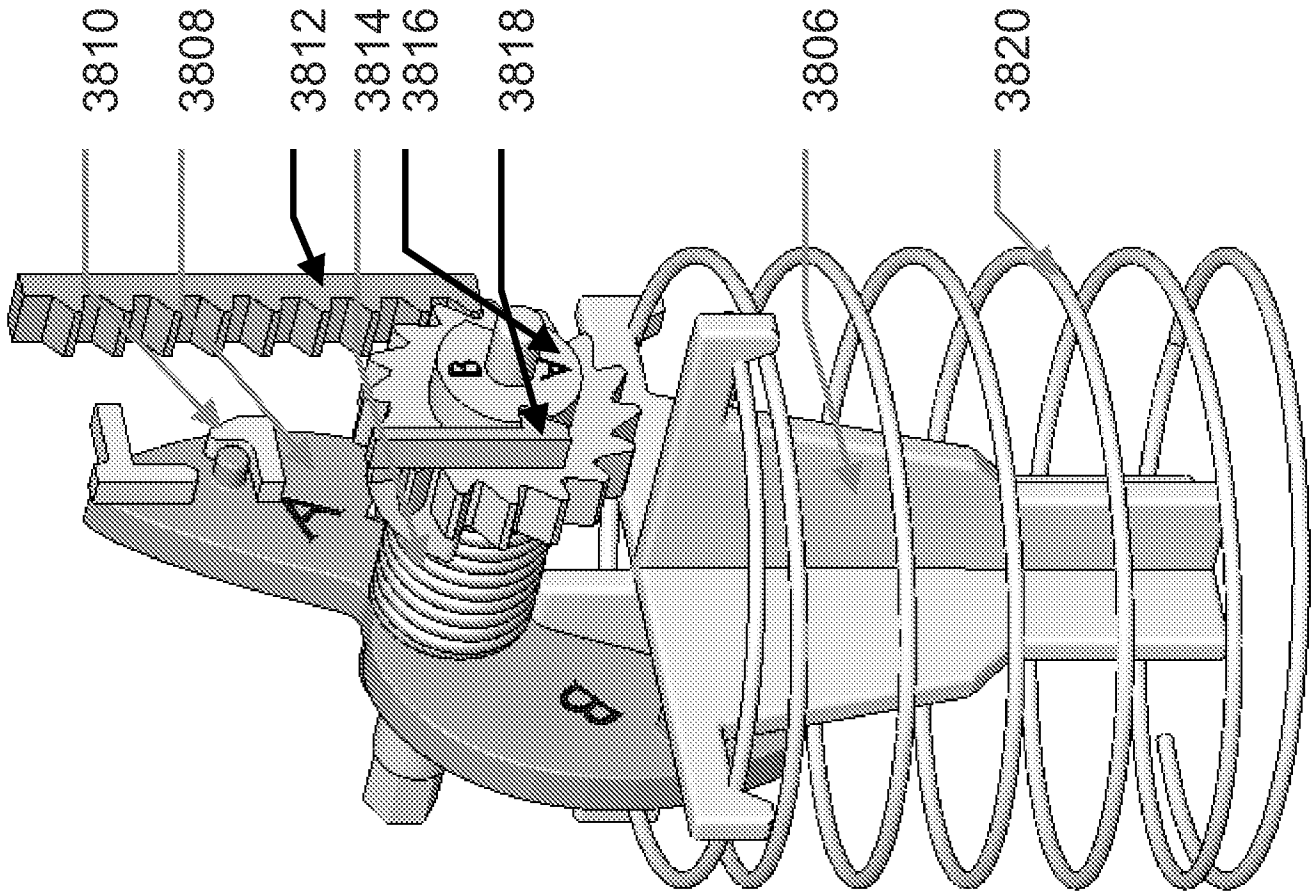


FIGURE 92D

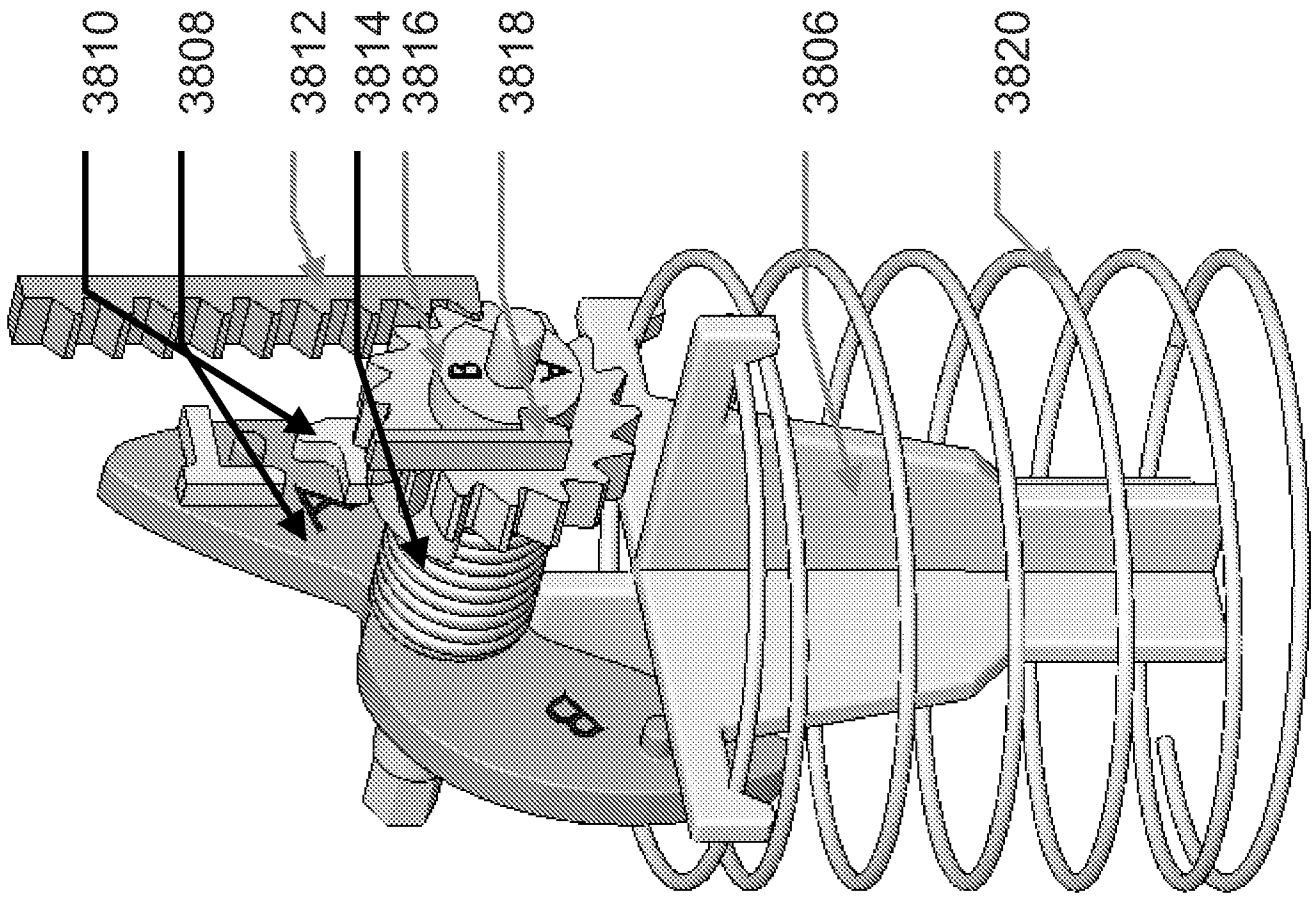


FIGURE 92E

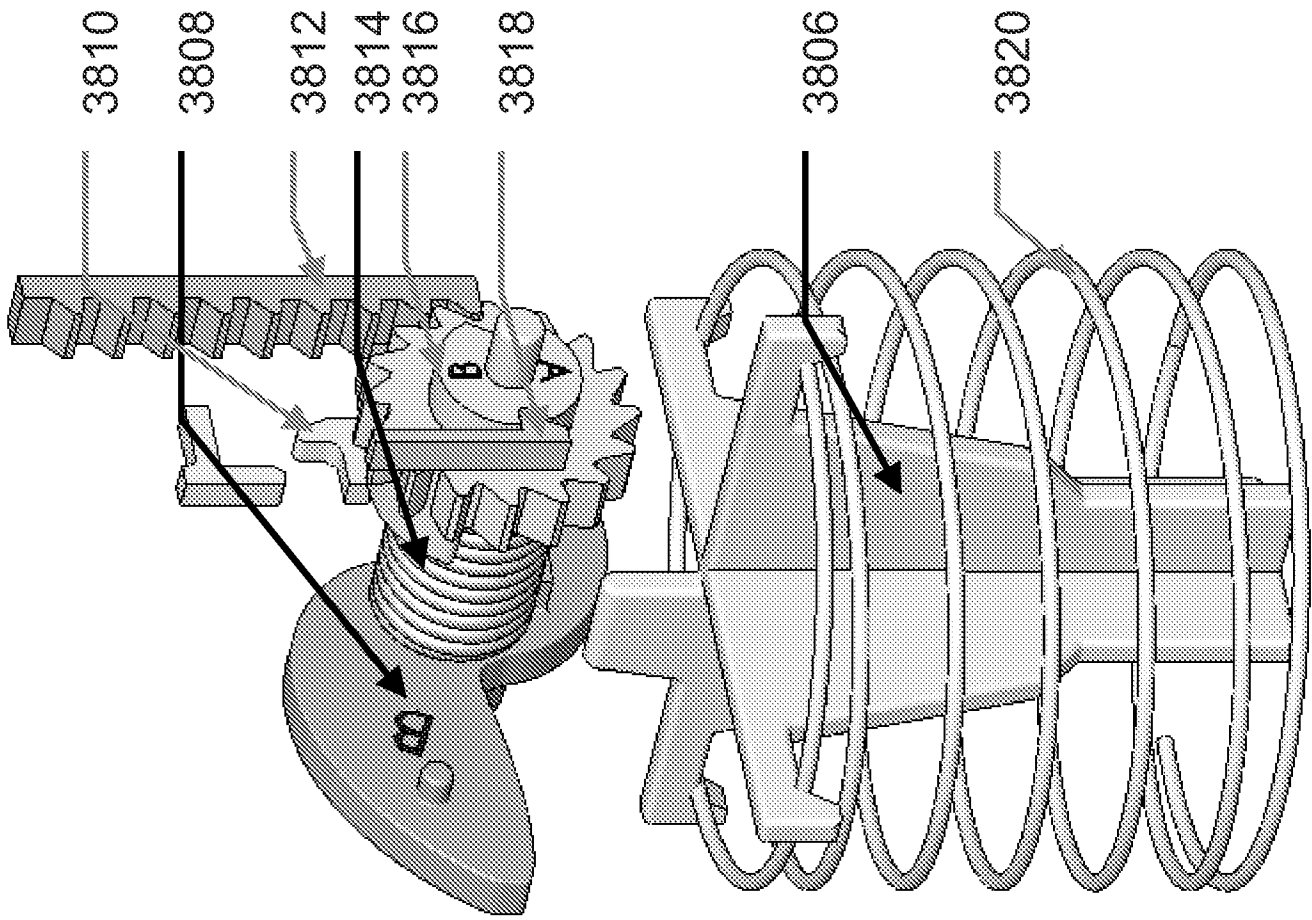


FIGURE 92F

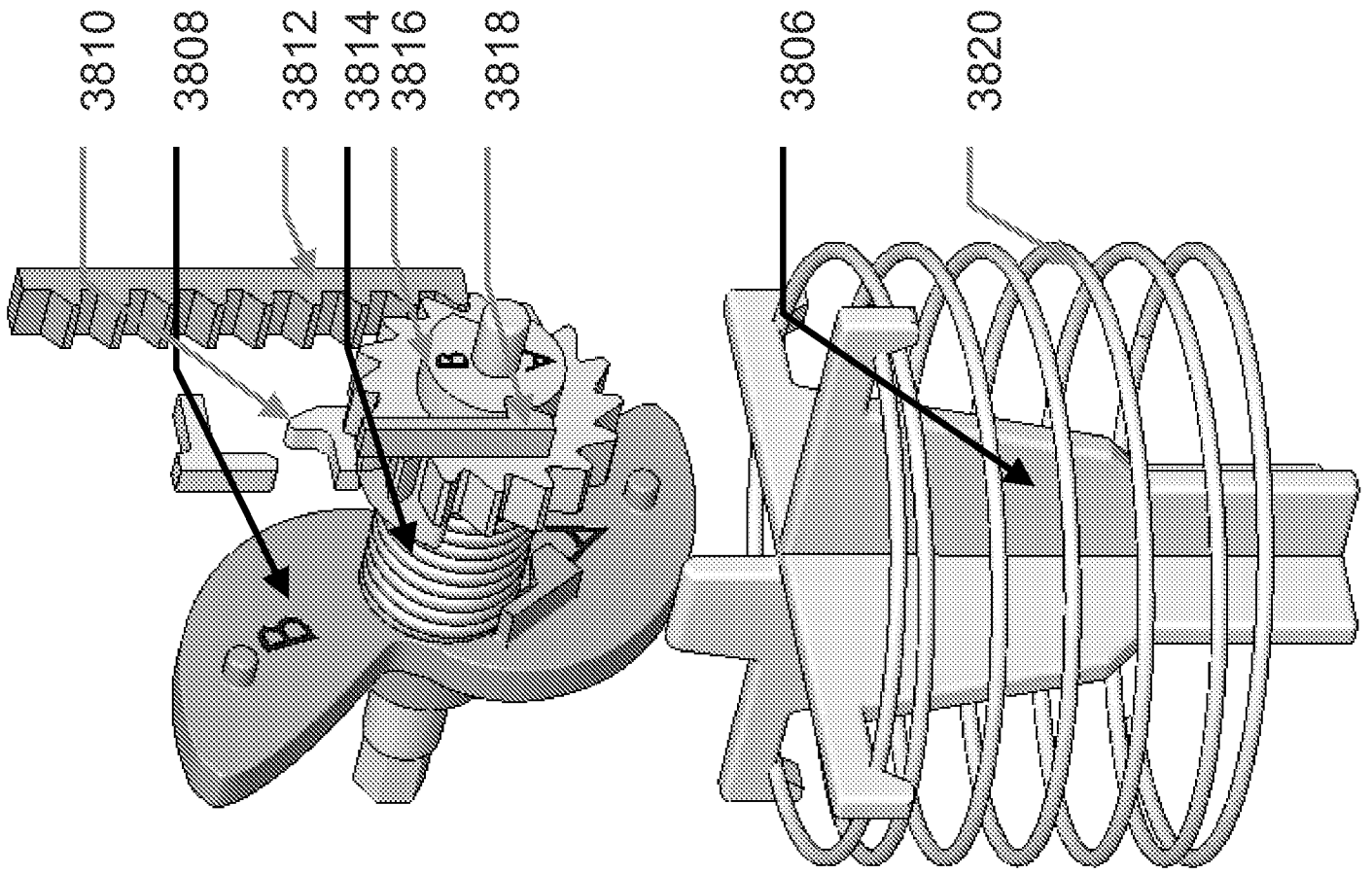


FIGURE 92G

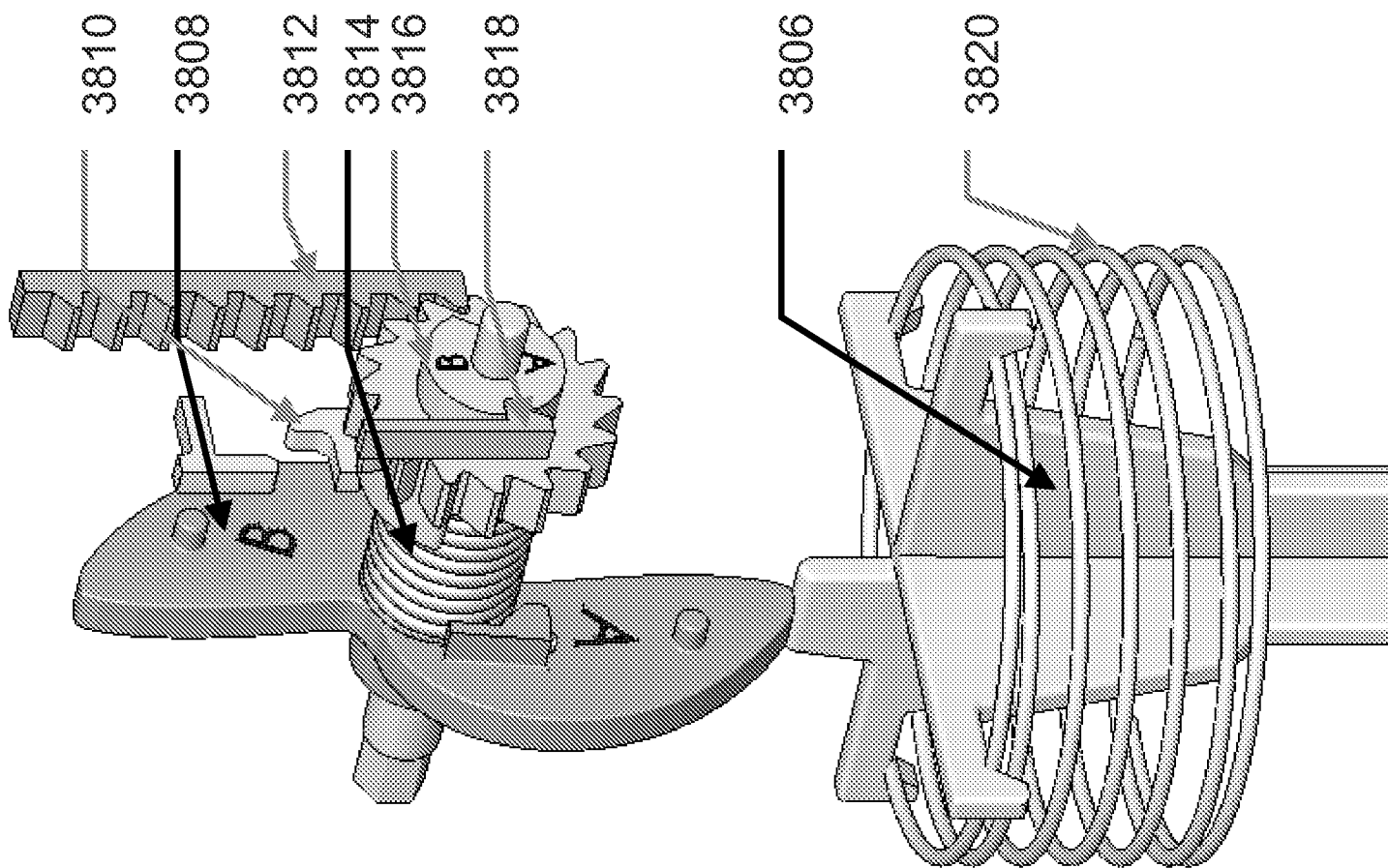


FIGURE 92H

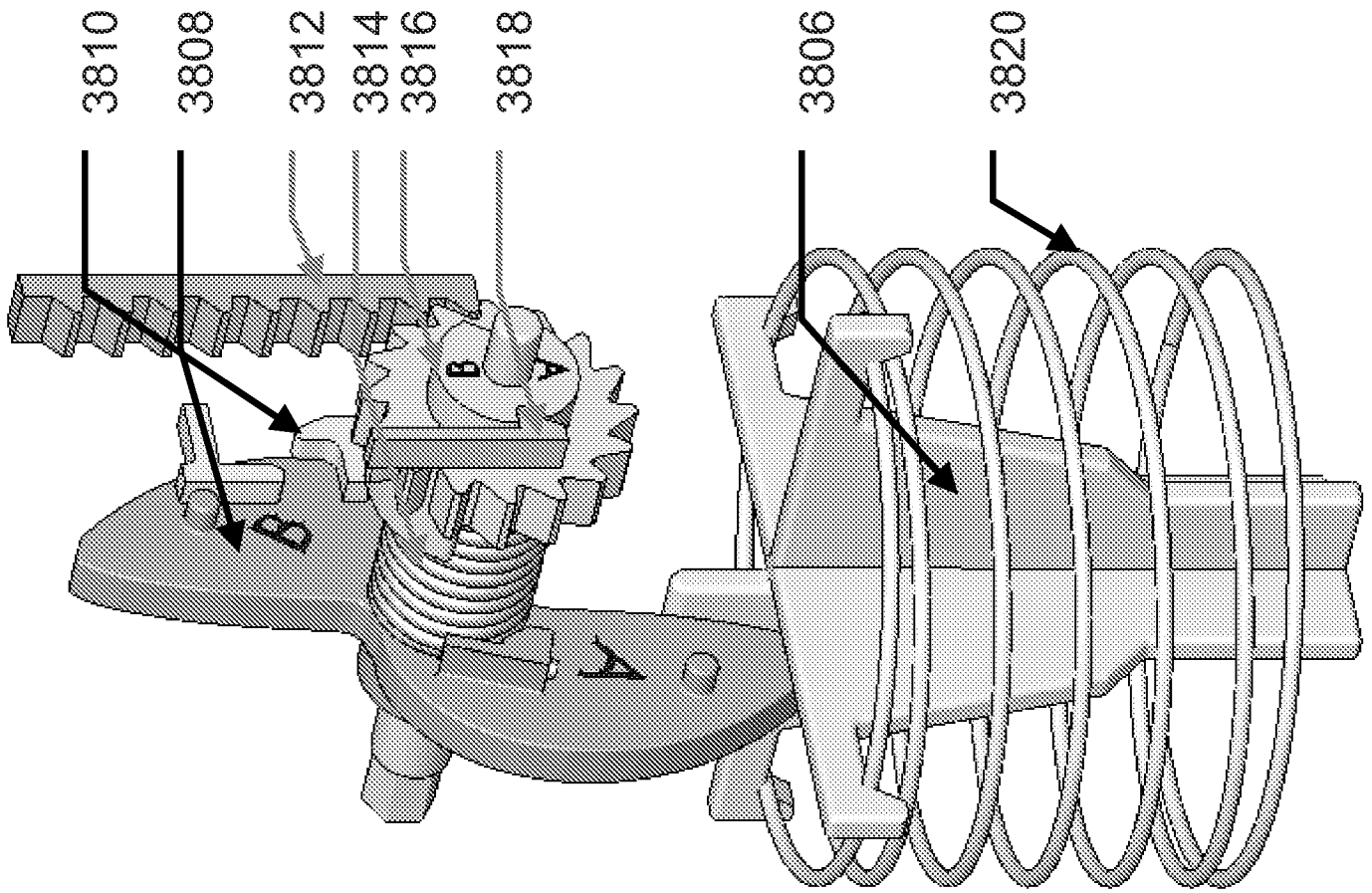


FIGURE 92I

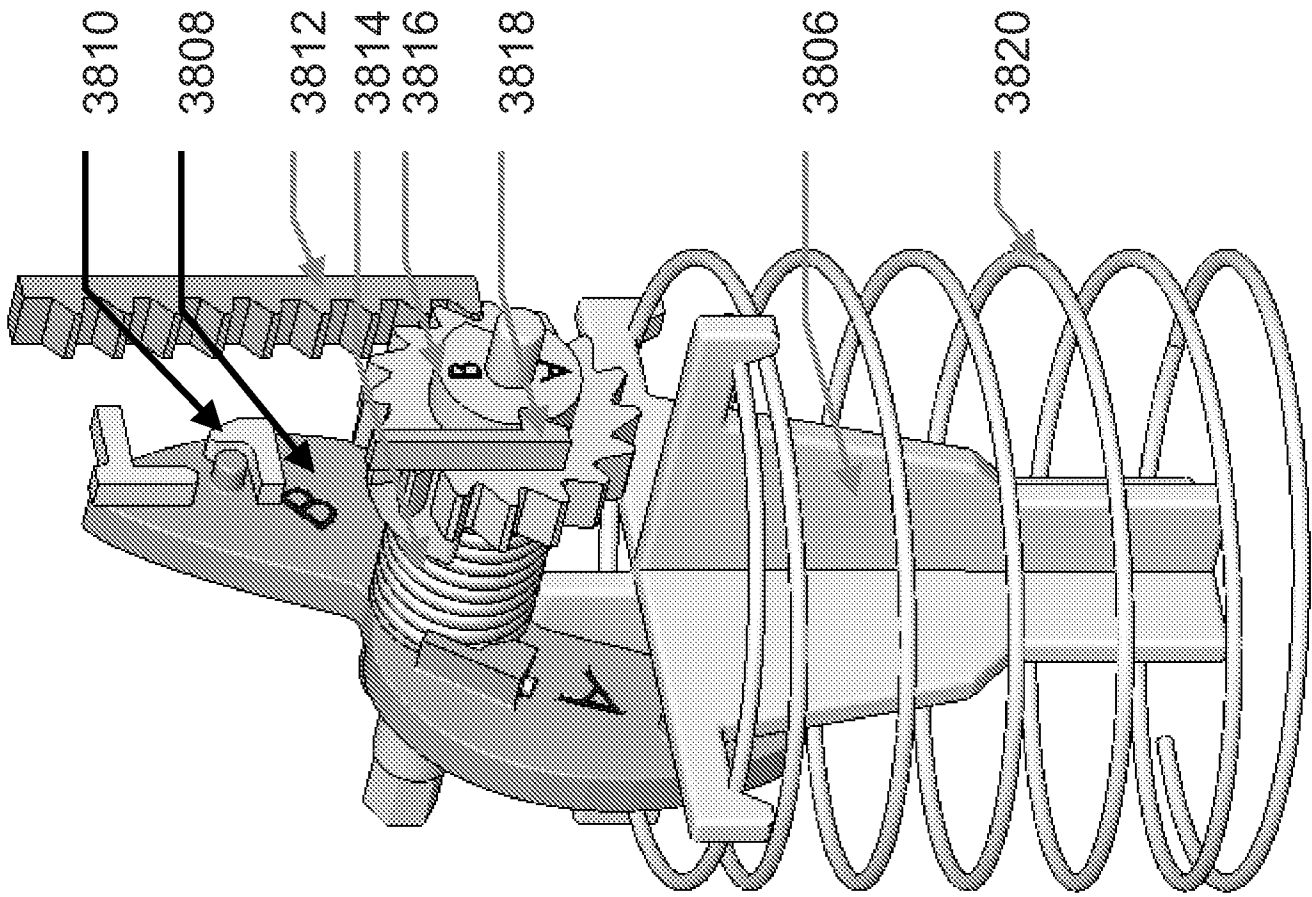


FIGURE 92J

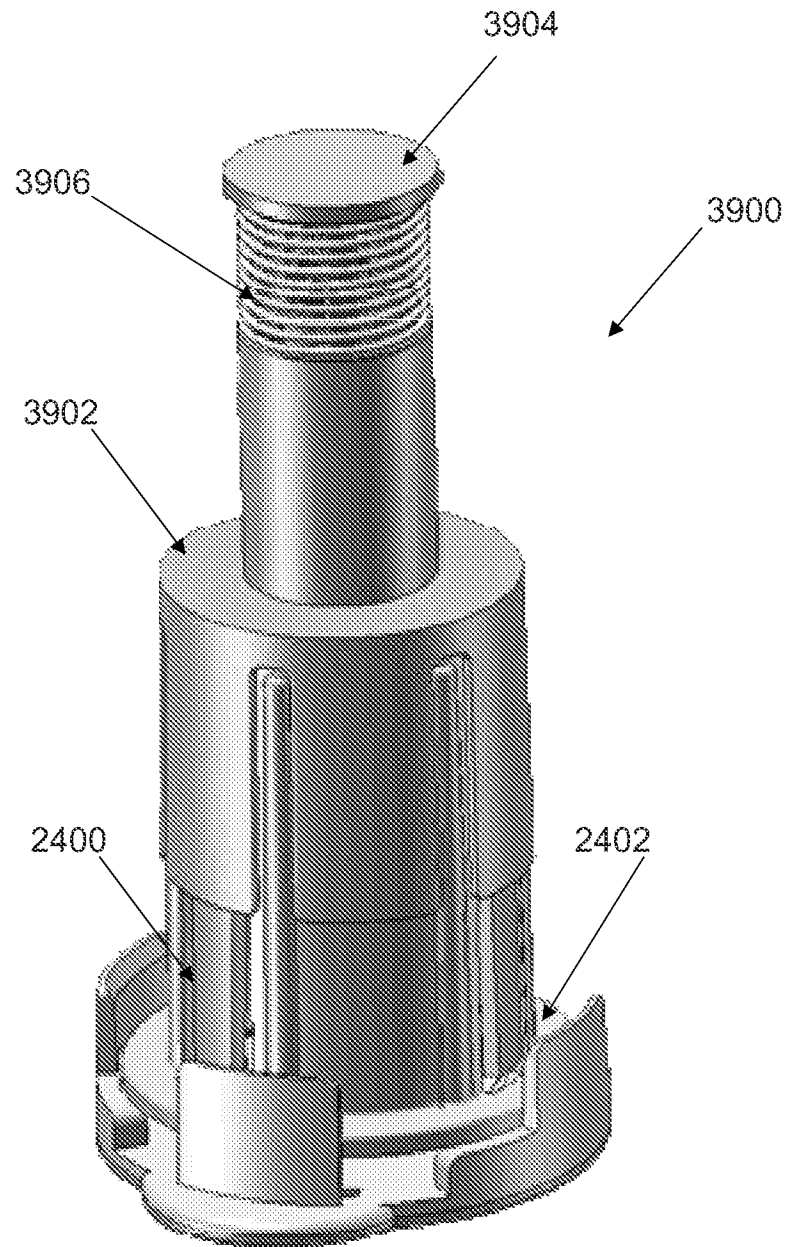


FIG. 93

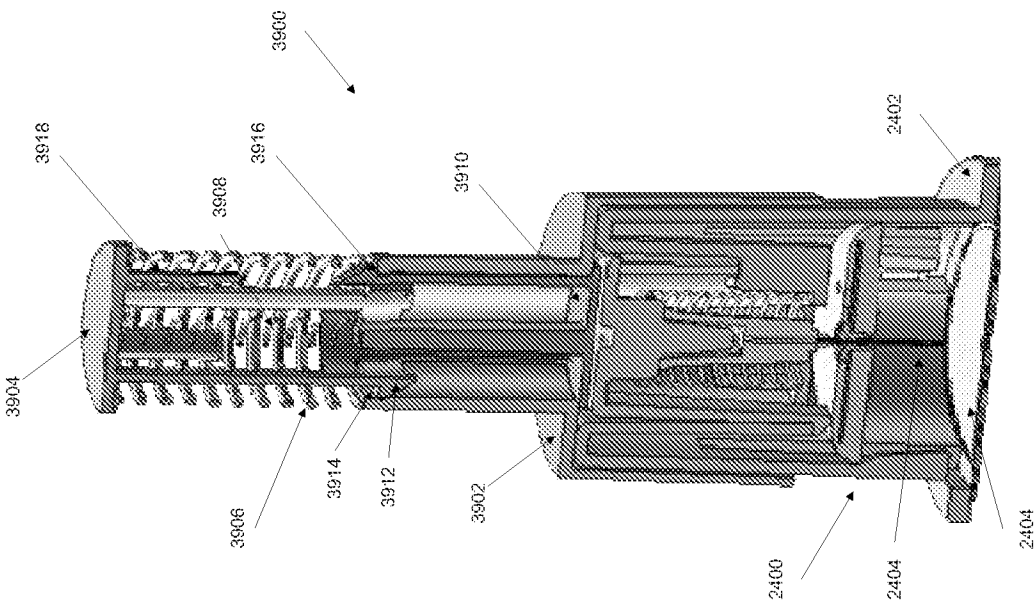


FIG. 93A

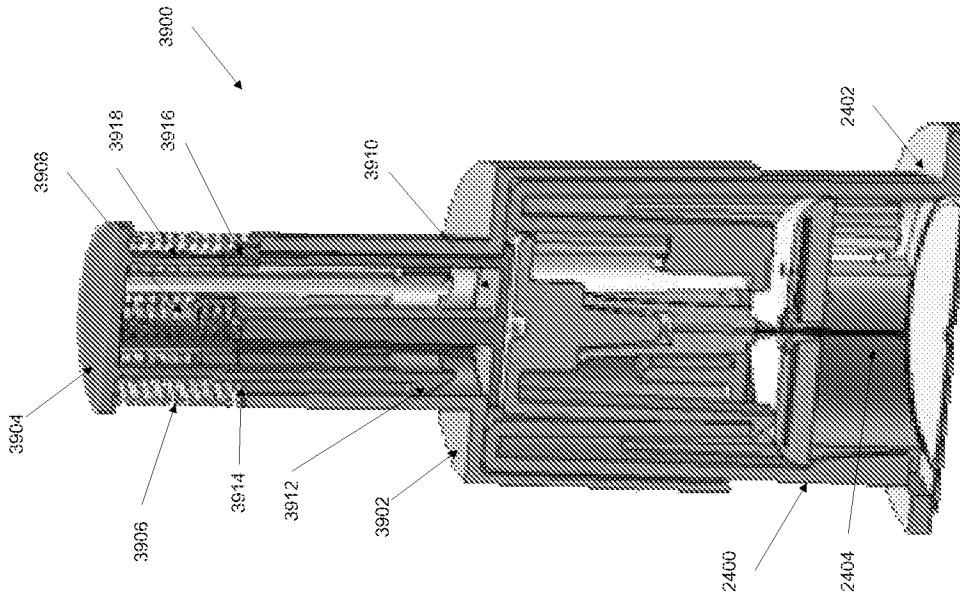


FIG. 93B

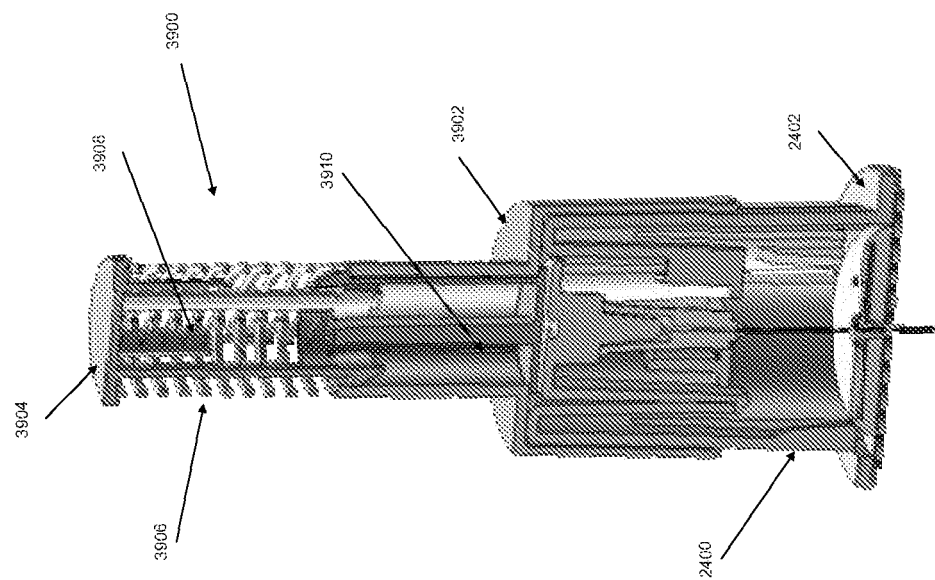


FIG. 93D

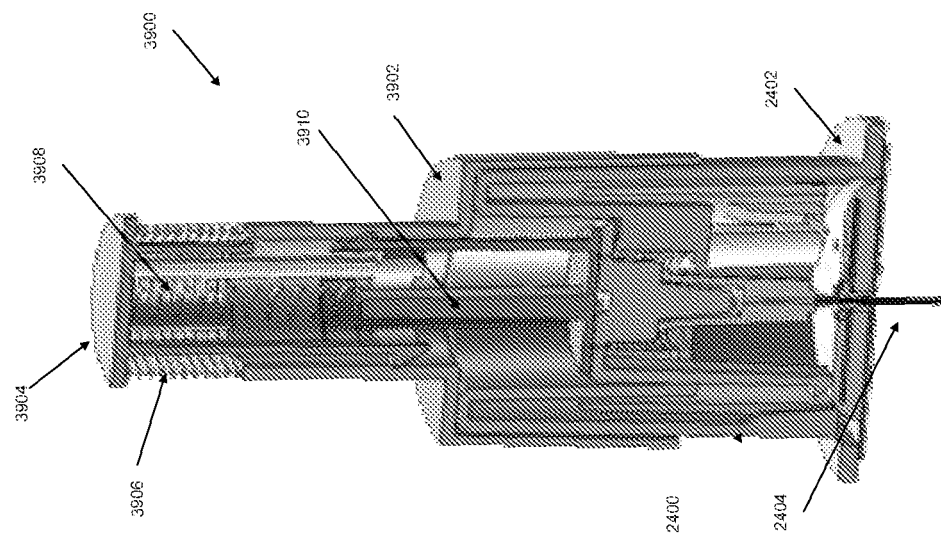


FIG. 93C

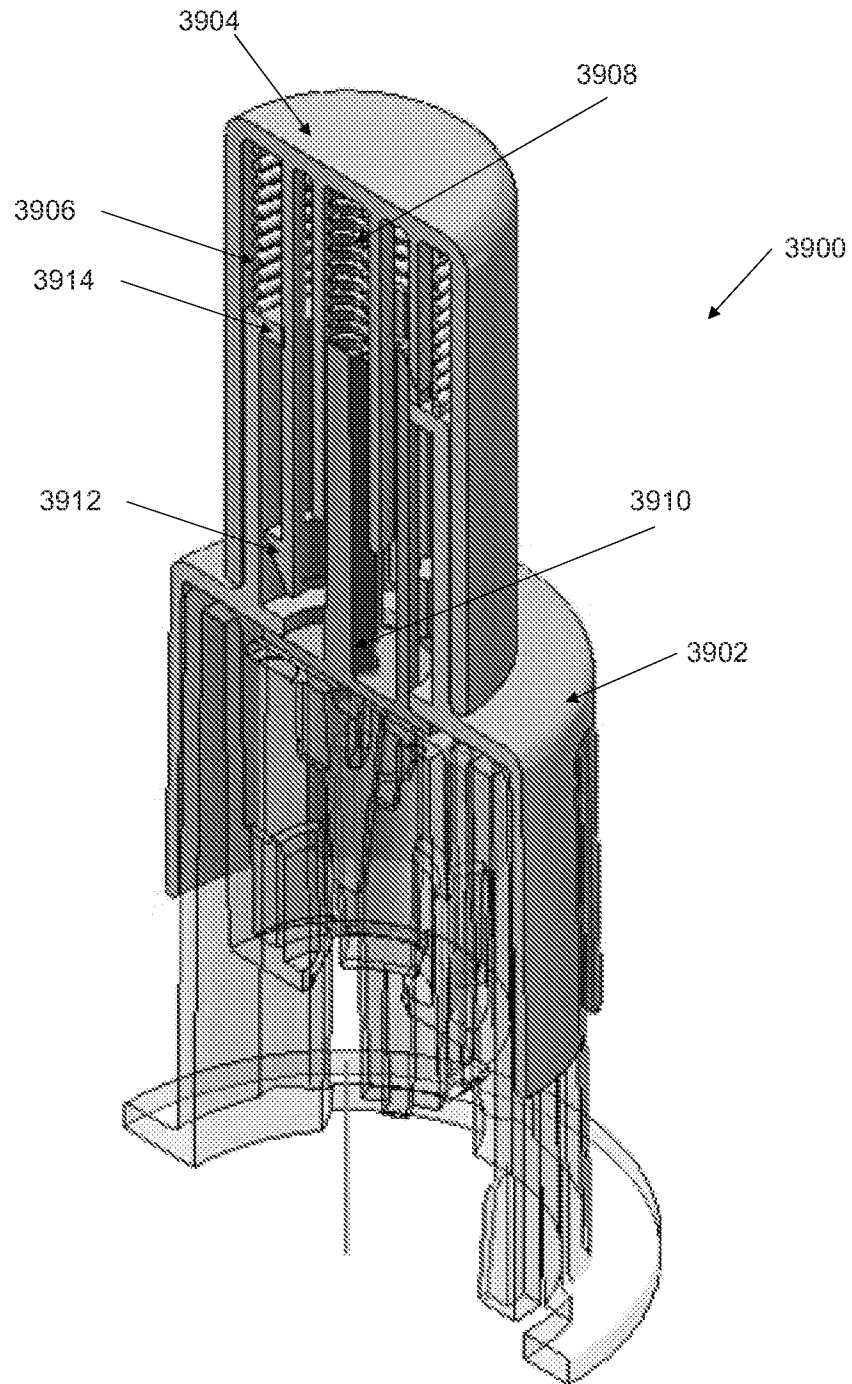


FIG. 93E

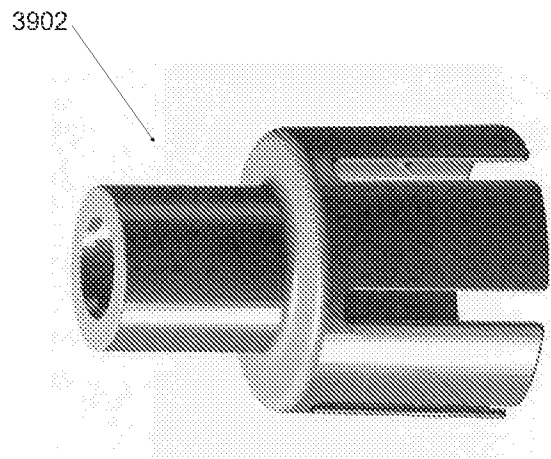


FIG. 93F

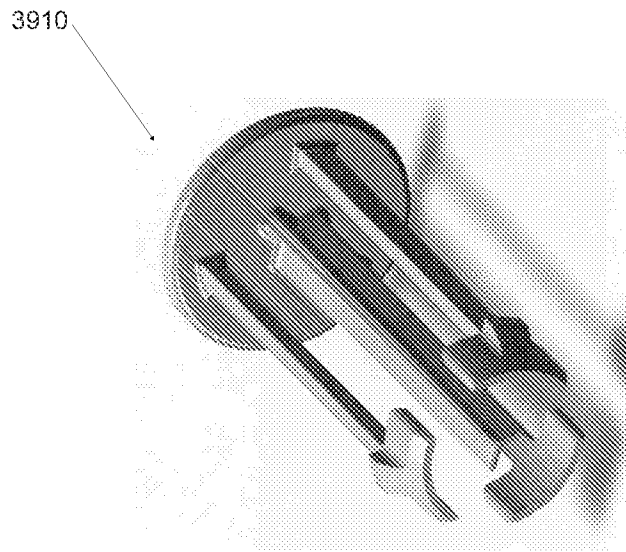


FIG. 93G

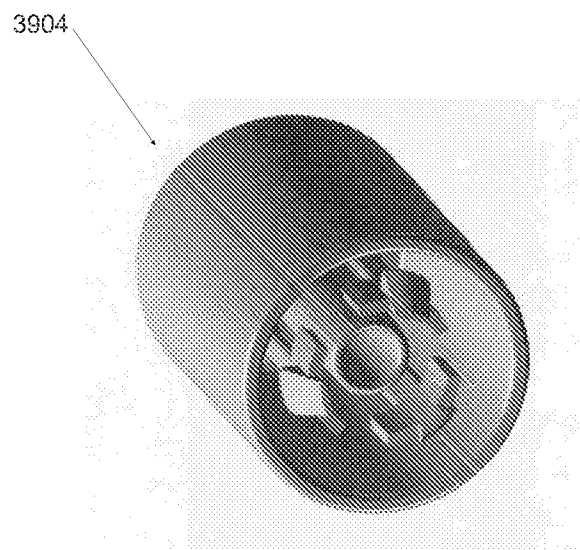


FIG. 93H

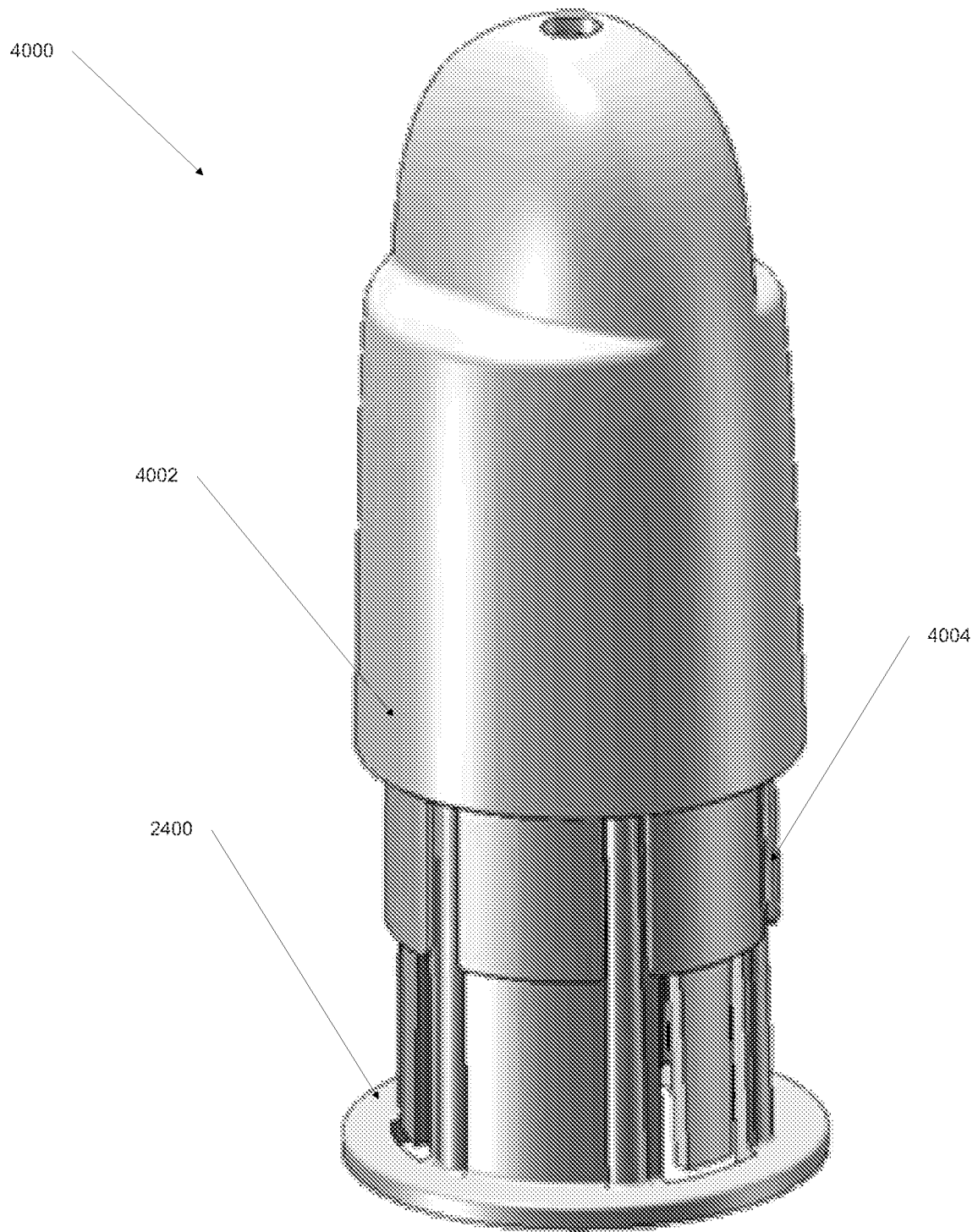


FIG. 94

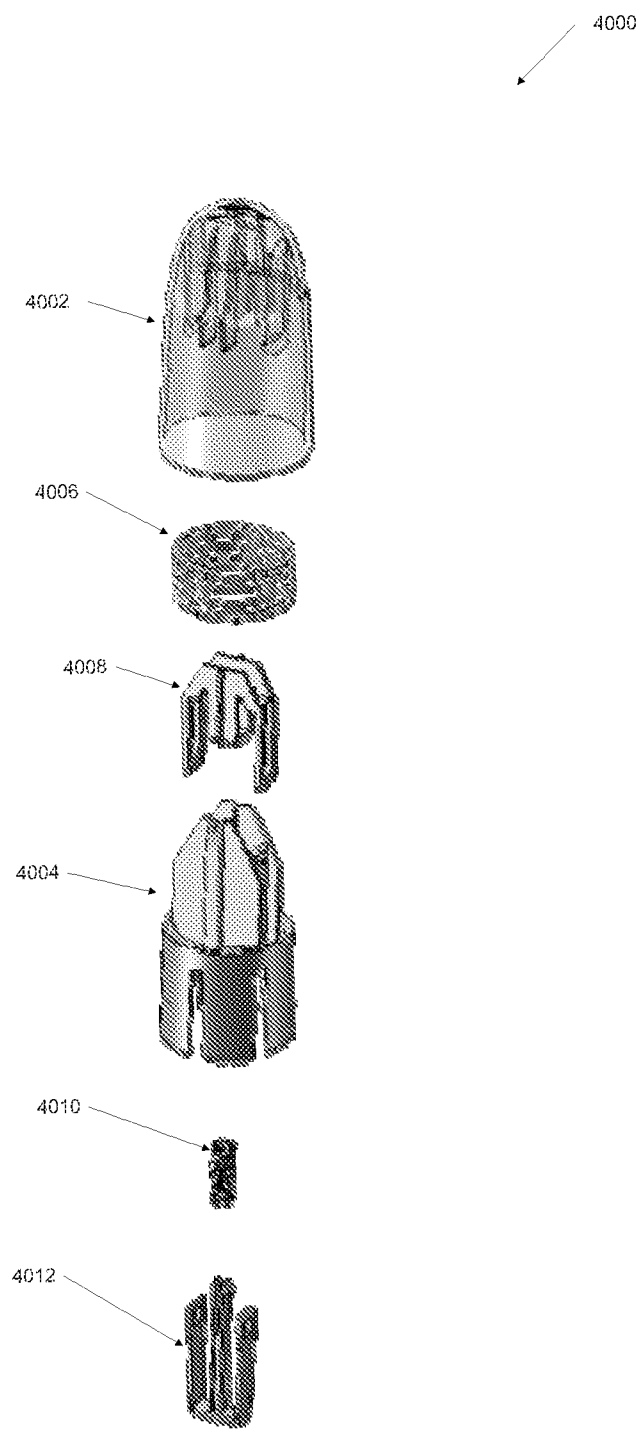


FIG. 94A

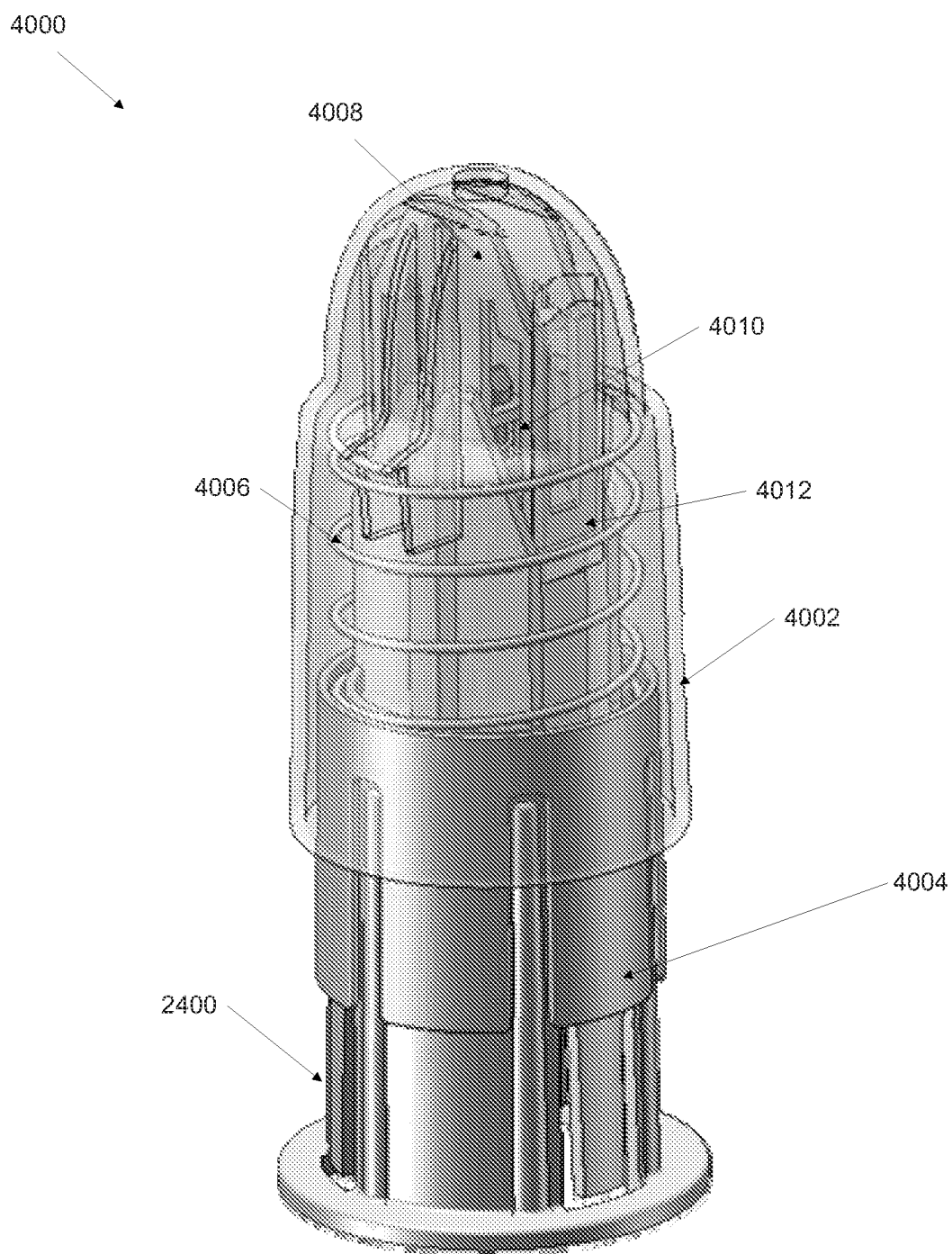


FIG. 94B

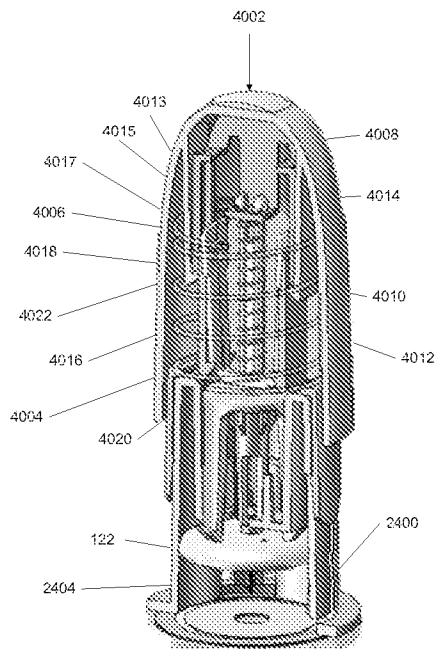


FIG. 94C

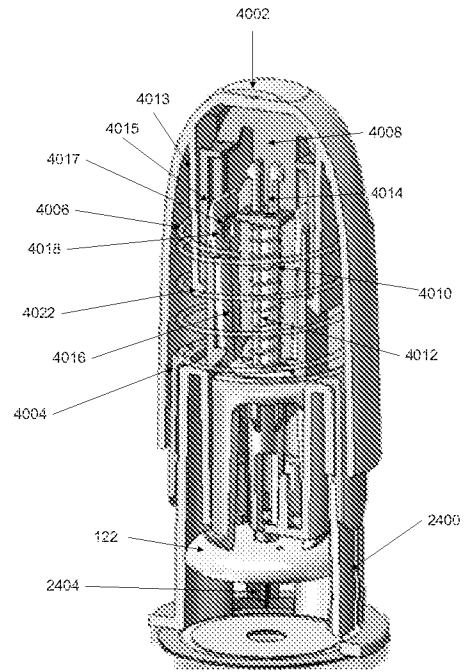


FIG. 94D

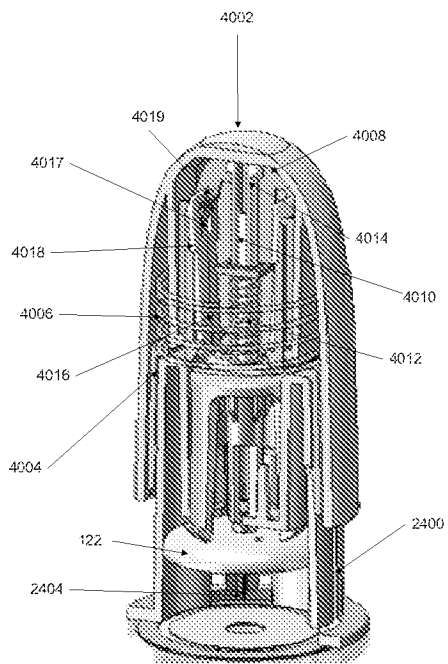


FIG. 94E

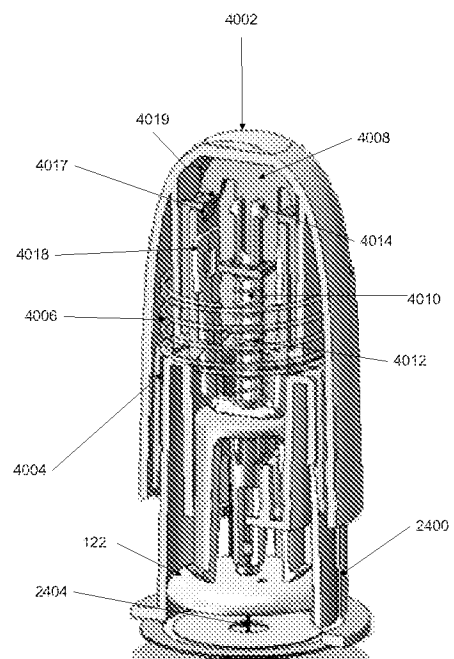


FIG. 94F

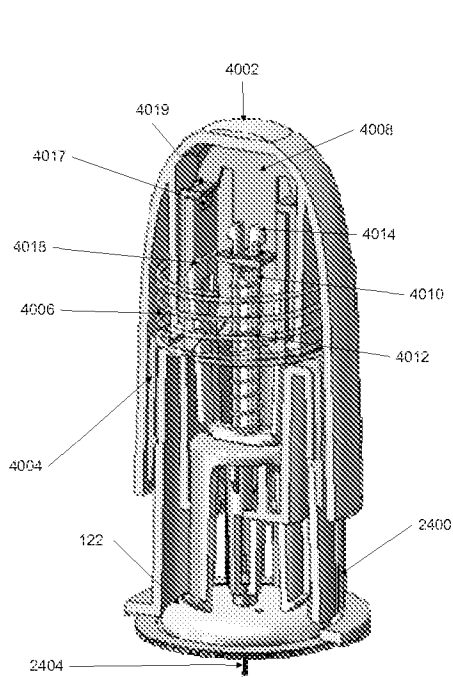


FIG. 94G

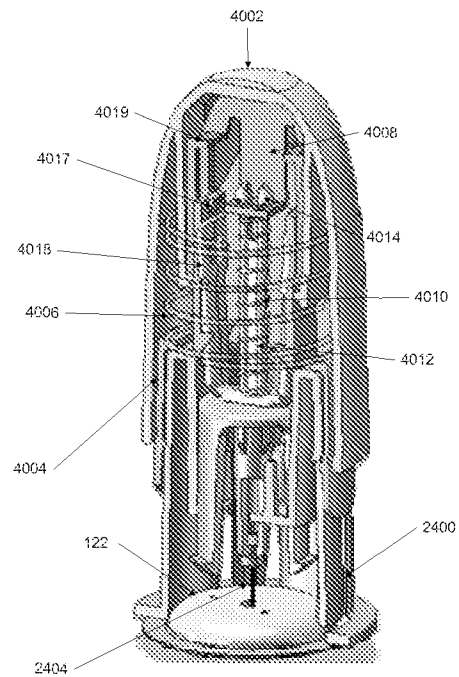


FIG. 94H

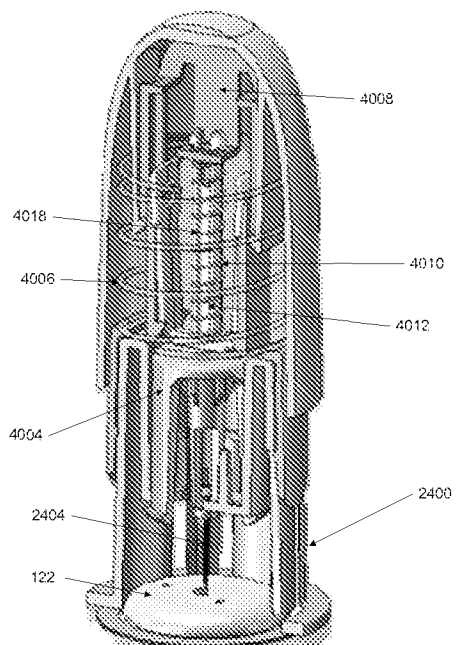


FIG. 94I

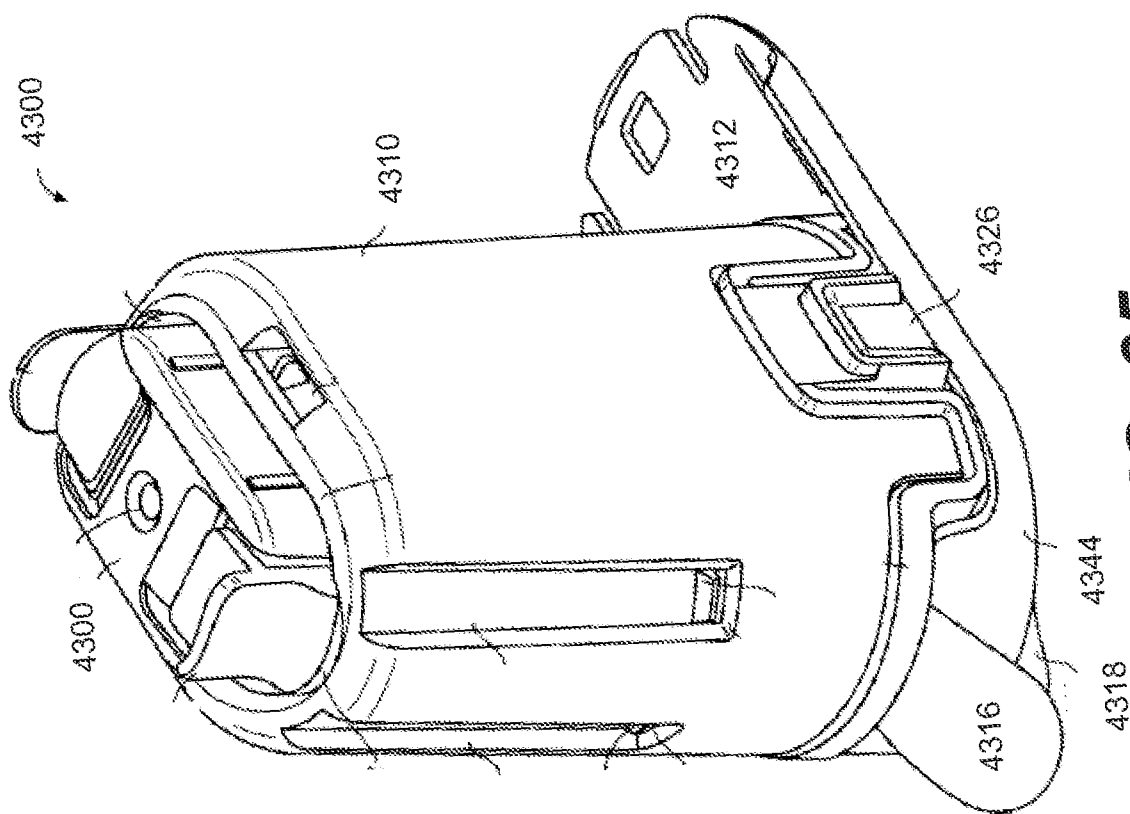


FIG. 95

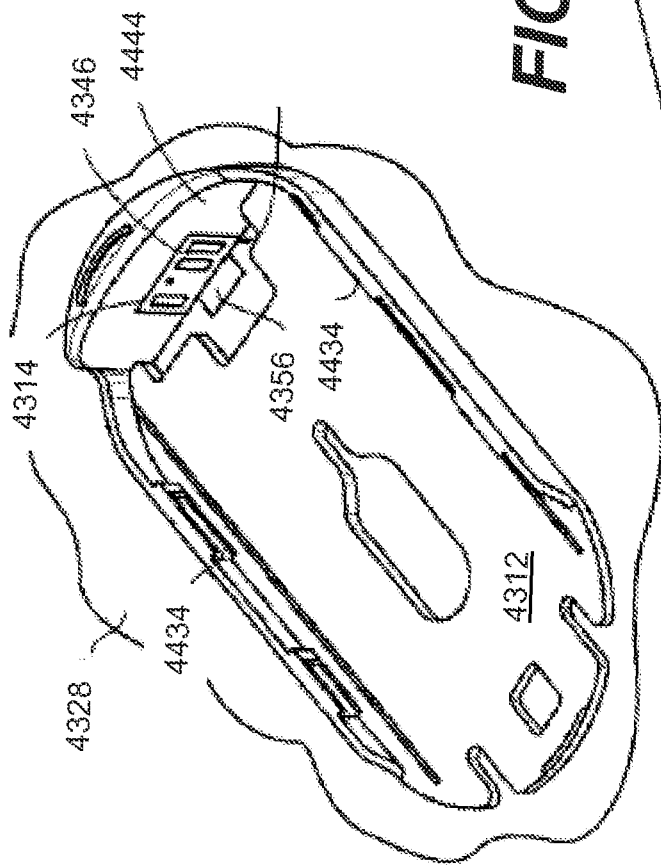


FIG. 96

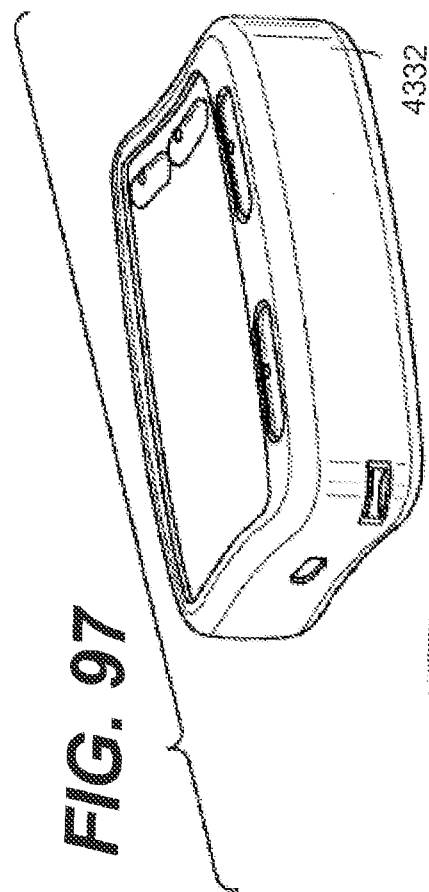
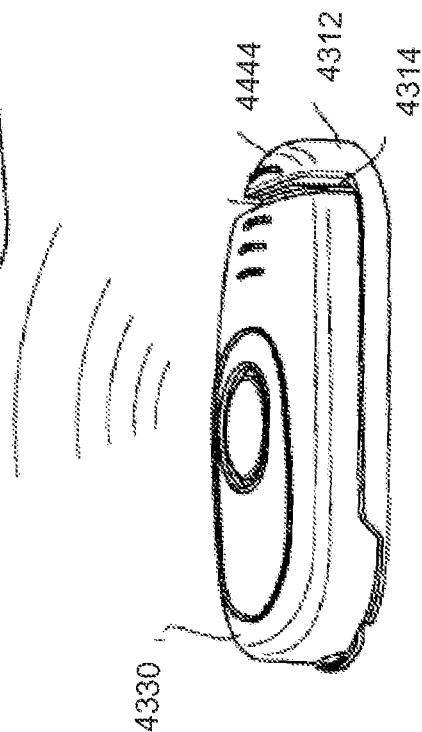


FIG. 97



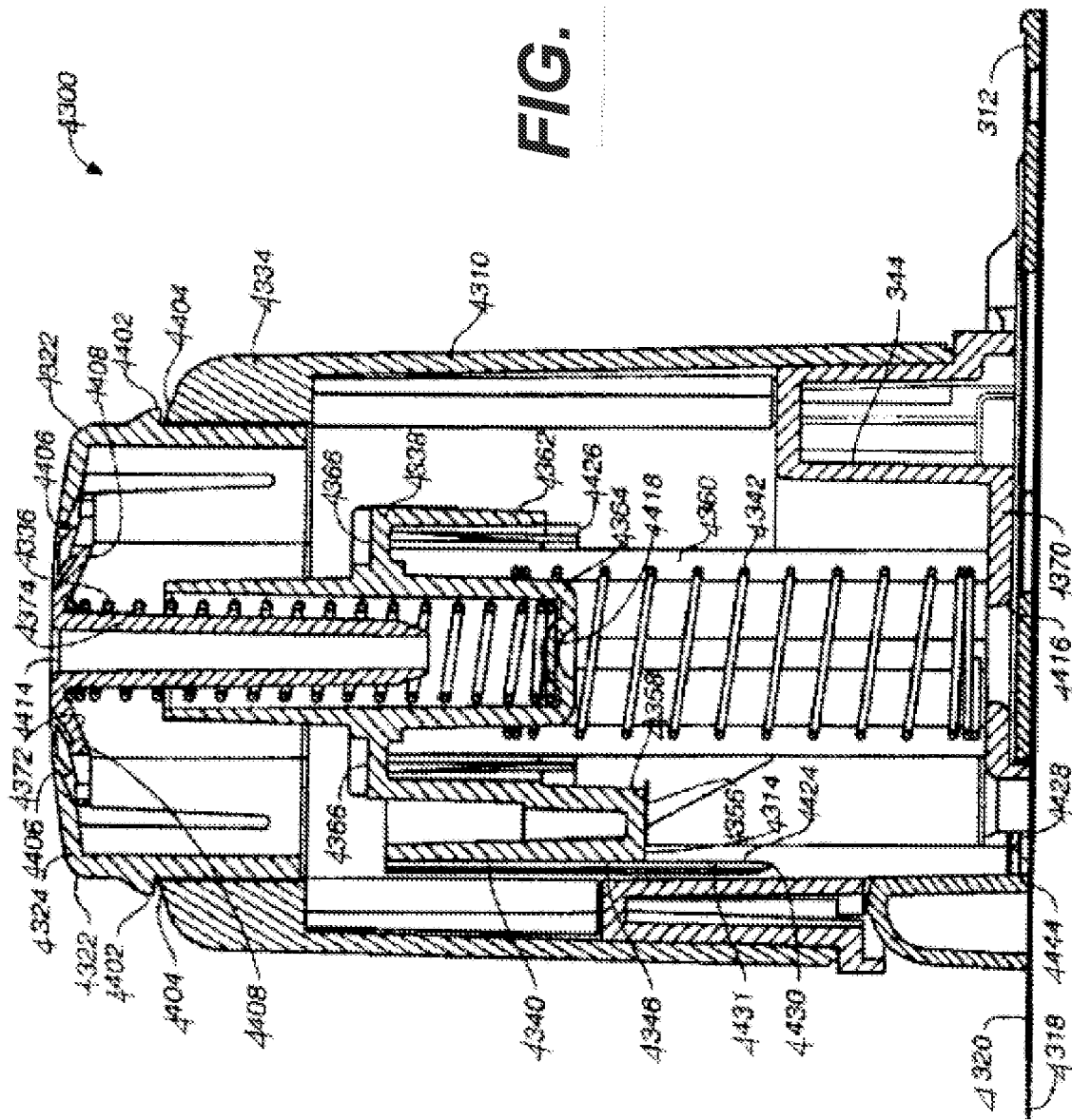


FIG. 99

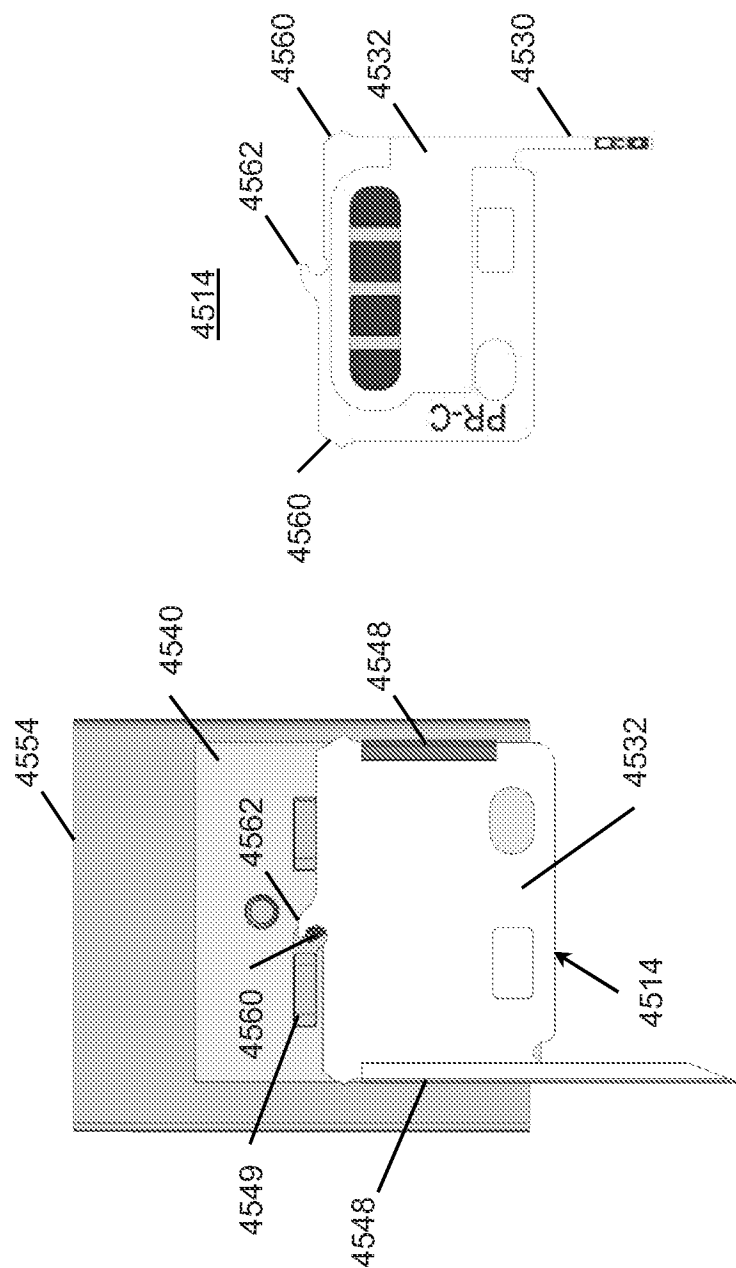


FIG. 101

FIG. 100

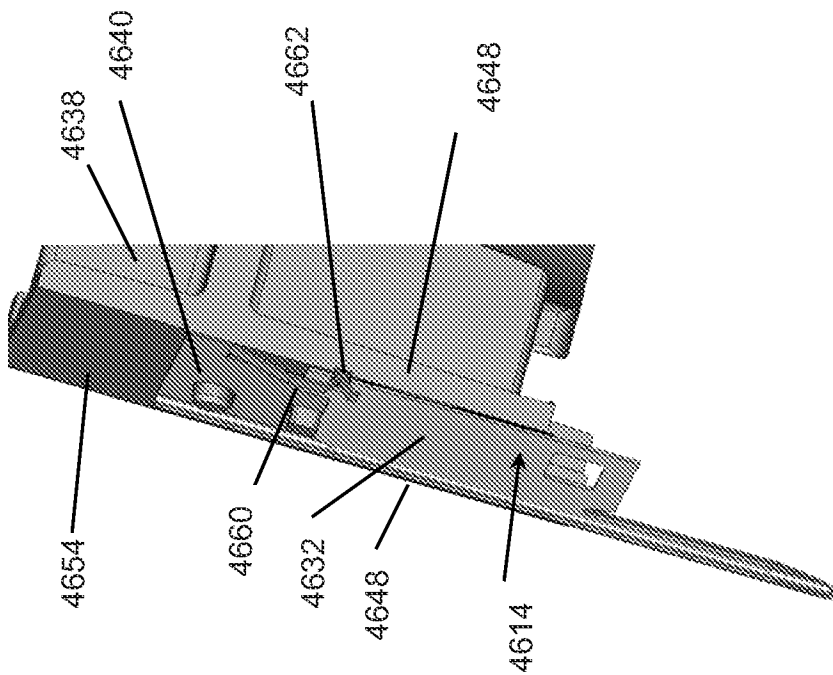


FIG. 103

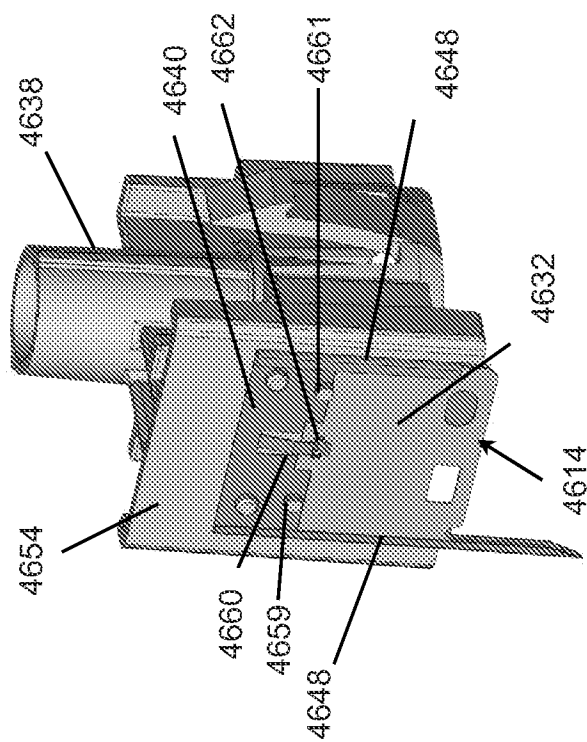


FIG. 102

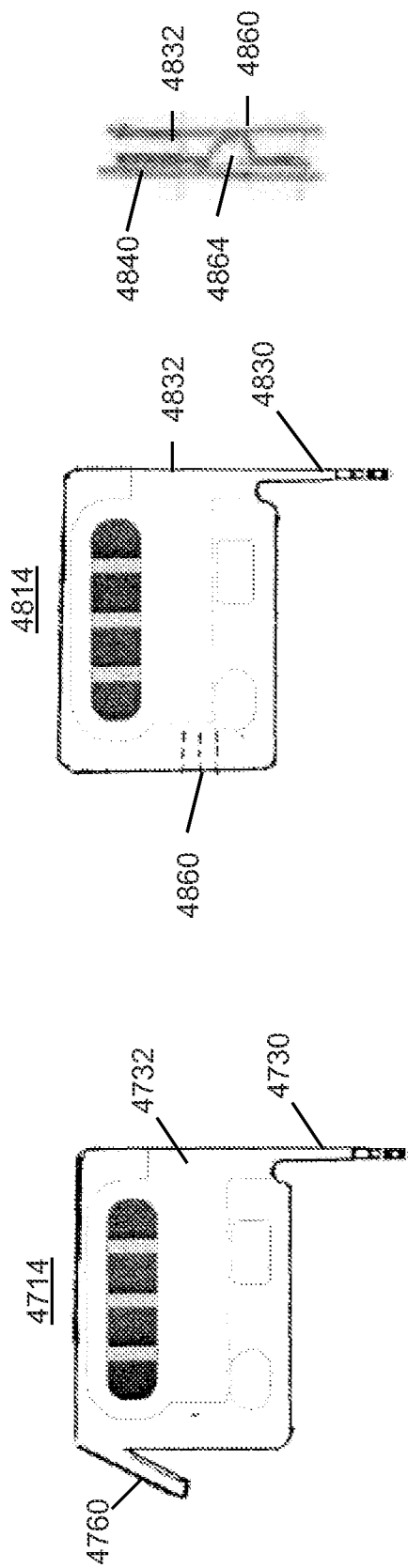


FIG. 104

FIG. 105

FIG. 106

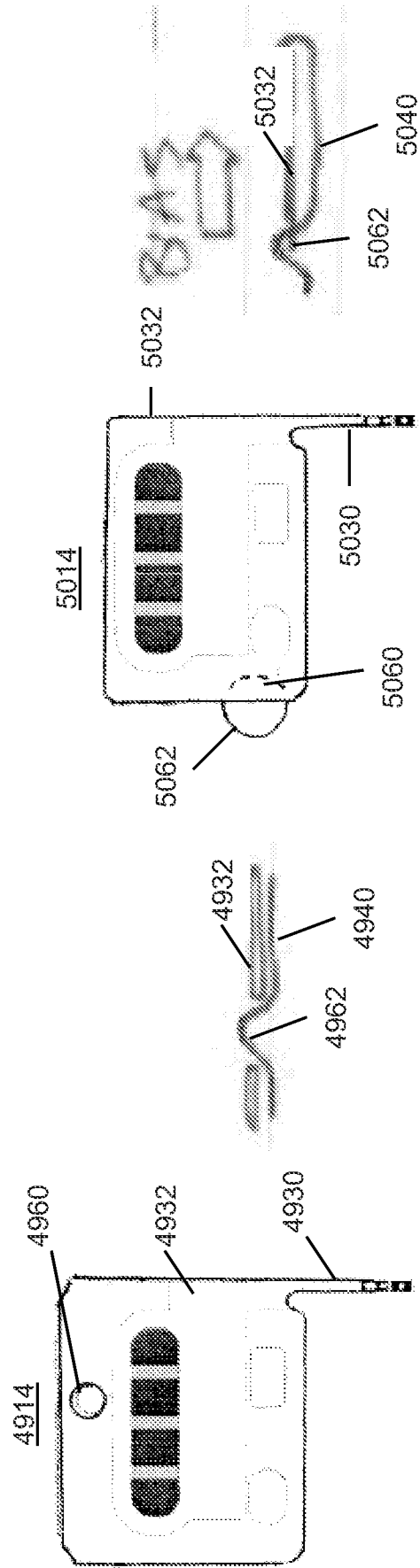


FIG. 107

FIG. 108

FIG. 109

FIG. 110

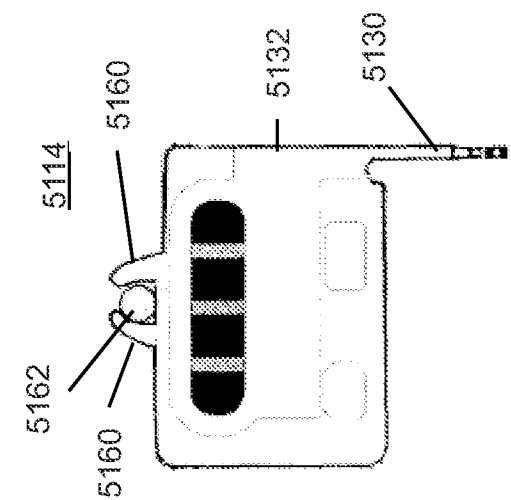


FIG. 111

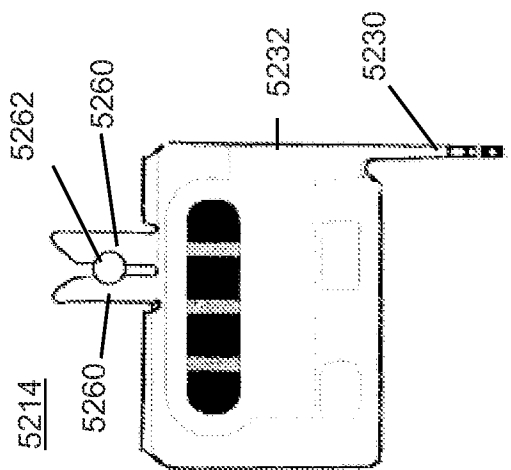


FIG. 112

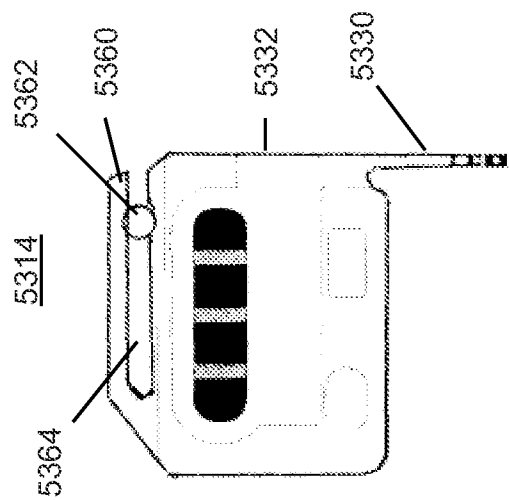


FIG. 113

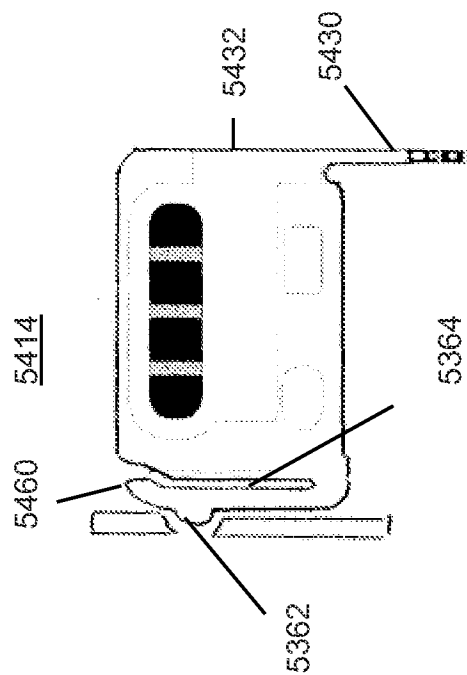


FIG. 114

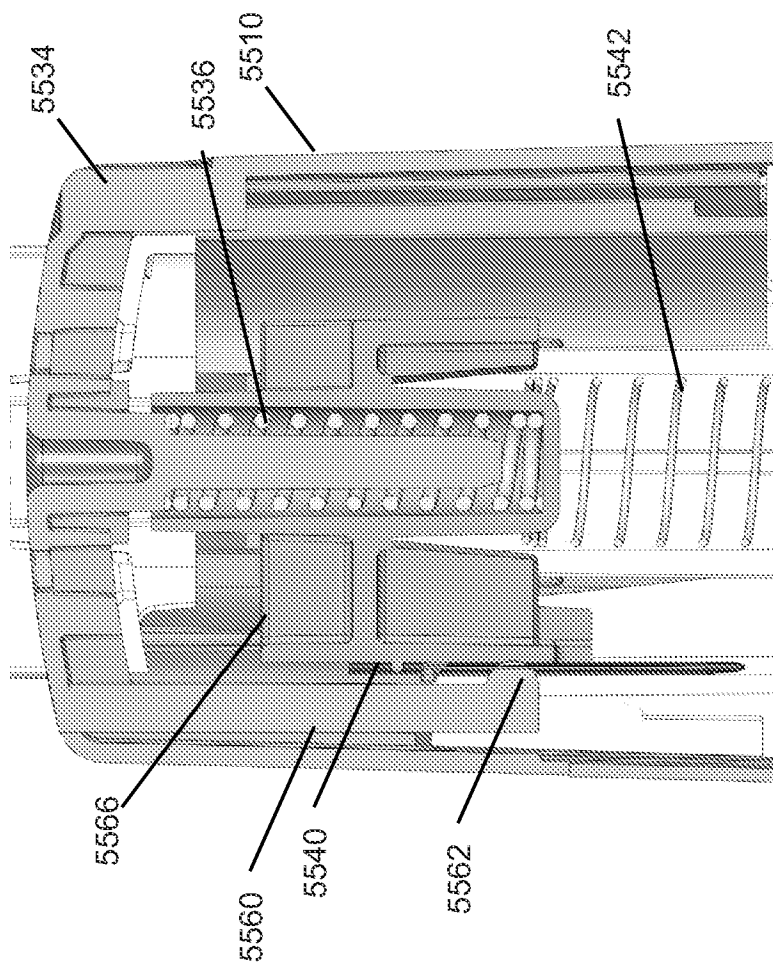


FIG. 115

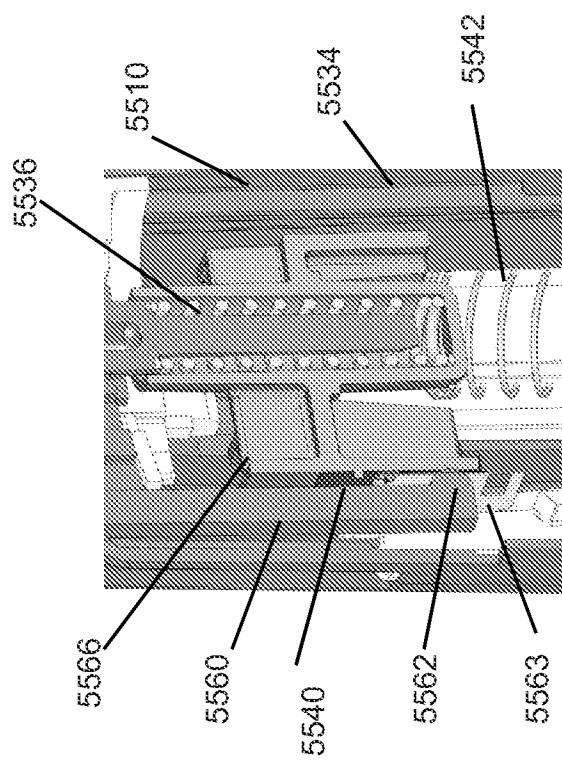


FIG. 116

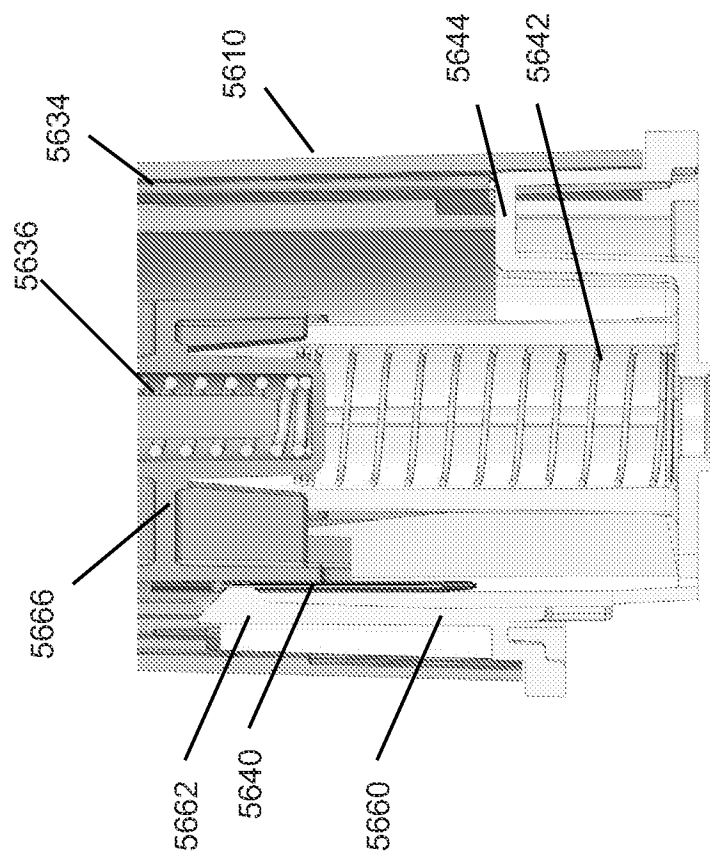


FIG. 117

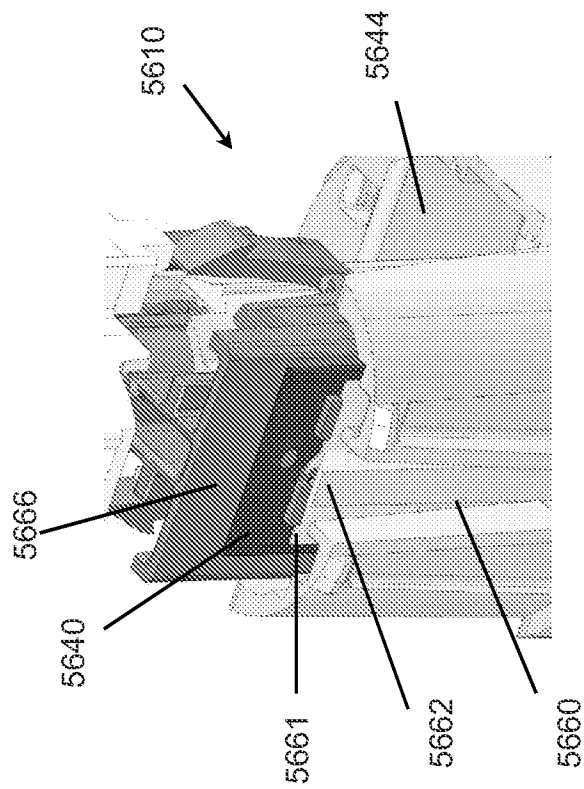


FIG. 118

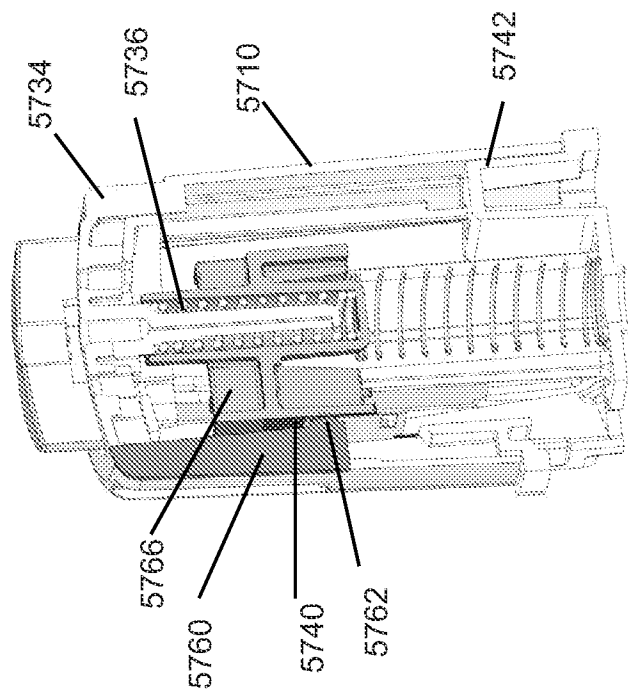


FIG. 119

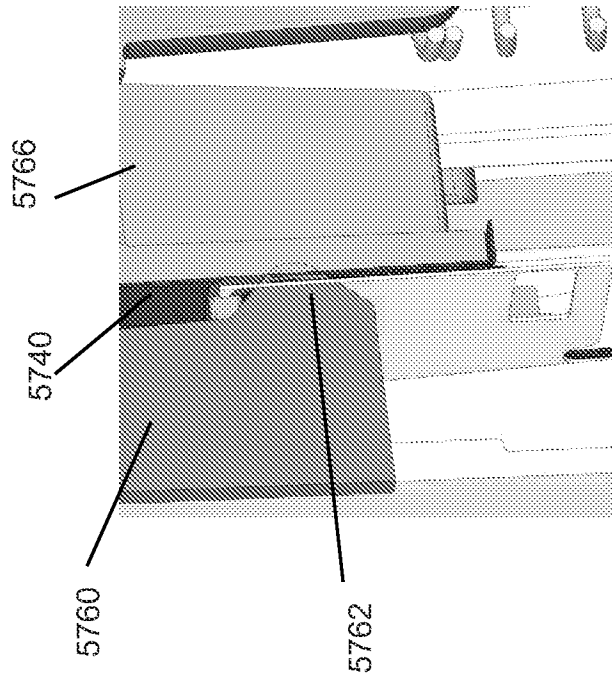


FIG. 120

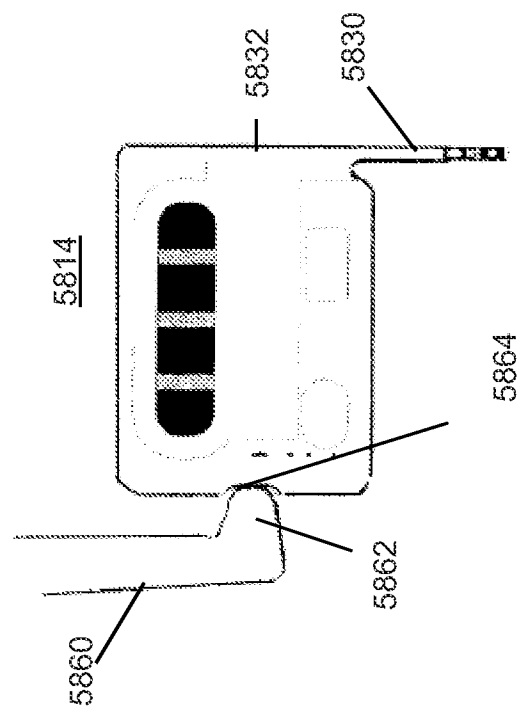


FIG. 121

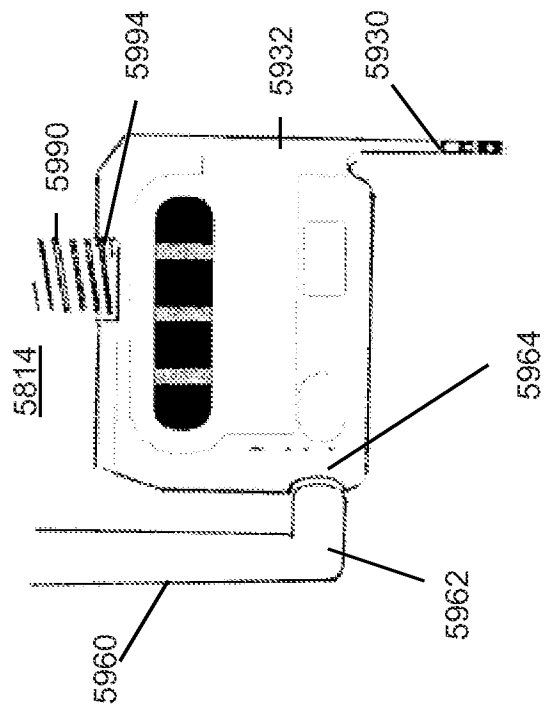


FIG. 122

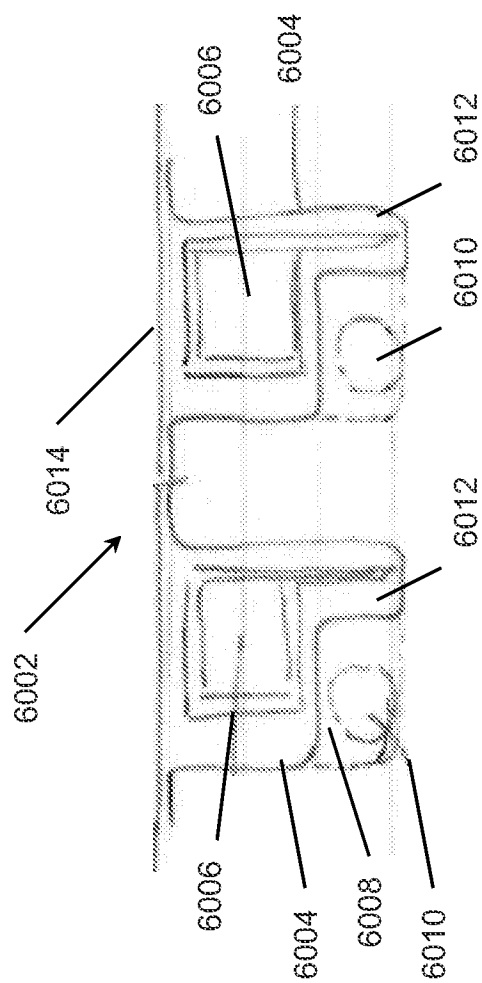


FIG. 123

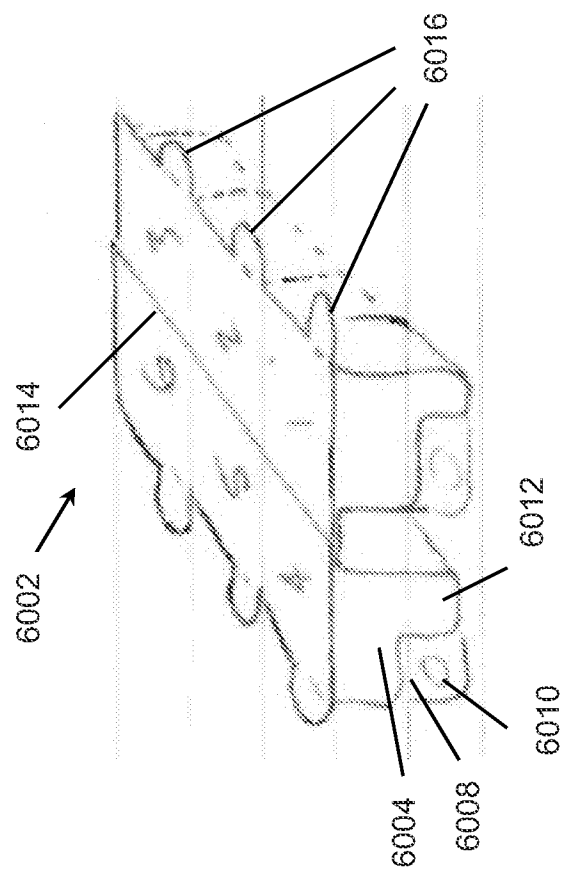


FIG. 124

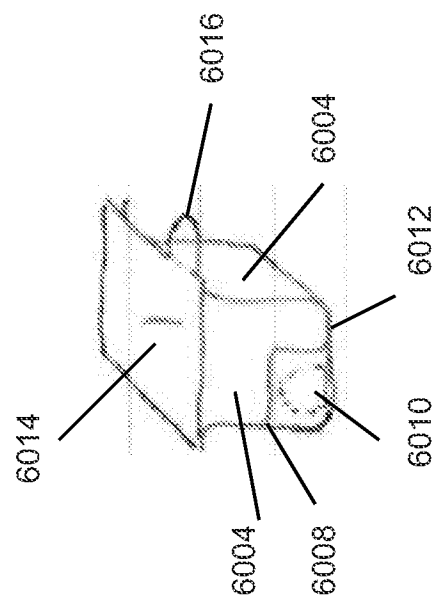


FIG. 125

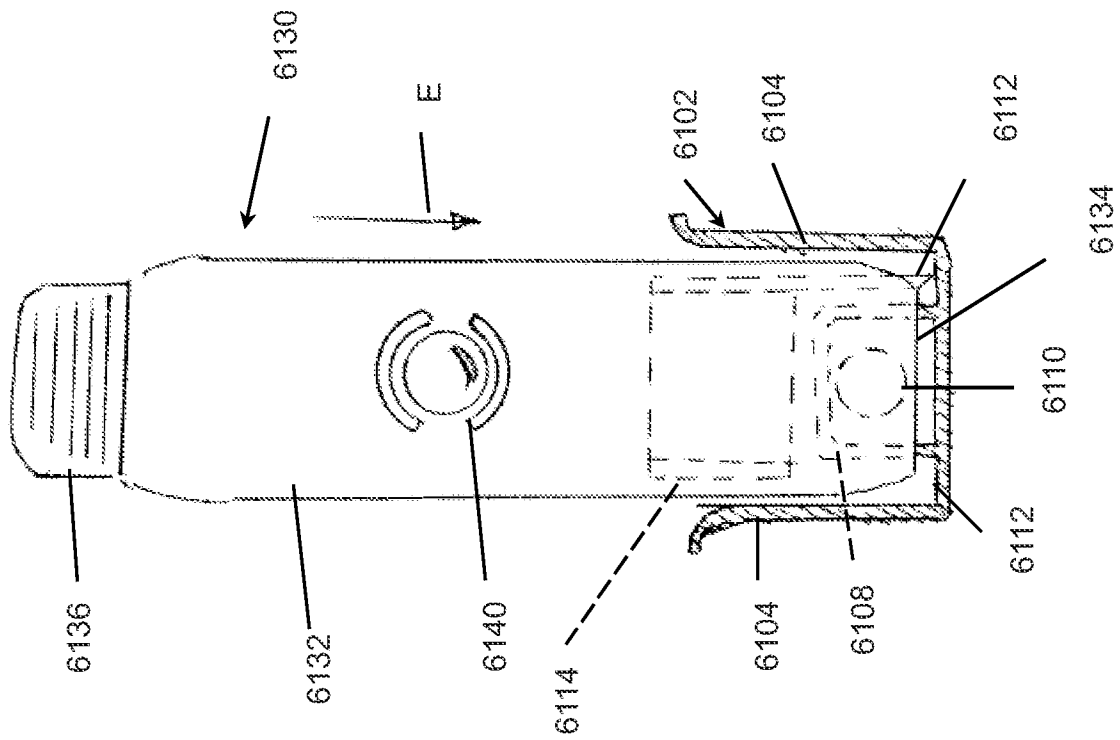


FIG. 127

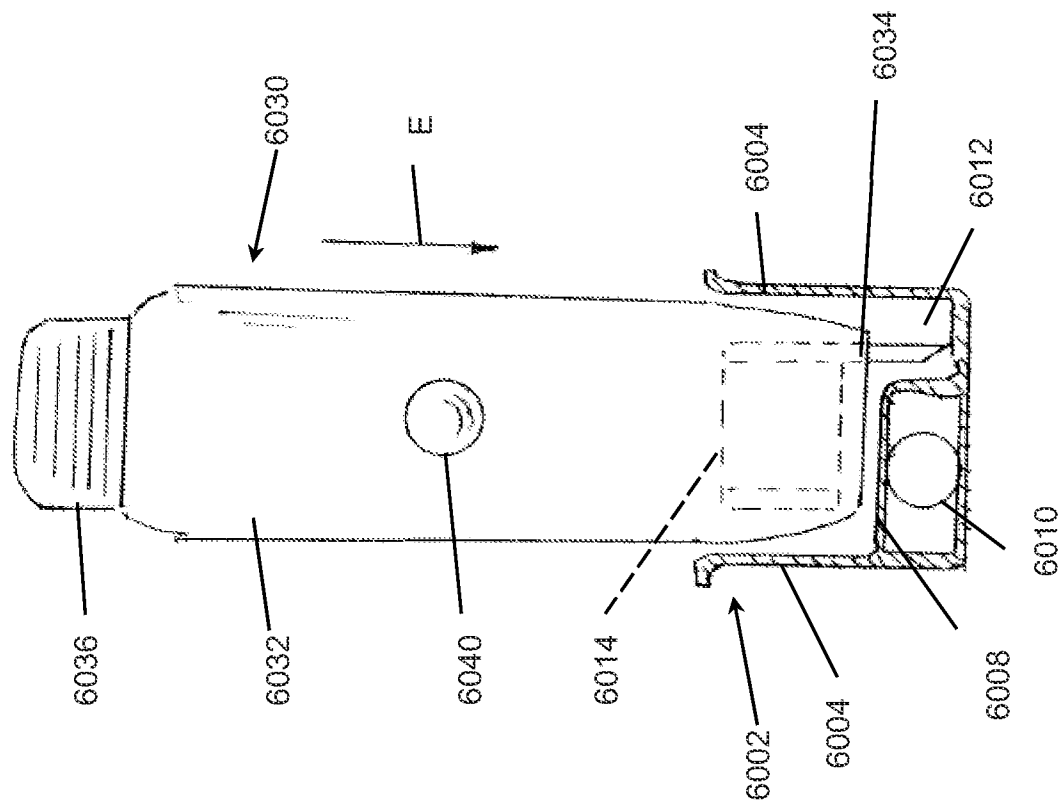


FIG. 126

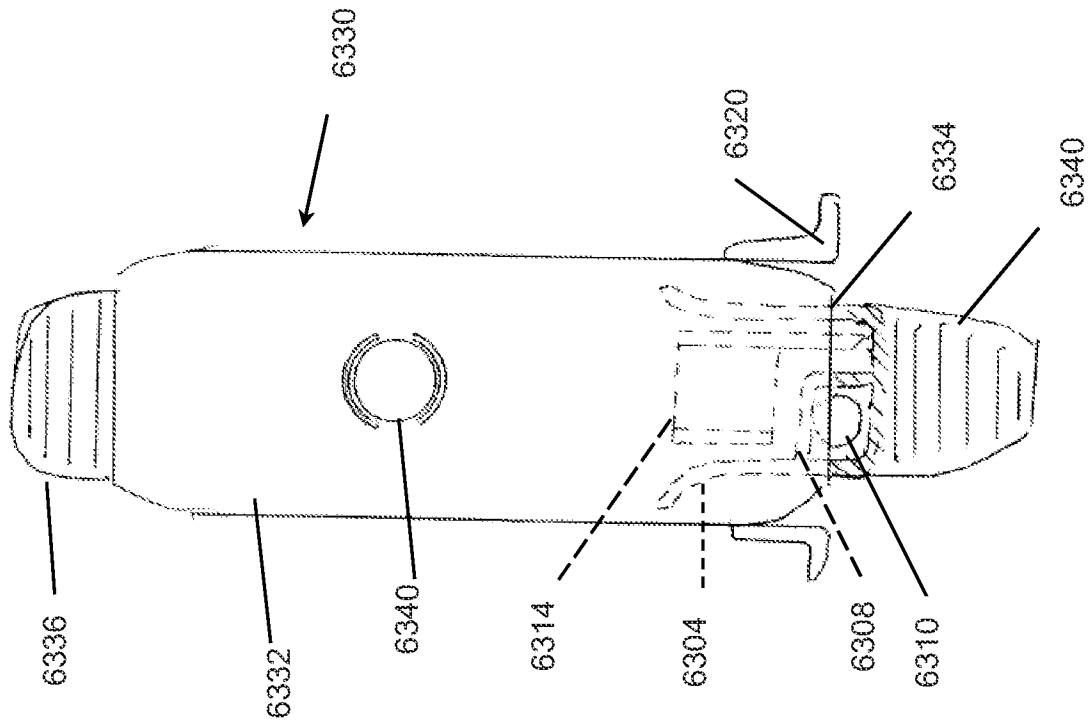


FIG. 129

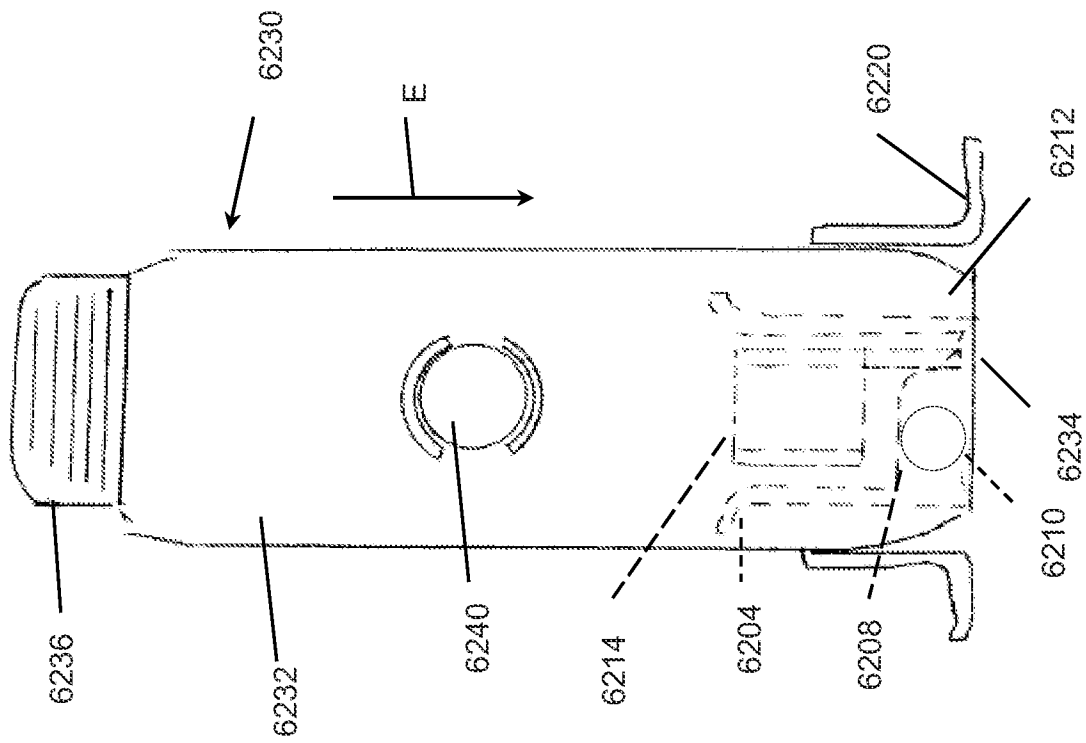


FIG. 128

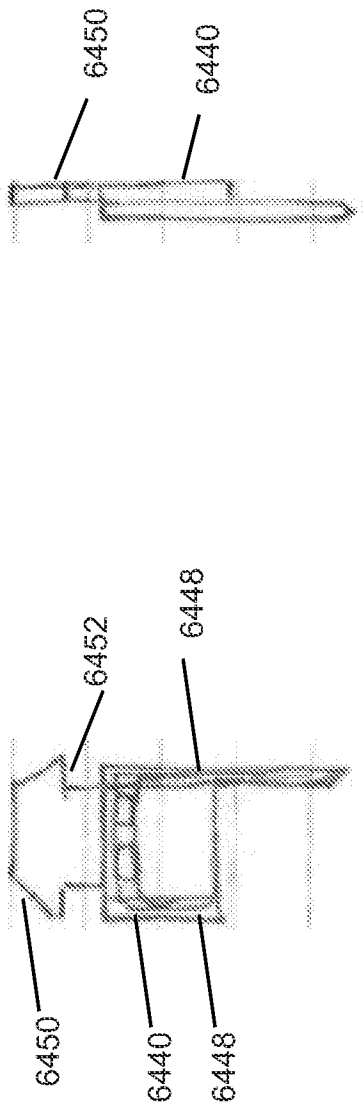


FIG. 130 **FIG. 131**

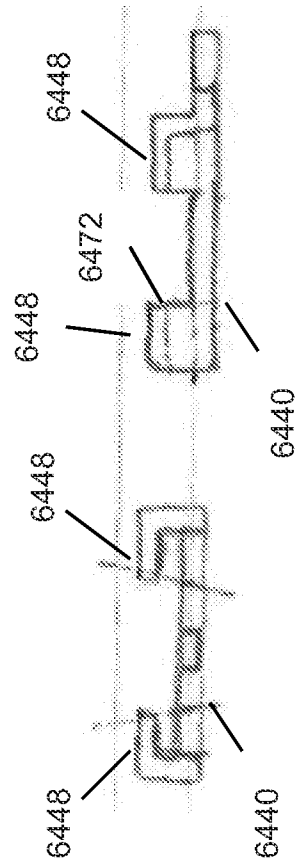


FIG. 132 **FIG. 133**

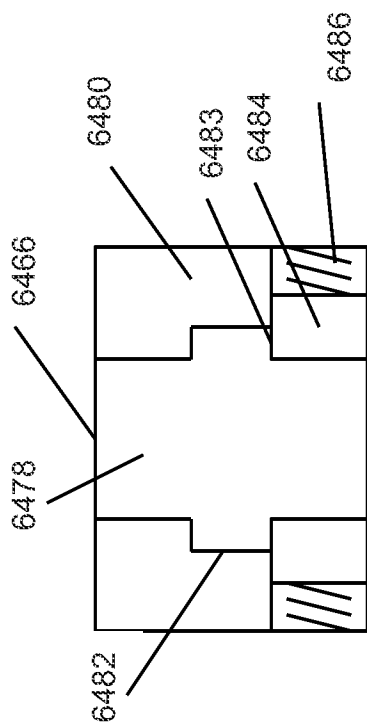


FIG. 134A

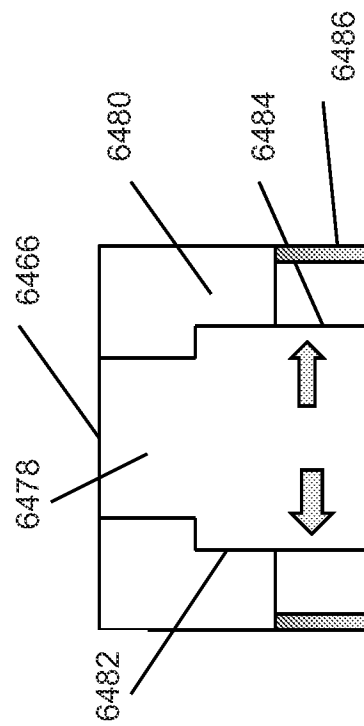


FIG. 134B

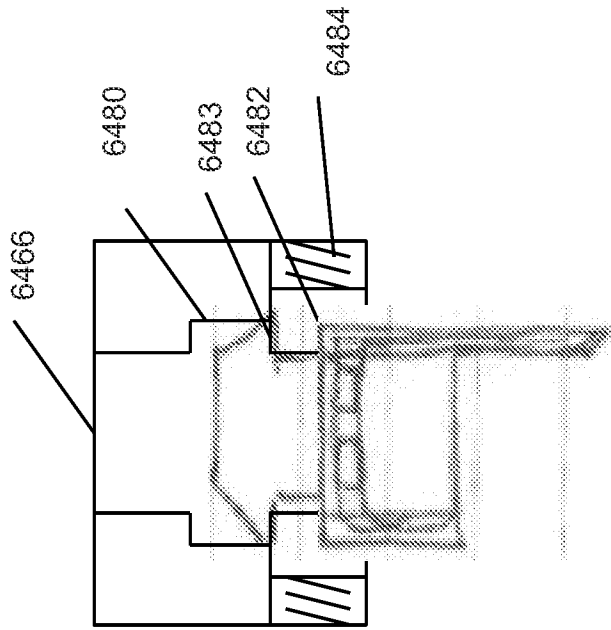


FIG. 135

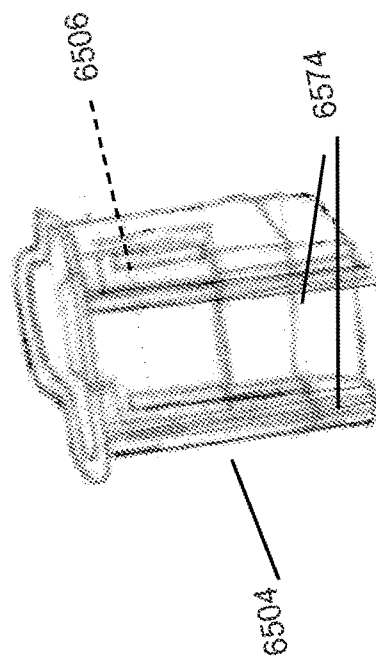
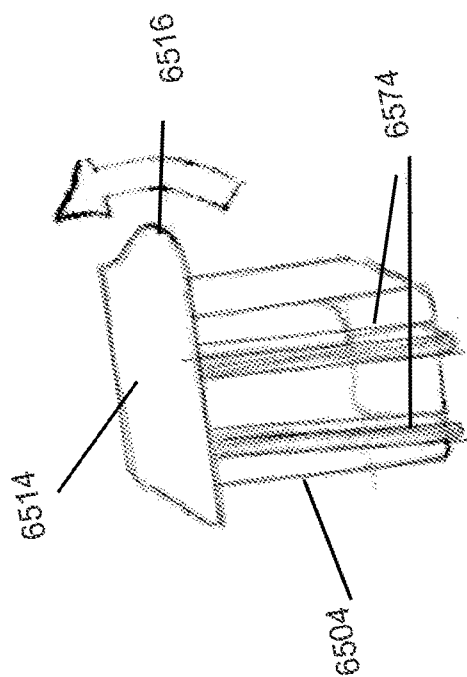
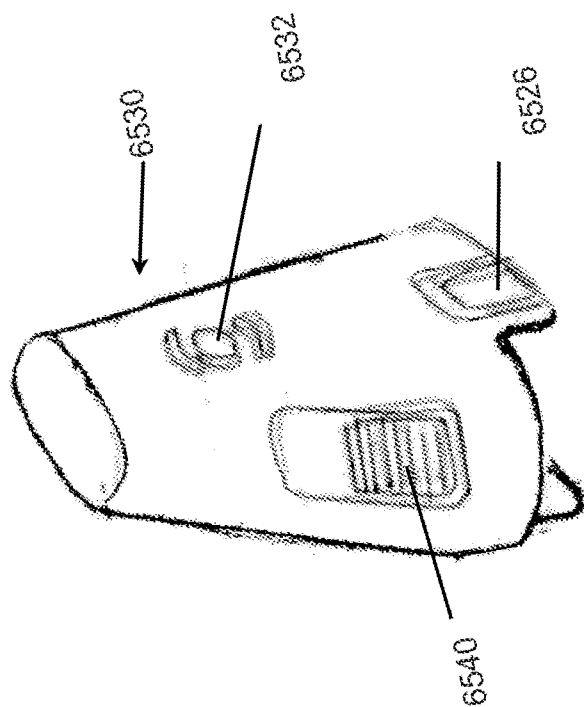


FIG. 136

FIG. 137

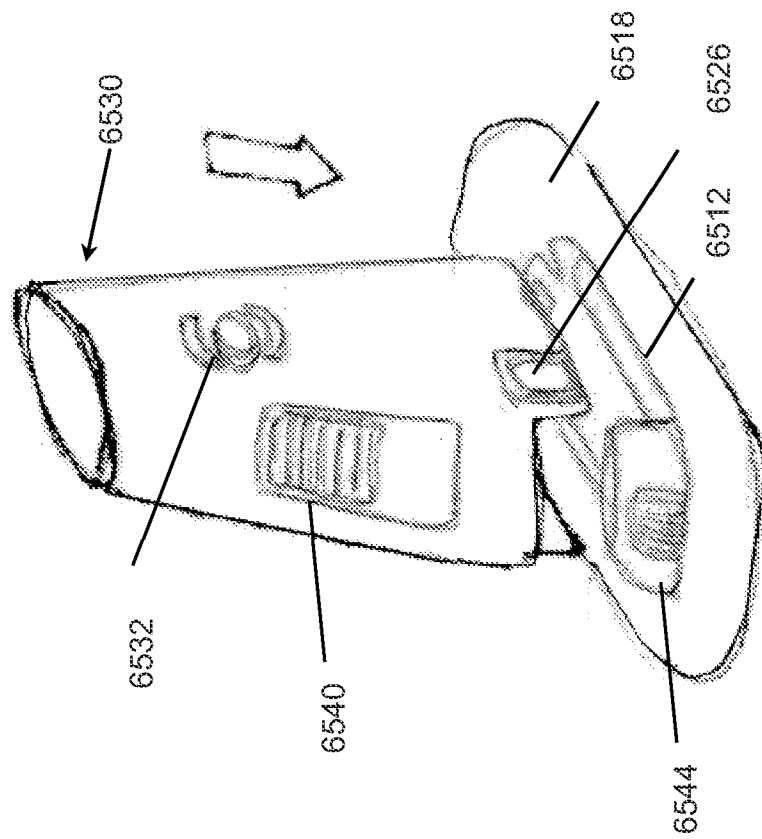


FIG. 138

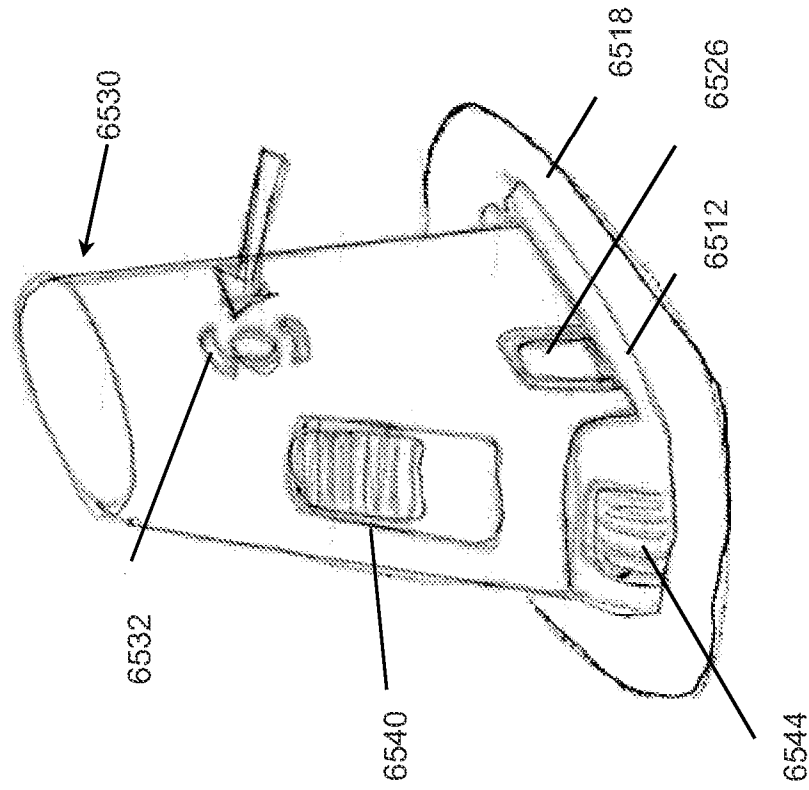


FIG. 139

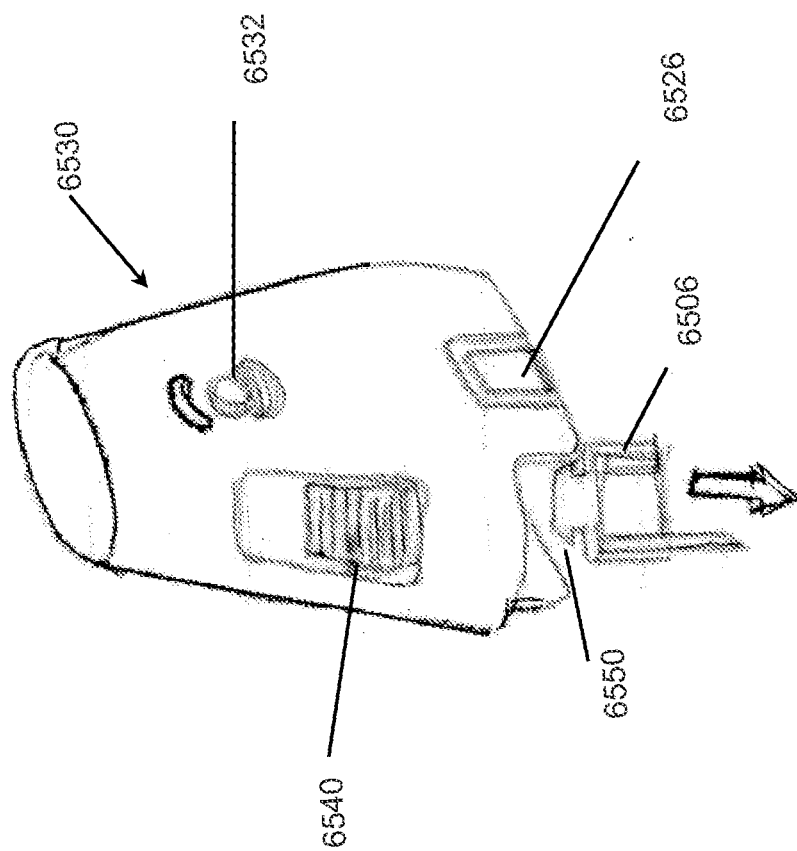


FIG. 140

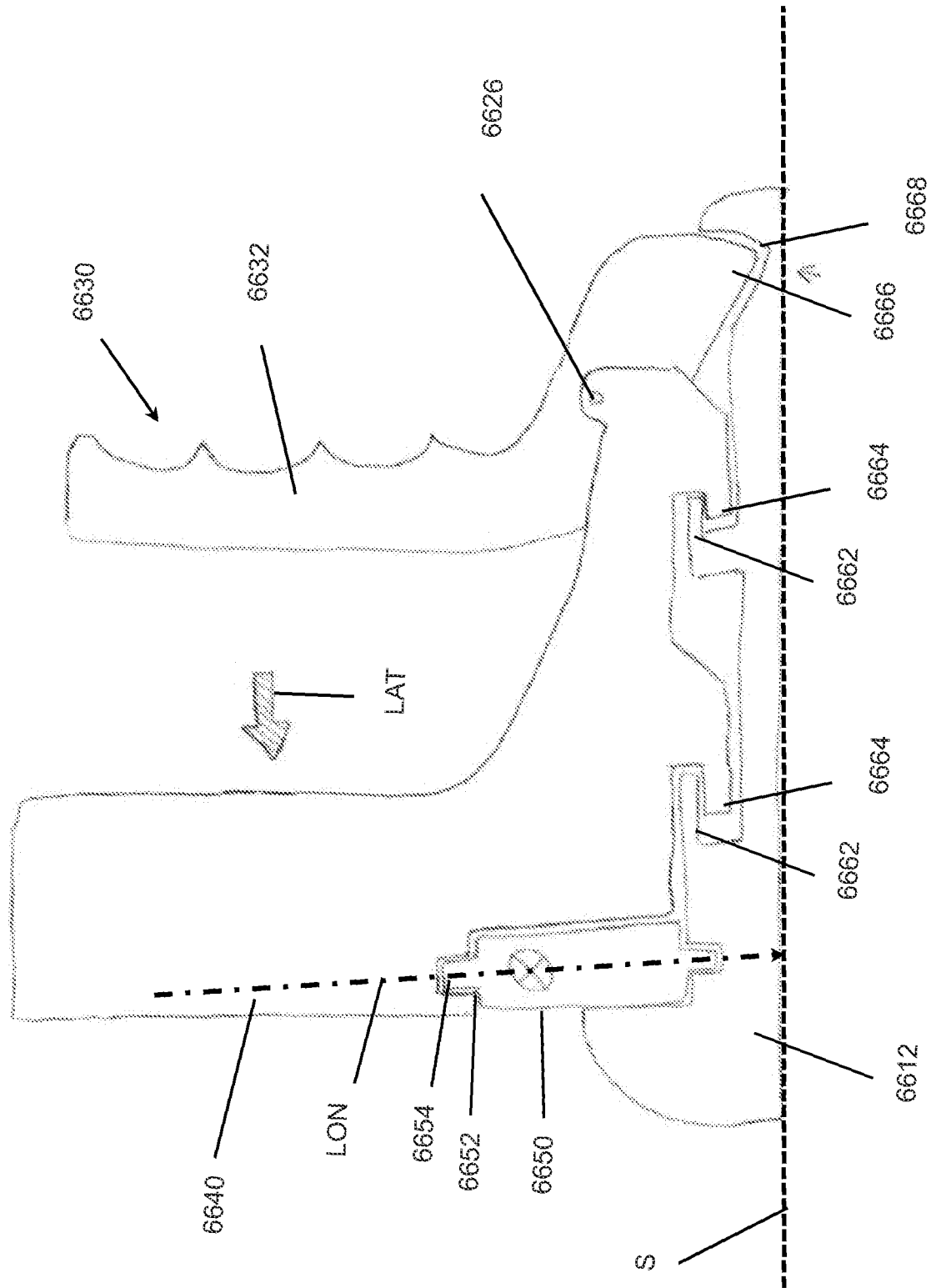


FIG. 141

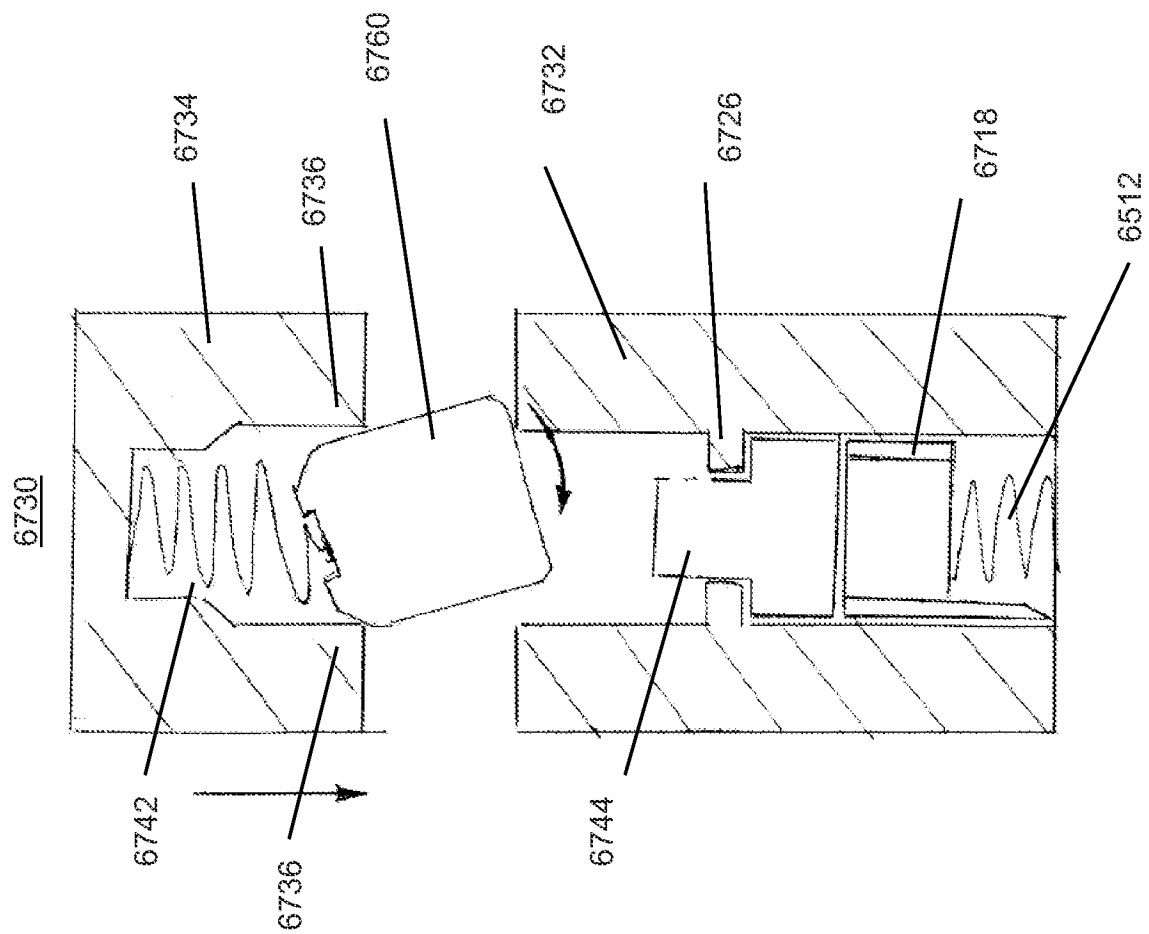


FIG. 142

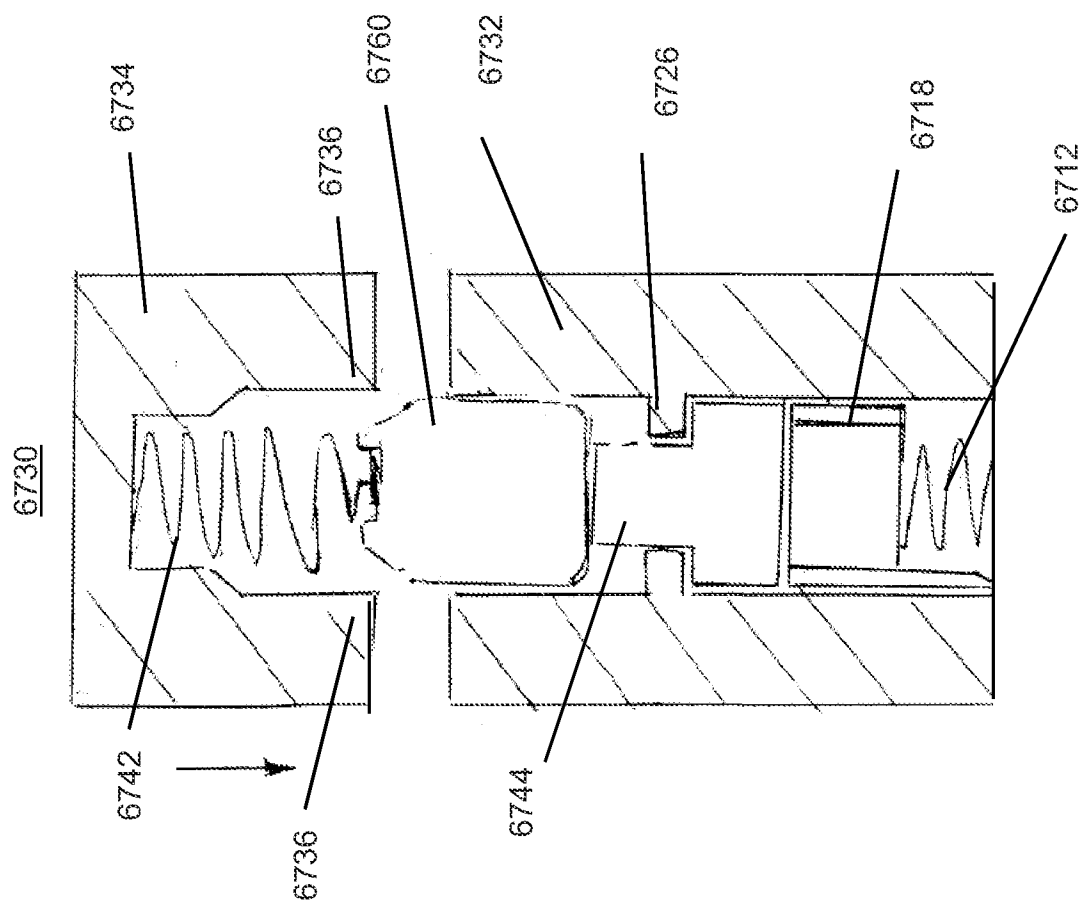


FIG. 143

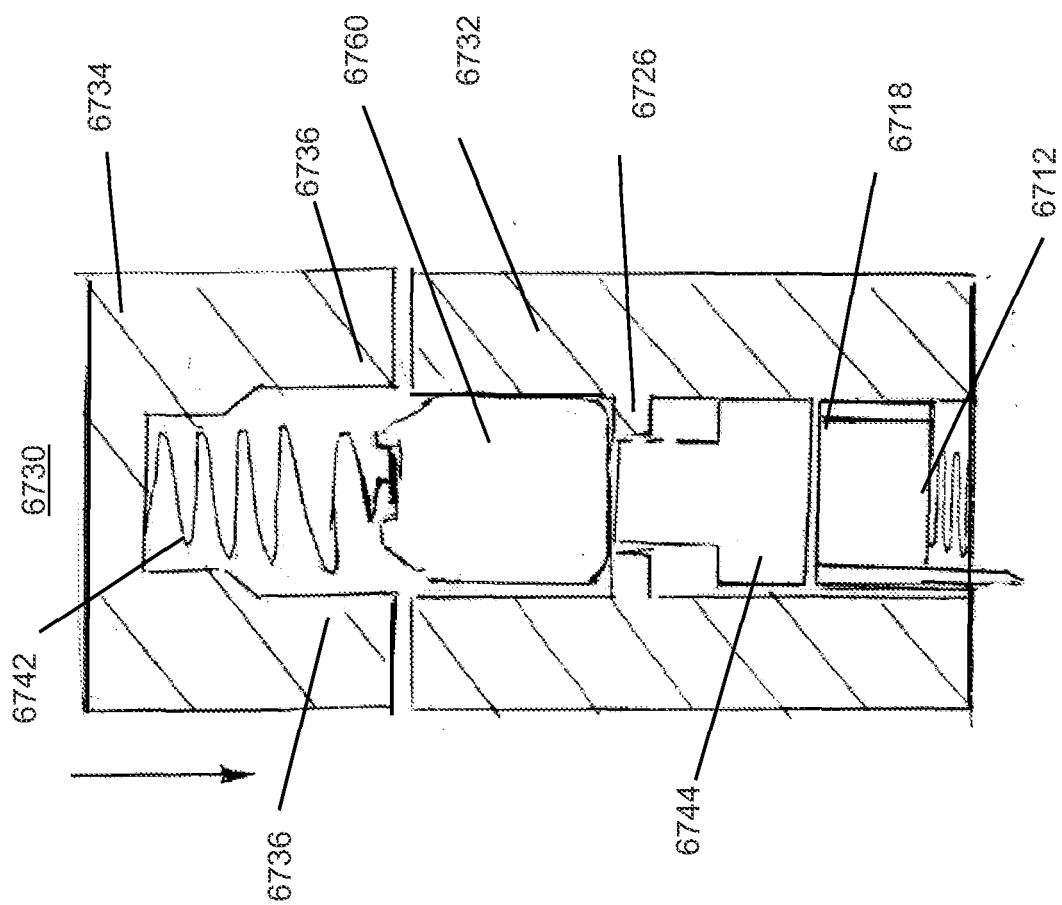


FIG. 144

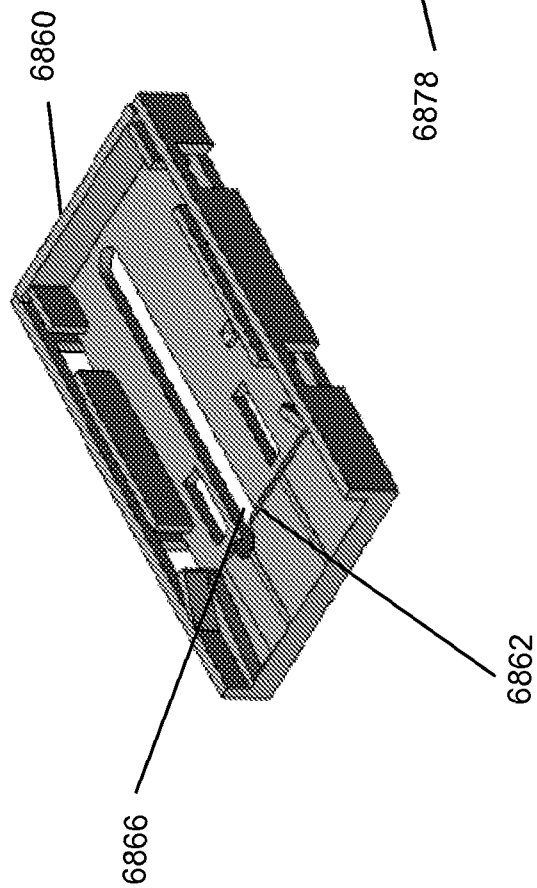
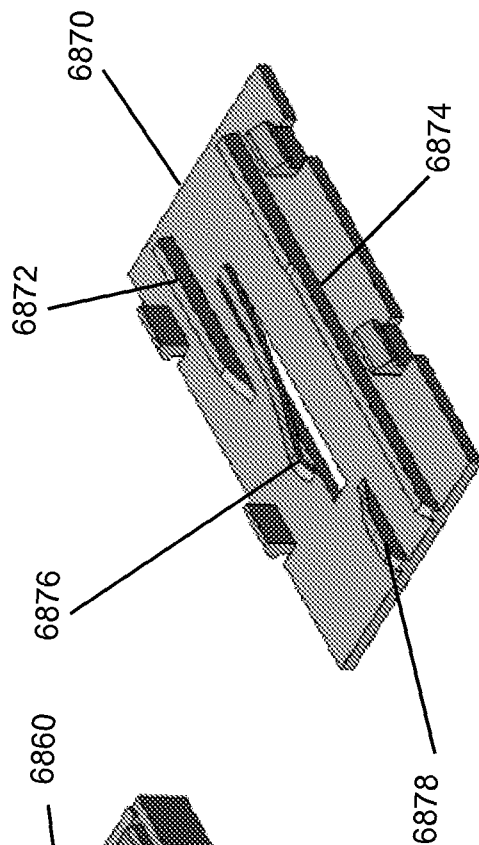
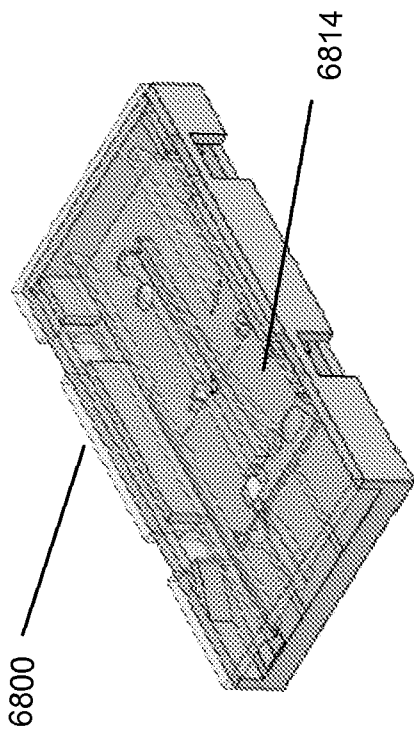
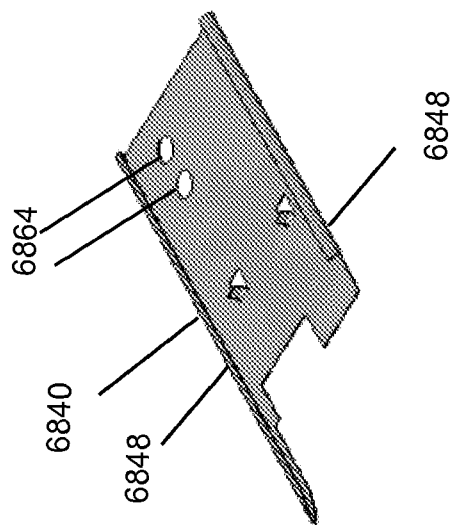


FIG. 145

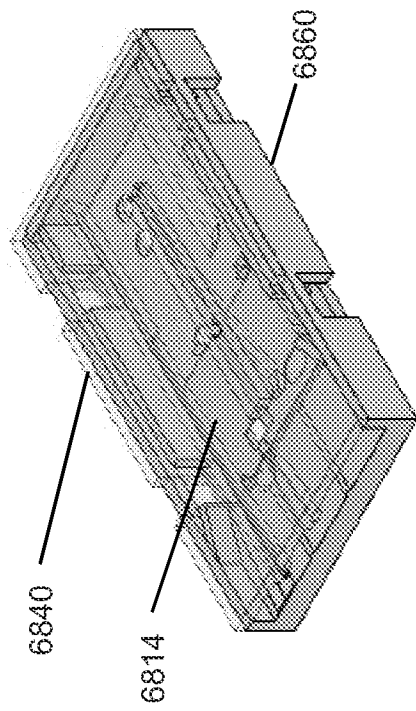


FIG. 146

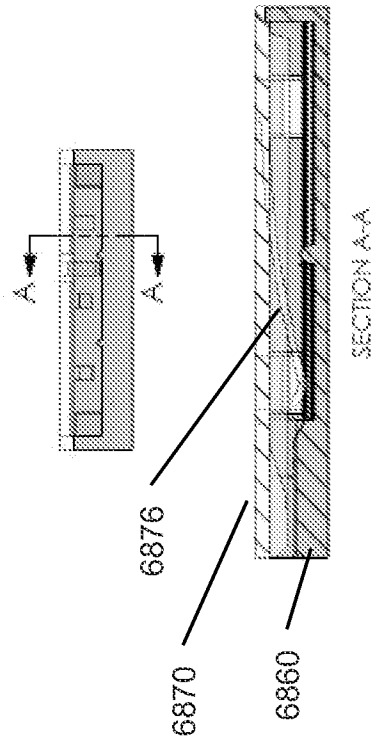


FIG. 147

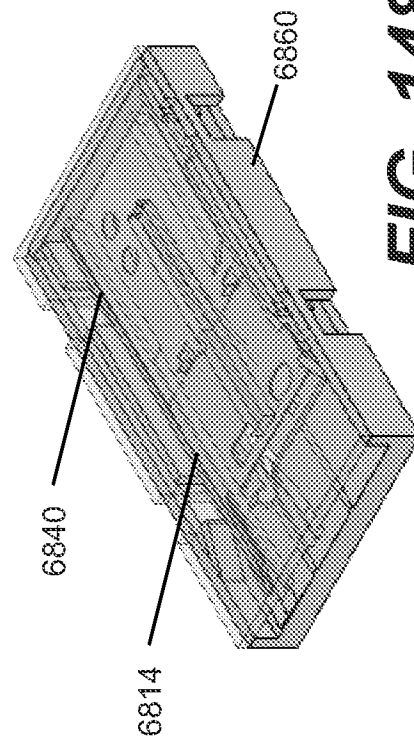


FIG. 148

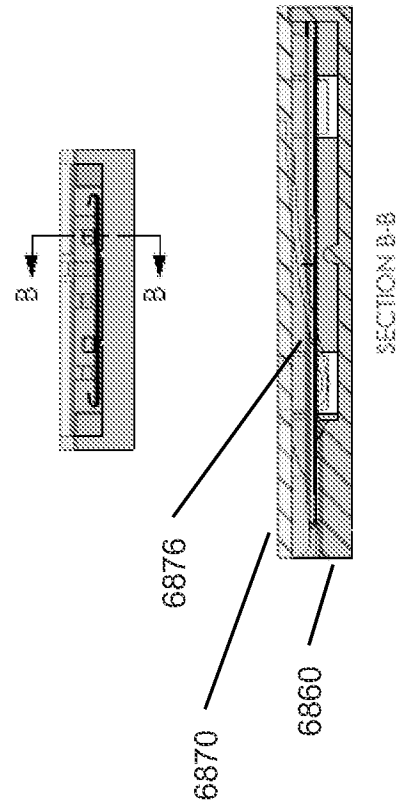


FIG. 149

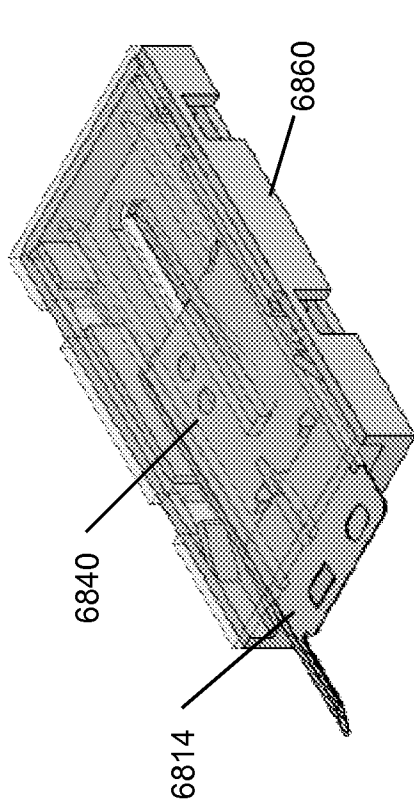


FIG. 150

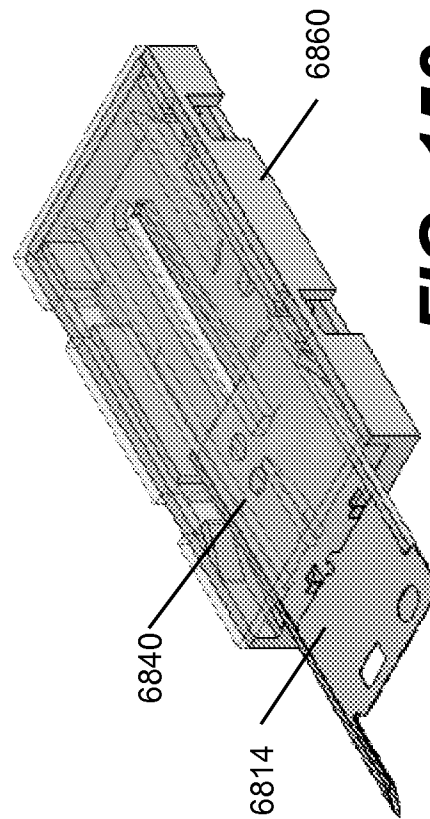


FIG. 152

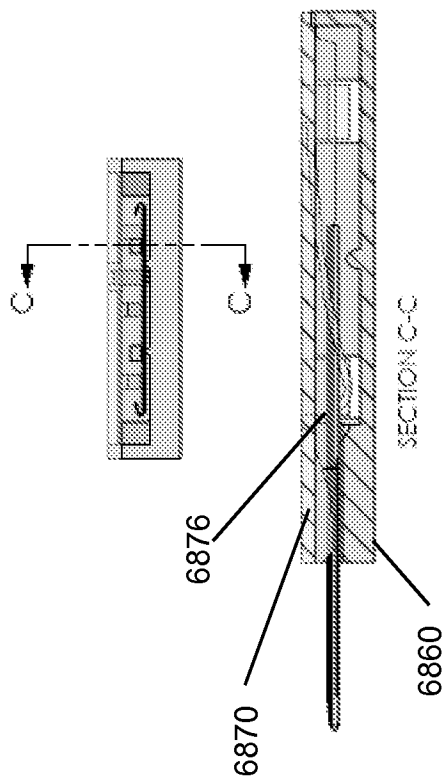


FIG. 151

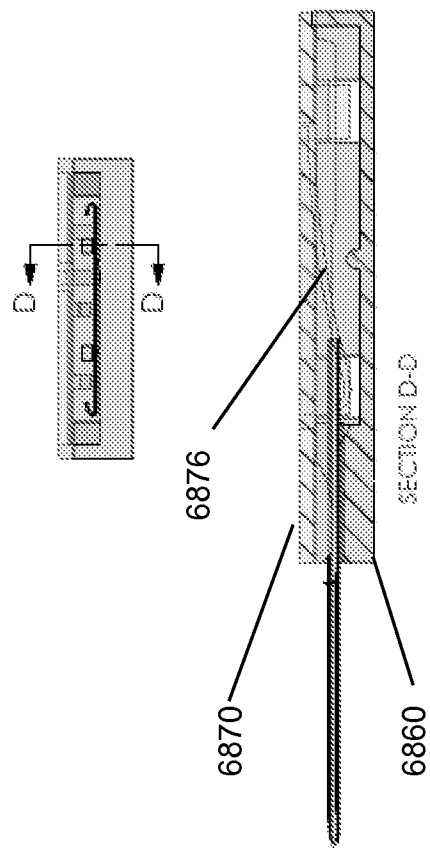


FIG. 153

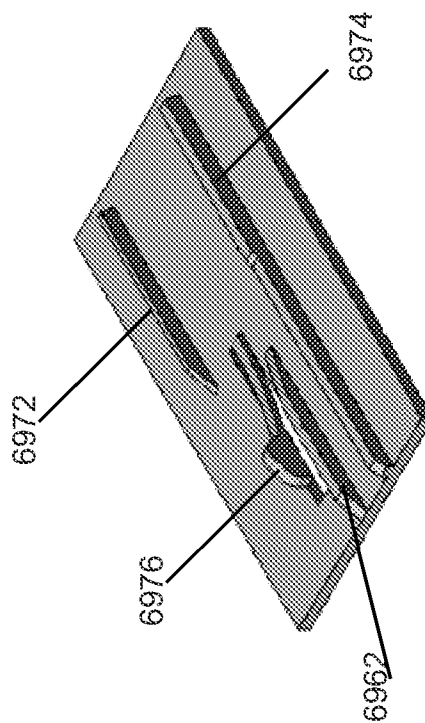
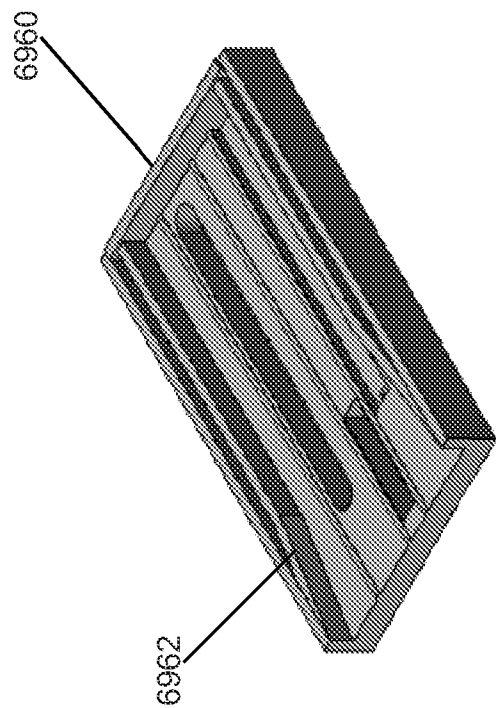
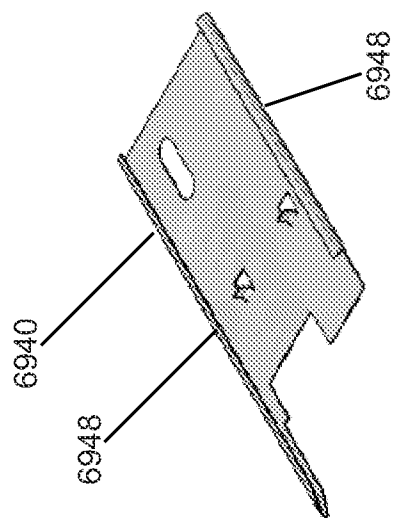


FIG. 154

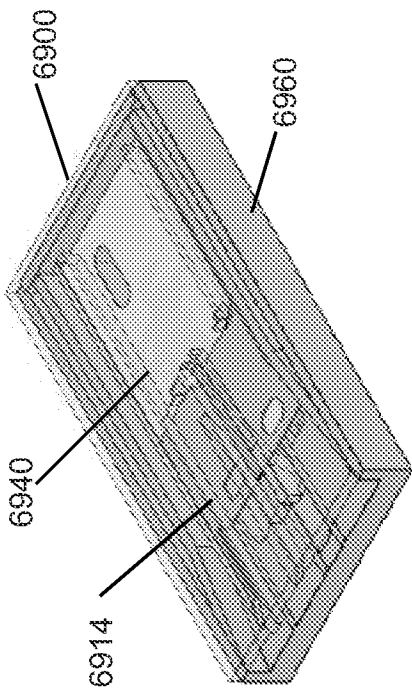


FIG. 155

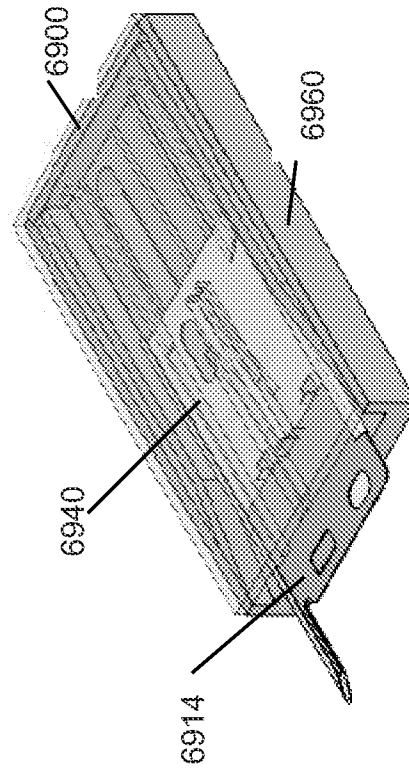


FIG. 157

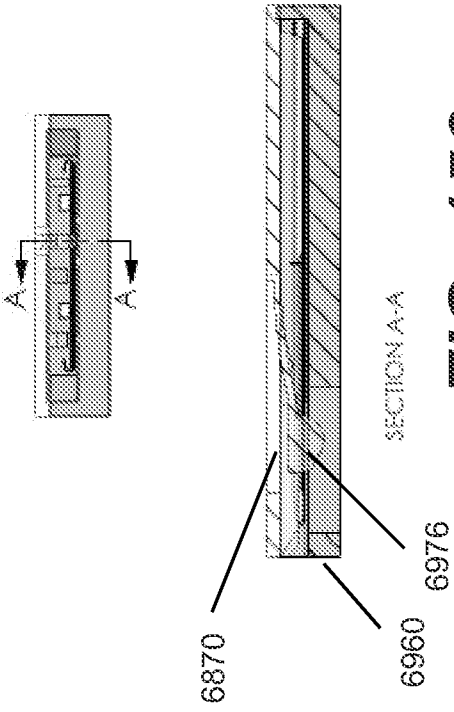


FIG. 156

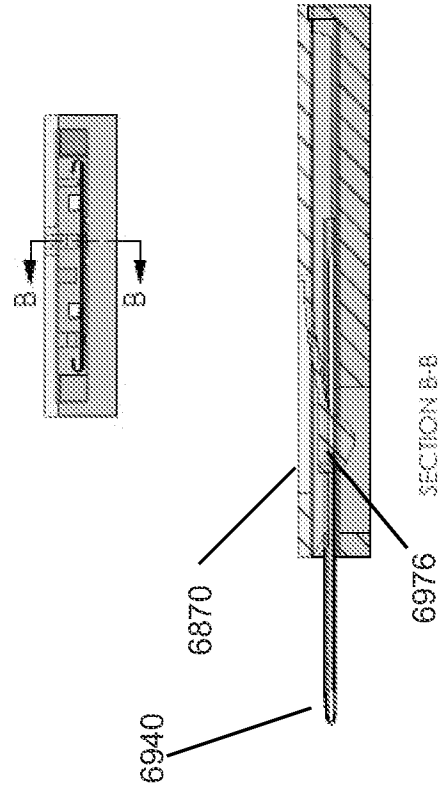


FIG. 158

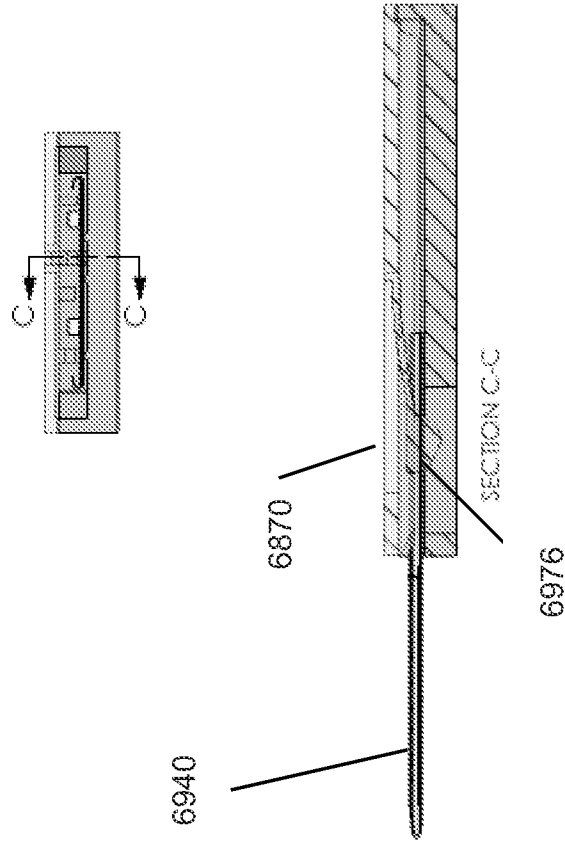


FIG. 160

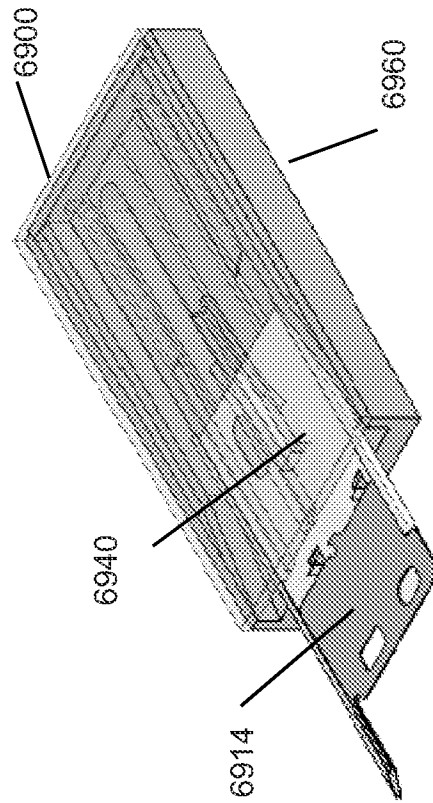


FIG. 159

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES		
First Named Inventor/Applicant Name:		Samuel Mason Curry		
Filer:		David W. Schalk		
Attorney Docket Number:				
Filed as Large Entity				
Provisional Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Provisional application filing	1005	1	220	220
Pages:				
Prov. Appl Size fee per 50 sheets >100	1085	2	270	540
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				760

Electronic Acknowledgement Receipt

EFS ID:	7629857
Application Number:	61345562
International Application Number:	
Confirmation Number:	3368
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Samuel Mason Curry
Customer Number:	90259
Filer:	David W. Schalk
Filer Authorized By:	
Attorney Docket Number:	
Receipt Date:	17-MAY-2010
Filing Date:	
Time Stamp:	21:30:26
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$760
RAM confirmation Number	7047
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Provisional Cover Sheet (SB16)	cover.pdf	1060600	no	4
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Warnings:					
Information:					
2	Specification	application.pdf	342393	no	120
			3fe57077601ef4623abe9196b717bb5cecdf9a0f		
Warnings:					
Information:					
3	Drawings-only black and white line drawings	USPTOdrawings.pdf	14229655	no	140
			178e448bcf2d2d121aa11801c09171ecd2081d8		
Warnings:					
Information:					
4	Fee Worksheet (PTO-875)	fee-info.pdf	31254	no	2
			8b278c4c06fef5dd91b7c9c85e8321c775002d3b		
Warnings:					
Information:					
Total Files Size (in bytes):			15663902		
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
61/345,562	05/17/2010		760	031312-06399		

CONFIRMATION NO. 3368

90259

Hughes Hubbard and Reed LLP
One Battery Park Plaza
New York, NY 10004

FILING RECEIPT



OC000000041937046

Date Mailed: 06/10/2010

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If Required, Foreign Filing License Granted: 06/03/2010

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Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

Title

MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

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