(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 October 2014 (09.10.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/164786 A1

(51) International Patent Classification:
*A61M 5/315* (2006.01)

(21) International Application Number:
PCT/US2014/023485

(22) International Filing Date:
11 March 2014 (11.03.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/776,269 11 March 2013 (11.03.2013) US

(72) Inventors; and
(71) Applicants : **MADSEN, Patrick** [US/US]; 540 East Butler Street, Litchfield, MN 55355 (US). **PFLAUMER, Hans** [US/US]; 2345 Woodbridge Street, Apartment 223, Roseville, MN 55113 (US). **SWANSON, Kevin, D.** [US/US]; 4640 Polaris Lane N, Plymouth, MN 55443 (US).

(74) Agents: **SERVANCE, Squire, J.** et al.; Morgan, Lewis & Bockius, LLP, 1701 Market Street, Philadelphia, PA 19103 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,

*[Continued on next page]*

(54) Title: DOSAGE INJECTOR WITH PINION SYSTEM

(57) Abstract: A dispensing mechanism for delivering a dosage of medicament including a housing, a push button, a crank arm that is slideably engageable with the push button, a ram, and a ratchet gear releasably engageable with the crank arm and ram, translation of the push button along an axis causing the crank arm to engage and rotate the ratchet gear which causes the ram to distally advance relative to the housing.

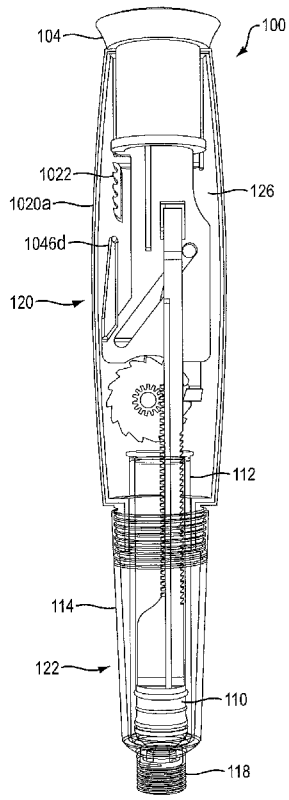



FIG. 1B

WO 2014/164786 A1

OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Published**:

— *with international search report (Art. 21(3))*

# TITLE

# DOSAGE INJECTOR WITH PINION SYSTEM

## CROSS REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims priority of U.S. Provisional Patent Application No. 61/776,269 filed March 11, 2013, which is incorporated by reference herein for all purposes.

## FIELD OF THE DISCLOSURE

**[0002]** The present invention relates to an injection device capable of delivering multiple doses of a liquid medicament contained therein without the need to refill the device between doses.

## BACKGROUND

**[0003]** Various types of drug treatments, including hormone therapy and the like, require administration of the drug-containing liquid medicament at regular intervals over an extended period of time. For example, a specific hormone treatment can require daily administration of the drug for a period of thirty days. In such a situation, it is advantageous to provide a device that allows the patient to self-administer the injection to avoid repeated trips to a doctor's office or the like.

**[0004]** A device is needed that allows for repeated administration of a dose of medicament that is easy to use correctly in self-administration.

## SUMMARY

**[0005]** In one embodiment, the present invention is a dispensing mechanism, including a housing having a proximal-distal axis; a ram within the housing and movable in a distal direction; a user-operable push button moveable along the proximal-distal axis relative to the housing, the push button including a slot at a distal portion of the push button; a crank arm having pawl tooth, a pivot point, and a crank arm protrusion slideably engageable with the slot such that movement of the push button causes the crank arm protrusion to move along the slot, causing rotation of the crank arm about the pivot point; and a ratchet gear having a first set of teeth releasably engageable with the pawl tooth and a second set of teeth releaseably engageable with the ram, wherein engagement of the pawl tooth with the first set of teeth of the ratchet gear causes the ratchet gear to rotate, causing the ram to distally advance relative to the housing.

**[0006]** In another embodiment, the dispensing mechanism further includes an anti-reverse mechanism including at least one housing ratchet integrally formed on an internal surface of the housing on both housing parts; and a flexible column integrally formed extending from a distal portion of the push button, the flexible column having a flexible column protrusion at a proximal end thereof, wherein as the push button moves along the proximal-distal axis, the flexible column protrusion slides between the integrally formed ratchets on both housing parts and engages the housing ratchets and restricts movement of the push button to one direction during a resetting motion. In another embodiment, the flexible column protrusion is almond shaped and thicker than said column. In one embodiment, having ratchets on both housing parts, the column sliding between them, and the almond engaging said ratchets allows the ratchet and column to be supported in a double shear type fashion further strengthening and balancing applied loads on said mechanism. In one embodiment, only one housing part contains an integrally formed ratchet, which makes the mechanism operate in single shear and tends to be unbalanced and weaker than other configurations.

**[0007]** In another embodiment, the ram includes at least two sets of teeth. In one embodiment, a first set of ram teeth are configured to engage the second set of teeth of the ratchet gear, and a second set of ram teeth are configured to engage a housing protrusion, the housing protrusion being integrally formed within the housing and configured to facilitate movement of the ram in one direction. In another embodiment, the second set of ratchet gear teeth are releasably engageable with a housing protrusion being integrally formed within the housing and configured to facilitate rotation of the gear in one direction.

**[0008]** In one embodiment, the push button slot is oriented at an oblique angle with respect to the proximal-distal axis.

**[0009]** In one embodiment, the push button slot has a portion that is oriented at an oblique angle with respect to the proximal-distal axis and a portion that has varying angles to the proximal-distal axis.

**[0010]** In one embodiment, the invention is an injector including the dispensing mechanism; a cartridge disposed within the housing; a plunger disposed in the cartridge to seal a medicament therein, wherein the ram is associated with the plunger for forcing the plunger in a distal direction for ejecting a dose of medicament; and a needle in fluid communication with the cartridge for injecting the doses into a patient. In one embodiment, the medicament is administered at a fixed dose repetitively. In one embodiment, the

medicament is administered in varying doses. In one embodiment, the medicament includes a parathyroid hormone. In another embodiment, the hormone is teriparatide. In one embodiment, the medicament includes a glucagon-like peptide-1 agonist. In another embodiment, the glucagon-like peptide-1 agonist is exenatide.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0011]** These and other objects, features and advantages of the invention will be apparent from a consideration of the following non-limiting detailed description considered in conjunction with the drawing figures, in which:

**[0012]** Figure 1A is a side view of an injection device according to an exemplary embodiment of the present disclosure;

**[0013]** Figure 1B is a cross-sectional rear side view of the injection device shown in Fig. 1A;

**[0014]** Figure 1C is a cross-sectional front side view of the injection device shown in Fig. 1A;

**[0015]** Figure 1D is a side partial view of an injection device according to an exemplary embodiment of the present disclosure;

**[0016]** Figure 2A is a side view of a first portion of housing of the injection device shown in Fig. 1A;

**[0017]** Figure 2B is a side view of a second portion of housing of the injection device shown in Fig. 1A;

**[0018]** Figure 3A is a front side view of a dosage mechanism of the injection device shown in Fig. 1A;

**[0019]** Figure 3B is a rear side view of a dosage mechanism of the injection device shown in Fig. 1A;

**[0020]** Figure 4 is a side view of a ram of the injection device shown in Fig. 1A;

**[0021]** Figure 5 is a side view of a ram and a second portion of housing of the injection device shown in Fig. 1A;

**[0022]** Figure 6 is a perspective view of a ratchet gear of the injection device shown in Fig. 1A;

**[0023]** Figure 7 is a perspective view of a ratchet arm of the injection device shown in Fig. 1A;

**[0024]** Figure 8 is a perspective view of a first exemplary user-manipulable push button of the injection device shown in Fig. 1A;

**[0025]** Figures 9A, 9B, and 9C are side exploded views of a second exemplary user-manipulable push button of the injection device shown in Fig. 1D;

**[0026]** Figures 10A, 10B, and 10C are partial side cutaway views of the injection device shown in Fig. 1D during operation;

**[0027]** Figures 11A, 11B, 11C, and 11D are a partial side cutaway views of the injection device shown in Fig. 1D showing compression of an exemplary force limiting biasing member;

**[0028]** Figures 12A, 12B, 12C, 12D, and 12E are partial side cutaway views of an anti-reverse feature of the injection device shown in Fig. 1D;

**[0029]** Figures 13A, 13B, 13C, and 13D are partial side cutaway views of a lock-out feature of the injection device shown in Fig. 1D;

**[0030]** Figure 14A is a side view of the injection device shown in Fig. 1D;

**[0031]** Figure 14B is a side view of the injection device shown in Fig. 1D;

**[0032]** Figure 15A is a cross-sectional rear side view of the injection device shown in Fig. 1D;

**[0033]** Figure 15B is a cross-sectional front side view of the injection device shown in Fig. 1D;

**[0034]** Figure 16A is a side view of a first portion of housing of the injection device shown in Fig. 1D;

**[0035]** Figure 16B is a side view of a second portion of housing of the injection device shown in Fig. 1D;

**[0036]** Figure 17A is a front side view of a dosage mechanism of the injection device shown in Fig. 1D;

**[0037]** Figure 17B is a rear side view of a dosage mechanism of the injection device shown in Fig. 1D;

**[0038]** Figure 18 is a side view of a ram of the injection device shown in Fig. 1D;

**[0039]** Figure 19 is a side view of a ram and a second portion of housing of the injection device shown in Fig. 1D;

**[0040]** Figure 20 is a perspective view of a ratchet gear of the injection device shown in Fig. 1D; and

**[0041]** Figure 21 is a perspective view of a ratchet arm of the injection device shown in Fig. 1D.

**[0042]** Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present disclosure will now be described in detail with reference to the figures, it is done so in connection with the illustrative embodiments and is not limited by the particular embodiments illustrated in the figures.

## DETAILED DESCRIPTION

**[0043]** With reference to the accompanying drawings, various embodiments of the present invention are described more fully below. Some but not all embodiments of the present invention are shown. Indeed, various embodiments of the invention may be embodied in many different forms and should not be construed as limited to the embodiments expressly described. Like numbers refer to like elements throughout. The singular forms "a," "an," and "the" include the singular and plural unless the context clearly dictates otherwise.

**[0044]** Referring to the drawings in detail, wherein like reference numerals indicate like elements throughout, there is shown in FIGS. 1-21 an injection device 100, in accordance with an exemplary embodiment of the present invention. It is noted that, in the context of this disclosure, the terms "distal" and "proximal" are used in reference to the position of injection device 100 relative to a user of the injection device when merely held by a user. Accordingly, a point located distal to a second point would be further from the user (e.g., towards an injection end of injection device 100) and vice versa.

**[0045]** FIGS. 1A-1C and 2-8 show one embodiment of the present invention and FIGS. 1D and 9-21 show another embodiment of the present invention.

**[0046]** Referring to FIGS. 1A, 1B, 1C, 1D, 14A, 14B, 15A, and 15B, in certain embodiments, injection device 100 is configured to administer a dose of medicament. In one embodiment, injection device 100 is configured in the shape of a pen, having an elongated,

substantially writing instrument-like form, although other forms are within the scope of the invention. Referring to FIGS. 14A and 14B, in one embodiment, injection device 100 includes a removable cap 128 attached to the distal section 122 of the injection device 100 thereto. In one embodiment, injection device 100 is a disposable injection pen, in that after the quantity of medicament contained therein is exhausted by multiple operations of the injection device 100, the injection device 100 is discarded rather than being reset and re-used with a replacement container of medicament. In other embodiments, injection device 100 can be reset and is reusable. In one embodiment, the injection device 100 is a re-usable pen, and that after the quantity of medicament contained therein is exhausted, the injection device can be re-set and a new medicament cartridge installed.

**[0047]** In one embodiment, injection device 100 is configured to administer repeated, successive doses of a medicament. In one embodiment, the medicament is delivered in successive repeated fixed doses. In one embodiment, the medicament is delivered in successive repeated variable doses. In other embodiments, the dosage can be controlled and adjusted. Further, in one embodiment, injection device 100 allows the injection to be administered by individuals that do not have formal training (e.g., self-administered or administered by another individual family member or other caregiver who may not be a formally trained healthcare provider, such as a parent administering a drug to a child). In one embodiment, injection device 100 is triggered by one hand of a user. In one embodiment, injection device 100 is held one hand of a user and triggered by the user's finger or thumb. In one embodiment, injection device 100 is useful in situations where self-injections/caregiver administered injections would be beneficial, including, but not limited to, the injection of a drug to treat osteoporosis, psoriasis, and psoriatic arthritis. In one embodiment, the injection device must administer a full dose prior to being able to reset. In one embodiment, the injection device must fully reset before it is able to be triggered.

**[0048]** The injection device 100 can be used to inject a wide range of drugs. For example, injection device 100 can be used to inject drugs, water soluble medicaments and oil soluble medicaments. Some medicaments that can be used with injector device 100 include parathyroid hormone ("PTH") and various other medications such as exenatide and the like. Injection device 100 can also be used to inject medicaments listed in the Physicians' Desk Reference (PDR®), 67th Edition (2013) (which is herein incorporated by reference in its entirety), and, without limitation, allergens, amebicides and trichomonacides, amino acid preparations, analeptic agents, analgesics, analgesics/antacids, anesthetics, anorexics,

antacids, antihelmintics, antialcohol preparations, antiarthritics, antiasthma agents, antibacterials and antiseptics, antibiotics, antiviral antibiotics, anticancer preparations, anticholinergic drug inhibitors, anticoagulants, anticonvulsants, antidepressants, antidiabetic agents, antidiarrheals, antidiuretics, antienuresis agents, antifibrinolytic agents, antifibrotics (systemic), antiflatulents, antifungal agents, antigonadotropin, antihistamines, antihyperammonia agents, anti-inflammatory agents, antimalarials, antimetabolites, antimigraine preparations, antinauseants, antineoplastics, anti-obesity preparations, antiparasitics, anti-parkinsonism drugs, antipruritics, antipyretics, antispasmodics and antichloinergics, antitoxoplasmosis agents, antitussives, antivertigo agents, antiviral agents, apomorphine, atropine, biologicals, biosimilars, bismuth preparations, bone metabolism regulators, bowel evacuants, bronchial dilators, calcium preparations, cardiovascular preparations, central nervous system stimulants, cerumenolytics, chelating agents, choleretics, cholesterol reducers and anti-hyperlipemics, colonic content acidifiers, cough and cold preparations, decongestants, diazepam, dihydroergotamine, epinephrine expectorants and combinations, diuretics, emetics, enzymes and digestants, fertility agents, fluorine preparations, galactokinetic agents, general anesthetic, geriatrics, germicides, glucagon, haloperidol, hematinics, hemorrhoidal preparations, histamine H receptor antagonists, hormones, hydrocholeretics, hyperglycemic agents, hypnotics, immunosuppressives, laxatives, lovenox, mucolytics, muscle relaxants, narcotic antagonists, narcotic detoxification agents, ophthalmological osmotic dehydrating agents, otic preparations, oxytocics, parashypatholytics, parathyroid preparations, pediculicides, peptide drugs, phosphorus preparations, premenstrual therapeutics, psychostimulants, quinidines, radiopharmaceuticals, respiratory stimulants, salt substitutes, scabicides, sclerosing agents, sedatives, sumatriptan, sympatholytics, sympathomimetics, thrombolytics, thyroid preparations, toradol, tranquilizers, tuberculosis preparations, uricosuric agents, urinary acidifiers, urinary alkalinizing agents, urinary tract analgesic, urological irrigants, uterine contractants, vaginal therapeutics and vitamins and each specific compound or composition listed under each of the foregoing categories in the PDR®. Some other medicaments that can be used with injector device 100 include Ergocalciferol (Calciferol), diethylstilbestrol, Diprovan (propofol), estradiol valerate, fluphenazine decanoate, fulvestrant, intralipid, liposyn, nandrolone decanoate, nebido, nutralipid, paclitaxel, progesterone, prograf, testosterone cypionate, zuclopenthixol, haloperidol dodecanoate, Enbrel, Humira, Lantus, Epogen (Procrit), Neulasta, Aranesp, Avonex, PEGasys, Rebif, Neupogen, Betaseron, Avastin, Remicade, Herceptin, Erbitux, Recombinate, Cerezyme, NovoSeven, Tysabri, Synagis,

Copaxone and Kogenate FS. In certain embodiments, the medicament is dissolved in soybean oil, ethyl oleate, castor oil, sesame oil, safflower oil, arachis oil, polyoxyyethylated castor oil (Cremophor® EL), polyoxyl 60 hydrogenated castor oil (HCO-60), cottonseed oil, or thin oil derived from coconut oil.

**[0049]** In some embodiments, the medicament may be a hazardous agent. "Hazardous Agent(s)" as used herein means any one or more medications that are toxic agents, cytotoxic agents and/or other dangerous agents that may cause serious effects upon contact with a subject as well as highly potent agents, agents that have profound physiological effects at low doses. Exemplary hazardous agents include, without limitation, analgesics, immunomodulating agents, IL-1 receptor antagonists, IL-2 alpha receptor antagonists, anti-rejection compounds, hormonal agents, prostaglandins, sedatives, anticholinergic agents, Parkinsons disease drugs, expensive agents, neuroleptic agents, tissue necrosis factor (TNF) blockers, and other dangerous agents. Examples of hazardous agents suitable for use with the injection device 100 in accordance with the present invention include, but are not limited to, those disclosed in U.S. Patent Application Publication No. 2012/0157965 entitled "Hazardous Agent Injection System" (to Paul Wotton *et. al*, published June 21, 2012), which is incorporated by reference herein in its entirety. Particular examples of cytotoxic agents include, without limitation, 6-mercaptopurine, 6-thioinosinic acid, azathioprine, chlorambucil, cyclophosphamide, cytophosphane, cytarabine, fluorouracil, melphalan, methotrexate, uramustine, anti-cytokine biologicals, cell receptor antagonists, cell receptor analogues, and derivatives thereof. Examples of highly potent agents include, without limitation, steroids such as dexamethasone, progesterone, somatostatin, and analogues thereof; biologically active peptides such as teriparatide; and anticholinergics such as scopolamine. Examples of agents that have profound physiological effects at low doses include, without limitation, antihypertensives and/or blood pressure down regulators. Examples of analgesics include, without limitation, fentanyl, fentanyl citrate, morphine, meperidine, and other opioids. Examples of immunomodulating agents include, without limitation, adalimumab (anti-tissue necrosis factor monoclonal antibody or anti-TNF). Examples of IL-1 receptor antagonists include, without limitation, anakinra. Examples of IL-2 alpha receptor antagonists include, without limitation, daclizumab and basiliximab. Examples of anti-rejection compounds include, without limitation, azathioprine, cyclosporine, and tacrolimus. Examples of hormonal agents include, without limitation, testosterone, estrogen, growth hormone, insulin, thyroid hormone, follicle stimulating

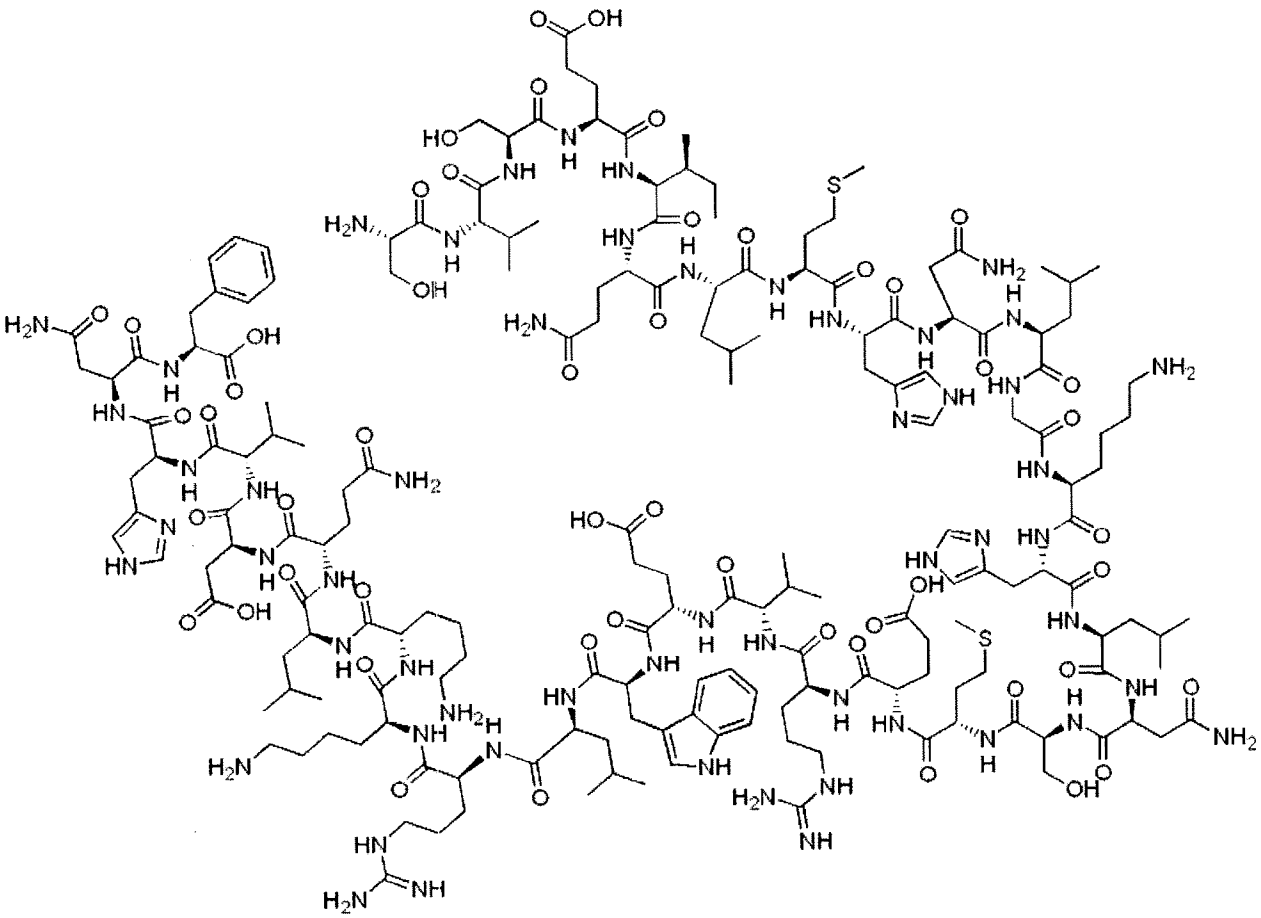
hormone (FSH), epinephrine/adrenaline, progesterone, parathyroid hormone, gonadotrophin releasing hormone (GHRH), leutinizing hormone releasing hormone (LHRH), other hormones such as those where contact with the hormone by members of the opposite sex can lead to side effects, and derivatives thereof. Examples of prostaglandins include, without limitation, gamma-linolenic acid, docosahexanoic acid, arachidonic acid and eicosapentaenoic acid. Examples of sedatives include, without limitation, barbiturates such as amobarbital, pentobarbital, secobarbital, and phenobarbitol; benzodiazepines such as clonazepam, diazepam, estazolam, flunitrazepam, lorazepam, midazolam, nitrazepam, oxazepam, triazolam, temazepam, chlordiazepoxide, and alprazolam; herbal sedatives such as ashwagandha, duboisia hopwoodii, prosanthera striatiflora, kava (piper methysticum), mandrake, valerian, and marijuana; non-benzodiazepine sedatives (a.k.a. "Z-drugs") such as eszopiclone, zaleplon, zolpidem, zopiclone; antihistamines such as diphenhydramine, dimenhydrinate, doxylamine, and promethazine; and other sedatives such as chloral hydrate. Examples of anticholinergic agents include, without limitation, dicyclomine, atropine, ipratropium bromide, oxitropium bromide, and tiotropium. Examples of Parkinson's disease drugs include, without limitation, levodopa, dopamine, carbidopa, benserazide, co-ceraldopa, co-beneldopa, tolcapone, entacapone, bromocriptine, pergolide, pramipexole, ropinirole, piribedil, cabergoline, apomorphine, and lisuride. Examples of expensive agents include, without limitation, human growth hormone and erythropoietin. Examples of neuroleptic agents includes, without limitation, antipsychotics; butyrophenones such as haloperidol and droperidol; phenothiazines such as chlorpromazine, fluphenazine, perphenazine, prochlorperazine, thioridazine, trifluoperazine, mesoridazine, periciazine, promazine, trifluprομazine, levomepromazine, promethazine, and pimozide; thioxanthenes such as chlorprothixene, clopenthixol, flupenthixol, thiothixene, and zuclopenthixol; atypical antipsychotics such as clozapine, olanzapine, risperidone, quetiapine, ziprasidone, amisulpride, asenapine, paliperidone, iloperidone, zotepine, and sertindole; and third generation antipsychotics such as aripiprazole and bifeprunox. Examples of TNF blockers includes, without limitation, etanercept.

**[0050]** In some embodiments, the hazardous agent can be selected from botulinum toxin, injectable gold, 6-mercaptopurine, 6-thioinosinic acid, azathioprine, chlorambucil, cyclophosphamide, cytophosphane, cytarabine, fluorouracil, melphalan, methotrexate, uramustine, anti-cytokine biologicals, cell receptor antagonists, cell receptor analogues, dexamethasone, progesterone, somatostatin, analogues of dexamethasone, analogues of

progesterone, analogues of somatostatin, teriparatide, scopolamine, antihypertensives, blood pressure down regulators, fentanyl, fentanyl citrate, morphine, meperidine, other opioids, adalimumab (anti-tissue necrosis factor monoclonal antibody or anti-TNF), anakinra, daclizumab, basiliximab, azathioprine, cyclosporine, tacrolimus, testosterone, estrogen, growth hormone, insulin, thyroid hormone, follicle stimulating hormone (FSH), epinephrine/adrenaline, gamma-linolenic acid, docosahexanoic acid, arachidonic acid, eicosapentaenoic acid, amobarbital, pentobarbital, secobarbital, phenobarbitol, clonazepam, diazepam, estazolam, flunitrazepam, lorazepam, midazolam, nitrazepam, oxazepam, triazolam, temazepam, chlordiazepoxide, alprazolam, ashwagandha, duboisia hopwoodii, prosanthera striatiflora, kava (piper methysticum), mandrake, valerian, marijuana, eszopiclone, zaleplon, zolpidem, zopiclone, diphenhydramine, dimenhydrinate, doxylamine, promethazine, chloral hydrate, dicyclomine, atropine, ipratropium bromide, oxitropium bromide, tiotropium, levodopa, dopamine, carbidopa, benserazide, co-ceraldopa, co-beneldopa, tolcapone, entacapone, bromocriptine, pergolide, pramipexole, ropinirole, piribedil, cabergoline, apomorphine, lisuride, human growth hormone, erythropoietin, haloperidol, droperidol, chlorpromazine, fluphenazine, perphenazine, prochlorperazine, thioridazine, trifluoperazine, mesoridazine, periciazine, promazine, triflupromazine, levomepromazine, promethazine, pimozide, chlorprothixene, clopenthixol, flupenthixol, thiothixene, zuclopenthixol, clozapine, olanzapine, risperidone, quetiapine, ziprasidone, amisulpride, asenapine, paliperidone, iloperidone, zotepine, sertindole, aripiprazole, bifeprunox, etanercept, derivatives of any of the foregoing, and combinations of any of the foregoing.

**[0051]** Because of the repeated nature of the dosing of certain types of medicaments, it is beneficial to use a device that aides a patient in self-administration of the doses. Repeat dosing includes repetitive injection of the same dose or variable dose. Medicaments that are administered intradermally, subcutaneously or intramuscularly can be used with the injector. Further, many such medicaments should be delivered in a precise amount to ensure efficacy and to reduce side-effects.

**[0052]** In one embodiment, the medicament includes a recombinant form of parathyroid hormone, e.g., teriparatide. Teriparatide has the following structure:



**[0053]** Teriparatide is typically administered by injection once a day in the thigh or abdomen. Teriparatide is indicated for use in postmenopausal women with osteoporosis at a high risk for fracture or with a history of osteoporotic fracture, patients with multiple risk factors for fracture, and for patients who have failed or are intolerant to other available osteoporosis therapy. Teriparatide is also indicated to increase bone mass in men with primary or hypogonadal osteoporosis at high risk of fracture, patients with multiple risk factors for fracture, and for patients who have failed or are intolerant to other available osteoporosis therapy. Teriparatide is indicated as well for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy. The typical recommended dose is 20 μg per day. In one embodiment, injection device 100 is configured to administer about 1μg, about 2 μg, about 3 μg, about 4 μg, about 5 μg, about 6 μg, about 7 μg, about 8 μg, about 9 μg, about 10 μg, about 11 μg, about 12 μg, about 13 μg, about 14 μg, 15 μg, about 16 μg, about 17 μg, about 18 μg, about 19 μg, about 20 μg, about 21 μg, about 22 μg, about 23 μg, about 24 μg, about 25 μg, about 26 μg, about 27 μg, about 28 μg, about 29 μg, about 30 μg, about 31 μg, about 32 μg, about 33 μg, about 34 μg, about 35 μg, about 36 μg, about 37 μg, about 38 μg, about 39 μg, about 40 μg or any range determinable from

the preceding dosage amounts (for example, about 15 μg to about 25 μg or about 1 μg to about 10 μg) of medicament, e.g., Teriparatide, per dose. In one embodiment, injection device 100 is configured to administer about .005 mL, about .010 mL, about .015 mL, about .020 mL, about .025 mL, about .030 mL, about .035 mL, about .040 mL, about .045 mL, about .050 mL, about .055 mL, about .060 mL, about .065 mL, about .070 mL, 75 μL, about .080 mL, about .085 mL, about .090 mL, about .095 mL, about .100 mL, about .105 mL, about .110 mL, about .115 mL, about .120 mL, about .125 mL, about .130 mL or any range determinable from the preceding dosage amounts (for example, about .025 mL to about .045 mL or about .005 mL to about .130 mL) of medicament, e.g., Teriparatide, per dose.

**[0054]** Referring to FIGS. 1A and 14A, in one embodiment, injection device 100 includes a proximal section 120 and a distal section 122. In one embodiment, distal section 122 contains the medicament to be dispensed at its distal end upon operation of injection device 100. In one embodiment, the proximal section 120 contains the dosage mechanism 126, as shown in FIGS. 3A, 3B, 15A and 15B used to force the contained medicament from the distal end of distal section 122.

**[0055]** In one embodiment, injection device 100 includes housing 102. In one embodiment, housing 102 has a proximal-distal axis 124. In one embodiment, housing 102 of injection device 100 is formed from a light weight material, e.g., an injected molded plastic. In one embodiment, housing 102 is covered in an opaque or elastomeric covering to alter the color, shape or texture of housing 102. In one embodiment, housing 102 is formed of at least two separate parts, e.g., first portion 1020a and second portion 1020b as shown in FIGS. 2A, 2B, 16A and 16B. In one embodiment, the housing parts 1020a and 1020b are aligned via mating pins and recesses provided therein and fixedly secured together during manufacture, such as via adhesives or ultrasonic welding. In one embodiment, the housing parts 1020a and 1020b are fixedly secured together by a mechanical joint system where part-to-part attachment is accomplished with locating and locking features. In one embodiment, housing parts 1020a and 1020b are fixedly secured using clips where said clips can be integral to one or the other or both housing parts. In another embodiment, securing clips are separate from housing parts 1020a and 1020b. In one embodiment, housing 102 is generally elliptical in transverse cross-section to accommodate dosage mechanism 126. In one embodiment, the generally elliptical housing 102 is configured with generally flat surfaces opposing one another on said housing. In one embodiment, housing 102 is configured with flat surfaces sufficient to minimize the potential for the device to roll. In one embodiment,

the flat surfaces found as part of elliptical housing 102 are designed to retain internal device components. In one embodiment, the flat surfaces of elliptical housing 102 are designed to retain dosing mechanism 126. In one embodiment, the flat surfaces for housing 102 contain rails and ribs for retaining internal device components. In one embodiment, housing 102 is provided with an external thread or another suitable connections means at a distal portion of the housing 102 to releasably connect a cartridge sleeve 114 thereto. In one embodiment, housing 102 is provided with suitable connection means at a distal portion of housing 102 to adjustably connect the cartridge sleeve 114 thereto.

**[0056]** In one embodiment, injection device distal section 122 includes a cartridge sleeve 114 which can be used to hold a number of differently-sized cartridges. Additionally, a number of differently-sized cartridge sleeves can be provided, as necessary for differently-sized cartridges. In one embodiment, the cartridge sleeve 114 is provided with an internal thread or another suitable connections means at a proximal portion of the cartridge sleeve 114 to releasably connect housing 102 thereto. In one embodiment, cartridge sleeve 114 is provided with suitable connection means at its proximal end to adjustably connect the cartridge sleeve 114 to housing 102 thereto. In one embodiment, the cartridge sleeve 114 is reversibly connected to housing 102. In one embodiment, the reversible connection of cartridge sleeve 114 to housing 102 allows replacement of medicament cartridge 112 and re-setting of device 114.

**[0057]** In one embodiment, cartridge sleeve 114 is provided with an external thread 118 or another suitable connections means 118 at a distal portion of cartridge sleeve 114 to releasably connect a pen-needle assembly thereto.

**[0058]** In one embodiment, a pen-needle assembly (not shown) is of known design and includes a double-ended needle cannula or injection needle. In one embodiment, the pen-needle assembly consists of an injection needle mounted in a tubular hub that is internally threaded to cooperate with the external thread 118 of cartridge sleeve 114 so as to be reversibly attached to the external threading of the cartridge sleeve 114. Other types of connection types, including a snap on connection, may be provided between the needle assembly and the cartridge sleeve 114. In one embodiment, the injection needle is fitted with a protective cover, e.g, a needle cap, thereover to protect those handling or who may otherwise encounter injection device 100. In one embodiment, the pen-needle assembly is a single injection needle. Various types of other needle assemblies known in the art may be used with injection device 100, including, but not limited to, assemblies with one or more

shortened injection needles, including microneedle arrays, pen needle assemblies incorporating sharps protection or assemblies compatible with or connectable to intravenous lines or the like including needle-free blunt connections.

**[0059]** In one embodiment, injection device 100 includes a cartridge 112. In one embodiment, cartridge 112 is of the type typically used in connection with injection devices, e.g., needled injector devices, and is formed of glass or certain types of plastic that have qualities that are necessary for storage of liquid medicament. Such qualities can include low air permeation, lubricity, low leeching of chemicals and corrosion resistance. In one embodiment, cartridge 112 is generally cylindrical in shape and can have a diameter configured to fit within cartridge sleeve 114, although other shapes can be used. In one embodiment, cartridge 112 and cartridge sleeve 114 are engage at an interface. In one embodiment, an adhesive is applied at the interface of cartridge 112 and cartridge sleeve 114. In one embodiment, the adhesive is light cured. In one embodiment, the cartridge 112 defines a medicament-filled reservoir that is closed at its proximal end by a plunger 110 that is axially slideably and sealably engaged with the cartridge interior wall to hold the medicament within the reservoir. In one embodiment, the distal, outlet end of the cartridge reservoir is sealed by a septum held by a cap that is secured to a stepped-down diameter neck portion of the cartridge 112. In one embodiment, the septum cap secured to the stepped-down diameter neck of the cartridge 112 is secured in the stepped down distal end of the cartridge sleeve 114 around which external threads 118 are present. In one embodiment, when the pen-needle assembly is mounted on cartridge sleeve 114, a proximal point of an injection needle penetrates the cartridge septum to provide a fluid flow outlet by which medicament within the cartridge reservoir can be dispensed from a needle tip during operations of injection device 100. In one embodiment, cartridge 112 is configured to contain a predetermined amount of a medicament. The predetermined amount of medicament that the cartridge is configured to contain can vary with the medicament injected and with the recommended dose size for the particular medicament and the patient. In one embodiment, distally advancing plunger 110 causes the volume of the cartridge reservoir to decrease and an amount of liquid medicament to expel from the injection needle in an amount that corresponds to the reduction in volume caused by the movement of the plunger.

**[0060]** To reliably provide repeated small doses of a liquid medicament, in one embodiment, cartridge 112 is constructed to hold a predetermined number of doses. In one embodiment, the doses in cartridge 112 correspond to a predetermined period of medicament

administration. In one embodiment, cartridge 112 is constructed to hold a predetermined volume of medicament. In one embodiment, the doses in cartridge 112 include sufficient medicament for purging air from the cartridge 112 and medicament to correspond to a predetermined period of medicament administration. In one embodiment, the medicament in the cartridge is sufficient for purging air from the cartridge, allow for practice injections, correspond to a predetermined period of medicament administration and allow for residual medicament assuring the last dose of medicament is a complete dose. For example, in one embodiment, injector device 100 is intended for use with a teriparatide solution that is to be administered once daily and sufficient drug is provided for the prescribed treatment over a pre-determined number of successive days at a dose of .08 mL administered through movement of a plunger 110 a distance of about 1.1 mm. For example, in one embodiment, injector device 100 is intended for use with a teriparatide solution that is to be administered once daily for twenty eight successive days at a dose of 0.08 mL administered through movement of a plunger 110 a distance of about 1.1 mm. In one embodiment, the injector device 100 is configured to administer a dose of medicament, e.g., teriparatide, once daily for 1 day, 2 successive days, 3 successive days, 4 successive days, 5 successive days, 6 successive days, 7 successive days, 8 successive days, 9 successive days, 10 successive days, 11 successive days, 12 successive days, 13 successive days, 14 successive days, 15 successive days, 16 successive days, 17 successive days, 18 successive days, 19 successive days, 20 successive days, 21 successive days, 22 successive days, 23 successive days, 24 successive days, 25 successive days, 26 successive days, 27 successive days, 28 successive days, 29 successive days, 30 successive days, 31 successive days, 32 successive days, 33 successive days, 34 successive days, 35 successive days, 36 successive days, 37 successive days, 38 successive days, 39 successive days, 40 successive days, or any range determinable from the preceding days (for example, 3 successive days to 5 successive days or 25 successive days to 35 successive days).

**[0061]** In one embodiment, cartridge 112 is configured to contain about 3 mL of teriparatide. In one embodiment, cartridge 112 is configured to contain about 2.7 mL of teriaparatide. In one embodiment, cartridge has a diameter of about 12 mm and a height of approximately 64 mm to contain 3 mL of medicament, although other dimensions can be used to achieve the desired accuracy. In another embodiment, cartridge 112 has a diameter of about 12 mm and a height of approximately 64 mm to contain about 2.7 mL of medicament, although other dimensions can be used to achieve the desired accuracy.

Cartridges 112 containing more or less medicament can be provided and can vary in diameter, height or both. In one embodiment, cartridge 112 is configured to hold between about 0.5 mL, 1.0 mL, about 1.5 mL, about 2.0 mL, about 2.5 mL, about 3.0 mL, about 3.5 mL, about 4.0 mL, about 4.5 mL, about 5.0 mL, about 5.5 mL, about 6.0 mL, about 6.5 mL, about 7.0 mL, about 7.5 mL, about 8.0 mL, about 8.5 mL, about 9.0 mL, about 9.5 mL, about 10.0 mL or any range determinable from the preceding amounts (for example, about 2 mL to about 5 mL or 3.0 mL to about 9.5mL) of liquid medicament. In one embodiment, injection device 100 is configured to dispense different amounts of liquid medicament per dose. Further, the overall volume can be increased to include a predetermined amount of additional volume that remains in cartridge 112 when the intended dosing is complete. This can reduce the likelihood of an incomplete final dose or the presence of air in an injection.

**[0062]** With additional reference to FIGS. 1B, 1C, 3A and 3B, 15A, 15B, 17A and 17B, proximal section 120 of injection device 100 contains the dosage mechanism 126 which is configured to cause movement of plunger 110 contained in cartridge 112 a predetermined dosing distance. This movement may occur in successive increments and such successive increments may correspond to the number of doses to be administered. In one embodiment, dosage mechanism 126 includes a ram 108, a ratchet gear 116, a crank arm 106 and a user-manipulable push button 104.

**[0063]** Referring to FIGS. 4 and 18, in one embodiment, ram 108 has a foot 1084, a shaft 1086, and a support bar 1088. In one embodiment, foot 1084 is at a distal end of shaft 1086 and includes a planar surface. In one embodiment, the planar surface is circular. In one embodiment, foot 1084 has a larger surface area than any transverse cross-sectional area of the shaft 1086 to distribute loading on the cartridge plunger 110 that foot 1084 contacts and thereby directly engages cartridge plunger 110 during advancement. In one embodiment, shaft 1086 has a distal portion 1090 having a larger transverse cross-sectional area than a transverse cross-sectional area of a proximal portion 1092 to distribute loading on the foot 1084. In one embodiment, shaft 1086 is not axially aligned with the center of foot 1084. In one embodiment, ram 108 includes a lock out protrusion 1094 (as shown in FIG. 4) or a lock out protrusion 1096 (as shown in FIGS. 13A, 13B, and 18) that extends from a proximal end of shaft 1086 configured for use with a lock-out feature (described in more detail below). In one embodiment, shaft 1086 has at least two sets of teeth, gear engaging teeth 1080 and pawl engaging teeth 1082 axially disposed along opposing sides of a portion of shaft 1086. In one embodiment, the geometry of gear engaging teeth 1080 matches the geometry of pinion teeth

1162 on ratchet gear 116 (discussed in more detail below). The pawl engaging teeth 1082 are spaced apart linearly according to the dose travel amount. In one embodiment, pawl engaging teeth 1082 include a pressure angle. In one embodiment, the pressure angle of pawl engaging teeth 1082 is axially aligned with the plunger axis. In another embodiment, support bar 1088 is axially disposed along a portion of shaft 1086. In another embodiment support bar 1088 is configured to interact with second portion of housing 1020b In another embodiment, support bar 1088 is on shaft 1086 to provide stiffness to the part.

**[0064]** Referring to FIGS. 5 and 19, in one embodiment, ram 108 is constrained by the internal shaping of the housing 102 to be axially translatable and rotatably fixed therein. As shown in FIG. 2B and 16B, in one embodiment, second portion of housing 1020b has a support bar receiving slot 1028 which is configured to hold support bar 1088 of ram 108 to prevent rotation and allow axial translation of the ram 108. In certain embodiments, lateral or rotational ram movement disengages the pinion teeth 1162. In one embodiment, ram 108 is movable in the distal direction and prevented from proximal movement relative to the housing 102. As shown in FIGS. 5 and 19, in one embodiment, pawl engaging teeth 1082 are employed with a portion of housing 102 to provide for these one-way axial motions.

**[0065]** In one embodiment, pawl engaging teeth 1082 are provided with a one-way ramping, and are engageable with a pawl 1026, which is integrally formed within in the second portion of housing 1020b and functions within housing 102. In one embodiment, ram teeth 1082 slide over pawl 1026 as the ram 108 is moved distally during injection, but pawl 1026 abuts pawl engaging teeth 1082 upon proximal movement of ram 108. In one embodiment, pawl 1026 is in interference with and presses ram 108 such that gear engaging teeth 1080 are in close contact with pinion teeth 1162. In one embodiment, pawl engaging teeth 1082 are equal in length, resulting in ram travel being of equal length per stroke and resulting in a single or fixed dose injection device. In a multiple dose, fixed dose embodiment, pawl engaging teeth 1082 are of unequal in length, resulting in unequal ram travel per stroke.

**[0066]** Referring to FIGS. 3B and 17B, in one embodiment, gear engaging teeth 1080 are engageable with ratchet gear 116. In one embodiment, pinion teeth 1162 and ratchet teeth 1164 are in one component connected through axis 1160. In one embodiment, the ratchet teeth 1164 are spaced at a predetermined angle. In one embodiment, the pinion teeth 1162 have a predetermined pitch diameter and involute gear teeth geometry. In one embodiment, the combination of the angular rotation of the ratchet gear 116, the pinion teeth 1162 and the

gear engaging teeth 1080 on the ram 108 control the dosage amount. Ram 108 is shown in FIGS. 4 and 18 as being integrally provided with its gear engaging teeth 1080 and pawl engaging teeth 1082, such as by being made of a one-piece plastic injection molding, or a one-piece metal part. Other constructions of ram 108, such as an assembly of separately formed component parts, are within the scope of the invention.

**[0067]** Referring to FIGS. 3A, 3B, 17A and 17B, in one embodiment, the dosage mechanism 126 includes a ratchet gear 116. In one embodiment, ratchet gear 116 is centered longitudinally within injection device 100. In one embodiment, ratchet gear 116 is not centered longitudinally within injection device 100. As shown in FIG. 6, in one embodiment, ratchet gear 116 includes housing engagement members 1166a and 1166b and two sets of gear teeth, pinion teeth 1162 and ratchet gear teeth 1164. In one embodiment, housing engagement member 1166a defines an axis 1160 for rolling rotation of ratchet gear 116. In one embodiment, as shown in FIG. 20, ratchet gear 116 includes a recess 1168 (rather than housing engagement member 1166b), which is configured to couple with housing mating pin 1024c (as shown in FIG. 16B) disposed on the internal surface of house part 1020b to aid in preventing axial translation and allowing rotation of the ratchet gear about axis 1160. In one embodiment, axis 1160 is perpendicular to axis 124. In one embodiment, ratchet gear 116 is constrained by the internal shaping of the housing 102 to be rotatable about axis 1160 and axial fixed therein. In one embodiment, housing parts 1020a and 1020b have ratchet gear engagement members 1024a and 1024b which are configured to engage housing engagement members 1166a and 1166b of ratchet gear 116, respectively, to prevent axial translation and allow rotation of the ratchet gear about axis 1160. In one embodiment, ratchet gear 116 includes housing engagement members 1166a and 1166b configured to engage protrusions of housing parts 1020a and 1020b, such configuration preventing axial translation and allowing rotation of the ratchet gear about axis 1160.

**[0068]** Referring to FIGS. 1B and 15A, in one embodiment, pinion teeth 1162 are a continuous ring of teeth that are configured to engage gear engaging teeth 1080 of ram 108 such that as ratchet gear 116 rotates about axis 1160, ram 108 axially advances. In one embodiment, the ratchet gear teeth 1164 are a continuous ring of teeth that are configured to engage a crank arm 106. In one embodiment, ratchet gear teeth 1164 have one-way ramping. In one embodiment, the diameter of pinion teeth 1162 is smaller than the diameter of ratchet gear teeth 1164. In one embodiment, the number of teeth in pinion teeth 1162 is less than the number of teeth in ratchet gear teeth 1164. In one embodiment, there are 15 pinion teeth

1162. In another embodiment, there are 20 ratchet gear teeth 1164. Although pinion teeth 1162 and ratchet teeth 1164 are shown integrally formed in FIG. 6, these components can be separately formed and assembled together so as to be co-rotatable. In one embodiment, ratchet gear 116 moves forward by turning counterclockwise to dispense medicament. In another embodiment, ratchet gear 116 moves forward by turning clockwise to dispense medicament. As shown in FIG. 15B, in one embodiment, ratchet gear 116 includes a ratchet gear marker 1168. In one embodiment, alignment of ratchet gear marker 1168 with a protrusion 1030 on either of housing parts 1020a or 1020b prior to a first use of injection device 100 ensures that dosage mechanism 126 is in a proper pre-fired orientation. In one embodiment, protrusion 1030 prevents ratchet gear 116 from turning backwards by only allowing ratchet teeth 1164 to ramp over housing protrusion 1030.

**[0069]** Referring to FIGS. 3A, 3B, 7, 17A, 17B, and 21, in one embodiment, the dosage mechanism 126 includes a crank arm 106. In one embodiment, as shown in FIGS. 7 and 21, crank arm 106 is generally V-shaped, having two legs, a crank arm leg 1066 and a pawl arm leg 1068. In one embodiment, crank arm leg 1066 includes a crank arm pivot hole 1064 at distal end which is configured to be slideably engageable with housing engagement member 1166a of the ratchet gear 116, which allows the crank arm 106 to be rotatable about axis 1160 but be axially fixed. In one embodiment, the crank arm pivot hole 1064 is generally aligned with axis 1160. In one embodiment, pawl arm leg 1068 includes a pawl tooth 1062 which is shaped to mesh with ratchet teeth 1164. In one embodiment, crank arm 106 includes a push button engagement member 1060, e.g., a projection, at the apex of crank arm 106 that extends from the apex towards slot 1046b on push button 104. In one embodiment, push button engagement member 1060 is configured to be slideably engageable with slot 1064b. In one embodiment, axially distal movement of push button 104 relative to housing 102 causes crank arm 106 to rotate about axis 1160 and pawl tooth 1062 to engage ratchet gear teeth 1164, causing ratchet gear 116 to rotate pinion teeth 1162 about axis 1160 that causes ram 108 to distally advance. In one embodiment, axially proximal movement of push button 104 relative to the housing 102 causes crank arm 106 to rotate about axis 1160 in an opposite direction and pawl tooth 1062 to disengage ratchet gear teeth 1164.

**[0070]** With continued reference to FIGS. 3A, 3B, 17A and 17B, in one embodiment, the dosage mechanism 126 includes a user-manipulable push button 104 that allows the user to actuate the injection device 100. In one embodiment, as shown in FIG. 8, push button 104 is a unitary structure. In one embodiment, as shown in FIGS. 9A, 9B, and 9C, push button 104 is

a non-unitary structure. In one embodiment, as shown in FIGS. 9A, 9B and 9C, push button 104 includes a cap 1040, a connector 1042, a force limiting biasing member 1044, and a base member 1046. In one embodiment, cap 1040 includes a user-contacting portion 1040a and tabs 1040b. In one embodiment, user-contacting portion 1040a has a hollow portion configured to facilitate connection with connector 1042. In one embodiment, tabs 1040b are configured to snap fit with corresponding features of connector 1042. In one embodiment, cap 1040 is molded from plastic. In other embodiments, cap 1040a is covered with a soft touch material. In one embodiment, tabs 1040b are sized and shaped to be fixed within connector 1042. In one embodiment, cap 1040 and connector 1042 are different colors. In one embodiment, when injection device 100 is in the fired state, connector 1042 is not visible. In one embodiment, when injection device 100 is not in a fired state, the connector 1042 is visible. In one embodiment, cap 1040 and connector 1042 are different colors so that a user can visually determine whether injection device 100 is in a fired state or not in a fired state.

**[0071]** Referring to FIGS. 9A, 9B and 9C, in one embodiment, connector 1042 of push button 104 includes connector body 1042a having a hollow portion 1042b, tabs 1042c, and a linear travel guide 1042f. In another embodiment, connector 1042 of push button 104 includes connector body 1042a having an indicating band 1042e. In one embodiment, tabs 1042c proximally extend from connector body 1042a. In another embodiment, tabs 1042c are sized and shaped to facilitate a fixed connection between cap 1040 and connector 1042. Cap 1040 and connector 1042 are shown as being fixedly connected via the use of tabs in FIG. 8. In other embodiments, cap 1040 and connector 1042 are integrally formed, such as by being made of a one-piece plastic injection molding, or a one-piece metal part.

**[0072]** In another embodiment, a linear travel guide 1042f extends from a distal portion of the connector body 1042a. In one embodiment, linear travel guide 1042f is configured to limit withdrawal of the push button from housing 102 and insertion of the push button into housing 102. In one embodiment, linear travel guide 1042f includes a shelf 1042d configured to engage housing 102 to limit withdrawal of the push button from housing 102. In one embodiment, linear travel guide 1042f includes a guide base 1042g configured to engage housing 102 to limit insertion of the push button into housing 102. In one embodiment, shelf 1042d is sized and shaped to engage with lip 1032 of housing 102 to limit withdrawal of the push button 104 from housing 102. In other embodiments, guide base 1042g is sized and shaped to engage a base engaging member 1034 of housing 102 to limit insertion of the push

button 104 into the housing. In other embodiments, the linear travel guide 1042f is sized and shaped to slideably fit within shelf engaging openings 1036 of housing 102 to limit both the withdrawal and insertion of push button 104 into and out of housing 102. In one embodiment, linear travel guide 1042f is used to keep connector body 1042 aligned axially with the housing parts 1020a and 1020b. As shown FIG. 8, in some embodiments, the linear travel guide 1042f extends continuously along the circumference of the connector body 1042a. As shown in FIGS. 9A, 9B, and 9C, in other embodiments, linear travel guide 1042f extends discontinuously along the circumference of the connector body 1042a. In one embodiment, indicating band 1042e is configured to be visible to a user when push button 104 has been properly withdrawn from the housing 102 to prepare injection device 100 for medicament delivery. As shown in FIG. 8, in one embodiment, indicating band 1042e extends continuously along the circumference of connector body 1042a. As shown in FIGS. 9A, 9B, and 9C, in other embodiments, indicating band 1042e extends discontinuously along the circumference of connector body 1042a. In one embodiment, indicating band 1042e can incorporate a color, e.g., red, to add to the affect thereof. In one embodiment, when indicating band 1042e is visible, injection device 100 is in the ready (or reset) state. In one embodiment, when injecting band 1042e is not visible, injection device 100 is in the fired state. In one embodiment, hollow portion 1042b of connector body 1042a is sized and shaped to hold force limiting biasing member 1044.

**[0073]** In one embodiment, force limiting biasing member 1044 of push button 104 is a metal, helically-coiled compression spring. In one embodiment, force limiting biasing member 1044 is disposed within hollow portion 1042b of connector body 1042a. In one embodiment, force limiting biasing member 1044 is captured in a pre-stressed force state between the interior end of cap 1040 and a top portion of flanges 1046a of base member 1046 (described in more detail below). In one embodiment, the pre-stressing force is at minimum as large as forces users exert on the push button during proper operation of injection device 100. In one embodiment, the pre-stressing force is no larger than what the dosing mechanism 126 can withstand without damage to the interacting components. Thus, in one embodiment, during normal actuation of injection device 100, force limiting biasing member 1044 does not further compress, as shown in FIGS. 10A, 10B, and 10C. FIGS. 10A, 10B, and 10C show an exemplary force limiting biasing member 1044 during normal operation of injection device 100. In another embodiment, as shown in FIGS. 11A, 11B, 11C, and 11D, force limiting biasing member 1044 is designed with sufficient spacing in its coiling, and

with proper elastic properties, such that the force limiting biasing member 1044, by compression, can accommodate movement of push button 104 from a ready (or reset) state to a fired stated without movement of ram 108, ratchet gear 116, or crank arm 106, whereby force limiting biasing member 1044 can absorb actuation forces that could damage components. FIGS. 11A, 11B, 11C, and 11D show an exemplary force limiting biasing member 1044 compressing within connector 1042 which can occur when for example there a needle is miscoupled or occluded.

**[0074]** Referring to FIGS. 12A-12E, in one embodiment, injection device 100 has a ready (or reset) state wherein push button 104 is withdrawn from the housing 102 and indicator 1042 is visible to the user, as shown in FIG. 12C. In another embodiment, injection device 100 has a fired state wherein push button 104 is actuated and the base rim of cap 1040 is flush against a top portion of the housing 102, as shown in FIGS. 12A and 12E. In one embodiment, movement of push button 104 distally along axis 124 from a ready (or reset) state towards a fired state is considered firing motion, as shown in FIGS. 12C through 12E. Whereas, in another embodiment, movement of push button 104 proximally along axis 124 from a fired state towards a ready (or reset) state is considered resetting motion, as shown in FIGS. 12A through 12C.

**[0075]** Referring to FIG. 8, in one embodiment, base member 1046 includes a lockout aperture 1046g configured for use with a lock-out feature (described in more detail below). In one embodiment, base member 1046 of push button 104 includes flanges 1046a that are configured to be slideably connected within the hollow portion 1042b of connector 1042. In one embodiment, flanges 1046a are configured to be slideably connected to tracks disposed within the hollow portion 1042b of connector 1042 to ensure axial alignment of base member 1046 and connector 1042. In certain embodiments, the connection of flanges 1046a and the hollow portion 1042b of connector 1042 are such that base member 1046 is restricted to sliding generally axially along the interior surface of the hollow portion 1042 and such that the base member 1046 is restricted from generally rotating about the interior surface of the hollow portion 1042. In one embodiment, base member 1046 and housing 1020b are integrally connected to restrict movement of push button 104 to linear movements along axis 124. In certain embodiments, base member 1046 is configured to engage housing 102 to restrict movement of push button 104 to linear movement along axis 124. In certain embodiments, as shown in FIGS. 16B and 17B, base member 1046 has housing engagement slots 1046e that engage base member engagement plates 1021of housing 1020b to restrict

movement of push button 104 to linear movement along axis 124. As shown in FIG. 8, in another embodiment, base member 1046 has a housing engagement protrusion 1046f that is configured to engage base member engagement slot 1038 of housing 1020b to restrict movement of push button 104 to linear movements along axis 124.

**[0076]** Referring to FIG. 3B, in one embodiment, base member 1046 includes a slot 1046b disposed through the base member 1046. In one embodiment, slot 1046b is configured to engage push button engagement member 1060 of crank arm 106. In one embodiment, slot 1046b is slideably engageable with push button engagement member 1060. In one embodiment, slot 1046b is generally rectangular shaped. In another embodiment, slot 1046b is generally rectangular shaped with curved ends. In another embodiment, slot 1046b is generally polygonal. in another embodiment, slot 1046 is curved. In one embodiment, slot 1046b is oriented at an oblique angle with respect to axis 124. In one embodiment, translation of push button 104 distally or proximally along axis 124 causes push button engagement member 1060 to translate along the path of slot 1046b. In one embodiment, translation of push button 104 from a ready (or reset) state distally along axis 124 causes push button engagement member 1060 to translate along the path of slot 1046b, causing crank arm 106 to rotate about axis 1160. The path traced by slot 1046b could be of any geometry that crank arm engagement member 1060 could travel in. While keeping the start position and end position of this slot the same, a fixed dose can be achieved while varying the button force profile exerted by the user.

**[0077]** Referring to FIG. 9A, in one embodiment, slot 1046b of base member 1046 has portion 1046i and portion 1046j. In one embodiment, portion 1046i and portion 1046j of slot 1046b are at different angles with respect to axis 124. In one embodiment, portion 1046i is oriented at an oblique angle with respect to axis 124. In another embodiment, portion 1046j is oriented parallel to axis 124. In one embodiment, slot portion 1046j allows a user to translate push button 104 from a ready (or reset) state distally along axis 124 for a distance without movement of any other components of dosing mechanism 126. In one embodiment, translation of push button 104 distally along axis 124 from a ready (or reset) state translates push button engagement member 1060 (Fig. 7) along the path of slot portion 1046j, which keeps crank arm 106 from rotating about axis 1160 (Fig. 3B). In one embodiment, when push button engagement member 1060 is positioned at the most distal portion of slot portion 1046i, further translation of push button 104 distally along axis 124 translates push button engagement member 1060 along the path of slot 1046i, causing crank arm 106 to rotate about

axis 1160. In one embodiment, the orientation of slot portion 1046j allows a user to press push button 104 for a period of time without injecting any medicament. In another embodiment, slot portion 1046i could have the same orientation with the same effect that push button 104 is pushed without the injection of medicament. The slot portion 1046j allows the user to build up momentum of push button 104 prior to injection of a medicament dose. Injection of medicament into a user can often time cause discomfort to the user, which can cause the user to withdraw the injection needle prior to full medicament dose injection. In one embodiment, the momentum of push button 104 that is built up as the user presses push button without injection of medicament is sufficient to allow for injection of a medicament dose with sufficient speed as to not provide the user time to react to any discomfort from medicament injection and withdraw the injection needle prior to full medicament dose injection. In another embodiment, the geometry of 1046j would have a vertical portion on the proximal end. In other embodiments, slot angles with longer or shorter sections alike 1046j or curved or parabolic slot would have changing force profiles of the button. In one embodiment a straight linear slot is implemented to keep constant force and contact with crank arm engagement member. In one embodiment, with a linear slot, the angle produced by the slot is a product of two dimensions. The vertical dimension, which stretches from the distal portion of the slot to the proximal portion of the slot and parallel to proximal-distal axis 124, is correlated to the desired button stroke. The horizontal dimension, perpendicular to proximal-distal axis 124 and stretching from the two furthest points on the slot directly correlate to the rotation of the crank arm 106.

**[0078]** In one embodiment, base member 1046 includes a flexible column 1046c extending proximally from a distal portion of base member 1046. In other embodiments, a column tooth 1046d extends perpendicularly from a proximal portion of flexible column 1046c. In certain embodiments, column tooth 1046d is generally almond shaped, as shown in FIG. 9A. In other embodiments, column tooth 1046d is generally cylindrically shaped, as shown in FIG. 8. In other embodiments, column tooth 1046d is generally polyhedronally shaped. Other shapes of column teeth 1046d are within the scope of this invention. In one embodiment, as shown in FIGS. 1B and 1C, column tooth 1046d is configured to engage the anti-retrograde ratchet side 1022b of unidirectional rack 1022. In one embodiment, a unidirectional rack 1022 is integrally formed on the internal surfaces of housing parts 1020a and 1020b. In one configuration, column tooth 1046d can be found in a double shear type load, which is known to be stronger and more stable than single shear configurations. In

another embodiment, unidirectional rack 1022 is formed on the internal surface of only of housing parts 1020a and 1020b, placing unidirectional rack 1022 and column tooth 1046d in a single shear configuration.

**[0079]** In one embodiment, unidirectional rack 1022 has a smooth linear ratchet side 1022a and an anti-retrograde ratchet side 1022b. In one embodiment, the anti-retrograde ratcheted side 1022b of unidirectional rack 1022 is configured to engage column tooth 1046d and only allow movement of push button 104 in one direction, e.g., from the fired state to the ready (or reset) state. In certain embodiments, the anti-retrograde ratchet side 1022b of unidirectional rack 1022 has curved surfaces at both a proximal end and a distal end. In one embodiment, the proximal curved surface of anti-retrograde ratchet side 1022b is configured to bias the flexible column in a way to force column tooth 1046d to the smooth linear ratchet side 1022a of the unidirectional rack 1022. In one embodiment, the distal curved surface of anti-retrograde ratchet side 1022b is configured to bias the flexible column 1046c in a way to force column tooth 1046d to the anti-retrograde ratchet side 1022b of unidirectional rack 1022. In one embodiment, during resetting motion of push button 104, protrusions 1046d engage the distal curved surfaces of unidirectional rack 1022 causing flexible column 1046 to bias and forcing protrusions 1046d to the anti-retrograde ratchet side 1022b of unidirectional rack 1022, as shown in FIGS. 12A and 12B. In certain embodiments, if push button 104 is moved in a distal direction prior to completion of the resetting motion, protrusions 1046d would engage the ratchets of anti-retrograde ratchet side 1022b of unidirectional rack 1022, preventing distal movement. In one embodiment, during firing motion of push button 104, protrusions 1046d engage the proximal curved surfaces of anti-retrograde ratchet side 1022b of unidirectional rack 1022, causing flexible column 1046 to bias and forcing column tooth 1046d to the smooth linear ratchet side 1022a of unidirectional rack 1022, as shown in FIGS. 12C and 12D . In certain embodiments, the column tooth 1046d slides along the smooth linear ratchet side 1022a of unidirectional rack 1022 until the device is in the fired state. In one embodiment, the full amount of medicament which is to be expelled during the firing motion is only fully expelled upon push button 104 reaching the fired state. In one embodiment, if the push button does not complete the firing motion, the full amount of medicament for that dose is not fully expelled. In certain embodiments, a successive dose cannot be effectuated until the previous dosage amount of medicament is fully expelled. In one embodiment, the combination of the flexible column 1046c, column tooth 1046d and anti-retrograde ratchet side 1022b of unidirectional rack1022 are considered the anti-reverse

feature. In another embodiment, the combination of the interactions between the flexible column 1046c, column tooth 1046d and anti-retrograde ratchet side 1022b of unidirectional rack 1022, and the engagement of pawl 1026 of the housing 1020b with pawl engaging teeth 1082 are considered the anti-reverse feature.

**[0080]** Referring to FIG. 1C, in certain embodiments, the dosing mechanism 126 includes a lock-out feature, e.g., prevention of push button 104 from resetting from its fired position upon completion of the allotted medicament doses. In one embodiment, as shown in FIGS. 3A and 3B, the lock-out feature includes a protrusion 1094, which extends from a proximal portion of ram shaft 1086 in an opposite direction of support bar 1088 (Fig. 4), and a lockout aperture 1046g disposed in the base member 1046 of push button 104 (Fig. 8). In one embodiment, lockout aperture 1046g is disposed above slot 1046b. In one embodiment, protrusion 1094 is sized and shaped to protrude into lockout aperture 1046g. In one embodiment, lockout aperture 1046g is of a complimentary shape of protrusion 1094. In one embodiment, after each firing of the injection device 100, ram 108 is translated distally relative to the housing. In one embodiment, ram 108 is prevented from moving proximally relative to the housing because of engagement of pawl 1026 of the housing with pawl engaging teeth 1082. In one embodiment, after the final dose of medicament is expelled from the injection device, ram shaft 1086 is sufficiently distally translated so that when push button 104 reaches the fired state, protrusion 1094 and lockout aperture 1046g are aligned. In one embodiment, protrusion 1094 slides into lockout aperture 1046g thereby restricting movement of push button 104, e.g., push button 104 cannot reset because it is connected to ram shaft 1086 which is prevented from moving proximally relative to the housing by pawl 1026. In one embodiment, the proximal surface of protrusion 1094 is designed to promote protrusion 1094 sliding into lock out aperture 1046g. In one embodiment, the distal surface of protrusion 1094 is designed to remain engaged with the proximal surface of lockout aperture 1046g.

**[0081]** Referring to FIGS. 13A and 13B, in another embodiment, the lock-out feature includes a protrusion 1096 (as shown in FIG. 18), which extends from a proximal portion of ram shaft 1086, a lock-out member 2000 integrally formed within housing part 1020b, and a flange 1046h extending from base member 1046 towards housing 1020b. In one embodiment, lock-out member 2000 is only attached to the housing via a housing cross plate at a distal end of the lock-out member 2000. In one embodiment, lock-out member 2000 is flexible. In one embodiment, lock-out member 2000 includes a lockout deflector 2000a and a

hook 2000b. In one embodiment, lockout deflector 2000a of lock-out member 2000 is centrally positioned on the lock-out member 2000. In one embodiment, lockout deflector 2000a of lock-out member 2000 is configured to engage protrusion 1096 of ram 108. In one embodiment, lockout deflector 2000a of lockout member 2000 is configured to slidingly engage protrusion 1096 of ram 108. In one embodiment, hook 2000b of lock-out member 2000 is positioned at a proximal end of lock-out member 2000. In another embodiment, hook 2000b is configured to engage flange 1046h of base member 1046. As shown in FIGS. 13A and 13B, in one embodiment, during the firing motion of push button 104 of the final medicament dose of the injection device 100, protrusion 1096 of ram 108 engages lockout deflector 2000a of lock-out member 2000. In one embodiment, engagement of protrusion 1096 and lockout deflector 2000a biases lock-out member 2000 such that hook 2000b extends into the path of flange 1046h. As shown in FIGS. 13C and 13D, in one embodiment, once hook extends into the path of flange 1046h, any attempted resetting motion of push button 104 would cause engagement of hook 2000b and flange 1046h. In one embodiment, engagement of hook 2000b and flange 1046h prevent any resetting motion of push button 104, thus, locking out the device from further use. In one embodiment, a portion of housing part 1020b is cut out in the shape of lock-out member 2000. The cut out portion of housing part 1020b is aligned with lock-out member 2000 so as to give a visual indication that the lock-out feature has been activated. In one embodiment, injection device 100 includes a cover 130 engagable with housing 102 that removably covers the cut out portion of housing part 1020b.

**[0082]** While the dosing mechanism described herein is shown as a part of a needled injection device for a liquid medicament, it is understood that the mechanism can be used in other dispensing devices that include a dispenser that is actuated by linear motion. This includes injection devices that use a mechanism other than a push button as well as other dispensing devices for gels or the like which may or may not contain a medicament.

**[0083]** In one embodiment, the dose size can be varied by changing the diameter of cartridge 112. In certain embodiments, a higher diameter will increase the dose size. In other embodiments, a smaller diameter will decrease the dose size. In one embodiment, varying the space between pawl engaging teeth 1082 and, correspondingly, pinion teeth 1162, can vary the dose size. In other embodiments, varying the shape of crank arm 106, the length of the crank arm leg 1066 or pawl arm leg 1068, or the angle of slot 1046b of base member 1046 can vary the dose size by varying the rotational angle of ratchet gear 116 caused by

crank arm 106. These factors can be adjusted to derive an injector that contains a desired amount of liquid medicament and will produce the desired number of doses at a desired amount, and in certain embodiments fixed amount, and will have the desired dosing and resetting motions.

**[0084]** Each and every reference identified herein is incorporated by reference in its entirety. The entire disclosure of U.S. patent application publication number 2010/0036320 is hereby incorporated herein by reference thereto as if fully set forth herein. The term "about," as used herein, should generally be understood to refer to both the corresponding number and a range of numbers. Moreover, all numerical ranges herein should be understood to include each whole integer within the range.

**[0085]** It is to be understood that at least some of the figures and descriptions of the invention have been simplified to focus on elements that are relevant for a clear understanding of the invention, while eliminating, for purposes of clarity, other elements that those of ordinary skill in the art will appreciate may also comprise a portion of the invention. However, because such elements are well known in the art, and because they do not necessarily facilitate a better understanding of the invention, a description of such elements is not provided herein.

CLAIMS

1. A dispensing mechanism, comprising:

a housing having a proximal-distal axis;

a ram within the housing, movable in a distal direction;

a user-operable push button moveable along the proximal-distal axis relative to the housing, the push button including a push button slot at a distal portion of the push button;

a crank arm having a pawl tooth, a pivot point, and a crank arm engagement member slideably engageable with the push button slot such that movement of the push button causes the crank arm engagement member to move along the push button slot, causing rotation of the crank arm about the pivot point; and

a ratchet gear having a first set of teeth releasably engageable with the pawl tooth and a second set of teeth releaseably engageable with the ram,

wherein engagement of the pawl tooth with the first set of teeth of the ratchet gear causes the ratchet gear to rotate, causing the ram to distally advance relative to the housing.

2. The dispensing mechanism of claim 1, further comprising an anti-reverse mechanism including:

at least one housing ratchet integrally formed on an internal surface of the housing; and

a flexible column integrally formed extending from a distal portion of the push button, the flexible column having a flexible column protrusion at a proximal end thereof,

wherein as the push button moves along the proximal-distal axis, the flexible column protrusion engages the housing ratchet and restricts movement of the push button to one direction during a resetting motion.

3. The dispensing mechanism of claim 2, wherein the flexible column protrusion is almond shaped.

4. The dispensing mechanism of claim 1, wherein the ram includes at least two sets of teeth.

5. The dispensing mechanism of claim 4, wherein at least one set of teeth has involute spur rack geometry.

6. The dispensing mechanism of claim 4, wherein a first set of ram teeth are configured to engage the second set of teeth of the ratchet gear, and a second set of ram teeth are configured to engage a housing protrusion, the housing protrusion being integrally formed within the housing and configured to facilitate movement of the ram in one direction.

7. The dispensing mechanism of claim 6, wherein first set of ram teeth and second set of teeth of the ratchet gear have similar corresponding involute gear teeth geometry.

8. The dispensing mechanism of claim 1, wherein the push button slot is oriented at an oblique angle with respect to the proximal-distal axis.

9. The dispensing mechanism of claim 1, wherein a push button slot has a portion that is oriented at an oblique angle with respect to the proximal-distal axis and a portion that oriented parallel to the proximal-distal axis.

10. The injector of claim 1, wherein the ratchet teeth of ratchet gear control the dose amount

11. An injector comprising:

the dispensing mechanism of claim 1;

a cartridge disposed within the housing;

a plunger disposed in the cartridge to seal a medicament therein, wherein the ram is associated with the plunger for forcing the plunger in a distal direction for ejecting a dose of medicament; and

a needle in fluid communication with the cartridge for injecting the doses into a patient.

12. The injector of claim 11, wherein the medicament includes a parathyroid hormone.

13. The injector of claim 12, wherein the parathyroid hormone is teriparatide.

14. The injector of claim 11, wherein the medicament includes glucagon-like peptide receptor agonists.

15. The injector of claim 14, wherein the glucagon-like peptide receptor agonist is exenatide.

16. The injector of claim 14, wherein the glucagon-like peptide receptor agonist is liraglutide.

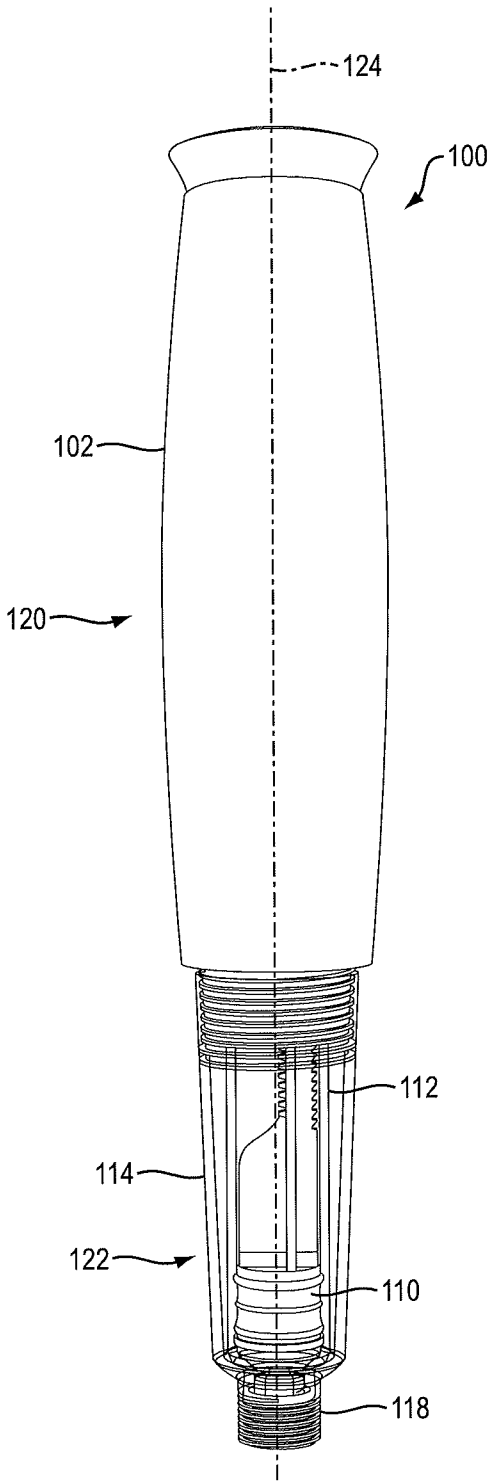



FIG. 1A

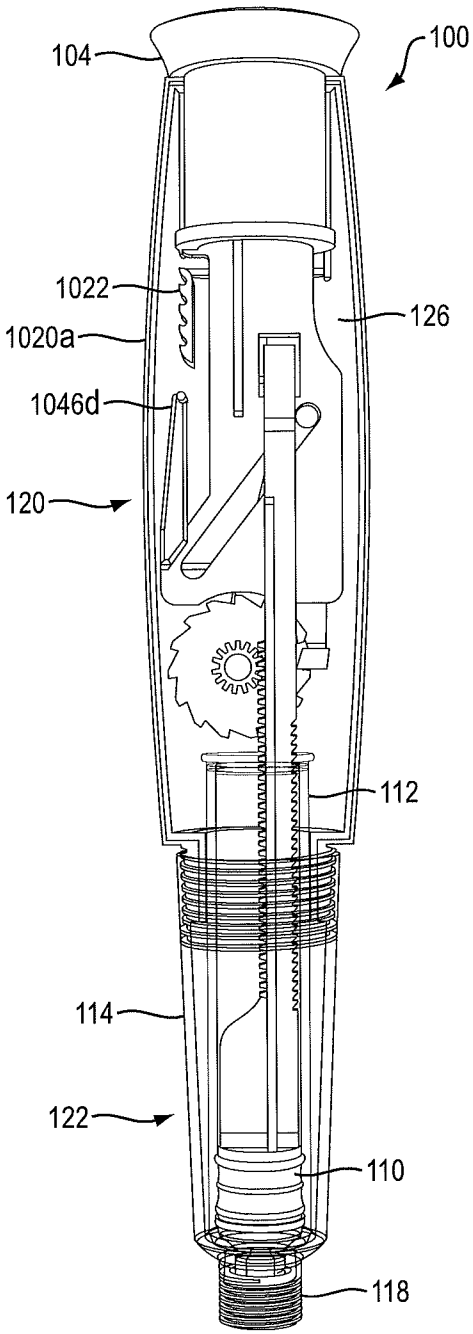



FIG. 1B

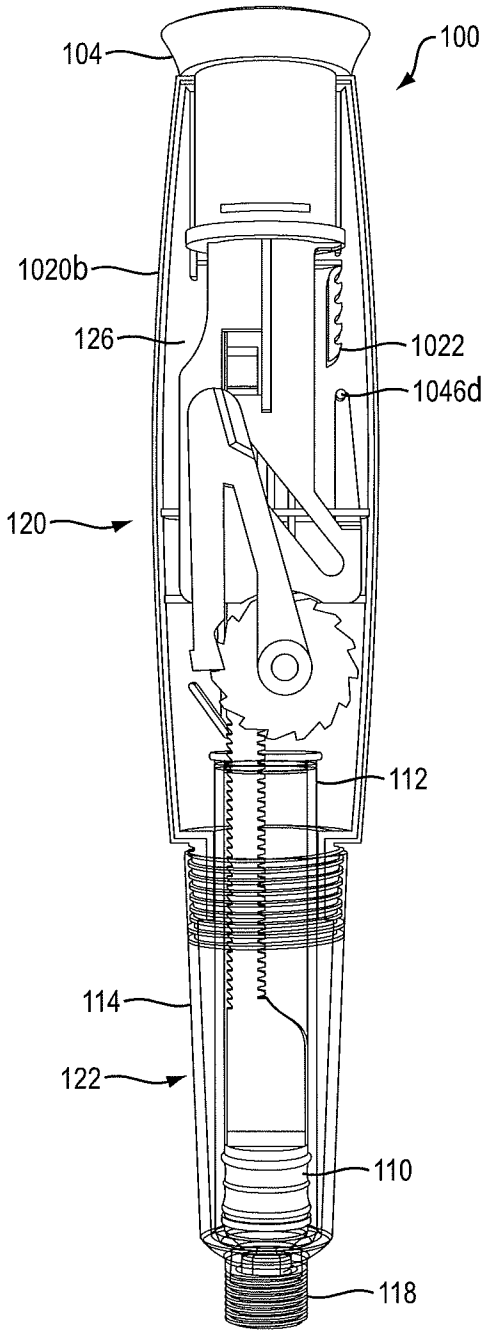



FIG. 1C

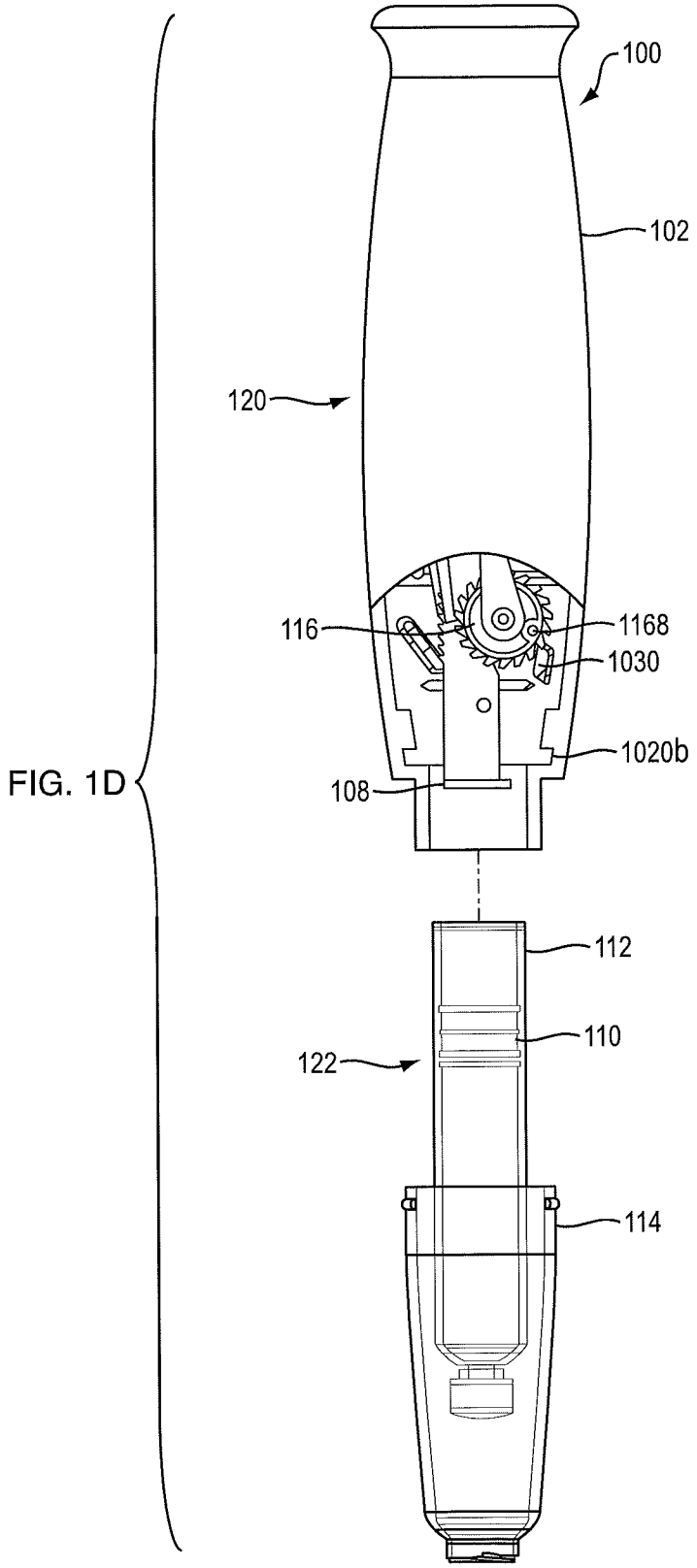



FIG. 1D

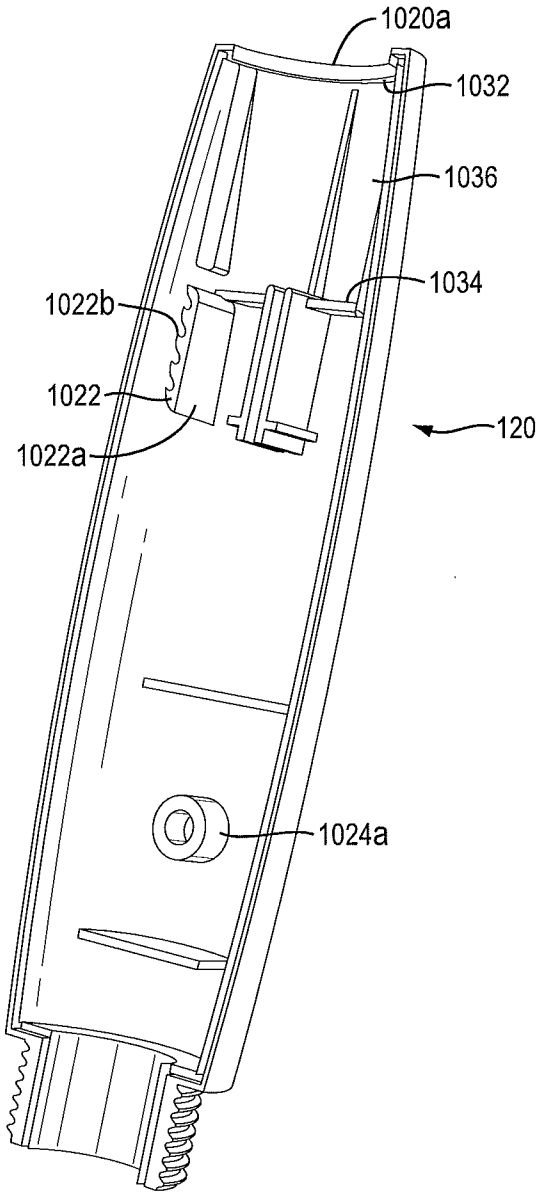



FIG. 2A

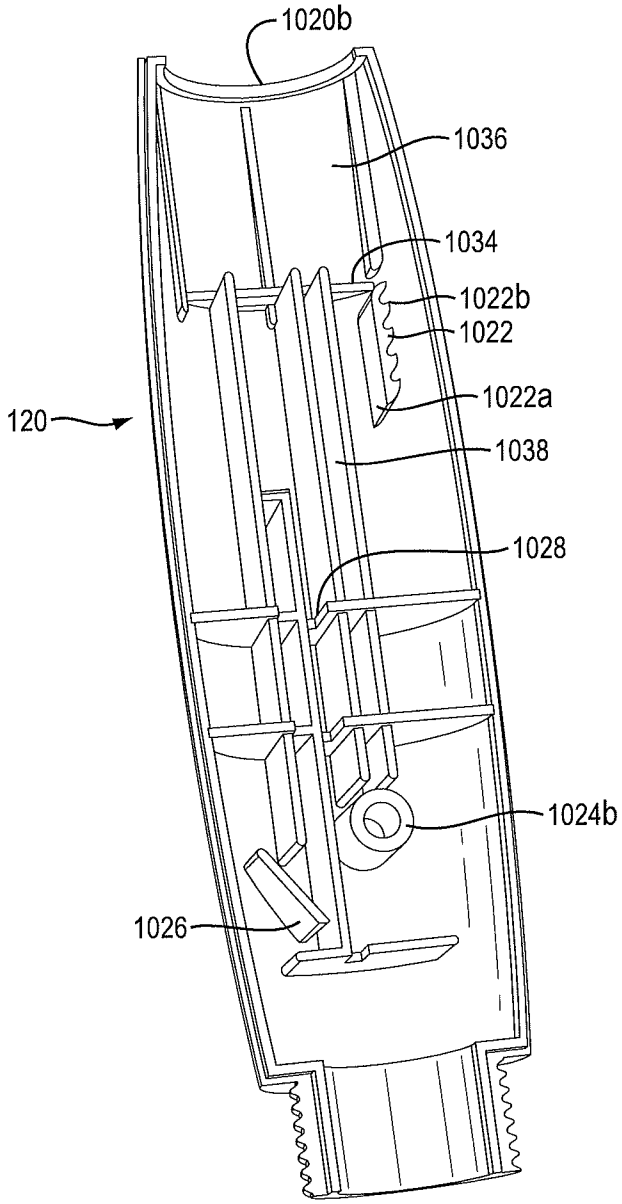



FIG. 2B

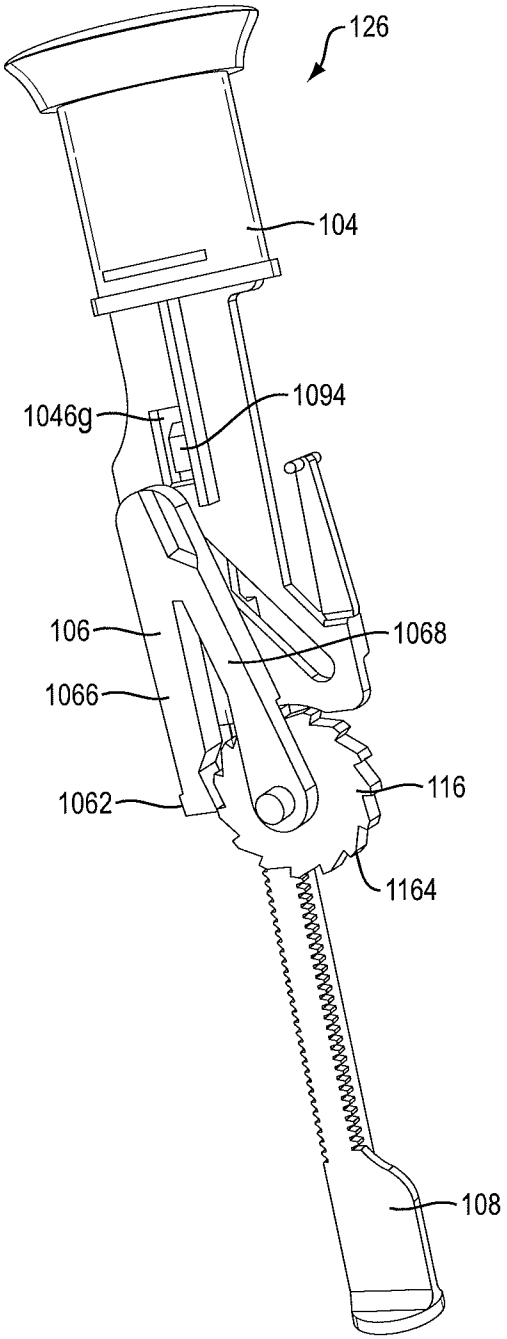



FIG. 3A

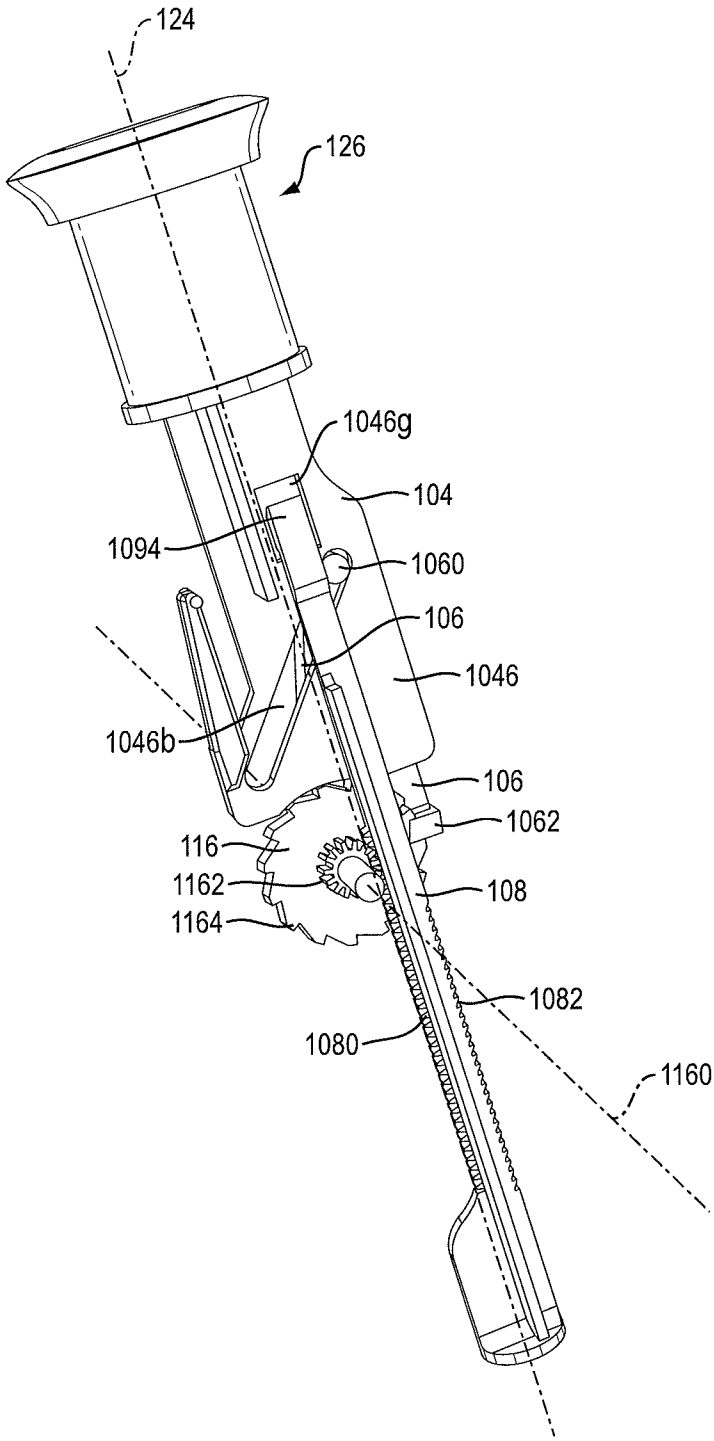

124
126
1046g
104
1094
1060
106
1046
1046b
106
1062
116
1162
108
1164
1082
1080
1160

FIG. 3B

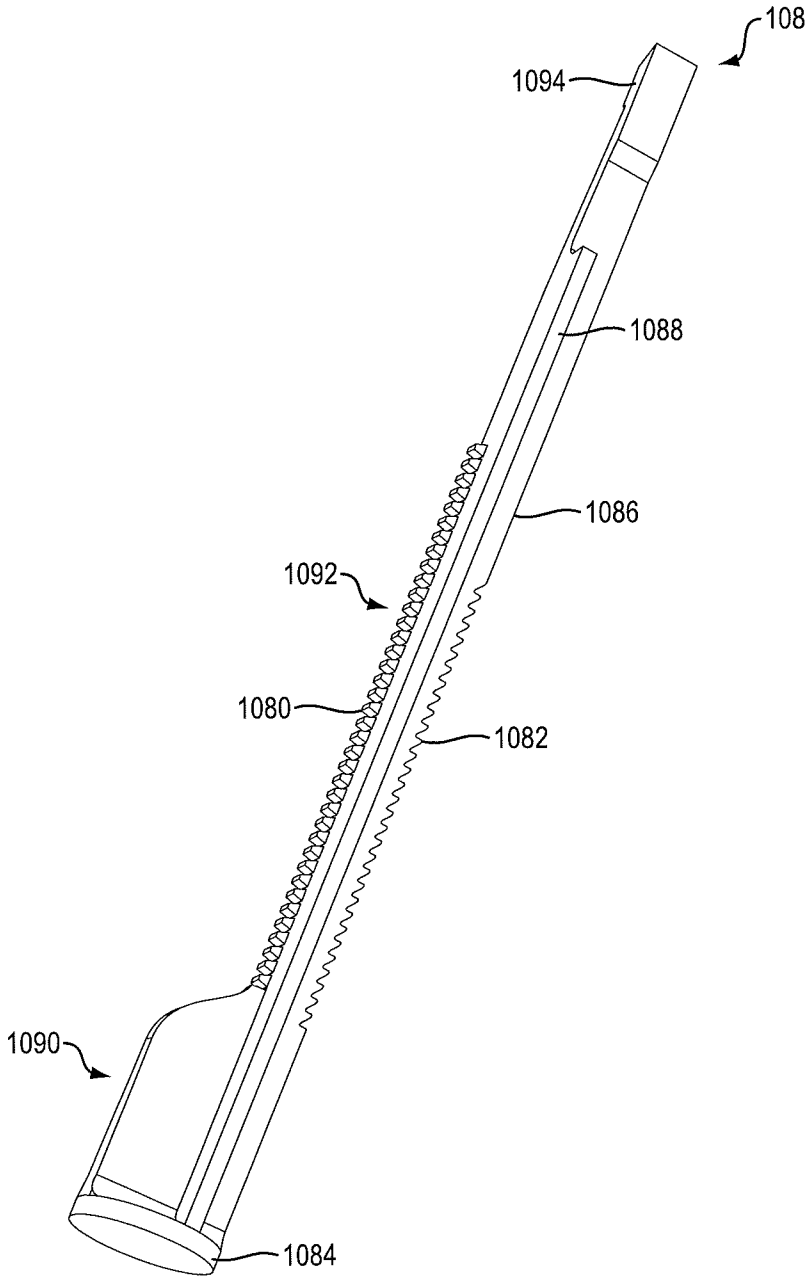



FIG. 4

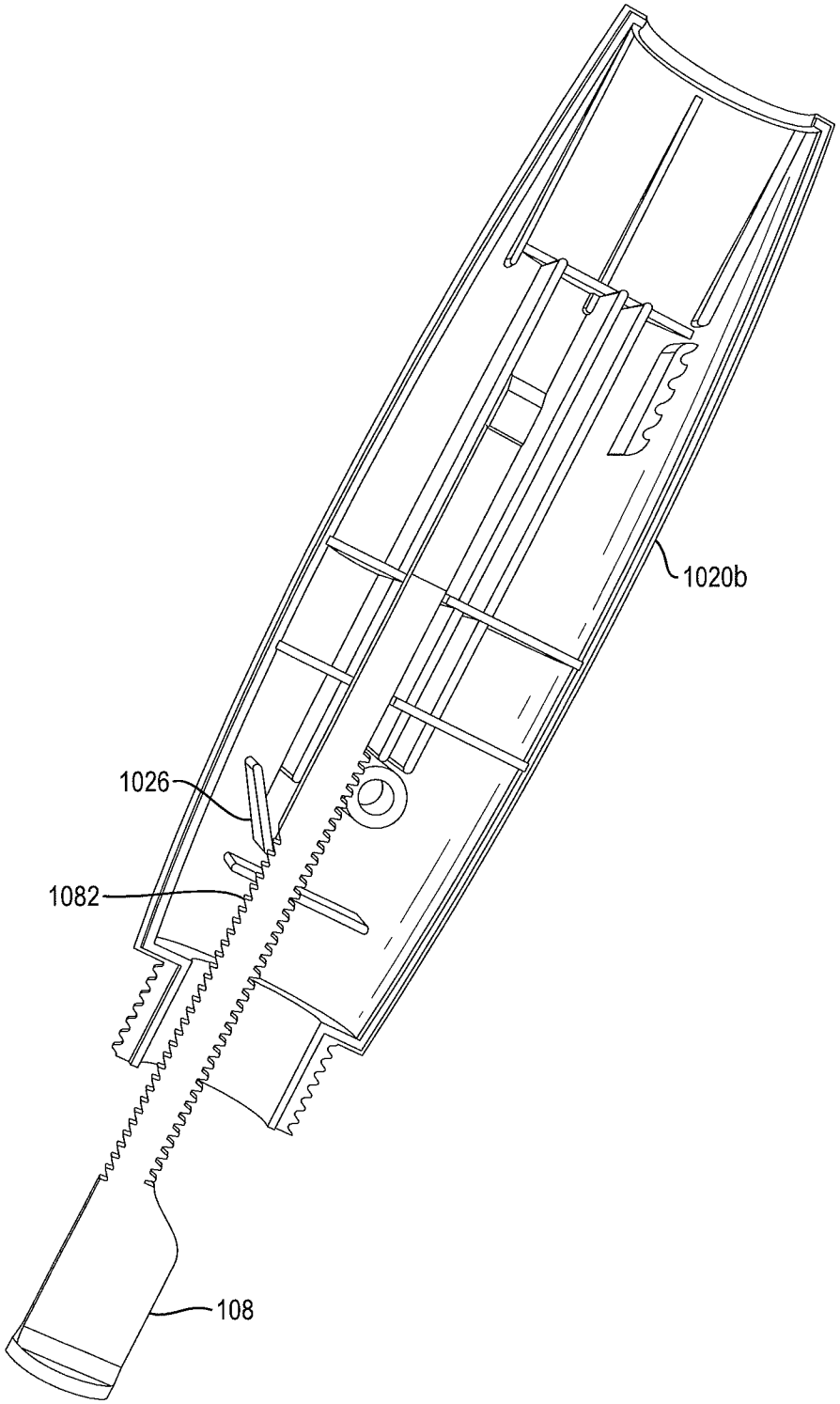



FIG. 5

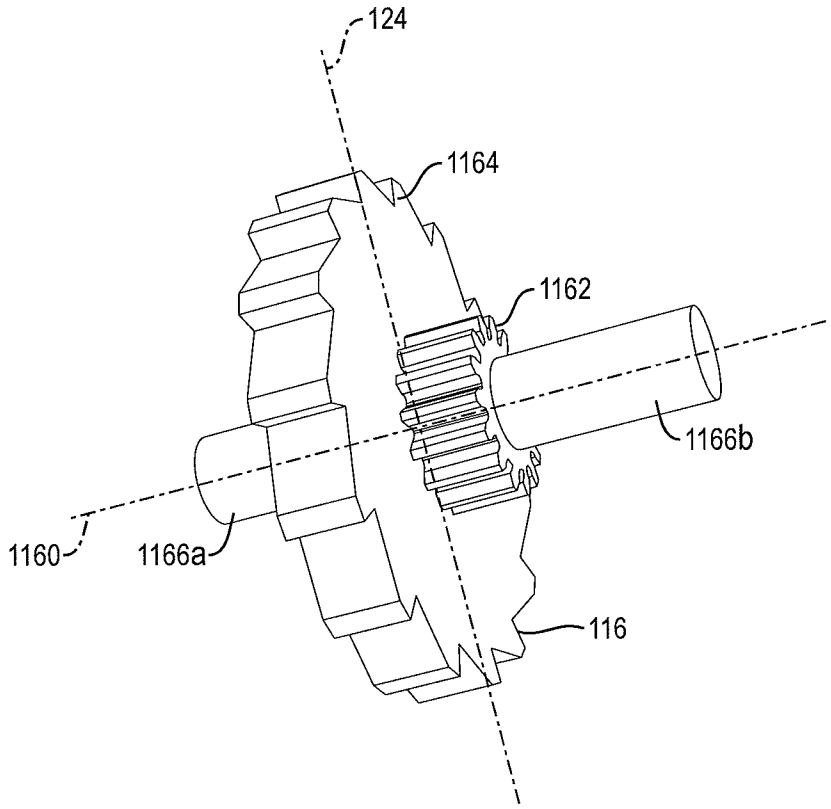



FIG. 6

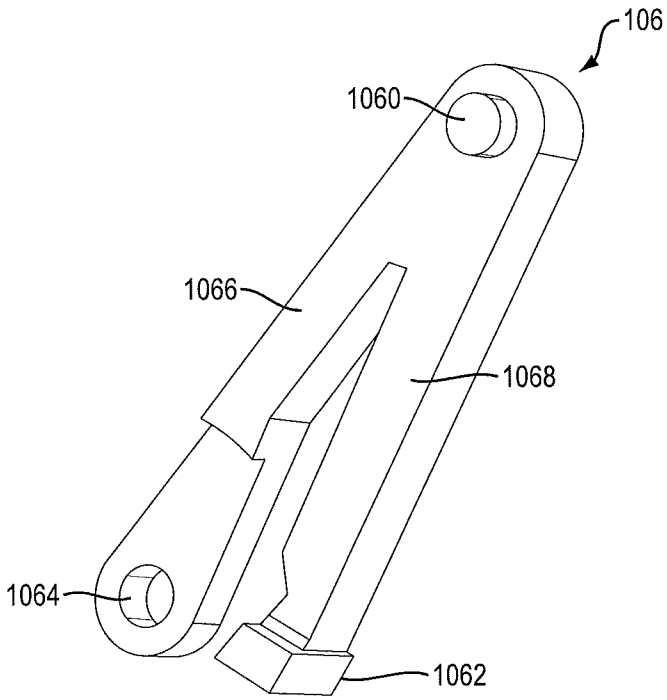



FIG. 7

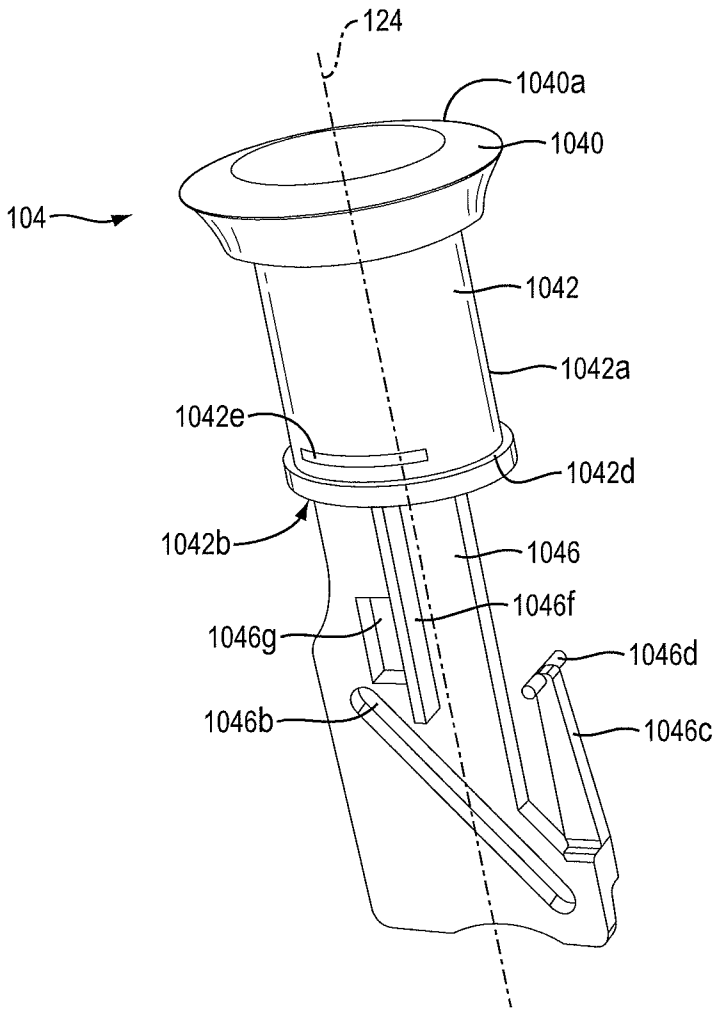

124
1040a
1040
104
1042
1042a
1042e
1042d
1042b
1046
1046f
1046g
1046d
1046b
1046c

FIG. 8

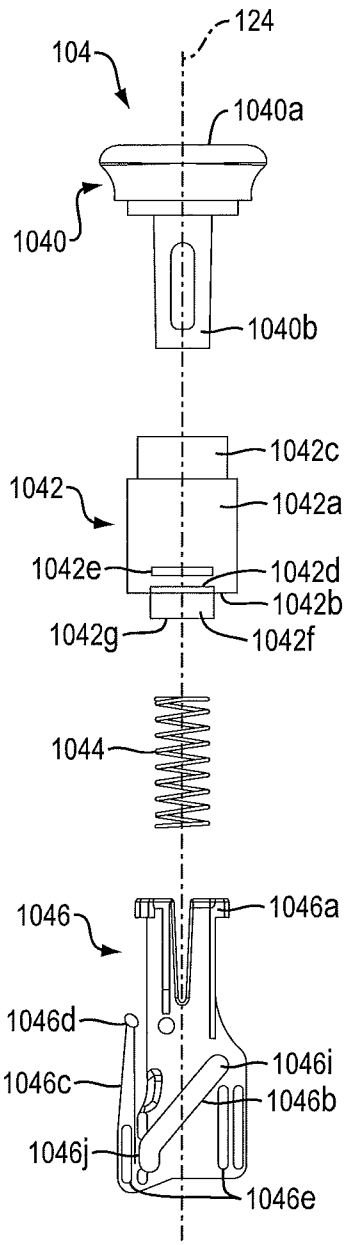



FIG. 9A

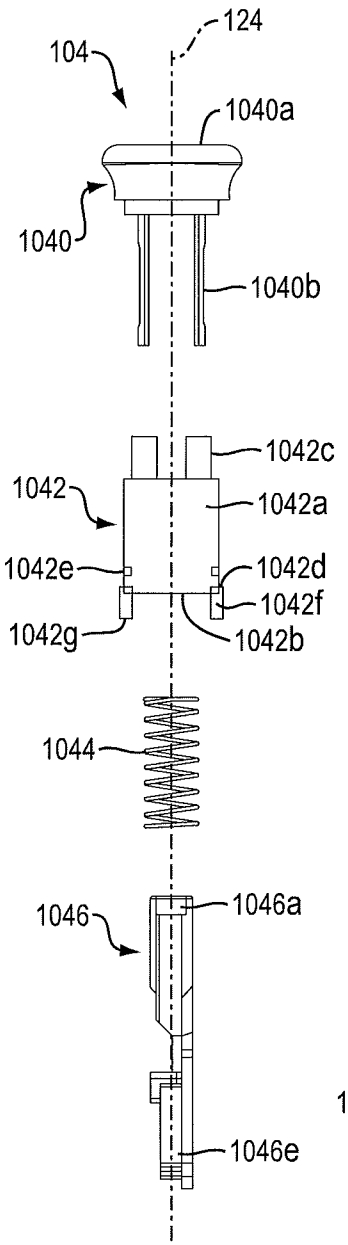



FIG. 9B

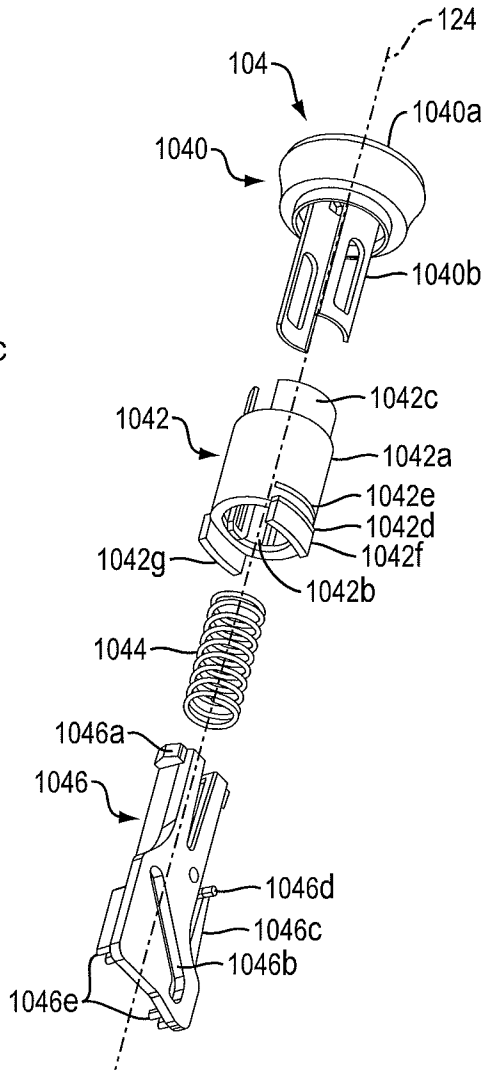



FIG. 9C

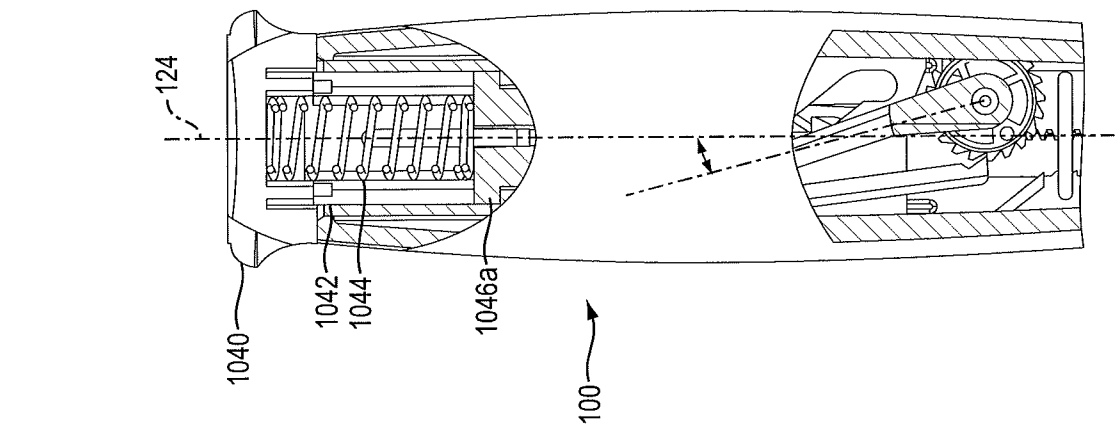



FIG. 10C

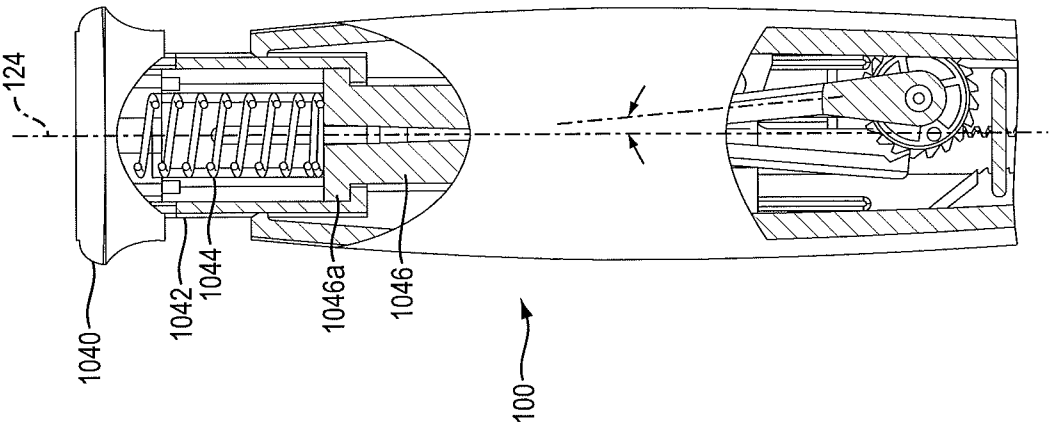



FIG. 10B

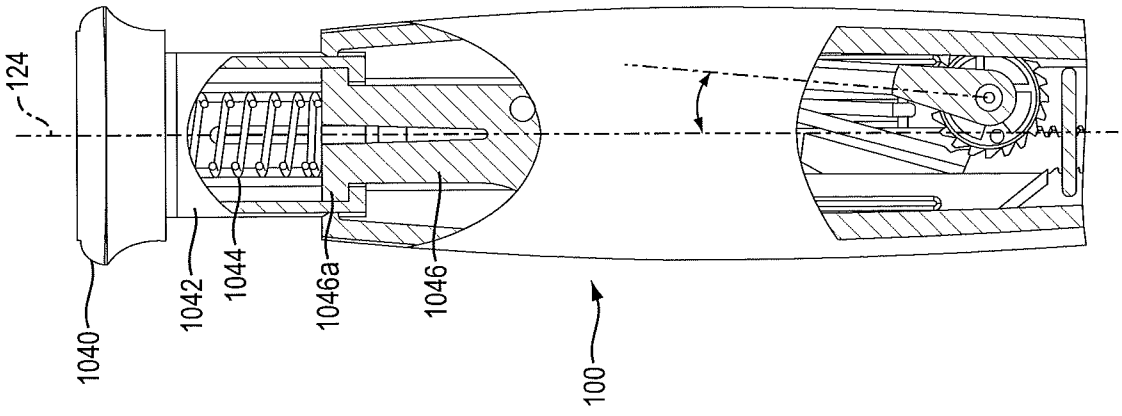



FIG. 10A

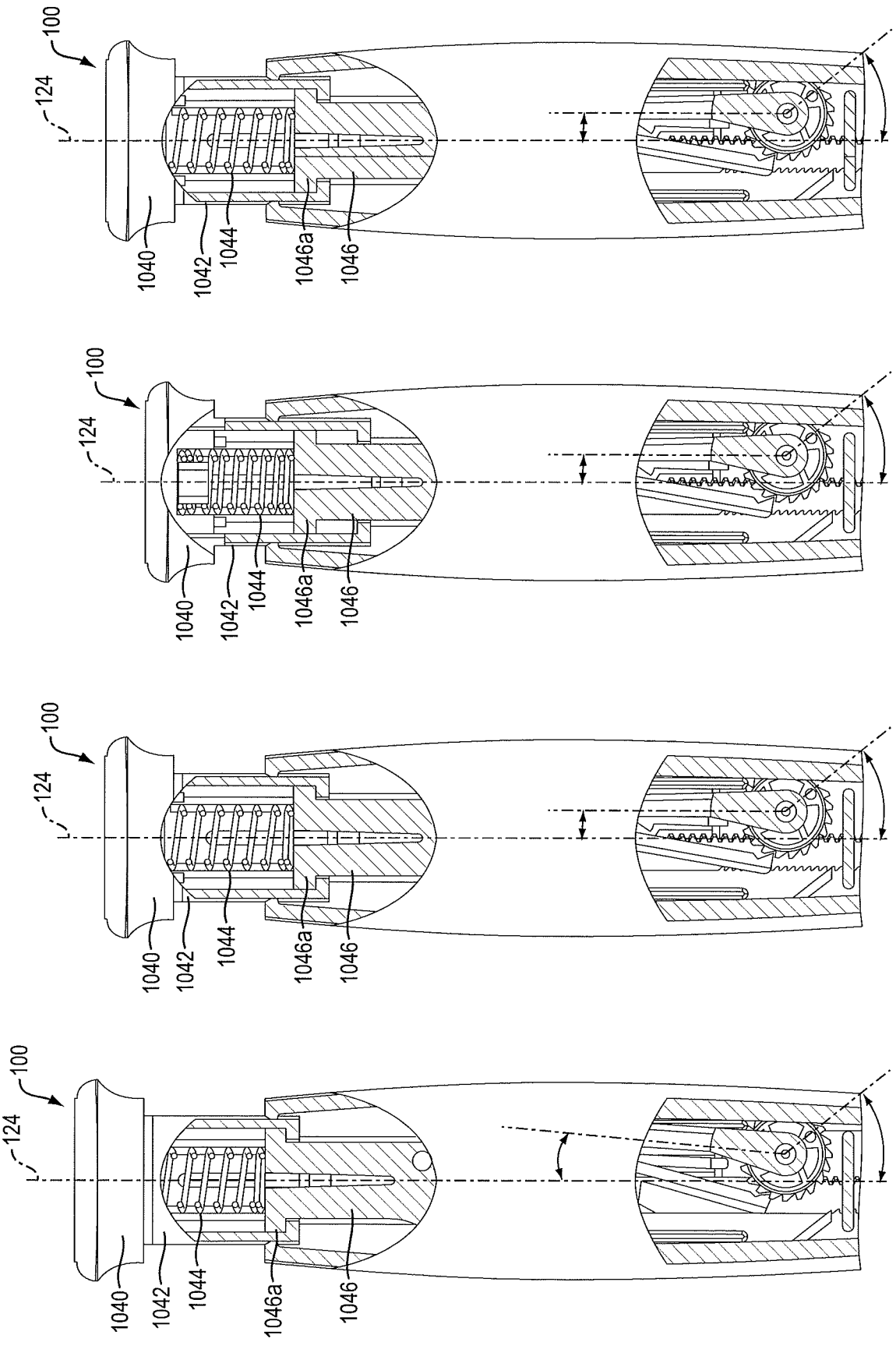



FIG. 11A

FIG. 11B

FIG. 11C

FIG. 11D

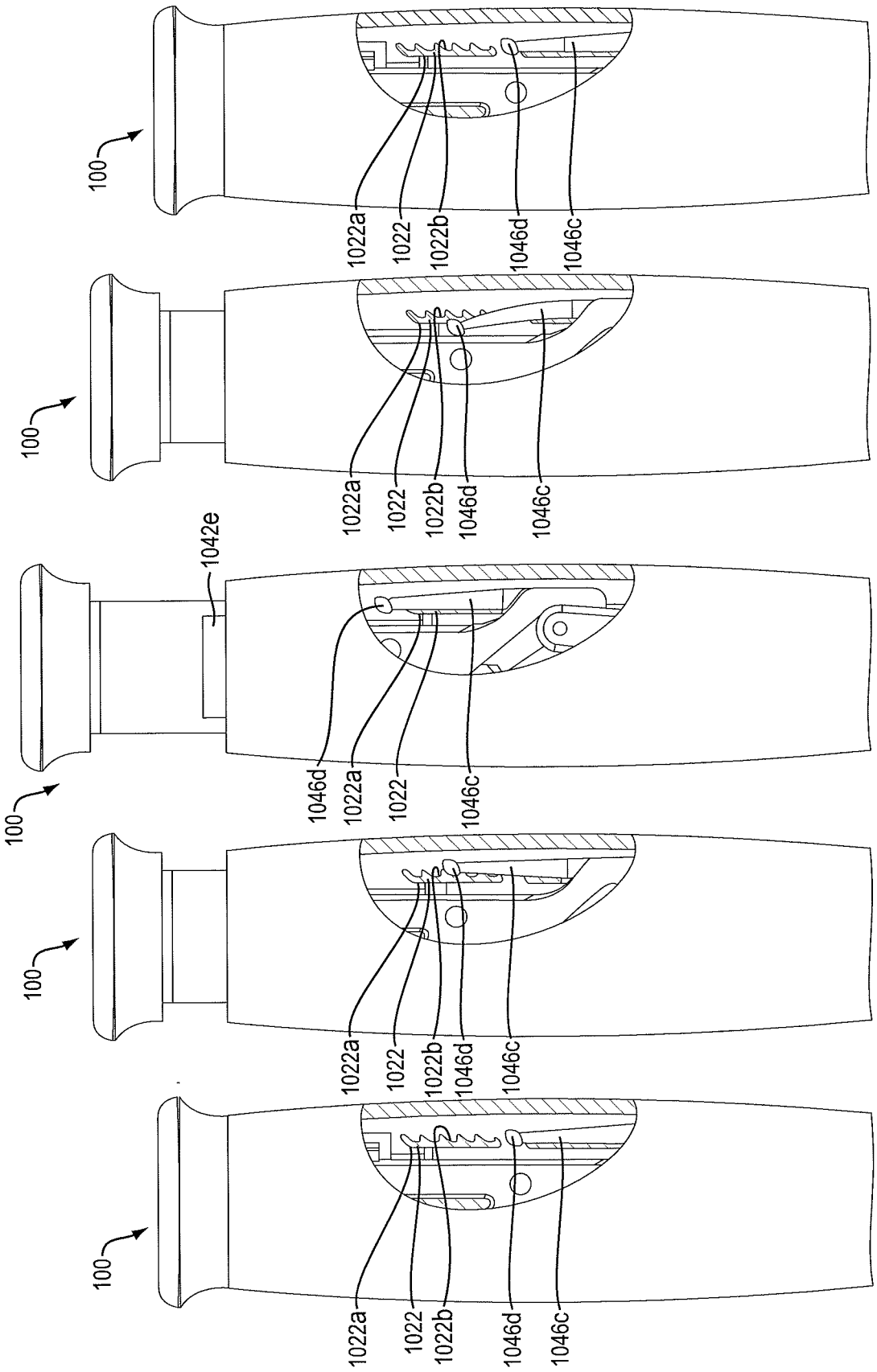



FIG. 12E

FIG. 12D

FIG. 12C

FIG. 12B

FIG. 12A

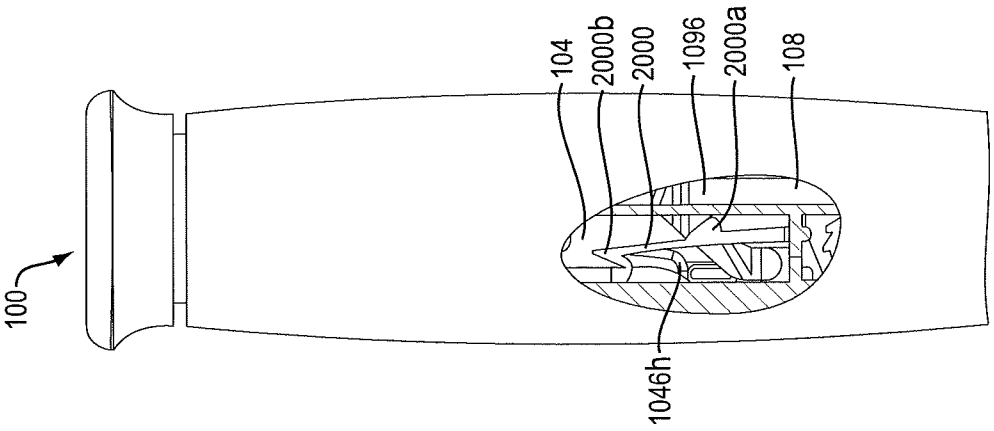



FIG. 13D

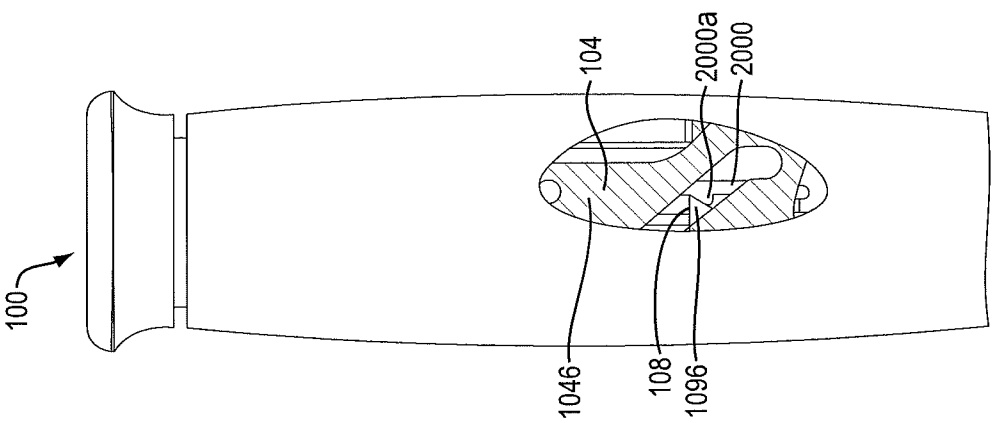



FIG. 13C

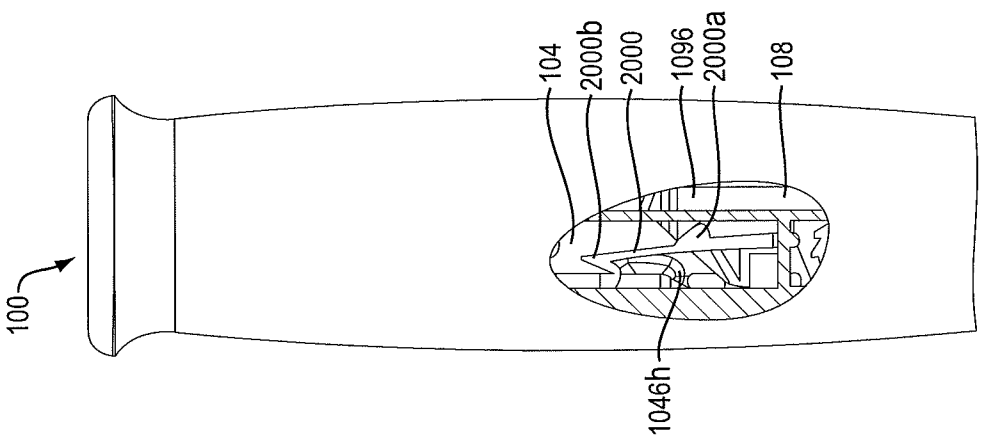



FIG. 13B

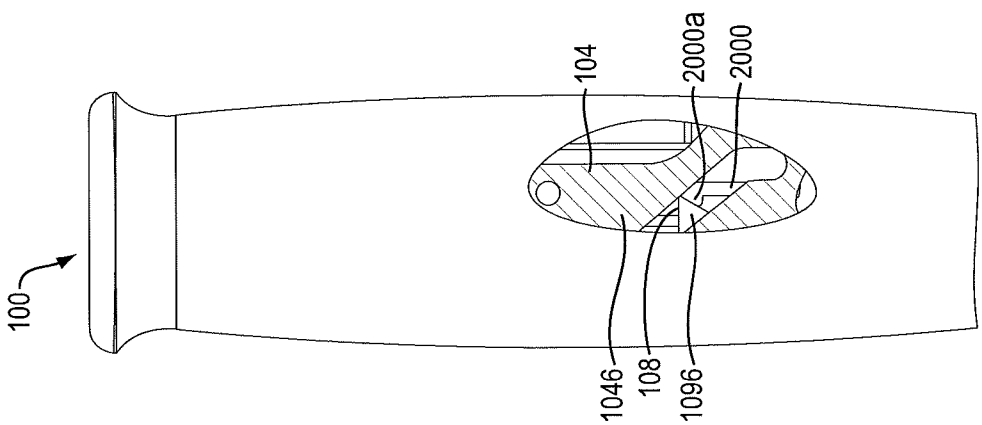



FIG. 13A

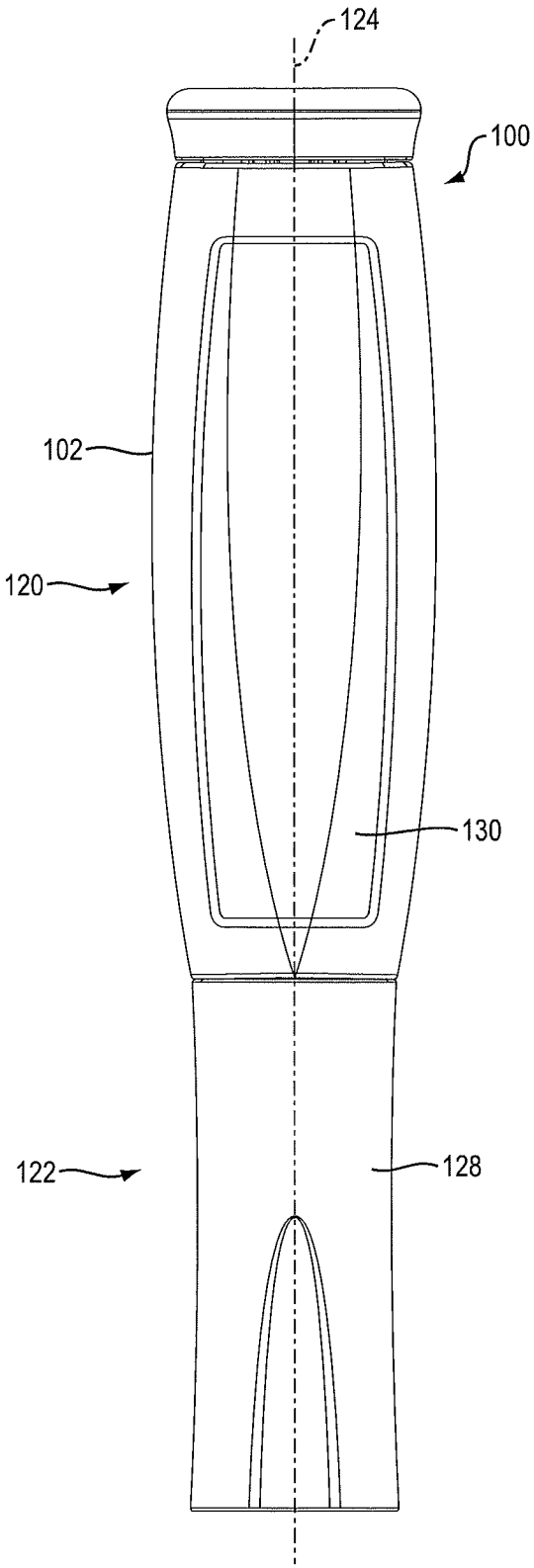



FIG. 14A

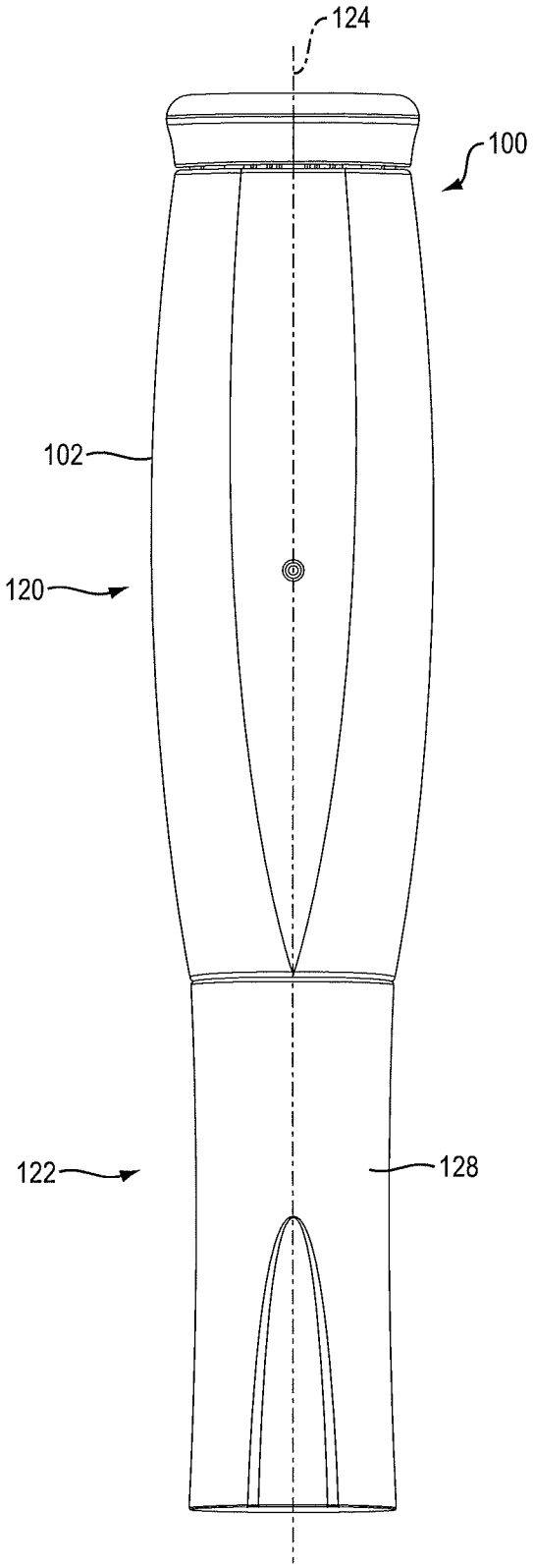



FIG. 14B

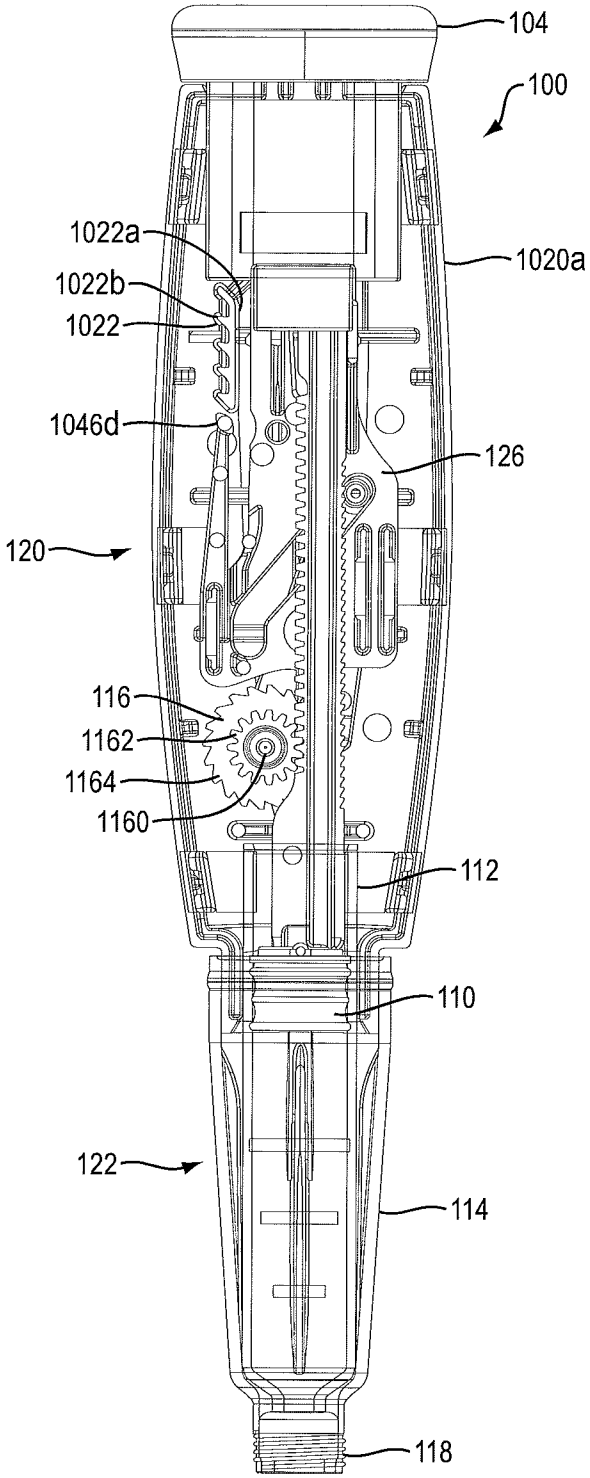

104
100
1022a
1020a
1022b
1022
1046d
126
120
116
1162
1164
1160
112
110
122
114
118

FIG. 15A

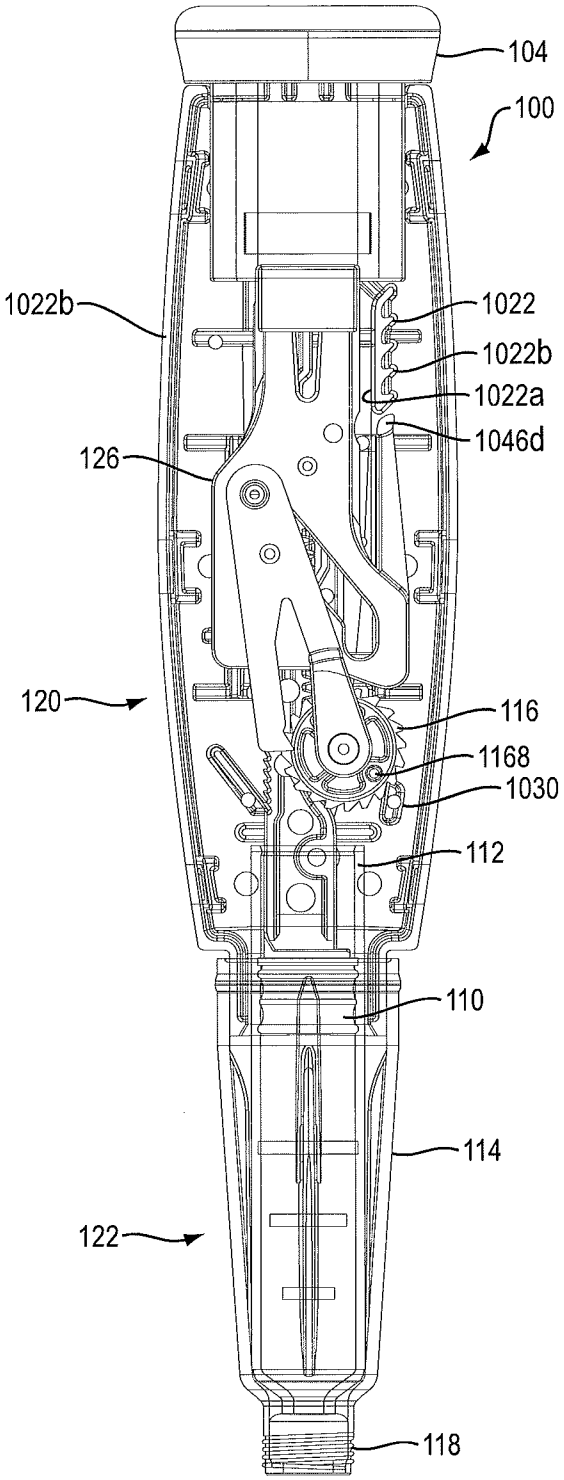

104
100
1022b
1022
1022b
1022a
1046d
126
120
116
1168
1030
112
110
114
122
118

FIG. 15B

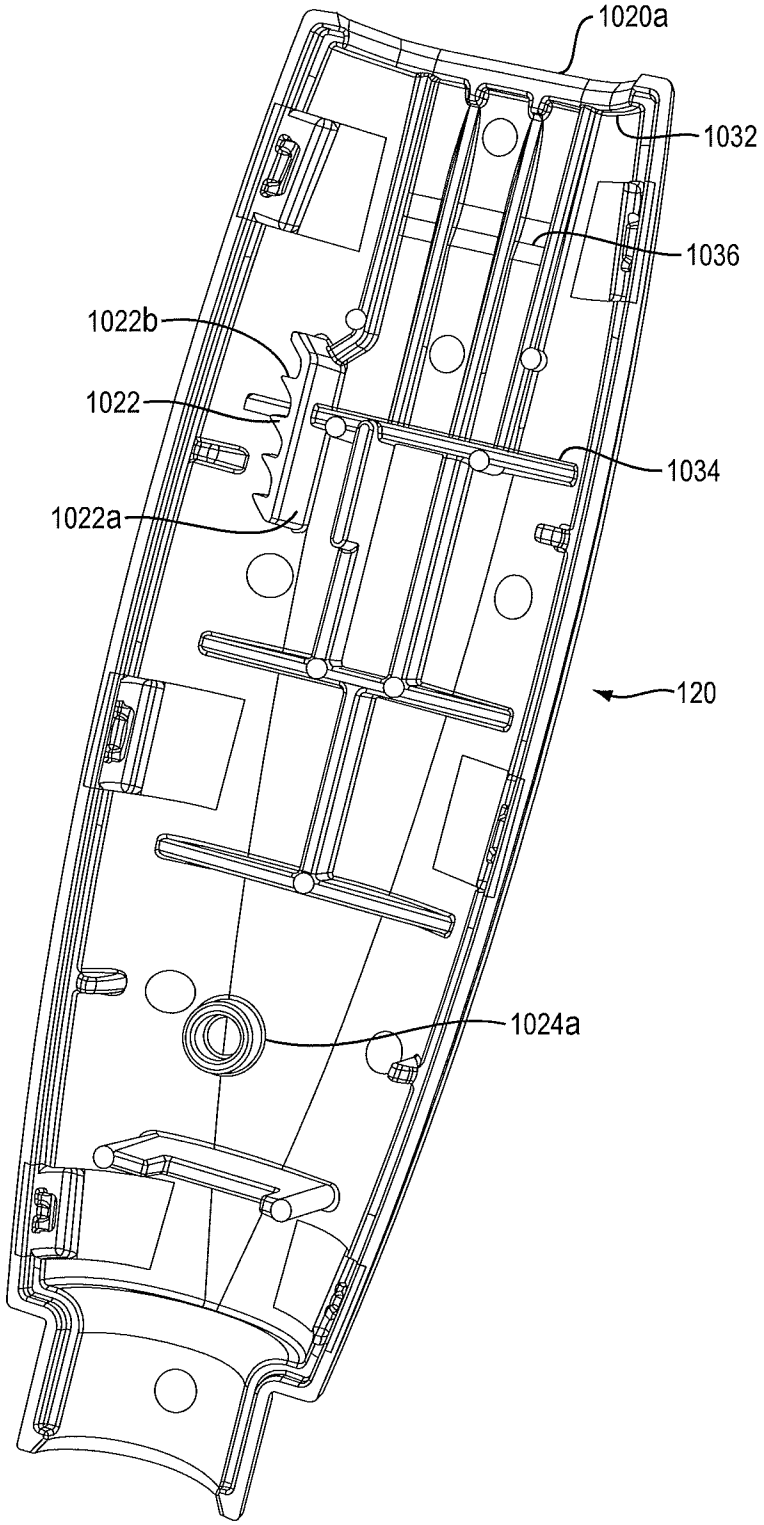



FIG. 16A

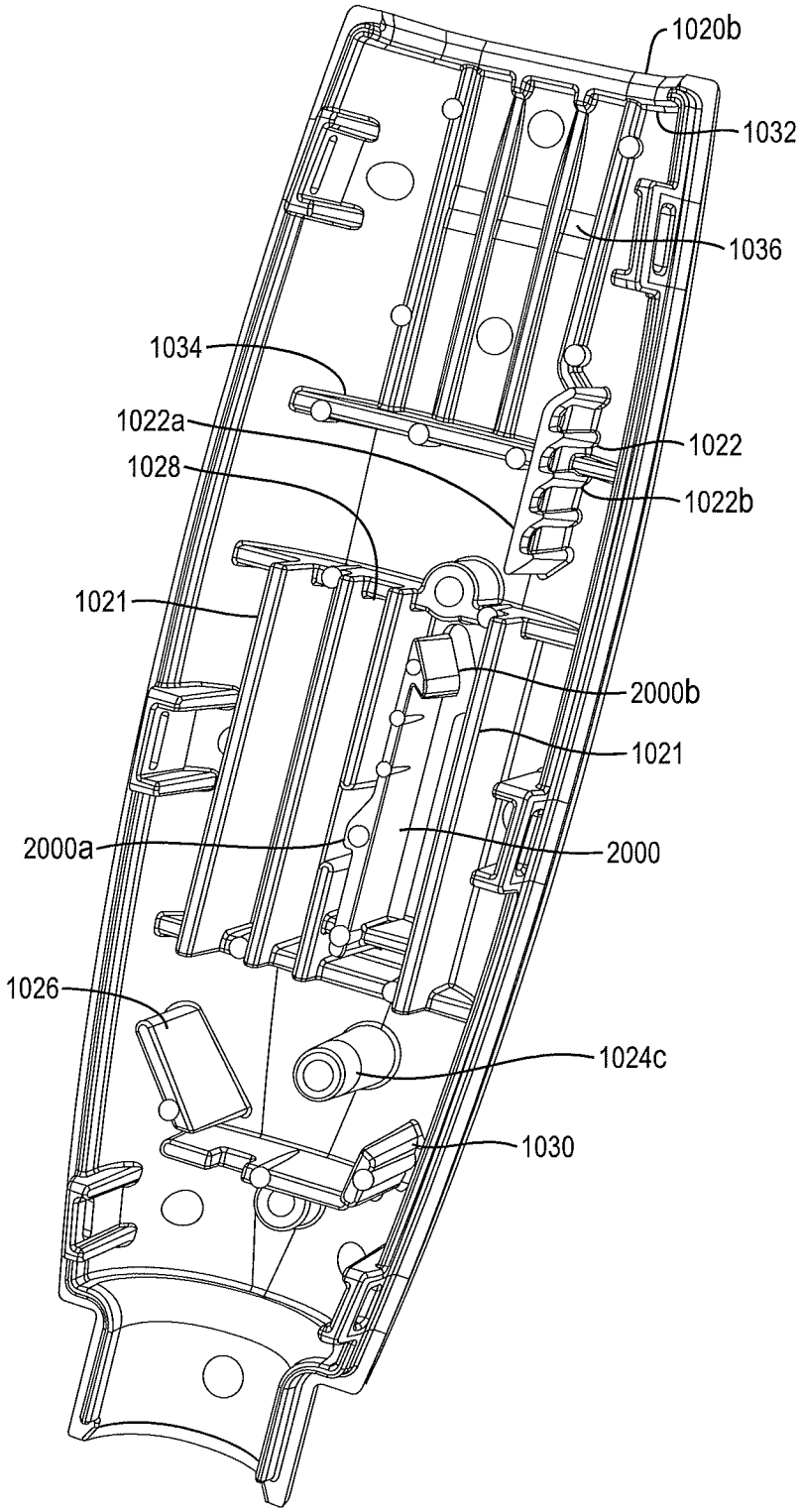

1020b
1032
1036
1034
1022a
1028
1022
1022b
1021
2000b
1021
2000a
2000
1026
1024c
1030

FIG. 16B

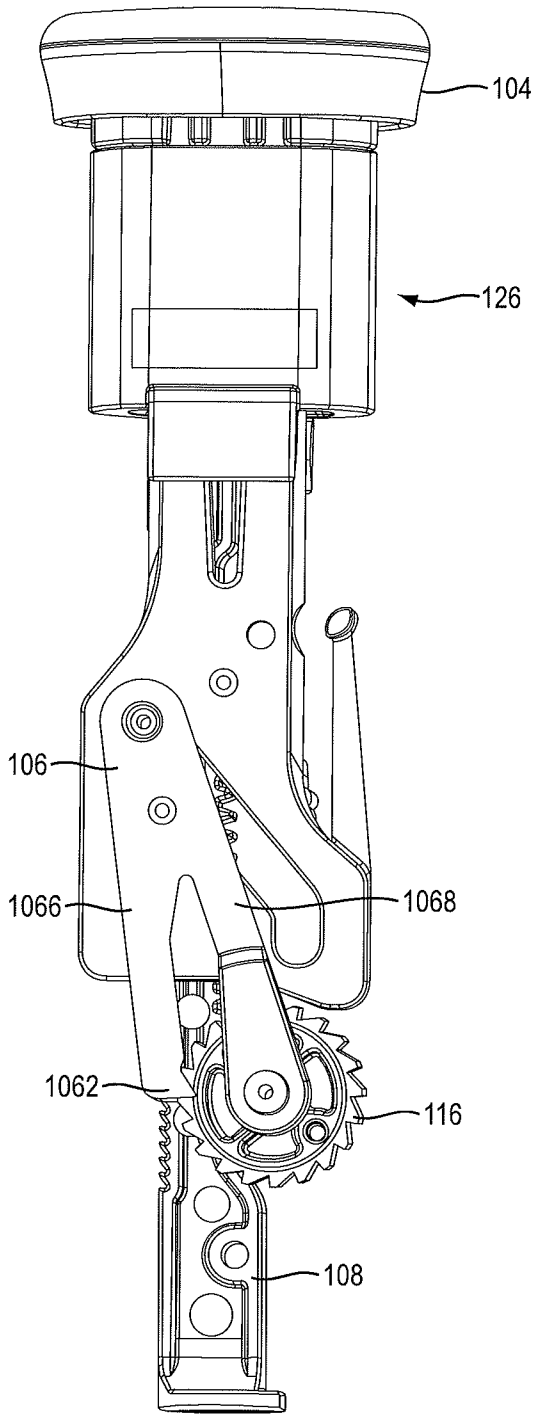



FIG. 17A

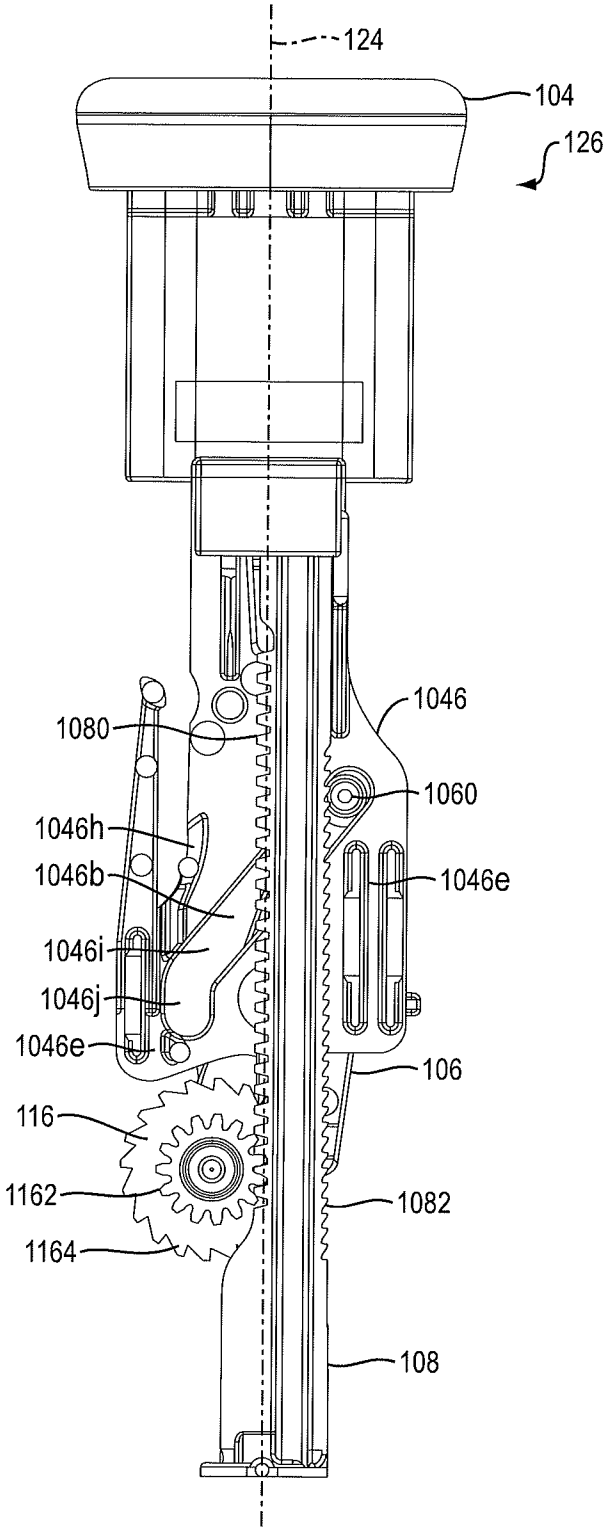

124
104
126
1046
1080
1060
1046h
1046b
1046e
1046i
1046j
1046e
106
116
1162
1082
1164
108

FIG. 17B

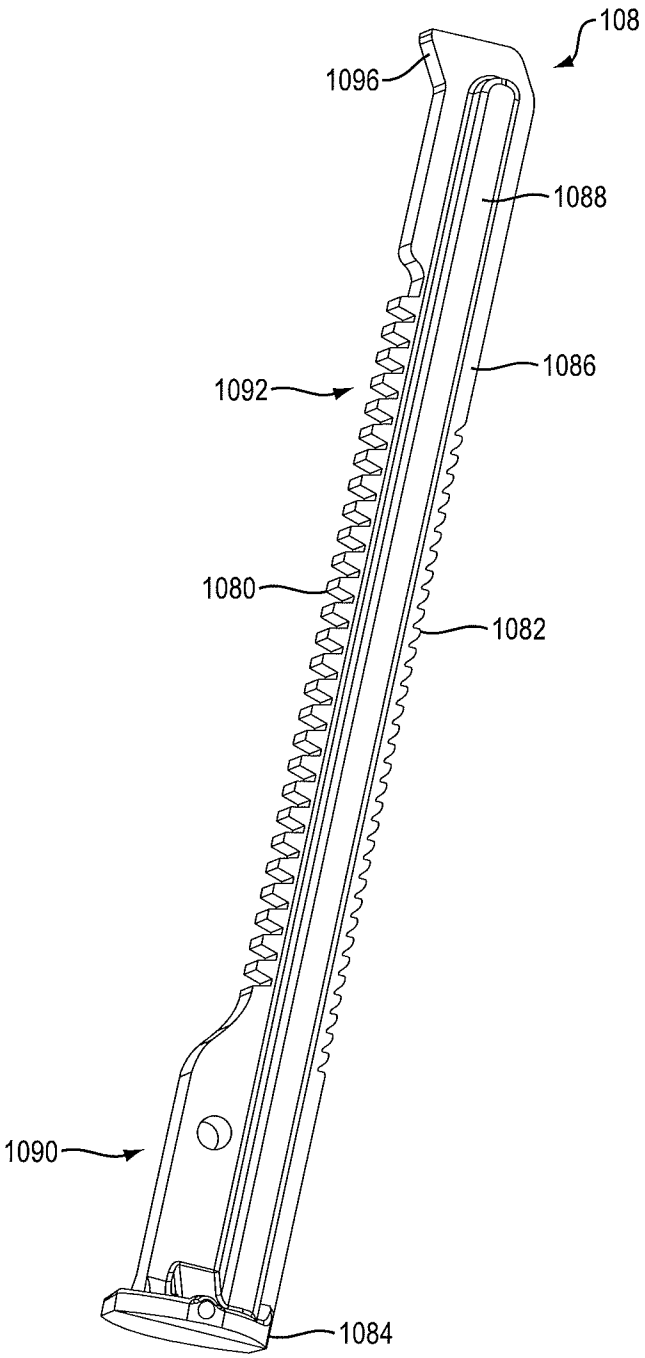



FIG. 18

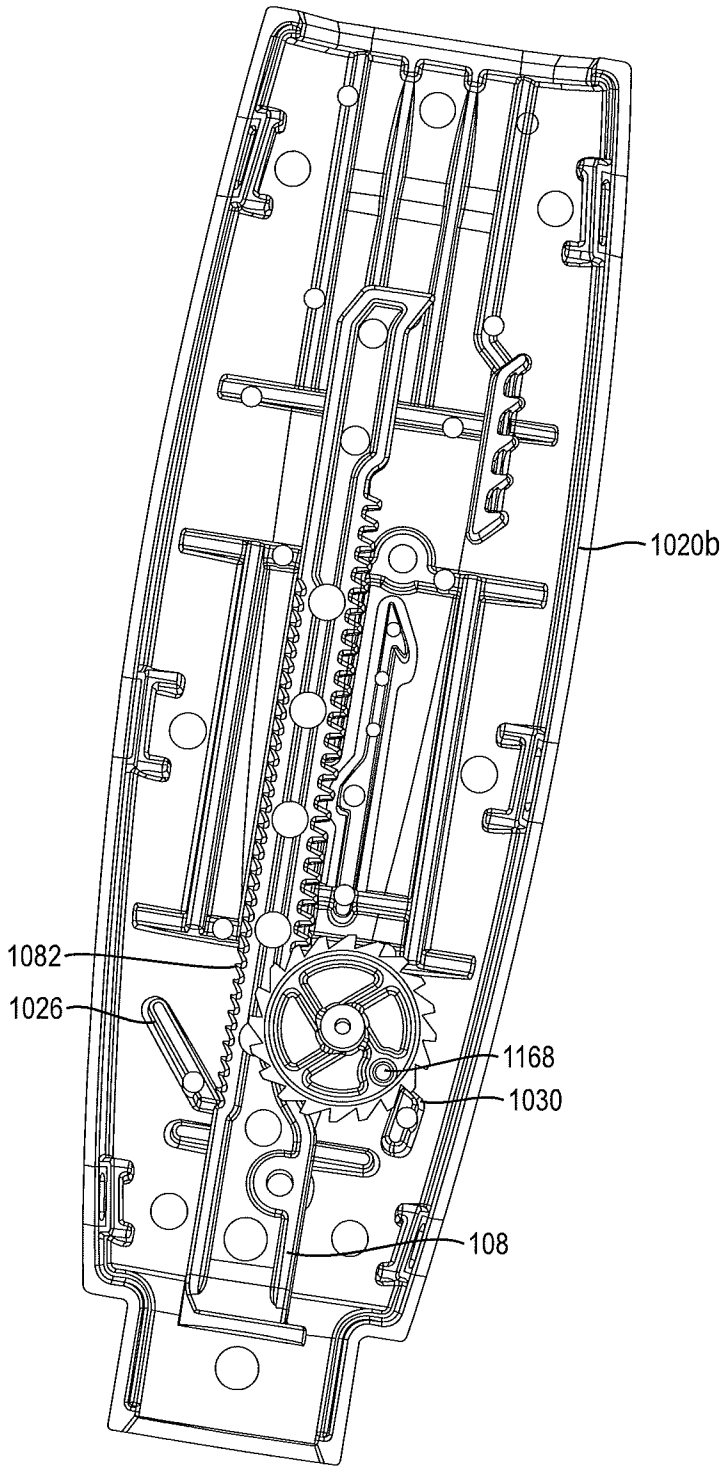



FIG. 19

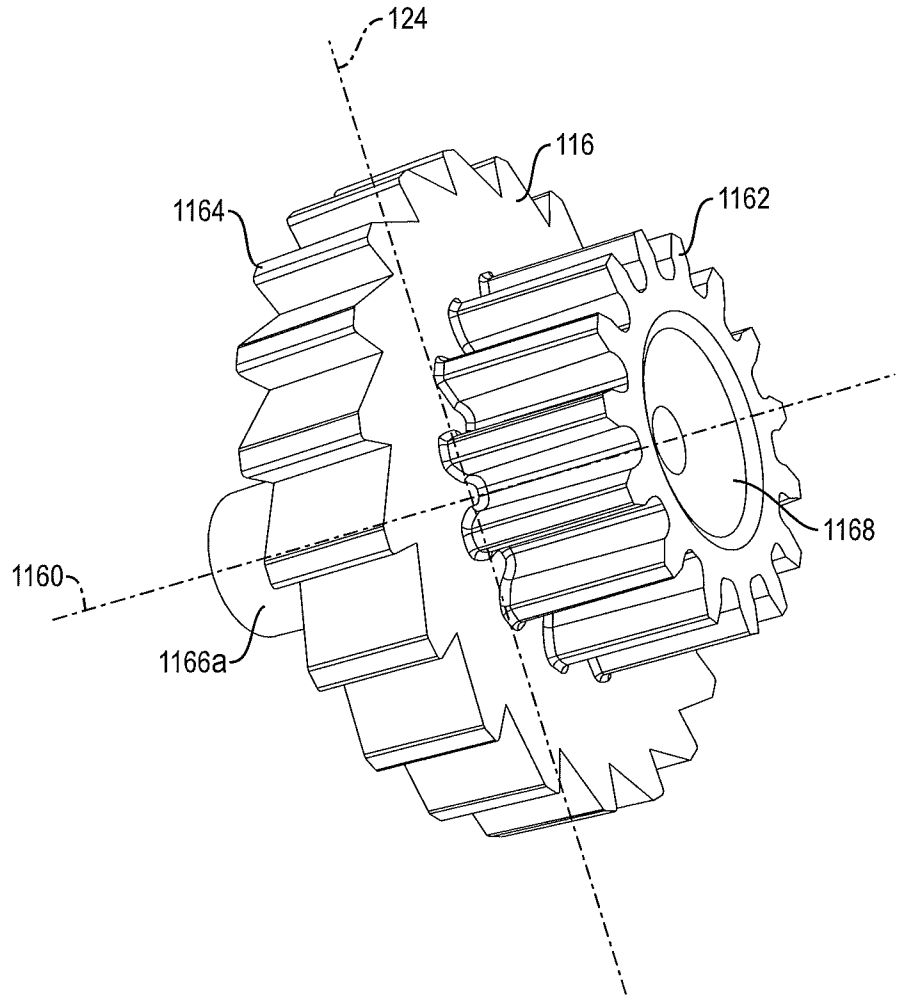



FIG. 20

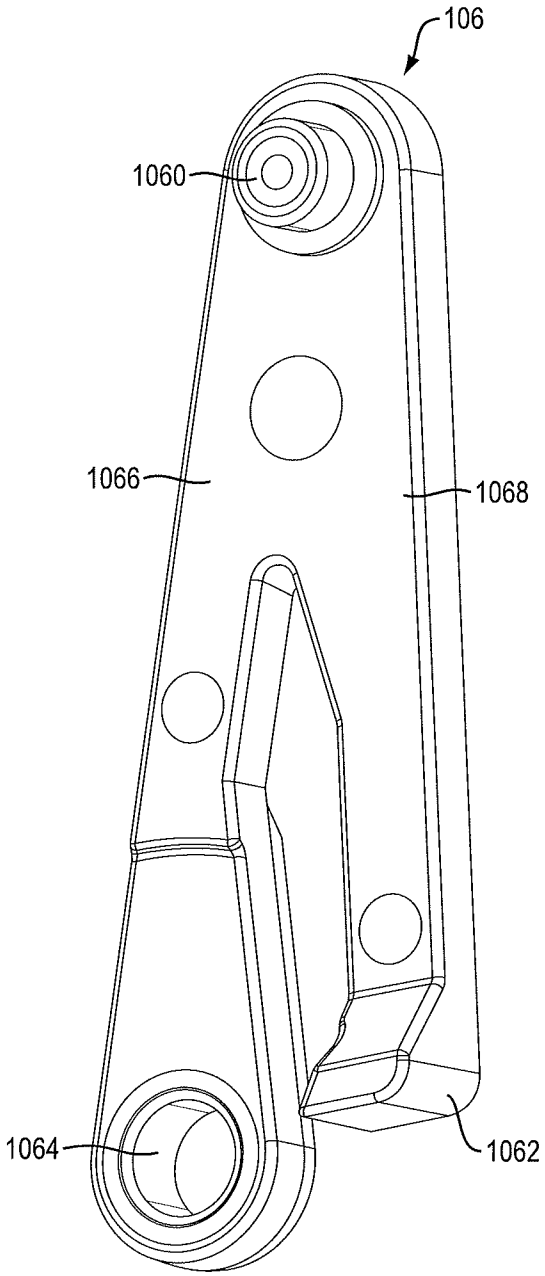



FIG. 21

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US14/23485

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/315 (2014.01)
USPC - 604/218
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) Classification(s): A61M 5/00, 5/20, 5/24, 5/28, 5/178, 5/315 (2014.01)
USPC Classification(s): 604/110, 131, 186, 187, 208, 218, 506

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); ProQuest (Derwent, INSPEC, NTIS, PASCAL, Current Contents Search, Dissertation Abstract Online, Inside Conference); IEEE/IEEEXplore; Google/Google Scholar
Keywords: Dispens*, Inject*, Insert*, Housing*, casing*, cover*, shell*, axis, proximal, distal, pivot*, Ram*, cam*, Push-button*, Button*, Push*1button*, Knob*, Crank*1arm* Crank*, Handle*, Lever*, Pawl*1tooth*, Pawl*, Prong*, Pinion*, Tooth* Teeth*, Ratchet*, Gear*

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>---<br>Y | US 2005/0165363 A1 (JUDSON, JA et al.) July 28, 2005; figures 1-3; paragraphs [0016], [0052], [0053], [0057], [0061], [0063], [0065] | 1-11<br>---<br>12-16 |
| Y | US 2012/0157965 A1 (WOTTON, P et al.) June 21, 2012; paragraphs [0011], [0013], [0014], [0060] | 12, 13 |
| Y | US 2011/0269750 A1 (KLEY, HP et al.) November 03, 2011; paragraphs [0009], [0048], [0071], [0111] | 14-16 |
| A | US 2012/0253287 A1 (GIAMBATISTA, L et al.) October 04, 2012; entire document | 1-16 |
| A | US 2007/0191784 A1 (JACOBS, AT et al.) August 16, 2007; entire document | 1-16 |

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 12 June 2014 (12.06.2014) | 07 JUL 2014 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | Authorized officer:<br>Shane Thomas<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

Form PCT/ISA/210 (second sheet) (July 2009)