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(54) **Title**: DRUG DELIVERY DEVICE AND DRUG RESERVOIR WITH MECHANICAL CODING MECHANISM

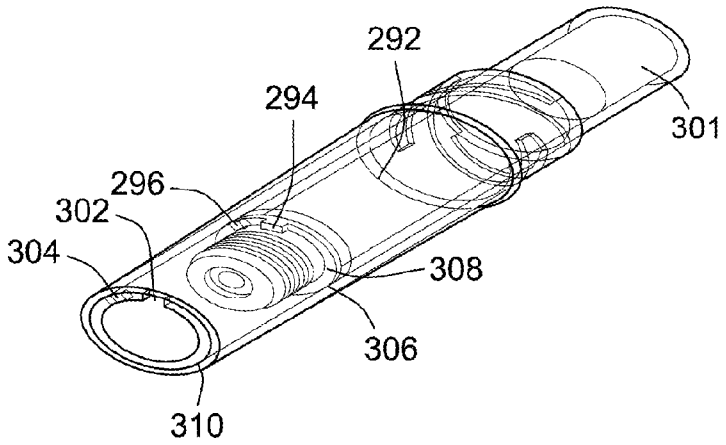

FIG. 10

(57) **Abstract**: An interface (306) for coding a reservoir (120) to a drug delivery device (1108, 100) is provided. The interface (306) comprises a first coding feature (294, 296). A corresponding coding feature (302, 304) is provided in the drug delivery device (1108, 100). The first coding feature (294, 296) cooperates with the corresponding coding feature (302, 304) provided on the drug delivery device (1108, 100) so as to allow the reservoir (120) to operate with the drug delivery device (1108, 100).

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Description

DRUG DELIVERY DEVICE AND DRUG RESERVOIR WITH MECHANICAL CODING MECHANISM

Field of the Disclosure

Specific embodiments of this disclosure relate to reservoirs, particularly reservoirs containing a medicament. More particularly, the present application is generally directed to a coding system for use with a reservoir and a reservoir holder so as to prevent unwanted reservoir cross use. As just one example, such medicament reservoirs may comprise an ampoule, a cartridge, a vial, or a pouch, and may be used with a medical delivery device. Exemplary medical delivery devices include, but are not limited to syringes, pen-type injection syringes, pumps, inhalers, or other similar injection or infusing devices that require at least one reservoir containing at least one medicament.

Background

Medicament reservoirs such as ampoules, cartridges, or vials are generally known. Such reservoirs are especially used for medicaments that may be self administered by a patient. The term “medicament“, as used herein, preferably means a pharmaceutical formulation containing at least one pharmaceutically active compound, wherein in one embodiment the pharmaceutically active compound has a molecular weight up to 1500 Da and/or is a peptide, a proteine, a polysaccharide, a vaccine, a DNA, a RNA, an enzyme, an antibody, a hormone or an oligonucleotide, or a mixture of the above-mentioned pharmaceutically active compound, wherein in a further embodiment the pharmaceutically active compound is useful for the treatment and/or prophylaxis of diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism, acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis, wherein in a further embodiment the pharmaceutically active compound comprises at least one peptide for the treatment and/or prophylaxis of

diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, wherein in a further embodiment the pharmaceutically active compound comprises at least one human insulin or a human insulin analogue or derivative, glucagon-like peptide (GLP-1) or an analogue or derivative thereof, or exedin-3 or exedin-4 or an analogue or derivative of exedin-3 or exedin-4. Insulin analogues are for example Gly(A21), Arg(B31), Arg(B32) human insulin; Lys(B3), Glu(B29) human insulin; Lys(B28), Pro(B29) human insulin; Asp(B28) human insulin; human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human insulin. Insulin derivates are for example B29-N-myristoyl-des(B30) human insulin; B29-N-palmitoyl-des(B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl LysB28ProB29 human insulin; B28-N-palmitoyl-LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-palmitoyl- ThrB29LysB30 human insulin; B29-N-(N-palmitoyl-Y-glutamyl)-des(B30) human insulin; B29-N-(N-lithocholyl-Y-glutamyl)-des(B30) human insulin; B29-N-(ω-carboxyheptadecanoyl)-des(B30) human insulin and B29-N-(ω-carboxyheptadecanoyl) human insulin. Exendin-4 for example means Exendin-4(1-39), a peptide of the sequence H-His-Gly-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Leu-Ser-Lys-Gln-Met-Glu-Glu-Glu-Ala-Val-Arg-Leu-Phe-Ile-Glu-Trp-Leu-Lys-Asn-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH2.

Exendin-4 derivatives are for example selected from the following list of compounds:
H-(Lys)4-des Pro36, des Pro37 Exendin-4(1-39)-NH2,
H-(Lys)5-des Pro36, des Pro37 Exendin-4(1-39)-NH2,
des Pro36 [Asp28] Exendin-4(1-39),
des Pro36 [IsoAsp28] Exendin-4(1-39),
des Pro36 [Met(O)14, Asp28] Exendin-4(1-39),
des Pro36 [Met(O)14, IsoAsp28] Exendin-4(1-39),
des Pro36 [Trp(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Trp(O2)25, IsoAsp28] Exendin-4(1-39),

des Pro36 [Met(O)14 Trp(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Met(O)14 Trp(O2)25, IsoAsp28] Exendin-4(1-39); or
des Pro36 [Asp28] Exendin-4(1-39),
des Pro36 [IsoAsp28] Exendin-4(1-39),
des Pro36 [Met(O)14, Asp28] Exendin-4(1-39),
des Pro36 [Met(O)14, IsoAsp28] Exendin-4(1-39),
des Pro36 [Trp(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Trp(O2)25, IsoAsp28] Exendin-4(1-39),
des Pro36 [Met(O)14 Trp(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Met(O)14 Trp(O2)25, IsoAsp28] Exendin-4(1-39),
wherein the group -Lys6-NH2 may be bound to the C-terminus of the Exendin-4 derivative;
or an Exendin-4 derivative of the sequence
H-(Lys)6-des Pro36 [Asp28] Exendin-4(1-39)-Lys6-NH2,
des Asp28 Pro36, Pro37, Pro38Exendin-4(1-39)-NH2,
H-(Lys)6-des Pro36, Pro38 [Asp28] Exendin-4(1-39)-NH2,
H-Asn-(Glu)5des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-NH2,
des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36 [Trp(O2)25, Asp28] Exendin-4(1-39)-Lys6-NH2,
H-des Asp28 Pro36, Pro37, Pro38 [Trp(O2)25] Exendin-4(1-39)-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-NH2,
des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36 [Met(O)14, Asp28] Exendin-4(1-39)-Lys6-NH2,
des Met(O)14 Asp28 Pro36, Pro37, Pro38 Exendin-4(1-39)-NH2,
H-(Lys)6-desPro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2,

H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2,
des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Asn-(Glu)5 des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Lys6-des Pro36 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-Lys6-NH2,
H-des Asp28 Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25] Exendin-4(1-39)-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-NH2,
des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(S1-39)-(Lys)6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2;
or a pharmaceutically acceptable salt or solvate of any one of the afore-mentioned Exedin-4 derivative.

Hormones are for example hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists as listed in Rote Liste, ed. 2008, Chapter 50, such as Gonadotropine (Follitropin, Lutropin, Choriongonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, Goserelin.

A polysaccharide is for example a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra low molecular weight heparin or a derivative thereof, or a sulphated, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium.

Pharmaceutically acceptable salts are for example acid addition salts and basic salts. Acid addition salts are e.g. HCl or HBr salts. Basic salts are e.g. salts having a cation selected from alkali or alkaline, e.g. Na+, or K+, or Ca2+, or an ammonium ion N+(R1)(R2)(R3)(R4), wherein R1 to R4 independently of each other mean: hydrogen, an optionally substituted C1-C6-alkyl group, an optionally substituted C2-C6-alkenyl group, an optionally substituted C6-C10-aryl group, or an optionally substituted C6-C10-heteroaryl group. Further examples of pharmaceutically acceptable salts are described in "Remington's Pharmaceutical Sciences" 17. ed. Alfonso R. Gennaro (Ed.), Mark Publishing Company, Easton, Pa., U.S.A., 1985 and in Encyclopedia of Pharmaceutical Technology.

Pharmaceutically acceptable solvates are for example hydrates.

For example, with respect to insulin, a patient suffering from diabetes may require a certain amount of insulin to either be injected via a pen-type injection syringe or infused via a pump. With respect to certain known reusable pen-type drug delivery devices, a patient may load a cartridge containing the insulin into a proximal end of a cartridge holder. After the cartridge has been correctly loaded, the user may then be called upon to select a dose of medicament. Multiple doses may be dosed from the cartridge. Where the drug delivery device comprises a reusable device, once the cartridge is empty, the cartridge holder may be disconnected from the drug delivery device and the empty cartridge may be removed and replaced with a new cartridge. Most suppliers of such cartridges recommend that the user may dispose of the empty cartridges properly. Where the drug delivery device comprises a disposable device, once the cartridge is empty, the user is recommended to dispose of the entire device.

Such known self administration systems requiring the removal and reloading of empty cartridges have certain limitations. For example, in certain generally known systems, a user simply loads a new cartridge into the delivery system without the drug delivery device or without the cartridge having any mechanism of preventing cross use of an incorrect cartridge. That is, the drug delivery device does not have a mechanism for

determining whether the medicament contained in the cartridge is indeed the correct type of medicament to be administered by the patient and, therefore, the device does not ensure that only the correct cartridge containing the correct medicament may be properly positioned within the drug delivery device. Alternatively, certain known drug delivery devices do not present a mechanism for determining whether the correct type of medicament within the cartridge should be used with that particular drug delivery system. This potential problem could be exacerbated given that certain elderly patients, such as those suffering from diabetes, may have limited manual dexterity. Identifying an incorrect medicament is quite important, since the administration of a potentially incorrect dose of a medicament such as a short-acting insulin in lieu of a long-acting insulin could result in injury or even death.

Some drug delivery devices or systems may use a color coding scheme to assist a user or care giver in selecting the correct cartridge to be used with a drug delivery device. However, such color coding schemes pose challenges to certain users, especially those users suffering from poor eyesight or color blindness: a situation that can be quite prevalent in patients suffering from diabetes.

Another concern that may arise with such disposable cartridges is that these cartridges are manufactured in essentially standard sizes and must comply with certain recognized local and international standards. Consequently, such cartridges are typically supplied in standard sized cartridges (e.g. 3 ml cartridges). Therefore, there may be a variety of cartridges supplied by a number of different suppliers and containing different medicament but they may fit a single drug delivery device. As just one example, a first cartridge containing a first medicament from a first supplier may fit a medical delivery device provided by a second supplier. As such, a user might be able to properly position or load an incorrect cartridge within the drug delivery device and then dispense an incorrect medicament (such as a rapid or basal type of insulin) into a drug delivery device without being aware that the medical delivery device was perhaps neither designed nor intended to be used with such a cartridge.

As such, there is a growing desire from users, health care providers, care givers, regulatory entities, and medical device suppliers to reduce the potential risk of a user properly loading an incorrect drug type into a drug delivery device. There is also, therefore, a desire to reduce the risk of dispensing an incorrect medicament (or the wrong concentration of the medicament) from such a drug delivery device.

There is, therefore, a general need to physically dedicate or mechanically code a cartridge or a cartridge holder to its drug type and design an injection device that only accepts or works with certain dedicated or coded features provided on or with the cartridge, on the cartridge holder, or on an intermediary component (e.g. a label provided on the cartridge) so as to prevent unwanted cartridge cross use. Similarly, there is also a general need for a dedicated cartridge that allows the medical delivery device to be used with only an authorized cartridge containing a specific medicament while also preventing undesired cartridge cross use.

There is also a general need to provide a dedicated cartridge that is difficult to tamper with so that the cartridge may not be compromised in that the cartridge can be used with an unauthorized drug or drug delivery device. Because such cartridges may be difficult to tamper with, they may also reduce the risk of counterfeiting: i.e. making it more difficult for counterfeiters to provide unregulated counterfeit medicament carrying products.

Problem to be solved

The problem to be solved by the present application is to provide an interface and a drug delivery system where the safety of the user is increased.

Summary

One aspect relates to an interface for coding a reservoir to a drug delivery device. The interface may be a component adapted and arranged for being coupled to the reservoir.

The interface may comprise a ring-like or sleeve-like member. The interface may further be configured for being coupled to a needle hub. In particular, the interface may comprise a distal end configured for being coupled to the needle hub.

The reservoir may comprise a cartridge. Alternatively, the reservoir may comprise a vessel. The interface may comprise a first coding feature. A drug delivery device may comprise a corresponding coding feature. The first coding feature may be configured to cooperate with the corresponding coding feature provided within, preferably on, the drug delivery device so as to position the reservoir within the drug delivery device.

According to an embodiment, an interface configured for coding and positioning a reservoir to a drug delivery device is provided. The reservoir may be configured for containing a medicament. The reservoir may comprise a cartridge or a vessel, for example. The interface may comprise a first coding feature. The first coding feature may be provided on an outer surface of the interface. When the reservoir is inserted into the drug delivery device, the first coding feature may be configured to mechanically cooperate with a corresponding second coding feature. The corresponding second coding feature may be provided by the device, preferably on an inner surface of the device. Mechanical cooperation between the first coding feature and the corresponding second coding feature may allow the reservoir to be properly positioned within the drug delivery device. In particular, mechanical cooperation between the first coding feature and the corresponding second coding feature may prevent insertion of a reservoir into the device which is not intended for use with the device. Furthermore, mechanical cooperation between the first coding feature and the corresponding second coding feature may help to prevent the reservoir slipping out of the device.

According to an embodiment, the interface may be coupled to the reservoir of the drug delivery device. Alternatively, the interface may be integral to said reservoir.

According to an embodiment, the interface may be configured to allow the reservoir to be properly positioned within a reservoir holder, e.g. a cartridge holder, of the drug

delivery device. The reservoir holder may be located between the reservoir and the drug delivery device. The corresponding second coding feature may be provided on the reservoir holder, in particular on an inner surface of the reservoir holder.

According to another embodiment, an interface that allows a reservoir to be used with a drug delivery device is disclosed. The interface may be coupled to the reservoir and a first coding feature may be provided on the interface. The first coding feature may include at least one protrusion and/or at least one groove. The presently disclosed coding feature may extend in any direction. As just one example, it may extend in a longitudinal direction, or an axial direction, or a radial direction, or a transverse direction. When the reservoir is inserted into the drug delivery device, the first coding feature may cooperate with a corresponding second coding feature of the drug delivery device so as to properly position the reservoir within the drug delivery device.

According to an embodiment, the corresponding coding feature may include at least one groove and/or at least one protrusion.

According to an embodiment, the coding feature may further include a plurality of similar or different coding features in different combinations. Each of the plurality of coding features may comprise a unique geometrical shape and/or a unique size. The plurality of coding features may comprise a first coding feature. The plurality of coding features may comprise a second coding feature. The first coding feature may cover a first area of the interface. The second coding feature may cover a second area of the interface. The second coding feature may include at least one groove. A corresponding second coding feature of the drug delivery device may include at least one protrusion.

According to an embodiment, the interface may comprise a third coding feature.

According to an embodiment, the interface also includes an alignment feature. The drug delivery device may include a corresponding alignment feature. In particular, the alignment feature may be adapted and arranged to mechanically cooperate with the

corresponding alignment feature provided by the drug delivery device. The alignment feature may be located on a flange of the interface. The alignment feature may comprise at least one protrusion. The corresponding alignment feature may comprise at least one ramp provided on the drug delivery device or provided on the reservoir holder of the device. The alignment feature may help to prevent relative rotation between the drug delivery device and the interface. This alignment feature may also help ensure that the coding features are aligned on the mating parts.

According to an embodiment, the first coding feature may comprise a non-circular section.

According to an embodiment, the first coding feature includes at least one ramp. The first coding feature may include a plurality of ramps. The ramp may comprise a face at an angle relative to a transverse plane of the interface.

According to an embodiment, the interface comprises a flange. The first coding feature may be provided along the flange. The first coding feature may extend outwardly from the interface, preferably in an axial direction. Alternatively, the first coding feature may extend outwardly from the flange.

According to an embodiment, the first coding feature is provided on a sidewall of the reservoir.

According to an embodiment, the interface includes a main body. The main body may comprise an engagement member, e.g. a thread. The main body may be configured for receiving a needle hub. The needle hub may be connected to the main body by means of the engagement member. The main body may be coupled to the reservoir. A first coding feature may be provided on the main body. The first coding feature may comprise at least one protrusion and/or at least one groove. When the reservoir is inserted into the drug delivery device, the first coding feature may cooperate with a corresponding second coding feature of the drug delivery device so as to properly

position the reservoir within the drug delivery device. The coding feature may comprise at least one shoulder. The shoulder may have a constant or a varying diameter. This shoulder may be continuous.

According to an embodiment, the interface comprises a main body. The main body may be configured to be, permanently or releasably, coupled to the reservoir. The main body may comprise a bore. The bore may be configured to define a diameter. The diameter may be measured to receive the reservoir, in particular a distal end of the reservoir. The first coding feature may include at least one, preferably continuous, shoulder. The shoulder may protrude from the main body. Preferably, the at least one continuous shoulder comprises a varying diameter.
According to an embodiment, the main body further comprises a thread. The thread may be configured for receiving a needle hub.

According to an embodiment the interface is representative of the medicament contained within the reservoir.

A further aspect relates to a drug delivery system. The system may include a drug delivery device. The drug delivery device may comprise a dose setting mechanism. A cartridge holder may be, preferably releasably, secured to the dose setting mechanism. A cartridge may be contained within the cartridge holder. An interface for securing the cartridge within the cartridge holder may be provided. The interface may include a first coding feature. The first coding feature may include at least one protrusion and/or at least one groove. When the cartridge is inserted into the cartridge holder, the first coding feature may cooperate with a corresponding second coding feature. The corresponding second coding feature may be provided by the cartridge holder. Cooperation of the first coding feature and the corresponding second coding feature may secure the cartridge to the cartridge holder. The interface may also include an alignment feature to prevent relative rotation between the drug delivery device and the interface.

According to an embodiment, a drug delivery system may be provided. The drug delivery system may comprise a drug delivery device. The drug delivery device may be a pen-type device, preferably a pen-type injector. The drug delivery device may comprise a dose setting mechanism. The drug delivery device may comprise a cartridge holder. The cartridge holder may be secured to the dose setting mechanism. A cartridge may be contained within the cartridge holder. The drug delivery system may comprise the previously described interface. When the cartridge is inserted into the cartridge holder, the first coding feature may be configured to mechanically cooperate with the corresponding second coding feature provided by the drug delivery device, preferably by the cartridge holder of the drug delivery device. Said mechanical cooperation may help to properly position the cartridge into the drug delivery device, in particular into the cartridge holder.

According to an embodiment, the cartridge holder may be removably secured to the dose setting mechanism. The cartridge may be removably contained within the cartridge holder. The drug delivery device may comprise a reusable drug delivery device.

According to an embodiment, the dose setting mechanism comprises a rotating piston rod for expelling a set dose from the cartridge.

According to a preferred embodiment, an interface configured for coding and positioning a reservoir configured for containing a medicament to a drug delivery device is provided, the interface comprising a first coding feature. When the reservoir is inserted into the drug delivery device, the first coding feature is configured to mechanically cooperate with a corresponding second coding feature provided by the device so as to allow the reservoir to be properly positioned within the drug delivery device.

According to a preferred embodiment, an interface for coding a reservoir to a drug delivery device is provided, the interface comprising a first coding feature and a drug delivery device comprising a corresponding coding feature. The first coding feature cooperates with the corresponding coding feature provided within the drug delivery

device so as to allow the reservoir to be properly positioned within the drug delivery device.

According to a preferred embodiment, an interface for positioning a reservoir within a drug delivery device is provided, the interface comprising a main body coupled to the reservoir and a first coding feature provided on the main body. The first coding feature comprises at least one protrusion or at least one groove.

When the reservoir is inserted into the delivery device, the first coding feature cooperates with a corresponding second coding feature so as to properly position the reservoir to the drug delivery device.

According to a preferred embodiment, a drug delivery system is provided. The drug delivery system comprises a drug delivery device comprising a dose setting mechanism, a cartridge holder being secured to the dose setting mechanism and a cartridge being contained within the cartridge holder. The drug delivery system comprises the previously described interface. When the cartridge is inserted into the cartridge holder, the first coding feature is configured to mechanically cooperate with the corresponding second coding feature provided by the drug delivery device or by the cartridge holder of the drug delivery device so as to properly position the cartridge into the drug delivery device or into the cartridge holder.

According to a preferred embodiment, a drug delivery system is provided, the system comprising a drug delivery device comprising a dose setting mechanism. The system comprises a cartridge holder secured to the dose setting mechanism. The system comprises a cartridge contained within the cartridge holder. The system comprises an interface for properly positioning the cartridge within the cartridge holder, the interface including a first coding feature comprising at least one protrusion or at least one groove. When the cartridge is inserted into the cartridge holder, the first coding feature cooperates with a corresponding second coding feature of the cartridge holder so as to properly position the cartridge to the cartridge holder.

These as well as other advantages of various aspects of the present disclosure will become apparent to those of ordinary skill in the art by reading the following detailed description, with appropriate reference to the accompanying figures.

The scope of the disclosure is defined by the content of the claims. The disclosure is not limited to specific embodiments but comprises any combination of elements of different embodiments. Moreover, the disclosure comprises any combination of claims and any combination of features disclosed by the claims.

Brief Description of the Figures

Exemplary embodiments are described herein with reference to the figures, in which:

Figure 1 illustrates an exemplary pen-type drug delivery device;

Figure 2 illustrates a cartridge that may be loaded into a cartridge holder of the pen-type drug delivery device illustrated in Figure 1;

Figure 3A illustrates a first arrangement of a coding system that may be provided on an interface for use with a cartridge that may be used with a pen-type drug delivery device, such as the drug delivery device illustrated in Figure 1;

Figure 3B illustrates another arrangement of a coding system that may be provided on an interface for use with a cartridge that may be used with a pen-type drug delivery device, such as the drug delivery device illustrated in Figure 1;

Figure 4 illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 5A and 5B illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 6 illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 7 illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 8 illustrates a top view of the interface illustrated in Figure 7;

Figure 9 illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 10 illustrates one alternative arrangement of an interface partially inserted into a cartridge holder;

Figure 11 illustrates the interface of Figure 10 in a final, properly seated position;

Figure 12A illustrates another alternative arrangement a coding system on an interface for use with a cartridge;

Figure 12B illustrates the interface illustrated in Figure 12A in a final, properly seated position;

Figures 12C-E illustrates other alternative arrangements of a coding system;

Figure 13 illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 14 illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 15A illustrates a top view of another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 15B illustrates a portion of the top view of the alternative arrangement illustrated in Figure 15A;

Figure 16 illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 17 illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 18 illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 19 illustrates another alternative arrangement of a coding system on an interface for use with a cartridge;

Figure 20A-D illustrate one arrangement of a coding system for use with an interface for use with a cartridge;

Figure 21A illustrates another arrangement of a coding system on an interface for use with a cartridge;

Figure 21B illustrates a top view of the interface illustrated in Figure 21A;

Figure 22 illustrates another arrangement of a coding system on an interface for use with a cartridge;

Figure 23 illustrates another arrangement of a coding system on an interface for use with a cartridge;

Figure 24 illustrates an interface having an alignment feature for use with a cartridge that may be used with a pen-type drug delivery device, such as the drug delivery device illustrated in Figure 1;

Figure 25 illustrates the interface illustrated in Figure 24 attached to a distal cartridge holder portion (without a cartridge);

Figure 26 illustrates the interface illustrated in Figure 24 attached to the distal cartridge holder portion with a cartridge and a double ended needle;

Figure 27A illustrates an interface having an alignment feature and coding features for use with a cartridge that may be used with a pen-type drug delivery device, such as the drug delivery device illustrated in Figure 1;

Figure 27B illustrates a distal cartridge holder portion that may be used with the interface illustrated in Figure 27A;

Figure 28 illustrates a top view of an alternative configuration of alignment features and coding feature that may be located on the interface;

Figure 29 illustrates an alternative arrangement of a coding system comprising a plurality of interfaces;

Figure 30A illustrates one arrangement of a coding system for use with an interface for use with a cartridge;

Figure 30B illustrates one arrangement of a coding system for use with an interface comprising an alignment feature for use with a cartridge;

Figure 31A illustrates yet another embodiment of a coding system for a drug cartridge;

Figure 31B illustrates yet another embodiment of a coding system for a drug cartridge;

Figure 32 illustrates yet another embodiment of a coding system for a drug cartridge;

Figure 33 illustrates the coding system of Figure 32 in a first position in a drug delivery device; and

Figure 34 illustrates an alternative reservoir that may be used with any interface disclosed in the present application.

Detailed Description

Referring to Figure 1, there is shown a drug delivery device 100 in the form of a pen-type syringe. This drug delivery device 100 comprises a dose setting mechanism 102, a cartridge holder 104, and a removable cap 106. A proximal end 105 of the cartridge holder 104 and a distal end 103 of the dose setting mechanism 102 are removably secured together. The pen-type syringe may comprise a re-usable or a disposable pen-type syringe. Where the syringe comprises a reusable device, the cartridge holder 104 and the dose setting mechanism 102 are removably coupled together. In a disposable device, they may be permanently coupled together. In Figure 1, the dose setting mechanism 102 comprises a piston rod 109, such as a threaded piston rod that rotates when a dose is injected.

To inject a previously set dose, a double ended needle assembly is attached to a distal end 108 of the cartridge holder 104. Preferably, the distal end of the holder 104 comprises a thread 121 (or any other suitable connecting mechanism such as a snap

lock, snap fit, form fit, or bayonet lock mechanism) so that the needle assembly may be removably attached to the distal end of the holder 104. When the drug delivery device 100 is not in use, the removable cap 106 can be releasably retained over the cartridge holder 104.

An inner cartridge cavity 111 defined by the cartridge holder 104 is dimensioned and configured to securely receive and properly retain a cartridge 120. In an alternate embodiment, the cartridge 120 may comprise an integral cartridge assembly wherein the assembly is inserted directly into the drug delivery device 100 without the use of a separate cartridge holder 104. Figure 2 illustrates a perspective view of the cartridge 120 that may be used with the drug delivery device 100 illustrated in Figure 1. The cartridge 120 includes a generally tubular barrel 122 extending from a distal end 130 to a proximal end 132. The distal end 130 is defined by an inwardly converging shoulder 131.

At the distal end 130, the cartridge 120 includes a smaller diameter neck 126 and this neck 126 projects distally from the shoulder 131 of the barrel 122. Preferably, this smaller diameter neck 126 is provided with a large diameter annular bead 123 and this bead extends circumferentially thereabout at the extreme distal end of the neck 126. A pierceable seal or septum 133 is securely mounted across the open distal end defined by the neck 126. The seal 121 may be held in place by a metallic sleeve or ferrule 124. This ferrule 124 may be crimped around the circumferential bead at the distal end of the neck 126. The medicament 125 is pre-filled into the cartridge 120 and is retained within the cartridge 120, in part, by the pierceable seal 133, the metallic sleeve 124, and a stopper 128. The stopper 128 is in sliding fluid-tight engagement with the inner tubular wall of the barrel 122. Axially directed forces acting upon the stopper 128 during dose injection or dose administration may urge the medication 125 from the cartridge 120 through the double ended needle mounted onto the distal end 130 of the cartridge holder 104 and into the injection site. Such axially directed forces may be provided by the piston rod, such as the rotatable piston rod 109 of the drug delivery device illustrated in Figure 1.

Preferably, a label 129 or some other similar type printed matter is provided along an outer surface of the cartridge 120. This label 129 may be used to provide indicia relating to the cartridge contents, the medicament 125 contained within the cartridge 120, manufacturing and/or lot information related to the assembly and filling of the cartridge 120 along with expiration data. In one arrangement, the coding methods and systems disclosed herein may be provided either on the cartridge 120 or on the label 129 provided along this outer surface of the cartridge 120. In addition, where the cartridge 120 comprises a molded cartridge that can be directly inserted into the drug delivery device 100, the presently disclosed coding systems and methods may be integral with such molded cartridges. Alternatively, the presently disclosed coding systems and methods may be provided by way of an element that is separate and apart from either the cartridge 120, the cartridge holder 104, or the dose setting mechanism 102 illustrated in Figure 1.

Returning to Figure 1, a portion of the cartridge holder 104 defining the cartridge holder cavity 111 is of substantially uniform diameter represented in Figure 1 by D_1 134. This diameter D_1 134 is preferably slightly greater than the diameter D_2 136 of the cartridge 120. The interior of the cartridge holder 104 includes an inwardly-extending annular portion or stop that is dimensioned to prevent the cartridge 120 from moving within the cartridge holder 104. In this manner, when the cartridge 120 is loaded into the cavity 111 of the cartridge holder 104 and the cartridge holder 104 is then connected to the dose setting member 102, the cartridge 120 will be securely held and properly positioned within the cartridge cavity 111. More particularly, the neck 126 and ferrule 124 of the cartridge 120 are inserted in a proximal to a distal direction into the open proximal end of the cartridge holder 104 with the ferrule 124 eventually passing entirely into the holder 104. With the holder 104 removably coupled to the dose setting mechanism 102, the proximal end of the cartridge 120 will typically abut a stop provided by the dose setting member 102.

A number of doses of a medicament 125 may be dispensed from the cartridge 120. Preferably, the cartridge 120 contains a type of medicament 125 that must be administered often, such as one or more times a day. One such medicament 125 is insulin and another such drug is human growth hormone. The movable piston or stopper 128 is retained in a first end or proximal end of the cartridge 120 and receives the axial force created by the piston rod 109 of the dose setting mechanism 102.

The dose setting mechanism 102 comprises a dose setter 117 at the proximal end of the dose setting mechanism 102. In one preferred arrangement, the dose setter 117 is rotated to set a dose and in this manner translates in a proximal direction away from the attached cartridge holder 104. To administer this set dose, the user attaches the needle assembly comprising the double ended needle on the distal end of the cartridge holder 104. In this manner, the needle assembly pierces the septum 133 of the cartridge 120 and is therefore in liquid communication with the medicament 125. The user pushes on the dose setter 117 to inject the set dose and the dose setter translates and rotates in a opposite direction back towards and into the drug delivery device 100. The same dose setting and dose administration procedure is followed until the medicament 125 in the cartridge 120 is expended and then a new cartridge must be loaded in the device 100. If the drug delivery device 100 comprises a reusable drug delivery device, to exchange an empty cartridge 120, the user is called upon to remove the cartridge holder 104 from the dose setting mechanism 102.

Figure 3A illustrates a first arrangement of an interface 204 comprising a coding feature 200 for use with a cartridge or cartridge holder that may be used with a pen-type drug delivery device, such as the drug delivery device 100 illustrated in Figure 1. Alternatively, the coding feature 200 illustrated in Figure 3A (as well as other herein disclosed coding features) may be provided on a cartridge label, a cartridge holder, a dose setting member, an integral or moldable cartridge, or on an element that is separate from the cartridge or cartridge holder. The proposed coding feature 200 helps to ensure that a proper cartridge is used with a proper cartridge holder and, therefore, a preferred drug delivery device. If the coding features do not correctly mate or mesh with

corresponding coding features to properly position the cartridge, the user of the drug delivery device may become quickly aware that the cartridge and, hence, the drug contained within the cartridge, is not a cartridge that is intended to be used with a particular drug delivery device.

Alternatively, the proposed coding feature methods and systems also tend to help to ensure that a proper cartridge holder is used with a proper drug delivery device. If the coding features do not correctly mate or mesh with corresponding coding features to properly position the cartridge, the user of the drug delivery device may become quickly aware that the cartridge holder and, hence, the drug contained within the cartridge holder, is not a cartridge holder that that is intended to be used with a particular drug delivery device.

Returning to Figure 3A, a first coding feature 200 may comprise one or more separate coding elements 201a-c and these elements 201a-c may be located on a flange 202 of an interface 204. For example, and as illustrated in Figure 3A, the interface 204 may take the form of a single flange or plate 202. Alternatively, the interface 204 may take the form of a longitudinal wall such as a ring, as illustrated in Figure 3B. Coding features 200 may then be located on a flange or a sidewall of the interface 204, or on both as illustrated. Such an interface 204 may be applied to a distal end of a cartridge, such as a glass cartridge or a molded cartridge. Alternatively, the interface 204 and coding features 200 may be provided at a different location within the drug delivery device, such as the device 100 illustrated in Figure 1. For example, the interface 204 may be provided along the ferrule 124 of the cartridge 120, along the label 129, somewhere along the cartridge holder 104, within the drug delivery device 100, or on the cap 106. In addition, the interface 204 may be provided along a cartridge sidewall such as directly on a cartridge sidewall or on an additional component connected to the cartridge sidewall.

Figure 3B illustrates an alternative interface 1200 that may be used to code a cartridge holder to a drug delivery device wherein the interface 1200 comprises a sleeve or a

ring. In this arrangement, a first coding feature 1202 may comprise one or more separate coding elements 1204, 1206, and 1208 and these elements may be located on an outer surface 1203 of an interface 204. In one arrangement, each coding element 1204, 1206, and 1208 has a unique geometrical configuration. In this arrangement, each coding element 1204, 1206, and 1208 may be spaced equally (90 degrees) from one another however alternative arrangements may also be used.

Figure 4 illustrates an alternative arrangement of an interface 220. In this arrangement, unlike the interface 204 illustrated in Figure 3A-B, the interface 220 illustrated in Figure 4 may comprise a cylindrically shaped cap comprising a main body 226. This main body 206 may define a centrally located aperture 228, which is described in greater detail herein.

This aperture 228 extends from a proximal end 230 to a distal end 232 of the main body 226. When in use, the aperture 228 is placed over the ferrule located at the distal end of a cartridge, such as cartridge 120. Preferably, this main body 228 has a diameter D_2 214 that is slightly larger than the diameter of the ferrule 124 of the cartridge 120. The interface 220 further comprises an axially extending wall 225 that extends from a flange 222 located near the proximal end of the main body 226. This axially extending wall 225 extends towards the distal end of the main body 226.

In one arrangement, aperture 228 is sized or configured so that, when the interface 220 is snapped over the ferrule of a cartridge, such as the cartridge 120 illustrated in Figure 2, the aperture 228 can expose a portion of the ferrule 124 of the cartridge 120 and will provide access to at least a portion of the pierceable septum 133 of the cartridge 120. In one arrangement, the interface 220 comprises an outer thread and is intended for use with a double ended needle, such as comprised by the needle arrangement 872 illustrated in Figure 26. Such a needle arrangement 872 may have a hub having an internal thread. As such, an outer surface of the axially extending wall of the main body 226 is provided with an outer thread 236 that receives such a hub of the double ended needle. Such an outer thread 236 could comprise a single or a double start outer

thread. In addition, when such double ended needle is mounted onto the interface 220, the piercing distal needle projects through the aperture 228 and into the pierceable seal of the cartridge 120. In an alternative arrangement, the interface 220 may be provided without an outer thread.

As shown in Figures 3 and 4, in certain exemplary embodiments, a first coding feature may comprise one or more coding elements. For example, the interface 204 illustrated in Figure 3A comprises a plurality of coding elements 201a, 201b, and 201c. The coding elements 201a, 201b, and 201c may comprise three protrusions. Similarly, with the interface 220 illustrated in Figure 4, this interface 220 comprises three coding elements 223a, 223a, and 223c. In one arrangement, these coding elements may mechanically code the interface to the cavity 111 of the cartridge holder 104. Alternatively, these coding elements may mechanically code the interface to another component of the drug delivery device, such as the dose setting member 102 of the drug delivery device 100. In yet another alternative arrangement, these coding elements may mechanically code the interface to a separate component independent of the cartridge 120, the cartridge holder 104, or the drug delivery device 100.

As just one example, the protrusions (*e.g.*, coding elements 201 a-c or coding elements 223 a-d) may cooperate with corresponding indentations within the cartridge holder 104 or drug delivery device 100. In the interface 220 illustrated in Figure 4, the interface 220 comprises three coding elements 223a, 223b, and 223c. The coding elements 223a, 223b, and 223c comprise protrusions.. Each of these coding elements 223a, 223b, and 223c comprises a different geometrical shape. For example, coding element 223a comprises a triangular shape, coding element 223b comprises a round shape, and coding element 223c comprises a rectangular shape. Each coding element 223a, 223b, 223c is offset from an adjacent coding element 223a, 223b, and 223c by 90 degrees. However, as those of skill in the art will recognize alternative protrusion geometries, protrusion configurations, and protrusion locations (such as around the perimeter) may also be utilized. For example, the coding elements 223a-c may be of different sizes and shapes, may be offset from an adjacent protrusion or protrusions by the same or

varying degrees, or there may be any number of protrusions, grooves, or different features as illustrated herein. As just one example, Figures 5A and 5B illustrate a coding system for coding two different medicaments. In a first interface 227 illustrated in Figure 5A, this first interface 227 has a set of three protrusions 229 a-c and this set comprises a rectangle, a half-circle and a triangle. The second interface 231 of this coding system illustrated in Figure 5B comprises three protrusions 242, 244, and 246. Two of these protrusions 244, 246 comprise a triangular shaped protrusion and the third protrusion 242 comprises a rectangular shaped protrusion. Although only certain shapes are shown, it should be understood that the various set of interfaces making up the coding system may comprise any collection of protrusions and/or grooves. In order to help ensure that a protrusion does not properly fit into the wrong mating part (of a cartridge holder, of the drug delivery device or a separate component part), the area covered by one protrusion must not be completely covered by the area of any other protrusions that might be used at the same location for different medicaments. In other words, each shape may be smaller in one area and larger in another than all of the other shapes in the coding system.

Figure 6 illustrates yet another alternative arrangement of an interface comprising a coding feature arrangement. Figure 6 illustrates an interface 250 having a coding feature 252 that comprises a single coding element and this single coding element takes the form of a protrusion 256. This protrusion 256 extends upwardly away from the plate or flange 254 in a longitudinal direction. Figure 6 illustrates the longitudinal coding features as being attached to a flange 254 and not attached to the sidewall of the interface 250, but in alternative embodiments it may be attached to the sidewall. The coding feature 252 illustrated in Figure 6 may also be attached to an interface 204 similar to the one illustrated in Figure 3.

Figures 7-8 illustrate other alternative arrangements of interfaces, in which the coding features are orientated in different directions. For example, and as illustrated in Figure 7, the interface 260 will have the same cap like structure as the interface 220 illustrated in Figure 4. However, the interface 260 will comprise a different coding arrangement

264. For example, the interface 260 may comprise one or more protrusions wherein the protrusions 266, 268 extend outwardly from the plate or flange 272 in a radial direction away from the interface main body. In other embodiments, the protrusions might extend in a transverse direction, so that each protrusion has parallel sides. Figure 8 illustrates a top perspective view of the interface illustrated in Figure 7. As illustrated in Figure 7 and 8, these protrusions 266, 268 extend radially away from the flange 272, and are attached only to the flange 272 and are not attached to a sidewall of the interface. However, in alternative embodiments, the protrusions may extend outwardly from a sidewall of the main body. These protrusions 266, 268 do not extend longitudinally in a distal direction towards the distal end of the interface, but they may do so in other embodiments. As those of ordinary skill in the art will recognize, alternative protrusion arrangements may also be utilized. As just one example, the coding features illustrated in Figures 7 and 8 could also be attached to an interface 204 similar to the one illustrated in Figure 3.

If a coded component is not aligned with its mating component in a known orientation, it may be difficult to achieve a large number of coding combinations. If the two components are aligned with each other, the number of coding combinations may be increased. Alignment can be achieved if one or more of the coding features (or an additional feature) has an asymmetric position or size around the axis, or if one of the features is unique, for example a protrusion that is larger than all of the other coding features. Figure 9 illustrates yet another alternative arrangement of an interface 280 for use with a drug delivery device. As illustrated, this interface 280 comprises another cap like structure comprising plurality of asymmetric coding features. Here, the interface 280 comprises both alignment features and asymmetric coding features. Specifically, the interface 280 comprises two alignment features 284 a, b and two asymmetric coding features 282 a, b. The alignment features 284 a, b provide a means of aligning the interface 280 when the cartridge (and hence the interface 280) are inserted into a cartridge holder. Alternatively, the coding 282 a, b and alignment features 284 a, b illustrated in Figure 9 could also be attached to an interface 204 similar to the one illustrated in Figure 3. As those of skill in the art will recognize, alternative coding

feature and alignment arrangements may also be used where the various protrusion can vary in height, length, width and/or orientation.

Where the coding feature is provided on an interface, a corresponding second coding feature may be located within the drug delivery device, for example, in the cavity 111 of the cartridge holder 104. Alternatively, a corresponding second coding feature may be located directly in the cavity of the drug delivery device 100. As just one example, the interface may be snapped over the distal end 108 of the cartridge 120 such that the interface form fits or snaps around the ferrule 124 of the cartridge. It should be understood that the interface may also be secured to the cartridge 120 by any suitable means known in the art. In addition, the interface may comprise a flexible material so that the interface deforms when it is passed over the distal end of the cartridge 120.

In one arrangement, the coding methods and systems described herein can be used with a cartridge holder similar to the cartridge holder 104 of Figure 1 but somewhat modified. For example, Figure 10 illustrates an interface 306 that is mounted onto a cartridge 301 and then partially inserted into the cartridge holder. Figure 11 illustrates this interface 306 in a fully seated or inserted position within the cartridge holder 292, with the distal end of flange 308 on interface 306 abutting the proximal end of the inwardly directed flange 310 on cartridge holder 292. More specifically, Figure 10 illustrates a perspective view of a distal end of a modified cartridge holder 292 that could be used with an interface 306 comprising a coding scheme consisting of a first coding feature, for example a first and a second protrusion 294, 296. The proximal end of the cartridge holder 292 would include a similar releasable connection mechanism (e.g., thread, snap lock, snap fit, bayonet lock, etc.) as the cartridge holder 104 illustrated in Figure 1.

In this modified cartridge holder 292, the threaded distal end 108 of the cartridge holder 104 illustrated in Figure 1 is removed since this thread (or similar connection mechanism) is now provided by the interface 306. As can be seen from Figure 10, the cartridge holder 292 now comprises a bore located near the distal end of the holder

292. In addition, and as can be seen when comparing the cartridge holder 104 of Figure 1 with the cartridge holder 292 in Figure 10, the distal end of this modified cartridge holder 292 defines a second coding feature, for example a first and a second cut out 302, 304. Cut outs 302, 304 are so configured that, when a cartridge with a correctly coded interface is inserted into a proximal end of the cartridge holder 292, the interface properly meshes the radially extending protrusions 294, 296 of the interface to an end position located at the distal end of the holder 292. In this manner, the correct combination of the first and the second coding features, for example the radially extending protrusions 294, 296 and the cut outs 302, 304, allow the distal end of the interface 306 to pass through the bore so that it achieves its proper seated position as illustrated in Figure 11. An incorrect combination would prevent complete insertion of the cartridge into the cartridge holder 292, which may in turn prevent assembly or proper positioning of the cartridge holder onto the dose setting mechanism.

Figure 12A and 12B illustrate yet another arrangement of an interface 320, in which there is more than one coding feature on the interface. In Figure 12A, the interface 320 is illustrated as being partially inserted into a proximal end of a cartridge holder 322. For example, Figure 12A illustrates an interface 320 in the form of a sleeve having a side wall 324. This side wall 324 is generally smooth and may be provided with a coding feature 326 comprising a plurality of radially extending protrusions 328, 330. The protrusions 328, 330 may be positioned at different axial or circumferential locations along an outer surface of the main body of the interface 320. These protrusions 328, 330 are configured to mate with a first and a second corresponding protrusion such as an inner ridge or blocking feature 332, 334 provided along an inner surface of the cartridge holder 322. Alternatively, these protrusions 328, 330 may be configured to mate with a first and a second corresponding protrusion provided by a drug delivery device or a separate component, separate and apart from either the cartridge holder or the drug delivery device.

Alternatively, in a coding system with only one coding feature, a cartridge might fit into an incorrect device. For example, an exemplary coding system 336 for three drugs is

illustrated in Figures 12C-E. This coding system 336 may be used to code three drugs where the coding system 336 only comprises one coding feature. For example, Figure 12C illustrates an interface 342 similar to the interface of Figure 12A where the interface 342 comprises a form in the shape of a cap having a side wall 344. This side wall 344 is generally smooth and may be provided with a coding feature 346 comprising a radially extending protrusion 328. As illustrated in the other coding schemes illustrated in Figures 12D and 12E, this protrusion may be positioned at different axial or circumferential locations along an outer surface of the main body of the interface. For example, the protrusion 368 of the coding feature of Figure 12D is positioned higher in a distal direction along the interface 362 than the protrusion 328 of interface 342. In addition, the protrusion 388 of the interface 382 is positioned higher than the protrusion 368 of Figure 12D. Similar to the coding arrangement illustrated in Figures 12A-B, these protrusions 328, 368, and 388 are configured to mate with a first corresponding protrusion provided as an inner ridge or blocking feature provided along an inner surface of the cartridge holder.

As just one example, for each different cartridge and, therefore, for each different drug or drug concentration, one of the coding features may be located earlier in the assembly direction and one is located later. As such, in Figures 12C-E, the coding feature for a first drug contained within Figure 12C is located earlier in the assembly direction than for the drug contained within Figure 12D and this is located earlier in the assembly direction than the drug contained within Figure 12E. This coding might prevent the interface for drug in Figure 12E fitting into the device for drug contained in Figure 12C. However, the interface for drug in Figure 12C could still fit into the holder for drug Figure 12E. In one preferred arrangement, if more than one coding feature is used, all drugs can be prevented from fitting into an incorrect device.

In alternative interface systems and/or arrangements, the disclosed coding systems and methods may depend on the size and/or on the position of coding features in more than one dimension. For example, as illustrated in Figures 13-14, a first coding feature may include at least one circular shoulder 402. As illustrated in Figure 13, the interface 400

comprises a sleeve 404 comprising a first continuous circular shoulder 402. The shoulder 402 may be coded to the cavity 111 of the cartridge holder 104 or may be coded to the drug delivery device 100 by means of the diameter and/or location of the shoulder 402. In a system where coding is provided in only one dimension, a drug contained within a reservoir might fit into an incorrect device. For example, a large shoulder 402 would not fit into a device intended for a smaller shoulder, but a small shoulder would fit into a device intended for a larger shoulder. Similar problems might exist where an interface is coded only by the axial position of a shoulder. However, if a system is coded by more than one dimension, a plurality of drugs can be prevented from fitting into an incorrect device. For example, one drug might have a shoulder with a small diameter located a small distance from the end face, and another drug might have a larger diameter shoulder located a larger distance from the end. In order to prevent assembly of a drug into an incorrect device, the volume swept by the coding for one drug during assembly must not be completely covered by the volume swept for another drug.

In one embodiment, shown in Figure 13, a shoulder 402 may be secured to the sleeve 404 a distance L from a distal end of the interface 400. The interface shoulder 400 may have a single constant outer diameter Ø D as illustrated in Figure 13. In an alternative arrangement, this sleeve 404 could be applied to a surface of a cartridge glass, a ferrule, a label, a separate component interface on a sidewall of a cartridge, a cartridge holder, the drug delivery device body, or a drug delivery cap. Alternatively, the shoulder 402 may be integrally molded to either a cartridge or a cartridge holder. As such, a corresponding second coding feature, such as a groove or a shoulder, may be located in the cavity 111 of the cartridge holder 104 or elsewhere within the drug delivery device 100.

The shoulder 402 may alternatively be secured to a main body of an interface in the form of a cap or sleeve, similar to the cap like interface illustrated in Figure 4. For example, Figure 14 illustrates an interface 410 having a shoulder 412 similar to that of interface 400 illustrated in Figure 13. For example, the shoulder 412 may be secured to

the sleeve a distance L from a distal end of the interface 410 and the interface shoulder 412 may have a single constant outer diameter Ø D as illustrated.

In an alternative arrangement, a protrusion is coded in two dimensions, for example by its radial and circumferential extents. Such an interface arrangement 420 is illustrated in Figures 15A, where an interface is overlaid on an incorrect mating part 421. Mating part 421 may be provided on a drug delivery device, a cartridge or reservoir holder or as a component part separate from the drug delivery device. Figure 15B shows a detailed view of the coding protrusion 460 on the mating part 421 and the coding indentation 450 on the interface. In a system where coding is only in one dimension, a drug might fit into an incorrect device. For example, a coding protrusion 460 would fit into an indentation 450 with a larger circumferential extent, or with a larger radial extent. However, if a system is coded by more than one dimension, drugs can be prevented from fitting into an incorrect device. For example, coding protrusion 460 does not fit into the coding indentation 450 on the interface. Although the protrusion 460 fits into indentation in the circumferential direction, its radial extent is too large. In order to prevent assembly of a cartridge containing a drug into an incorrect device, a coding feature for one drug must be smaller in one dimension and larger in another than corresponding features for other drugs. In other words, the coding feature must cover an area that is not completely covered by the area of any other protrusions that might be used at the same location for different medicaments.

Referring now to Figures 16 and 17, the proposed interface systems may comprise a plurality of shoulders 600, so that coding is achieved using more than one coding feature on the interface. Such an interface may comprise a variety of different diameters and/or widths and at various locations. For example, Figure 16 illustrates an interface 600 comprising a coding feature 606 that comprises two shoulders 602, 604 wherein each shoulder 602, 604 has a different diameter but a similar width. For example, as illustrated in Figure 16, the first shoulder 602 comprises a first width W1 and has a first diameter D1. This first shoulder 602 extends a distance L1 from a proximal end of the interface 600 to a distal end of the interface 600. Similarly, the second shoulder 604 of

the coding feature 606 comprises a second width W2 and a second diameter D2 and extends a distance L2 from the proximal end to a distal end. To create a coding system for a range of drugs, the width W, diameter D, and length L can be varied, so that no drug fits into an incorrect device. In order to prevent assembly of a drug into an incorrect device, the volume swept by the coding for one drug during assembly must not be completely covered by the volume swept for another drug. As those of skill will recognize, alternative shoulder arrangements having a plurality of shoulders of varying widths, diameters, and geometric locations along the interface may also be used. Similar coding systems may also apply to non-circular shoulders.

As just one example, Figure 17 illustrates a similar interface coding arrangement for an interface 620 comprising a coding scheme 626 comprising a first and a second shoulder 622, 624, respectively. As illustrated, the first shoulder 622 comprises a first width W1 and has a first diameter D1. This first shoulder 622 extends a distance L1 from a proximal end of the interface 620 to a distal end of the interface 620. Similarly, the second shoulder 624 of the coding feature 626 comprises a second width W2 and a second diameter D2 and extends a distance L2 from the proximal end to a distal end. As those of skill will recognize, alternative interface arrangements having a plurality of shoulder of varying widths, diameters, and geometric locations along the interface may also be used.

Figures 18-23 show alternate coding feature arrangements. In one alternate interface arrangement, as shown in Figure 18, the interface 640 comprises a first coding feature 642 that includes one or more indentations or grooves. In this arrangement, the coding feature 642 comprises a first indentation 644, a second indentation 646, and a third indentation 648. Each indentation 644, 646, 648 comprises a unique or proprietary geometric shape. These indentations 644, 646, 648 may reside along a flange 641 of the interface 640, but alternatively, the indentations 644, 646, 648 may be cut into the sidewall of the main body. Therefore, the corresponding coding or mating feature or features could comprise a corresponding protrusion or protrusions that mesh or that interface with the one or more indentations or grooves. Such indentations and/or

grooves may be located within the cavity 111 of the cartridge holder 104 or drug delivery device 100. Alternatively, the coding features illustrated in Figure 18 could also be attached to an interface 204 similar to the one illustrated in Figure 3.

In another arrangement, shown in Figure 19, the interface 660 comprises a first coding feature 662 comprising a protrusion 664 formed around an indentation 666. Again, such a coding feature 662 may reside on an interface 204 similar to the one illustrated in Figure 3. Such a protrusion 664 may be utilized to increase the length and robustness of the coding features 662. As just one example, longer coding (or more strictly longer overlap between coding on the mating parts) can be more effective at preventing errors. In one preferred arrangement, the longer the coding, the more an incorrect cartridge will protrude from the cartridge holder, and either be more obvious to the user, or prevent fastening of the holder to the device. Tolerances may reduce the protrusion (for example, a short cartridge in a long cartridge holder), so longer coding may be needed where tolerances are large. Alternatively, the first coding feature may comprise a combination of both protrusions and indentations in a number of different configurations.

Figures 20 a-d illustrate one exemplary coding system 680 comprising a plurality of interfaces 682 a-d. Such a system of interfaces 682 a-d may be used for coding a plurality of different medicaments. In this illustrated arrangement, the coding system 680 may be used to code at least four different types of medicaments. This coding system 680 utilizes a combination of at least one protrusion and at least one groove or recess. In one preferred embodiment, each coding location has either an indentation or a protrusion, which ensures a large difference in the height of coding features at each location. This combination of coding protrusion and groove features may be spaced an equal distance around the circumference of the interface 682 a-d. In one preferred arrangement, these coding features are equally spaced around the outer circumference of the interface 682 a-d.

For example, in this illustrated arrangement, these coding features are spaced approximately by 120 degrees from each other around the outer circumference of the

respective interface 682 a-d. As illustrated in Figure 20A, this first interface 682a comprises a coding feature 684 in the form of three radial protrusions 686 a-c. In this arrangement, the first protrusion 686a is spaced 120 degrees from the second protrusion 686b which is spaced 120 degrees from the third protrusion 686c.

Similarly, in the third interface arrangement 682c illustrated in Figure 20C, the interface 682c comprises a coding feature 688 comprising a first groove 690a and a second groove 690b and a first protrusion 690c. In this arrangement, the first groove 690a is spaced 120 degrees from the second groove 690b which is spaced 120 degrees from the first protrusion 690c. As such, with the coding features 688 illustrated in Figure 20C, an arrangement of protrusions and grooves may be used to code four different medicaments. However, as those of skill in the art will recognize, alternative coding systems of different shapes, geometries, and/or circumferential arrangements may also be utilized. As just one example, the coding features illustrated in Figures 20 A-D may be provided on an interface as illustrated in the various figures herein or alternatively on a label, a cartridge holder, a dose setting member, an integral or moldable cartridge, a dose setting member, or an element that is separate from the cartridge or cartridge holder.

In yet another arrangement, an interface may comprise a first coding feature that may be a non-circular coding feature and that is coded by its geometric shape. For example, Figure 21A illustrates an interface 700 comprising a coding feature 702 located on the outer edge of the plate or flange 702 in a transverse plane. Alternatively, the non-circular coding may form part of the interface main body itself. A top view of such a coding feature is illustrated in Figure 21B. With such a coding arrangement, a corresponding non-circular second coding feature may be located in the cavity 111 of the cartridge holder 104 or drug delivery device 100. In order to prevent assembly of a drug into an incorrect device, the coding feature may cover an area that is not completely covered by the area of corresponding coding features for different medicaments.

Figure 22 illustrates yet another embodiment of an interface 720 comprising a first coding feature 722. In this arrangement, the first coding feature 722 comprises one or more ramps 724, or in other words one or more faces that are angled relative to a transverse plane. The ramp 724 may extend upwardly from a proximal end of the interface 720. A corresponding ramp-shaped second coding feature may be included in the cavity 111 of the cartridge holder 104 or drug delivery device 100. In order to prevent assembly of a drug into an incorrect device, the coding feature for one drug may cover an area in a longitudinal plane that is not completely covered by the area of coding features for other medicaments.

Figure 23 illustrates yet another embodiment of an interface 730 comprising a first coding feature, somewhat similar to the coding features illustrated in Figure 22. For example, in the arrangement illustrated in Figure 23, the first coding feature 732 comprises a first ramp 734 and a second ramp 736 directed in an opposite directions. For example, the first ramp 734 extends upwardly from a proximal end of the interface 730 in a first direction “A” and the second ramp 736 extends upwardly from the proximal end in a second opposite direction “B”. For each respective ramp 734, 736 provided on the interface 730, a corresponding ramp-shaped coding feature may be included in the cavity 111 of the cartridge holder 104 or drug delivery device 100.

It should be understood that any of the coding features herein may be used alone or in combination with any other coding feature to create a unique coding mechanism for the drug delivery device 100.

In another interface arrangement, as shown in Figure 24, an interface 804 may be provided with at least one alignment feature 824. In this illustrated arrangement, the alignment feature 824 is provided along a flange 802 and comprises a generally rounded rectangular shape having an outer diameter D3 814. However, those of skill in the art will recognize, alternative geometries of alignment features 824 may also be used. In addition, in this arrangement, the alignment feature 824 comprises a single protrusion that is directed radially outwards away from the main body of the interface

804. In this arrangement, when mounted onto a cartridge, the protrusion 824 extends beyond an outside diameter of a cartridge, such as diameter D_2 136 of cartridge 120 (Figure 2).

The interface 804 is intended for use with a cartridge holder similar to the cartridge holder 104 of Figure 1 but somewhat modified. For example, Figure 25 illustrates a cross-sectional view of a distal end 852 of a modified cartridge holder 850 that could be used with the interface 804 having a single protrusion feature 824. The proximal end (not shown) of the cartridge holder 850 would include a similar releasable connection mechanism (e.g., thread, snap lock, snap fit, bayonet lock, etc.) as the cartridge holder 104 illustrated in Figure 1.

In this modified cartridge holder 850, the threaded distal end 108 of the cartridge holder 104 illustrated in Figure 1 is removed since this thread (or similar connection mechanism) may be provided by the interface 804. As can be seen from Figure 25, the cartridge holder comprises a bore 854 located near the distal end 852 of the holder. In addition, and as can be seen when comparing the cartridge holder 104 of Figure 1 with the cartridge holder 850 in Figure 25, an inner wall 856 of the modified cartridge holder 850 defines a ramp 858 having a predefined ramp projection around an inner circumference. This ramp 858 is so configured that, when a cartridge with a correctly coded interface 804 is inserted into a proximal end of the cartridge holder 850, the ramp 858 guides the radially extending protrusion 824 of the interface 804 to an end alignment position 860 located at the distal end 852 of the holder 850. In this manner, the correct combination of the radially extending protrusion 824 and ramp projection will allow the distal end of the interface 804 to pass through the bore 854. Consequently, when a cartridge carrying the interface 804 is inserted into the cartridge holder 850, the alignment feature 824 cooperates with the ramp 858 until the interface resides in a final alignment position 860.

When a cartridge 820 (see Figure 26) containing the interface 804 is placed within the cartridge holder 850 and the alignment feature 824 travels both axially and rotationally

into the cartridge holder 850 (either pushed manually or under gravity), the contact between the alignment feature 824 and the ramp 858 causes the interface 804 to rotate. That is, when the cartridge 820 is placed into the proximal end of the cartridge holder 850, the alignment feature 824 will travel along the ramp projection around the circumference of the cartridge. This alignment feature 824 will eventually align the cartridge 820 within the cartridge holder 850 with the alignment feature 824 eventually residing in the final alignment position 860. By adjusting the angles of the ramped projection around the circumference, the insertion force required to align the interface 804 (and hence the cartridge) within the cartridge holder 840 can be increased or decreased. In this manner, the alignment feature 824 may help a user align coding on the cartridge 820 with corresponding coding on the cartridge holder 850. The coding may include any of the coding features herein discussed.

One advantage of using the interface 804 is that the cooperation between the alignment feature 824 and corresponding ramp 858 may prevent the interface 804 (and, hence, the cartridge 820) from unwanted rotation within the cartridge holder 850 once properly inserted. That is, the alignment feature 824 may prevent unwanted rotation of the interface 804 when a double ended needle is either attached or removed from the distal end of the interface 804. Figure 25 illustrates the alignment feature 824 in the final alignment position 860 (the cartridge has been omitted for clarity) where the distal end 812 of the interface 804 is allowed to pass through the cartridge holder bore 854.

Figure 26 illustrates schematically certain relevant parts of the drug delivery device with a needle assembly mounted onto the interface arrangement 804 illustrated in Figure 24. As illustrated, cartridge 820 has a neck with a flange against which a rubber membrane is secured by a ferrule 825 beaded under the flange. In one preferred method of securing the interface 804 to the cartridge 820, the interface 804 may be passed with its bore over a bead 823 and pressed down to make the protrusion pass the ferrule 825 and grip under the lower beaded edge of this bead. Other methods of securing the interface 804 to the cartridge may also be used.

A needle arrangement 872 comprises a tubular skirt 870 having an internal thread to be screwed onto the outer thread of the interface 804 with its needle 874 piercing the membrane and projecting into the opening of the neck part of the cartridge 820. This is just one arrangement of how the proposed interface systems may be used to align the cartridge 820 within the cartridge holder 850.

In this manner, when a user attempts to load the cartridge 820 into a cartridge holder 850, the interface 804 and ramp 858 cooperates so as to allow the proper positioning of an acceptable cartridge 820. Alternatively, if an incorrect interface is used, the interface 804 and ramp 858 will not cooperate and will, therefore, prohibit an incorrect cartridge from being properly inserted into or properly positioned within the drug delivery device. Depending on the mechanical structure of the drug delivery device, the interface 804, or the drug administration system, the coding feature (such as a projection, a plurality of projections, or projection arrays) may be provided along a different portion of the cartridge 820. For example, the coding feature could be provided along the tubular member of the cartridge 820 or, alternatively, towards the proximal end of the cartridge 820. Alternatively, the coding features may be provided on an interface that is illustrated in the various figures herein or, alternatively, on a cartridge label, a cartridge holder, a dose setting member, an integral or moldable cartridge, or an element that is separate from the cartridge or cartridge holder.

Although the alignment feature 824 on the interface 804 is shown as a single protrusion, the alignment feature 824 could comprise an indentation that matches a corresponding protrusion located on the internal wall of the cartridge holder 850. In addition, the alignment features 824 illustrated in Figures 24-26 may be provided on an interface similar to the one that is illustrated in Figure 3 or, alternatively, on a cartridge label, a cartridge holder, a dose setting member, an integral or moldable cartridge, or an element that is separate from the cartridge or cartridge holder.

In one alignment arrangement, more than one protrusion or indentation around the interface circumference may also be provided. One advantage of having two or more

alignment features is that the ramp 858 can have a shorter axial extent for the same ramp angle, and the cartridge 820 may not have to rotate as much during cartridge insertion so as to properly align the coding features.

For example, Figure 27A illustrates an alternative arrangement of an interface 904 having both an alignment feature 924 for use with a cartridge, such as the cartridge illustrated in Figure 2, as well as at least one coding feature 200. More specifically, the interface 904 may be snapped over the distal end 108 of the cartridge such that it fits around the ferrule of the cartridge and thereby provides a mechanical coding to the cartridge.

The interface 904 shown in Figure 27A comprises a cylindrically shaped main body 906 defining a centrally located aperture 908. In this preferred arrangement, the flange 902 is provided with the at least one alignment feature 924. In addition to the alignment feature 924, interface 904 further comprises at least one coding feature 900 comprising a first and a second protrusion 901a, 901b. This coding feature 900 may allow the interface 904 to be mechanically coded to the inner wall of the cartridge holder or the drug delivery device. In this arrangement, the coding feature 900 comprises the first and a second radial protrusion 901a, 901b that extend both axially away from the main body 906 as well as in a distal direction. As those of skill in the art will recognize, alternative arrangements may also be used.

For example, Figure 27B illustrates a cross-sectional view of a distal end of a modified cartridge holder 950 that could be used with the interface 904 illustrated in Figure 27A. This cartridge holder 950 comprises a bore 960 located near the distal end 955 of the holder 950. In addition, an inner wall of the cartridge holder 950 defines a ramp 970 having a profile for use with an interface having a single protrusion and a first and second coding feature. This ramp 970 is so configured that, when a cartridge with a correctly coded interface is inserted into a proximal end of the cartridge holder 905, the ramp 970 may guide the radially extending alignment interface 924 of the interface 904 illustrated in Figure 27A to an end alignment position 980 located at the distal end 955

of the holder 950. In this manner, when a cartridge carrying the interface 904 is inserted into the cartridge holder 950, the alignment feature 924 cooperates with the ramp 970 until the interface 904 resides in the final alignment position 980. Ramp 970 is also configured to guide the coding features 900 into corresponding coding receiving areas 990.

Although the interface 904 is illustrated as being coupled around the ferrule to the distal end of a cartridge, alternative interface arrangements may also be used. For example, the alignment feature 924 and/or coding 900 may be added to an interface that is provided at another location, such as a ring around a sidewall of the cartridge. The coding 900 may comprise mechanical features that mate with each other, or it may be read electronically. Alternatively, the interface may take the form of ridges or grooves provided along the cartridge glass or moulding. Alternatively or in addition, the ferrule itself of the cartridge may be provided with an interface that cooperates with an inner surface of the cartridge holder 950.

Figures 28-29 illustrate alternative configurations of alignment features and coding features that may be located on an interface, such as interface 904 illustrated in Figure 27A. Alternatively, the coding features may be provided on an interface as illustrated in the various figures herein or alternatively on a cartridge label, a cartridge holder, a dose setting member, an integral or moldable cartridge, or an element that is separate from the cartridge or cartridge holder.

As illustrated in Figure 28, the interface comprise three protrusions 962 a-c, and the size of each coding feature may be different from at least one of the others. One of the features may be used as an alignment feature 924, and may be located at any angle from one or more coding features 900. Further, the alignment feature 924 and coding features 900 may be identical. Alternatively, they may comprise unique shapes and/or sizes. As just one example, the alignment feature 924 is longer than the coding features. As illustrated, the long feature will only fit into a long slot that may be provided in the cartridge holder or the drug delivery device, this feature and slot combination so

fixing the orientation of coding on the cartridge relative to coding on the pen. Alternatively, a groove or a plurality of grooves may be provided along with an alignment protrusion and/or coding protrusions on the interface 960.

By utilizing such alignment features in combination with one or more coding features, the number of coding combinations may be increased. For example, Figure 28 illustrates an alignment feature 962a that has a certain width represented by W1 and a certain radial extension represented by R1. The interface further comprises a first coding feature 962b and a second coding feature 962c. As illustrated, the first coding feature 962b has a width W2 and has a radial extension R2. Similarly, the second coding feature 962c has a width W3 and has a radial extension R3. Given such an alignment feature 926a and coding features 926 b, c a plurality of coding schemes may be used with such features. For example, various different alignment and coding combinations are illustrated in Figure 29. These various different combinations may be utilized by an interface to distinguish among six different medicaments or concentration of medicaments. As illustrated, the alignment feature 962a always resides in the twelve o'clock a position for each of the six interface arrangements illustrated in Figure 29. In this coding arrangement, each of the other locations either has no pin, or at least two pins of two possible radial extents. Alternative arrangements would be possible by varying the axial or circumferential extent of each coding feature 962b, c. As those of skill will recognize, alternative alignment and coding feature arrangements may also be utilized so as to properly code a large number of different medicaments.

Figures 30A illustrates one exemplary coding system 975 comprising a first and a second interface 977, 979. Such a system of interfaces 977, 979 may be used for coding a plurality of different medicaments. In this illustrated arrangement, the coding system 975 may be used to code only two different types of medicaments. For example, the first interface 977 comprises a coding system 980 that utilizes a first groove 981 and a second groove 983. In this first arrangement, the first groove 981 is positioned at the 12 o'clock position of the interface 977 and is offset or spaced 72 degrees from the second groove 983. To properly position this interface 977 within a drug delivery device,

the first and second grooves 981, 983 must match up with corresponding protrusions that are also offset by 72 degrees.

Similarly, in the second interface arrangement 979 also illustrated in Figure 30A, the interface 979 comprises a coding arrangement 988 that also comprises a first groove 985 and a second groove 987. In this arrangement, the first groove 985 is situated at the twelve o'clock position and the second groove 987 is spaced or offset 144 degrees from the first groove 985. To properly position this interface 979 within a drug delivery device, the first and second grooves 985, 987 must match up with corresponding protrusions that are also offset by 144 degrees.

As such, with the coding features illustrated in Figure 30A, an arrangement of these two grooves may be used to code only two different medicaments. However, as those of skill in the art will recognize, alternative coding systems of different shapes, geometries, and/or circumferential arrangements may also be utilized. As just one example, the coding features illustrated in Figures 30A may be provided on an interface as illustrated in the various figures herein or alternatively on a label, a cartridge holder, a dose setting member, an integral or moldable cartridge, a dose setting member, or an element that is separate from the cartridge or cartridge holder.

In one arrangement, if the coding system illustrated in Figure 30A is configured to be positioned within a drug delivery device (such as within a cartridge holder) in only one orientation (e.g. by way of an alignment feature), the number of coding combinations of this system 975 can be increased. As just one example, with the introduction of an alignment feature into the system 975 illustrated in Figures 30A, this coding system may now allow for ten (10) different coding combinations. (i.e. nCr = 10 combinations). For example, Figure 30B provides an example of coding system 990 with r=2 coding features in n=5 possible positions. Figure 30B illustrates these ten different coding combinations.

As illustrated, this first interface 992 comprises a coding feature 991 in the form of two grooves 994, 996. In this first illustrated interface arrangement 992, first coding groove 994 is spaced approximately 72 or 144 degrees from the second groove 996 around the outer circumference of the interface 992 (similar to the first and second groove arrangement of interface 977, 979 in Figure 30A). The first interface arrangement 992 further comprises an alignment feature 998 positioned 180 degrees from the first coding feature 994. Alternatively, the interface 992 could be aligned by making one coding feature unique, e.g. a groove that is smaller than the others. As can be seen from the remaining nine interfaces in Figure 30B, each of the nine interfaces comprises two grooves that are positioned at various offsets and various locations around an outer perimeter of the respective interface. In this example, coding features are arranged in a number of fixed positions that are the same for all of the interfaces in the system, but for each interface, coding is only included at selected positions. As illustrated, each of the nine interfaces has the same type of alignment feature as interface 992 and this feature is located at the same location on the interface as alignment feature 998.

Figure 31A illustrates yet another embodiment of a coded drug cartridge. In this embodiment, a cartridge 1000 is coded to a cartridge holder 1002 with coding features 1004 located on the sidewall of the cartridge 1000. The coding features 1004 may be applied directly to the cartridge 1000, or on a label. Alternatively, the coding features 1004 may be located on an interface 1006 that is secured to a proximal end of the cartridge 1000. In yet another alternative arrangement, these coding features 1004 may be provided on a label affixed to the cartridge 1000 or perhaps part of a molded cartridge. The protrusion 1012 is a pin for fastening into a groove on the cartridge 1000. The cartridge holder 1002 includes corresponding coding features, grooves 1010, which mate with the coding features 1004 on the cartridge 1000. It should be understood that the coding features 1004 and corresponding coding features 1010 may be replaced with any of the coding features described herein. With such a coding system, the coding features 1004 will provide axial meshing with the corresponding coding features 1010 on the interface 1006.

Alternatively, the cartridge 1000 may be coded to the cartridge holder 1002 with the coding feature 1004 but without the radial extending portion 1008. For example, Figure 31B illustrates one such an arrangement. In this arrangement, the interface 1006b is provided with a plurality of coding features 1010b that mesh in an axial fashion with the corresponding coding features 1010 provided on the cartridge holder 1002b.

Figure 32 illustrates yet another embodiment of an interface. In this embodiment, the drug cartridge 1100 is coded directly to a drug delivery device by way of an interface 1102. The cartridge 1100 includes the interface 1102 and this interface 1102 is secured to a proximal end of the cartridge 1100. The interface 1102 may comprise a ring shaped geometry, and may include at least one coding feature. In this illustrated arrangement, the coding feature comprises a first protrusion 1104a and a second protrusion 1104b. The interface 1102 may comprise an alignment feature, here, the alignment feature comprises two grooves 1106 a, b.

Figure 33 illustrates the coding features of Figure 32 partially connected to a drug delivery device 1108. As illustrated in Figure 33, the drug delivery device 1108 may comprise a corresponding coding feature 1110, such as one or more grooves that are geometrically configured to mesh with the first 1104a and the second protrusions 1104b provided by the interface 1107. However, it should be understood that the coding feature 1104 and corresponding coding feature 1110 may be replaced with any of the coding features as described herein. In this arrangement, when inserted into the drug delivery device 1108, the coding features 1104 pass through the corresponding features 1110 on the drug delivery device, but do not mesh with them when fully inserted. Although illustrated with the coding traveling in an axial direction, it may travel in any direction (e.g. axial, helical, or rotational). Therefore, the user will be alerted that the incorrect cartridge has been inserted into the drug delivery device.

The interface 1102 may further include one or more alignment features as previously discussed herein. In this arrangement, a first and a second alignment feature 1106 a, b is provided. In one arrangement, the alignment feature or features 1106 a, b may

comprise a groove or a plurality of grooves. As such, the drug delivery device 1108 may include a corresponding alignment feature or features, such as a protrusion or protrusions. For example, as illustrated in Figure 33, the drug delivery device 1108 comprises a first and a second protrusion that is geometrically configured to mesh with the first and second alignment features of interface 1102. It should be understood that any suitable alignment features may be used. After the coding features on the cartridge 1100 and drug delivery device 1108 have passed through each other, alignment feature 1106 on the interface 1102 may prevent the coding features 1104, 1110 from rotating out of alignment with one another. The alignment feature 1112 may be a standard feature for all drugs, while the coding features may vary from one cartridge to another cartridge so as to indicate the type of drug.

One advantage of coding the cartridge 1100 directly to the drug delivery device 1108 is that such a system may remove the need for separate coding from the cartridge 1100 to the cartridge holder 1002, and then from the cartridge holder 1002 to the drug delivery device 1108. Further, such a system may allow the cartridge 1100 to be inserted into the drug delivery device 1108 before it is inserted into the cartridge holder 1002, thereby giving feedback regarding drug suitability.

In other situations, the disclosed coding systems and methods may apply to any drug delivery device, with any type of reservoir or primary pack, e.g. inhaler, pouch. For example, Figure 34 illustrates a drug reservoir 1220 comprising a vessel 1222 that contains a medicament 1124. A stopper 1260 is provided along a distal end of the vessel 1222 and is attached to the vessel 1222 so as to prevent the medicament 1124 from exiting the vessel 1222. An alignment feature 1228 may be provided on the vessel 1222. In this preferred arrangement, the alignment feature 1228 is provided near an output port 1230 of the vessel 1222 but may also be provided at alternative locations. This output port 1230 has a rigid neck and the alignment feature 1228 is provided along this neck so as to interface with a reservoir holder. Any of the coding features described herein may also be included on the vessel 1222 or on a label applied to such vessel 1222.

The disclosed alignment system results in a number of advantages. For example, the proposed alignment system may assist a user to distinguish between medicaments, thereby helping to ensure that a delivery device can only be used with a medicament for which the device is intended. Therefore, with the disclosed coding and alignment system applied to a cartridge, the cartridge may be prevented from being loaded into any other drug by loading a cartridge with an incorrect or unwanted interface. The disclosed cartridge coding and alignment system may prevent a user from completing one or more of the following actions: fully inserting the cartridge into an incorrect cartridge holder or attaching the cartridge and/or cartridge holder onto an incorrect dose setting mechanism. With certain existing coding systems, the user is called upon to manually align coding on one part with corresponding features on the other part. Users with limited dexterity might find this difficult, so the coding features must be large. With the disclosed system, complex codes can be aligned automatically, no matter in what orientation the user inserts the cartridge into the holder.

The disclosed coding and alignment system may also result in a low cost coding mechanism since the system does not require a large number of independent parts and can be manufactured in a cost effective manner. Moreover, there are quite a large number of different coding configurations between the interface and the cartridge holder that may be used. Consequently, with the disclosed coding and alignment system, a large number of medicaments can be distinguished from one another. In addition, with the disclosed coding and alignment system, if a user attempts to load an incorrect reservoir into a cartridge holder designed for a different cartridge, the user will be alerted at an early stage of the assembly process.

Exemplary embodiments of the present disclosure have been described. Those skilled in the art will understand, however, that changes and modifications may be made to these arrangements without departing from the true scope and spirit of the present disclosure, which is defined by the claims.

Reference numerals

100	drug delivery device
102	dose setting mechanism
103	distal end
104	cartridge holder
105	proximal end
106	removable cap
108	distal end
109	piston rod
111	inner cartridge cavity
117	dose setter
120	cartridge
121	thread
122	tubular barrel
123	diameter annular bead
124	metallic sleeve or ferrule
125	medicament
126	diameter neck
128	stopper
129	label
130	distal end
131	shoulder
132	proximal end
133	seal or septum
134	diameter D_1
136	diameter D_2
200	coding feature
201a-c	coding elements
202	flange

204	interface
214	diameter D_2
220	interface
222	flange
223a-c	coding element
225	extending wall
226	main body
227	interface
228	aperture
229 a-c	protrusion
230	proximal end
231	interface
232	distal end
236	outer thread
242	protrusion
244	protrusion
246	protrusion
250	interface
252	coding feature
254	plate / flange
256	protrusion
260	interface
264	coding arrangement
266	protrusion
268	protrusion
272	plate / flange
280	interface
282 a, b	asymmetric coding feature
284 a, b	alignment feature
292	cartridge holder
294	protrusion

296	protrusion
301	cartridge
302, 304	first and second cut out
306	interface
308	distal end of flange
310	proximal end of flange
320	interface
322	proximal end of cartridge holder
324	side wall
326	coding feature
328	protrusion
330	protrusion
332	blocking feature
334	blocking feature
336	coding system
342	interface
344	side wall
346	coding feature
362	interface
368	protrusion
382	interface
388	protrusion
400	interface
402	shoulder
404	sleeve
410	interface
412	shoulder
420	interface arrangement

421	mating part
450	coding / indentation
460	coding / protrusion
600	shoulder
602, 604	shoulder
606	coding feature
620	interface
622	first shoulder
624	second shoulder
626	coding scheme
640	interface
641	flange
642	first coding feature
644	first indentation
646	second indentation
648	third indentation
660	interface
662	first coding feature
664	protrusion
666	indentation
680	coding system
682 a-d	interface
684	coding feature
686 a-c	radial protrusion
688	coding feature
690a	first groove
690b	second groove
690c	first protrusion
700, 720, 730	interface

702	coding feature
722, 732	first coding feature
724	ramp
734	first ramp
736	second ramp
802	flange
804	interface
814	diameter D_3
820	cartridge
823	bead
824	alignment feature / protrusion
825	ferrule
850	cartridge holder
852	distal end
854	bore
856	inner wall
858	ramp
860	end alignment position
870	tubular skirt
872	needle arrangement
874	needle
900	coding feature
901a	first protrusion
901b	second protrusion
902	flange
904	interface
906	main body
908	aperture
924	alignment feature

962a	alignment feature
998	alignment feature
950	cartridge holder
955	distal end
960	bore
962 a-c	protrusion
970	ramp
975, 980	coding system
977, 992	first interface
979	second interface
980	alignment position
990	receiving areas
981, 985, 987	first groove
988	coding arrangement
983	second groove
991	coding feature
994, 996	groove

1000	cartridge
1002, 1002b	cartridge holder
1004	coding feature
1010	coding feature
1010b	coding feature
1005, 1006b	interface
1008	extending portion
1012	protrusion
1100	drug cartridge
1102	interface
1104a	first protrusion
1104b	second protrusion
1106 a,b	groove

1108	drug delivery device
1110	coding feature
1112	alignment feature
1124	medicament
1200	interface
1202	first coding feature
1203	outer surface
1204	coding element
1206	coding element
1208	coding element
1220	drug reservoir
1222	vessel
1228	alignment feature
1230	output port
1260	stopper

Claims

1. An interface (306) configured for coding and positioning a reservoir (120) configured for containing a medicament (125) to a drug delivery device (1108, 100), the interface (306) comprising a first coding feature (294, 296), wherein, when the reservoir (120) is inserted into the drug delivery device (1108,100), the first coding feature (294, 296) is configured to mechanically cooperate with a corresponding second coding feature (302, 304) provided by the device (1108, 100) so as to allow the reservoir (120) to be properly positioned within the drug delivery device (1108, 100),
wherein the interface (306) comprises a main body (226), wherein the main body (226) comprises an engagement member (236) configured for receiving a needle hub, and wherein the main body (226) is configured to be coupled to the reservoir (120).

2. The interface (306) of claim 1,
wherein the first coding feature (294, 296) is provided on an outer surface of the interface (306).

3. The interface (306) according to any of the previous claims,
wherein the interface (306) is configured to allow the reservoir (120) to be properly positioned within a reservoir holder (104) of the drug delivery device (1108, 100), the reservoir holder (104) being located between the reservoir (120) and the drug delivery device (1108, 100), and wherein the corresponding second coding feature (302, 304) is provided on the reservoir holder (104).

4. The interface (306) according to any of the previous claims,
wherein the first coding feature (294, 296) comprises at least one of a protrusion and a groove.

5. The interface (306) according to any of the previous claims,

wherein the corresponding second coding feature (302, 304) comprises at least one of a groove and a protrusion.

6. The interface (306) according to any of the previous claims, wherein the first coding feature (294, 296) comprises a non-circular section.

7. The interface (306) according to any of the previous claims, wherein the first coding feature (294, 296) includes at least one ramp (724), and wherein the ramp (724) comprises a face at an angle relative to a transverse plane of the interface (306).

8. The interface (306) according to any of the previous claims, wherein the interface (306) comprises a flange (202, 222), and wherein the first coding feature (294, 296) is provided along the flange (202, 222).

9. The interface (306) according to claim 8, wherein the first coding feature (294, 296) extends outwardly from the interface (306) in an axial direction or extends outwardly from the flange (202, 222) of said interface (306).

10. The interface (306) according to any of the previous claims, wherein the main body (226) comprises a bore which is configured to define a diameter measured to receive a distal end of the reservoir (120), wherein the first coding feature (294, 296) includes at least one continuous shoulder (412) protruding from the main body (226), wherein the at least one continuous shoulder (412) comprises a varying diameter.

11. The interface (306) according to any of the previous claims, wherein the first coding feature (294, 296) is provided on a sidewall of the reservoir (120).

12. The interface (306) according to any of the previous claims, wherein the interface (306) includes a plurality of coding features (642, 662).

13. The interface (306) of claim 12, wherein each of the plurality of coding features (642, 662) comprises a unique geometrical shape and/or a unique size.

14. The interface (306) according to any of the previous claims, further comprising at least one alignment feature (284), the alignment feature (284) being adapted and arranged to mechanically cooperate with a corresponding alignment feature provided by the drug delivery device (1108, 100).

15. The interface (306) of claim 14, wherein the alignment feature (284) comprises at least one protrusion, and wherein the corresponding alignment feature comprises a ramp provided on the drug delivery device (1108, 100).

16. The interface (306) of claim 14 or claim 15, wherein the alignment feature (284) is adapted and arranged to prevent relative rotation between the drug delivery device (1108, 100) and the interface (306).

17. The interface (306) according to any of the previous claims, wherein the interface (306) is representative of the medicament (125) contained within the reservoir (120).

18. The interface (306) according to any of the previous claims, wherein the engagement member (236) comprises a thread.

19. A drug delivery system comprising:

- a drug delivery device (1108, 100) comprising a dose setting mechanism (102), a cartridge holder (104) being secured to the dose setting mechanism (102) and a cartridge (120) being contained within the cartridge holder (104), and
- the interface (306) according to any of the previous claims,

wherein, when the cartridge (120) is inserted into the cartridge holder (104), the first coding feature (294, 296) is configured to mechanically cooperate with the corresponding second coding feature (302, 304) provided by the drug delivery device (1108, 100) or by the cartridge holder (104) of the drug delivery device (1108, 100) so as to properly position the cartridge (120) into the drug delivery device (1108, 100) or into the cartridge holder (104).

20. The drug delivery system of claim 19,
wherein the cartridge holder (104) is removably secured to the dose setting mechanism (102) and the cartridge (120) is removably contained within the cartridge holder (104), and wherein the drug delivery device (1108, 100) comprises a reusable drug delivery device (1108, 100).

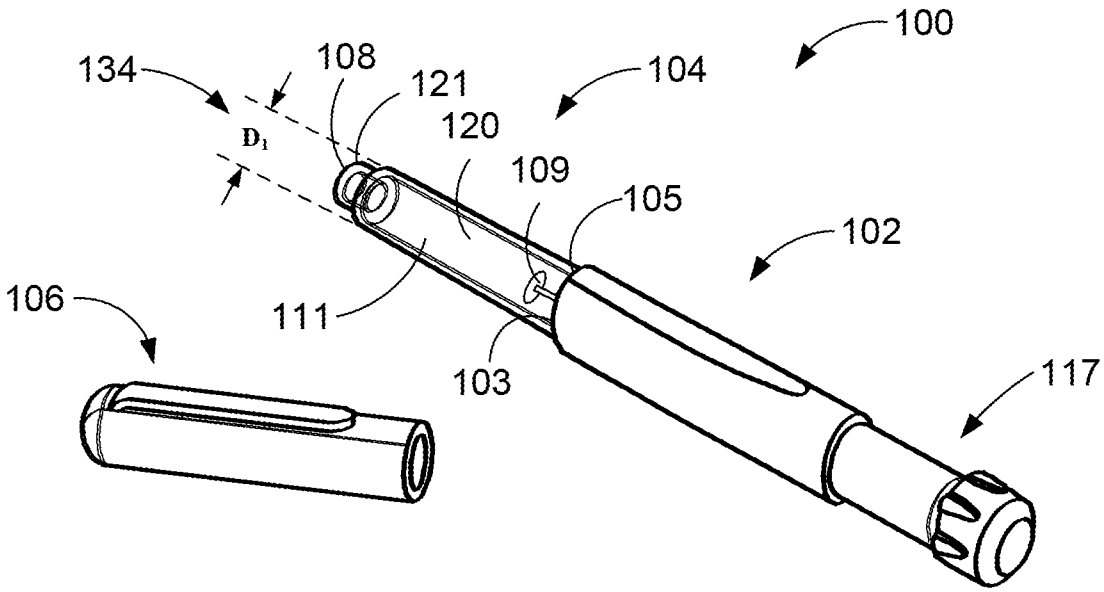
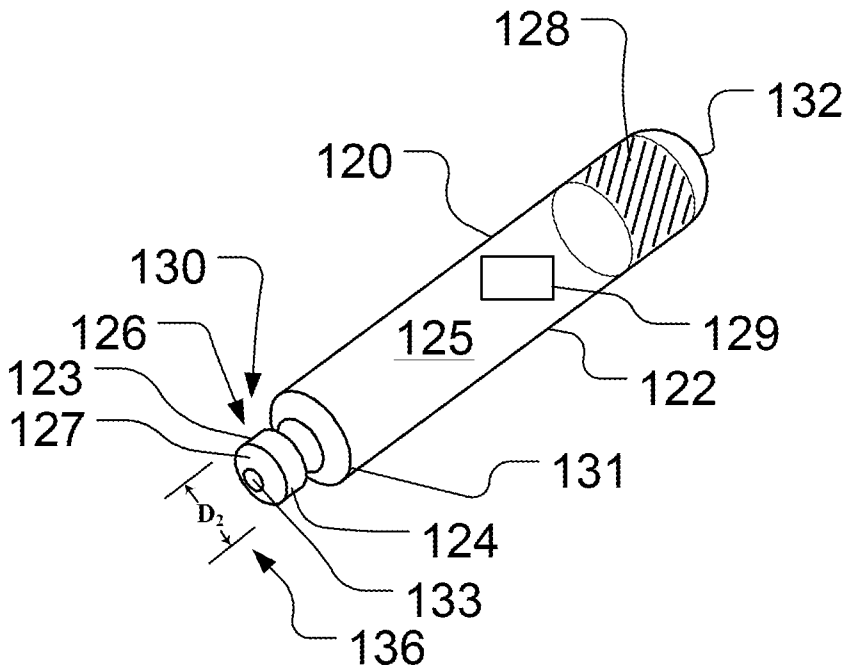

100
134
108
121
104
120
D_1
109
105
102
106
111
103
117

FIG. 1


128
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122
127
131
D_2
124
133
136

FIG. 2

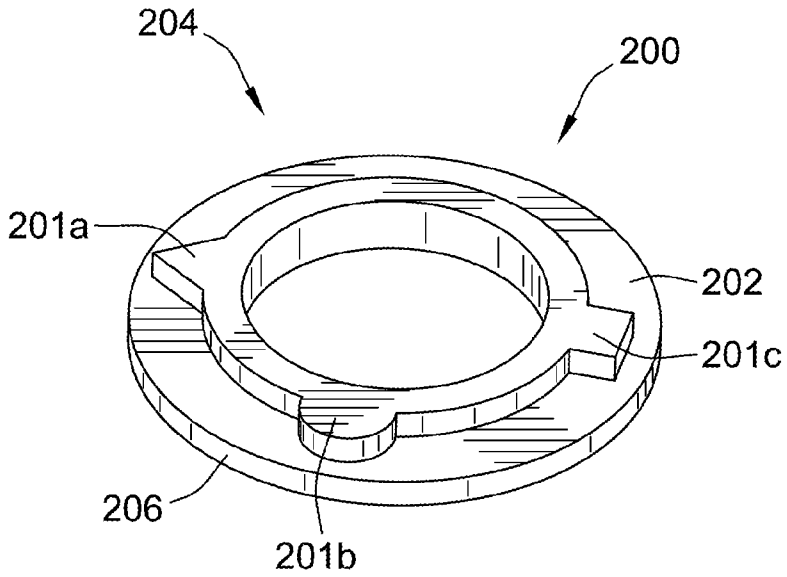

FIG. 3A

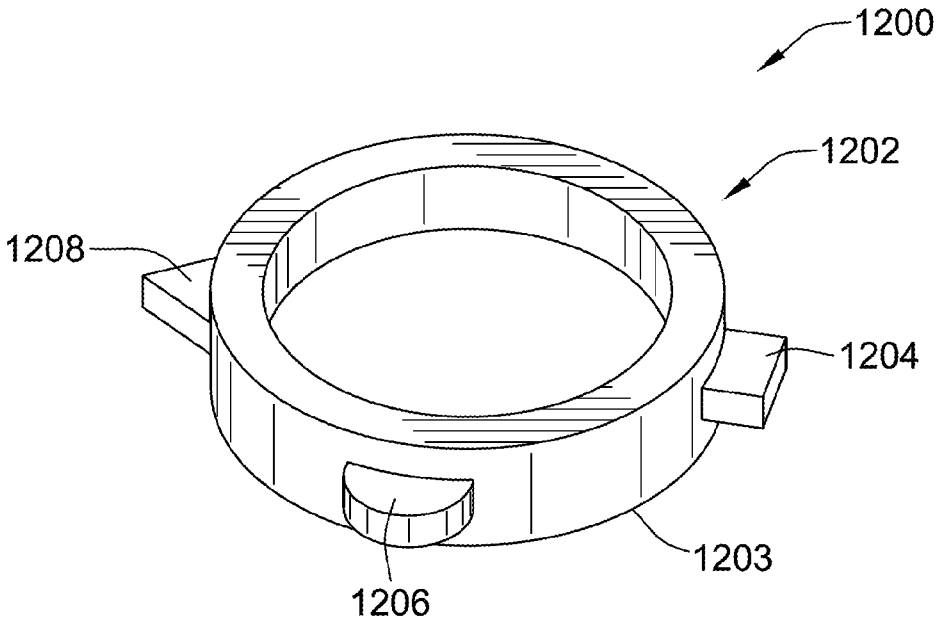

FIG. 3B

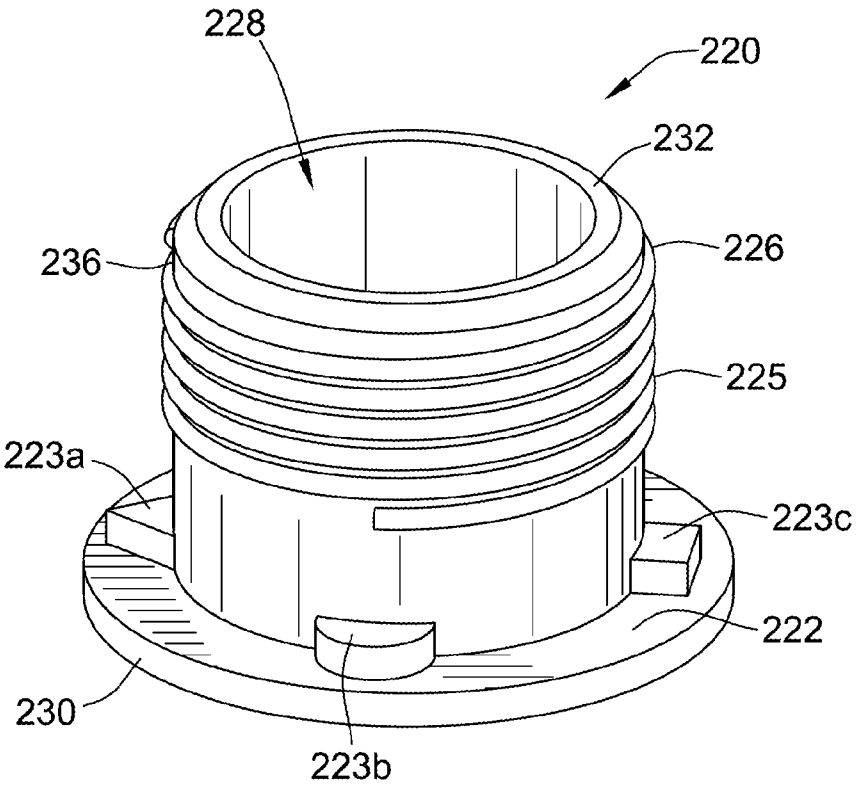

FIG. 4

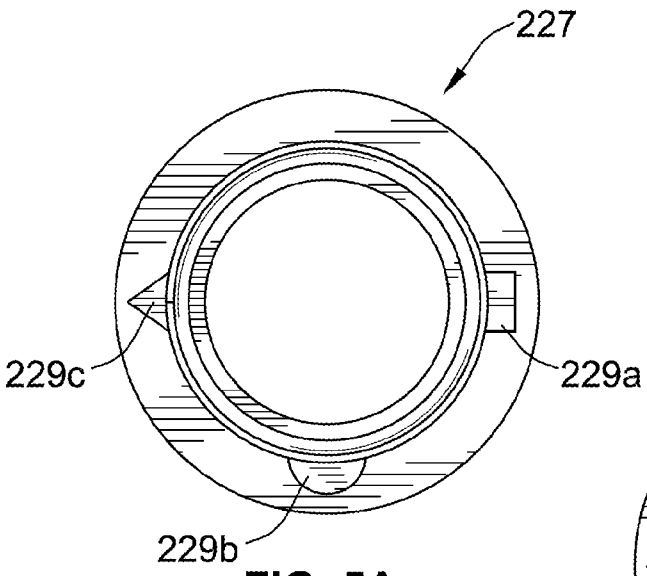

FIG. 5A

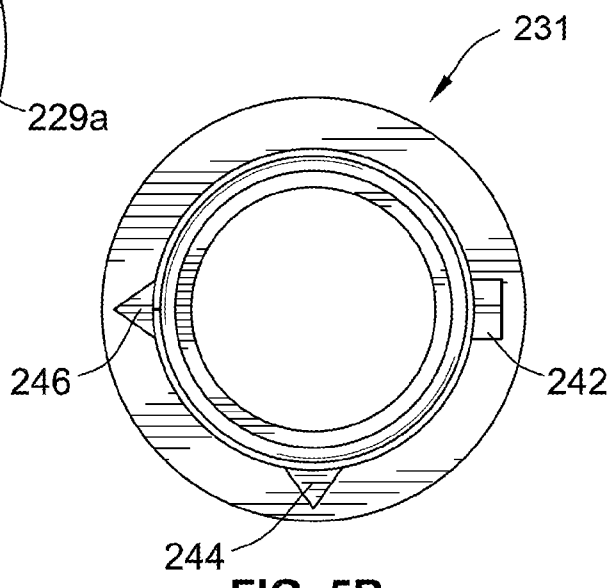

FIG. 5B

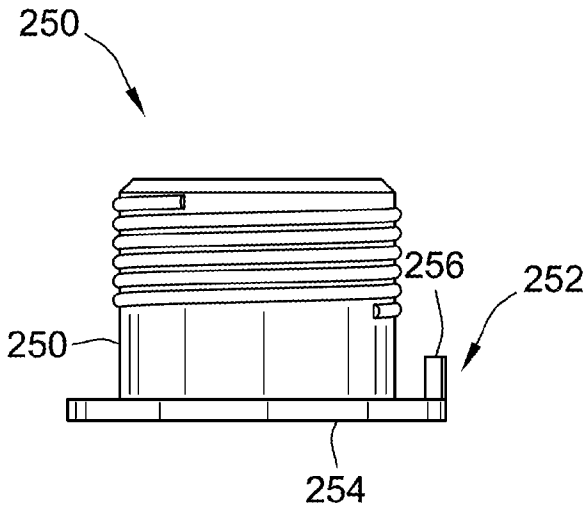

FIG. 6

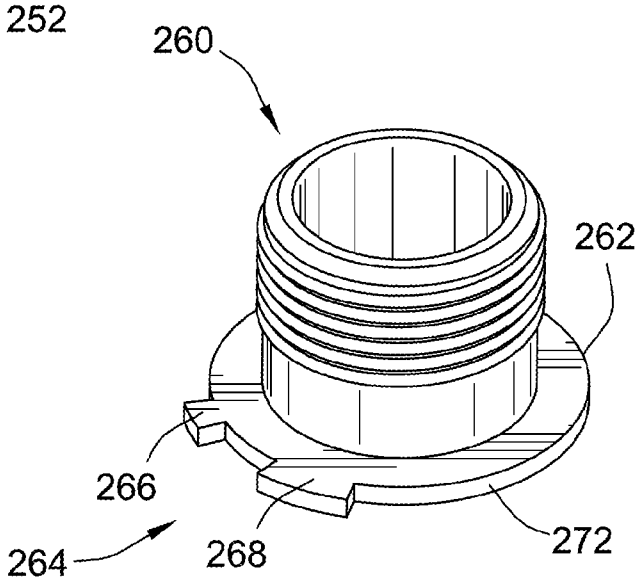

FIG. 7

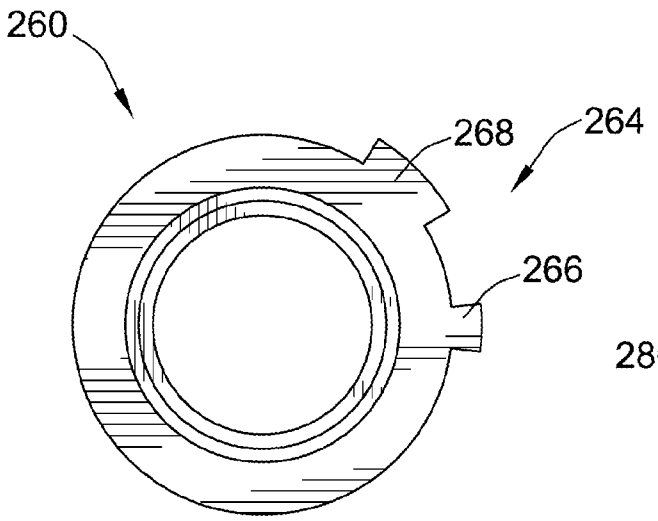

FIG. 8

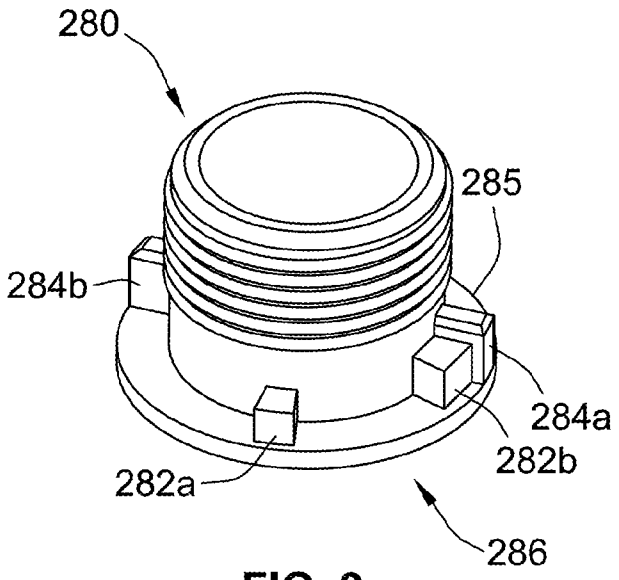

FIG. 9

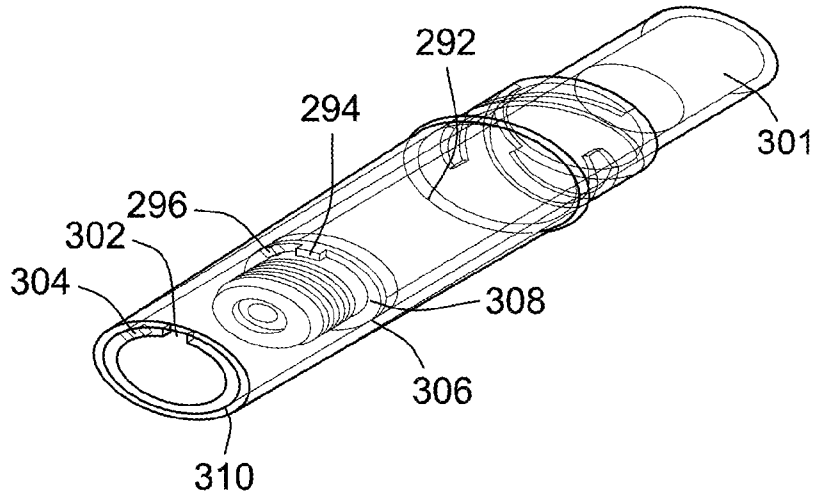

FIG. 10

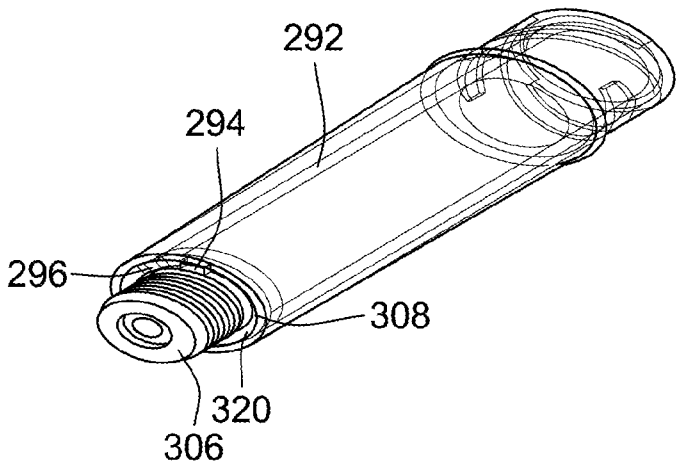

FIG. 11

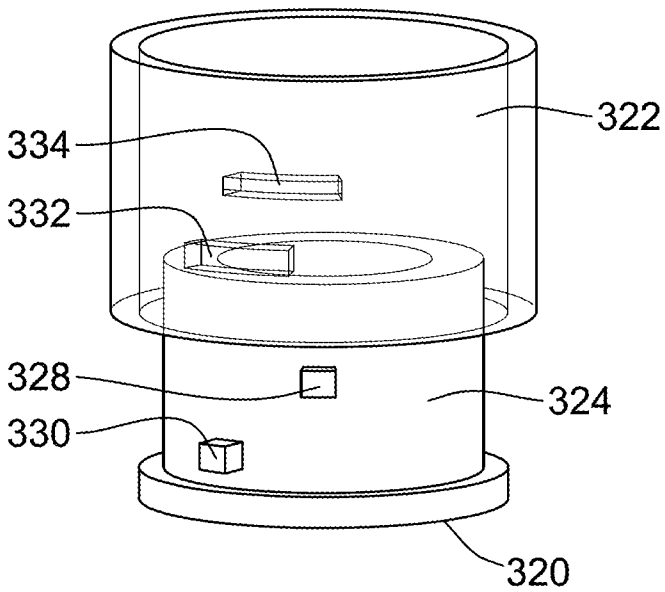

FIG. 12A

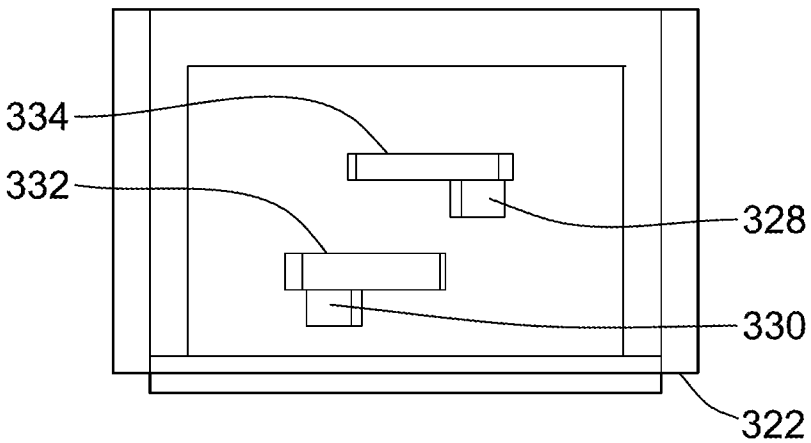

FIG. 12B

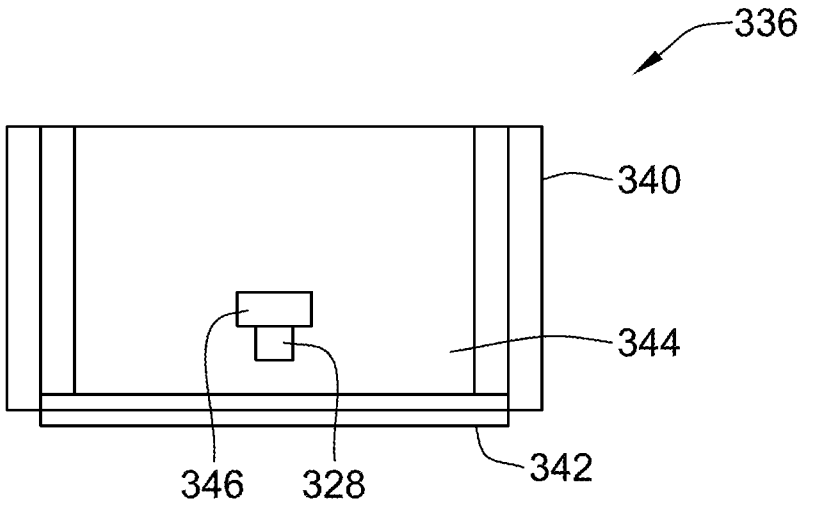

FIG. 12C

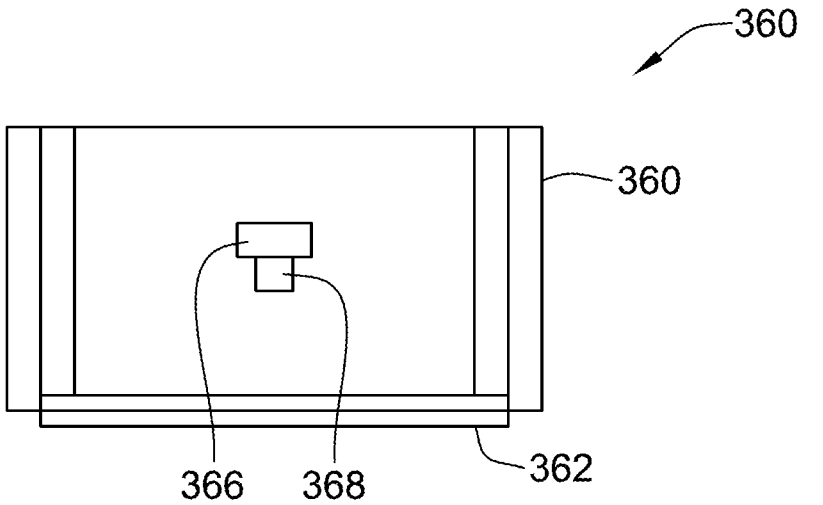

FIG. 12D

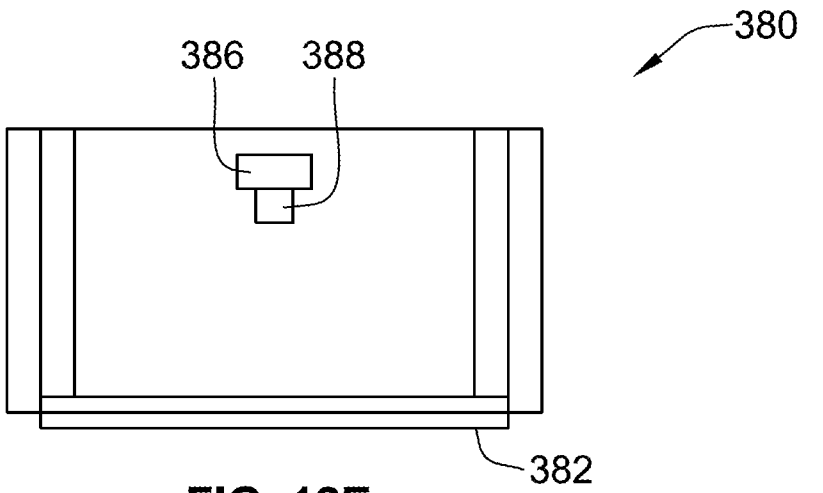

FIG. 12E

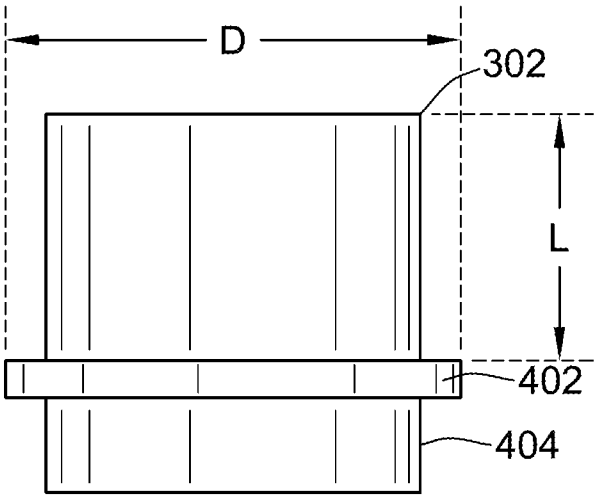

FIG. 13

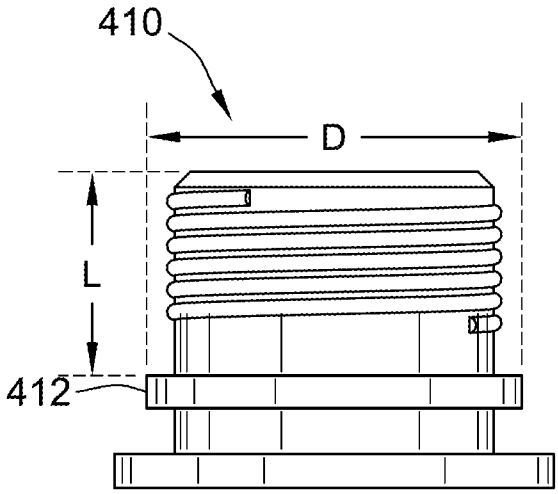

FIG. 14

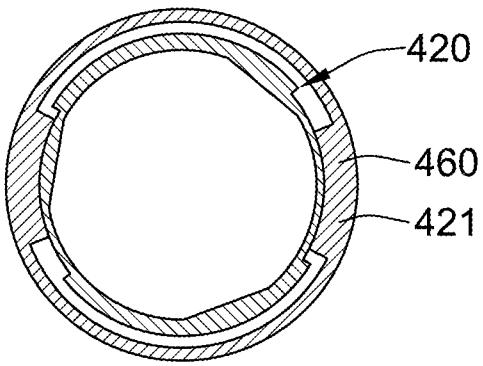

FIG. 15A

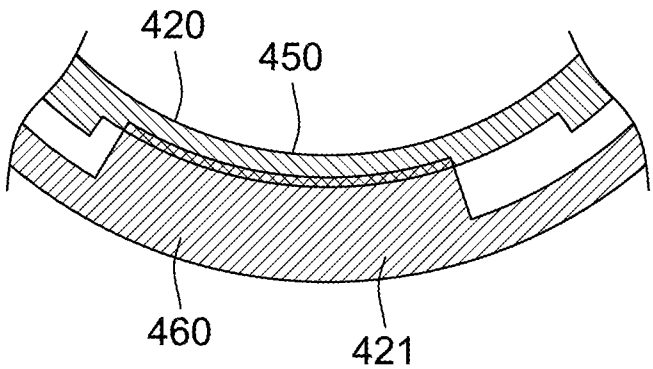

FIG. 15B

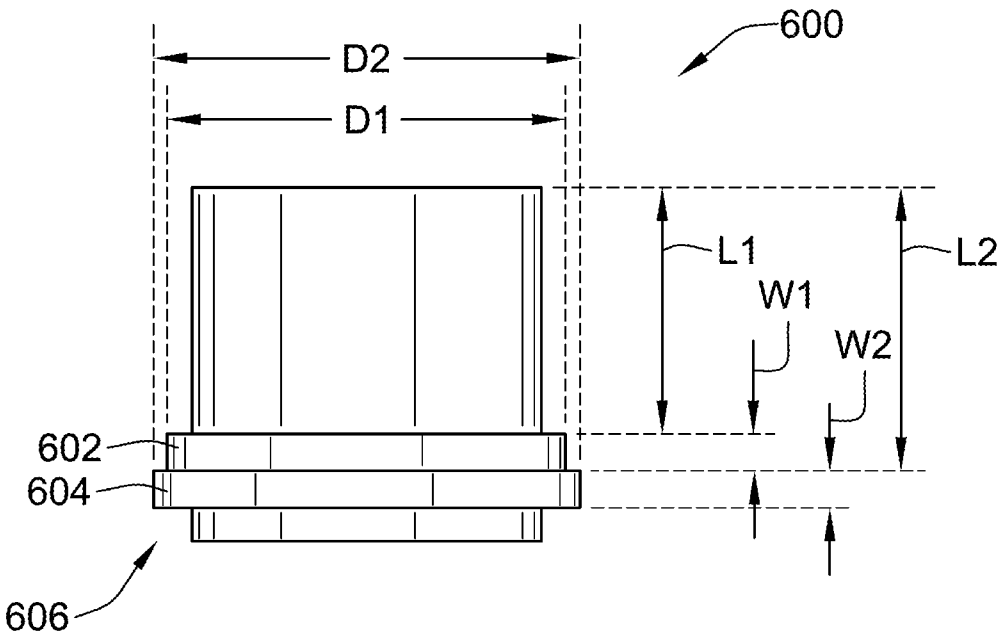

FIG. 16

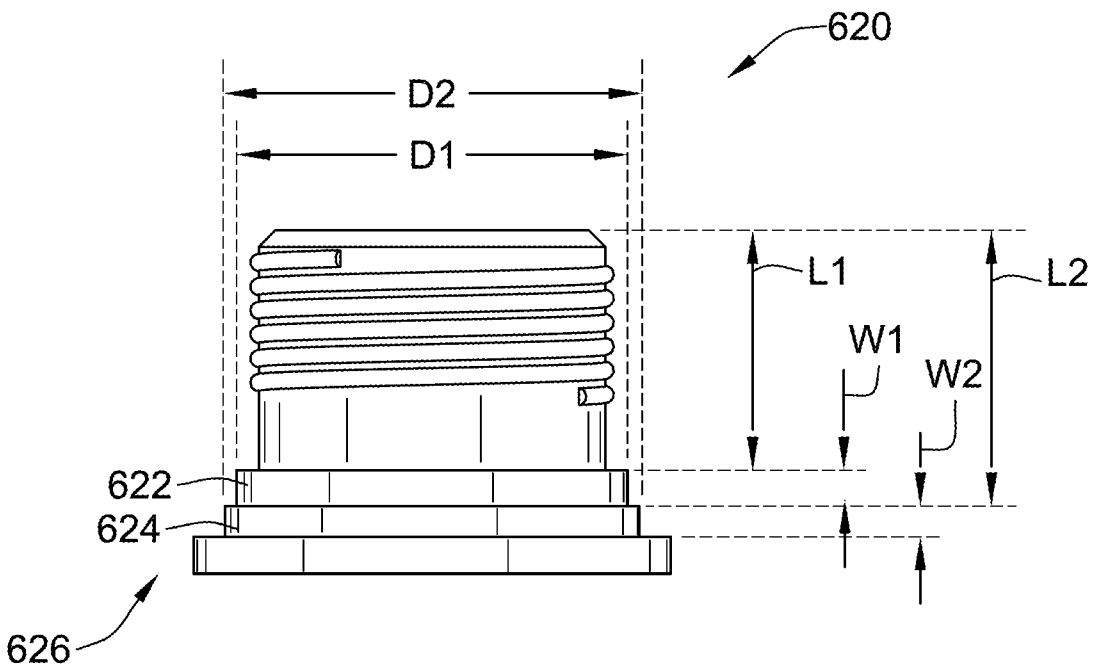

FIG. 17

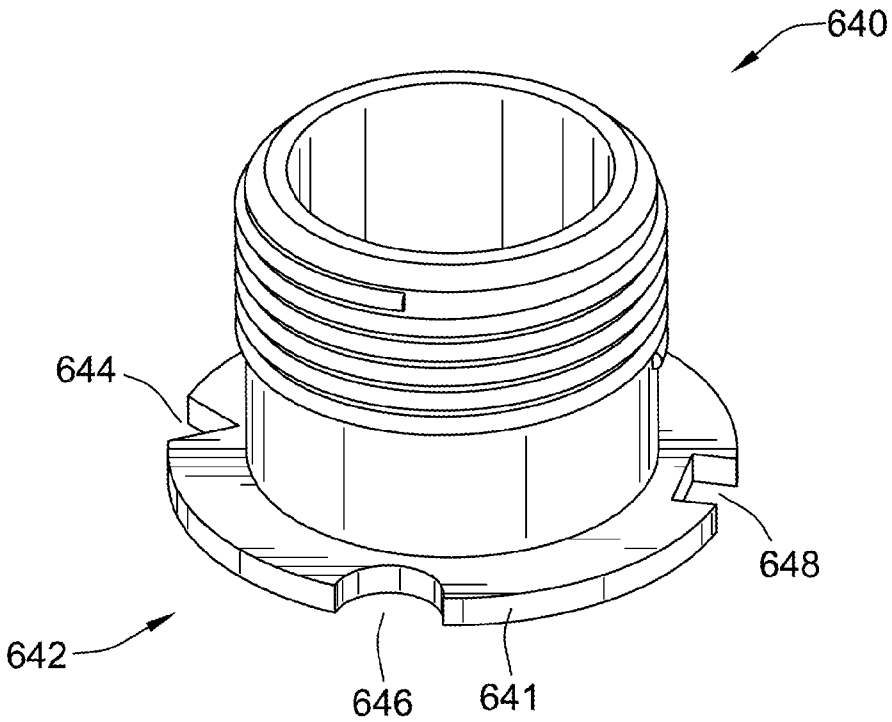

FIG. 18

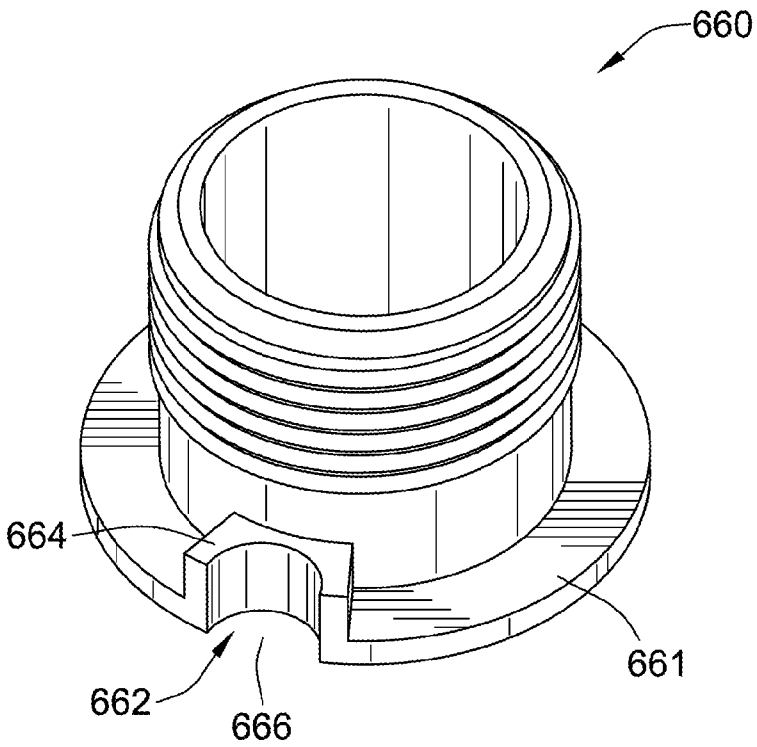

FIG. 19

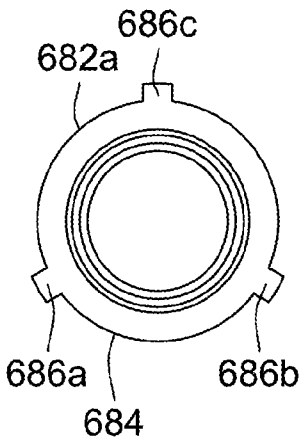

FIG. 20A

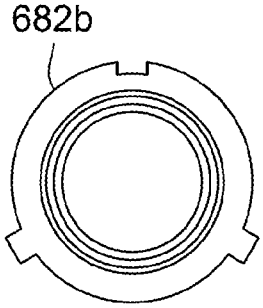

FIG. 20B

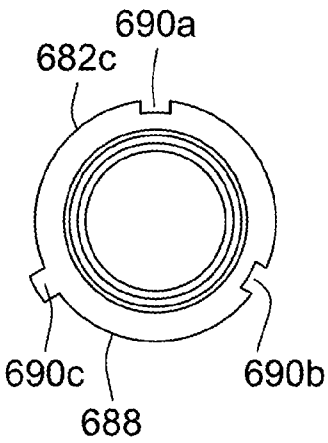

FIG. 20C

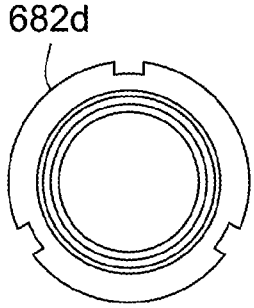

FIG. 20D

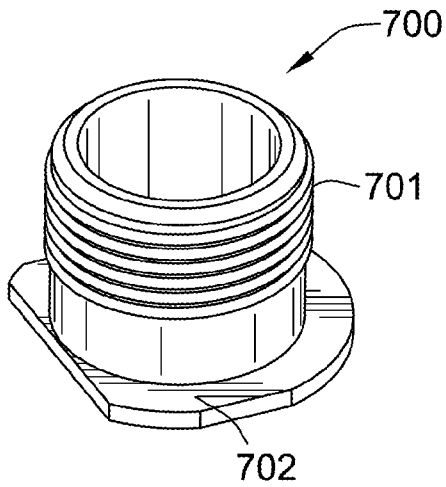

FIG. 21A

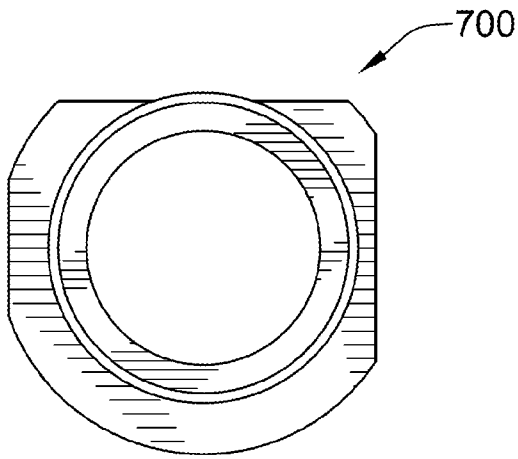

FIG. 21B

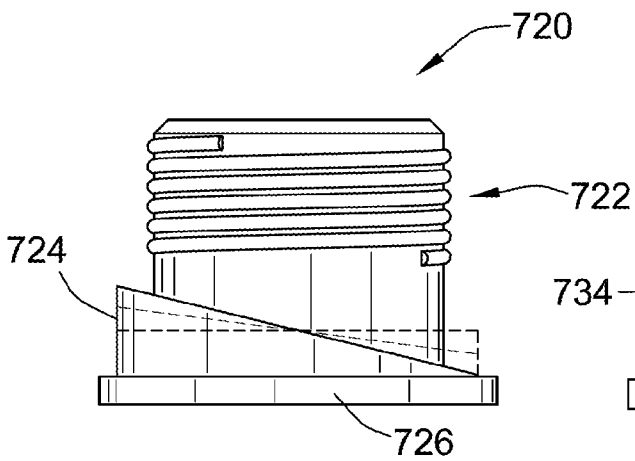

FIG. 22

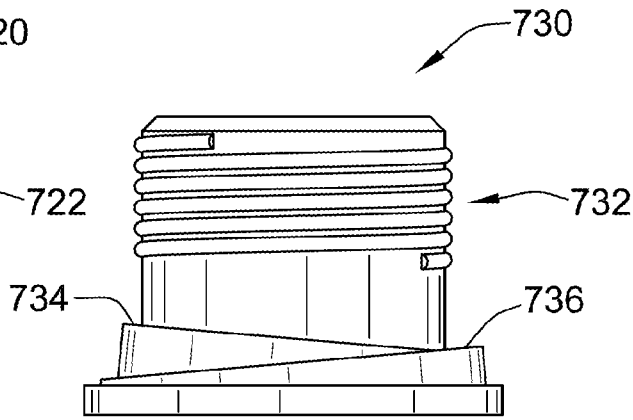

FIG. 23

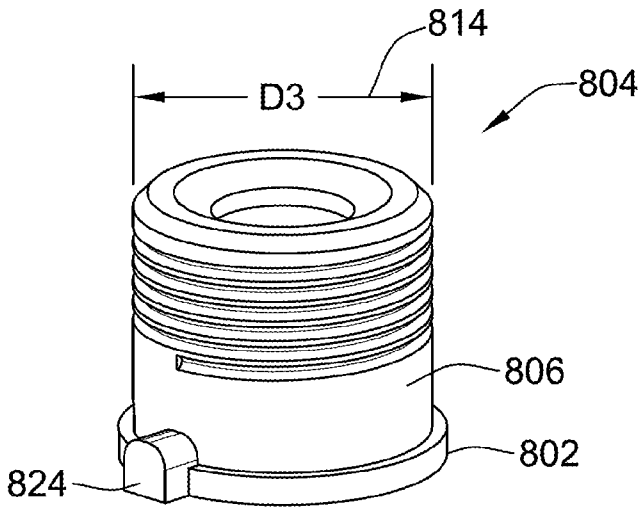

FIG. 24

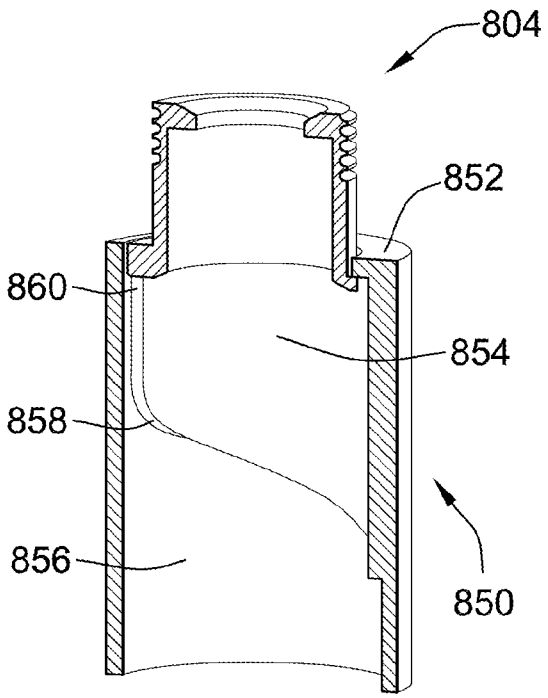

FIG. 25

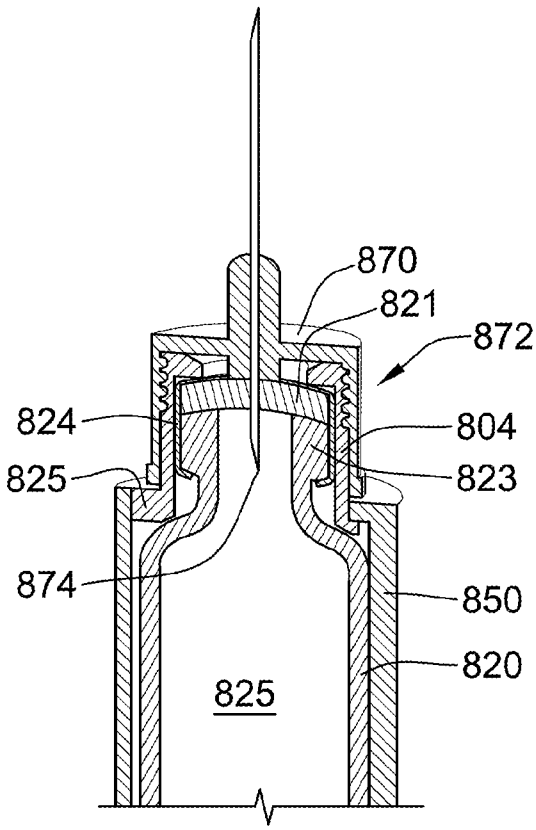

FIG. 26

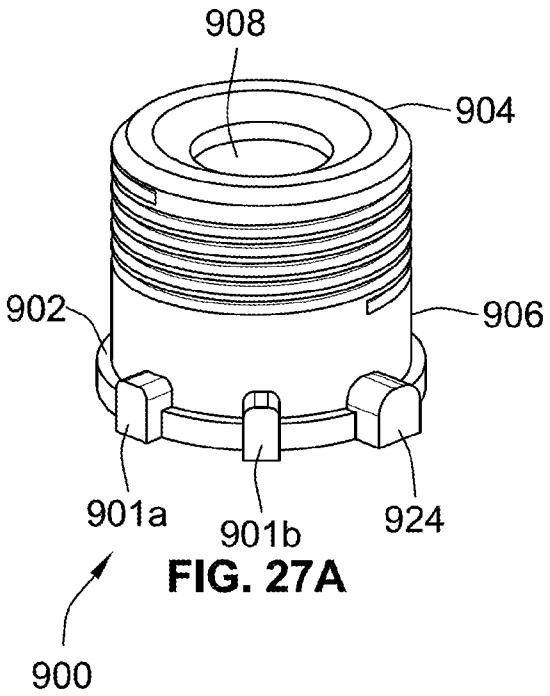

FIG. 27A

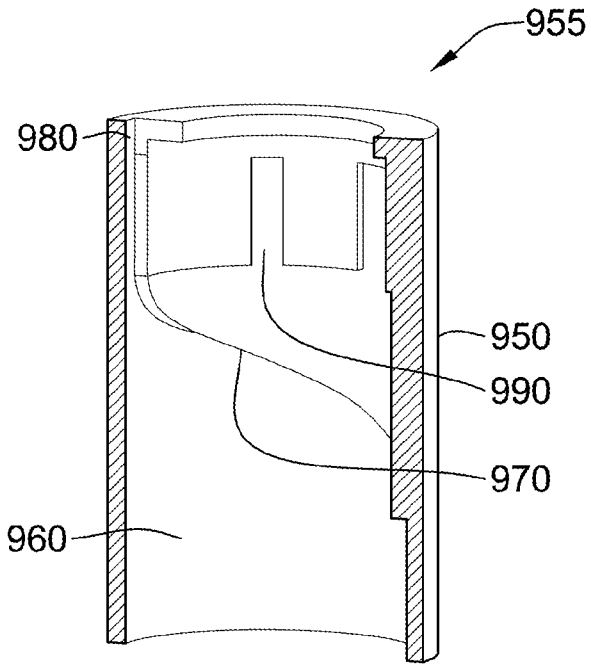

FIG. 27B

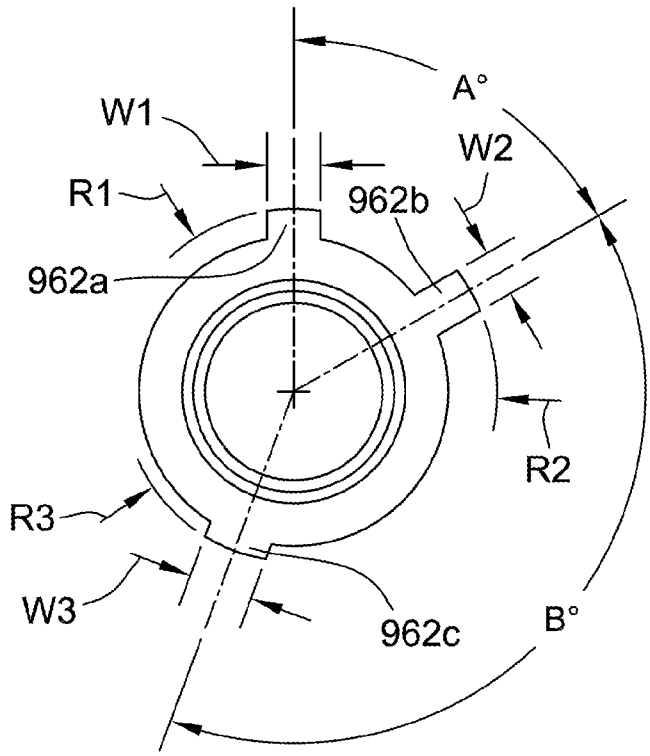

FIG. 28

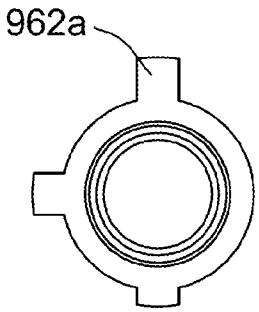

FIG. 29A

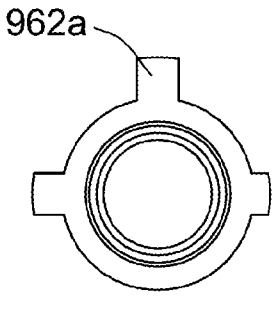

FIG. 29B

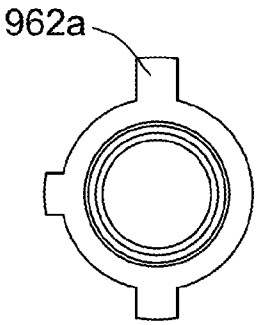

FIG. 29C

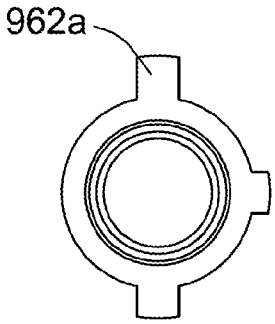

FIG. 29D

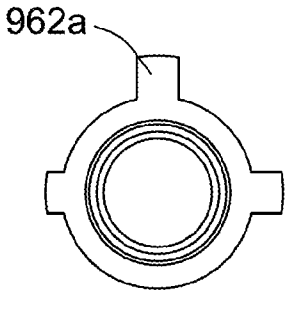

FIG. 29E

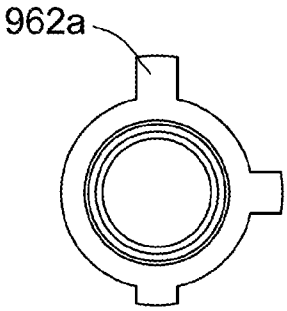

FIG. 29F

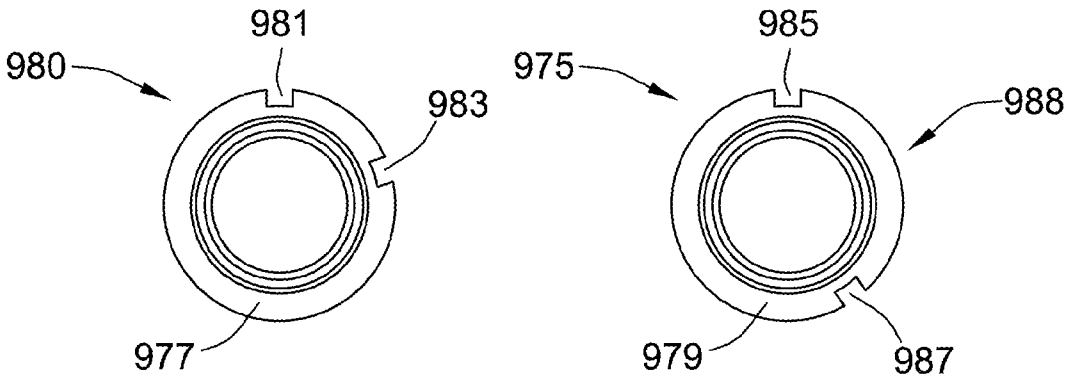

FIG. 30A

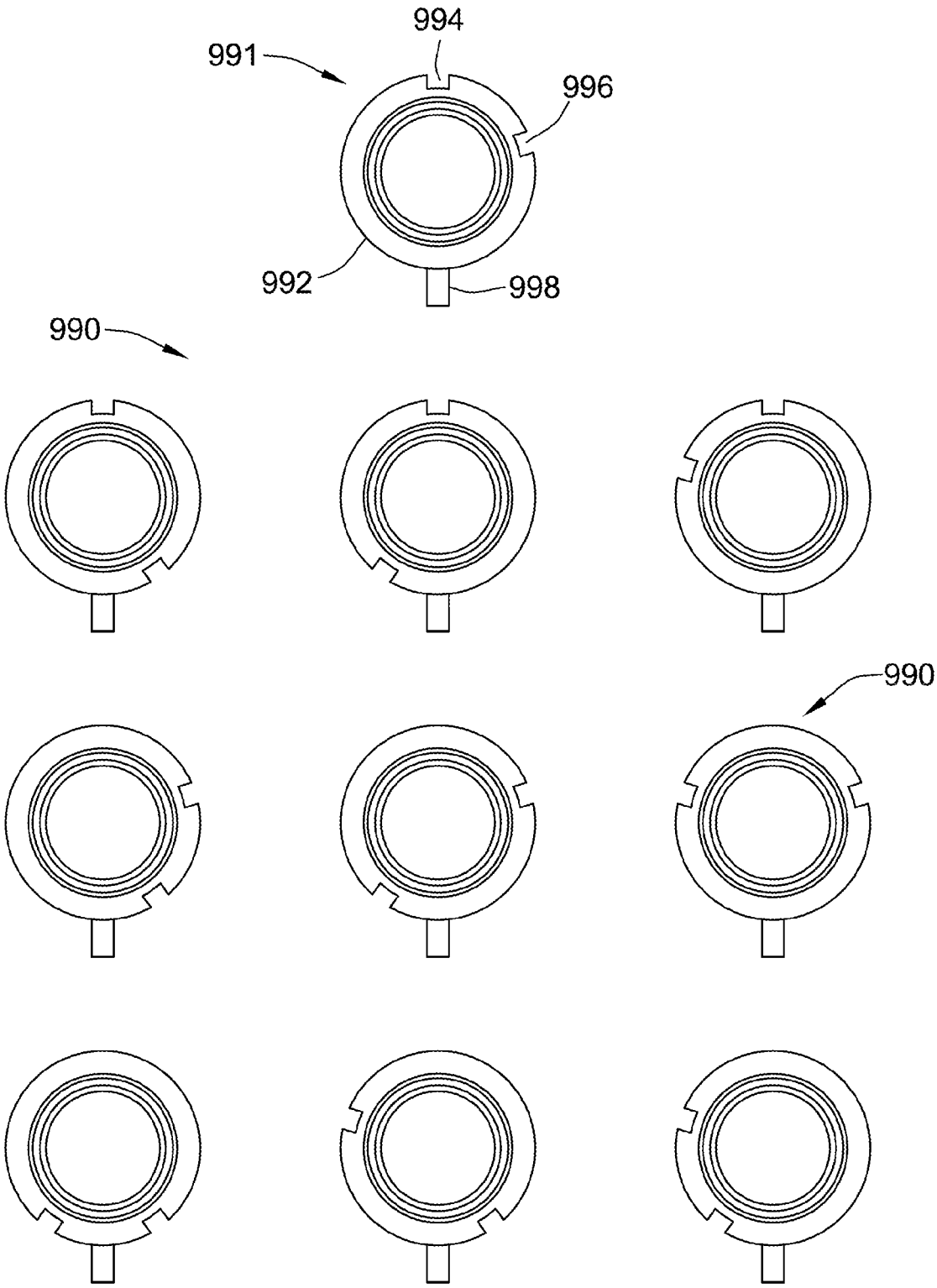

FIG. 30B

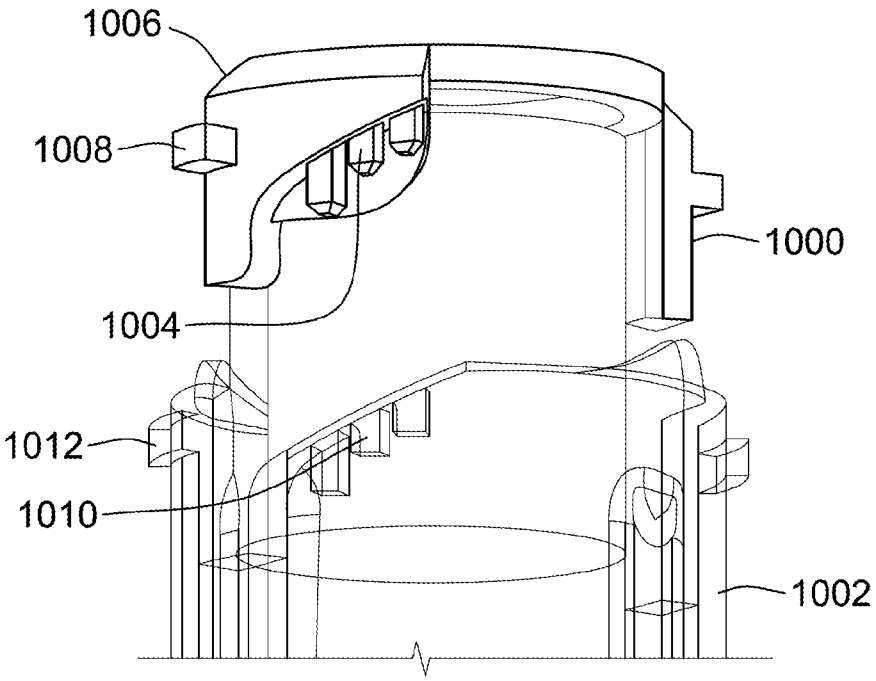

FIG. 31A

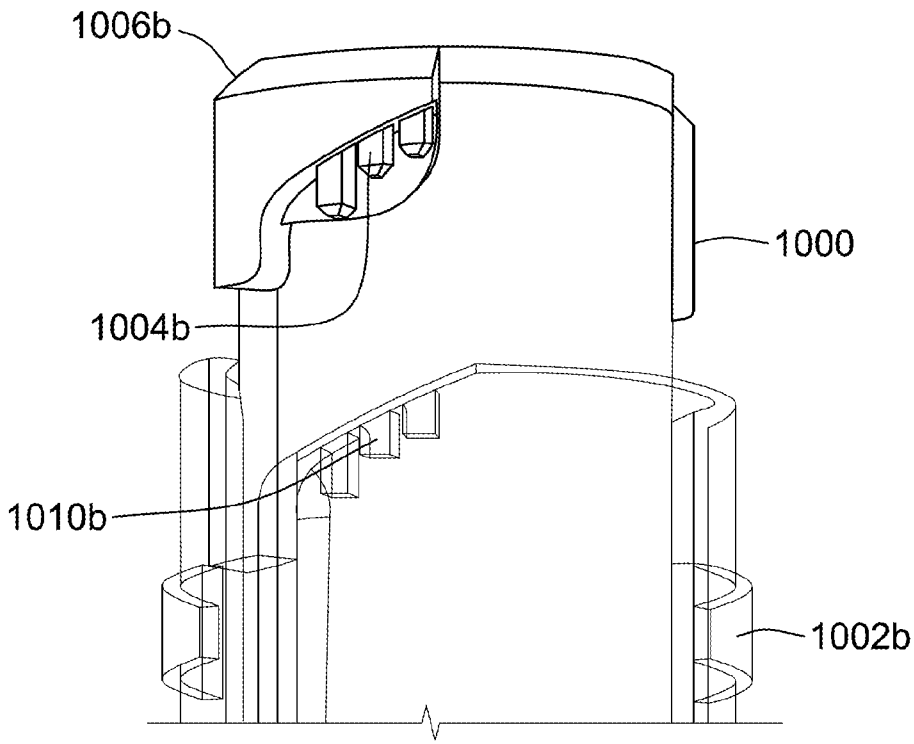

FIG. 31B

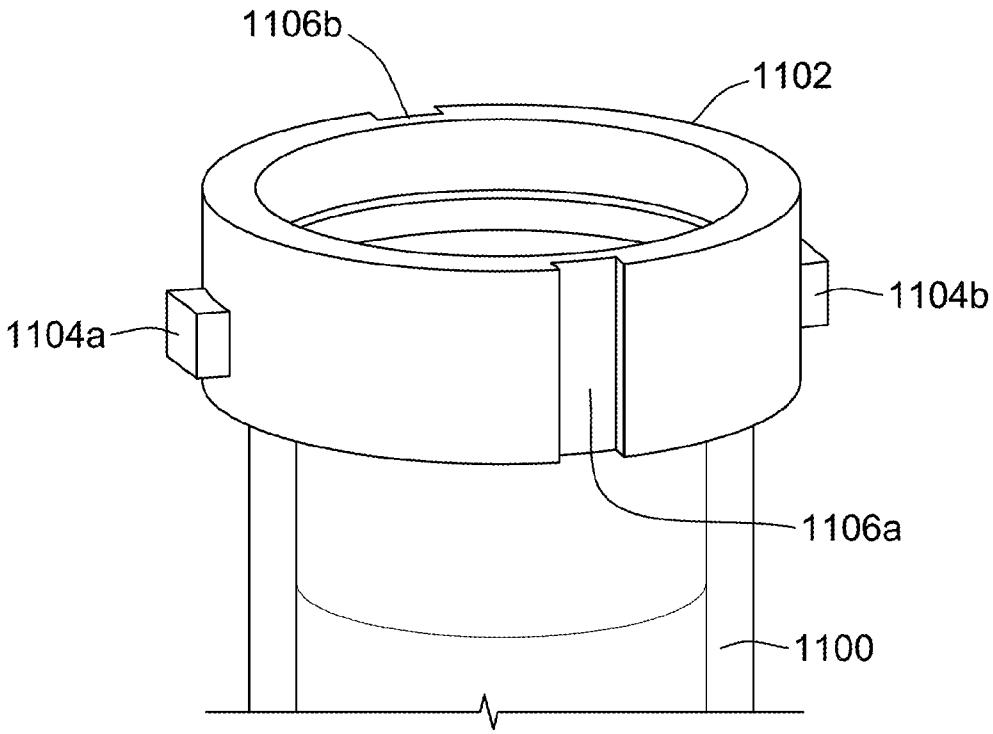
1106b
1102
1104b
1104a
1106a
1100

FIG. 32

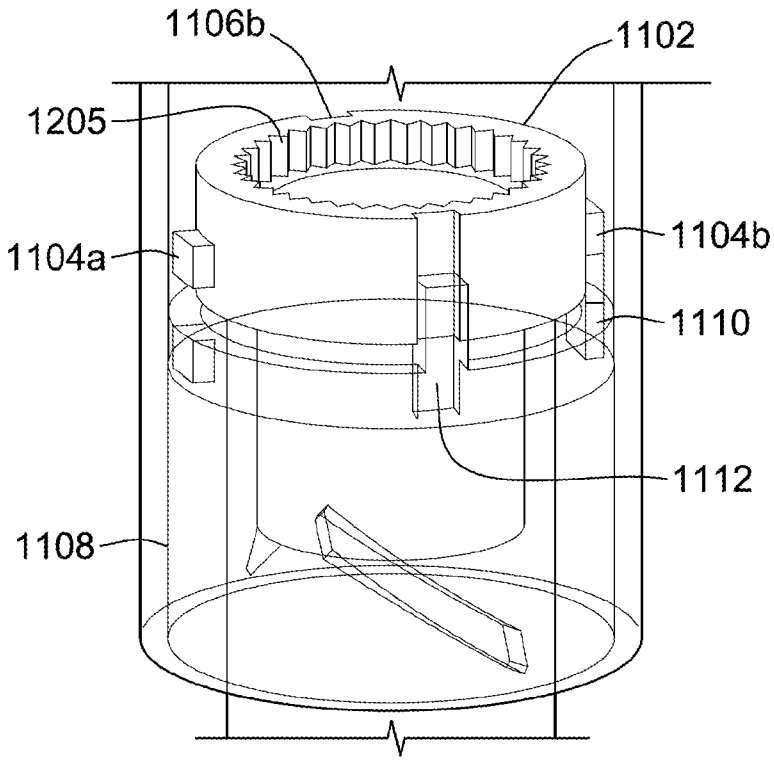
1106b
1102
1205
1104b
1104a
1110
1112
1108

FIG. 33

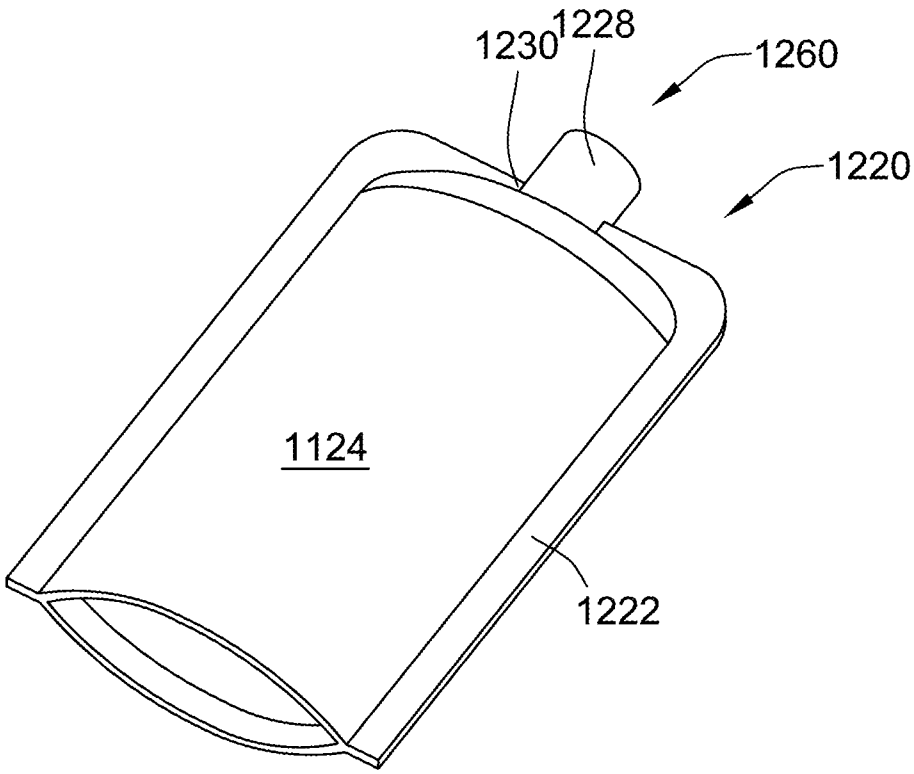

FIG. 34

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/056476

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/24
ADD.

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)
A61M

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 practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 201 10 690 U1 (SPYRA HEINRICH [DE]) 13 September 2001 (2001-09-13) the whole document	1-20
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
25 August 2011	31/08/2011

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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