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(54) Title: INFUSION PUMP DRUG DELIVERY SYSTEM FOR DELIVERING AT LEAST TWO MEDICAMENTS

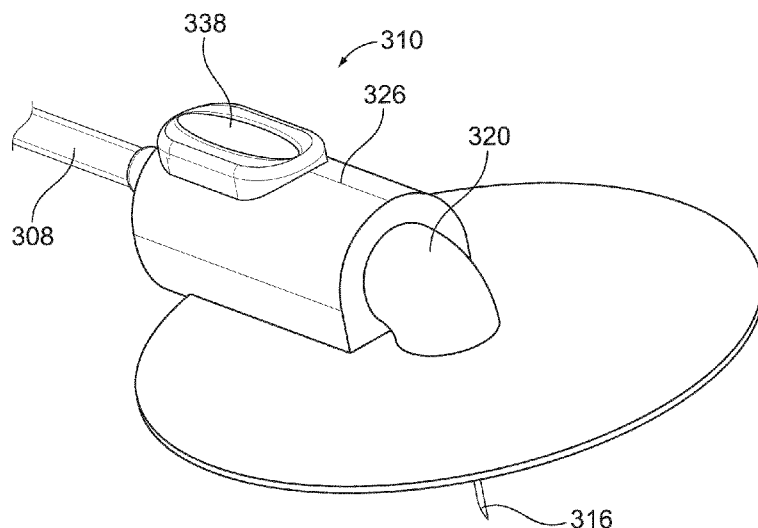


FIG. 3A

(57) Abstract: The infusion pump drug delivery system and corresponding method disclosed herein allow for continuous delivery of a first fluid and/or medicament (106) from a reservoir (104) operably connected to a pump and selective delivery of a second fluid and/or medicament (114) from a separate reservoir (112), where the second fluid and/or medicament may be delivered sequentially or simultaneously with the first fluid and/or medicament at the command of the user. Both fluids and/or medicaments are delivered via a single dispense interface (116).



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## Description

### INFUSION PUMP DRUG DELIVERY SYSTEM FOR DELIVERING AT LEAST TWO MEDICAMENTS

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#### Field of the Present Patent Application

The present application relates to medical systems and methods for delivering at least two medicaments from separate reservoirs (herein, sometimes referred to as “containers,” “cartridges,” and “packages”) to a user. In particular, the present application is concerned with continuous infusion therapy (CIT) pump systems designed to dispense one or more medicaments from respective reservoirs to a user via an infusion set. Each medicament may contain independent (single drug compound) or pre-mixed (co-formulated multiple drug compounds) drug agents.

#### Background

15 Certain disease states require and/or benefit from treatment using one or more different drug agents (i.e., combination therapy). For example, in some cases it might be beneficial to treat a diabetic with a long-acting insulin and with a glucagon-like peptide-1 (GLP-1), which is derived from the transcription product of the proglucagon gene. GLP-1 is found in the body and is secreted by the intestinal L cell as a gut hormone. GLP-1 possesses several physiological properties that make it (and its analogs) a subject of intensive investigation as a potential treatment of diabetes mellitus. Although combination therapy may be preferred in some cases, some drug agents need to be delivered in a specific relationship with each other in order to deliver the optimum therapeutic dose. The disclosed system and corresponding method is of particular benefit where combination therapy is desirable, but not possible in a single medicament formulation for reasons such as, but not limited to, stability, compromised therapeutic performance, and toxicology.

There are a number of potential problems associated with the storage and delivery of two active drug agents. For instance, the two active drug agents may interact with each other during long-term storage. Therefore, it is advantageous to store the active drug

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agents separately and only combine them at the point of delivery via injection, needleless injection, pumps, or inhalation. However, the process for combining the two active drug agents needs to be simple and convenient for the user to perform reliably, repeatedly, and safely.

- 5 A further problem is that the quantities and/or proportions of each active drug agent making up the combination therapy may need to be varied for each user or at different stages of their therapy. For example, certain active drug agents may require a titration period to gradually introduce a user to a "maintenance" dose. A further example would be if one active drug agent requires a non-adjustable fixed dose while the other is varied
- 10 in response to a user's symptoms or physical condition. This problem means that pre-mixed medicament formulations of multiple active drug agents may not be suitable as these pre-mixed formulations would have a fixed ratio of the active drug agents, which could not be varied by the healthcare professional or user.

15 Additionally, many users cannot cope with having to use more than one drug delivery system or having to make the necessary accurate calculation of the required dose combination. This is especially true for users with dexterity or computational difficulties. Accordingly, there exists a strong need to provide systems and methods for the delivery of two or more drug agents that is simple for the user to perform.

20 The disclosed system and corresponding method helps overcome the above-mentioned problems by providing separate reservoirs for the two or more drug agents making up the desired combination therapy. The two or more active drug agents are only combined and/or delivered to the user at delivery. Thus, the two or more active drug agents will not interact with each other during long-term storage. Further, the disclosed system and corresponding method is capable of achieving a wide variety of therapeutic

25 dose profiles, therefore, making combination therapy that may need to be varied for each user or at different stages of their therapy possible.

These and other advantages will become evident from the following more detailed description of the invention.

## SUMMARY

Disclosed herein are various examples of an infusion pump drug delivery system and corresponding method for delivering (herein, sometimes referred to as "dispensing") at least two medicaments and/or fluids to a user, where the medicament and/or fluid may contain independent (single compound) or pre-mixed (co-formulated multiple compounds) drug agents. More specifically, the disclosed system and corresponding method allow for continuous delivery of a first medicament from a reservoir operably connected to a pump and selective delivery of a second medicament from a separate reservoir, where the second medicament may be delivered sequentially or simultaneously with the first medicament. Although principally described in this application as an infusion pump drug delivery system, the basic principle could be applicable to other forms of drug delivery, such as, but not limited to, injection pen, inhalation, nasal, ophthalmic, oral, topical, and like systems. In one arrangement, the system may comprise one medicament and a fluid, such as saline or another type of fluid ordinarily used in a drug dispensing system.

By delivering two medicaments from respective reservoirs of a single system, via a single dispense interface the drug delivery system defines a combination therapy (i.e., a therapeutic dose profile between the various drug agents of the medicaments) for a user without the inherent risks associated with using multiple systems and/or multiple needle inputs. This increases patient safety while decreasing the complexity of administering the combination therapy. One or more of the medicaments may be a fluid, defined herein as a liquid, gas or powder that is capable of flowing and that changes shape at a steady rate when acted upon by a force tending to change its shape. Alternatively or additionally, one or more of the medicaments may be a solid, powder, suspension or slurry that may be carried, solubilized or otherwise dispensed with another fluid medicament.

Although Applicants' present patent application specifically mentions insulin, insulin analogs or insulin derivatives, and GLP-1 or GLP-1 analogs as two possible drug combinations, other drugs or drug combinations, such as an analgesics, hormones,

beta agonists or corticosteroids, or a combination of any of the above-mentioned drugs could be used with Applicants' proposed system and method.

As used herein, the term "insulin" shall mean insulin, insulin analogs, insulin derivatives or mixtures thereof, including human insulin or a human insulin analogs or derivatives.

- 5 Examples of insulin analogs are, without limitation, 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 or
- 10 Des(B30) human insulin. Examples of insulin derivatives are, without limitation, 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;
- 15 B29-N-(N-palmitoyl-Y-glutamyl)-des(B30) human insulin; B29-N-(N-lithocholyl-Y-glutamyl)-des(B30) human insulin; B29-N-( $\omega$ -carboxyheptadecanoyl)-des(B30) human insulin and B29-N-( $\omega$ -carboxyhepta-decanoyl) human insulin.

- As used herein the term "GLP-1" shall mean GLP-1, GLP-1 analogs, or mixtures thereof, including without limitation, exenatide (Exendin-4(1-39), a peptide of the sequence H-
- 20 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-NH<sub>2</sub>), Exendin-3, Liraglutide, or AVE0010 (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-Ser-Lys-Lys-Lys-Lys-Lys-NH<sub>2</sub>).

- 25 Examples of beta agonists are, without limitation, salbutamol, levosalbutamol, terbutaline, pirbuterol, procaterol, metaproterenol, fenoterol, bitolterol mesylate, salmeterol, formoterol, bambuterol, clenbuterol, indacaterol.

Hormones are for example hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists, such as Gonadotropine (Follitropin,

Lutropin, Choriongonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, Goserelin.

A drug delivery system according to the present disclosure may include (i) a pump operably connected to a first reservoir containing a first medicament, (ii) a delivery tube, wherein an end of the delivery tube is connected to the first reservoir, (iii) a dispense interface in fluid communication with the delivery tube, and (iv) a secondary medicament module in fluid communication with the delivery tube.

The secondary medicament module may comprise a housing, a bypass channel for delivery of the first medicament, a second reservoir containing a second medicament, and an actuation button. The actuation button may be configured to permit delivery of the first medicament when the actuation button is in a non-actuated position and selectively permit delivery of the second medicament when the actuation button is in an actuated position

In one exemplary embodiment of the drug delivery system disclosed herein, the system includes (i) a pump operably connected to a first reservoir containing a first medicament, (ii) a delivery tube, wherein an end of the delivery tube is connected to the first reservoir, (iii) a dispense interface in fluid communication with the delivery tube, and (iv) a secondary medicament module in fluid communication with the delivery tube. The secondary medicament module includes (i) a bypass channel for delivery of the first medicament, (ii) a second reservoir containing a second medicament, (iii) a proximal needle, (iv) a distal needle, and (v) an actuation button. The actuation button is configured to permit delivery of the first medicament when the actuation button is in a non-actuated position and selectively permit delivery of the second medicament when the actuation button is in an actuated position. When the actuation button is in the non-actuated position, the proximal and distal needles are in fluid communication with the bypass channel. When the actuation button is in the actuated position, the proximal and distal needles are in fluid communication with the second reservoir.

In another exemplary embodiment of the drug delivery system disclosed herein, the system includes (i) a pump operably connected to a first reservoir containing a first medicament, (ii) a delivery tube, wherein an end of the delivery tube is connected to the

first reservoir, (iii) a dispense interface in fluid communication with the delivery tube, and (iv) a secondary medicament module in fluid communication with the delivery tube. The secondary medicament module includes a housing and an actuation button that includes (i) a chamber for a cartridge containing a second medicament and (ii) a bypass channel for delivery of the first medicament. The actuation button is configured to permit delivery of the first medicament when the actuation button is in a non-actuated position and selectively permit delivery of the second medicament when the actuation button is in an actuated position. When the actuation button is in the non-actuated position, the cartridge is laterally offset from the delivery tube, and wherein, when the actuation button is in the actuated position, the cartridge is aligned with the delivery tube. The cartridge may comprise at least one one-way valve that is configured to open when the cartridge is aligned with the delivery tube and the first medicament is pumped through the delivery tube, thereby allowing the second medicament to be delivered.

In another exemplary embodiment of the drug delivery system disclosed herein, the system includes (i) a pump operably connected to a first reservoir containing a first medicament, (ii) a delivery tube, wherein an end of the delivery tube is connected to the first reservoir, (iii) a dispense interface in fluid communication with the delivery tube, and (iv) a secondary medicament module in fluid communication with the delivery tube. The secondary medicament module includes a housing and a rotary member that includes (i) a chamber for a cartridge containing a second medicament and (ii) a bypass channel for delivery of the first medicament. The rotary member is configured to permit delivery of the first medicament when the bypass channel is aligned with the delivery tube and selectively permit delivery of the second medicament when the cartridge is aligned with the delivery tube. When a user desires to deliver the second medicament, the user rotates the rotary member until the cartridge is aligned with the delivery tube. Like the example described above, the cartridge may include at least one one-way valve that is configured to open when the cartridge is aligned with the delivery tube and the first medicament is pumped through the preliminary tube, thereby allowing the second medicament to be delivered.

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

## 5 BRIEF DESCRIPTION OF THE DRAWINGS

Various examples of Applicants' drug delivery system and corresponding method are described herein with reference to the following drawings, wherein like numerals denote like entities:

Figure 1 is a front view of an exemplary infusion pump drug delivery system;

- 10 Figure 2 is a back view of the infusion pump drug delivery system of Figure 1 and shows various possible locations of the secondary medicament module;

Figure 3a illustrates an exemplary embodiment of a secondary medicament module that can be used with the system shown in Figures 1 and 2;

- 15 Figure 3b illustrates a cross-sectional view of the secondary medicament module of Figure 3a when the button is in its non-actuated position;

Figure 3c illustrates another cross-sectional view of the secondary medicament module of Figure 3a when the button is in its non-actuated position;

Figure 3d illustrates another cross-sectional view of the secondary medicament module of Figure 3a when the button is in its actuated position;

- 20 Figure 3e illustrates a partially transparent view of the secondary medicament module of Figure 3a when the button is in its actuated position;

Figure 3f illustrates another partially transparent view of the secondary medicament module of Figure 3a when the button is in its actuated position;

Figure 4a illustrates a partially exploded view of another exemplary embodiment of a secondary medicament module that can be used with the infusion pump drug delivery system shown in Figures 1 and 2;

5 Figure 4b illustrates the secondary medicament module of Figure 4a when the button is in its non-actuated position;

Figure 4c illustrates the secondary medicament module of Figure 4a when the button is in its actuated position;

10 Figure 5a illustrates another exemplary embodiment of a secondary medicament module that can be used with the infusion pump drug delivery system shown in Figures 1 and 2;

Figure 5b illustrates the rotary member and cartridge of the secondary medicament module of Figure 5a;

Figure 5c illustrates a partially transparent view of the secondary medicament module of Figure 5a when the rotary member is in its non-actuated position;

15 Figure 5d illustrates a partially transparent view of the secondary medicament module of Figure 5a when the rotary member is being rotated;

Figure 5e illustrates a partially transparent view of the secondary medicament module of Figure 5a when the rotary member is in its actuated position;

20 Figure 5f illustrates the secondary medicament module of Figure 5a when the rotary member is in its actuated position; and

Figure 6 illustrates another exemplary embodiment of a secondary medicament module that can be used with the infusion pump drug delivery system shown in Figures 1 and 2.

## DETAILED DESCRIPTION

The infusion pump drug delivery system and corresponding method disclosed herein allow for continuous delivery of a first medicament from a reservoir operably connected to a pump and selective delivery of a second medicament from a separate reservoir, where the second medicament may be delivered sequentially or simultaneously with the first medicament at the command of the user. Both medicaments are delivered via a single dispense interface (e.g., a needle). Although the medicaments are referred to herein as being different (i.e., a first and a second medicament), the second medicament need not be different than the first medicament (e.g., an insulin bolus added to basal insulin flow). By activating (e.g., actuating a button operably connected to the reservoir containing the second medicament) a secondary medicament module, the user (or person assisting the user, e.g., a healthcare provider) can select when to deliver the second medicament, which is beneficial where delayed dosing of the second medicament is preferred or required.

As shown in the exemplary embodiments disclosed herein, the second medicament is incorporated into the system's infusion set, which may include a delivery tube, dispense interface, and hub that connects the dispense interface to the delivery tube and that helps maintain the position of the dispense interface on the user's body. To help the dispense interface maintain its position on the user's body, the hub may include or be attached to a disposable patch that includes adhesive for adhering to the user's skin. Where only a single dose is required throughout the limited life of the infusion set, the second medicament may be fully/permanently incorporated (e.g., pre-filled) into the infusion set and thereby can only be dispensed once without replacing the entire infusion set or various components thereof (e.g., the delivery tube and/or secondary medicament module). However, if several doses are required, or the second medicament needs to be varied, the infusion set may feature a port for accepting the introduction of the second medicament or may allow for the replacement of the capsule or cartridge containing the second medicament. Where the infusion set features a port, the port may feature an exclusive attachment means in order to prevent the introduction of inappropriate medicaments.

The majority of exemplary embodiments described herein depict the secondary medicament module near the dispense interface. This helps minimize the impact on the

flow of the first medicament and helps avoid flushing of the second medicament during system priming. However, under certain circumstances, these considerations may not be necessary or important and the second medicament may be incorporated further upstream (i.e., closer to the first medicament reservoir).

- 5 An exemplary infusion pump drug delivery system is shown in Figures 1 and 2. As shown, the system 100 generally includes a housing 102 for a pump (not shown) that is operably connected to a first reservoir 104 containing a first medicament 106, a delivery tube 108, a secondary medicament module 110 including a second reservoir 112 containing a second medicament 114, and a dispense interface 116. The secondary
- 10 medicament module 110 may be located anywhere along the delivery tube 108 between the first reservoir 104 and the dispense interface 116. For example, as shown in Figure 2, the secondary medicament module 110 may be located (i) within or close to the hub 118 that helps connect the delivery tube 108 to the first reservoir 104, (ii) within or near the hub 120 that helps connect the delivery tube to the dispense interface and that
- 15 helps maintain the position of the dispense interface on the user's body, and/or (iii) anywhere between (i) and (ii). Although the exemplary embodiments of the system disclosed herein are described as having a single secondary medicament module 110, any number of secondary medicament modules 110 may be used with any of the exemplary systems.
- 20 As shown best in Figure 2, controls 122, 124 (e.g., dose dials, power switches, etc.) are mounted on the outer surface of the housing 102. These controls may power on/off the system 100 and/or may be used to set the desired dose of the first medicament 106. Alternatively, the controls may be provided remotely from the housing 102. For sake of brevity and clarity, additional components such as electronic circuits, controllers,
- 25 processors, power sources, memory, converters, multiplexers, and the like are not illustrated. However, it should be understood that such components are commonly included in CIT pump systems and are known in the art. Thus, the exemplary embodiments of the system disclosed herein may include such components where appropriate. These components may reside on or in the housing 102 for example.
- 30 Figures 3a-6 illustrate various exemplary embodiments of a secondary medicament module 110 that can be used with Figures 1 and 2. Turning to Figures 3a-f, a first

exemplary embodiment of a secondary medicament module 310 is shown. The secondary medicament module 310 is located near dispense interface 316 and generally includes a housing 326 (which may be part of hub 320) inside which a slidable capsule 328 is located, a reservoir 312 within the capsule 328 that contains a second medicament 314, a proximal needle 330, a distal needle 332, a bypass channel 336 (see Figure 3c) for delivering a first medicament (not shown), and an actuation button 338.

When the button 338 is in its non-actuated position (i.e., at its proximal most position, as shown in Figures 3b and 3c), delivery of the first medicament is permitted but delivery of the second medicament 314 is not possible. In this position, the proximal needle 330 provides a fluid conduit from the delivery tube 308 to the bypass channel 336 while the distal needle 332 provides a fluid conduit from the bypass channel 336 to the dispense interface 316. Accordingly, while the pump is running, the first medicament is forced in the distal direction 340 through the delivery tube 308, then through the proximal needle 330, then through the bypass channel 336 (see Figure 3c), then through the distal needle 332, and finally through the dispense interface 316, thereby delivering the first medicament to the user.

When the user desires to deliver the second medicament 314, the user activates the secondary medicament module 310 by sliding the actuation button 338 in the distal direction 340 until the button 338 reaches its actuated position (i.e., when the proximal and distal needles 330, 332 are both in fluid communication with the reservoir 312 containing the second medicament 314). As the user slides the button 338 in the distal direction 340 the proximal needle 330 correspondingly moves in the distal direction 340 because the proximal needle 330 is fixed to the button 338 (perhaps by adhesive). Alternately, the proximal needle 330 may be mechanically trapped or bonded through co-molding. A sliding septum or seal 334 located between the delivery tube 308 and the capsule 328 helps guide the proximal needle 330 as it moves in the distal direction 340 while preventing the first medicament from leaking into the cavity 342 of the housing 326. The sliding seal 334 may be fixed to, or part of, the distal end of the delivery tube 308 or the housing 326 of the secondary medicament module 310.

As the user slides the button 338 in the distal direction 340, the distal end of the proximal needle 330 pierces the proximal seal 344 of the reservoir 312 at a first predetermined axial position of the button 338, thereby placing the proximal needle 330 in fluid communication with the reservoir 312 containing the second medicament 314.

5 At a second predetermined axial position of the button 338, the internal portion 348 of the button 338 comes into abutment with the capsule 328, thus, further distal movement 340 of the button 338 causes corresponding movement of the slidable capsule 228. At a third predetermined axial position of the button 338, the proximal end of the distal  
10 needle 332 (which is fixed to the housing 326) pierces the distal seal 346 of the reservoir 312, thus placing the distal needle 332 in fluid communication with the reservoir 312 containing the second medicament 314. After both the proximal and distal needles 330, 332 are in fluid communication with the reservoir 312, the button 338 is in its actuated position (as shown in Figure 3d). Although described herein as the first, second, and third predetermined axial positions of the button 338, the first and second  
15 predetermined axial positions may be the same. In other words, the distal end of the proximal needle 330 may pierce the proximal seal 344 of the reservoir 312 at substantially the same time that the internal portion 348 of the button 338 comes into abutment with the capsule 328.

After both needles 330, 332 are in fluid communication with the reservoir 312, the  
20 distally directed force of the first medicament, which is generated by the pump, forces the second medicament 314 out of the reservoir 312, through the distal needle 330, and through the dispense interface 316, thereby delivering the second medicament 314 to the user. The secondary medicament module 310 may be configured such that, when the button 338 is in its actuated position, the distal and proximal ends of the proximal  
25 and distal needles 330, 332 respectively are very close to the proximal and distal seals 344, 346 respectively, thus minimizing the amount of dead space inside the reservoir 312. After the second medicament 314 is delivered to the user, the first medicament will continue to be delivered to the user (via the flow path created by the reservoir 312 being in fluid communication with both needles 330, 332) as long as the pump  
30 continues to pump first medicament from its reservoir .

As shown in Figures 3e and 3f, the housing 326 of the secondary medicament module 310 may be provided with grooves 350 that are configured to engage snap arms 352 of the button 338, thus providing tactile and/or audible feedback to the user. As shown, the housing 326 may be provided with two rows of three grooves 350 that are

5 configured to engage two snap arms 352 of the button 338, where the rows are disposed opposite to one another on the inner surface of the housing 326 and the snap arms 352 are disposed opposite each other on the outer edge of the portion 348 of the button 338 that interfaces with the capsule 328. Each groove 350 may correspond with one of the predetermined axial positions of the button 338 described above. For

10 instance, the proximal most groove 350 may correspond to the first predetermined axial position of the button 338, the middle groove 350 may correspond to the second predetermined axial position of the button 338, and the distal most groove 350 may correspond to the third predetermined axial position of the button 338. Any number of grooves 350 and snap arms 352 may be used. Regardless of the number of grooves

15 350 and snap arms 352, it is desirable to provide a groove 350 that corresponds to the actuated position of the button 338 so that the user knows when the button 338 is in its actuated position and thus when the second medicament 314 will be delivered.

The grooves 350 and corresponding snap arms 352 may be configured to prevent the button 338 from being reversed to its non-actuated position after reaching its actuated

20 position, thus making the secondary medicament module 310 disposable (i.e., single use). This may be accomplished using a one-way ratchet-type system. Accordingly, after delivery of the second medicament 314, the secondary medicament module 310 and/or entire infusion set would need to be replaced in order to deliver a second dose of the same or different second medicament. Alternatively, the secondary medicament

25 module 310 may be reusable (i.e., multi-use). As such, the button 338 may be configured to be reversed to its non-actuated position. Further, the secondary medicament module 310 may be provided with a port for (i) receiving a refill dose of a second medicament and (ii) transferring the refill dose to the reservoir 312. In another reusable embodiment, the secondary medicament module 310 may be configured such

30 that the entire capsule 328 can be replaced.

Figures 4a-c illustrate another exemplary embodiment of a secondary medicament module 410. As shown, the secondary medicament module 410 is located near dispense interface 416 and generally includes a housing 426 (which may be part of hub 420) and an actuation button 438 that includes (i) a chamber 428 for holding a cartridge 412 that contains a second medicament 414 and (ii) a bypass channel 436 (see Figure 4c). The secondary medicament module 410 may be disposable (i.e., single use) or reusable (i.e., multiuse). If the secondary medicament module 410 is disposable, it may be provided with a pre-installed permanent cartridge 412. If the secondary medicament module 410 is reusable, then the user may have to install the cartridge 412 into the chamber 428 when the user desires to deliver a second medicament dose. In such a case, it is important to maintain sterility of the cartridge 412 and the second medicament 414 contained therein and to prevent leakage of the second medicament 414 prior to activating the secondary medicament module 410. Thus, the cartridge 412 may be provided with seals (not shown) that cover its proximal and distal ends. These seals may be foil seals that can be removed by the user prior to activating the secondary medicament module 410. Further, the chamber 428 may feature an exclusive attachment means that only accepts certain cartridges, which prevents the introduction of inappropriate medicaments.

When the secondary medicament module 410 is in its non-actuated position (i.e., when the bypass channel 436 is in fluid communication with the delivery tube 408 and the dispense interface 416, and when the cartridge 412 is laterally offset from the delivery tube 408, as shown best in Figure 4b), delivery of the first medicament is permitted but delivery of the second medicament 414 is prohibited. In this position, the bypass channel 436 provides a fluid conduit from the delivery tube 408 to the dispense interface 416. Accordingly, while the pump is running, the first medicament is forced in the distal direction 440 through the delivery tube 408, then through the bypass channel 436, and finally through the dispense interface 416, thereby delivering the first medicament to the user.

When the user desires to deliver the second medicament 414, the user activates the secondary medicament module 410 by depressing the button 438 until it reaches its actuated position (i.e., when the cartridge 412 is aligned with the delivery tube 408 such

that the cartridge channel 454 is in fluid communication with the delivery tube 408 and the dispense interface 416, as shown in Figure 3c). Although not shown, both the proximal and distal ends of the cartridge channel 454 are provided with one-way flow valves that are designed to open under the force of the first medicament when it is being pumped from its reservoir. Thus, once the cartridge 412 is aligned with the delivery tube 408 such that the cartridge channel 454 is in fluid communication with the delivery tube 408 and the dispense interface 416, the force of the first medicament causes the one-way valves to open. Once the valves are open, the first medicament forces the second medicament 414 out of the cartridge 412 and through the dispense interface 416, thereby delivering the second medicament 414 to the user. After the second medicament 414 is delivered to the user, the first medicament will continue to be delivered to the user (via the flow path created by the cartridge channel 454 being in fluid communication with the delivery tube 408 and the dispense interface 416) as long as the pump continues to pump first medicament from its reservoir.

Although not shown, the housing of the secondary medicament module 410 may be provided with grooves 450 that are configured to engage snap arms 452 of the button 438, thus providing tactile and/or audible feedback to the user. Any number of grooves 450 and snap arms 452 may be used. Regardless of the number of grooves 450 and snap arms 452, it is desirable to provide a groove 450 that corresponds to the actuated position of the button 438 so that the user knows when the button 438 is in its actuated position and thus when the second medicament 414 will be delivered.

The grooves 450 and corresponding snap arms 452 may be configured to prevent the button 438 from being reversed to its non-actuated position after reaching its actuated position, thus making the secondary medicament module 410 disposable (i.e., single use). This may be accomplished using a one-way ratchet-type system. Accordingly, after delivery of the second medicament 414, the secondary medicament module 410 and/or entire infusion set would need to be replaced in order to deliver a second dose of the same or different second medicament. Alternatively, as noted above, the secondary medicament module 410 may be reusable. As such, the button 438 may be configured to be reversed to its non-actuated position. Once the button 438 is in its non-actuated position, the used cartridge may be replaced with new one.

Figures 5a-f illustrate another exemplary embodiment of a secondary medicament module 510. As shown, the secondary medicament module 510 is located near dispense interface 516 and generally includes a housing 526 (which may be part of hub 520) and a rotary actuation member 538 that includes (i) a chamber 528 for holding a cartridge 512 that contains a second medicament 514 and (ii) a bypass channel 536 (see Figure 5b) for delivering a first medicament from a reservoir operably connected to a pump. The secondary medicament module 510 may be disposable (i.e., single use) or reusable (i.e., multiuse). If the secondary medicament module 510 is disposable, it may be provided with a pre-installed permanent cartridge 512. If the secondary medicament module 510 is reusable, then the user may have to install the cartridge 512 into the chamber 528 when the user desires to deliver a second medicament dose. In such a case, it is important to maintain sterility of the cartridge 512 and the second medicament 514 contained therein and to prevent leakage of the second medicament 514 prior to activating the secondary medicament module 510. Thus, the cartridge 512 may be provided with seals (not shown) that cover its proximal and distal ends. These seals may be foil seals that can be removed by the user prior to activating the secondary medicament module 510. Further, the chamber 528 may feature an exclusive attachment means that only accepts certain cartridges, which prevents the introduction of inappropriate medicaments.

When the secondary medicament module 510 is in its non-actuated position (i.e., when the bypass channel 536 is in fluid communication with the delivery tube 508 and the dispense interface 516, and when the cartridge 512 is laterally offset from the delivery tube 508, as shown in Figures 5a and 5c), delivery of the first medicament is permitted but delivery of the second medicament 514 is prohibited. In this position, the bypass channel 536 provides a fluid conduit from the delivery tube 508 to the dispense interface 516. Accordingly, while the pump is running, the first medicament is forced in the distal direction 540 through the delivery tube 508, then through the bypass channel 536, and finally through the dispense interface 516, thereby delivering the first medicament to the user.

When the user desires to deliver the second medicament 514, the user activates the secondary medicament module 510 by rotating the rotary member 538 (Figure 5d

shows the rotary member 538 during rotation from its non-actuated position to its actuated position) until it reaches its actuated position (i.e., when the cartridge 512 is aligned with the delivery tube 508 such that the cartridge channel 554 is in fluid communication with the delivery tube 508 and the dispense interface 516, as shown in  
5 Figures 5e and 5f). Although not shown, both the proximal and distal ends of the cartridge channel 554 are provided with one-way flow valves that are designed to open under the force of the first medicament when it is being pumped from its reservoir. Thus, once the cartridge 512 is aligned with the delivery tube 508 such that the cartridge channel 554 is in fluid communication with the delivery tube 508 and the dispense  
10 interface 516, the force of the first medicament causes the one-way valves to open. Once the valves are open, the first medicament forces the second medicament 514 out of the cartridge 512 and through the dispense interface 516, thereby delivering the second medicament 514 to the user. After the second medicament 514 is delivered to the user, the first medicament will continue to be delivered to the user (via the flow path  
15 created by the cartridge channel 554 being in fluid communication with the delivery tube 508 and the dispense interface 516) as long as the pump continues to pump first medicament from its reservoir.

The housing 526 of the secondary medicament module 510 may be provided with grooves 550 that are configured to engage snap arms 552 of the rotary member 538,  
20 thus providing tactile and/or audible feedback to the user. Any number of grooves 550 and snap arms 552 may be used. Regardless of the number of grooves 550 and snap arms 552, it is desirable to provide a groove 550 that corresponds to the actuated position of the rotary member 538 so that the user knows when the button 538 is in its actuated position and thus when the second medicament 514 will be delivered.

25 The grooves 550 and corresponding snap arms 552 may be configured to prevent the rotary member 538 from being reversed to its non-actuated position after reaching its actuated position, thus making the secondary medicament module 510 disposable (i.e., single use). This may be accomplished using a one-way ratchet-type system. Accordingly, after delivery of the second medicament 514, the secondary medicament  
30 module 510 and/or entire infusion set would need to be replaced in order to delivery a second dose of the same or different second medicament. Alternatively, as noted

above, the secondary medicament module 510 may be reusable. As such, the rotary member 538 may be configured to be reversed to its non-actuated position. Once the rotary member 538 is in its non-actuated position, the used cartridge 512 may be replaced with a new one. In order to replace the cartridge, the rotary member 538 may  
5 need to be removed from the housing 526.

Figure 6 illustrates yet another exemplary embodiment of a secondary medicament module 610. As shown, the secondary medicament module 610 is not permanently incorporated/fixed to the hub 620 of the infusion set. Instead, the hub 620 acts as an injection port for receiving the secondary medicament module 610. As such, the  
10 benefits of continuous therapy using the first medicament are maintained while allowing a user to deliver the second medicament 614 without requiring the user to pierce their skin at a separate injection site. This is especially beneficial for users with a phobia of needles and/or dexterity problems.

The hub 620 includes a self-sealing septum 656 that may be made of silicone rubber or a similar elastomeric or self-healing material known in the art. Thus, after a dose of the secondary medicament 614 is delivered and the dispense interface 660 of the secondary medicament module 610 is removed from the septum 658 of the hub 620, the septum 656 re-seals such that contamination of the first medicament flow is prevented. This arrangement allows multiple doses of the same or different secondary  
20 medicaments from the same or different secondary medicament modules to be delivered over the life of the infusion set.

The secondary medicament module 610 generally comprises a housing 662, a button 638, a cartridge 612 containing the second medicament 614, and a dispense interface 660. The connection between the hub 620 and the secondary medicament module 610  
25 may be made exclusive. This helps to promote user safety by allowing the hub 620 to interface with specific secondary medicament modules only. However, in other embodiments, the hub 620 may be configured to accept any dispense interface, such as but not limited to a needle of a syringe and/or injection pen known in the art.

In operation, a user inserts the dispense interface 660 of the secondary medicament  
30 module 610 into the septum 656 of the hub 620 such that the dispense interface 660 is

in fluid communication with the dispense interface (not shown) that is inserted into the skin of the user. The user then activates the secondary medicament module 610 by actuating the button 638. Upon actuation of the button 638 the second medicament 614 is delivered. Although not shown, the secondary medicament module 610 may include  
5 a means (e.g., a dial) for setting a user settable dose of the first medicament.

Examples of the present drug delivery system and its various components have been described. Those skilled in the art will understand, however, that changes and modifications may be made to these examples without departing from the true scope and spirit of the present invention, which is defined by the claims.

## List of references

	100	system
	102	housing
	104	first reservoir
5	106	first medicament
	108	delivery tube
	110	second medicament/medicated module
	116	dispense interface
	118	hub
10	120	hub
	122	controls
	124	controls
	308	delivery tube
	310	medicated module
15	312	reservoir
	314	second medicament
	316	dispense interface
	320	hub
	326	housing
20	328	slidable capsule
	330	proximal needle
	332	distal needle
	334	slidable seal
	336	bypass channel

	338	actuation button
	340	distal direction
	342	cavity
	344	proximal seal
5	346	distal seal
	348	internal portion
	350	grooves
	352	snap arms
	408	delivery tube
10	410	medicated module
	412	cartridge
	414	secondary medicament
	416	dispense interface
	420	hub
15	426	housing
	428	chamber
	436	bypass channel
	440	distal direction
	450	grooves
20	452	snap arms
	454	cartridge channel
	508	delivery tube
	510	medicated module
	512	cartridge

	514	second medicament
	516	dispense interface
	520	hub
	526	housing
5	528	chamber
	536	bypass channel
	538	rotating actuation member
	550	grooves
	552	snap arms
10	554	cartridge channel
	610	medicated module
	612	cartridge
	614	second medicament
	620	hub
15	638	button
	656	septum
	658	septum
	660	dispense interface
	662	housing

## Claims

1. A drug delivery system (100) for delivering at least two medicaments, comprising:
  - 5 a pump operably connected to a first reservoir (104) containing a first fluid or medicament (106);  
a delivery tube (108), wherein an end of the delivery tube is connected to the first reservoir;
  - a dispense interface (116) in fluid communication with the delivery tube; and
  - 10 a secondary module (110) in fluid communication with the delivery tube, wherein the secondary module comprises (i) a bypass channel (336) for delivery of the first fluid or medicament, (ii) a second reservoir (312) containing a second fluid or medicament (314), (iii) a proximal needle (330), (iv) a distal needle (332), and (v) an actuation button (338), wherein the actuation button is configured to permit delivery of the first fluid or  
15 medicament when the actuation button is in a non-actuated position and selectively permit delivery of the second fluid or medicament when the actuation button is in an actuated position.
2. The drug delivery system of claim 1, wherein, when the actuation button  
20 (338) is in the non-actuated position, the proximal and distal needles are in fluid communication with the bypass channel (336).
3. The drug delivery system of any of the preceding claims, wherein, when  
25 the actuation button (338) is in the actuated position, the proximal and distal needles are in fluid communication with the second reservoir (312).

4. The drug delivery system of any of the preceding claims, wherein the delivery tube (108) is connected to the first reservoir (104) via a hub (118).

5. The drug delivery system of any of the preceding claims, wherein, when the actuation button (338) is in the non-actuated position, the first fluid or medicament can be delivered via the bypass channel (336).

6. The drug delivery system of any of the preceding claims, wherein the actuation button (338) is actuated by sliding the button, the actuation button comprises at least one snap arm (352) configured to engage at least one groove (350) in an inner surface of a housing of the secondary module, the proximal needle (33) is fixed to the actuation button and the at least one groove corresponds to the actuated position of the actuation button (338).

7. The drug delivery system of claim 8, wherein the at least one groove corresponds to the actuated position of the actuation button (338).

8. The drug delivery system of any of the preceding claims, wherein the secondary module (110) is configured to prevent the actuation button from being reversed to the non-actuated position after actuation.

9. The drug delivery system of any of the preceding claims, wherein the secondary module (110) is located near the end of the delivery tube (108) that is connected to the first reservoir (104).

10. The drug delivery system of any of the preceding claims, wherein the secondary module (110) is located at a position between the end of the delivery tube (108) that is connected to the first reservoir (104) and the dispense interface (116).

5

11. The drug delivery system of any of the preceding claims, wherein the secondary module is located near the dispense interface.

12. The drug delivery system of any of the preceding claims, wherein the secondary module (110) in fluid communication with the delivery tube comprises a reusable secondary module.

13. The drug delivery system of any of the preceding claims, wherein the secondary module (11) is releasably coupled to a hub 620.

15

14. A drug delivery system for delivering at least two fluids and/or medicaments, comprising:

a pump operably connected to a first reservoir containing a first fluid and/or medicament;

20 a delivery tube (408), wherein an end of the delivery tube is connected to the first reservoir;

a dispense interface (416) in fluid communication with the delivery tube; and

a secondary module (410) in fluid communication with the delivery tube, wherein the secondary module comprises a housing (426) and an actuation button (438) that

includes (i) a chamber for a cartridge containing a second fluid and/or medicament and (ii) a bypass channel (436) for delivery of the first fluid and/or medicament, wherein the actuation button is configured to permit delivery of the first fluid and/or medicament when the actuation button is in a non-actuated position and selectively permit delivery of the second fluid and/or medicament when the actuation button is in an actuated position.

15. The drug delivery system of claim 16, wherein, when the actuation button is in the non-actuated position, the cartridge is laterally offset from the delivery tube, and wherein, when the actuation button is in the actuated position, the cartridge is aligned with the delivery tube.

16. The drug delivery system of claims 16 or 17, wherein the cartridge comprises at least one one-way valve that is configured to open when the cartridge is aligned with the delivery tube and the first fluid and/or medicament is pumped through the delivery tube, thereby allowing the second fluid and/or medicament to be delivered.

17. A drug delivery system for delivering at least two fluids and/or medicaments, comprising:

a pump operably connected to a first reservoir containing a first fluid and/or medicament;

a delivery tube (508), wherein an end of the delivery tube is connected to the first reservoir;

a dispense interface in fluid communication with the delivery tube; and

a secondary module (510) in fluid communication with the delivery tube, wherein the secondary module comprises a housing (526) and a rotary member (538) that includes (i) a chamber for a cartridge (512) containing a second fluid and/or medicament (514) and (ii) a bypass channel (536) for delivery of the first fluid and/or medicament, wherein the rotary member is configured to permit delivery of the first fluid and/or medicament when the bypass channel is aligned with the delivery tube and selectively permit delivery of the second fluid and/or medicament when the cartridge is aligned with the delivery tube.

10           18. The drug delivery system of claim 17, wherein the cartridge comprises at least one one-way valve that is configured to open when the cartridge is aligned with the delivery tube and the first medicament is pumped through the preliminary tube, thereby allowing the second medicament to be delivered.

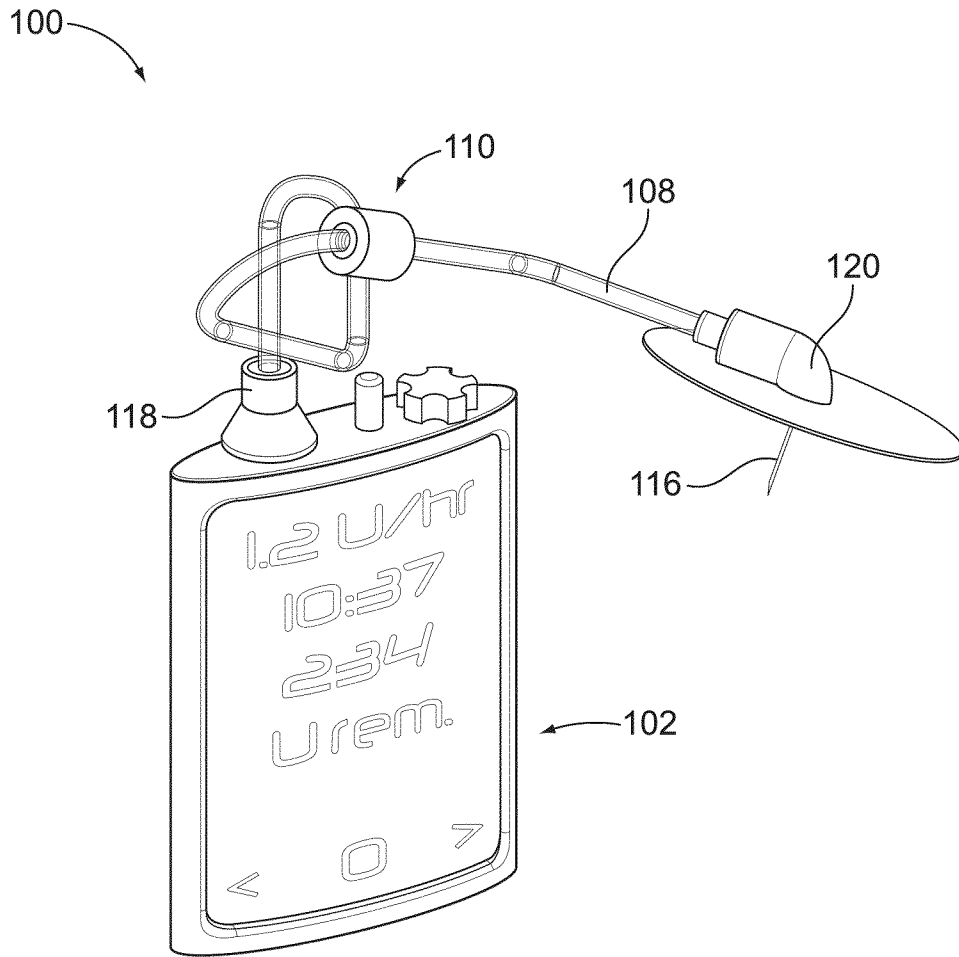


FIG. 1

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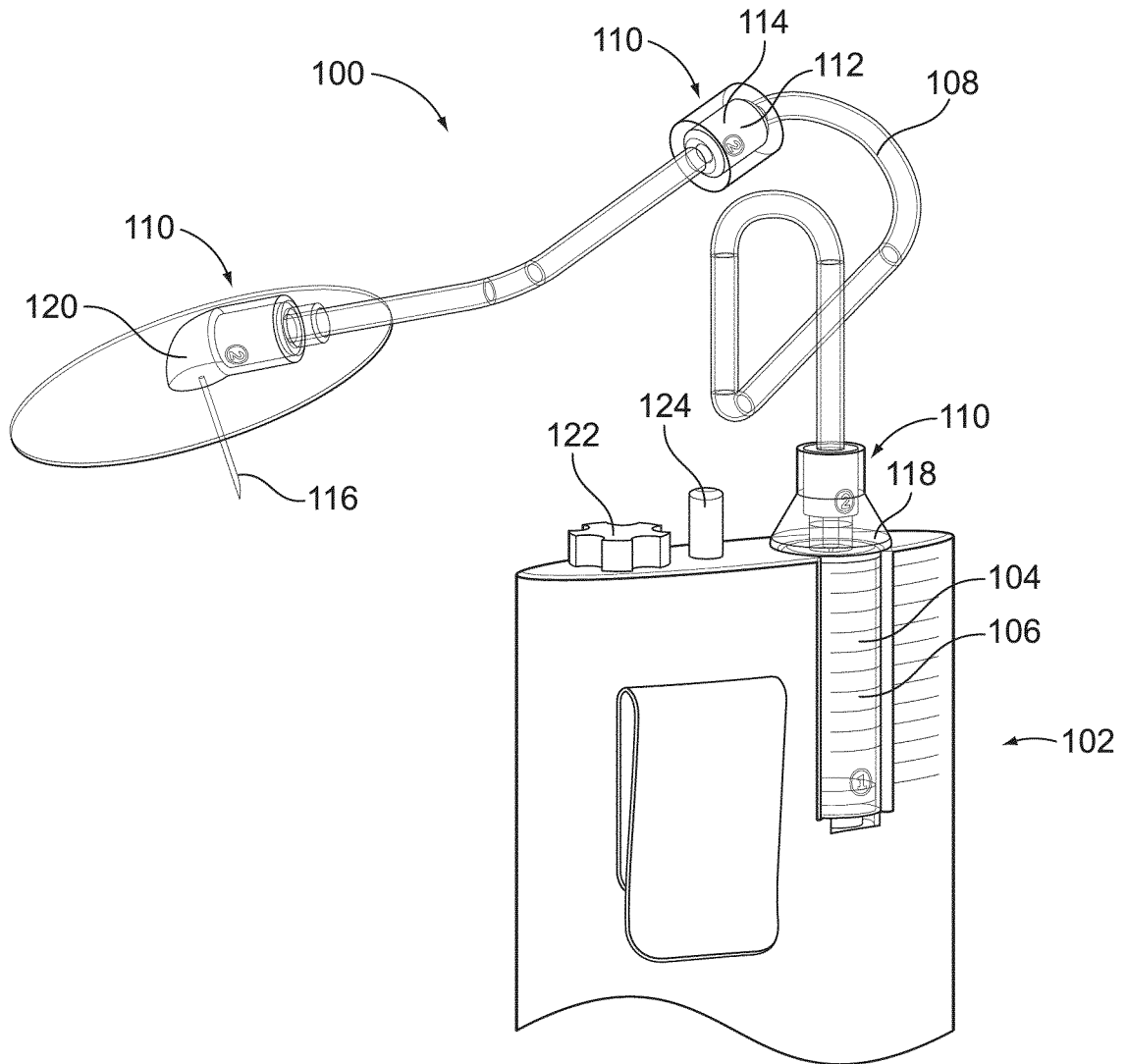


FIG. 2

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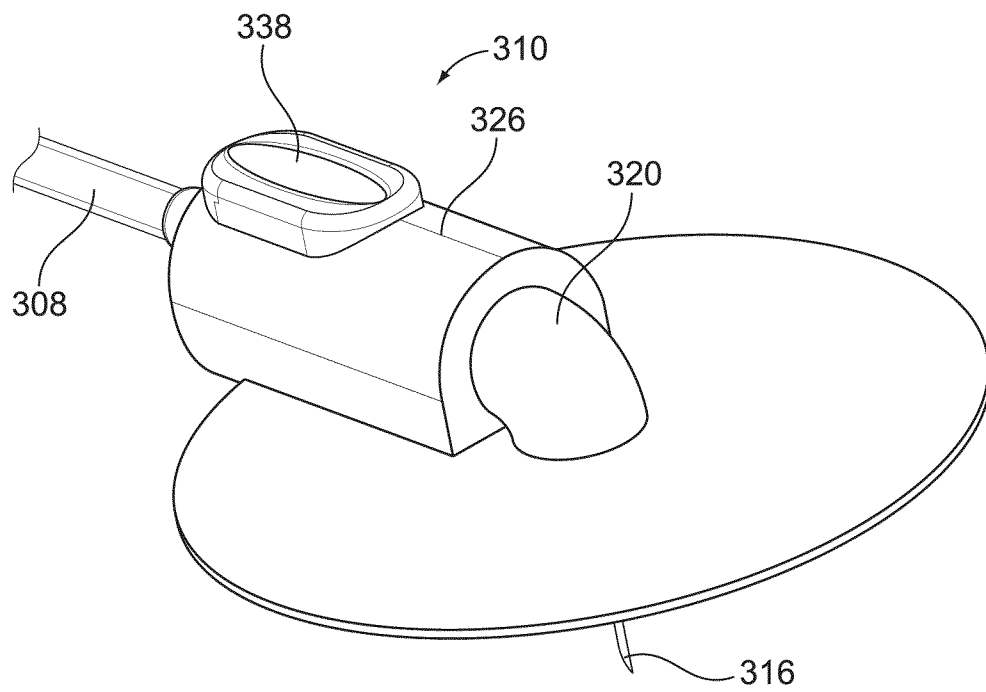


FIG. 3A

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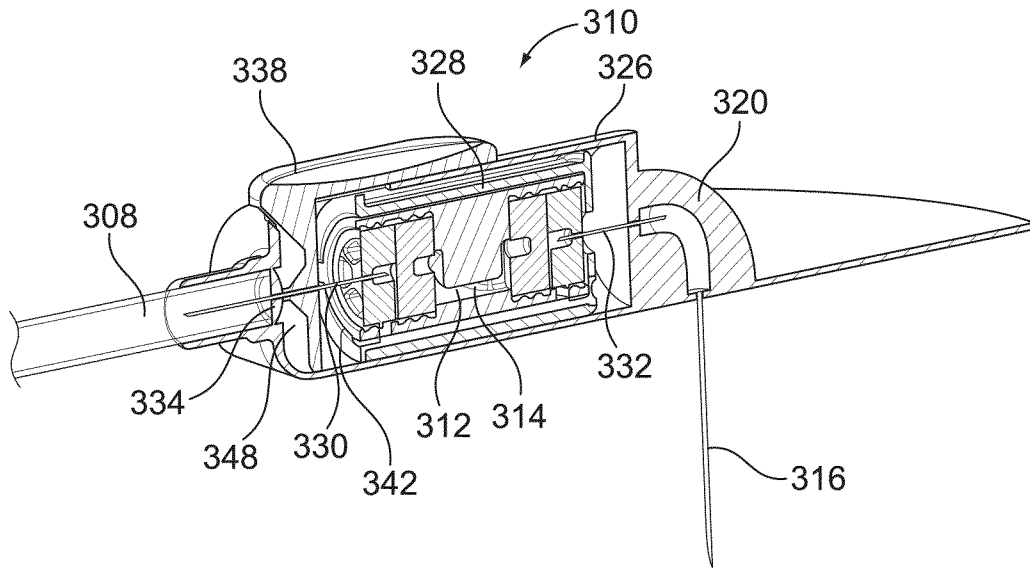


FIG. 3B

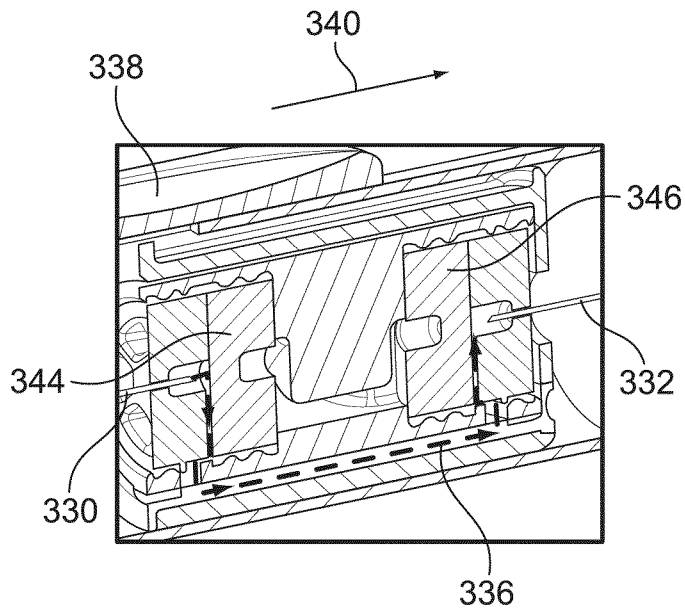


FIG. 3C

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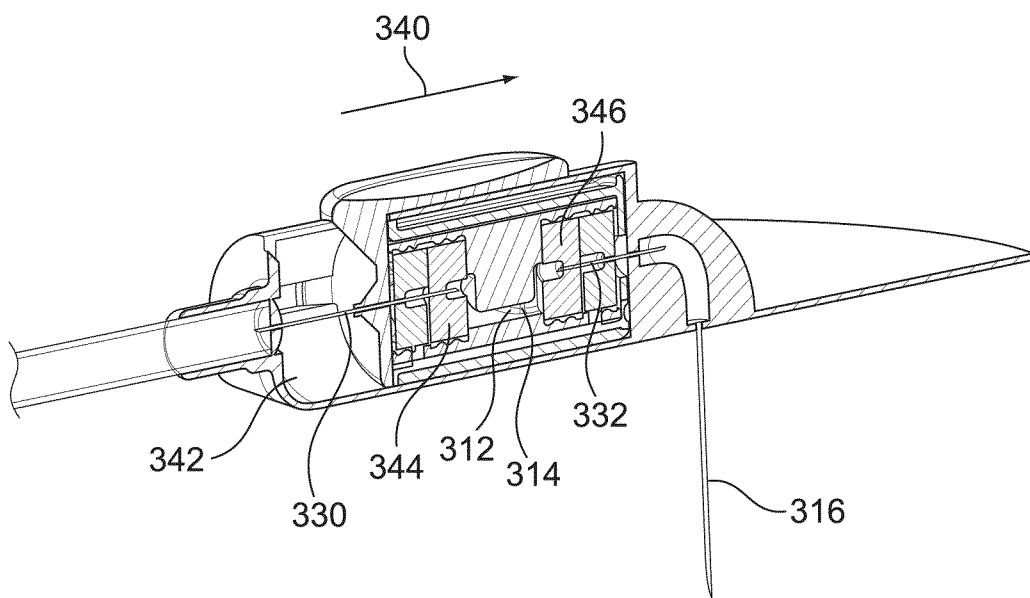


FIG. 3D

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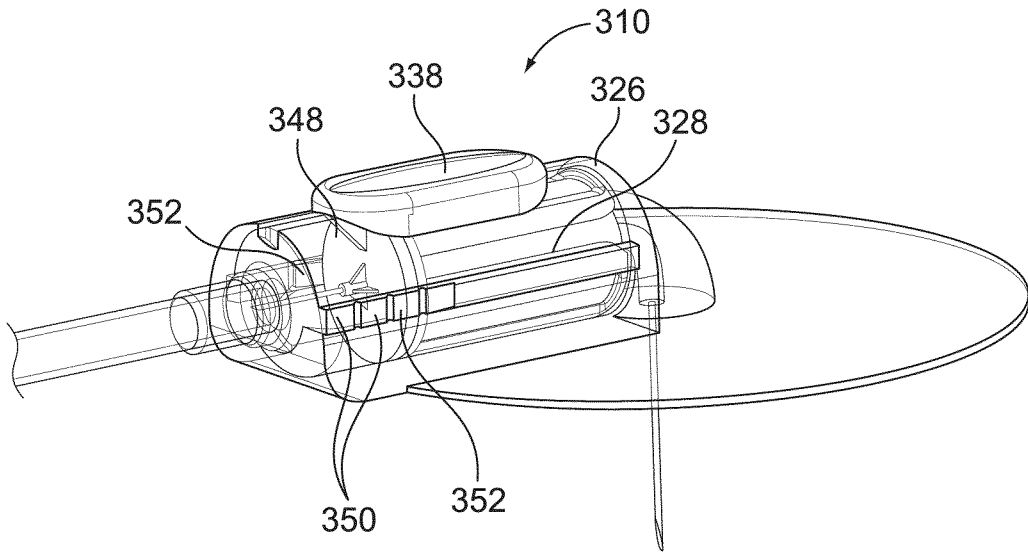


FIG. 3E

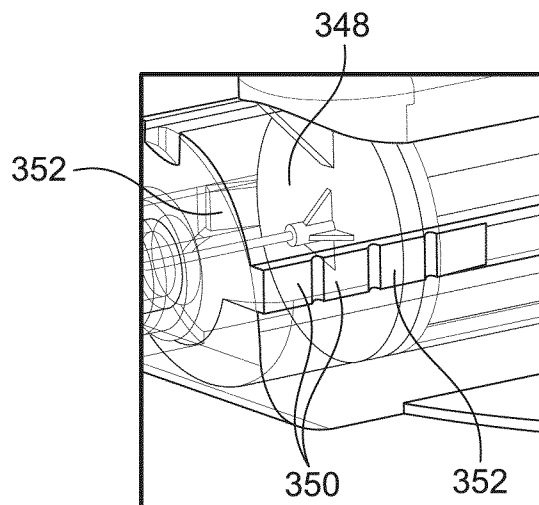


FIG. 3F

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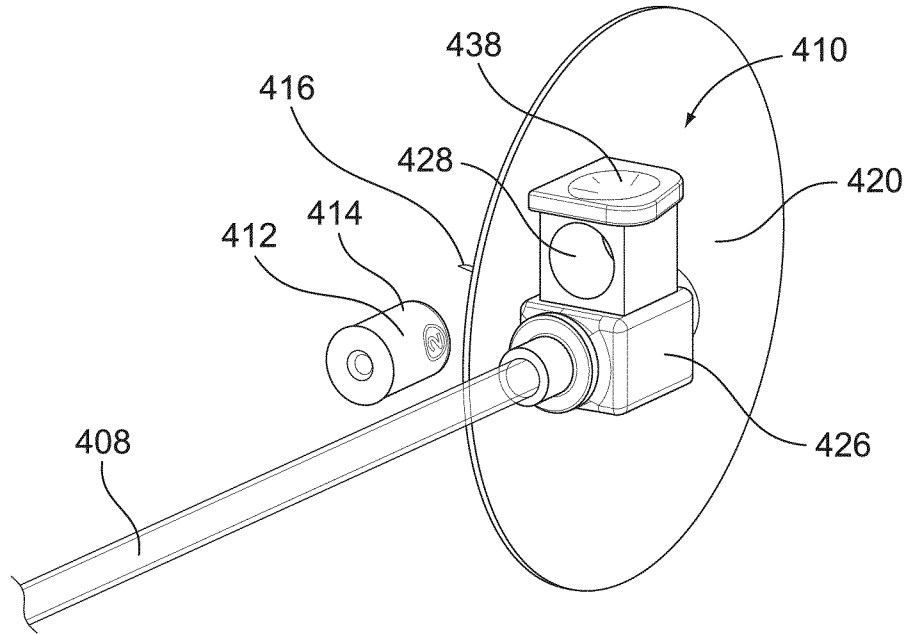


FIG. 4A

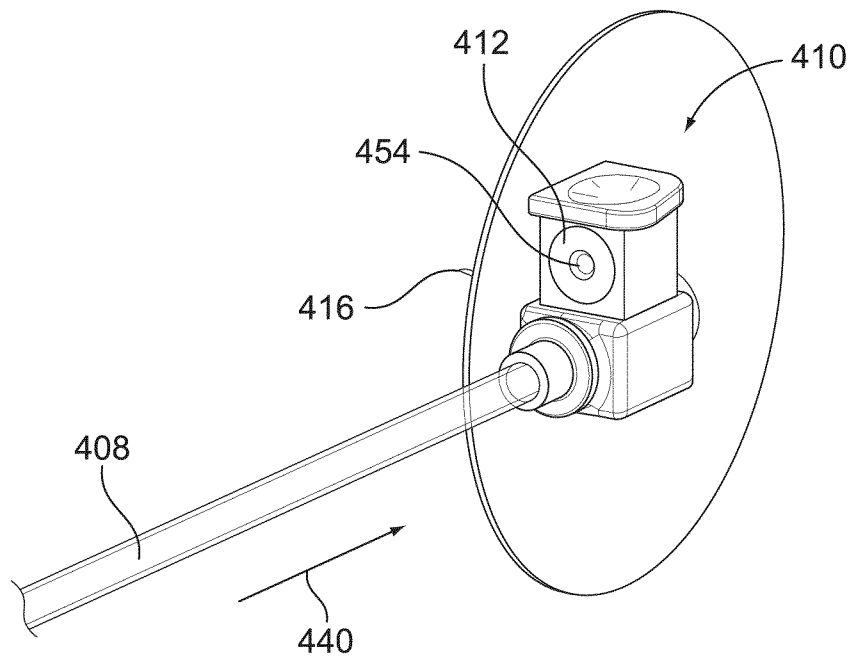


FIG. 4B

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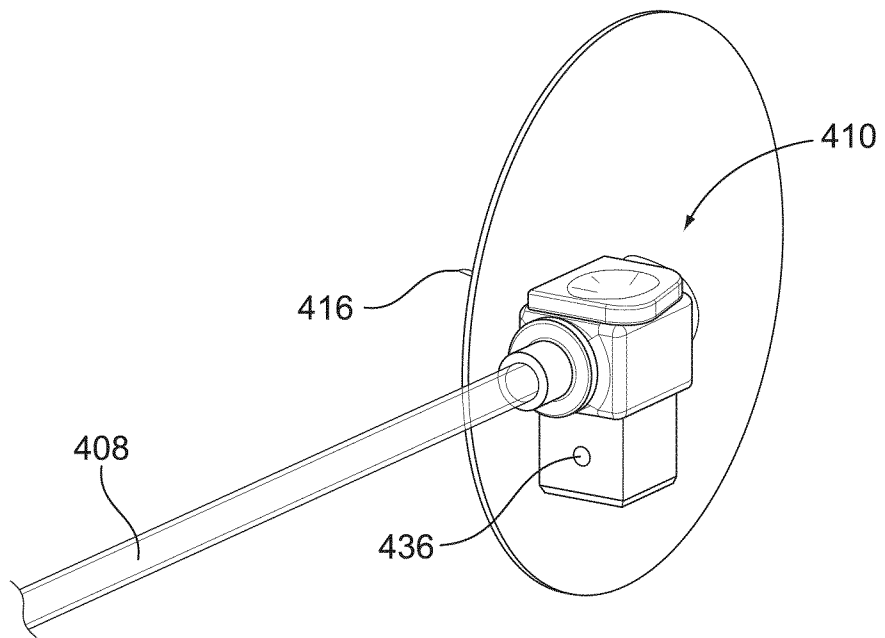


FIG. 4C

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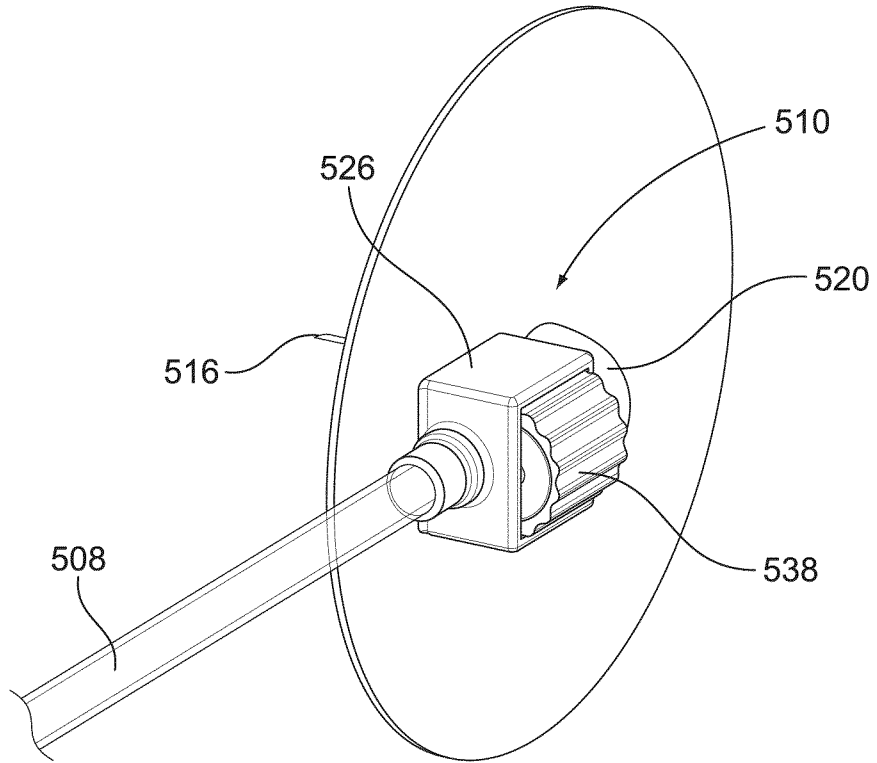


FIG. 5A

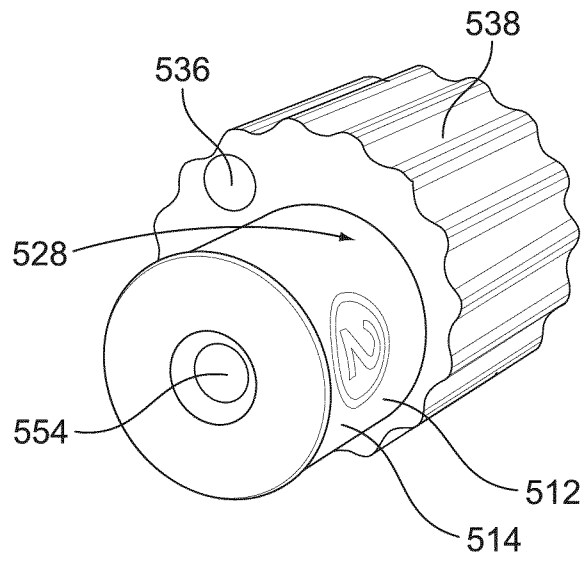


FIG. 5B

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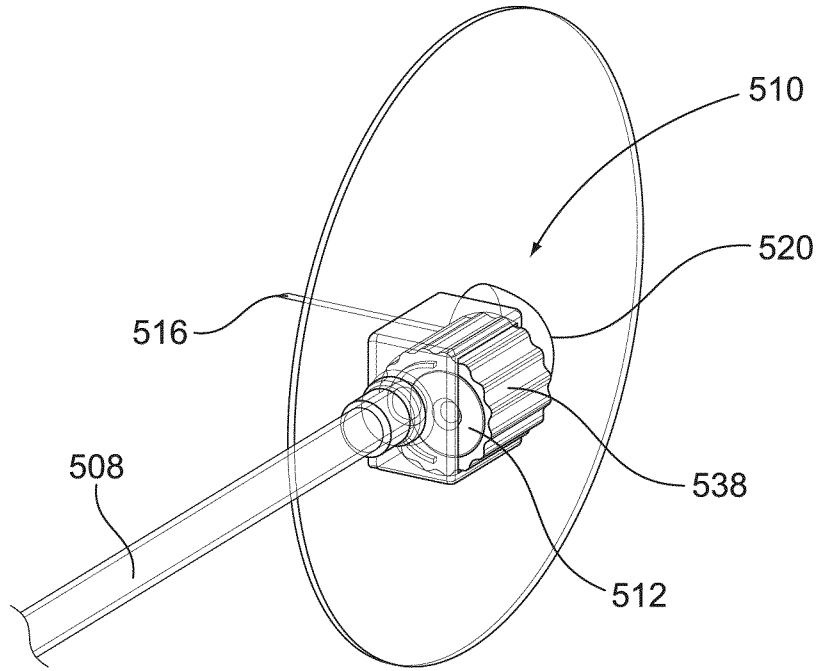


FIG. 5C

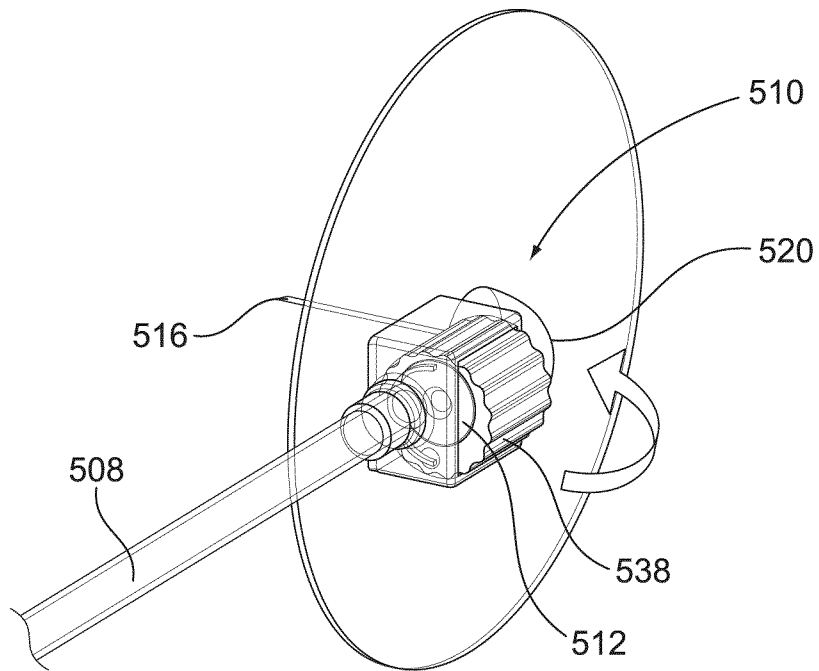


FIG. 5D

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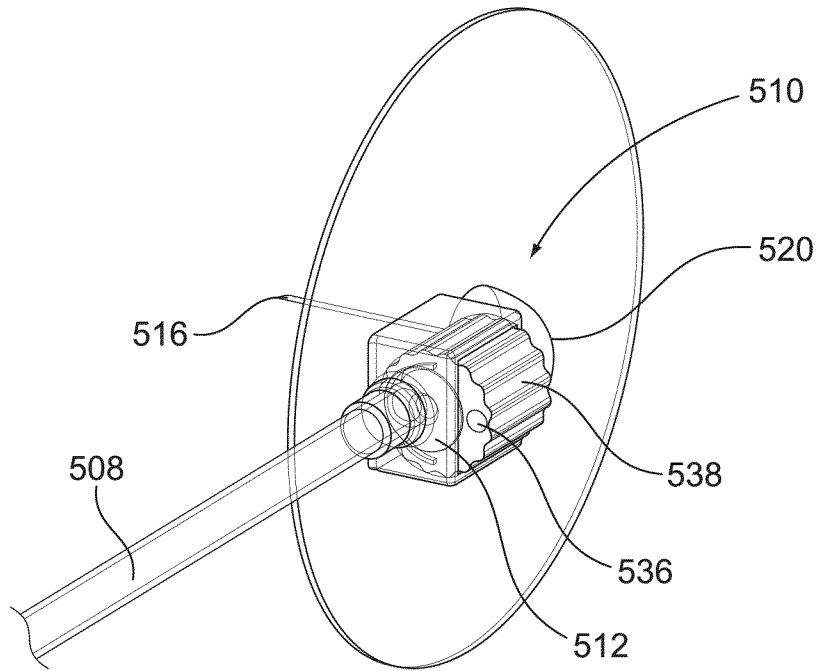


FIG. 5E

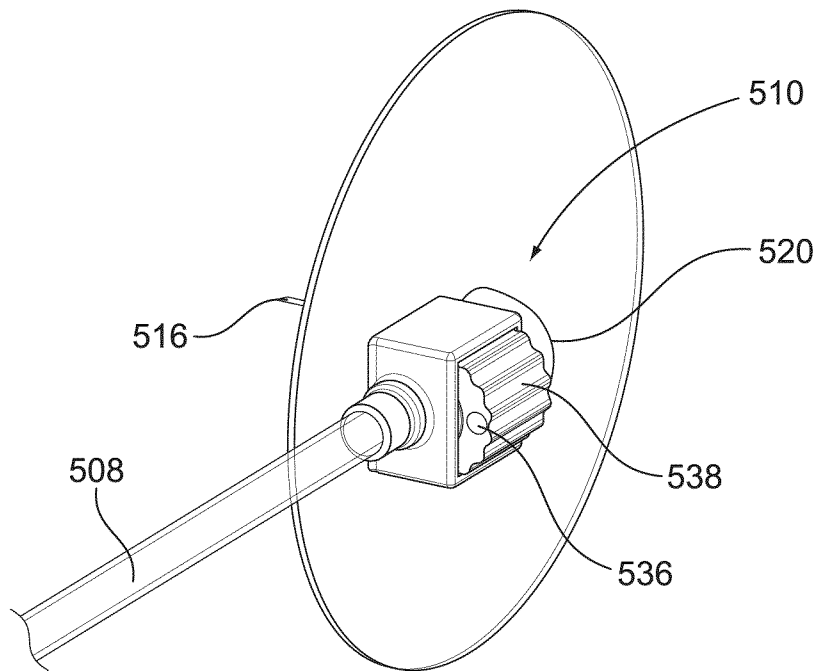


FIG. 5F

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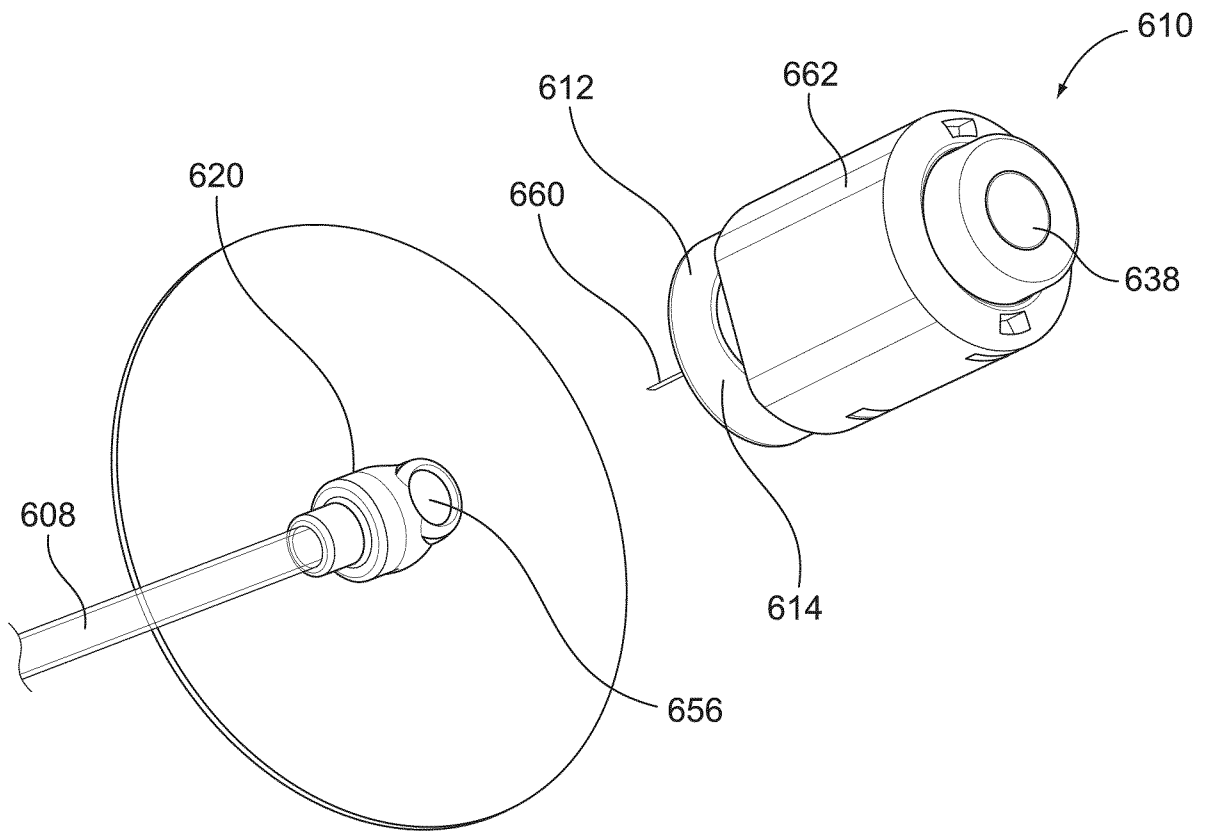


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2011/071137

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61M5/14  
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 A	US 4 596 555 A (THEEUWES FELIX [US]) 24 June 1986 (1986-06-24) abstract claim 1 figures 5,6	1-16 17,18
X A	US 4 511 352 A (THEEUWES FELIX [US] ET AL) 16 April 1985 (1985-04-16) abstract figure 2	1-16 17,18
A	US 5 776 103 A (KRIESEL MARSHALL S [US] ET AL) 7 July 1998 (1998-07-07) abstract figures	1-18
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Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents :

<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p>
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Date of the actual completion of the international search <b>22 February 2012</b>	Date of mailing of the international search report <b>05/03/2012</b>
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer <b>Türkavci, Levent</b>
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# INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2011/071137

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010/160897 A1 (DUCHARME RICHARD W [US] ET AL) 24 June 2010 (2010-06-24) abstract figures  -----	1-18

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2011/071137

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US 4511352	A	16-04-1985	NONE
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US 2010160897	A1	24-06-2010	AU 2009330505 A1 30-06-2011
			CA 2747390 A1 01-07-2010
			EP 2375960 A1 19-10-2011
			US 2010160897 A1 24-06-2010
			WO 2010074949 A1 01-07-2010
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