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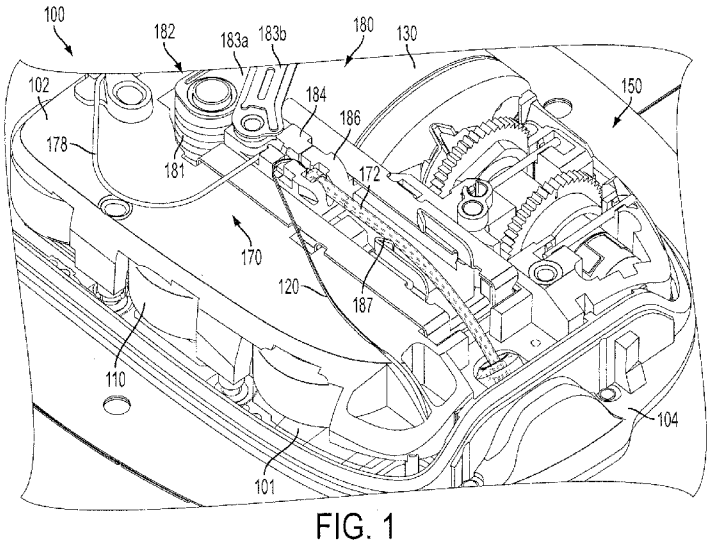

FIG. 1

(57) Abstract: A fluid delivery device comprising a fluid reservoir; a transcutaneous access tool fluidly coupled to the fluid reservoir, the transcutaneous access tool including a needle or a trocar; and a transcutaneous access tool insertion mechanism for deploying the transcutaneous access tool, wherein the insertion mechanism is configured to insert and retract the needle/trocar in a single, uninterrupted motion. In certain embodiments, the fluid delivery device may comprise an infusion device comprising a fluid reservoir for containing a therapeutic fluid; and a transcutaneous access tool fluidly coupled to the fluid reservoir for delivering the therapeutic fluid subcutaneously and for introducing a monitoring test strip subcutaneously, and methods of use thereof.

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FLUID DELIVERY DEVICE WITH TRANSCUTANEOUS ACCESS TOOL, INSERTION MECHANSIM AND BLOOD GLUCOSE MONITORING FOR USE THEREWITH

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of the filing date of U.S. Provisional Application Serial No. 61/618,028, filed March 30, 2012, the teachings of which are incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention relates to fluid delivery devices for delivering therapeutic liquids to a patient, and more particularly, to an infusion pump for delivering therapeutic liquids to a patient.

BACKGROUND INFORMATION

[0003] Fluid delivery devices have numerous uses such as delivering a liquid medicine or other therapeutic fluid to a patient subcutaneously. In a patient with diabetes mellitus, for example, ambulatory infusion pumps have been used to deliver insulin to a patient. These ambulatory infusion pumps have the ability to offer sophisticated fluid delivery profiles including variable basal rates and bolus requirements. The ability to carefully control drug delivery can result in better efficacy of the drug and therapy and less toxicity to the patient.

[0004] Some existing ambulatory infusion pumps include a reservoir to contain the liquid medicine and use electromechanical pumping or metering technology to deliver the liquid medicine via tubing to a needle and/or soft cannula that is inserted subcutaneously into the patient. These existing devices allow control and programming via electromechanical buttons or switches located on the housing of the device. The devices include visual feedback via text or graphic screens and may include alert or warning lights and audio or vibration signals and alarms. Such devices are typically worn in a harness or pocket or strapped to the body of the patient.

[0005] Some infusion pumps have been designed to be relatively small, low cost, light-weight, and easy-to-use. One example of such a pump is the OMNIPOD® insulin infusion pump available from Insulet Corporation.

Examples of infusion pumps are also described in greater detail, for example, in U.S. Patent Nos. 7,128,727; 7,018,360; and 7,144,384 and U.S. Patent Application Publication Nos. 2007/0118405, 2006/0282290, 2005/0238507, and 2004/0010207, which are fully incorporated herein by reference. These pumps include insertion mechanisms for causing a transcutaneous access tool, such as a needle and/or soft cannula, to be inserted into a patient. Although such pumps are effective and provide significant advantages over other insulin infusion pumps, the design of the insertion mechanism may be improved, for example, to reduce the size of the pump, to improve the comfort to the user, and/or to incorporate continuous glucose monitoring (CGM). These pumps also include fluid driving mechanisms for driving fluid from a reservoir through the transcutaneous access tool. The fluid driving mechanisms may also be improved to facilitate assembly and use of the pump.

SUMMARY

[0006] The present disclosure provides various fluid delivery devices to deliver a liquid medicine or other therapeutic fluid to a patient subcutaneously. In certain embodiments the fluid delivery device may comprise an ambulatory insulin infusion device to administer insulin to a patient. The fluid delivery device may include one or more batteries for providing a power source, a fluid reservoir for holding a fluid, a fluid drive mechanism for driving the fluid out of the reservoir, a fluid passage mechanism for receiving the fluid from the reservoir and passing the fluid to a destination via a transcutaneous access tool, and a transcutaneous access tool insertion mechanism for deploying the transcutaneous access tool.

[0007] In certain embodiments, an infusion device may comprise a fluid reservoir for containing a therapeutic fluid; and a transcutaneous access tool fluidly coupled to the fluid reservoir, which may deliver the therapeutic fluid subcutaneously and introduce a monitoring test strip subcutaneously.

[0008] In certain embodiments, a method to treat diabetes mellitus may be provided comprising providing an infusion device with integrated monitoring, with the device comprising a fluid reservoir for containing a therapeutic fluid; and a transcutaneous access tool fluidly coupled to the fluid reservoir, which may deliver the therapeutic fluid subcutaneously and introduce a monitoring test strip

subcutaneously; delivering the therapeutic fluid subcutaneously with the transcutaneous access tool to a patient, and introducing the monitoring test strip subcutaneously with the transcutaneous access tool to the patient.

[0009] In certain embodiments, the transcutaneous access tool includes a needle/trocar, and the transcutaneous access tool insertion mechanism is configured to insert and retract the needle/trocar in a single, uninterrupted motion. In such a manner, the pain of insertion and retraction of the needle/trocar experienced by the patient may be reduced.

[0010] In certain embodiments, the fluid delivery device may comprise a fluid reservoir; a transcutaneous access tool fluidly coupled to the fluid reservoir, the transcutaneous access tool including a needle/trocar; and a transcutaneous access tool insertion mechanism for deploying the transcutaneous access tool, wherein the insertion mechanism is configured to insert and retract the needle/trocar in a single, uninterrupted motion.

[0011] In certain embodiments, the fluid delivery device may comprise a fluid reservoir; a transcutaneous access tool fluidly coupled to the fluid reservoir, the transcutaneous access tool including at least a needle/trocar; and a transcutaneous access tool insertion mechanism for deploying the transcutaneous access tool, wherein the insertion mechanism is configured to insert the needle/trocar with an increasing insertion force as the needle/trocar moves in an insertion direction.

[0012] In certain embodiments, the transcutaneous access tool insertion mechanism for deploying a transcutaneous access tool including a cannula and a needle/trocar located inside of the cannula may comprise a first sliding member configured to move the needle/trocar in an insertion direction and a retraction direction; a second sliding member configured to move the cannula in the insertion direction; a torsion spring; and linkages coupled between the torsion spring and the first sliding member such that energy stored in the torsion spring causes the linkages to move the first sliding member in the insertion direction and the retraction direction.

[0013] In certain embodiments, the drive mechanism may comprise a clutch mechanism. As explained herein, by using a clutch mechanism, the number of fluid path prime pulses to prime the pump may be reduced and a full and proper priming of the fluid path before placement on the body may be better assured. The clutch mechanism may also be made suitable for other drug applications

without significant redesign, and be more easily inspected than conventional drive mechanisms for infusion devices.

[0014] In certain embodiments, the fluid delivery device may comprise a fluid reservoir; a transcutaneous access tool fluidly coupled to the fluid reservoir; and a drive mechanism for driving fluid from the reservoir. The drive mechanism may comprise a plunger received in the reservoir; a leadscrew extending from the plunger; a nut threadably engaged with the leadscrew; a drive wheel; and a clutch mechanism coupled to the drive wheel, wherein the clutch mechanism is configured to allow the nut to pass through the clutch mechanism when disengaged and is configured to grip the nut when engaged such that the drive wheel rotates the nut to advance the leadscrew and the plunger into the reservoir.

[0015] In certain embodiments, the fluid delivery device may comprise a fluid reservoir; a transcutaneous access tool fluidly coupled to the fluid reservoir; and a drive mechanism for driving fluid from the reservoir The drive mechanism may comprise a plunger received in the reservoir; an elongated assembly comprising a first elongated member and a second elongated member; the first elongated member extending from the plunger; the second elongated member coupled to the first elongated member; a drive wheel; and a clutch mechanism coupled to the drive wheel, wherein the clutch mechanism is configured to allow the second elongated member to pass through when disengaged and is configured to grip the second elongated member when engaged such that the drive wheel rotates the second elongated member to advance the first elongated member and the plunger into the reservoir.

[0016] In certain embodiments, a method of operating a foregoing fluid delivery device may comprise providing the fluid delivery device; holding the clutch mechanism in a disengaged position; filling the fluid reservoir with fluid; passing the second elongated member through the clutch mechanism such that the plunger is retracted within the reservoir; releasing the clutch mechanism from the disengaged position; and engaging the clutch mechanism with the second elongated member.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] These and other features and advantages will be better understood by reading the following detailed description, taken together with the drawings wherein:

[0018] FIG. 1 is a top perspective view of a fluid delivery device with a transcutaneous access tool insertion mechanism in a pre-deployment position, consistent with the present disclosure;

[0019] FIG. 2 is a bottom perspective view of a needle and cannula retracted into the fluid delivery device in the pre-deployment position shown in FIG. 1;

[0020] FIG. 3 is a top perspective view of the fluid delivery device shown in FIG. 1 with the insertion mechanism in an intermediate position;

[0021] FIG. 4 is a bottom perspective view of the needle and cannula extending from the fluid delivery device in the intermediate position shown in FIG. 3;

[0022] FIG. 5 is a top perspective view of the fluid delivery device shown in FIG. 1 with the insertion mechanism in a post-deployment position;

[0023] FIG. 6 is a bottom perspective view of the cannula extending from the fluid delivery device in the post-deployment position shown in FIG. 5;

[0024] FIG. 7 is a side perspective view of another embodiment of the insertion mechanism, consistent with the present disclosure, in a pre-deployment position;

[0025] FIG. 8 is a side perspective view of the insertion mechanism shown in FIG. 7 in an intermediate position;

[0026] FIG. 9 is a side perspective view of the insertion mechanism shown in FIG. 7 in a post-deployment position;

[0027] FIG. 10 is a top perspective view of the second sliding member of the insertion mechanism shown in FIG. 7 locked in the pre-deployment and post-deployment positions;

[0028] FIG. 11 is a top perspective view of a fluid driving mechanism of the fluid delivery device shown in FIG. 1 with a clutch mechanism in a disengaged position prior to filling;

[0029] FIG. 12 is a side cross-sectional view of the fluid driving mechanism shown in FIG. 11;

[0030] FIG. 13 is a top perspective view of the fluid driving mechanism shown in FIG. 11 with the clutch mechanism in a disengaged position after filling;

[0031] FIG. 14 is a top perspective view of the fluid driving mechanism shown in FIG. 11 with the clutch mechanism being released to the engaged position; and

[0032] FIGS. 15 and 16 are top perspective views of the fluid driving mechanism shown in FIG. 11 with the clutch mechanism in the engaged position.

[0033] FIGS. 17-23 are views of a bi-lumen cannula used in the fluid delivery device shown in FIGS. 1-6 to insert a monitor test strip transcutaneously;

[0034] FIGS. 24-29 are views of another embodiment of a fluid delivery device including a cannula with a D-shaped lumen for inserting a monitor test strip transcutaneously;

[0035] FIGS. 30-32 are views of the D-lumen cannula used in the fluid delivery device of FIGS. 24-29;

[0036] FIGS. 33 and 34 are views of a semi-circular trocar used with the D-lumen cannula in the fluid delivery device of FIGS. 18-23;

[0037] FIGS. 35-41 are views of another embodiment of a fluid delivery device including an oval trocar for inserting a monitor test strip transcutaneously;

[0038] FIG. 42 is a side view of the oval trocar for use in the fluid delivery device shown in FIGS. 35-41;

[0039] FIG. 43 is a top perspective view of a second sliding member for use in the fluid delivery device shown in FIGS. 35-41.

DETAILED DESCRIPTION

[0040] A fluid delivery device, consistent with embodiments of the present disclosure, may be used to deliver a therapeutic fluid (e.g. a liquid medicine) to a patient via a transcutaneous access tool, such as a needle/trocar and/or a cannula. A transcutaneous access tool insertion mechanism may be used to deploy the transcutaneous access tool, for example, by inserting and retracting a needle/trocar in a single, uninterrupted motion. The insertion mechanism may also provide an increasing insertion force as the needle/trocar moves in the insertion direction. The fluid delivery device may also include a clutch mechanism to facilitate filling a reservoir and engagement of a drive mechanism for driving fluid out of the reservoir. In certain embodiments, the fluid delivery device may comprise an ambulatory insulin infusion device.

[0041] In other embodiments, a fluid delivery device may be used to deliver a therapeutic fluid to a patient with integrated monitoring, such as continuous glucose monitoring (CGM). In these embodiments, the fluid deliver device may include a transcutaneous access tool configured to introduce a monitoring test strip through the skin of the patient, for example, using one or more needles, cannulas and/or trocars.

[0042] Referring to FIGS. 1-6, one embodiment of a fluid delivery device 100 is shown and described. In the exemplary embodiment, the fluid delivery device 100 is used to subcutaneously deliver a fluid, such as a liquid medicine (e.g. insulin), to a person or an animal. Those skilled in the art will recognize that the fluid delivery device 100 may be used to deliver other types of fluids. The fluid delivery device 100 may be used to deliver fluids in a controlled manner, for example, according to fluid delivery profiles accomplishing bolus requirements, continuous infusion and variable flow rate delivery.

[0043] According to one embodiment, the fluid delivery device 100 may include one or more batteries 110 for providing a power source, a fluid reservoir 130 for holding a fluid, a fluid drive mechanism 150 for driving the fluid out of the reservoir 130, a fluid passage mechanism 170 for receiving the fluid from the reservoir 130 and passing the fluid to a destination via a transcutaneous access tool 172, and a transcutaneous access tool insertion mechanism 180 for deploying the transcutaneous access tool 172. The fluid delivery device 100 may include a circuit board 101 with control circuitry for controlling the device and a chassis 102 that provides mechanical and/or electrical connections between components of the fluid deliver device 100. The fluid delivery device 100 may also include a housing 104 to enclose the circuit board 101, the chassis 102, and the components 110, 130, 150, 170, 180.

[0044] The fluid delivery device 100 may also include integrated monitoring such as continuous glucose monitoring (CGM). A monitor test strip 120 coupled to a monitor (not shown) in the device 100 may be introduced by the transcutaneous access tool 172 subcutaneously. One example of the monitor test strip is a CGM test strip (such as the type available from Nova Biomedical) which may be understood as a glucose sensor configured to test for a concentration level of glucose in the blood of a patient. The fluid delivery device 100 may be configured to receive data from the monitoring test strip concerning a glucose level of the patient, and determining an output of insulin from the reservoir based on the glucose level.

[0045] The transcutaneous access tool 172 includes an introducer trocar or needle 174 at least partially positioned within a lumen 175 of a cannula 176 (e.g., a soft flexible cannula), which is capable of passing the fluid into the patient. In particular, the introducer needle/trocar 174 may initially penetrate the skin such

that both the introducer needle/trocar 174 and the cannula 176 are introduced (inserted) into the patient, and the introducer needle/trocar 174 may then be retracted within the cannula 176 such that the cannula 176 remains inserted. A fluid path, such as tubing 178, fluidly couples the reservoir 130 to the lumen 175 of cannula 176 of the transcutaneous access tool 172. The transcutaneous access tool 172 may also be used to introduce a monitoring test strip subcutaneously into the patient for monitoring purposes, as described in greater detail below.

[0046] The transcutaneous access tool insertion mechanism 180 is coupled to the transcutaneous access tool 172 to deploy the transcutaneous access tool 172, for example, by inserting the needle/trocar 174 and cannula 176 through the skin of a patient and retracting the needle/trocar 174. In the illustrated embodiment, the insertion mechanism 180 includes a spring-biased linkage mechanism 182 and sliding members 184, 186 coupled to the needle/trocar 174 and cannula 176, respectively, for moving the needle/trocar 174 and cannula 176 in the insertion direction and for moving the needle/trocar 174 in the retraction direction. In a single, uninterrupted motion, the spring-biased linkage mechanism 182 moves from a pre-deployment position (FIG. 1) with both needle/trocar 174 and cannula 176 retracted (FIG. 2) to an intermediate position (FIG. 3) with both needle/trocar 174 and cannula 176 inserted (FIG. 4) to a post-deployment position (FIG. 5) with the needle/trocar 174 retracted and the cannula 176 inserted (FIG. 6).

[0047] One embodiment of the spring-biased linkage mechanism 182 includes a helical torsion spring 181 and first and second linkages 183a, 183b coupled between the torsion spring 181 and the first sliding member 184. Energy stored in the torsion spring 181 applies a force to the linkages 183a, 183b, which applies a force to the first sliding member 184 to move the first sliding member 184 in both the insertion direction and in the retraction direction. In the pre-deployment position (FIG. 1), the torsion spring 181 is loaded and the sliding members 184, 186 are locked and prevented from moving. When the sliding members 184, 186 are released, the energy stored in the torsion spring 181 causes the first linkage 183a to rotate (e.g., clockwise as shown), which applies a force to the first sliding member 184 through the second linkage 183b causing the first sliding member 184 with the needle/trocar 174 to move (with the second sliding member 186) in the insertion direction. In the intermediate position (FIG. 3), the linkages 183a, 183b are fully extended with the needle/trocar 174 and cannula 176 being

inserted, the second sliding member 186 is locked, and the remaining energy stored in the torsion spring 181 causes the first linkage 183a to continue to rotate, which applies an opposite force to the first sliding member 184 through the second linkage 183b causing the first sliding member 184 with the needle/trocar 174 to move in the retraction direction to the post-deployment position (FIG. 5). In the illustrated embodiment, the second sliding member 186 is locked against retraction by one or more latches 187. Thus, in the foregoing manner, the continuous uninterrupted clockwise rotation of first linkage 183a via the energy of torsion spring 181 provides the transcutaneous access tool insertion mechanism 180 with the ability to insert and retract the needle/trocar 174 in a single, uninterrupted motion.

[0048] The spring-biased linkage mechanism 182 allows a single spring and motion to achieve both the insertion and retraction and has a relatively small size. The spring-biased linkage mechanism 182 also reduces the static stresses caused by locking and holding back the sliding members 184, 186 and provides a smoother and more comfortable needle/trocar insertion because of the way the linkages 183a, 183b vector the forces applied to the sliding members 184, 186. The static forces on the sliding members 184, 186 are relatively small in the pre-deployment position when the linkages 183a, 183b are fully retracted. When the deployment starts and the linkages 183a, 183b start to become extended, the insertion forces increase because the force vectors increase in the insertion direction as the linkages extend 183a, 183b until a maximum insertion force is reached at the fully extended, intermediate position. By gradually increasing the insertion forces, the needle/trocar insertion and retraction is smoother, quieter and less painful.

[0049] Another embodiment of an insertion mechanism 280 is shown in greater detail in FIGS. 7-10. The sliding members 284, 286 are slidably received in a frame 290 and moved by a spring-biased linkage mechanism 282 including torsion spring 281 and linkages 283a, 283b. In this embodiment, a cam finger 292 (e.g., extending from the frame 290) engages beneath one or both of the sliding members 284, 286 to lock the sliding members in the retracted or pre-deployment position (FIG. 7). In this pre-deployment position, the cam finger 292 is held against the sliding members 284, 286 by a release bar 296, which may be moved (rotated) to allow the cam finger 292 to move and release the sliding members

284, 286 (FIG. 8). The cam finger 292 may be biased in a downward direction and/or the second sliding member 286 may include a cam surface 287 to help facilitate movement along the cam finger 292 over locking mechanism 293 upon actuation.

[0050] The release bar 296 includes a lever 297 for pivoting the release bar 296 between an engaged position against the cam finger 292 (FIG. 7) and a disengaged position releasing the cam finger 292 (FIG. 8). The release bar 296 may be biased toward the disengaged position and held against the cam finger 292 in the engaged position until the lever 297 is released allowing the release bar 296 to move to the disengaged position. In the illustrated embodiment, the lever 297 engages a rotating surface 257 of a drive wheel 256 of the fluid drive mechanism 150 such that the lever 297 is held in the engaged position for part of the rotation and is released at a certain point during the rotation (e.g., when a flat portion of the rotating surface 257 allows the lever 297 to move).

[0051] As shown in FIGS. 9 and 10, the cam finger 292 may also be used to lock the second sliding member 286 in the insertion position. A locking portion 288 of the second sliding member 286 engages a locking portion 293 of the cam finger 292 when the linkage mechanism 282 is fully extended in the intermediate position and prevents the second sliding member 286 from retracting such that the cannula remains inserted. As discussed above, the second sliding member 286 may also be locked by one or more latches (not shown) extending from a top of the frame 290.

[0052] Referring to FIGS. 11-16, one embodiment of the fluid drive mechanism 150 uses a clutch mechanism 160 to facilitate filling of the reservoir 130 and engagement of the fluid drive mechanism 150 for driving fluid out of the reservoir 130. The fluid drive mechanism 150 includes a first threaded member in the form of an elongated shaft such as a threaded drive rod or leadscrew 152, with external threads extending from a plunger 136 received in the reservoir 130 and sealed with an o-ring 137 against the inside surface of the reservoir 130. The leadscrew 152 and plunger 136 may be an inseparable, insert-molded assembly. A second threaded member in the form of an elongated shaft such as a tube nut 154 with internal threads threadably engages the leadscrew 152 and may be driven by a drive wheel 156 via a clutch mechanism 160.

[0053] When the reservoir 130 is empty (FIGS. 11 and 12), the plunger 136 is positioned at one end of the reservoir 130 such that the plunger 136 is extended and the clutch mechanism 160 is disengaged. In certain embodiments, the reservoir 130 may be filled with fluid, particularly insulin, by opening an inlet port to the reservoir 130 and pumping in the insulin under sufficient hydraulic pressure to retract the plunger 136 within the reservoir 130. Thereafter, the inlet port may be closed. When the reservoir 130 is filled and the plunger 136 moves to the opposite (retracted) end of the reservoir 130 (FIG. 13), the clutch mechanism 160 remains disengaged to allow the tube nut 154 to pass into an elongated cylindrical bore (along the drive axis) of a hub of the drive wheel 156. The clutch mechanism 160 may then be engaged (FIGS. 14-16) such that rotation of the drive wheel 156 causes the clutch mechanism 160 to rotate the tube nut 154, which causes the leadscrew 152 to advance the plunger into the reservoir 130 to deliver the fluid from the reservoir 130. In alternative embodiments, the reservoir 130 may be filled when the plunger 136 is already retracted.

[0054] In the illustrated embodiment, the clutch mechanism 160 includes a clutch spring 162 (e.g., a helical torsion spring) located in a counterbore at one end of the drive wheel 156, adjacent the reservoir 130. The inside diameter of the clutch spring 162 is larger than the outside diameter of the tube nut 154 when the clutch spring 162 is loaded, thereby disengaging the clutch spring 162 from the tube nut 154 and allowing the tube nut 154 to pass through the center aperture of the spring 162 and into the elongated bore of the drive wheel 156. Alternatively, the inside diameter of the clutch spring 162 is smaller than the outside diameter of the tube nut 154 when the clutch spring 162 is unloaded, thereby engaging or gripping the tube nut 154 and allowing the drive wheel 156 to rotate the tube nut 154. In the illustrated embodiment, prior to filing the reservoir 130, the clutch spring 162 is held in the loaded, disengaged position by a spring latch 164 engaged with the drive wheel 156 (FIGS. 11-13). After the reservoir 130 has been filled, the clutch spring 162 may thus be engaged by rotating the drive wheel 156 until the spring latch 164 releases the clutch spring 162 (FIG. 14) allowing the clutch spring 162 to unload and grip the tube nut 154 (FIGS. 15 and 16), at which time fluid may be dispensed from the reservoir 130 with continued rotation of the drive wheel 156.

[0055] As shown, the spring latch 164 may be biased by the clutch spring 162 such that as the drive wheel 156 rotates the spring latch 164 moves rotationally against a surface of a reservoir cap 132 until clutch spring 162 deflects the spring latch 164 into a window 133 in the reservoir cap 132. When the spring latch 164 moves into the window 133, the end of the clutch spring 162 held by the spring latch 164 is released, thus engaging the clutch mechanism 160. When the clutch spring 162 is engaged, the drive wheel 156 contacts an end 163 of the clutch spring 162 to create a thrust on the clutch spring 162 that causes the clutch spring 162 to rotate the tube nut 154. The fluid drive mechanism 150 may also use other clutch mechanisms capable of allowing the tube nut 154 or other type of nut or threaded member to pass through the clutch mechanism and then being activated to engage the nut or threaded member.

[0056] In the illustrated embodiment, the drive wheel 156 includes ratchets 157 that are engaged by an actuator 158 to incrementally drive the wheel 156 and advance the plunger 136 into the reservoir 130. Examples of this actuation mechanism are described in greater detail in U.S. Patent Application Publication No. 2005/0238507, which is fully incorporated herein by reference.

[0057] By using a clutch mechanism, the engagement between the leadscrew and the nut occurs at assembly, and thus no rotation is needed for the nut to engage the leadscrew by operation of the device. This reduces the number of fluid path prime pulses to prime the pump and assures a full and proper priming of the fluid path before placement on the body. The clutch mechanism also enables the changing of thread pitch for other drug applications without a need to redesign the tilt nut used in fluid driving mechanisms in other existing pumps. The components of the clutch mechanism are also more easily inspected than the tilt nut assembly.

[0058] According to one embodiment, as shown in FIGS. 17-23, the cannula 176 providing the transcutaneous access for delivery the fluid may also be used to introduce the monitor test strip 120. In this embodiment, the cannula 176 includes a first lumen 175 for receiving the needle/trocar 174 and a second lumen 177 for receiving the test strip 120. As shown, the first lumen 175 has a circular (cylindrical) profile and the second lumen 177 has a rectangular profile. The cannula 176 may also include one or more windows 179a, 179b providing access to one or more sensors 122a, 122b on the test strip 120. As shown, the plurality of

windows 179a, 179b of the cannula 176 may be arranged on a same side of the sidewall of cannula 176, with the first window 179a arranged at a distance from the distal end tip of the cannula 176 which is less than the distance of the second window 179b from the distal end tip of the cannula 176.

[0059] To insert the test strip 120 into second lumen 177, the test strip 120 passes into second lumen 177 at the head 178 of the cannula 176 and extends to the window(s) 179a, 179b. Thus, at least one window 179a, 179b exposes a sensor 122a, 122b of the monitoring test strip 120. In the example embodiment, two windows 179a, 179b are provided with the window 179a closest to the tip of the cannula 176 providing access to the main sensor area and the window 179b farthest from the tip providing a reference. Although a specific shape and configuration of a bi-lumen cannula is shown, other configurations of a cannula with first and second lumens may also be used to both deliver a therapeutic fluid and introduce a test strip subcutaneously.

[0060] According to another embodiment, as shown in FIGS. 24-34, a fluid delivery device 300 may include a transcutaneous access tool 372 with a first cannula 376 for delivering fluid and a second cannula 377 for introducing a test strip 320. The first cannula 376 receives a first needle/trocar 374 (shown as a circular needle) to facilitate insertion of the first cannula 376 and the second cannula 377 receives a second needle/trocar 375 (shown as a semi-circular trocar) to facilitate insertion of the second cannula 377. The fluid deliver device 300 includes an insertion mechanism 380, similar to the first described embodiment above, but with sliding members 384, 386 coupled to both the needle 374 and the trocar 375 and both cannulas 376, 377. The insertion mechanism 380 inserts the second cannula 377 and the trocar 375 and then retracts the trocar 375 in the same manner as described above. The test strip 320 remains inserted after the trocar 375 is retracted. Thus, both the first needle/trocar 374 and the second needle/trocar 375 may be introduced into the patient simultaneously, particularly to reduce the pain of sequential insertions.

[0061] Similar to the above described embodiment, first cannula 376 includes a circular (cylindrical) lumen 376a. As shown in greater detail in FIGS. 30-32, the second cannula 377 includes a semi-circular (D-shaped) lumen 377a to allow the monitor strip to sit relatively flat within the cannula 377. The second cannula 377 also includes one or more windows 379a, 379b providing access to one or

more sensors 320a, 320b on the test strip 320 (see FIGS. 27 and 29). As shown, similar to the prior embodiment, the plurality of windows 379a, 379b, of the cannula 377 may be arranged on a same side of the sidewall of the cannula 377, with the first window 379a arranged at a distance from the distal end tip of the cannula 377 which is less than the distance of the second window 379b from the distal end tip of the cannula 377. Thus, at least one window 379a, 379b exposes a sensor 320a, 320b of the monitoring test strip 320. In the example embodiment, two windows 379a, 379b are provided with the window 379a closest to the tip of the cannula 377 providing access to the main sensor area and the window 379b farthest from the tip providing a reference. As shown in greater detail in FIGS. 33 and 34, the trocar 375 has a shape corresponding to the D-shaped lumen 377a to allow the trocar 375 to be retracted leaving the test strip 320 inserted (see FIG. 29). As shown, the trocar includes a planar side surface 373 which corresponds to a planar test strip 320 such that, when assembled, the planar test strip 320 may be located adjacent the planar side surface 373 of the trocar 375 in the second cannula 377.

[0062] According to another embodiment, as shown in FIGS. 35-43, a fluid delivery device 400 may include a transcutaneous access tool 472 with a cannula 476 for delivering fluid and a needle or trocar 475 (shown as a semi-circular trocar) for introducing a test strip 420. The cannula 476 receives a needle/trocar 474 (shown as circular needle) to facilitate insertion of the cannula 476 and the trocar 475 is inserted with the test strip 420. The fluid deliver device 400 includes an insertion mechanism 480, similar to the first described embodiment above, but with sliding members 484, 486 coupled to both the needle 474 and the trocar 475. The insertion mechanism 480 inserts the trocar 475 (FIGS. 37 and 38) and then retracts the trocar 475 (FIGS. 39 and 40) in the same manner as the needle/trocar described above. The test strip 420 remains inserted after the trocar 475 is retracted (FIG. 41). In contrast to the prior embodiment, the needle/trocar 475 introduces the monitoring test strip 420 subcutaneously solely (i.e. without the monitoring test strip 420 being introduced with a cannula).

[0063] The trocar 475 is shown in greater detail in FIG. 42. The second sliding member 486 is shown in greater detail in FIG. 43. In this embodiment, the second sliding member 486 is designed to capture the cannula 476 and to receive and allow the trocar 475 to pass through.

[0064] Accordingly, various embodiments of the fluid delivery device may use the transcutaneous access tool both to deliver fluid and to introduce a test strip subcutaneously to provide integrated monitoring.

[0065] While the principles of the invention have been described herein, it is to be understood by those skilled in the art that this description is made only by way of example and not as a limitation as to the scope of the invention. Other embodiments are contemplated within the scope of the present invention in addition to the exemplary embodiments shown and described herein. Modifications and substitutions by one of ordinary skill in the art are considered to be within the scope of the present invention, which is not to be limited except by the following claims.

CLAIMS

What is claimed is:

1. An infusion device, the device comprising:

a fluid reservoir for containing a therapeutic fluid; and

a transcutaneous access tool fluidly coupled to the fluid reservoir, the transcutaneous access tool for delivering the therapeutic fluid subcutaneously and for introducing a monitoring test strip subcutaneously.

2. The infusion device of claim 1 wherein the transcutaneous access tool includes a cannula and a needle/trocar passing through a first lumen of the cannula, and wherein the monitoring test strip is located in a second lumen of the cannula.

3. The infusion device of claim 2 wherein the cannula includes at least one window for exposing a sensor area of the monitoring test strip subcutaneously.

4. The infusion device of claim 3 wherein the at least one window of the cannula includes a plurality of windows, and wherein at least one window exposes a sensor of the monitoring test strip.

5. The infusion device of claim 4 wherein the plurality of windows of the cannula include a first window arranged at a first distance from a tip of the cannula and a second window arranged at a second distance from the tip of the cannula, wherein the first distance is less than the second distance.

6. The infusion device of claim 1 wherein the transcutaneous access tool includes first and second cannulas, a first needle/trocar passing through a lumen of the first cannula, and a second needle/trocar passing through a lumen of the second cannula, and wherein the monitoring test strip is located in the second cannula.

7. The infusion device of claim 6 wherein the second needle/trocar passing through a lumen of the second cannula is a trocar having a planar surface and the monitoring test strip comprises a planar strip, and wherein the planar strip is located adjacent the planar surface of the trocar in the second cannula.

8. The infusion device of claim 6 wherein the second cannula includes at least one window for exposing a sensor area on the monitoring test strip subcutaneously.

9. The infusion device of claim 8 wherein the at least one window of the cannula includes a plurality of windows, and wherein at least one window exposes a sensor of the monitoring test strip.

10. The infusion device of claim 8 wherein the plurality of windows of the cannula include a first window arranged at a first distance from a tip of the cannula and a second window arranged at a second distance from the tip of the cannula, wherein the first distance is less than the second distance.

11. The infusion device of claim 1 wherein the transcutaneous access tool includes a cannula, a first needle/trocar passing through a lumen of the cannula, and a second needle/trocar configured to introduce the monitoring test strip subcutaneously.

12. The infusion device of claim 11 wherein the needle/trocar is configured to introduce the monitoring test strip subcutaneously solely without the monitoring test strip being introduced with a cannula.

13. The infusion device of claim 1 wherein the fluid reservoir comprises an insulin reservoir, and wherein the monitoring test strip comprises a continuous glucose monitoring test strip.

14. A method to treat diabetes mellitus comprising:

providing an infusion device, the device comprising:

a fluid reservoir for containing a therapeutic fluid; and

a transcutaneous access tool fluidly coupled to the fluid reservoir, the transcutaneous access tool for delivering the therapeutic fluid subcutaneously and for introducing a monitoring test strip subcutaneously;

delivering the therapeutic fluid subcutaneously to a patient with the transcutaneous access tool, and introducing the monitoring test strip subcutaneously to the patient with the transcutaneous access tool.

15. The method of treating diabetes mellitus of claim 14 wherein:

the transcutaneous access tool includes a cannula and a needle/trocar passing through a first lumen of the cannula, and wherein the monitoring test strip is located in a second lumen of the cannula, and further comprising

inserting the needle/trocar and the cannula subcutaneously into the patient;

retracting the needle/trocar from the patient; and

providing the therapeutic fluid through the first lumen of the cannula to deliver the therapeutic fluid subcutaneously to a patient.

16. The method of treating diabetes mellitus of claim 15 wherein

the cannula includes at least one window which exposes a sensor of the monitoring test strip to blood of the patient, and further comprising

receiving data from the sensor concerning a glucose level of the patient, and

determining an output of the therapeutic fluid from the reservoir based on the glucose level.

17. The method of treating diabetes mellitus of claim 14 wherein:

the transcutaneous access tool includes first and second cannulas, a first needle/trocar passing through a lumen of the first cannula, and a second needle/trocar passing through a lumen of the second cannula, wherein the monitoring test strip is located in the second cannula, and further comprising

inserting the first needle/trocar and the first cannula subcutaneously into the patient, retracting the first needle/trocar from the patient and providing the therapeutic fluid through the lumen of the first cannula to deliver the therapeutic fluid subcutaneously to a patient;

inserting the second needle/trocar, the monitoring test strip and the second cannula subcutaneously into the patient to introduce the monitoring test strip subcutaneously to the patient.

18. The method of treating diabetes mellitus of claim 17 wherein:

the second cannula includes at least one window which exposes a sensor of the monitoring test strip to blood of the patient, and further comprising

receiving data from the sensor concerning a glucose level of the patient, and

determining an output of the therapeutic fluid from the reservoir based on the glucose level.

19. The method of treating diabetes mellitus of claim 14 wherein:

the transcutaneous access tool includes cannula, a first needle/trocar passing through a lumen of the cannula, and a second needle/trocar trocar including the monitoring test strip, and further comprising

inserting the first needle/trocar and the cannula subcutaneously into the patient, retracting the first needle/trocar from the patient and providing the therapeutic fluid through the lumen of the cannula to deliver the therapeutic fluid subcutaneously to a patient;

inserting the second/needle trocar with the monitoring test strip subcutaneously into the patient to introduce the monitoring test strip subcutaneously to the patient.

20. The method of treating diabetes mellitus of claim 19 wherein:

inserting the first needle/trocar and the cannula subcutaneously into the patient and inserting the second/needle trocar with the monitoring test strip subcutaneously into the patient are performed simultaneously.

21. A fluid delivery device comprising:

a fluid reservoir;

a transcutaneous access tool fluidly coupled to the fluid reservoir, the transcutaneous access tool including a needle or a trocar; and

a transcutaneous access tool insertion mechanism for deploying the transcutaneous access tool, wherein the insertion mechanism is configured to insert and retract the needle/trocar in a single, uninterrupted motion.

22. The fluid delivery device of claim 21 wherein the insertion mechanism is configured to increase an insertion force as the needle/trocar moves in an insertion direction.

23. The fluid delivery device of claim 22 wherein the transcutaneous access tool includes a cannula, and wherein the needle/trocar is located within the cannula such that the cannula remains inserted when the needle/trocar is retracted.

24. The fluid delivery device of claim 23 wherein the insertion mechanism comprises:

a first sliding member configured to move the needle/trocar in an insertion direction and in a retraction direction;

a second sliding member configured to move the cannula in the insertion direction;

a torsion spring; and

linkages coupled between the torsion spring and the first sliding member such that energy stored in the torsion spring causes the linkages to move the first sliding member in the insertion direction and the retraction direction in the single, uninterrupted motion.

25. The fluid delivery device of claim 24 wherein the insertion mechanism further comprises:

a frame slidably receiving the sliding members and configured to lock the sliding members in a pre-deployment position and to lock the second sliding member in a post-deployment position.

26. The fluid delivery device of claim 25 wherein the frame includes a cam finger configured to lock the sliding members in the pre-deployment position.

27. The fluid delivery device of claim 26 wherein the cam finger is configured to lock the second sliding member in the post-deployment position.

28. The fluid delivery device of claim 26 wherein the insertion mechanism further comprises:

a release bar configured to hold the cam finger when the cam finger locks the sliding members in the pre-deployment position and configured to release the cam finger to allow the sliding members to move in the insertion direction.

29. The fluid delivery device of claim 28 further comprising a drive mechanism for driving fluid from the reservoir, wherein the drive mechanism engages the release bar and triggers movement of the release bar to release the cam finger.

30. A fluid delivery device comprising:

a fluid reservoir;

a transcutaneous access tool fluidly coupled to the fluid reservoir, the transcutaneous access tool including at least a needle or a trocar; and

a transcutaneous access tool insertion mechanism for deploying the transcutaneous access tool, wherein the insertion mechanism is configured to insert the needle/trocar with an increasing insertion force as the needle/trocar moves in an insertion direction.

31. The fluid delivery device of claim 30 wherein

the transcutaneous access tool insertion mechanism comprises a spring-biased linkage mechanism to increase the insertion force as the needle/trocar moves in the insertion direction.

32. The fluid delivery device of claim 30 wherein the transcutaneous access tool includes a cannula, and wherein the needle/trocar is located within the cannula such that the cannula remains inserted when the needle/trocar is retracted.

33. The fluid delivery device of claim 32 wherein the insertion mechanism comprises:

a first sliding member configured to move the needle/trocar in an insertion direction and in a retraction direction;

a second sliding member configured to move the cannula in the insertion direction;

a torsion spring; and

linkages coupled between the torsion spring and the first sliding member such that energy stored in the torsion spring causes the linkages to move the first sliding member in the insertion direction and the retraction direction.

34. The fluid delivery device of claim 33 wherein the insertion mechanism further comprises:

a frame slidably receiving the sliding members and configured to lock the sliding members in a pre-deployment position and to lock the second sliding member in a post-deployment position.

35. The fluid delivery device of claim 34 wherein the frame includes a cam finger configured to lock the sliding members in the pre-deployment position.

36. The fluid delivery device of claim 35 wherein the cam finger is configured to lock the second sliding member in the post-deployment position.

37. The fluid delivery device of claim 35 wherein the insertion mechanism further comprises:

a release bar configured to hold the cam finger when the cam finger locks the sliding members in the pre-deployment position and configured to release the cam finger to allow the sliding members to move in the insertion direction.

38. The fluid delivery device of claim 37 further comprising a drive mechanism for driving fluid from the reservoir, wherein the drive mechanism engages the release bar and triggers movement of the release bar to release the cam finger.

39. A transcutaneous access tool insertion mechanism for deploying a transcutaneous access tool including a cannula and a needle or a trocar located inside of the cannula, the insertion mechanism comprising:

a first sliding member configured to move the needle/trocar in an insertion direction and a retraction direction;

a second sliding member configured to move the cannula in the insertion direction;

a torsion spring; and

linkages coupled between the torsion spring and the first sliding member such that energy stored in the torsion spring causes the linkages to move the first sliding member in the insertion direction and the retraction direction.

40. The transcutaneous access tool insertion mechanism of claim 39 further comprising:

a frame slidably receiving the sliding members and configured to lock the sliding members in a pre-deployment position and to lock the second sliding member in a post-deployment position.

41. The transcutaneous access tool insertion mechanism of claim 40 wherein the frame includes a cam finger configured to lock the sliding members in the pre-deployment position.

42. The transcutaneous access tool insertion mechanism of claim 41 wherein the cam finger is configured to lock the second sliding member in the post-deployment position.

43. The transcutaneous access tool insertion mechanism of claim 42 further comprising:

a release bar configured to hold the cam finger when the cam finger locks the sliding members in the pre-deployment position and configured to release the cam finger to allow the sliding members to move in the insertion direction.

44. A fluid delivery device comprising:

a fluid reservoir;

a transcutaneous access tool fluidly coupled to the fluid reservoir; and

a drive mechanism for driving fluid from the reservoir, the drive mechanism comprising:

a plunger received in the reservoir;

a leadscrew extending from the plunger;

a nut threadably engaged with the leadscrew;

a drive wheel; and

a clutch mechanism coupled to the drive wheel, wherein the clutch mechanism is configured to allow the nut to pass through the clutch mechanism when disengaged and is configured to grip the nut when engaged such that the drive wheel rotates the nut to advance the leadscrew and the plunger into the reservoir.

45. The fluid delivery device of claim 44 wherein the nut is a tube nut.

46. The fluid delivery device of claim 45 wherein the clutch mechanism includes a clutch spring that grips the tube nut when released.

47. The fluid delivery device of claim 46 wherein the clutch mechanism further includes a spring latch configured to hold the clutch spring in a disengaged position and configured to release the clutch spring such that the clutch spring moves to an engaged position.

48. The fluid delivery device of claim 47 wherein the spring latch is configured to release the clutch spring in response to movement of the drive wheel.

49. A fluid delivery device comprising:

a fluid reservoir;

a transcutaneous access tool fluidly coupled to the fluid reservoir; and

a drive mechanism for driving fluid from the reservoir, the drive mechanism comprising:

a plunger received in the reservoir;

an elongated assembly comprising a first elongated member and a second elongated member;

the first elongated member extending from the plunger;

the second elongated member coupled to the first elongated member;

a drive wheel; and

a clutch mechanism coupled to the drive wheel, wherein the clutch mechanism is configured to allow the second elongated member to pass through when disengaged and is configured to grip the second elongated member when engaged such that the drive wheel rotates the second elongated member to advance the first elongated member and the plunger into the reservoir.

50. The fluid delivery device of claim 49 wherein:

the first elongated member comprises a first threaded member;

the second elongated member comprises a second threaded member;

the second threaded member is in threaded engagement with the first threaded member; and

the clutch mechanism is configured to allow the second threaded member to pass through when disengaged and is configured to grip the second threaded member when engaged such that the drive wheel rotates the second threaded member to advance the first threaded member and the plunger into the reservoir.

51. The fluid delivery device of claim 50 wherein the first elongated threaded member comprises a first threaded shaft having external threads.

52. The fluid delivery device of claim 50 wherein the second elongated threaded member comprises a second threaded shaft having internal threads.

53. The fluid delivery device of claim 49 wherein the clutch mechanism includes a clutch spring that grips the second elongated member when released.

54. The fluid delivery device of claim 53 wherein the clutch mechanism further includes a spring latch configured to hold the clutch spring in a disengaged position and configured to release the clutch spring such that the clutch spring moves to an engaged position.

55. The fluid delivery device of claim 54 wherein the spring latch is configured to release the clutch spring in response to movement of the drive wheel.

56. A method of operating a fluid delivery device comprising:

providing the fluid delivery device, the device comprising

a fluid reservoir;

a transcutaneous access tool fluidly coupled to the fluid reservoir; and

a drive mechanism for driving fluid from the reservoir, the drive mechanism comprising

an elongated assembly comprising a first elongated member and a second elongated member;

the first elongated member extending from the plunger;

the second elongated member coupled to the first elongated member;

a drive wheel; and

a clutch mechanism coupled to the drive wheel, wherein the clutch mechanism is configured to allow the second elongated member to pass through when disengaged and is configured to grip the second elongated member when engaged such that the drive wheel rotates the second elongated member to advance the first elongated member and the plunger into the reservoir;

holding the clutch mechanism in a disengaged position;

filling the fluid reservoir with fluid;

passing the second elongated member through the clutch mechanism such that the plunger is retracted within the reservoir;

releasing the clutch mechanism from the disengaged position; and

engaging the clutch mechanism with the second elongated member.

57. The method of claim 56 wherein:

the first elongated member comprises a first threaded member;

the second elongated member comprises a second threaded member;

the second threaded member is in threaded engagement with the first threaded member; and

the clutch mechanism is configured to allow the second threaded member to pass through when disengaged and is configured to grip the second threaded member when engaged such that the drive wheel rotates the second threaded member to advance the first threaded member and the plunger into the reservoir.

58. The method of claim 56 wherein:

the clutch mechanism includes a clutch spring; and

passing the second elongated member through the clutch mechanism further comprises passing the second elongated member through the clutch spring of the clutch mechanism.

59. The method of claim 58 wherein:

engaging the clutch mechanism with the second elongated member further comprises gripping the second elongated member with the clutch spring.

60. The method of claim 58 wherein:

the clutch mechanism includes a spring latch; and

holding the clutch mechanism in a disengaged position further comprises holding the clutch spring in a disengaged position with the spring latch.

61. The method of claim 60 wherein:

releasing the clutch mechanism from the disengaged position further comprises releasing the clutch spring from the spring latch.

62. The method of claim 61 further comprising:

rotating the drive wheel to release the clutch spring from the spring latch.

63. The method of claim 61 further comprising:

rotating the drive wheel to dispense the fluid from the reservoir.

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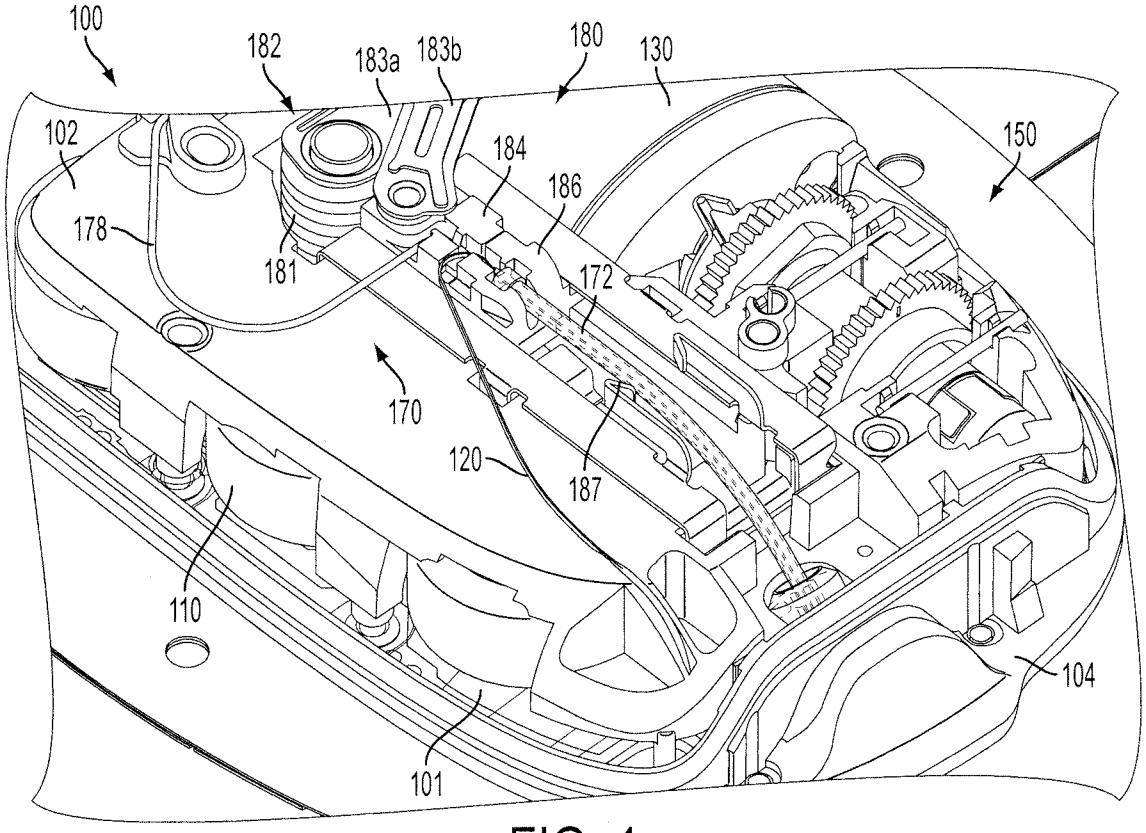
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FIG. 1

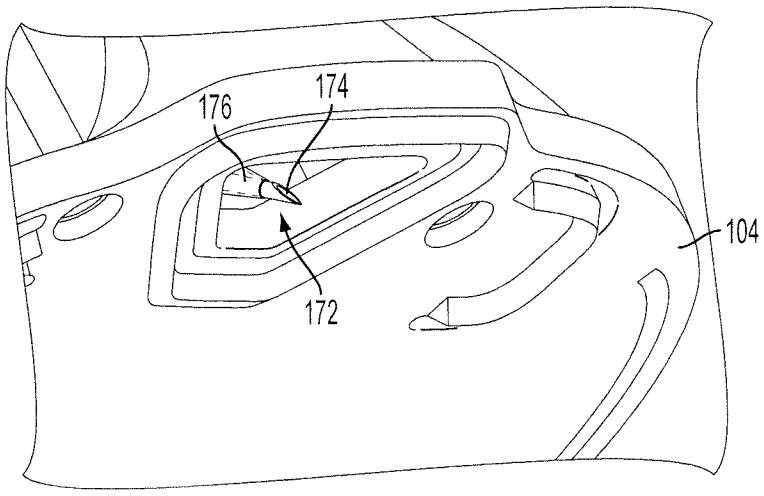
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FIG. 2

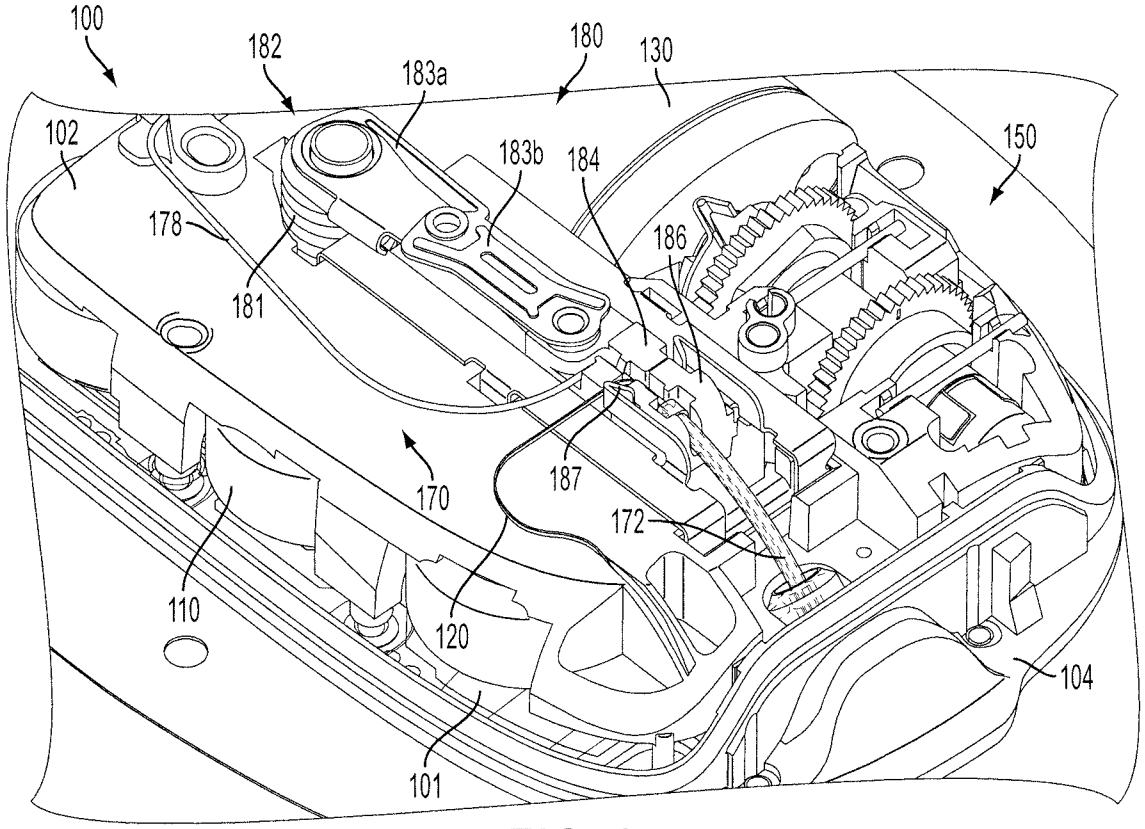
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FIG. 3

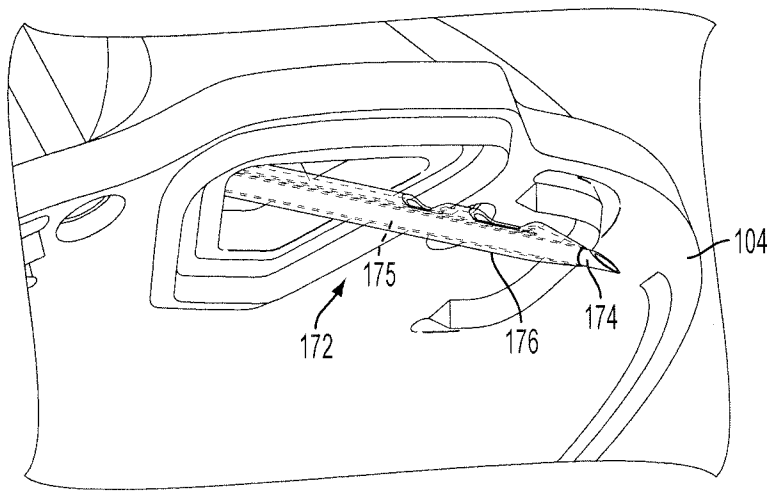
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FIG. 4

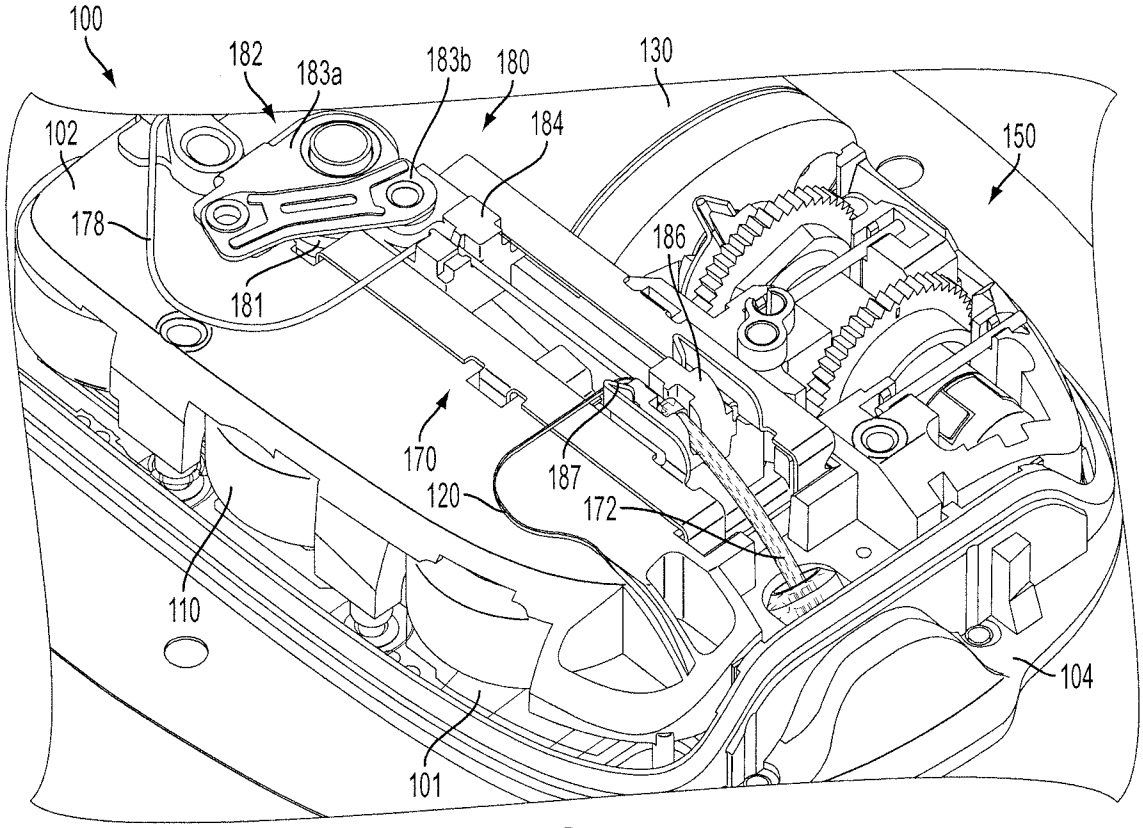
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FIG. 5

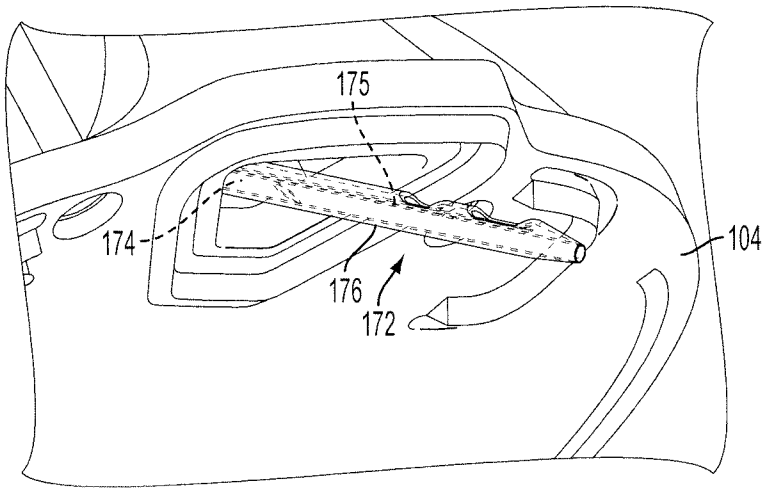
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FIG. 6

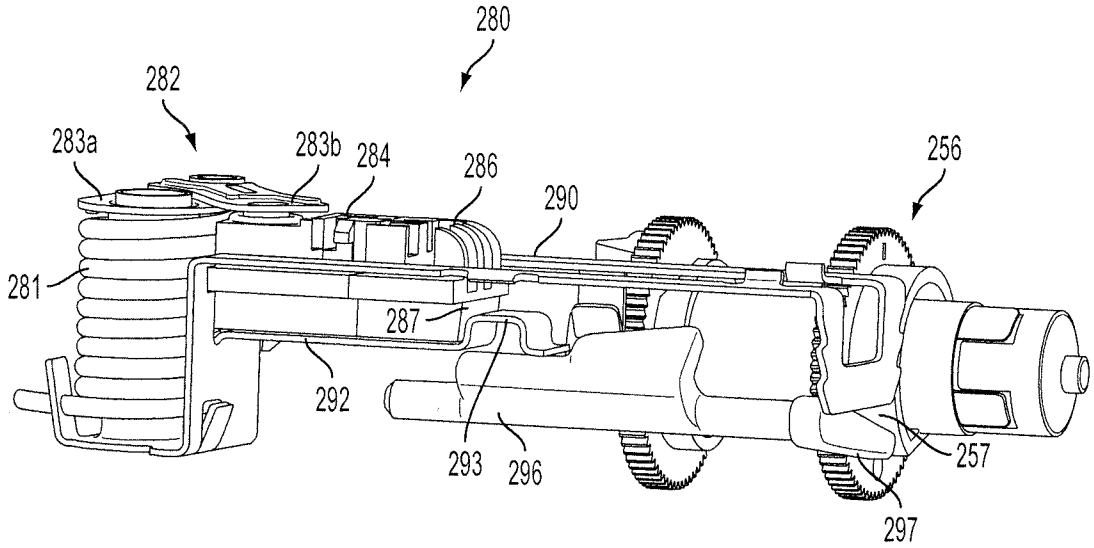
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FIG. 7

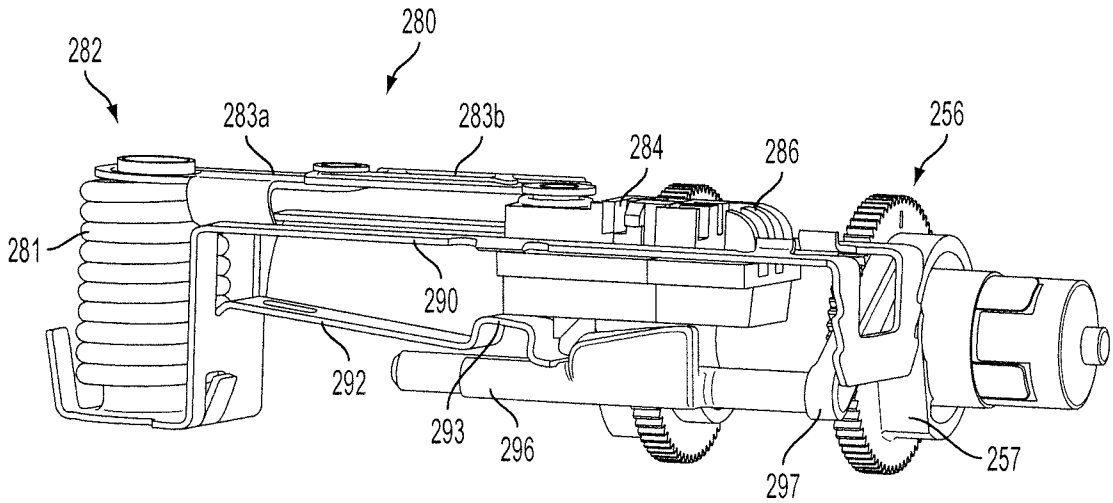
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FIG. 8

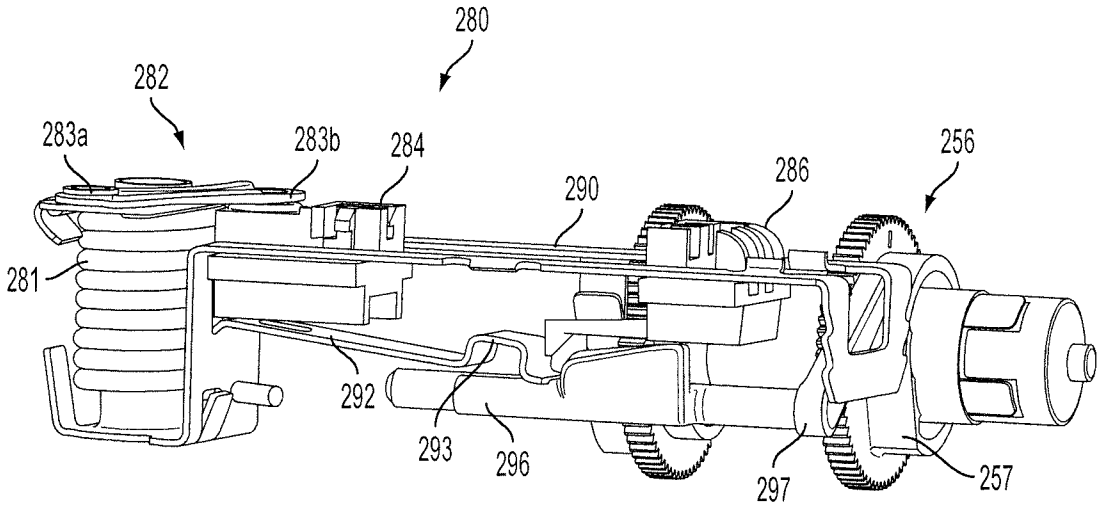
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FIG. 9

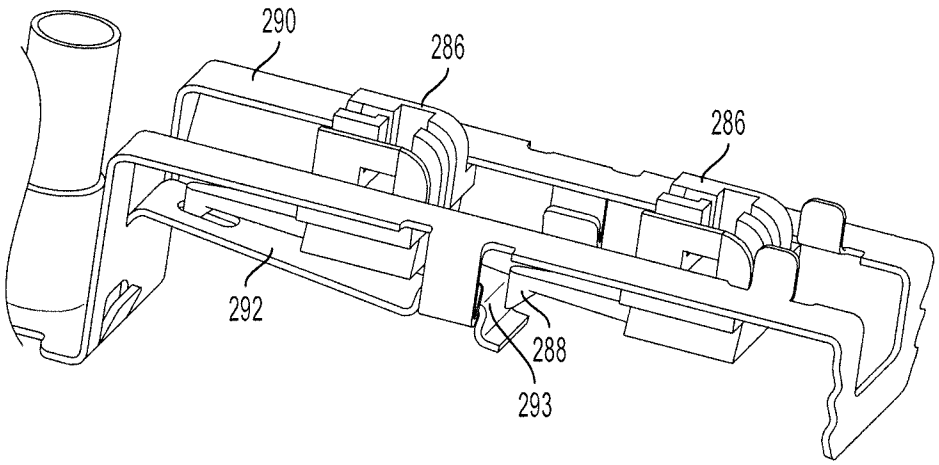
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FIG. 10

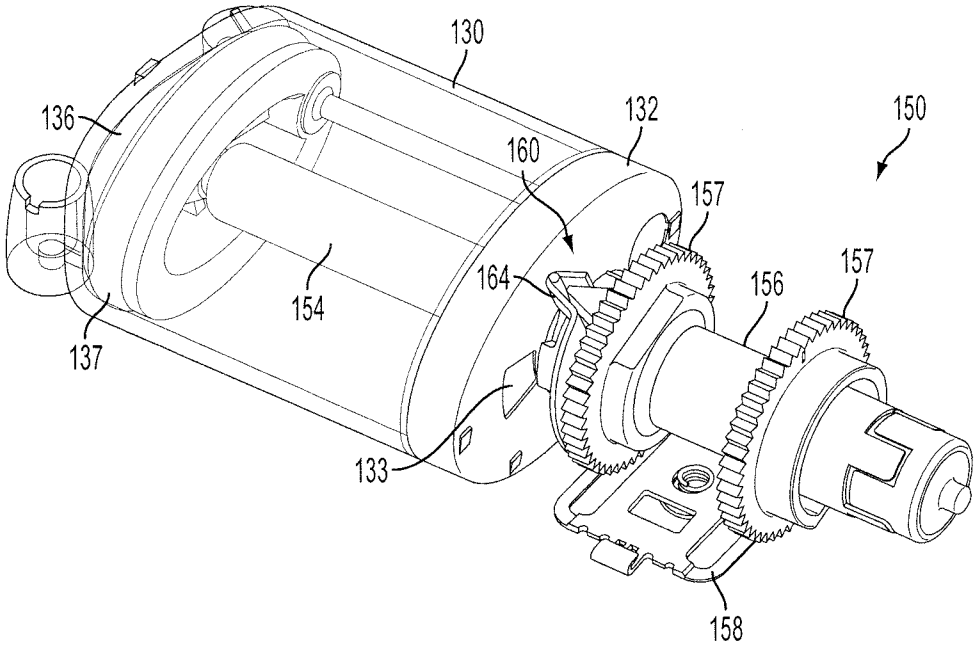
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FIG. 11

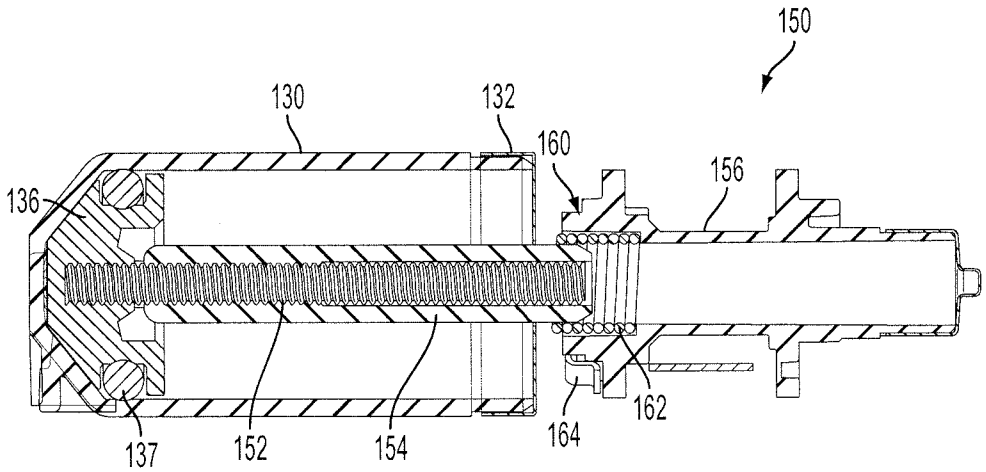
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FIG. 12

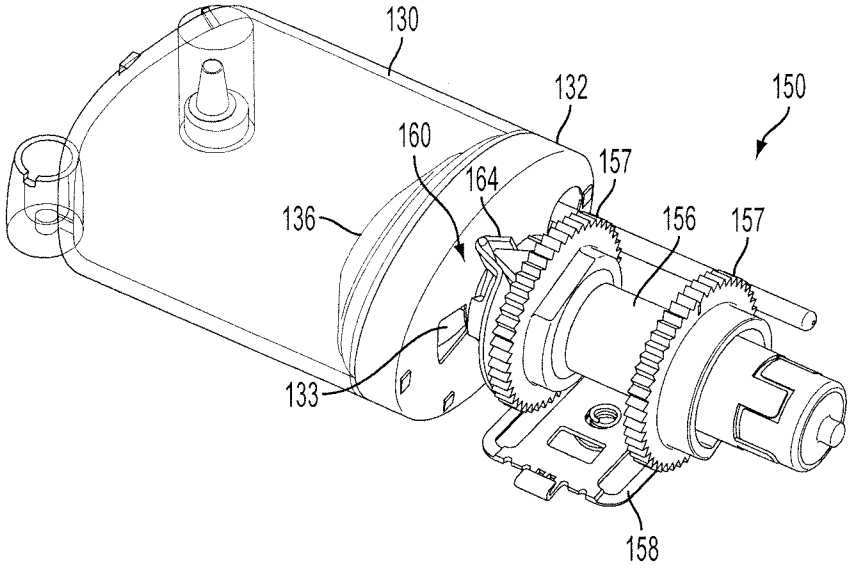
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FIG. 13

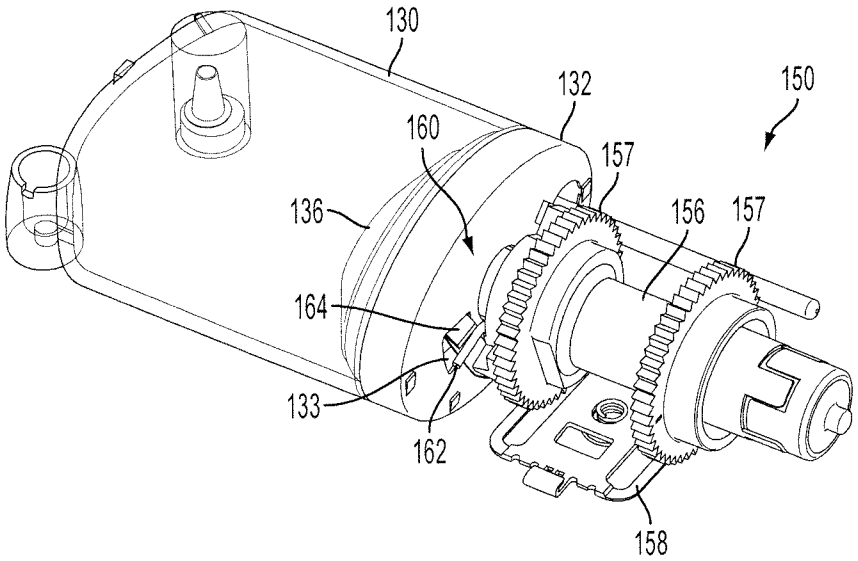
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FIG. 14

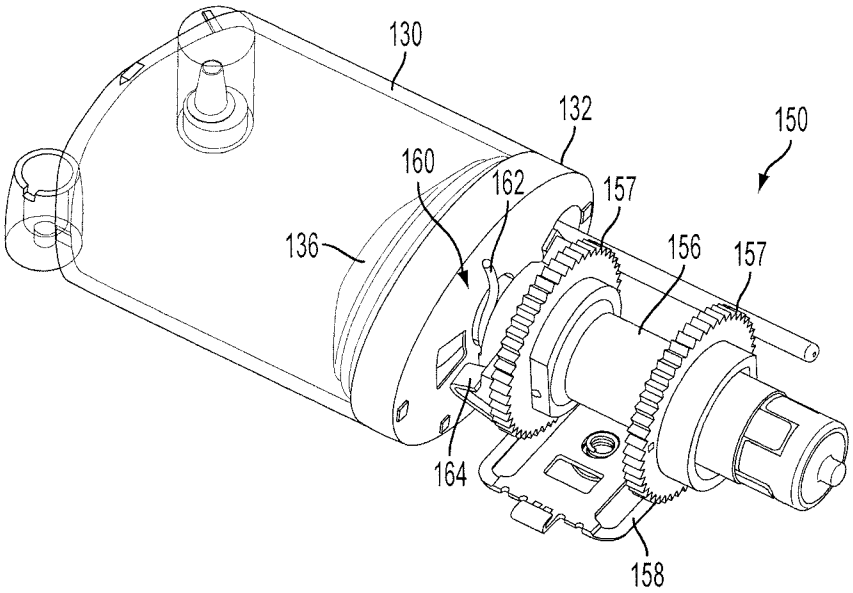
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FIG. 15

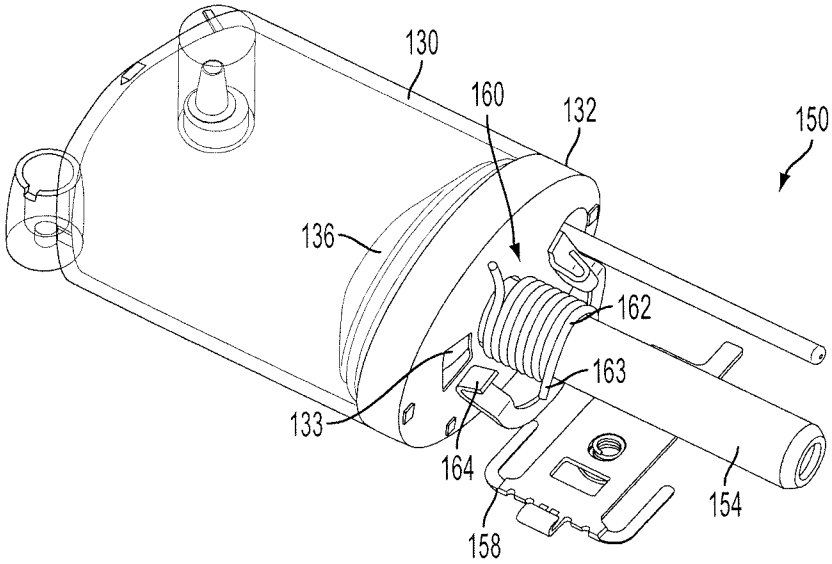
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FIG. 16

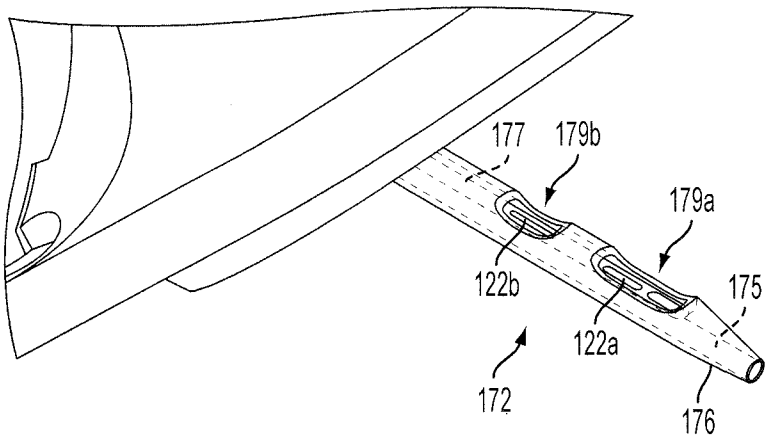

FIG. 17

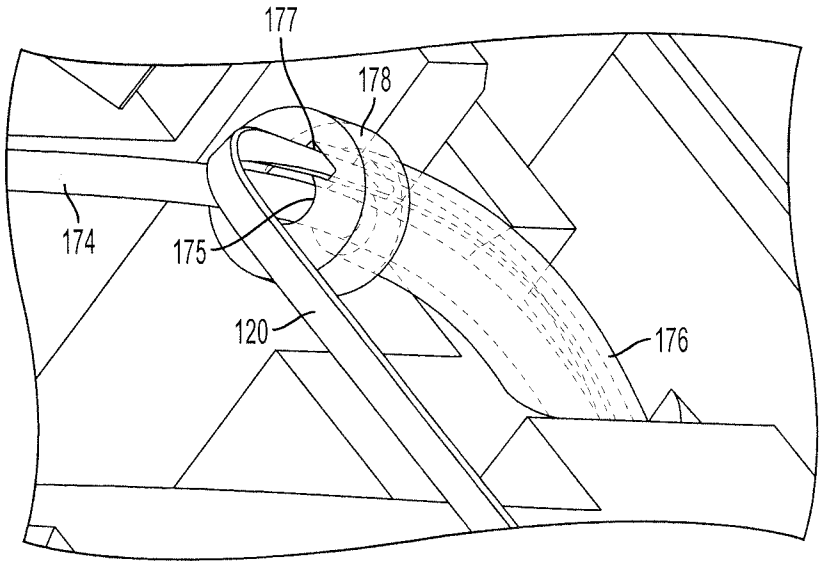

FIG. 18

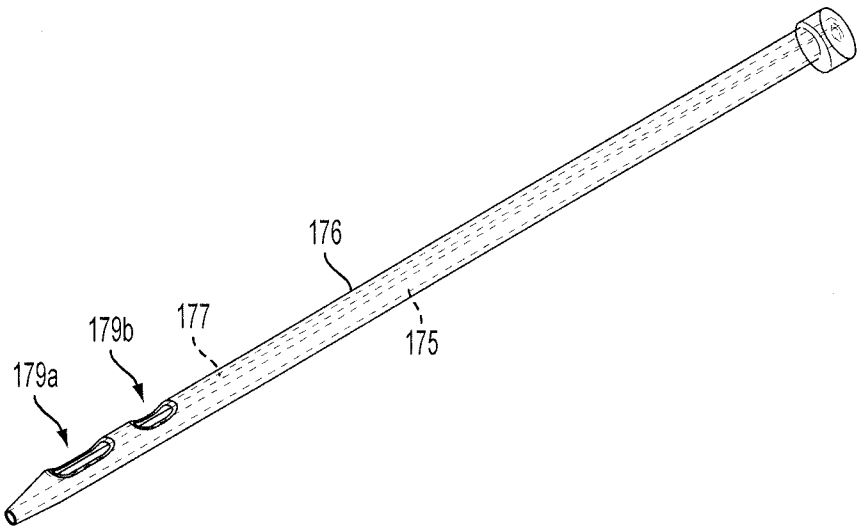

FIG. 19

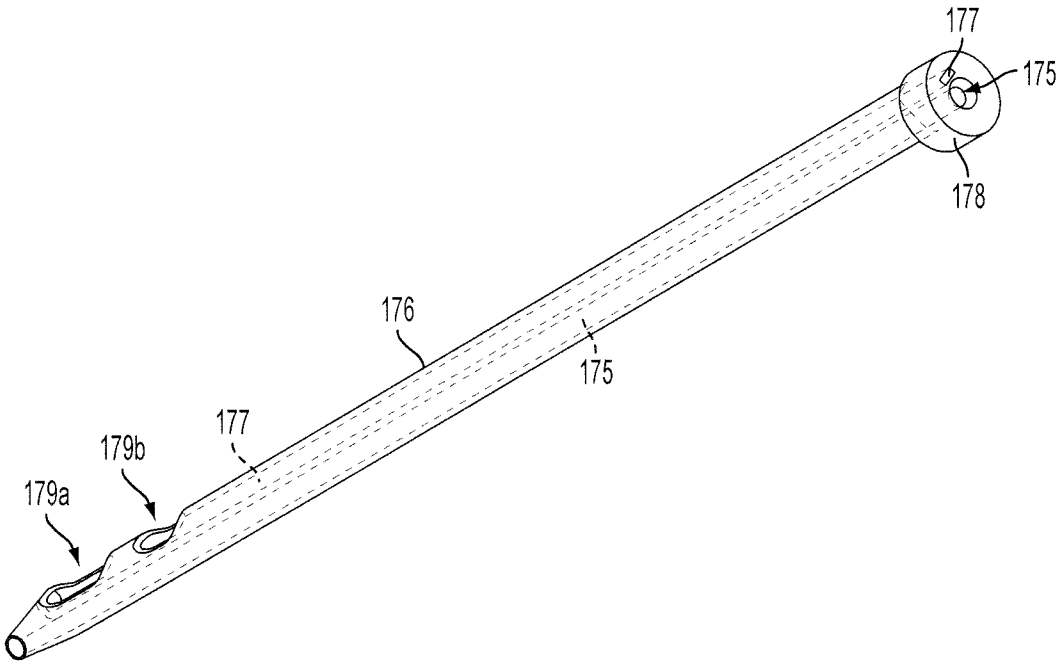

FIG. 20

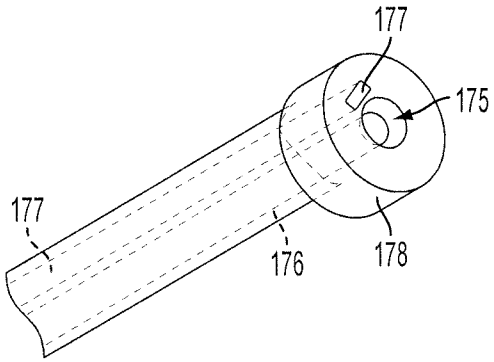

FIG. 21

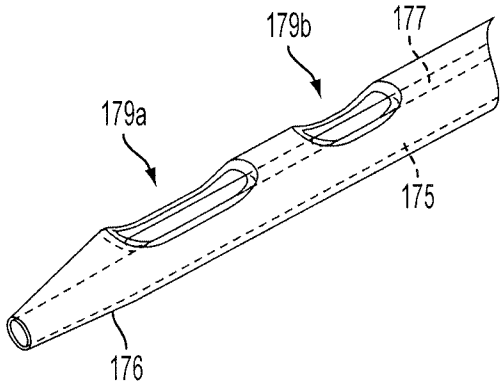

FIG. 22

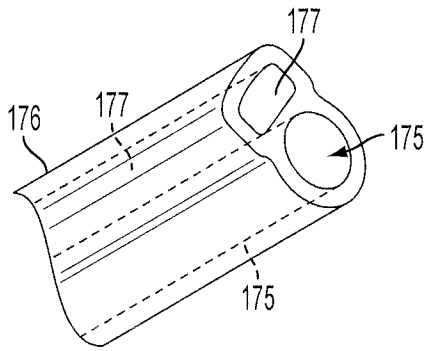

FIG. 23

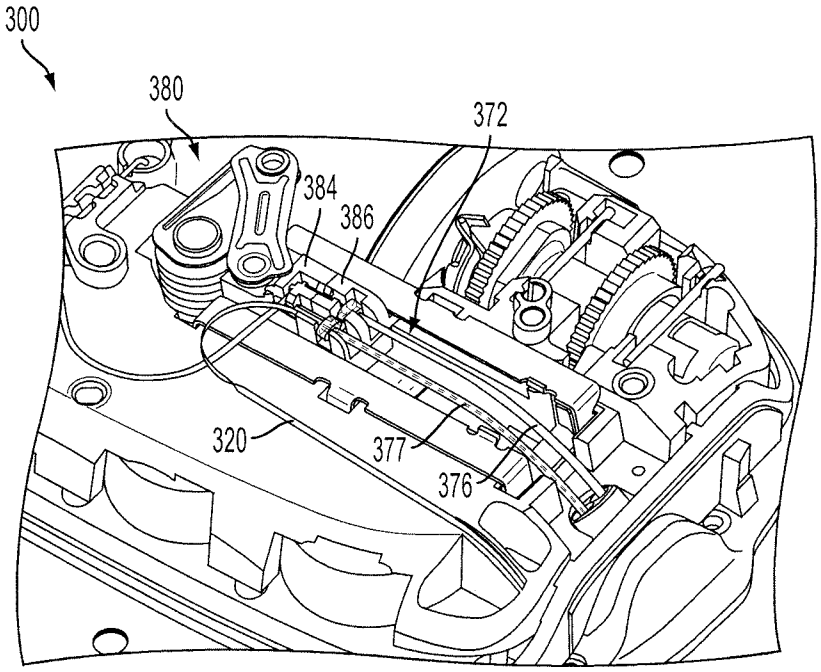

FIG. 24

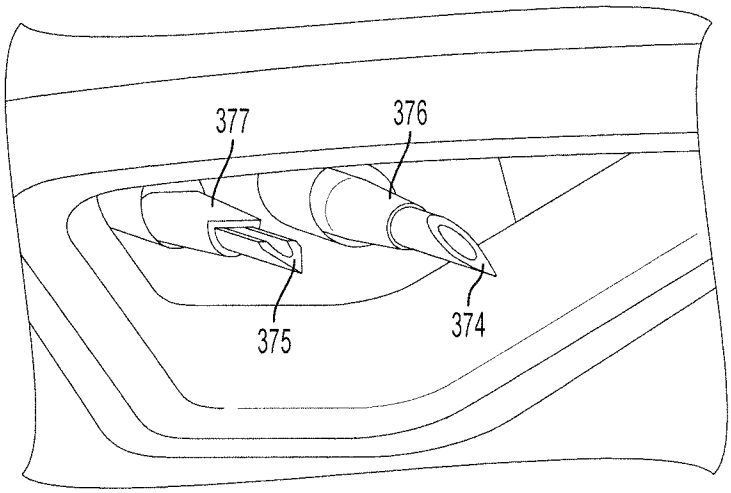

FIG. 25

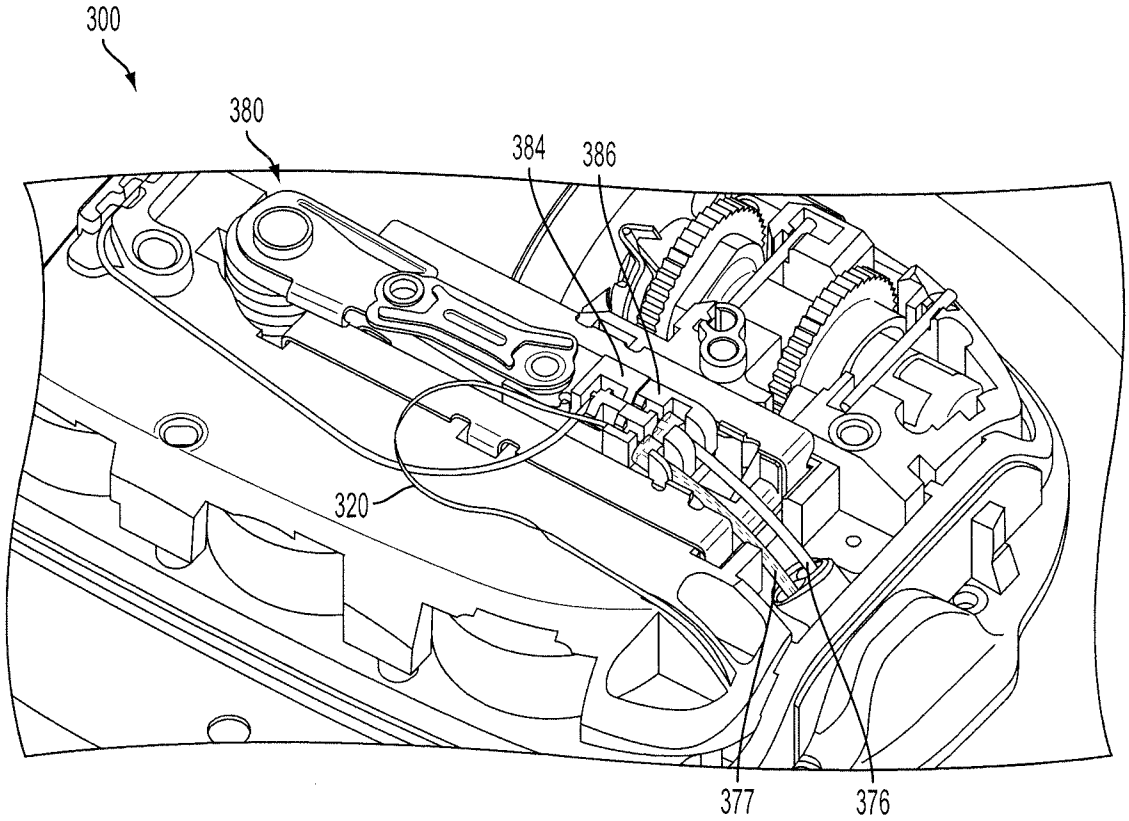

FIG. 26

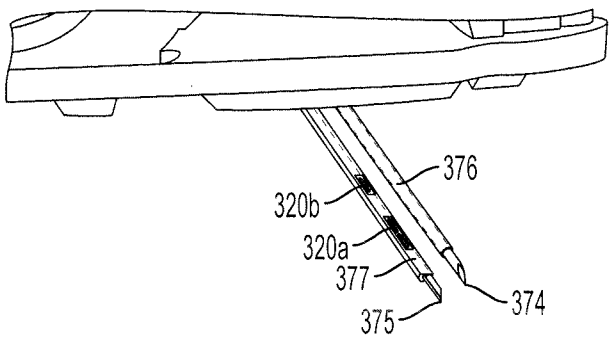

FIG. 27

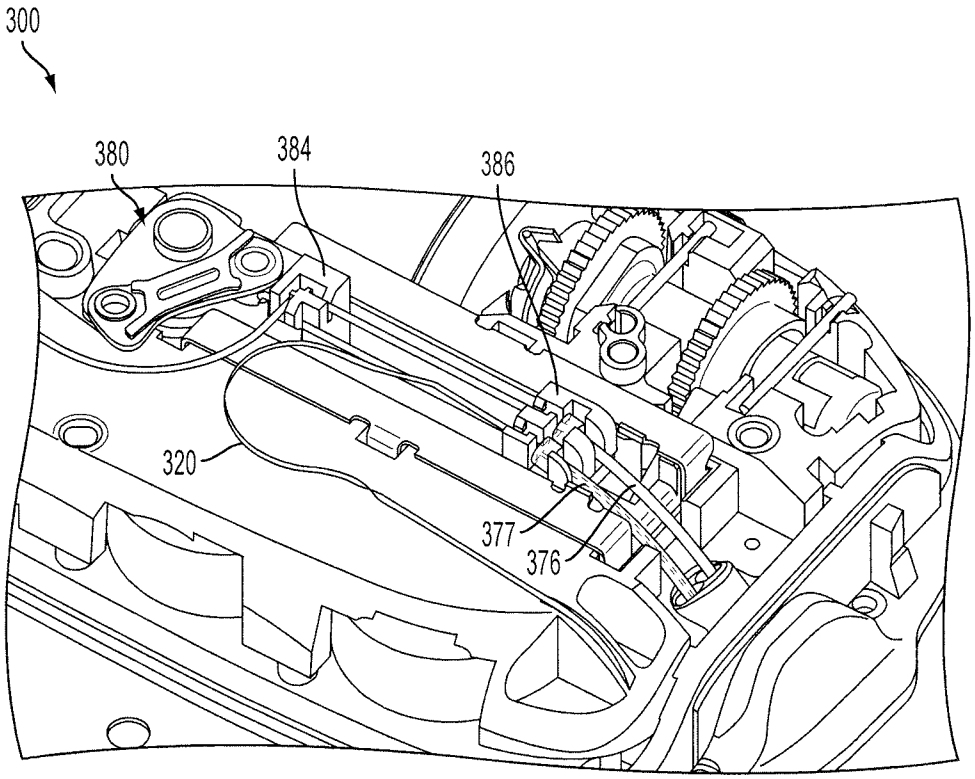

FIG. 28

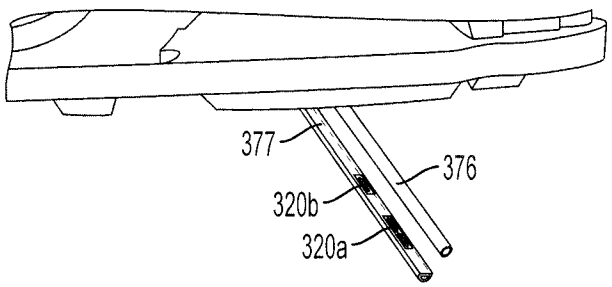

FIG. 29

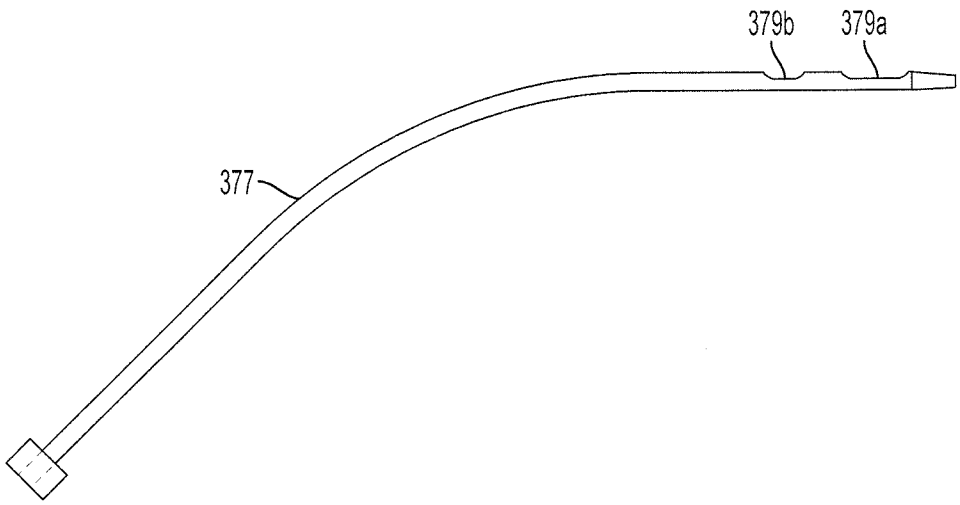

FIG. 30

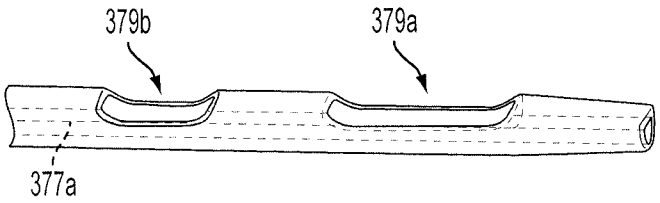

FIG. 31

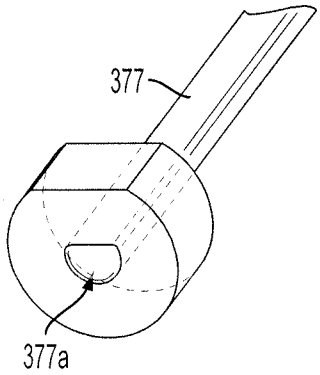

FIG. 32

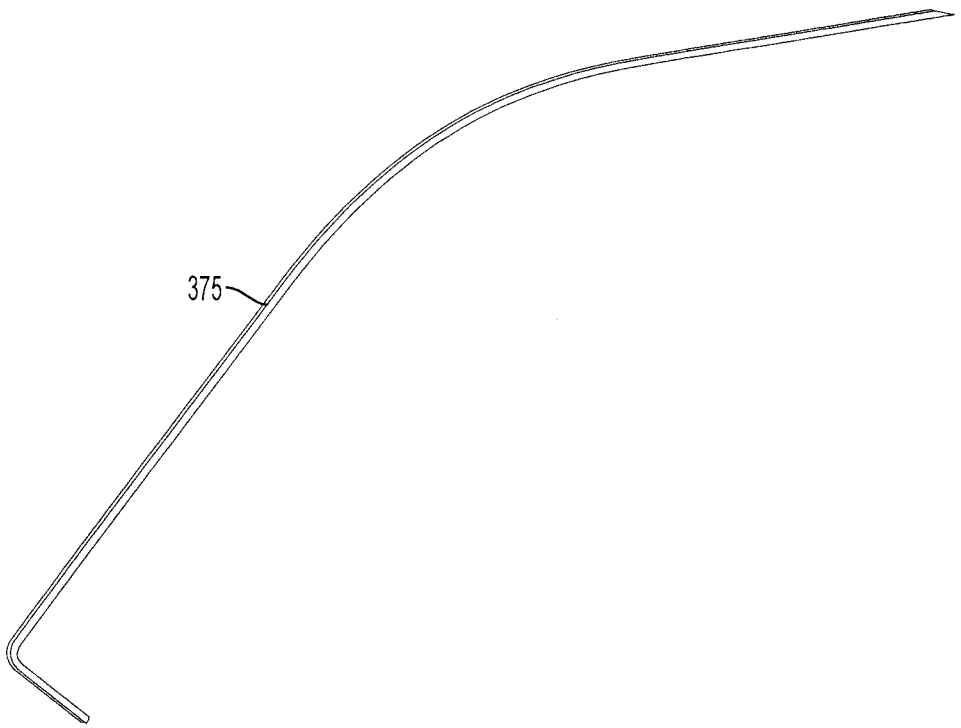

FIG. 33

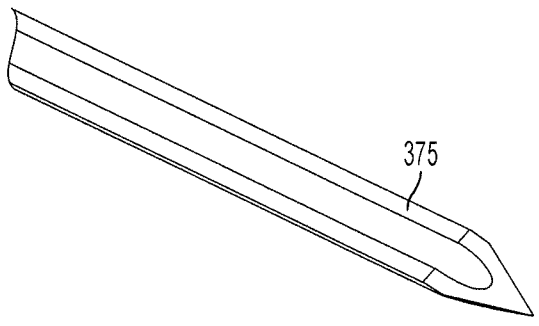

FIG. 34

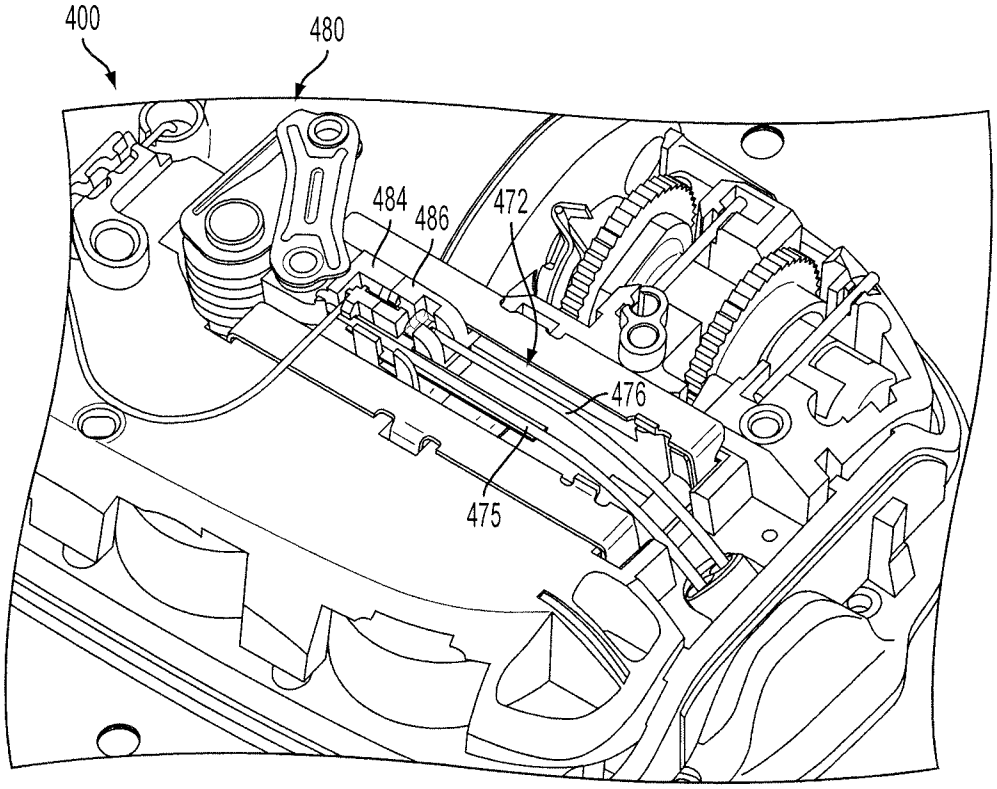

FIG. 35

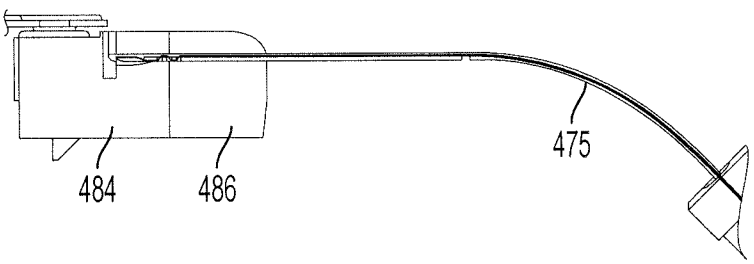

FIG. 36

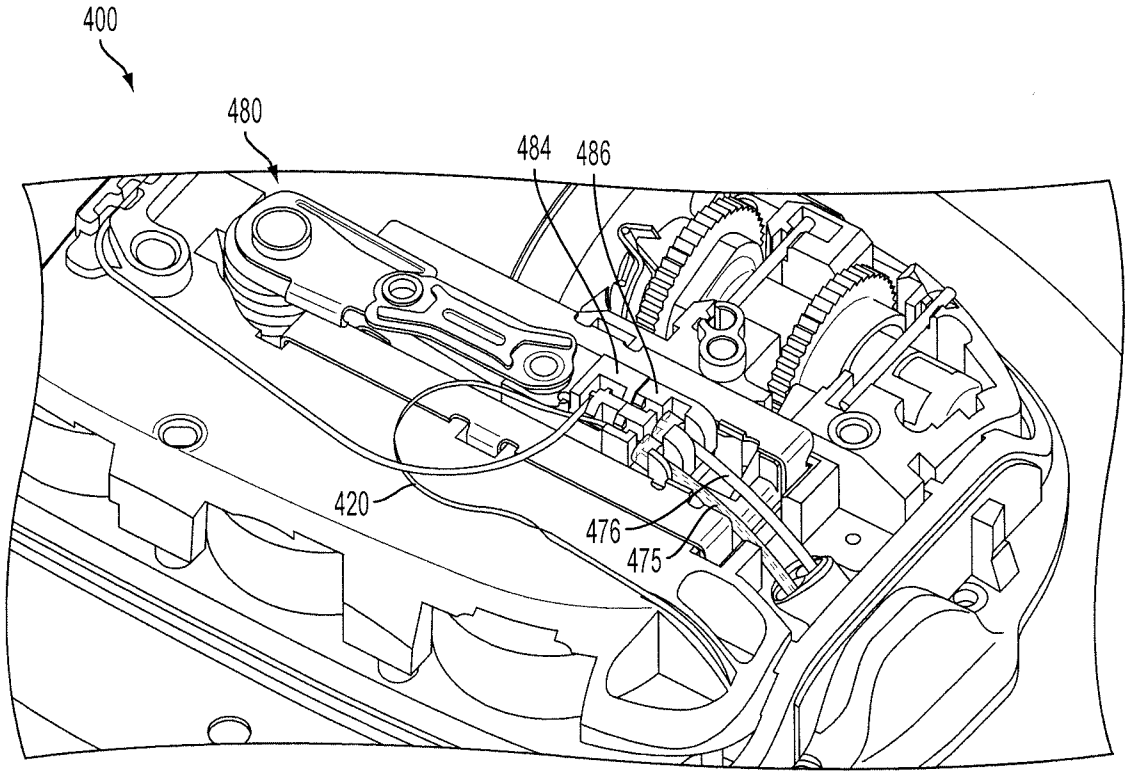

FIG. 37

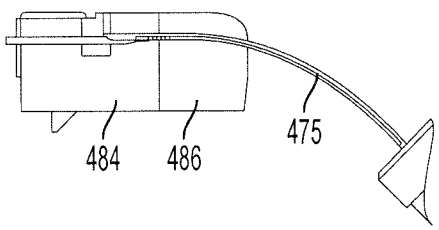

FIG. 38

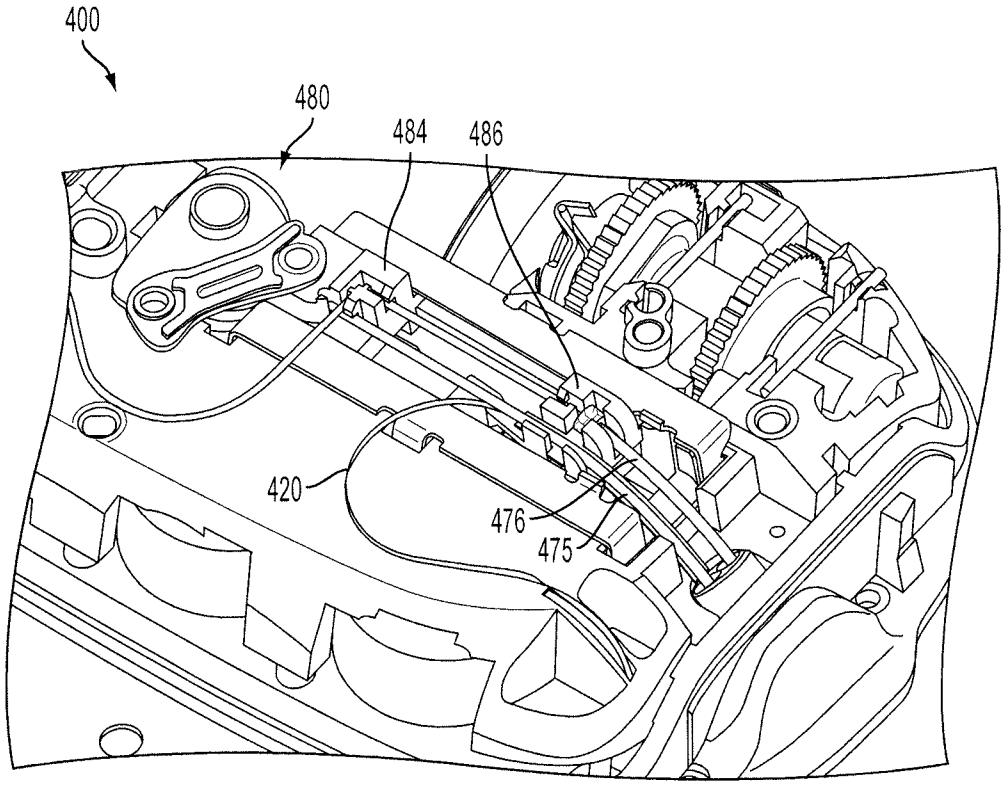

FIG. 39

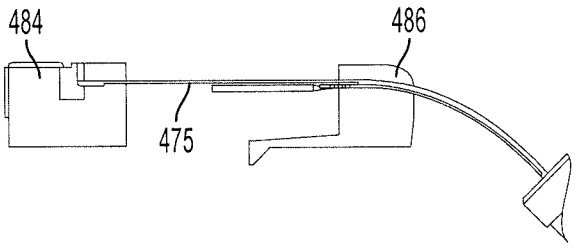

FIG. 40

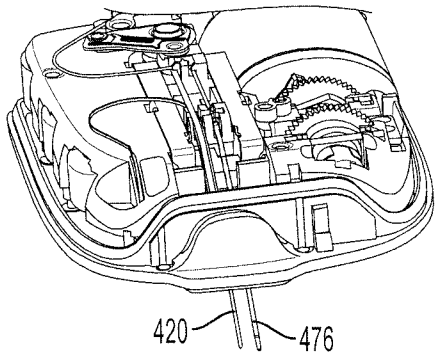

FIG. 41

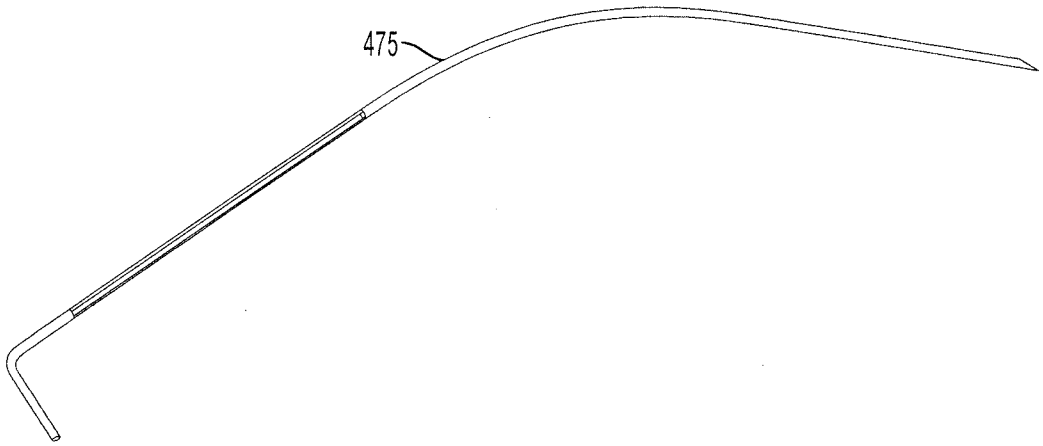

FIG. 42

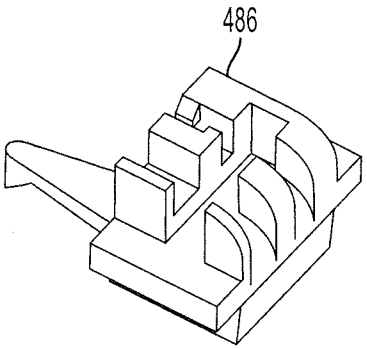

FIG. 43

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/034674

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/157 (2013.01)
USPC - 604/504
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/145, 5/157; A61M 5/142 (2013.01)
USPC - 600/316, 582, 583; 604/65, 173, 504, 891.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 5/14865, 5/4839; A61M 2005/1726 (2013.01)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/0062767 A1 (VAN ANTWERP et al) 05 March 2009 (05.03.2009) entire document	1-5, 11-16, 19-21
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Y		6, 8-10, 17-18, 22-38
Y	US 2008/0004515 A1 (JENNEWINE) 03 January 2008 (03.01.2008) entire document	6, 8-10, 17-18
Y	US 2012/0078161 A1 (MASTERSON et al) 29 March 2012 (29.03.2012) entire document	22-38
Y	US 2006/0178633 A1 (GARIBOTTO et al) 10 August 2006 (10.08.2006) entire document	24-29, 33-38
Y	US 2011/0230833 A1 (LANDMAN et al) 22 September 2011 (22.09.2011) entire document	24-29, 31, 33-38
Y	US 2003/0163097 A1 (FLEURY et al) 28 August 2003 (28.08.2003) entire document	24-29, 33-38

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
30 July 2013	06 AUG 2013
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/034674

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

(See Continuation Sheet Attached)

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
claims 1-38

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US2013/034674

Continuation of Box III

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-38 are drawn to an infusion device.

Group II, claims 39-43 are drawn to a transcutaneous access tool insertion mechanism.

Group III, claims 44-63 are drawn to a fluid delivery device.

The inventions listed as Groups I - III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I, a fluid reservoir for containing a therapeutic fluid; and a transcutaneous access tool fluidly coupled to the fluid reservoir, the transcutaneous access tool for delivering the therapeutic fluid subcutaneously, are not present in Groups II or III; the special technical features of Group II, a first sliding member; a second sliding member; a torsion spring; linkages coupled between the torsion spring and the first sliding member, are not present in Groups I or III; and the special technical features of Group III, a drive mechanism for driving fluid from the reservoir, the drive mechanism comprising: a plunger received in the reservoir; a leadscrew extending from the plunger; a nut threadably engaged with the leadscrew; a drive wheel; and a clutch mechanism coupled to the drive wheel, are not present in Groups I or II.

However, Groups I and III share the technical features of a fluid reservoir for containing a therapeutic fluid; and a transcutaneous access tool fluidly coupled to the fluid reservoir.
Yet, these technical features do not represent a contribution over the prior art.
Specifically, EP1501573 (A2) to Flaherty et al. disclose a transcutaneous fluid delivery system (810) comprising a fluid reservoir (830) for containing a therapeutic fluid (the types of liquids that can be delivered by the fluid delivery device of the present invention include, but are not limited to, insulin, antibiotics, nutritional fluids, total parenteral nutrition or TPN, analgesics, morphine, hormones or hormonal drugs, gene therapy drugs, anticoagulants, cardiovascular medications, AZT or chemotherapeutics; pg. 27) and a transcutaneous access tool (Figs. 1 and 2; pg. 27) fluidly coupled to the fluid reservoir; the transcutaneous access tool for delivering the therapeutic fluid subcutaneously (Referring to Fig. 2, the device 810 generally includes an exit port assembly 870 including a transcutaneous patient access tool, a dispenser 840 for causing fluid from a reservoir 830 to flow to the exit port assembly 870, and a processor or electronic microcontroller (hereinafter referred to as the"local"processor) 850 connected to the dispenser 840. Figs. 1 and 2; pg. 27).

Since none of the special technical features of the Groups I - III inventions is found in more than one of the inventions, unity is lacking.