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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
7 September 2012 (07.09.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/118762 A1

(51) International Patent Classification:
A61M 5/00 (2006.01) *A61M 37/00* (2006.01)

(21) International Application Number:
PCT/US2012/026811

(22) International Filing Date:
27 February 2012 (27.02.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/447,661 28 February 2011 (28.02.2011) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) **Title**: FLOW-RESTRICTING INFUSION DEVICES AND METHODS OF USE THEREOF

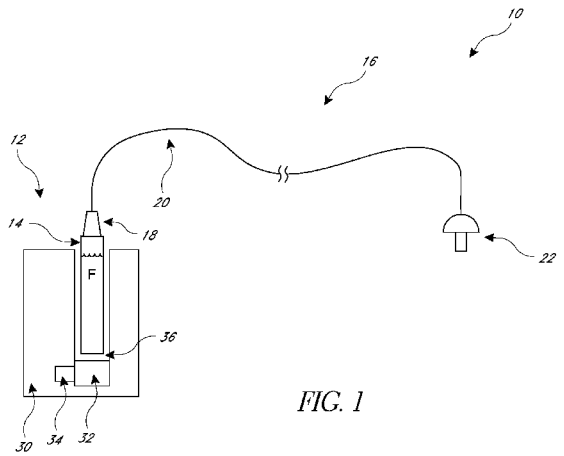


FIG. 1

(57) **Abstract**: An infusion system can include a pump, a reservoir, and an infusion set. The infusion set includes a connector, a length of tubing, and an infusion port. In some embodiments, the connector and the reservoir can be connected by standard luer fittings. In some embodiments, the infusion system comprises a restriction in a fluid flow path. The restriction can be configured to influence the backpressure generated during certain operations of the pump. Some embodiments include a flow-restricting element, which can be a separate component, dulled, and/or recessed within a component of the infusion system, such as the connector. In some embodiments, a method is employed to prime and/or prepare the infusion set.

WO 2012/118762 A1

FLOW-RESTRICTING INFUSION DEVICES AND METHODS OF USE THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the priority benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application No. 61/447,661, filed February 28, 2011, the entirety of which is incorporated herein by reference.

FIELD OF THE DISCLOSURE

[0002] Certain embodiments disclosed herein relate to infusion systems comprising a flow restriction, and are particularly related to infusion systems comprising a flow-restricting element configured to affect an upstream pressure, which may be monitored or detected during a priming operation of the infusion system.

BACKGROUND OF THE RELATED ART

[0003] Subcutaneous injection is a standard method for the delivery of medication into the body of a patient. To facilitate frequent or continuous subcutaneous injection of medication, infusion systems are often used. Infusion systems include injection ports that extend through the patient's skin and may remain in place for several days. Currently, a major application of infusion systems is the delivery of liquid medication, such as insulin, by diabetic patients.

[0004] Infusion systems generally include a pump configured to receive a reservoir, a connector connectable with the reservoir, and a length of tubing that is connectable with the connector at one end and an injection port at the other end. Liquid medication is normally added to the reservoir by the user connecting a vial containing the liquid with an end of the reservoir having an opening, which can be sealed by an elastic septum. Some embodiments of the reservoir have a movable plunger (similar to a syringe plunger) that is drawn backward to draw a volume of a liquid from the vial, through the opening, and into the reservoir. The reservoir containing the liquid is inserted into the pump, which is controllable to deliver the medication from the reservoir. The connector is connected to the reservoir. If the reservoir opening is sealed by a septum, a needle of the connector pierces the septum of the reservoir, thereby opening a fluid path for the medication to travel out from the reservoir. The tubing is connected with the connector and the infusion

port, which is at least partly disposed in the body of the patient. Thus, liquid medication can be delivered from the reservoir, through the connector, tubing, and injection port, and into the patient's body.

[0005] To avoid infusing an embolus into the patient, the tubing of the infusion system is normally primed prior to connecting the tubing with the infusion port. Priming generally involves evacuating air in the tubing by pumping liquid into one end of the tubing, thereby driving the air out the other end of the tubing. Often, priming is accomplished by pumping a volume of the liquid from the reservoir through one end of the tubing until the liquid begins to flow from the other end of the tubing.

SUMMARY OF THE DISCLOSURE

[0006] In some embodiments, a pump in an infusion system can be configured to monitor or detect a backpressure of a fluid during a priming operation. In some instances, the backpressure is indirectly monitored or detected. For example, in some arrangements, the pump monitors or detects how much force would be needed to advance a plunger in the pump, then uses that force value (possibly in conjunction with other data, e.g., the plunger's surface area) to calculate the backpressure. In certain embodiments, as the fluid is pumped through the tubing during the priming operation, the monitored or detected backpressure and/or values relating thereto (e.g., length of time at a certain backpressure value, inside diameter of the tubing, length of the tubing, and combinations thereof) can be employed in an algorithm configured to approximate when the tubing has been primed and thus discontinue or pause the priming operation.

[0007] However, in certain instances, problems can arise with control of the priming operation. For example, in embodiments in which the tubing has a larger inside diameter or shorter length than the values used by the algorithm, the backpressure may not reach the level that the algorithm has determined would correspond to the tubing being about full of liquid, so the pump may shut-off belatedly or not at all. This can result in a waste of medicine and battery power of the pump. In embodiments in which the tubing has a smaller inside diameter or longer length than the values used by the algorithm, the backpressure may prematurely reach the level that the algorithm has determined would correspond to the tubing

being about full of liquid, so the pump may shut-off too early and leave a volume of air in the tubing. This could result in an embolus being infused into the patient.

[0008] In some embodiments, the backpressure is affected by a flow restriction disposed in the fluid flow path. As such, reliable and repeatable operation of processes which depend upon backpressure detection typically require manufacturing the flow restriction with a high degree of precision and accuracy. However, given that the flow restriction is normally the smallest diameter section of the fluid flow path, the flow restriction can be one of the more difficult portions of the infusion system to manufacture precisely and accurately. Furthermore, secondary operations, such as boring of the flow restriction (e.g., by laser, drill, or other process), add processing time, steps, and expense to the infusion system.

[0009] A separate flow-restricting element can be incorporated into the infusion system. In some embodiments, the flow-restricting element can precisely, accurately, and cost-effectively provide the flow restriction. Generally, the flow-restricting element includes a lumen having an inside diameter configured to restrict flow therethrough (and thus affect the backpressure) and an outside diameter configured to be fixedly received in a component of the infusion system, such as the connector. As such, in certain embodiments, only the flow-restricting element is made to the exacting tolerances for the flow restriction; the other components of the infusion system can be made to more easily manufactured tolerances, unless necessary to meet other requirements.

[0010] In some embodiments, improper location of the flow restriction in the infusion system can lead to adverse results. For example, if the flow restriction is located in a position through which the liquid flows during the process of drawing liquid into the syringe, then the risk of embolus may be increased. Transfer of fluid from a vial into the syringe can be performed quickly. The consequent high fluid pressure, turbulence, or both, may create bubbles in the fluid. Such bubbles may be small enough to present difficulty in purging them. Further, over time, these small bubbles may join to form a bubble that is large enough to be delivered into the patient, thereby creating a dangerous embolus. On the other hand, if the flow-restricting element is disposed in a location through which the fluid does not flow during filling of the syringe (e.g., the connector or tubing), then the formation of such bubbles can be reduced or avoided.

[0011] Employing a needle in the connection between the reservoir and the tubing can entail significant disadvantages and risks. For example, government and/or industry may require specialized packaging and/or disposal of implements that have needles (e.g., "sharps" disposal containers and processing), which can add cost and inconvenience to the device and its use. Also, in the process of removing the component with the needle from its packaging and/or during manipulation of the same, the patient—or anyone who comes in contact with the connector—may inadvertently stick themselves with the needle. Indeed, the risk of unintentional needle sticks can be particularly acute for diabetics, who may suffer from poor manual dexterity. Such needle sticks can be painful as well as result in damage to the needle. Moreover, when a person receives an unintentional needle stick they may bleed, which can be hazardous to that person and others. Further, an unintentional needle stick can expose a person to dangerous blood-born pathogens. In some embodiments, the flow-restrictor is non-piercing (e.g., not sharp, blunt, and/or positioned and/or oriented to avoid piercing a septum on a vessel or a finger).

[0012] Significant problems can be associated with infusion systems having an elastic septum in the reservoir and/or the connector. For example, the septum can constitute a barrier that generally needs to be penetrated by the needle to open the flow path for the liquid medication inside the reservoir. The septum can, thus, increase the amount of force that the user is asked to employ to open the reservoir, which could increase the chance of a component slipping when mating the reservoir with the connector and potentially resulting in a needle stick (as discussed above). Further, repeated puncturing of the septum can result in pieces of the septum becoming dislodged, falling into the medication, obstructing the flow path, and potentially being infused into the patient. Furthermore, the septum is an additional component that can add material and manufacturing cost to the infusion system.

[0013] Some embodiments of an infusion system can employ a flow-restricting element that is substantially blunt. Some embodiments include a flow-restricting element that is manufactured separately from other elements of the infusion system. Some embodiments include a flow-restricting element that is located outside of the fill path for the reservoir. Some embodiments comprise a substantially unobstructed fluid flow path from the

reservoir to the flow-restricting element. Some embodiments comprise more than one of the features disclosed here.

[0014] In some embodiments, a method of preparing an infusion system includes obtaining an infusion pump, a vessel having a substantially unobstructed opening, and an infusion set. The infusion set can comprise a cap and a port in fluid communication by a tube. The cap can have a passage therethrough. The passage can house at least part of a flow-restricting member having a lumen therethrough and being configured to restrict fluid flow through the cap. The flow-restricting member can be made of a first material and the remainder of the cap or another portion of the cap can be made of a second material. For example, in some embodiments, the flow-restricting member can be made of a metal (e.g., stainless steel) and another portion of the cap can be made of a polymer. In some embodiments, an inner diameter of the flow-restricting member is smaller, or substantially smaller, than an inner diameter of at least a portion of the infusion tubing (or a substantial portion of the tubing) positioned between the cap and an infusion set configured to be inserted into a patient and configured to be in contact with flowing fluid during infusion. In some embodiments, the flow-restricting member is an integral, unitary portion of the cap and/or is made of the same material as the cap.

[0015] Some embodiments of the method include drawing a fluid into the vessel. Some embodiments include connecting the vessel and the cap. Certain embodiments include inserting at least a part of the vessel into the pump. Some embodiments include urging a portion of the fluid through the cap and the tube. For example, the urging can be accomplished such that at least some of the portion of the fluid is expelled from the end of the infusion set.

[0016] Certain embodiments of the method are useful in detecting a backpressure in the vessel or the infusion set. The flow restriction can be configured to affect the detected backpressure. Certain embodiments include employing the detected backpressure in an algorithm to estimate the completion of the priming step.

[0017] According to some embodiments, the method can include employing the detected backpressure in an algorithm to recognize the presence of a leak in the infusion system. In some embodiments, the method includes triggering an alarm if the detected

backpressure is less than or equal to about 0.5 psi when the portion of the fluid is urged through the cap.

[0018] Some embodiments include disconnecting the cap from the vessel, the flow-restricting member being recessed in the cap (in some embodiments, recessed to an extent that it inhibits contact with a human finger). In some embodiments, the flow-restricting member is configured to be positioned within the cap such that the flow-restricting member is spaced from, and is not required to pierce, an end of the vessel when the cap and vessel are connected and fluid is flowing through the cap. Some embodiments include maintaining a distance between the vessel and the flow-restricting member when fluid is flowing through the cap, the distance being along the direction of the flow of the fluid.

[0019] In certain embodiments, the cap is directly connected with the vessel. In some embodiments, the backpressure is detected by the pump. In certain embodiments, the passage is formed in a radially inwardly extending shoulder of the cap, and the flow restriction further comprises a hollow shaft joined with the passage.

[0020] According to certain embodiments, the flow-restricting member further comprises ends that are dull. In some embodiments, the flow-restricting member is spaced apart from the vessel when the vessel is connected with the cap. In certain embodiments, the first material is stainless steel and the second material is a thermoplastic. In some embodiments, the flow-restricting member is longitudinally recessed in the cap by a recess distance. For example, the recess distance can be greater than an inside diameter of the cap.

[0021] Some embodiments of a method of manufacturing an infusion set cap include forming a flow-restricting element from a first material. The flow-restricting element can have a channel therethrough. The flow-restricting element can have a first end and a second end. Some embodiments of the method include forming a first blunt end on the first end of the flow-restricting element and a second blunt end on the second end of the flow-restricting element.

[0022] Certain embodiments of the method include molding a luer lock connector from a second material. The luer lock connector can have a first side and a second side. The luer lock connector can be molded around a portion of the flow-restricting element such that the flow-restricting element is retained in the luer lock connector and the channel provides a

fluid flow path between the first side and the second side. The first side can be configured to connect with a vessel having a corresponding luer lock connection and the second side can be configured to connect with a tube for transmitting liquid to an infusion port.

[0023] Certain embodiments of the method include recessing the flow-restricting element in the luer lock connector such that contact between the flow-restricting element and a human finger is inhibited. In some embodiments, the first blunt end is disposed within the first side of the luer lock connector, and the second blunt end is disposed within the second side of the luer lock connector. In certain embodiments, the first material is stainless steel and the second material is a thermoplastic. In some embodiments, the flow-restricting element is formed with an inside diameter that is less than an inside diameter of the corresponding luer lock connection of the vessel.

[0024] According to some embodiments, a method of priming a tube for an infusion system includes coupling a connection member with a vessel having a substantially unimpeded opening. The connection member can be connected with a first end of a tube, thereby putting the connection member and a second end of the tube in fluid communication with a flow path therebetween. Some embodiments of the method include placing a flow-restricting member in the flow path. The flow-restricting member can be configured to restrict a flow of a liquid from the vessel to the second end of the tube. The flow-restricting element can have a distal end directed toward the vessel. For example, the distal end can be nearer to the vessel than the other end of the flow-restricting element (e.g., the other end is located a greater distance from the vessel than a distance between the distal end and the vessel). The distal end can be recessed within the connection member.

[0025] Some embodiments of the method include controlling a pump to urge a liquid from the vessel. Certain embodiments include detecting a force resisting the urging of the fluid from the vessel. Some embodiments include estimating when the tube has been substantially filled with the liquid such that some of the liquid begins to exit a second end of the tube. For example, the estimation can be accomplished at least in part on the detected force. Some embodiments include disabling the pump after estimating that the tube has been substantially filled with the liquid.

[0026] In some embodiments, the flow-restricting member is disposed in the connection member. In certain embodiments, the flow-restricting member is disposed in the tube. In some embodiments, the distal end of the flow-restricting member further is blunt or rounded. According to certain embodiments, the distal end of the flow-restricting element is spaced apart from the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Various embodiments are depicted in the accompanying drawings for illustrative purposes, and should in no way be interpreted as limiting the scope of the embodiments. In addition, various features of different disclosed embodiments can be combined to form additional embodiments, which are part of this disclosure.

[0028] Figure 1 illustrates a schematic diagram of an embodiment of an infusion system.

[0029] Figure 2 illustrates a partial isometric view of an embodiment of a reservoir that can be employed in an infusion system, such as that of Figure 1.

[0030] Figure 3A illustrates an isometric view of an embodiment of a connector that can be employed in an infusion system, such as that of Figure 1.

[0031] Figure 3B illustrates an isometric view of an embodiment of a connector that can be employed in an infusion system, such as that of Figure 1.

[0032] Figures 4A illustrates an isometric exploded view of the reservoir of Figure 2 and the connector of Figure 3A.

[0033] Figure 4B illustrates an isometric exploded view of the reservoir of Figure 2 and the connector of Figure 3B.

[0034] Figure 5A illustrates a partial cross-section of the reservoir of Figure 2 and the connector of Figure 3A in a mated configuration.

[0035] Figure 5B illustrates a partial cross-section of the reservoir of Figure 2 and the connector of Figure 3B in a mated configuration.

[0036] Figure 6 illustrates a schematic diagram of an embodiment of an infusion system.

[0037] Figure 7 illustrates an isometric view of an embodiment of a coupling element that can be employed in an infusion system, such as that of Figure 1 and/or Figure 6.

[0038] Figure 8 illustrates a schematic diagram of a method of priming an embodiment of an infusion system.

DETAILED DESCRIPTION OF CERTAIN EMBODIMENTS

[0039] A variety of infusion systems are described below to illustrate various examples that may be employed to achieve one or more desired improvements. These examples are only illustrative and not intended in any way to restrict the general inventions presented and the various aspects and features of these inventions. For example, although embodiments and examples are provided herein in the medical field, the inventions are not confined exclusively to the medical field and certain embodiments can be used in other fields. Furthermore, the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. No features, structure, or step disclosed herein is essential or indispensible.

[0040] As shown in Figure 1, an infusion system 10 can include a pump 12, a reservoir 14, and an infusion set 16, which can include a connector 18, a length of tubing 20, and an infusion port 22 that can be attached to a patient or to another component that is attached to a patient. The connector 18 can comprise a vessel cap. Further details regarding some example embodiments of infusion ports (and insertion devices therefore) are provided in United States Patent Application Publication Nos. 2007/0185441 and 2009/0124979 as well as United States Patent No. 7,309,326, each of which is incorporated herein by reference in its entirety.

[0041] In some embodiments, the pump 12 includes a housing 30, a drive mechanism 32, a controller 34, and a compartment 36 configured to receive at least part of the reservoir 14. In some embodiments, the pump 12 is configured to drive a fluid F (e.g., insulin) from the reservoir 14 and through the infusion set 16. Further, the pump 12 can be configured to monitor or detect a backpressure that is generated as the fluid is driven by the pump 12. Used herein, the term "backpressure" means a pressure in opposition to a driving force. Backpressure can include, for example, the fluid pressure opposing the impelling force of the pump 12, the frictional force between the fluid and the components of the reservoir 14 and the infusion set 16, and the elevation head of the fluid.

[0042] Referring to Figure 2, the reservoir 14 can have an elongate body 40 forming a chamber 42 (Figures 5A and 5B) and a proximal end 44. As used herein, "proximal," or any derivative thereof, refers to a direction toward the end of the infusion system 10 configured to penetrate the skin of the patient (e.g., the infusion port 22); "distal," or any derivatives thereof, refers to the opposite direct (e.g., the direction moving away from the infusion port 22 and toward the pump 12). The proximal end 44 of the reservoir 14 can include an extension portion 46, an inner flange 48, and an outer flange 50. The extension portion 46 can include an aperture 52 and a passage 54 in fluid communication with the chamber 42 to allow the fluid to flow substantially unimpededly and/or unobstructedly between the chamber 42 and the aperture 52. As shown, the extension portion 46 can be shaped as a nozzle and can project proximally of the chamber 42 and/or the inner and outer flanges 48, 50. In some embodiments, the proximal end 44 is configured as a luer fitting in accordance with an industry standard (e.g., ISO594-1, ISO594-2, and the like), as discussed below.

[0043] The inner flange 48 and outer flange 50 can each include one or more mating structure (e.g., threads, detents, ratchets, frustoconical surfaces, and the like). For example, the outer flange 50 or other portion of the reservoir 14 can include threads configured to mate with corresponding threads formed in the housing 30 of the pump 12, to thereby allow the reservoir 14 to be securely held within the compartment 36 of the pump 12. As shown, the outer flange 50 can intersect, or in some embodiments comprise, a projection 56 to facilitate grasping and/or manipulation of the reservoir (e.g., rotating the reservoir to engage the mating threads discussed above). The inner flange 48 can be configured to mate with the connector 18. For example, the inner flange 48 can include threads configured to mate with threads formed on the connector 18 to secure the reservoir 14 to the connector 18 and/or place the passage 54 in fluid communication with the connector 18.

[0044] With reference to Figures 3A and 3B, the connector 18 can include a proximal end 60 with a proximal extension portion 62 and a distal end 64 with a distal extension portion 66. As shown, the distal extension portion 66 can have a generally elongate shape, such as cylindrical, conical, frustoconical, rectangular, and the like. The

distal extension portion 66 can include one or more mating structures 68 (e.g., threads, detents, ratchets, frustoconical surfaces and the like) that can be configured to mate with portions of the reservoir 14, such as the inner flange 48 as discussed above. In some embodiments, the connector 18 includes threads with a flattened and/or radially truncated portion 88. A distal passage 70 with a distal opening 72 can extend through at least some of the distal extension portion 62 and can abut against the radially inwardly extending shoulder portion 86 of the connector 18.

[0045] Generally, a channel 76 extends through the shoulder portion 86 and connects to a proximal passage 78 that extends through the proximal extension portion 62. As shown, the proximal passage 78 can terminate in a proximal opening 80, thereby placing the distal opening 72 in fluid communication with the proximal opening 80. In some embodiments, the proximal passage 78 has a smaller axial cross-sectional area than the distal passage 70. For example, in certain embodiments, the proximal passage 78 has an axial cross-sectional area that is at least about 10% and/or equal to or less than about 90% of the axial cross-sectional area of the distal passage 70. Certain embodiments of the proximal extension portion 62 have an elongate shape, such as cylindrical, conical, frustoconical, rectangular, and the like. In the illustrated embodiment, the proximal extension portion 62 is roughly S-shaped in axial cross section, which can assist the user in rotating the connector 18 to engage and/or disengage the mating structures 68 to couple and/or decouple the connector 18 with the reservoir 14.

[0046] In some aspects, portions of the connector 18 and/or the reservoir 14 are configured in accordance with an industry standard, such as ISO 594-1 and/or ISO 594-2, each of which is incorporated herein by reference in its entirety. For example, in some arrangements, the proximal end 44 of the reservoir 14 has an inside diameter and threads, and the connector 18 has an outside diameter and threads, formed according to ISO 594-1 and such that the connector 18 can be threadably secured to the inner flange 48. In some instances, after the connector 18 has been connected with the reservoir 14, a pressure differential can occur between passages 70, 78 of the connector and the ambient environment, which can adversely effect pumping of the fluid and/or disassembly of the connector 18 from the reservoir 14. To avoid the occurrence and/or maintenance of such a pressure differential,

some embodiments of the connector 18 include a valve or filter configured to permit the passage of air between one or more of the passages 70, 78 and the ambient environment, while also inhibiting the passage of liquids.

[0047] As illustrated in Figures 3A and 3B, the infusion system 10 can include a restriction 74 in the fluid path. When a pressure is applied to the fluid (e.g., by operation of the pump 12) the restriction 74 can affect the backpressure by, for example, restricting the volume and/or rate of fluid flow. In some arrangements, the pump 12 is configured to monitor or detect the backpressure of the fluid. The monitored or detected backpressure of the fluid can be used in an algorithm configured to, for example, approximate when the infusion set 16 has been primed.

[0048] In some embodiments, an algorithm employs the monitored or detected backpressure to sense or detect an abnormal condition of the infusion system 10. For example, the monitored or detected backpressure can be used to determine and/or monitor for a leak in the reservoir 14, infusion set 16, and/or other part of the infusion system 10. In certain instances, an unexpectedly low backpressure can indicate a leak (e.g., an unintended opening in the infusion system 10 that allows some of the fluid to escape therethrough, thereby inhibiting the formation and/or amount of the backpressure). In certain embodiments, the algorithm is configured to signal an error and/or trigger an alarm when the reservoir 16 is not empty and the monitored or detected backpressure is less than or equal to a certain value, for example: about 0.25 psi, about 0.5 psi, about 1 psi, about 2 psi, about 3 psi, about 4 psi, about 5 psi, about 6 psi, about 8 psi, about 10 psi, about 15 psi, about 20 psi, about 25 psi, about 30 psi, values in between, or otherwise. In some embodiments, the algorithm is configured to signal an error and/or trigger an alarm if the monitored or detected backpressure is about 0 psi during operation of the pump 12 (e.g., driving liquid from the reservoir 14 into the infusion set 16). In some embodiments, the algorithm is implemented by a general purpose computer, processor, or otherwise.

[0049] Many configurations for the restriction 74 are contemplated. In some embodiments, the restriction 74 includes a radially inwardly extending shoulder portion 86. In some variants, the restriction 74 includes a screen, filter, nozzle, obstruction, or the like disposed in the fluid flow path. In some embodiments, the restriction 74 includes a passage

that is substantially unimpeded and/or unobstructed. For example, as shown in Figure 3A, the restriction 74 can be the channel 76. In some embodiments, the channel 76 can be configured (e.g., cross-sectional area, shape, etc.) to provide a desired influence on the fluid flow (e.g., flow rate), which in turn can influence the backpressure. Among other advantages, such embodiments can aid in manufacturing by facilitating the forming of the connector 18 and the restriction 74 in a single process, e.g., injection molding.

[0050] In some embodiments, the restriction 74 has an inside diameter that is less than or equal to an inside diameter of the aperture 52 of the reservoir 14. For example, in some implementations, the ratio of the inside diameter of the restriction 74 to the inside diameter of the aperture 52 is less than or equal to about: 0.01:1, 0.05:1, 0.1:1, 0.2:1, 0.3:1, 0.4:1, 0.5:1, 0.6:1, 0.7:1, 0.8:1, 0.9:1, values in between, or otherwise. In some embodiments, the inside diameter of the restriction 74 is less than or equal to about: 0.2 mm, 0.4 mm, 0.6 mm, 0.8 mm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, values in between, or otherwise.

[0051] With reference to Figure 3B, in some embodiments, the restriction 74 includes a flow-restricting element 82 disposed in the channel 76. The flow-restricting element 82 can be an elongate member having a lumen 84 therethrough such that fluid can flow between the distal and proximal passages 70, 78. As illustrated in Figure 3B, the flow-restricting element 82 can be located in the connector 18 and can have a smaller axial cross-sectional area than each of the distal and proximal passages 70, 78, thereby making the flow-restricting element 82 the narrowest portion in the fluid flow path of the connector 18. In some embodiments, the flow-restricting element 82 can be the narrowest portion in the fluid flow path of the infusion system 10.

[0052] Some embodiments of the flow-restricting element 82 have a relatively simple shape (e.g., a cylinder) and can be substantially unimpeded and/or unobstructed, which can facilitate precise and accurate manufacturing. For example, the flow-restricting element 82 can be cylindrical in shape with an inside diameter of at least about 0.108 mm and/or equal to or less than about 0.311 mm. In some embodiments, the flow-restricting element 82 has a nominal inside diameter of at least about a 24 gauge needle and/or equal to or less than about a 32 gauge needle. For example, the flow-restricting element 82 can have a

nominal inside diameter of about a 26 gauge needle (about 0.260 mm). Some embodiments of the flow-restricting element 82 can have a nominal inside diameter of about a 27 gauge needle (about 0.210 mm). Some embodiments of the flow-restricting element 82 can have a nominal inside diameter of about a 28 gauge needle (about 0.184 mm). Some embodiments of the flow-restricting element 82 can have a nominal inside diameter of about a 31 gauge needle (about 0.133 mm). Certain embodiments of the flow-restricting element 82 are substantially rigid, which can inhibit disruption of the fluid flow path by radial compression of the connector 18 and/or the flow-restricting element 82.

[0053] As shown, the flow-restricting element 82 can be mounted in the channel 76. For example, the flow-restricting element 82 can be fixed into the channel 76 by glue, epoxy, press-fit or interference fit, welded (e.g., ultrasonic welding), injection molding or other operation. In some embodiments, the flow-restricting element 82 is heated beyond a melting point of the material of the connector 18, then the flow-restricting element 82 is pressed into the channel 76, thereby momentarily melting a portion of the connector 18 and retaining the flow-restricting element 82 therein. In some embodiments, the flow-restricting element 82 includes radial features, such as grooves or fins, which can facilitate connecting and/or retaining the flow-restricting element 82 in the connector 18.

[0054] In the embodiment shown in Figure 3B, the flow-restricting element 82 axially extends into the distal passage 70. In some embodiments, the flow-restricting element 82 can also or alternately axially extend into the proximal passage 78. In some embodiments, the flow-restricting element 82 does not extend into the passages 70, 78 (e.g., is flush with or recessed within the channel 76). Generally, the flow-restricting element 82 is positioned in the channel 76 such that an appendage, such as a human finger, is unable to contact the flow-restricting element 82, thereby inhibiting potential damage to the flow-restricting element 82 and/or injury to the appendage.

[0055] In some embodiments, the flow-restricting element 82 has a recess distance (e.g., the longitudinal distance between a distal end of the flow-restricting element 82 and a distal end of connector 18). In some embodiments, the recess distance is less than the inside diameter of the connector 18. In certain implementations, the recess distance is greater than the inside diameter of the connector 18. In some embodiments, the

ratio of the inside diameter of the connector 18 to the recess distance can be greater than or equal to about: 1:1.05, 1:1.1, 1:1.2, 1:1.3, 1:1.4, 1:1.5, 1:2, 1:3, 1:4, 1:5, values in between, or otherwise. In certain embodiments, the recess distance is greater than or equal to about: 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, values in between, or otherwise.

[0056] In some embodiments, the flow-restricting element 82 includes ends that are dulled, such as rounded, chamfered, blunt, and the like. An infusion system having a sharp lumen (e.g., a needle) can result in a person (e.g., the user) being inadvertently stuck, which can result in damage to the infusion system, as well as expose the person to pathogens and infections. In contrast, ends that are dulled can inhibit and/or avoid the potential for such injury. Ways of dulling the ends can include, for example, tumbling, filing, grinding, vibratory deburring, electrochemical deburring, and otherwise.

[0057] The flow-restricting element 82 can be a separate component from other components of the infusion system 10. In other words, the flow-restricting element 82 can be formed independently from the other parts of the infusion system 10. A flow-restricting element 82 that is a separate component can, in some embodiments, aid in manufacturing. For example, the connector 18 can be a relatively complex shape that is large compared to the channel 76, so manufacturing the connector 18 and the channel 76 as a single piece—and with precision and accuracy—can be difficult. In contrast, as discussed above, the flow-restricting element 82 can be configured to facilitate precise and accurate manufacturing. Thus, by disposing the separate flow-restricting element 82 in the channel 76, the nominal diameter of the channel 76 and/or the manufacturing tolerance thereof can be relaxed (thereby allowing for easier manufacture) yet the size of the flow restriction 74 between the distal and proximal passages 70, 78 can be provided precisely and accurately. The ability to precisely and accurately control the characteristics of the restriction 74 can be particularly significant in embodiments of the infusion system 10 in which the pump 12 is configured to monitor or detect backpressure, since the restriction 74 can have a significant effect on the backpressure.

[0058] In the embodiments illustrated in Figures 3A and 3B, the restriction 74 is located in the connector 18. However, additional and/or alternate locations for the restriction 74 are contemplated. For example, in some embodiments, the restriction 74 is

located in the reservoir 14, e.g., in the extension portion 46. In some embodiments, the restriction 74 is located within or in-line along the tubing 20. In some embodiments, the restriction 74 is located in the infusion port 22. Some embodiments include restrictions 74 located in at least two of the reservoir 14, the connector 18, the tubing 20, and the infusion port 22.

[0059] The restriction 74 preferably is located such that the fluid does not pass through the restriction 74 during the process of drawing fluid into the reservoir 14. If the restriction 74 is located in a position through which the fluid flows during the process of drawing fluid into the reservoir 14, then high pressures and/or turbulence can be experienced, thereby creating undesirable bubbles in the fluid. On the other hand, the formation of such bubbles can be reduced or avoided by those embodiments in which the restriction 74 is disposed in a location through which the fluid does not flow during the process of drawing fluid into the reservoir 14. For example, in embodiments wherein the flow restriction is located in the connector, the fluid avoids the restriction 74 because the connector 18 is not connected with the reservoir 14 during the process of drawing fluid into the reservoir 14. Likewise, in those arrangements in which the restriction 74 is located in the tubing 20, the fluid does not pass through the restriction 74 during the process of drawing fluid into the reservoir 14.

[0060] As illustrated in Figures 4A and 4B, the connector 18 and the reservoir 14 can be placed in connectable alignment. In the exploded views shown, the connector 18 can be rotatably connected with the reservoir 14, thereby placing the reservoir 14 in fluid communication with the connector 18. For clarity, the exploded view of Figure 4B depicts the separate flow-restricting element 82 outside the connector 18 and reservoir 14. In certain embodiments, the flow-restricting element 82 is received in a component of the infusion set 16. Recessing the flow restriction member 82 in the infusion set 16 can advantageously inhibit persons' appendages (e.g., fingers) from contacting the flow-restricting element 82, which can maintain the patency of the lumen 84 and avoid contamination of the same.

[0061] As shown in Figures 5A and 5B, the reservoir 14 and the connector 18 can be engaged (e.g., by a luer lock connection) so as to place the reservoir 14 in fluid communication with the connector 18. In some embodiments, engagement of

the connector 18 with the reservoir 14 produces a tactile or audible alert. As shown, the flow-restricting element or fluid-flow restrictor 82 can be spaced-apart from the extension portion 46 of the reservoir 18. Generally, the lumen 84 of the flow-restricting element 82 has a reduced axial cross-sectional area compared to the inner diameter of the extension portion 46 of the reservoir 18, which can affect the backpressure during fluid flow from the reservoir 18. For example, the lumen 84 can have an axial cross-sectional area that is at least about 1% and/or equal to or less than about 50% of the axial cross-sectional area of the extension portion 46. In some arrangements, the lumen 84 has about 10% of the axial cross-sectional area compared to the extension portion 46 of the reservoir 18. In some embodiments, the length of the flow-restrictor is greater (or substantially greater) than a thickness of a portion of the vessel cap, as illustrated in Figure 5B.

[0062] The infusion system 10, and in particular the infusion set 16, is preferably constructed from corrosion-resistant materials. In some embodiments, one or more of the components of the infusion set 16 are plastic (e.g., polyetheretherketone, polyurethane, and the like), silicone, metal (e.g., stainless steel, aluminum, titanium, and the like), or a composite material (e.g., resin impregnated carbon fiber). In some embodiments, the connector 18 is made of a thermoplastic. In some arrangements, one or more of the components of the infusion set 16 are constructed of materials that are clear, which can facilitate confirmation of proper mating between the connector 18 and the reservoir 14 and/or can facilitate confirmation of fluid flow.

[0063] The infusion set 16, and components thereof, can be formed using many manufacturing processes sufficient to provide the desired shape of the components. In some embodiments, one or more components are made by a molding process, such as insert molding, injection molding, compression molding, blow molding, rotational molding, transfer molding, thermoforming, or similar. In some embodiments, one or more components are formed by forging, machining, casting, stamping, extrusion, a combination thereof, and the like. For example, in some embodiments, the connector 18 is manufactured by an overmolding process, whereby the flow-restricting element 82 is placed in a mold and a thermoplastic material is molded around the flow-restricting element 82 to form the connector 18, including the flow-restricting element 82 embedded therein. Generally,

different components are formed using different materials and/or processes. For instance, in some embodiments, the flow-restricting element 82 is stainless steel and is formed by an extrusion process, and the remainder of the connector 18 is a thermoplastic that is molded around the flow-restricting element 82.

[0064] Figure 6 illustrates another embodiment of an infusion system 10a. Several features and components of the infusion system l0a are similar in form and function to those described above with respect to the infusion system 10, and have been provided with like numerals with the addition of "a" (e.g., "10a"). The components of the infusion system 10a differ in some respects from those of the infusion system 10, described above; some of those differences are described and explained below. Any features and/or components of the disclosed embodiments can be combined or used interchangeably.

[0065] The infusion system 10a can include a pump 12a, a reservoir 14a, and an infusion set 16a, which can include a connector 18a, a length of tubing 20a, an infusion port 22a, and a coupling element 23a. As shown in Figure 7, the coupling element 23a can include a first side 25a, a second side 27a, and a passage 29a therethrough to allow fluid to flow from the first side 25a to the second side 27a. In some embodiments, the coupling element 23a is configured to join one or more components of the infusion system 10a. For example, in one embodiment, the coupling element 25a is configured to connect the reservoir 14a and the connector 18a, e.g., by a male luer connection on the first side 25a and a female luer connection on the second side 27a. In some embodiments, the coupling element 23a is configured to be located in-line with the tubing 20a, such that a first length of the tubing 20a joins to the first side 25a of the coupling element 23a and a second length of the tubing 20a joins to the second side 27a of the coupling element 23a, either directly or by suitable connectors. Of course, in other embodiments, the coupling element 23a can be located in other locations and can couple other components of the infusion system 10a, such as coupling the tubing 20a with the infusion port 22a. Furthermore, in some embodiments, the coupling element 23a includes a flow-restricting element 82a, which can be disposed in the passage 29a. The flow-restricting element 82a can be similar to the flow-restricting element 82, described above. For example, similar to the flow-restricting element 82, the

flow-restricting element 82a typically is dulled, recessed, and is manufactured separately from the other parts of the coupling element 23a.

[0066] With regard to Figure 8, the invention can include a method for priming and/or preparing the infusion system 10, 10a. A first block 101 of the method can include obtaining and/or providing the infusion system 10, 10a. For example, a patient may procure the infusion system 10, for example by purchase or otherwise from a health care provider, a manufacturer, or a distributor. For example, a medical device manufacturer may sell the infusion system 10 to a distribution system (e.g., wholesalers, distributors, medical supply vendors, and the like) from which the patient may purchase the infusion system 10. An infusion fluid (e.g., insulin) is normally provided in a vial. A second step 102 can include drawing an amount of fluid from the vial into the reservoir 14, after which the vial is disconnected from the reservoir 14.

[0067] In some embodiments, the reservoir includes a plunger extension, which can be removed after the drawing step. The next block 103 can include disposing the reservoir 14 containing the fluid into the pump 12. The fourth block 104 can include joining the reservoir 14 with the connector 18, so as to place the reservoir 14 in fluid communication with the tubing 20 and the restriction 74. In some embodiments, the connector 18 houses the restriction 74. In other embodiments, the restriction 74 is housed in the reservoir 14 (e.g., in the extension portion 46), coupling element 23a, the tubing 20, or the infusion port 22. In some embodiments, the restriction 74 includes a channel 76, which in turn can have a flow-restricting element 82 disposed at least partly therein. In preferred embodiments, the flow-restricting element 82 and/or reservoir 14 are substantially unblocked (e.g., without a septum). Further, the flow-restricting element 82 is normally dulled (e.g., not sharp like a needle). Also, the flow-restricting element 82 is preferably recessed within the connector 18 so as to inhibit foreign objects (e.g., fingers) from contacting the flow-restricting element 82. In block 105, the pump 12 encourages an amount of the fluid from the reservoir 14 to travel through the tubing 20 and the restriction 74.

[0068] In some embodiments, a backpressure in opposition to the encouragement of the flow of the fluid can develop. The backpressure can be affected, for example, by the rate and volume of fluid flowing through the restriction 74, thus in certain embodiments the

configuration of the restriction 74 influences the backpressure. In some embodiments, the pump 12 is configured to monitor or detect the backpressure. In decision block 106 an inquiry is made whether a portion of the fluid has been, or is estimated, calculated, or determined to have been, expelled from an end of the tubing 20. In some embodiments, the decision block includes an algorithm configured to estimate whether a portion of the fluid has been expelled from an end of the tubing 20. In some embodiments, the algorithm includes, for example, detecting the backpressure and taking an action based at least in part on the detected backpressure, e.g., comparing the detected backpressure to a value having a correspondence with a characteristic of the fluid. In certain implementations of the algorithm, if the detected backpressure is greater than or equal to a value (e.g., 0.25 psi, 0.5 psi, 1 psi, 2 psi, 3 psi, 4 psi, 5 psi, values in between, or otherwise) then the pump 12 is deactivated for a period of time. In some embodiments, the algorithm can consider, among other data, the monitored or detected backpressure. If the answer to the inquiry of block 106 is negative, then block 105 is repeated. If the answer to the inquiry of block 106 is affirmative, then the method continues to block 107, which generally includes momentarily or temporarily disabling the pump 12. The method then ends.

[0069] Although the infusion system 10, 10a has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the infusion system extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and certain modifications and equivalents thereof. For example, in some embodiments, the reservoir 14 can have a male luer connection and the connector 18 can have a corresponding female luer connection; in other embodiments the reservoir 14 can have a female luer connection and the connector 18 can have a corresponding male luer connection. It should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the infusion system. Thus, it is intended that the scope of the infusion system herein-disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

THE FOLLOWING IS CLAIMED:

1. An infusion set configured to be removably connected to a vessel on an infusion pump, the infusion set comprising:

an infusion port configured to removably attach to a patient or to a component attached to a patient;

a vessel cap configured to removably attach to a fluid vessel in an infusion pump;

infusion tubing extending between the infusion cap and the vessel cap, the infusion tubing comprising an inner diameter along a substantial portion of its length that is configured to be in contact with flowing fluid during infusion;

wherein the vessel cap comprises a non-piercing fluid-flow restrictor portion with an inner diameter that is smaller than the inner diameter of the infusion tubing.

2. The infusion set of Claim 1, wherein the length of the fluid-flow restrictor is greater than a thickness of a portion of the vessel cap.

3. The infusion set of Claim 1, wherein the fluid-flow restrictor is made as a separate component from a main body of the vessel cap.

4. The infusion set of Claim 3, wherein the fluid-flow restrictor is made of a different material than another portion of the vessel cap.

5. The infusion set of Claim 4, wherein the fluid-flow restrictor is made of metal.

6. A method of preparing an infusion system, comprising:

obtaining an infusion pump, a vessel having a substantially unobstructed opening, and an infusion set comprising a cap and a port in fluid communication by a tube, the cap having a passage therethrough, the passage housing at least part of a non-piercing flow-restricting member having a lumen therethrough and being configured to come into contact with fluid and to restrict fluid flow through the cap, the flow-restricting member being made of a first material and another portion of the cap being made of a second material different from the first material;

drawing a fluid into the vessel;

connecting the vessel and the cap;

inserting at least a part of the vessel into the pump;

urging a portion of the fluid through the cap and the tube such that at least some of the portion of the fluid is expelled from the end of the infusion set;

detecting a backpressure in the vessel or the infusion set; wherein the flow restriction is configured to affect the detected backpressure; and

employing the detected backpressure in an algorithm to estimate the completion of the priming step.

7. The method of Claim 6, further comprising employing the detected backpressure in an algorithm to recognize the presence of a leak in the infusion system.

8. The method of Claim 6, further comprising triggering an alarm if the detected backpressure is less than or equal to about 0.5 psi when the portion of the fluid is urged through the cap.

9. The method of Claim 6, further comprising disconnecting the cap from the vessel, the flow-restricting member being recessed in the cap so as to inhibit contact with a human finger.

10. The method of Claim 6, further comprising maintaining a distance between the vessel and the flow-restricting member, the distance being along the direction of the flow of the fluid.

11. The method of Claim 6, wherein the cap is directly connected with the vessel.

12. The method of Claim 6, wherein the backpressure is detected by the pump.

13. The method of Claim 6, wherein the passage is formed in a radially inwardly extending shoulder of the cap, and the flow restriction further comprises a hollow shaft joined with the passage.

14. The method of Claim 6, wherein the flow-restricting member further comprises ends that are dull.

15. The method of Claim 6, wherein the flow-restricting member is longitudinally recessed in the cap a recess distance, the recess distance being greater than an inside diameter of the cap.

16. The method of Claim 6, wherein the first material is stainless steel and the second material is a thermoplastic.

17. A method of manufacturing an infusion set cap, comprising:

forming a flow-restricting element from a first material, the flow-restricting element having a channel therethrough, the flow-restricting element having a first end and a second end;

forming a first non-piercing end on the first end of the flow-restricting element and a second non-piercing end on the second end of the flow-restricting element; and

molding a luer lock connector from a second material, the luer lock connector having a first side and a second side, the luer lock connector being molded around a portion of the flow-restricting element such that the flow-restricting element is retained in the luer lock connector and the channel provides a fluid flow path between the first side and the second side, the first side being configured to connect with a vessel having a corresponding luer lock connection and the second side being configured to connect with a tube for transmitting liquid to an infusion port.

18. The method of Claim 17, further comprising recessing the flow-restricting element in the luer lock connector such that contact between the flow-restricting element and a human finger is inhibited.

19. The method of Claim 17, wherein the flow-restricting element is formed with an inside diameter that is less than an inside diameter of the corresponding luer lock connection of the vessel.

20. The method of Claim 17, wherein the first blunt end is disposed within the first side of the luer lock connector, and the second blunt end is disposed within the second side of the luer lock connector.

21. A method of priming a tube for an infusion system, the method comprising:

coupling a connection member with a vessel having a substantially unimpeded opening, the connection member being connected with a first end of a tube, thereby putting the connection member and a second end of the tube in fluid communication with a flow path therebetween;

placing a flow-restricting member in the flow path, the flow-restricting member being configured to restrict a flow of a liquid from the vessel to the second

end of the tube, the flow-restricting element including a distal end directed toward the vessel, the distal end being recessed within the connection member;

controlling a pump to urge a liquid from the vessel;

detecting a force resisting the urging of the fluid from the vessel;

estimating when the tube has been substantially filled with the liquid such that some of the liquid begins to exit a second end of the tube, the estimation being accomplished at least in part on the detected force; and

disabling the pump after estimating that the tube has been substantially filled with the liquid.

22. The method of Claim 21, wherein the flow-restricting member is disposed in the connection member.

23. The method of Claim 21, wherein the flow-restricting member is disposed in the tube.

24. The method of Claim 21, wherein the distal end of the flow-restricting member further is blunt or rounded.

25. The method of Claim 21, wherein the distal end of the flow-restricting element is spaced apart from the vessel.

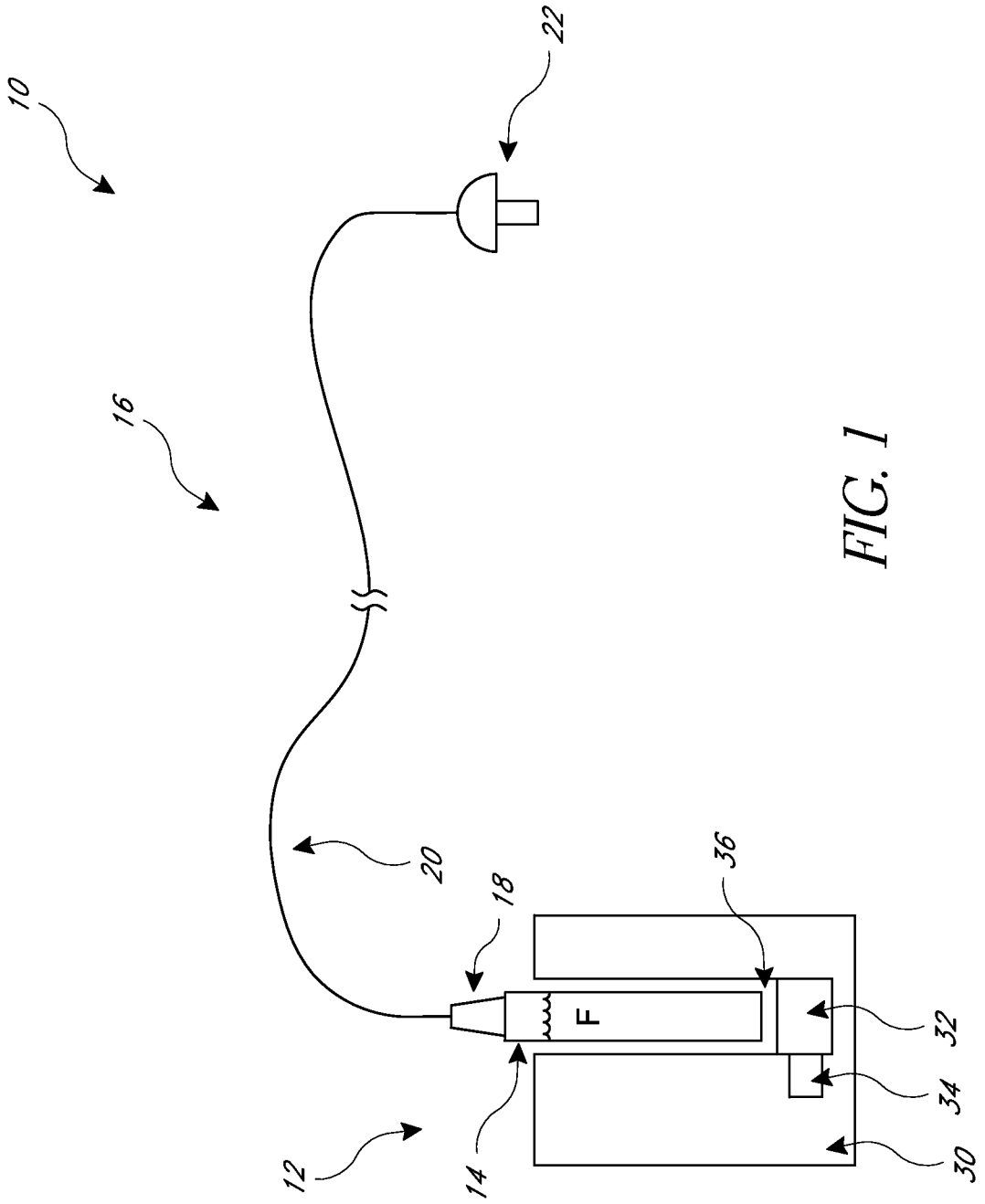


FIG. 1

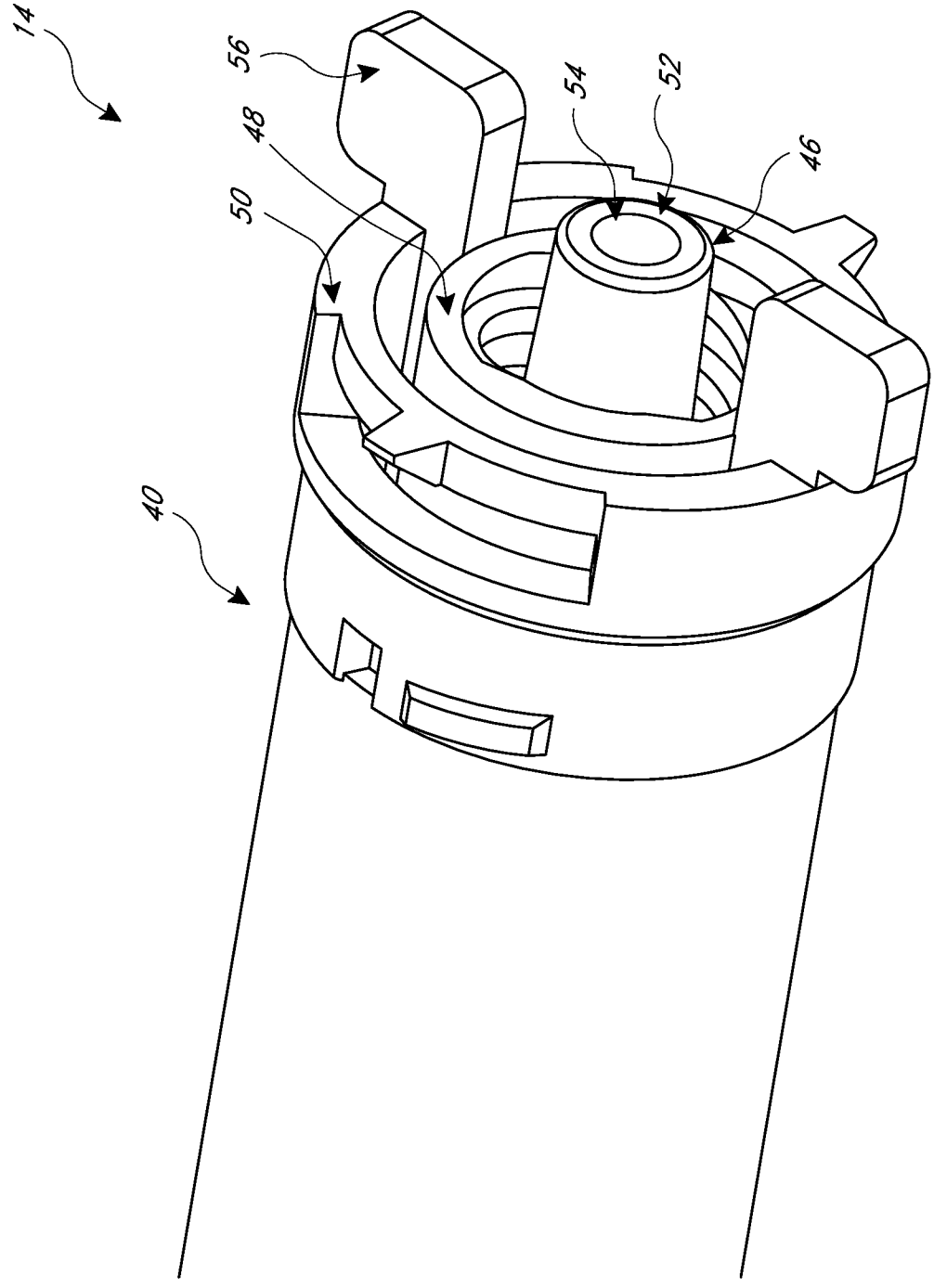


FIG. 2

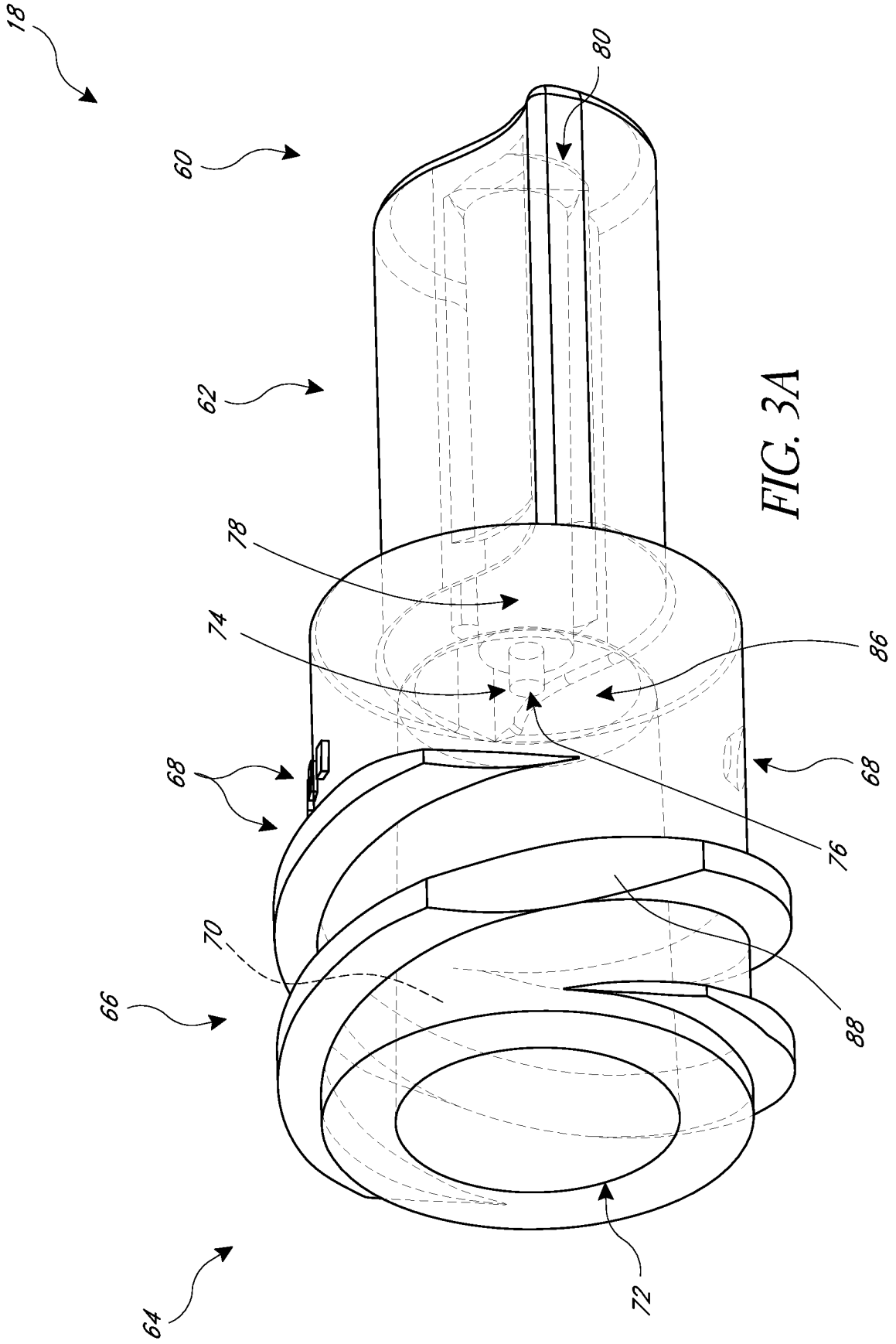


FIG. 3A

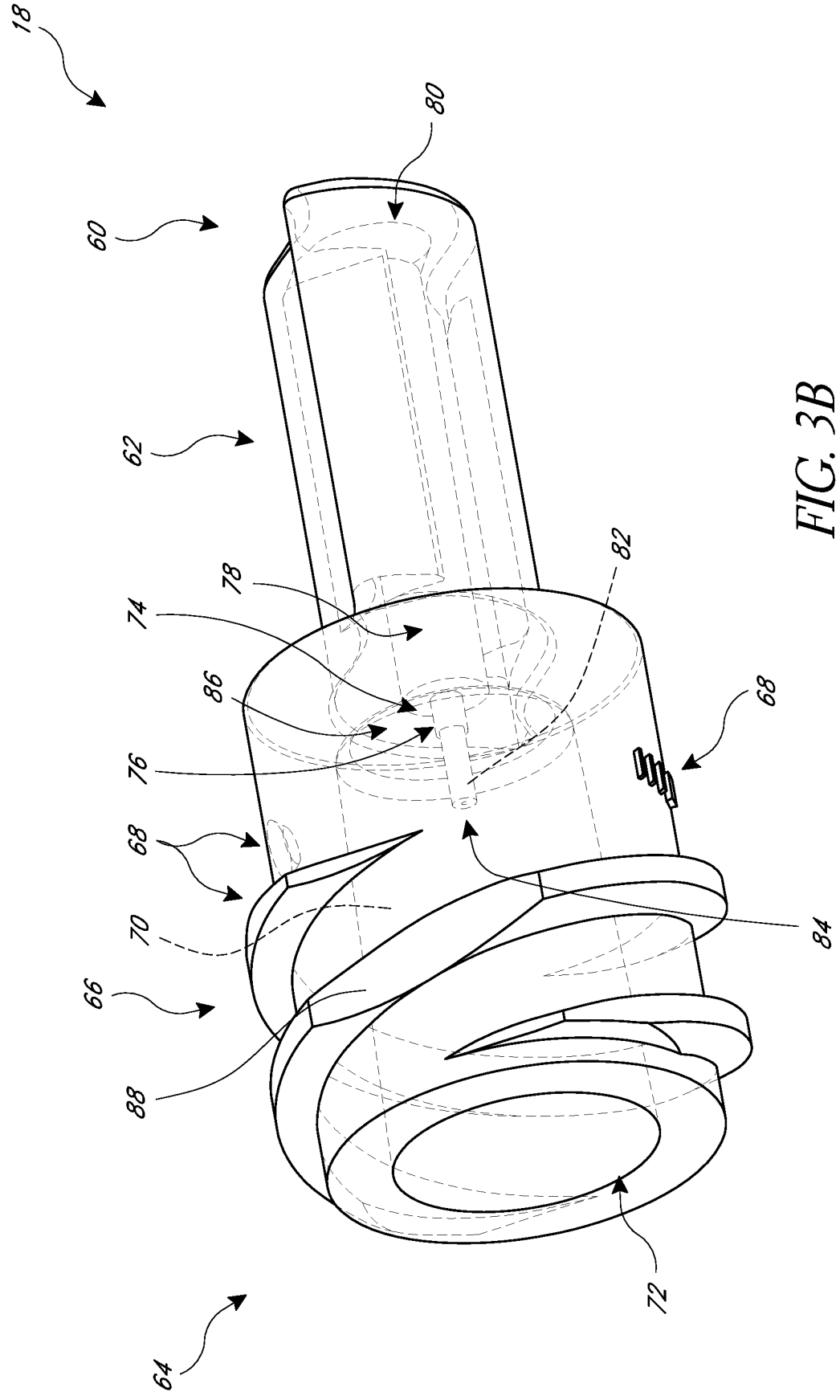


FIG. 3B

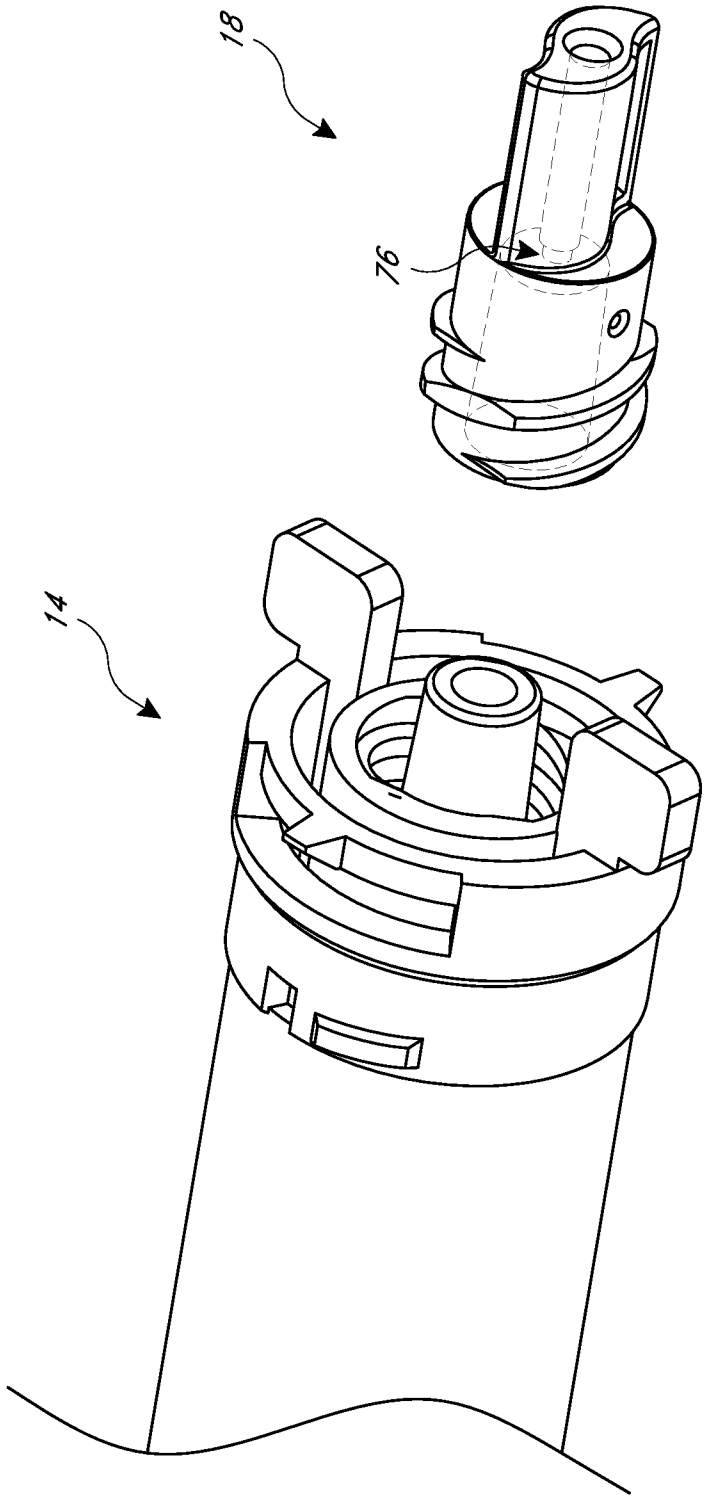


FIG. 4A

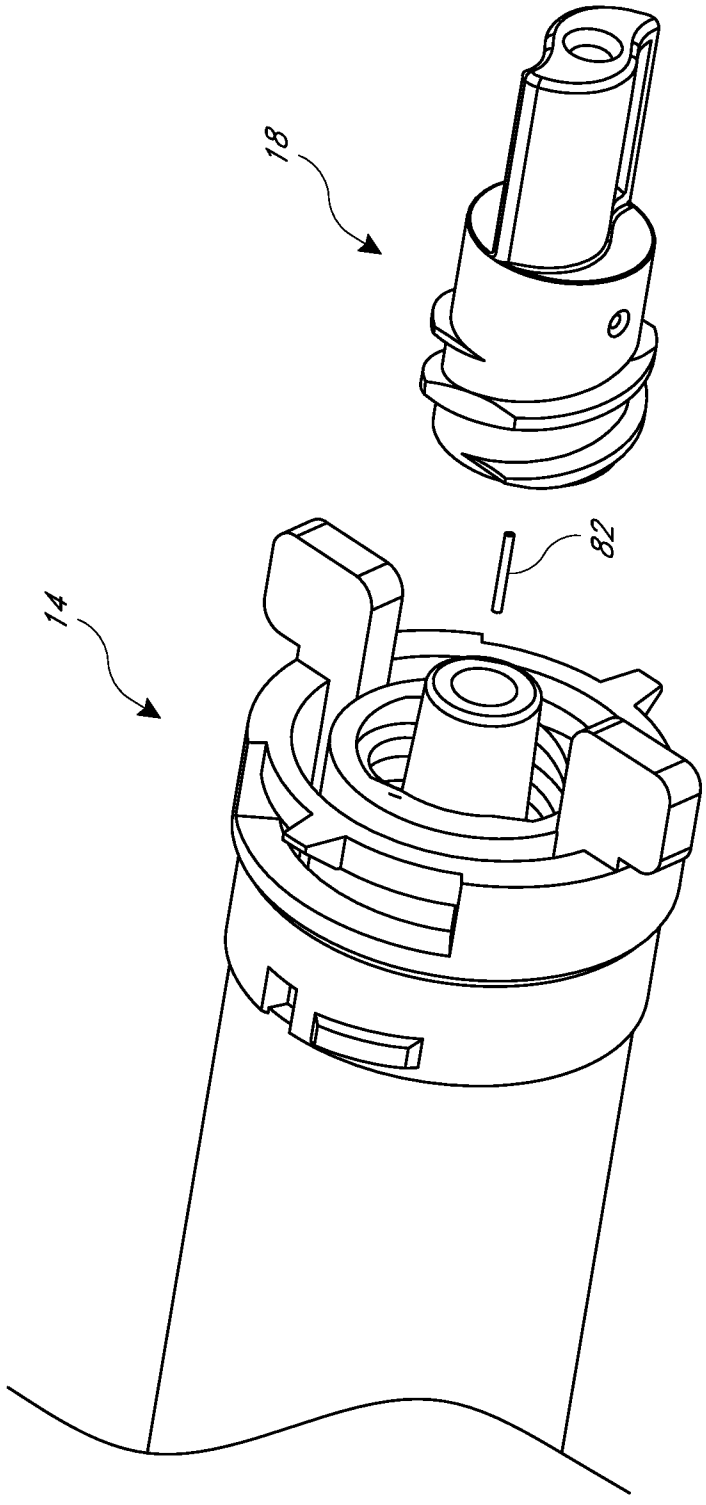


FIG. 4B

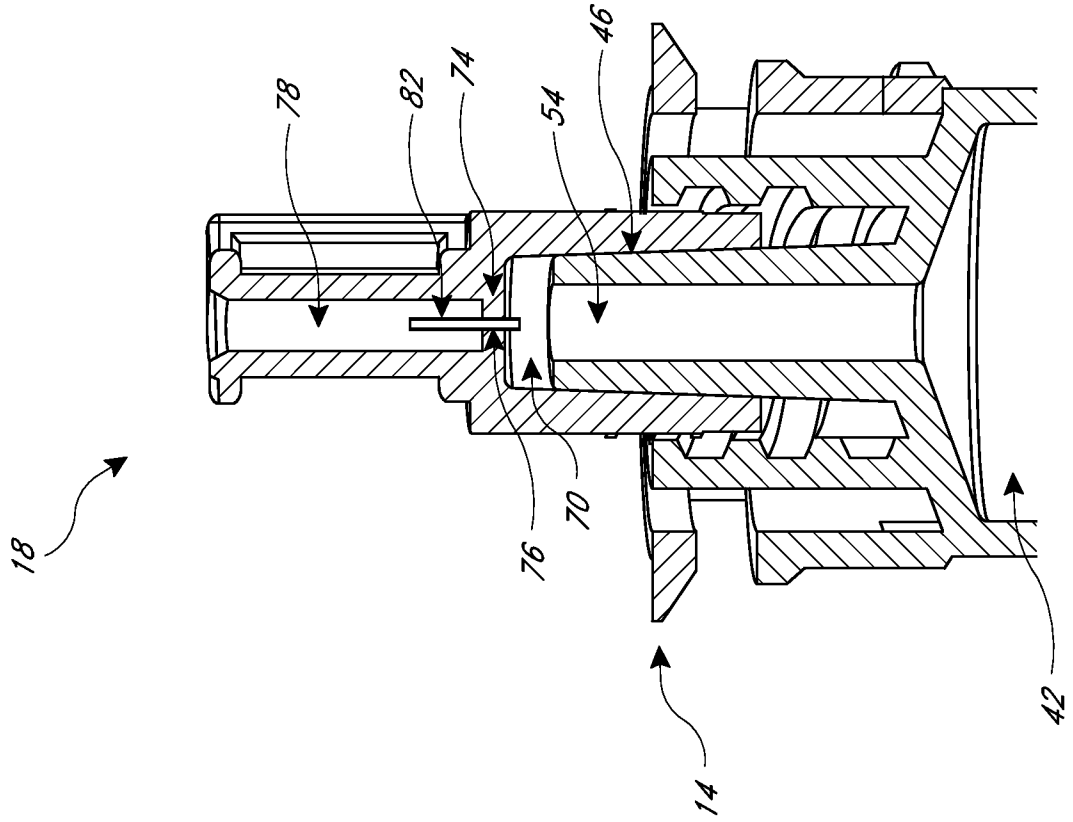


FIG. 5B

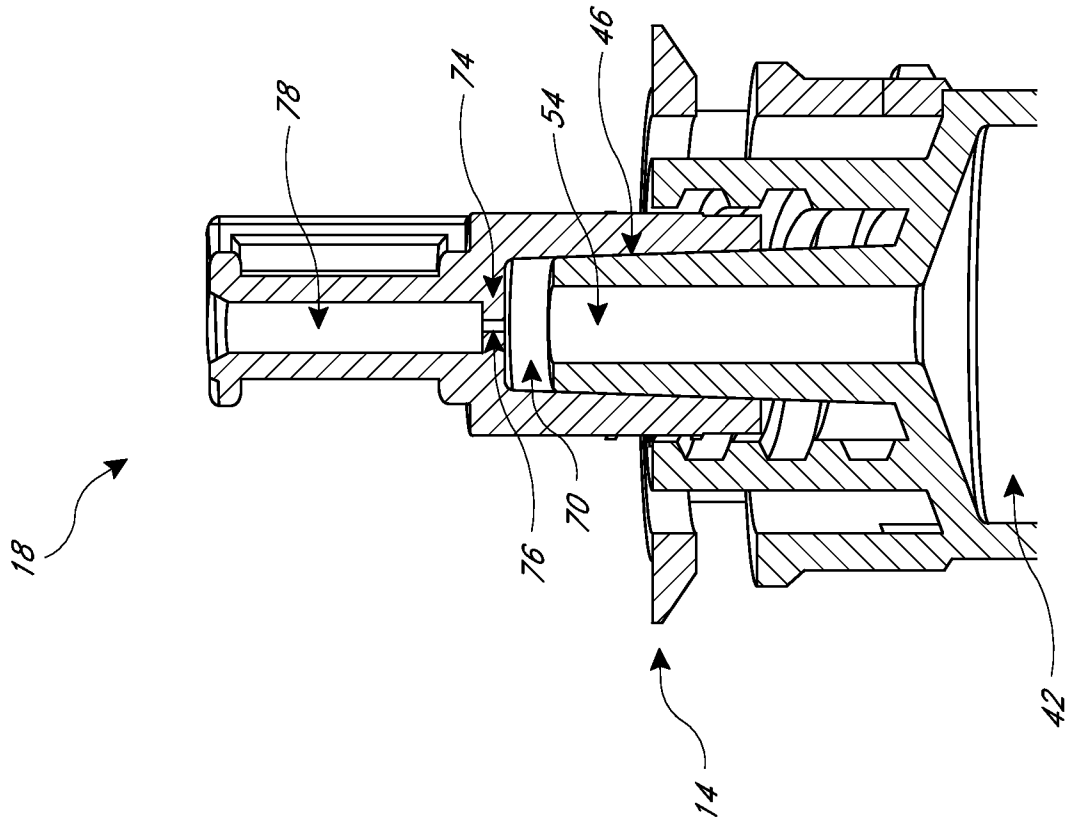


FIG. 5A

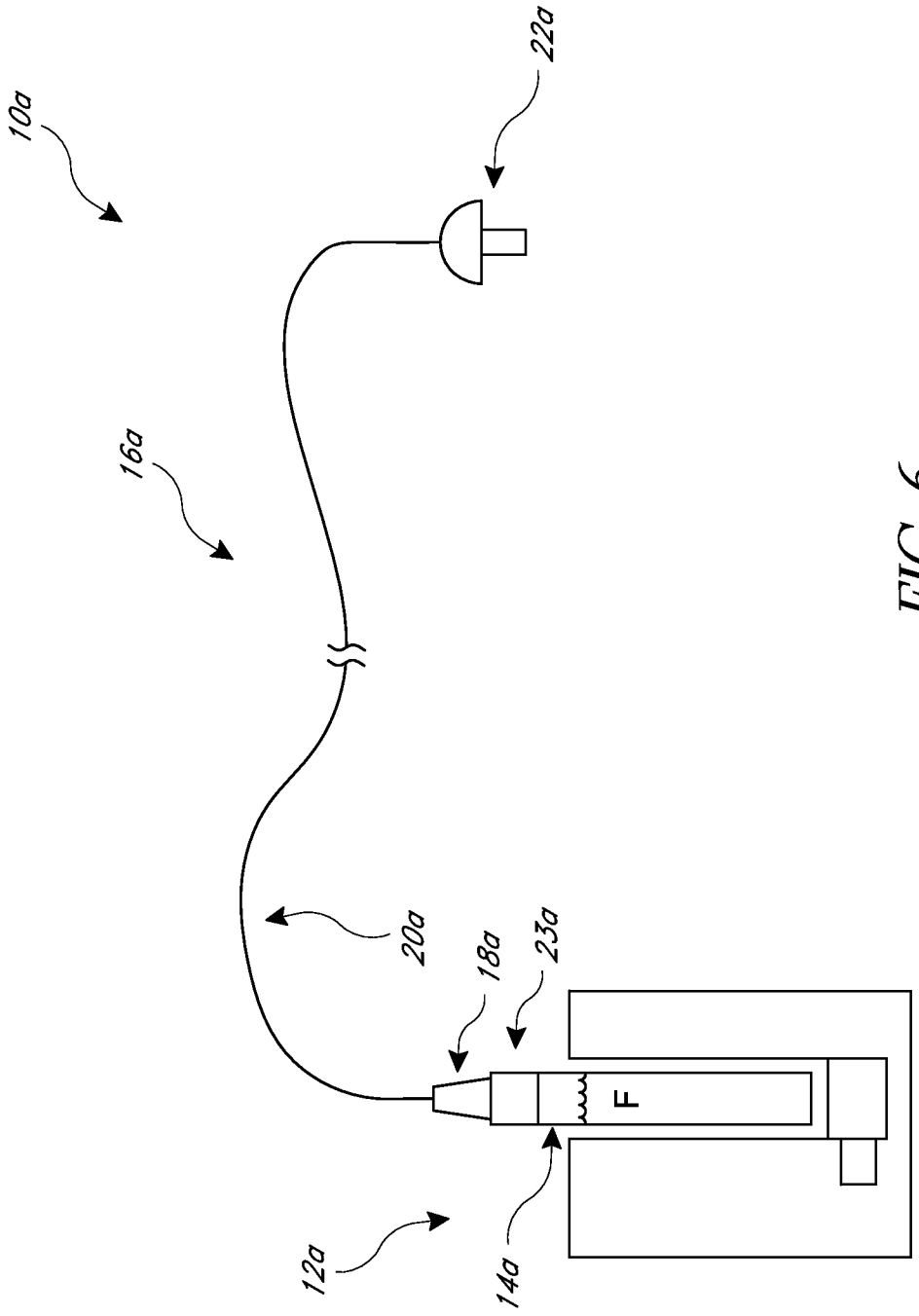


FIG. 6

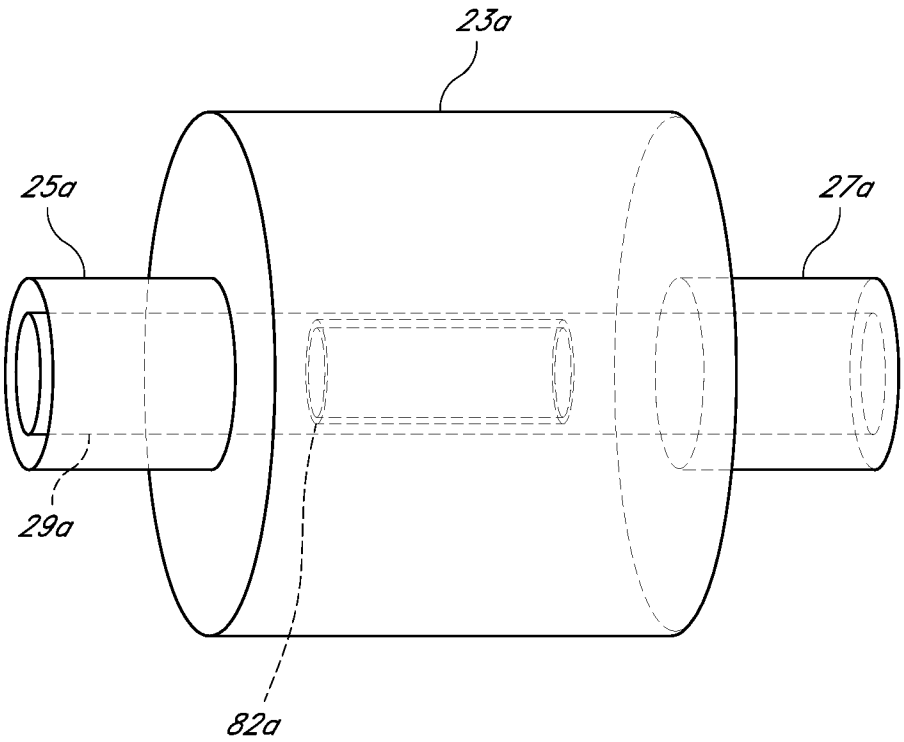


FIG. 7

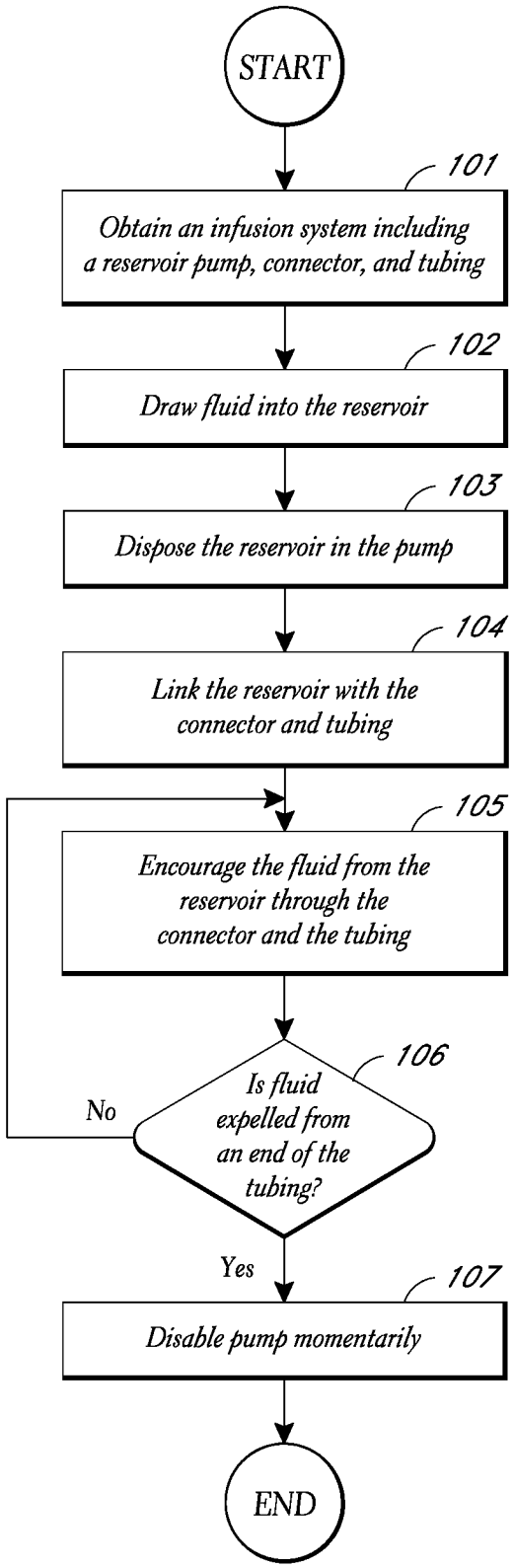

START
101
Obtain an infusion system including a reservoir pump, connector, and tubing
102
Draw fluid into the reservoir
103
Dispose the reservoir in the pump
104
Link the reservoir with the connector and tubing
105
Encourage the fluid from the reservoir through the connector and the tubing
106
Is fluid expelled from an end of the tubing?
No
Yes
107
Disable pump momentarily
END

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US12/26811

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/00, 37/00 (2012.01)
USPC - 604/246, 65, 132, 131, 151; 700/282, 275
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): A61M 5/00, 37/00 (2012.01)
USPC: 604/246, 65, 132, 131, 153, 48, 151, 93.01; 700/282, 275, 90; 128/DIG12, DIG13

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent (US Granted, US Applications, EP-A, EP-B, WO, JP (bibliographic data only), DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); DialogPRO; Medline/PubMed, Elsevier, Google Scholar; Google Patents, Google; infusion, pump, vessel, container, cap, connector, non-piercing, non-penetrate, non-puncture, dull, blunt, diameter, flow, fluid, restrict, control, backpressure, priming, tube, delivery, luer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2010/0217196 A1 (NELSON, BD) August 26, 2010, figures 1-6, paragraphs [0081], [0085]-[0087], [0097], [0120], [0147]	1-4 --- 5-25
Y	US 7608061 B2 (SCHINAZI, RG et al.) October 27, 2009, figures 1B, 1C; column 2, lines 35-47; column 3, lines 15-26; column 4, lines 6-21	5, 16-20
Y	WO 2010/030602 A1 (STERNBERG, S et al.) March 18, 2010, figures 5, 11, 14; paragraphs [0011], [0012]	21-25
Y	US 7654127 B2 (KRULEVITCH, P et al.) February 2, 2010, column 18, ines 32-54; column 44, lines 16-53	8
Y	EP 1930039 A2 (POPE, B et al.) June 11, 2008, paragraph [0063]	6-16, 21-25

☐ 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
06 July 2012 (06.07.2012)	27 JUL 2012
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: Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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