



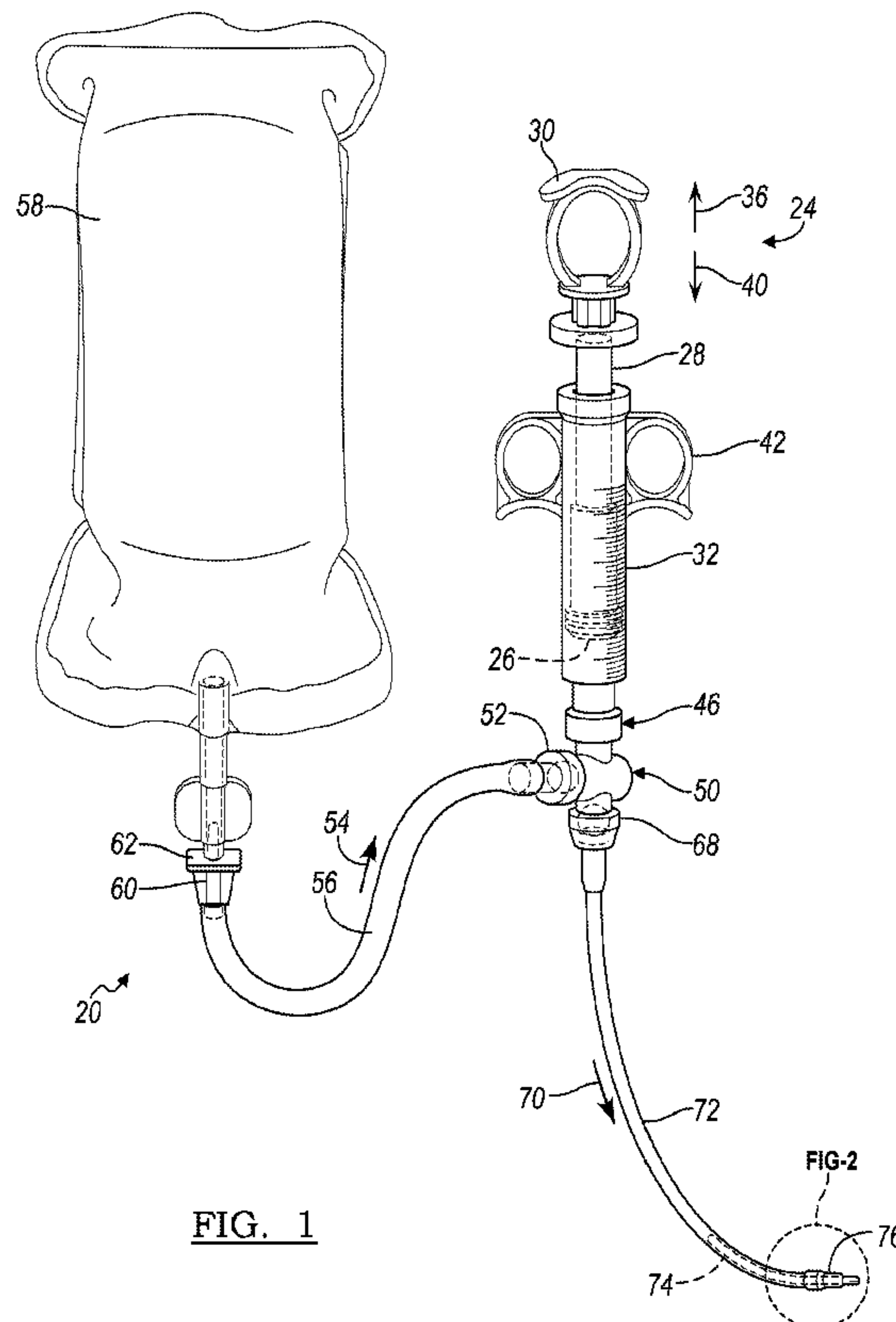
(12) **DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION**

(13) **A1**

(86) Date de dépôt PCT/PCT Filing Date: 2016/10/26
(87) Date publication PCT/PCT Publication Date: 2017/05/04
(85) Entrée phase nationale/National Entry: 2018/04/27
(86) N° demande PCT/PCT Application No.: US 2016/058871
(87) N° publication PCT/PCT Publication No.: 2017/075058
(30) Priorités/Priorities: 2015/10/30 (US14/928,066);
2016/10/24 (US15/332,693)

(51) Cl.Int./Int.Cl. *A61M 1/00* (2006.01),
A61M 3/02 (2006.01), *A61M 39/24* (2006.01),
A61M 5/14 (2006.01), *A61M 5/142* (2006.01)
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(54) Titre : PROCEDE ET APPAREIL D'IRRIGATION
(54) Title: METHOD AND APPARATUS FOR IRRIGATION



(57) **Abrégé/Abstract:**

Disclosed is an irrigation system. The irrigation system includes a manual pump. The manual pump can provide pressurized liquid through a tube at an outlet.

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

(19) World Intellectual Property
Organization
International Bureau(10) International Publication Number
WO 2017/075058 A1(43) International Publication Date
4 May 2017 (04.05.2017)

(51) International Patent Classification:

A61M 1/00 (2006.01) A61M 5/142 (2006.01)
A61M 3/02 (2006.01) A61M 39/24 (2006.01)
A61M 5/14 (2006.01)

(21) International Application Number:

PCT/US2016/058871

(22) International Filing Date:

26 October 2016 (26.10.2016)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

14/928,066 30 October 2015 (30.10.2015) US
15/332,693 24 October 2016 (24.10.2016) 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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR IRRIGATION

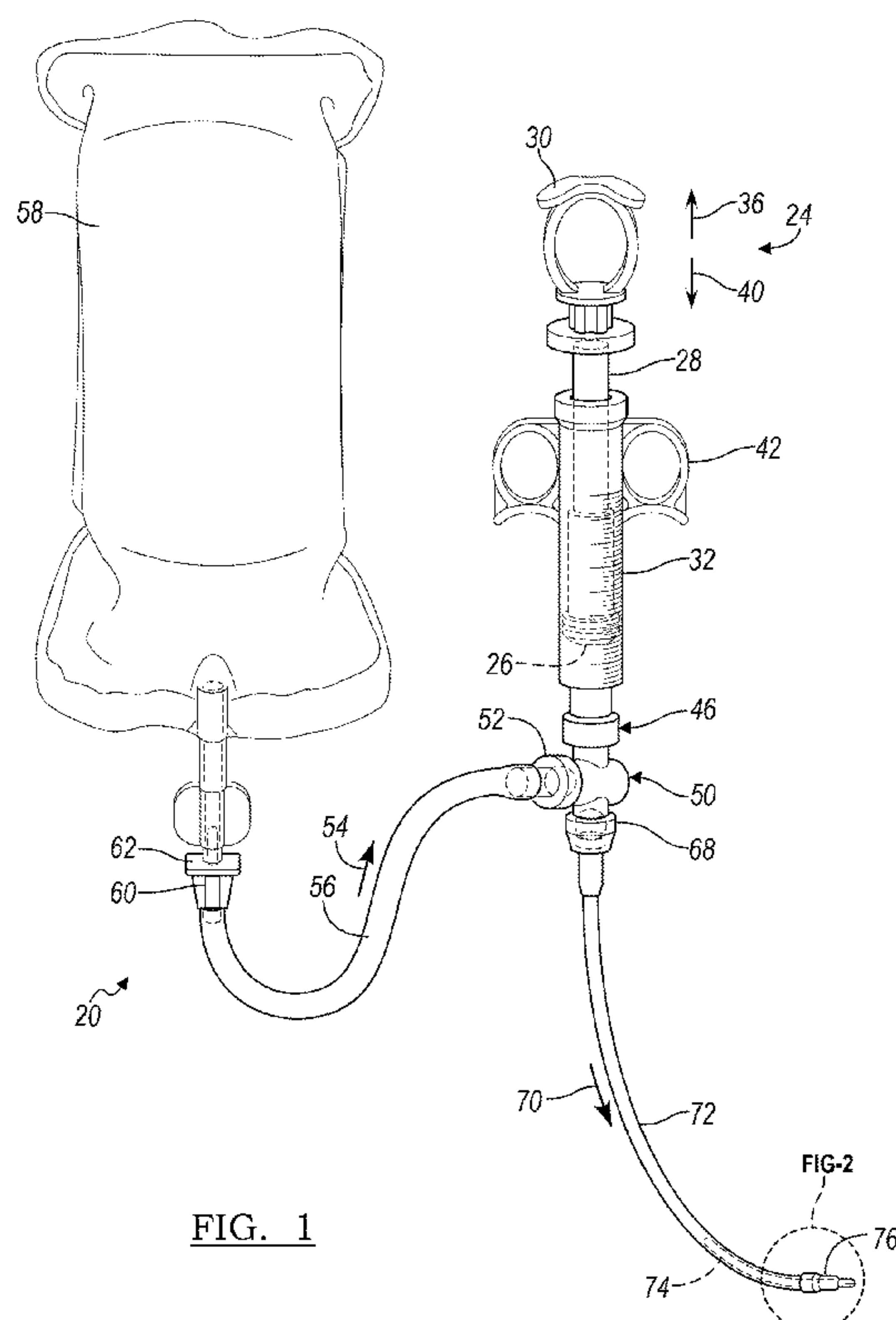


FIG. 1

(57) Abstract: Disclosed is an irrigation system. The irrigation system includes a manual pump. The manual pump can provide pressurized liquid through a tube at an outlet.

WO 2017/075058 A1

WO 2017/075058 A1

SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

- Published:**
- *with international search report (Art. 21(3))*
 - *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))*

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

METHOD AND APPARATUS FOR IRRIGATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to and is a continuation-in-part of United States Patent Application No. 14/928,066 filed on October 30, 2015. This application also claims priority to United States Patent Application No. 15/332,693
5 filed on October 24, 2016. The entire disclosures of the above applications are incorporated herein by reference.

FIELD

[0002] The subject disclosure relates to an irrigation system, and
10 particularly relates to a manually powered irrigation system having a nozzle.

BACKGROUND

[0003] This section provides background information related to the present disclosure which is not necessarily prior art.

[0004] During selected procedures, it may be selected to provide a liquid to
15 a specific location. Generally, fluid may be delivered through a tube that may be powered by a pump. Further, the tube may include suction portions to withdraw/remove material and/or irrigation liquid from a site. Selected systems include a Hydrodebrider® pressurized sinus irrigation system sold by Medtronic, Inc. and systems such as those disclosed in U.S. Patent Application Publication
20 Nos. 2009/0270796 and 2011/0009699 and U.S. Patent Nos. 8,790,301 and 8,206,349. Such systems are disclosed to include a vacuum source and a control to control a vacuum and irrigation.

SUMMARY

[0005] This section provides a general summary of the disclosure, and is
25 not a comprehensive disclosure of its full scope or all of its features.

[0006] According to various embodiments, a manual pump may be fitted with a valve system. The manual pump may include a syringe or other hand-held

and/or operated pump mechanism. The valve system may allow for unidirectional or one-directional delivery of a fluid.

[0007] The valve system may include two one-way valves to allow for filling of a syringe barrel during a first movement of a syringe piston and delivery of a liquid from the filled barrel during a second motion of the piston. The valve system, therefore, allows for generally continuous delivery of a fluid from a source to a selected area while connected to a source.

[0008] Delivery of the fluid may be through a nozzle to provide a selected pressure of fluid to an irrigation site. Irrigation sites may include both living and non-living sites. Living tissue or anatomical sites may include body surfaces, such as nasal and sinus cavities. Non-living sites may include cleaning or preparing surgical equipment, implants, or work surfaces, such as degreasing. During irrigation, the pressure may assist in loosening or removing a selected material from a selected surface or breaking up large agglomerations of material into smaller portions for removal.

[0009] Further areas of applicability will become apparent from the description provided herein. The description and specific examples in this summary are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

DRAWINGS

[0010] The drawings described herein are for illustrative purposes only of selected embodiments and not all possible implementations, and are not intended to limit the scope of the present disclosure.

[0011] Fig. 1 is a plan view of an irrigation system, according to various embodiments;

[0012] Fig. 2 is a detailed end view of an irrigation nozzle, according to various embodiments;

[0013] Fig. 3 is a schematic environmental view of an irrigation site; and

[0014] Fig. 4 is a plan view of an irrigation system, according to various embodiments;

[0015] Fig. 5 is a detailed view of an irrigation tip assembly, according to various embodiments;

[0016] Fig. 6 is a further detailed view of an irrigation tip assembly, according to various embodiments; and

[0017] Fig. 7 is a plan view of an irrigation system, according to various embodiments.

5

[0018] Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION

[0019] Example embodiments will now be described more fully with reference to the accompanying drawings.

[0020] With initial reference to Fig. 1, an irrigation system 20 is illustrated. The irrigation system 20 is generally a manual irrigation system powered by a user that holds a syringe assembly 24 in one or more hands to operate the syringe assembly 24. The syringe assembly 24 may include a piston head 26 interconnected with a piston rod 28. The piston rod 28 may include various features such as a thumb hole or loop 30 to assist in operation of the syringe assembly 24 with one hand of a human user.

[0021] The syringe assembly 24 may be a manual pump that may include various features such as further including finger or digit rings 42 to assist in manipulating the syringe assembly 24, in addition to the thumb hole or loop 30, again with one hand of a human user. Further, a connection portion 46 may include connection mechanisms such as a Luer-Lok® syringe connection, twist lock, press fit, or the like. Therefore, a mechanism may be interconnected with the syringe assembly 24 for use of the irrigation system 20.

[0022] As is generally understood by one skilled in the art, the syringe assembly 24 may be operated to fill a syringe barrel 32 by moving the piston head 26 with the piston rod 28 generally in the direction of arrow 36 and may be emptied by moving the piston head 26 with the piston rod 28 generally in the direction of arrow 40. It is understood, however, that the syringe assembly 24 may also have a self-return or self-priming system. Self-return systems may include a spring (not illustrated) to bias the piston head 26 away from the connection portion 46 generally in the direction of arrow 36. The user, to express the material from

the syringe, would overcome the biasing force of the spring to express the material and the biasing force would assist in moving or move the piston head away from the connection portion 46 to refill the syringe barrel.

[0023] Connected with the syringe assembly 24 at the connection portion 5 46 may be a valve assembly 50. The valve assembly 50 may include the dual check valve 80187 sold by Qosina, having a place of business at Ronkonkoma, NY. The valve assembly 50 may include various valve portions, including two one-way valves. The two one-way valves may include a one-way valve assembly 52, which may be a first one-way valve assembly, that opens when negative 10 pressure is formed within the valve assembly 50. Negative pressure may be produced when the piston head 26 moves generally in the direction of arrow 36 to allow a flow of material through the one-way valve assembly 52 generally in the direction of arrow 54. The material may flow generally in the direction of arrow 54 through a tubing 56. The tubing 56 may be a flexible tubing to connect with a 15 source container 58 holding or containing a volume or liquid, such as an irrigant liquid.

[0024] The source container 58 may be a container, such as an IV bag or other appropriate volume of an irrigation fluid. The irrigation fluid may be a selected material such as saline. The irrigation fluid may further include various 20 therapeutic reagents such as antibacterial, antimicrobial, anti-inflammatory, analgesic, hemostatic, and wound healing components.

[0025] The tubing 56 may be connected with a connector 60 to a connection receptacle 62 of the irrigant volume container. The connector 60 and the connection receptacle 62 can be any appropriate connection members, as is 25 generally understood in the art. The connection of the connector 60 with the connection receptacle 62 may generally be an open connection such that fluid will generally flow from the source container 58 through the tubing 56 once the connector 60 is connected with a connection receptacle 62. The one-way valve assembly 52, however, may control flow of the fluid from the source container 58 30 to the syringe assembly 24, including within the syringe barrel 32.

[0026] Accordingly, as noted above, when the piston head 26 generally moves in the direction of arrow 36, the irrigant is drawn from the source container 58 through the connection receptacle 62 and the connector 60 through the tubing

56 and generally in the direction of arrow 54. The movement of the piston head 26 in the direction of arrow 36 may cause a negative pressure through the connection portion 46 to the valve assembly 50 to open the one-way valve assembly 52. Therefore, the syringe barrel 32 fills with the irrigant fluid.

5 **[0027]** Once a selected volume of the irrigant is positioned within the syringe barrel 32, however, movement of the piston head 26 in the direction of arrow 36 may be ceased. The piston head 26 may then be moved in the direction of arrow 40 to move the piston head 26 generally towards the connection portion 46 to assist in removing or evacuating the irrigant material from the syringe barrel
10 32.

[0028] When the piston head 26 is moved generally in the direction of arrow 40, the pressure at the valve assembly 50 may be increased. The increased pressure in the valve assembly 50 can close the one-way valve assembly 52 and open a one-way valve assembly 68, which may be a second one-way valve
15 assembly. The increased pressure at the one-way valve assembly 68 may cause the one-way valve assembly 68 to open to allow the irrigant to flow from the syringe barrel 32 through the valve assembly 50 and generally in the direction of arrow 70 through a tubing 72. The tubing 72 may extend along a selected length and may bend according to a selected configuration.

20 **[0029]** The tubing 72 may be formed of a material that may be rigid or bendable. In various embodiments, the tubing 72 may be bent for use and may maintain the selected bent configuration. Alternatively, or in addition thereto, the tubing 72 may only be flexible and a bendable support structure 74 may be positioned at at least a region of the tubing 72 to assist in supporting and holding
25 the tubing 72 in a selected shape. According to various embodiments, the bendable support structure 74 may be a malleable tube, such as an aluminum tube, fixed within the tubing 72. Various embodiments, may also include malleable wires embedded in a wall of the tubing 72. Further, multiple tubes may be concentrically placed to support a bend. In still further various embodiments, a
30 distal tube may be formed of a second material different from a proximal portion of the tubing 72 that may be malleable. It is understood, however, in various embodiments the tubing 72 may be a single type flexible non-malleable tubing.

[0030] The tubing 72 may be bent at a selected radius, such as near a tip 76 to assist in positioning the tip 76 at a selected location. For example, the tip 76 may be selected to be positioned in a sinus cavity, as discussed further herein, and forming a radius or angle near the tip 76 may assist in positioning the tip 76 within the selected sinus. The radius may be supported by the bendable support structure 74 that may be different than the material of the tubing 72.

[0031] With continued reference to Fig. 1 and additional reference to Fig. 2, the tip 76 may be formed to cause a selected shape of a spray that exits the tubing 72 and the tip 76. As illustrated in Fig. 2, a detailed view generally along or at the tip 76 of the tubing 72 is illustrated. The tip 76 may include a selectively shaped opening 80. The opening 80 may include a slit that has a first surface 82 and a second surface 84. The first and second surfaces 82, 84 may be angled relative to one another and may include an elongated configuration such that a fan-shaped spray emanates from the tip 76. The opening 80 may also include sidewalls adjacent to the first and second surfaces 82, 84 to further direct the spray. The tip 76 may alternatively to the opening 80 and/or in addition to the opening 80 include one or more holes 85. The holes 85 may be selectively shaped, such as circular, oval, discrete slits, etc.

[0032] At the tip 76, the first surface 82 may be angled relative to the second surface 84 to form a selected configuration of the spray, as noted above, which may be a fan shape. Further, due to the angle of the second surface 84, the spray may be directional, such as spraying generally at the angle of the second surface 84 and away from an axis 88 through the tip 76. This can allow the tip 76 to be rotated around the axis 88, such as by rotating the syringe assembly 24, to select a direction of the spray through the opening 80.

[0033] The tip 76, as discussed above may include one or more holes 85. If a single one of the holes 85 is included the single hole may direct a stream of the fluid. The single hole may be positioned at any appropriate location around or along the tip 76. Alternatively, there may be many holes 85 positioned at selected locations on the tip 76. For example, the holes 85 may be formed as a ring around an axis 88. The ring of holes may be partial or complete to spray in a selected direction at the tip 76 relative to the axis 88.

[0034] Visualization of the location and/or direction of the spray may be made by direct endoscopic or direct visual inspection of the spray. Further, a navigational marker, such as a radiopaque indicator 90 may be included to indicate the location and/or direction of the spray from the opening 80. For example, as illustrated in Fig. 2, a triangle or arrowhead may be the radiopaque indicator 90 that points towards the direction of the spray. Therefore, an imaging may be made to determine the location and/or direction of the spray from the tip 76, such as through the opening 80 and/or the holes 85.

[0035] Further, a cross-sectional area or volume of the opening 80 relative to a cross-sectional area of an opening or lumen through the tubing 72 may be selected at an appropriate ratio of about 1:1 to about 1:10,000, including about 1:2 to about 1:100, including about 1:6. Further, more than one of the tips 76 may be provided on the tubing 72. Multiple tips may provide for a spray being directed in a plurality of directions at once. Further, the tips 76 may be selectable or changeable during use. Different tips providing different ratios may be used to provide different spray patterns and/or pressures. Accordingly, a kit may be provided that includes the irrigation system 20 with one or more tips 76. The tips may be assembled during use. The kit may be provided in a container that allows sterilization of the kit prior to use. The ratio of the volume of the opening 80 relative to cross-sectional area of the lumen can allow for a selected pressure to be provided through the opening 80. Providing a selected pressure, such as a pressure of about 1 pounds per square inch (PSI) to about 70 PSI may be provided. The selected PSI may assist in a procedure, such as debridement of a region. For example, debridement may include removing a biofilm, breaking an agglomeration, or otherwise providing pressure to an area to assist in removing one or more selected materials (e.g. debris, bacteria, irritant or allergen), or clearing a selected area.

[0036] With continuing reference to Figs. 1 and 2 and additional reference to Fig. 3, the irrigation system 20 may be used to debride or irrigate a selected nasal passage or sinus cavity. As is generally understood by one skilled in the art, a subject, such as a human subject 100, may include or have a first nasal passage 110 or a second nasal passage 112. Further, the human subject 100 may include one or more sinus cavities including schematically illustrated sinus

cavities, including maxillary sinuses 114a and 114b and frontal sinuses 116a and 116b.

[0037] During a procedure, the tip 76 may be introduced through the first nasal passage 110 and moved into the maxillary sinus 114a. The tip 76 may be carried on the tubing 72 and may be manipulated into position via holding and operating the syringe assembly 24. During use, the user may then move the piston head 26 generally in the direction of arrow 36 to fill the syringe barrel 32 and then generally in the direction of arrow 40 to express the irrigation material through the tubing 72 and out of the tip 76.

[0038] When expressing the irrigation material out of the tubing 72 and tip 76, a spray 120 may be formed as the irrigation fluid impinges upon an internal surface of the maxillary sinus 114a. It is understood that the tip 76 may be moved through either or both of the first and second nasal passages 110, 112 into any of the selected sinus cavities, including either of the maxillary sinuses 114a or 114b, or frontal sinuses 116a or 116b or other sinuses such as the sphenoid or ethmoid sinuses. Nevertheless, the user may operate the syringe assembly 24 to irrigate the sinus cavities and/or nasal passages.

[0039] During operation, the user may continuously irrigate using a reciprocating action of the piston head 26. By first moving the piston head 26 generally in the direction of arrow 36, the syringe barrel 32 may be filled and then expressing material by moving the piston head 26 generally in the direction of arrow 40. As noted herein, the repeated movement of the piston head 26 in the direction of the first arrow 36 then the second direction arrow 40 a continuous irrigation may be performed.

[0040] The reciprocating motion of the piston head 26 may be manually operated by the user and may not cause a continuously steady stream (e.g. the continuous flow may be pulsatile) during the emptying of the source container 58. However, due to the connection of the syringe assembly 24 to the source container 58 through the tubing 56 and the position of the valve assembly 50, the source container 58 may be emptied or continuously used until debridement or irrigation is complete or the source container 58 is empty. Therefore, the user need not remove the syringe assembly 24 from the irrigation site to refill the syringe assembly 24 during an irrigation procedure, but may maintain the tip 76 at

a selected irrigation position during an entire irrigation procedure while manually operating the syringe assembly 24 during the irrigation procedure.

[0041] It is understood that the irrigation assembly, according to various embodiments, as discussed herein, may be use to irrigate selected surfaces or volumes. Fig. 3 is merely exemplary of irrigating a surface or cavity within a human subject. It is understood, however, that other cavity within a subject may be irrigated. Further, devices, such as implants or treatment devices may have the irrigant applied to their surfaces before, during, or after positioning with in a subject. For example, an implant may have its surface irrigated after implantation to assist in removing an infection, etc.

[0042] An irrigation system 220, according to various embodiments, is illustrated in Fig 4, Fig. 5, and Fig. 6. The irrigation system 220 is a manual irrigation system that is configured to be powered by a user. For example, a user may apply manual pressure to operate the irrigation system 220. Further, the irrigation system 220 may include components similar to the irrigation system 20, discussed above. Identical components to the irrigation system 20 will be given the same reference numeral in the irrigation system 220 and not discussed in detail below.

[0043] The irrigation system 220 may include a syringe system or assembly 224. The syringe assembly 224 may be operated by one or more hands of a user as a manual pump to express or spray an irrigant from the syringe assembly 224. The irrigant may be the same as that discussed above, and may be sprayed into various portions of the human subject 100, as discussed above and illustrated in Fig. 3. It is understood, however, that the irrigation system 220 may be used to irrigate any selected volume and the irrigation of a human patient is not required.

[0044] The syringe assembly 224 may be similar to the BD Cornwall™ disposable syringe system, sold by Becton, Dickinson & Co., having a place of business in Franklin Lakes, NJ, USA. The syringe assembly 224 may include a syringe barrel 226 and a syringe plunger 228. As discussed herein, the syringe barrel 226 may operate as a pump barrel having a volume and the syringe plunger 228 may be a plunger for a pump. Connecting the syringe barrel 226 and the syringe plunger 228 may be a spring member 232. The spring member 232 may be held within a casing or handle 234. The spring member 232 may be any

appropriate biasing member or system to apply a bias force to the handle 234 and/or the syringe plunger 228.

[0045] The spring member 232 may be formed of a selected material, such as a metal or metal alloy, that causes it to be biased to an expanding or open position. Thus, the spring member 232 may be a biasing member that biases the handle 234 and/or the syringe plunger 228. In biasing the syringe plunger 228, the spring member 232 may bias and/or draw the syringe plunger 228 generally in the direction of arrow 236 to move a plunger head 238 in a first direction in the syringe barrel 226. By moving the syringe plunger 228 in the direction of arrow 236, a pressure in the syringe barrel 226 may be reduced so that it may be filled with a fluid from the source container 58. The spring member 232, therefore, biases the syringe assembly 224 to assist in filling the syringe barrel 226 and generally towards a full position. The handle 234 may further include a stopping or an arresting strap 240 that connects to a stop member or portion 242. The stop member or portion 242 is configured to engage a fixed portion of the syringe barrel 226 or is fixed to the syringe barrel 226. The arresting strap 240 engages the stop member or portion 242 to limit travel of the handle 234 when biased by the spring member 232.

[0046] The irrigant may be manually expressed from the syringe assembly 224 by the user grasping the handle 234 and squeezing or pressing a first handle member 234a towards the syringe barrel 226 and towards a second handle member 234b generally in the direction of arrow 250, which may be opposite the direction of the arrow 236. In squeezing the handle 234, the user moves the syringe plunger 228 in a second direction in the syringe barrel 226, and generally in the direction of arrow 250. This forces a fluid out of the syringe barrel 226 and through the valve assembly 50, connected to the syringe barrel 226. The expressed material is directed, by the valve assembly 50, through the tubing 72.

[0047] Once a selected material has been expressed or emptied from the syringe barrel 226, the user may release or stop squeezing the handle 234. Once the handle 234 is released, the spring member 232 in applying the biasing force, will cause the handle 234, connected to the syringe plunger 228, to generally move in the direction of arrow 236. The spring member 232 may be configured and manufactured to overcome any force applied by the first handle member and

the second handle member 234a, 234b, alone, and friction of the syringe plunger 228 within the syringe barrel 226. In this manner, the syringe barrel 226 may be refilled with an irrigant from the source container 58 as the spring member 232 biases the handle 234 in the direction of arrow 236 to move the syringe plunger 228 in the direction of arrow 236. The spring member 232, therefore, may also make continuous or extended irrigation easier and less stressful to a user. The biasing spring may provide all of the force necessary to refill the syringe barrel 226. Thus, the user may only need to provide the force to express material from the irrigation system 220. As noted herein, expressing material may be performed by the user squeezing the handle 234.

[0048] The source container or source container 58 may be connected with the syringe barrel 226 via or with tubing, such as flexible tubing 56. The source container 58 may hold any selected irrigation fluid, such as those discussed above including sterile saline or other materials that may include therapeutic agents such as antimicrobials, antibacterials, or the like. Further, the source container 58 may be any appropriate container, such as an IV bag.

[0049] The source container 58 may be connected with the tubing 56 using the connector 60 at the connection receptacle 62 with the source container 58. The tubing 56 and connector 60 and connection receptacle 62 may be substantially similar to that discussed above. Further, as material exits the source container 58 it may flow in through the tubing generally in the direction of the arrow 54 through the valve assembly 50. The valve assembly 50 may be similar or identical to the valve assembly discussed above including the check valve 80187 sold by Qosina. The valve assembly 50 may include two one-way valves, as discussed above. Accordingly, the valve assembly 50 may allow material only to flow from the source container 58 into the syringe barrel 226 and not from the syringe barrel 226 into the source container 58. Further, the valve assembly 50 may allow material to be expressed only from the syringe barrel 226 through the irrigation tubing 72 while not allowing material to move through the valve assembly 50 from the irrigation tubing 72 either into the syringe barrel 226 or into the source container tubing 56. Therefore, the valve assembly 50 allows material to be drawn from the source container 58 into the syringe barrel 226 and then expressed and irrigated through the irrigation tubing 72 generally in the direction

of arrow 70. The valve assembly 50, however, will generally not allow flow in the directions opposite of arrows 54 and 70.

[0050] The valve assembly 50 allows the irrigation system 220 to be used to draw an irrigation material from the source container 58 into the syringe barrel 226 and then express the irrigation material from the syringe barrel 226 through the tubing 72, in a manner similar to that discussed above. The irrigation system 220 may be operated by the user squeezing the handle 234 to empty the syringe barrel 226 (at least a selected amount). The spring member 232 may then bias the syringe plunger 228 out of the syringe barrel 226 generally in direction of arrow 236 to refill the syringe barrel 226 from the source container 58. This operation allows for substantially continuous irrigation by reciprocating the syringe plunger 228 in the syringe barrel 226. The user squeezes the handle 234 to express material and then releases the handle 234 to allow the spring member 232 to move the syringe plunger 228 to refill the syringe barrel 226 for the user to then express more fluid, if selected.

[0051] The tubing 72 may be connected to a terminal irrigation assembly or tip assembly 300. The terminal irrigation assembly 300, as illustrated in Fig. 4, Fig. 5, and Fig. 6, may include a vacuum tube connection region 302 that may include a connection member 304 having a proximal male connector 306 and a distal male connector 308. The proximal male connector 306 may be received within a female connector 309 of a vacuum source tube 311. The distal male connector 308 may be received within a proximal connection portion 312 of an irrigation tip holder 320. It is understood, however, that the irrigation tip holder 320 need not be included as a separate or separable member.

[0052] The vacuum source tube 311 may be connected to a vacuum source 321. The vacuum source may be any appropriate source, such as a PM61 Power Vac Aspirator, sold by Precision Medical, Inc., having a place of business in Northampton, PA. The vacuum source may also be a non-portable system such as a constant suction system, such as one generally available in hospitals as a central suction system.

[0053] If selected, the irrigation tip holder 320 may include an external wall 322 that defines an internal cannula 324. The suction may be drawn through the internal cannula 324 and the suction or vacuum source tube 311. The irrigation

tip holder 320 may be formed from a syringe barrel such as a syringe Luer-Lok® hypodermic syringe sold by Becton, Dickinson and Company Corporation, having a place of business in Franklin Lakes, NJ. The syringe barrel may have the vacuum tube connection region 302 positioned within a proximal end 326 of the syringe barrel that defines the proximal connection portion 312. As discussed herein, therefore, suction may be drawn through the irrigation tip holder 320 at a selected time. The irrigation tip holder 320 may further include a Luer-lok® hypodermic syringe with a partial or half-twist connection at a distal end connector 330. A Y-connector or Y-connection portion 340 may connect with the distal end connector 330. As noted above, the irrigation tip holder 320 need not be included and the vacuum source tube 311 may be connected directly to the Y-connector 340.

[0054] The Y-connector 340, as discussed further herein, may communicate with or have an irrigation tip tube 350 passed through at least a portion of the Y-connector 340, including an “Y”-arm or extension 354 extending from a central member 356 of the Y-connector 340. The central member 356 may define a first, main, or central cannula 358 and the Y-arm or extension 354 may also define a second, auxiliary, or extension cannula 360. The central cannula 358 may intersect with the extension cannula 360 and be in fluid communication. The Y-connector 340 may be connected at the distal end connector 330 to the irrigation tip holder 320. As discussed herein, suction may draw material through the central cannula 358 and the internal cannula 324 through the vacuum source tube 311.

[0055] The Y-connector 340 connects at a connection region 352 with one or more sheaths that are sheathed so the tip tube 350. The tip tube 350 may be sheathed or covered in one or more fixed shape sheaths or sleeves. The sheaths may include a 70° curved sheath 370, a 120° curved sheath 372, and a 130° curved sheath 374. It is understood, however, that more sheaths may be provided and that sheaths of other curvatures may be provided. Each of the sheaths 370, 372, 374 may be passed over the tip tube 350. The tip tube 350 may be flexible enough that it will obtain or be held in the shape of the sheath 370, 372, 374 when placed inside of the sheath 370, 372, 374. Each of the sheaths 370, 372, 374 may be selectively and/or separately connected to the connection

region 352. Each of the sheaths may include an outer diameter of about 1 millimeter (mm) to about 10 mm, including about 1 mm to about 6 mm, and further including about 3 mm to about 5 mm.

[0056] The tip 76 may extend from the tip tube 350. In various
5 embodiments, the tip 76 may be formed separate from the tip tube 350 and inserted into and connected to the tip tube 350. In various embodiments, the tip 76 may be formed at a distal end of the tip tube 350. The tip tube 350 extends from the tip 76 through a portion of the Y-connector 340 at the connection region 352 and into the extension cannula 360 of the Y-arm or extension 354. The tip
10 tube 350 further extends through an extension arm connector 380 and a directional control system that may include a direction control member (e.g. a grip or handle) 382 to a tip tube connector 400. The tip tube connector 400 may connect with a female connector 310 of the tubing 72. When connected, as material is expressed from the syringe barrel 226, the material may travel past the
15 valve assembly 50 (in the general direction of arrow 70) through the tubing 72 and through the tip tube 350 and the tip 76 to a selected location, such as within a sinus passage as discussed above. Therefore, material may be irrigated through the tip 76 of the irrigation tip tube 350 from the syringe barrel 226.

[0057] The tip tube 350 may be fixedly connected to the direction control
20 member 382 which may rotate within the extension arm connector 380. As the direction control member 382 rotates, such as around an axis 410 in the direction of double headed arrow 412, the tip tube 350 may also rotate causing the tip 76 to also rotate. As the tip 76 rotates it may be rotated around an axis 420 that may be defined by the tip tube 350 and the selected sheath positioned over the tip tube
25 350, such as the sheath 370 as illustrated in Figs. 5 and 6.

[0058] As discussed above, the tip 76 may include the opening 80 that forms a fan or other selected shape of the spray of the material being expressed through the tip or from the tip 76. In rotating the direction control member 382 around the axis 410, which in turn rotates the tip 76 around the axis 420, generally
30 in direction of the double headed arrow 424, allows the fan or other shaped spray to also be rotated around the axis 420. Therefore, if a substantially flat fan is expressed from the tip 76 and the fan rotates around the axis 420, the fan may cover a surface generally defining a circle or disc shape around the axis 420.

[0059] Further, the sheath 370 (as may all of the sheaths 370, 372, 374) may include an opening or passage between an internal wall 430 and an outer wall 434 of the tip tube 350. The sheath 370, in forming the passage, will allow the suction or vacuum formed from the vacuum source 321 to be drawn through the sheath 370 and, in turn, through the central cannula 358 of the Y-connector 340 and the internal cannula 324 of the irrigation tip holder 320 and then through the vacuum source tube 311. The suction may be passed the tip 76 and through the selected sheath 370, 372, 374, generally in the direction of arrow 450.

[0060] As discussed above, the vacuum source 321 may be a constant vacuum source providing a constant vacuum and suction through the terminal irrigation assembly 300. Thus, suction may always be provided at or near the tip 76 through the sheath, such as the sheath 370, even during expressing or irrigation of a selected area. In providing constant suction or vacuum, the irrigation material may not build up at a selected location and removed or debrided material may be withdrawn once it is loosened from a selected surface. Therefore, the terminal irrigation assembly 300 may provide both a suction and irrigation at or near the tip 76 of the terminal irrigation assembly 300.

[0061] Accordingly, the irrigation system 220 may be operated to irrigate at the tip 76 and vacuum or suction material near the tip 76 through the sheath 370 (or other appropriate sheath 370, 372, 374) connected to the connection region 352. A user may irrigate an area, such sinus or other selected volume, and material once expressed from the tip 76 and/or debrided from a surface may be removed with the suction.

[0062] It is understood that the irrigation system 220 may be operated in performing a procedure on a human, such as for irrigation of the nasal passage or sinus cavity. It is further understood, however, that irrigation system 220 may be used in a non-human subject for irrigating, providing a selected material (e.g., a lubricant) or cleaning a selected volume of any appropriate object. For example, the irrigation system 220 may be used to provide a selected liquid to a machine system for a selected purpose, including those expressed above.

[0063] In addition, the user may remove the syringe assembly 224 from the Y-connector 340 and place a cap or other member 391 in its place. The cap 391 may be tethered to the Y-connector 340 or otherwise obtained to block the

irrigation passage of the Y-connector 340. When blocked, the vacuum source 321 would provide the only flow through the Y-connector 340 and the system may operate in a suction only mode. Thus, the irrigation system 220 may be blocked to allow only suction, for various purposes.

5 **[0064]** According to various embodiments an irrigation system 220', as illustrated in Fig. 7, may be altered relative to the irrigation system 220 illustrated in Fig. 4 above. The irrigation system 220' illustrated in Fig. 7 may include the syringe assembly 224 connected to the Y-connector 340 without the tubing 72 between the syringe assembly 224 and the Y-connector 340. The syringe
10 assembly 224 may be connected to the Y-connector 340 through the female connector 310 and the direction control member 382. Therefore, the direction control member 382 may be still operated to change direction of the tip 76 by moving the tip tube connector 400, as discussed above.

[0065] Further, as illustrated in Fig. 7, the irrigation system 220' may have
15 the syringe assembly 224 connected to the central member 356 rather than to the Y-arm or extension 354 as illustrated in Figs. 4, 5, and 6. It is understood that this is not required, but that the Y-connector 340 may be connected in either manner for the irrigation system 220, illustrated in Fig. 4, or the irrigation system 220', illustrated in Fig. 7. In the irrigation system 220', however, the cannula 358
20 through the central member 356 is not operated as the suction cannula, but is the irrigation cannula. Further, the extension cannula 360 in the Y-arm or extension 354 is not the irrigation cannula, but is the suction cannula. Therefore, the cannula in either the central member 356 or the Y-arm or extension 354 is determined by which portion to which it is connected.

25 **[0066]** In this manner, the irrigation system 220' may be operated with a substantially single hand (as illustrated in Fig. 7) of the user or operator without requiring the user to hold the syringe assembly 224 in one hand and the terminal irrigation assembly 300 in a separate hand. The user, therefore, may be able to move the tip 76 with the sheath 370 by moving the syringe assembly 224 rigidly
30 connected to the sheath 370 through the Y-connector 340. The user may further be able to operate or rotate the tip tube connector 400 with the direction control member 382, as discussed above. Nevertheless, the syringe assembly 224 may be rigidly connected to the terminal irrigation assembly 300 to assist in efficiently

operating the irrigation system 220' without the need for the separate tubing 72. The irrigation system 220', however, may operate substantially similar to the irrigation system 220 as described above without the tubing 72. That is, upon squeezing the handle 234, the syringe plunger 228 may move in the direction of arrow 250 to move the irrigation fluid generally in direction of arrow 70 through the terminal irrigation assembly 300 and the tip 76 to irrigate a selected location.

[0067] Example embodiments are provided so that this disclosure will be thorough, and will fully convey the scope to those who are skilled in the art. Numerous specific details are set forth such as examples of specific components, devices, and methods, to provide a thorough understanding of embodiments of the present disclosure. It will be apparent to those skilled in the art that specific details need not be employed, that example embodiments may be embodied in many different forms and that neither should be construed to limit the scope of the disclosure. In some example embodiments, well-known processes, well-known device structures, and well-known technologies are not described in detail.

[0068] The foregoing description of the embodiments has been provided for purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure. Individual elements or features of a particular embodiment are generally not limited to that particular embodiment, but, where applicable, are interchangeable and can be used in a selected embodiment, even if not specifically shown or described. The same may also be varied in many ways. Such variations are not to be regarded as a departure from the disclosure, and all such modifications are intended to be included within the scope of the disclosure.

CLAIMS

What is claimed is:

1. A system for irrigation of a selected location, comprising:

a manual pump assembly having a pump barrel forming a volume;

5 a fluid source fluidly connected to the pump barrel;

a tip having an opening to deliver a selected pressure spray to a surface;

a valve assembly configured to control flow from the fluid source to the pump barrel and from the pump barrel to the tip; and

10 wherein the manual pump is configured to be powered and operated by a user to at least express material from the pump barrel;

wherein the manual pump is configured to be reciprocally operated by the user to irrigate the selected location with a fluid through the tip.

- 15 2. The system of Claim 1, further comprising:

a plunger moveable within the pump barrel between a first barrel end and a second barrel end;

a biasing system to apply a biasing force to bias the plunger towards the first barrel end;

20 wherein the user overcomes the biasing force of the biasing system to irrigate the selected location by moving the plunger towards the second barrel end.

3. The system of Claims 1 or 2, wherein the valve assembly includes:

25 a first one-way valve configured to control flow from the fluid source to the pump barrel; and

a second one-way valve configured to control flow from the pump barrel to the tip.

- 30 4. The system of Claim 3, wherein the valve assembly is coupled directly to the pump barrel;

wherein the first one-way valve opens when the plunger moves toward a first pump barrel end and the second one-way valve opens when the plunger moves toward a second pump barrel end.

5 5. The system of any of Claims 1 to 4, wherein the opening of the tip has a cross-sectional area ratio relative to a cross-sectional area of a tubing extending from the pump volume of about 1:1 to about 1:10,000.

10 6. The system of any of Claims 1 to 5, further comprising:
a tip tube, wherein the tip extends from a terminal end of the tip tube;
a tip sheath having a selected configuration and an internal passage;
wherein the tip tube is positioned within the tip sheath.

15 7. The system of Claim 6, wherein the selected configuration includes an elongated portion and a curved portion;
wherein the tip tube conforms to the selected configuration.

20 8. The system of Claims 6 or 7, wherein the tip and the tip tube are formed as separate members and connected together for operation of the manual pump.

25 9. The system of any of Claims 1 to 8, further comprising:
a Y-connection portion having a first cannulated section and a second cannulated section; and
a tip tube, wherein the tip extends from an end of the tip tube;
wherein the tip tube extends through the first cannulated section.

30 10. The system of Claim 9, further comprising:
a vacuum tube connected to the second cannulated section;
wherein a suction is operable to be formed at or near the tip through the second cannulated section.

11. A system for irrigation of a selected location, comprising:
a manual pump assembly having:
a pump barrel forming a volume between a first barrel end
and a second barrel end,
5 a plunger moveable within the pump barrel, and
a biasing system to apply a biasing force to bias the plunger
towards the first barrel end;
a fluid source tube configured to fluidly interconnect a fluid source of
fluid and the pump barrel;
10 a tip assembly to deliver a selected material from the pump barrel;
and
a valve assembly configured to control flow from the fluid source to
the pump barrel and from the pump barrel to the tip assembly;
wherein the manual pump is configured to be reciprocally operated
15 by the user by applying a user force to overcome the biasing force to move the
plunger towards a second end and stopping application of the user force to allow
the biasing force to move the plunger towards the first end.

12. The system of Claim 11, wherein the valve assembly includes:
20 a first one-way valve configured to control flow from the fluid
source tube into and out of the pump barrel, and
a second one-way valve configured to control flow from out of
the pump barrel;
wherein the fluid is controlled by the valve assembly to flow only
25 from the fluid source tube into the pump barrel when the plunger moves towards
the first end and only from the pump barrel to the tip when the plunger moves
towards the second end.

13. The system of Claims 11 or 12, further comprising:
30 a handle interconnecting the plunger and the pump barrel;
wherein the handle is configured receive the user force to assist the
user in overcoming the biasing force by squeezing a first handle portion towards a
second handle portion.

14. The system of Claim 13, further comprising:
a direction control grip;
wherein the tip assembly includes:
a tip tube extending from and fixed to the direction control
5 grip, and
a tip extending from the tip tube;
wherein the direction control grip is configured to be rotated relative
to the tip assembly to rotate the tip around and axis.

10 15. The system of Claim 14, wherein the tip includes an opening
configured to form the fluid exiting the tip into a fan shape.

16. The system of Claim 15, wherein the tip assembly further includes:
a Y-connector having a first passage to receive the tip tube and a
15 second passage forming a suction passage.

17. A method of irrigating a selected location with a manual pump,
comprising:

moving a plunger in a first direction in a pump barrel to draw a liquid
20 from a container through a valve assembly into the pump barrel;

positioning a tip at the selected location;

squeezing a handle manually to move the plunger in a second
direction in the pump barrel to express the liquid from the pump barrel through the
valve assembly and through the tip at the selected location; and

25 operating a direction control to move the tip relative to the selected
location.

18. The method of Claim 17, further comprising:
holding at least the handle in a hand of a user that is connected to
30 the pump barrel and the plunger.

19. The method of Claim 18, wherein moving the plunger in the first direction includes closing a first one-way valve of the valve assembly and opening a second one-way valve of the valve assembly.

5 20. The method of Claim 19, wherein manually moving the plunger in the second direction includes closing the second one-way valve of the valve assembly and opening the first one-way valve of the valve assembly.

10 21. The method of Claim 20, wherein moving the plunger in the first direction in the pump barrel includes allowing a biasing member to bias the plunger in the first direction.

 22. The method of Claim 21, further comprising:
 continuously irrigating the selected location by repeatedly squeezing
15 the handle to move the plunger in the second direction in the pump barrel to express the liquid and releasing the handle to allow the biasing member to apply the biasing force to move the plunger in the first direction in the pump barrel.

 23. The method of Claim 22, wherein positioning the tip at the selected
20 location includes positioning the tip relative to a nasal passage;
 wherein the tip is configured to irrigate the nasal passage or a sinus cavity.

 24. A system for irrigation of a selected location, comprising:
25 a container configured to contain a selected volume of a liquid;
 a manual pump system having a pump volume, wherein the manual pump is configured to be powered and operated by a user;
 a first one-way valve configured to control flow from the container to the pump volume;
30 a tip having an opening to deliver a selected pressure spray to a surface; and
 a second one-way valve configured to control flow from the pump volume to the tip;

wherein the pump is configured to be reciprocally operated by the user to irrigate the selected location with the liquid through the tip.

25. The system of Claim 24, wherein the manual pump includes a syringe having:

a piston head and a piston rod moveable within the pump volume;
and

a syringe barrel forming the pump volume;
wherein the user moves the piston head with the piston rod to power
and operate the manual pump.

26. The system of Claim 25, further comprising:
a valve assembly including the first one-way valve and the second
one-way valve;

wherein the valve assembly is coupled to the syringe barrel;
wherein the first one-way valve opens when the piston head moves
in a first direction and the second one-way valve opens when the piston head
moves in a second direction.

27. The system of Claim 25, further comprising:
a valve assembly including the first one-way valve and the second
one-way valve;

wherein the valve assembly is coupled to the syringe barrel;
wherein the first one-way valve opens when the piston head moves
in a first direction to form a vacuum in the syringe barrel and the second one-way
valve opens when the piston head moves in a second direction to increase
pressure in the valve assembly.

28. The system of any of Claims 24 to 27, wherein the opening of the tip
has a cross-sectional area ratio relative to a cross-sectional area of a tubing
extending from the pump volume of about 1:1 to about 1:10,000.

29. The system of any of Claims 24 to 27, further comprising:
a tubing extending from the pump volume configured to be bent to
be placed in a selected anatomical location.

5 30. The system of Claim 25, wherein the first one-way valve and the
second one-way valve are operably connected to the syringe barrel to allow
continuous operation of the manual pump with the piston head and the piston rod
during irrigation of the selected location with the liquid from the container.

10 31. The system of Claim 24, further comprising:
a valve assembly including the first one-way valve and the second
one-way valve;
wherein the valve assembly is coupled to the manual pump.

15 32. A system for irrigation of a selected location, comprising:
a container configured to contain a selected volume of a liquid;
a manual syringe system having a piston head and a piston rod
moveable within a syringe barrel forming a pump volume, wherein the piston head
and the piston rod are configured to be powered and operated by a user;

20 a valve assembly including:
a first one-way valve configured to control flow from the
container to the pump volume, and
a second one-way valve configured to control flow from the
pump volume;

25 a tip fluidly connected to the second one-way valve and having an
opening to deliver a selected pressure spray to the selected location; and
wherein the pump is configured to be reciprocally operated by the
user to continuously irrigate the selected location with the liquid through the tip.

30 33. The system of Claim 32, wherein the piston head and the piston rod
are configured to be powered and operated by a single hand of the user.

34. The system of Claims 32 or 33, wherein the piston head is configured to be moved in a first direction within the syringe barrel to reduce a pressure in the syringe barrel and the valve assembly thereby closing the second one-way valve and opening the first one-way valve and draw the liquid from the container into the pump volume.

35. The system of Claim 34, wherein the piston head is configured to be moved in a second direction within the syringe barrel to increase a pressure in the syringe barrel and the valve assembly thereby opening the second one-way valve and closing the first one-way valve and to express the liquid from the pump volume through the tip.

36. The system of Claim 35, wherein the second direction is opposite the first direction within the syringe barrel.

37. The system of any of Claims 32 to 36, wherein the opening in the tip has a first surface angled relative to a second surface to cause a directional flow spray from the tip.

38. The system of any of Claims 32 to 37, further comprising:
a tubing coupled to the valve assembly and extending from the syringe barrel configured to be bent to be placed in a selected anatomical location.

39. A method of irrigating a selected location with a manual pump, comprising:

moving a piston head in a first direction to draw a liquid from a container through a first one-way valve into a pump volume;

positioning a tip at the selected location; and

manually moving the piston head in a second direction to express the liquid from the pump volume through a second one-way valve through the tip at the selected location.

40. The method of Claim 39, further comprising:
holding a syringe barrel in a hand of a user;
wherein manually moving the piston head in the first direction
includes pulling the piston head to reduce a pressure within the pump volume.

5

41. The method of Claim 39, further comprising:
holding a syringe barrel in a hand of a user;
wherein manually moving the piston head in the second direction
includes pushing the piston head to increase a pressure within the pump volume.

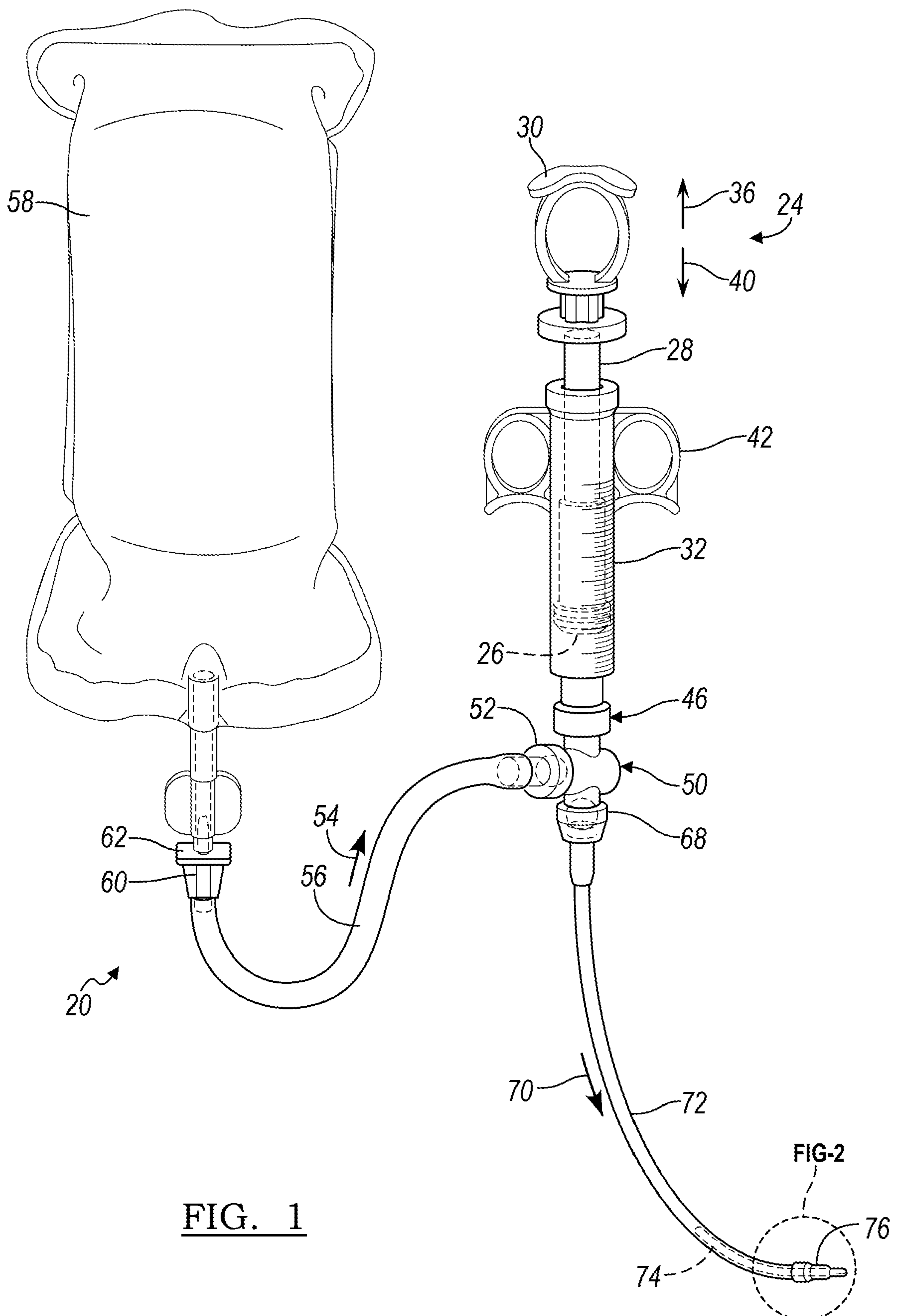
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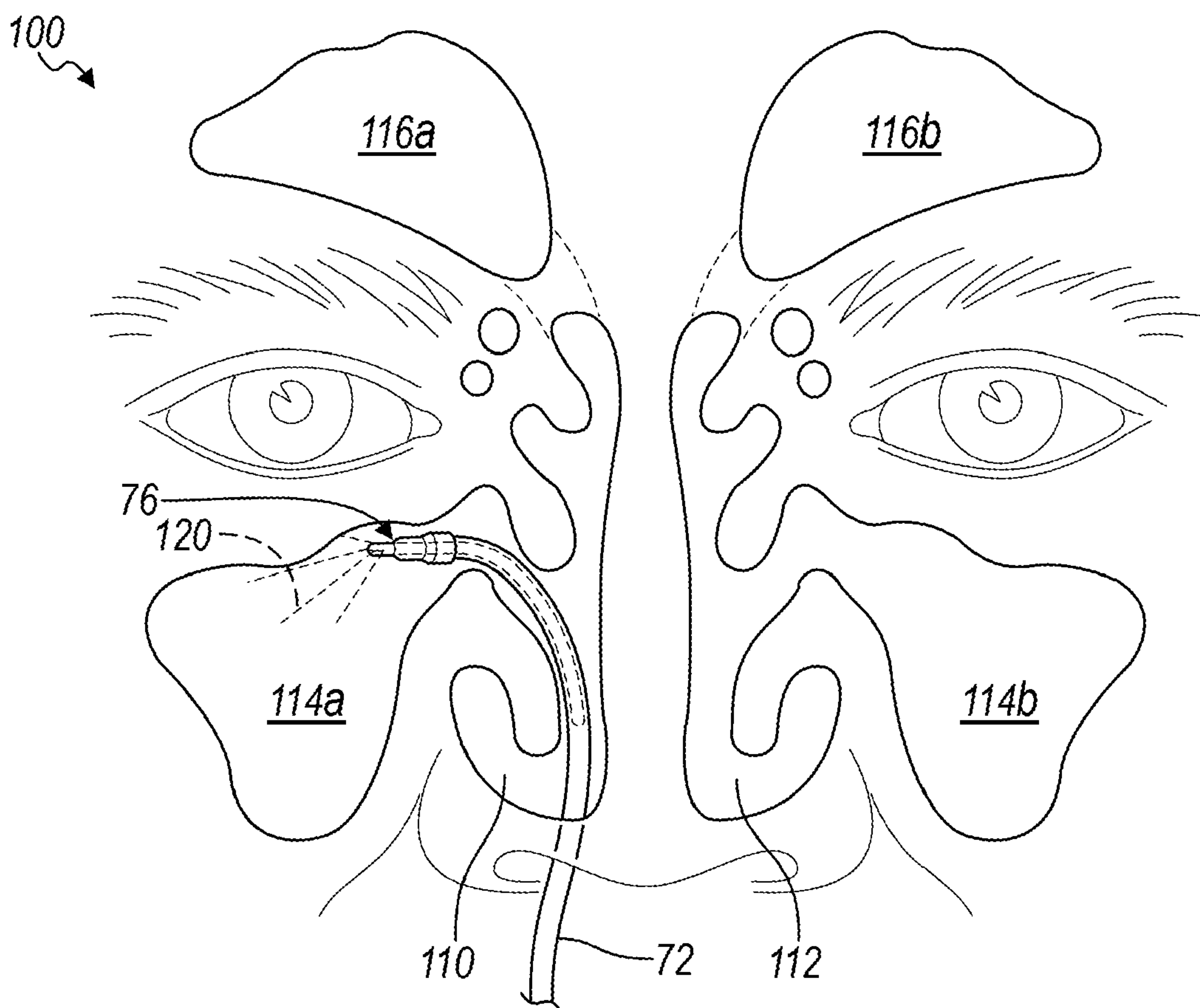
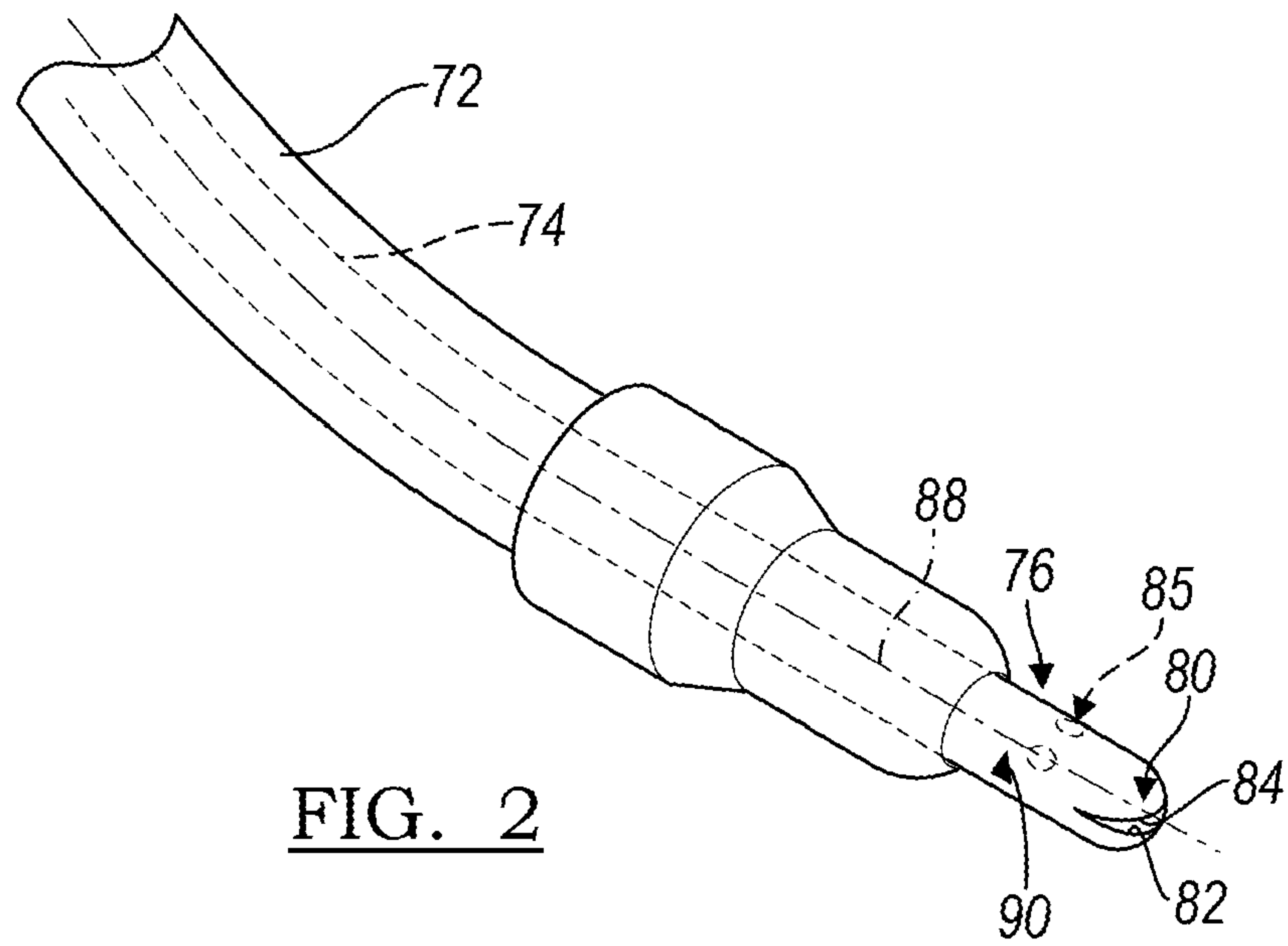
42. The method of Claim 39, wherein manually moving the piston head
in the first direction includes closing the second one-way valve.

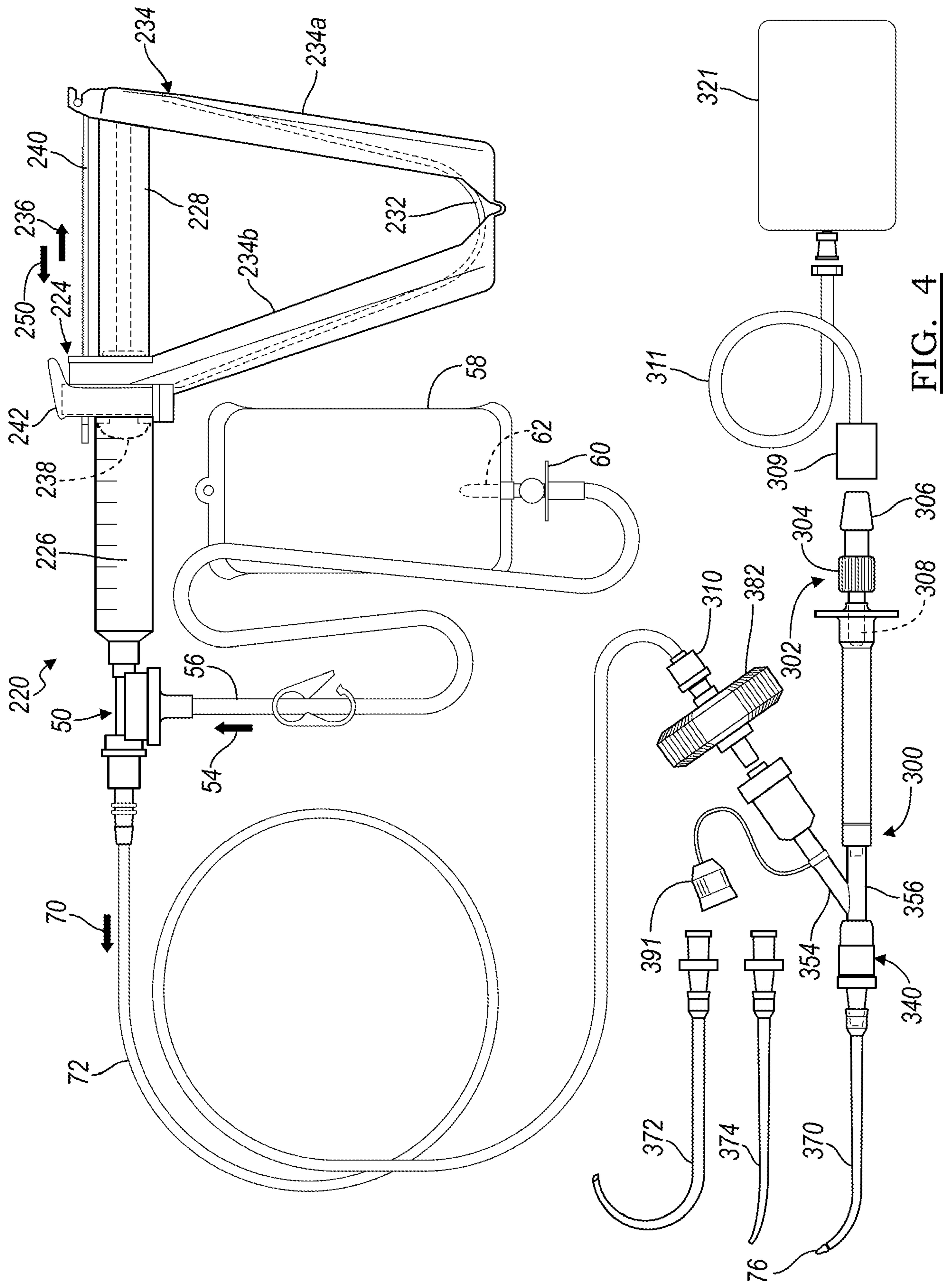
43. The method of Claim 39, wherein manually moving the piston head
15 in the second direction includes closing the first one-way valve.

44. The method of Claim 39, further comprising:
continuously irrigate the selected location by repeatedly moving the
piston head in the first direction followed by manually moving the piston head in
20 the second direction to express the liquid.

45. The method of Claim 39, further comprising:
continuously irrigate a surface of an implant by repeatedly manually
moving the piston head in the first direction followed by manually moving the
25 piston head in the second direction.







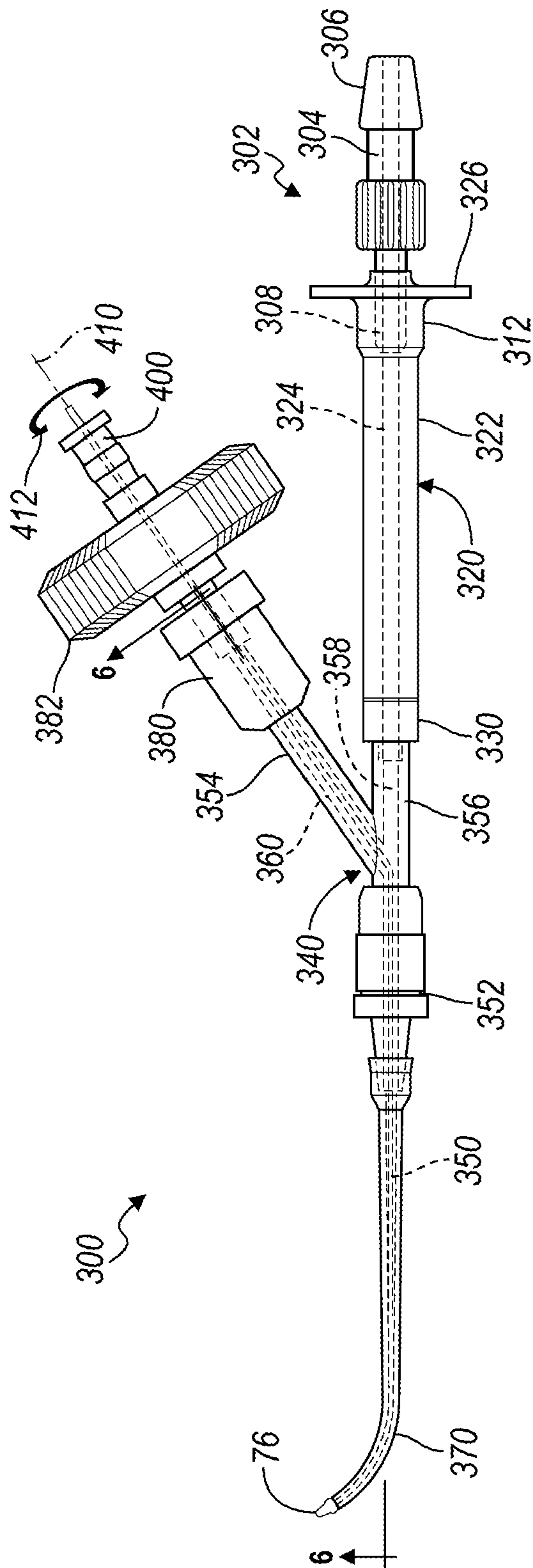


FIG. 5

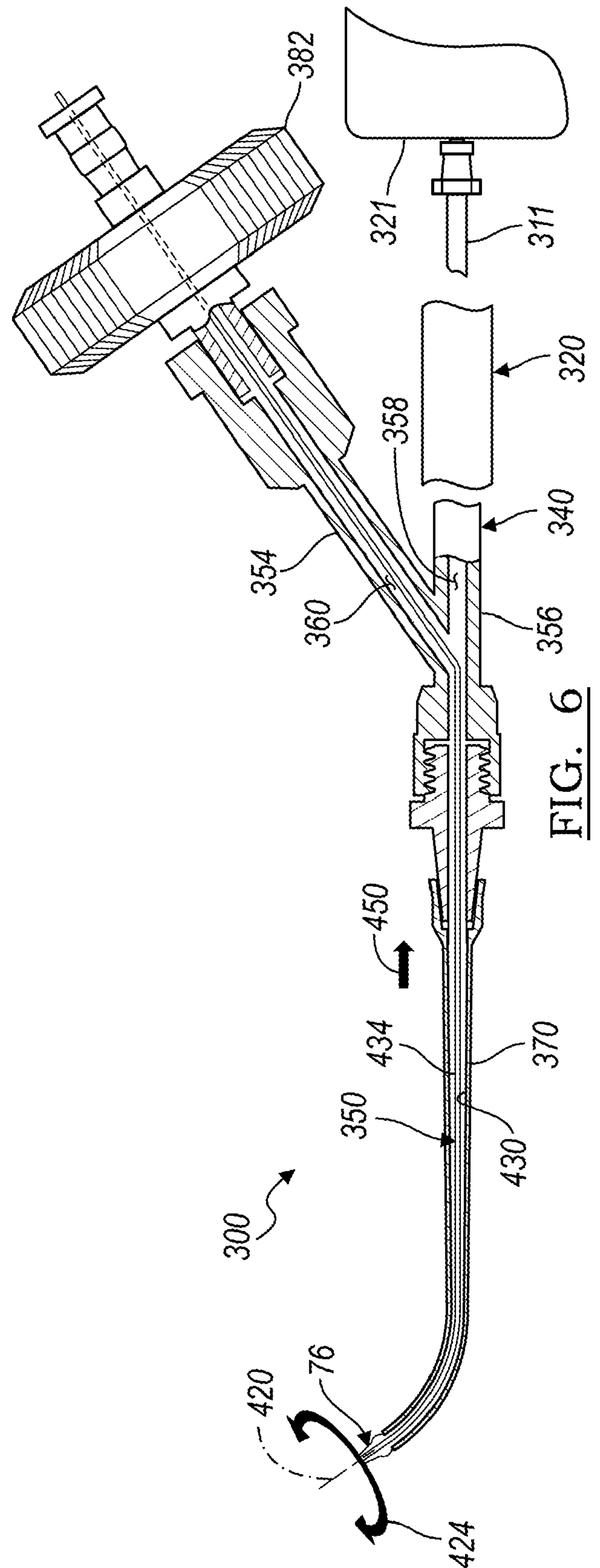


FIG. 6

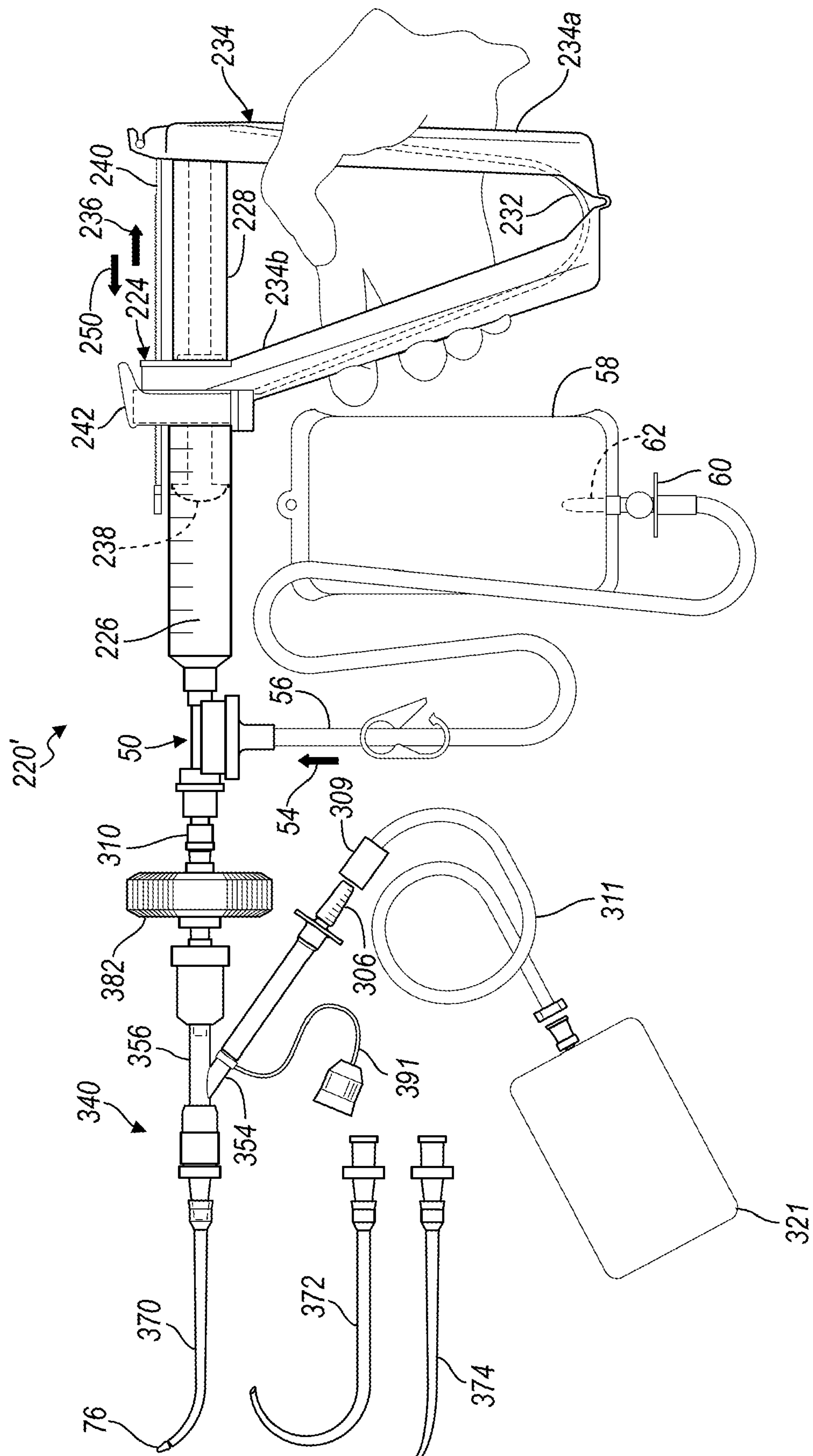


FIG. 7

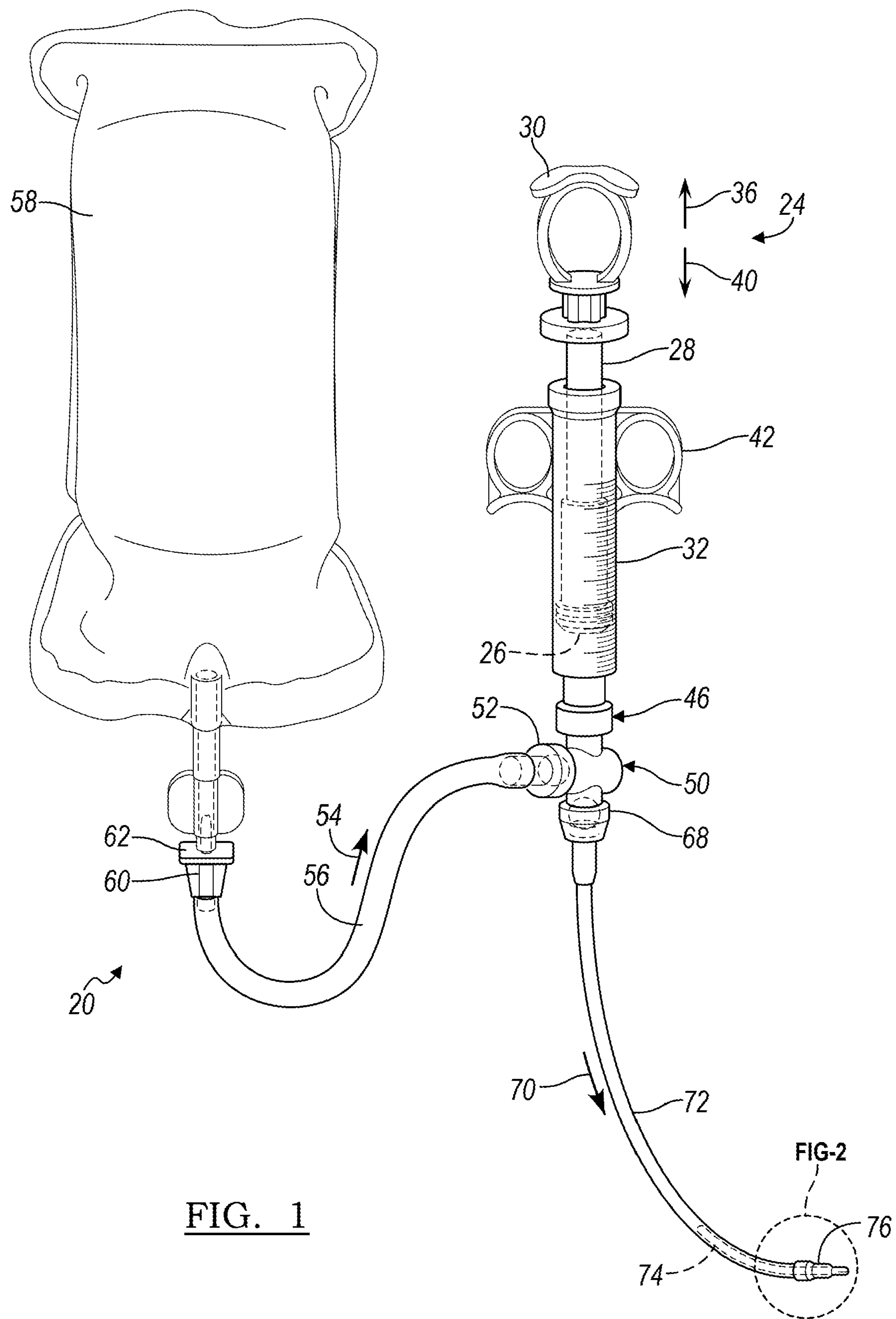


FIG. 1