



(51) International Patent Classification:

Not classified

(21) International Application Number:

PCT/US2021/020910

(22) International Filing Date:

04 March 2021 (04.03.2021)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/988,318 11 March 2020 (11.03.2020) US

(71) Applicant: **C. R. BARD, INC.** [US/US]; 1 Becton Drive, Franklin Lakes, NJ 07417 (US).

(72) Inventors: **BROOKS, Christopher K.**; 991 Summit Lake Trail, Lawrenceville, GA 30030 (US). **HUGHETT, James David Sr.**; 2046 Windfield Drive, Monroe, GA 30655 (US). **JACKSON, Benjamin**; 1225 Greenleffe Drive, Statham, GA 30066 (US).

(74) Agent: **WIGHT, Todd W.**; Rutan & Tucker LLP, 18575 Jamboree Road, 9th Floor, Irvine, CA 92612 (US).

(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, IT, JO, JP, KE, KG, KH, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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, SM,

(54) Title: PRESSURE ACTIVATED CATHETER

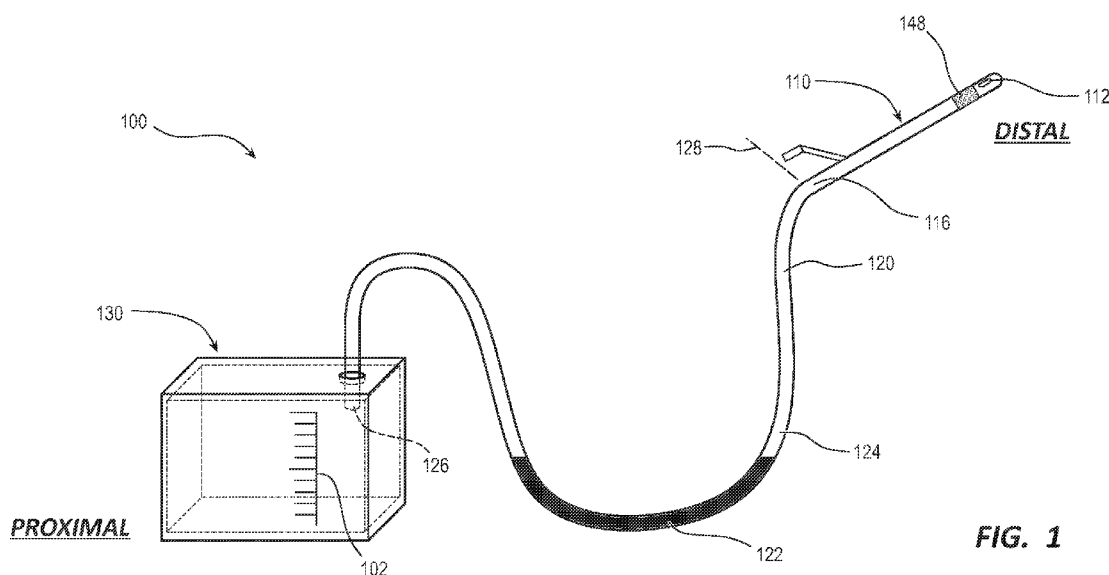


FIG. 1

(57) Abstract: Embodiments disclosed herein are directed a catheter for draining a fluid from a bladder of a patient and includes an elongate body defining a drainage lumen and a flow control system. The flow control system can include a valve configured to control a fluid flow through the drainage lumen, and a sensor configured to actuate the valve when a pressure within the bladder reaches a between 25% and 100% of a maximum capacity of the bladder. The valve can then close once the bladder is evacuated. This provides a natural cycle of filling and emptying that prevents fluid from pooling and stagnating either within the bladder or within a fluid collection system. Further the cyclical filling and emptying can prevent atrophy of the muscles and prevents induced catheterization urinary incontinence.

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

Declarations under Rule 4.17:

- *as to the applicant's entitlement to claim the priority of the
earlier application (Rule 4.17(iii))*
- *of inventorship (Rule 4.17(iv))*

Published:

- *without international search report and to be republished
upon receipt of that report (Rule 48.2(g))*

PRESSURE ACTIVATED CATHETER**PRIORITY**

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 62/988,318, filed March 11, 2020, which is incorporated by reference in its entirety into this application.

SUMMARY

[0002] Briefly summarized, embodiments disclosed herein are directed to a catheter including a flow control system having a sensor and a valve. The sensor detects an input, e.g. a pressure level or user actuated input, and transitions the valve between an open and closed state. The flow control system can allow fluid to accumulate before releasing the fluid, allowing the fluid to flush through and into a collection system. This provides a turnover of fluid through the system and prevents an accumulation of fluid, e.g. as dependent loops, which can be a source of catheter associated urinary tract infection (“CAUTI”) causing agents.

[0003] Dependent loops can cause fluid to pool within drainage tubes, which in turn can cause various complications. For example, urine pooling can be a source of catheter associated urinary tract infection (“CAUTI”) causing agents such as bacteria, microbes, and the like. Hospital Acquired Infections (“HAI”), such as CAUTI, are detrimental to the patient, and also incur extra costs in treating these additional complications.

[0004] Disclosed herein is a catheter configured to drain a fluid from a bladder of a patient, including an elongate body defining a drainage lumen, and a flow control system including a valve configured to transition between an open position and a closed position to control a fluid flow through the drainage lumen, and a pressure sensor disposed within the bladder and configured to actuate the valve between the open position and the closed position when a pressure within the bladder reaches a first pressure level.

[0005] In some embodiments, the valve is disposed within the bladder when the catheter is placed within the patient. The valve and the pressure sensor are communicatively coupled by one of wired or wireless communication. The pressure sensor actuates the valve to transition from a closed position to an open position when the first pressure level reaches between 25% and 100% of a maximum capacity of the bladder. The pressure sensor transitions the valve from an open position to a closed position when a second pressure level is reached,

the second pressure level being less than the first pressure level. The catheter further includes a sensor lumen extending parallel to the drainage lumen, and providing fluid communication between the bladder and the pressure sensor. A proximal outlet of the drainage lumen is disposed adjacent a urethral opening.

[0006] Also disclosed is a method of catheterizing a patient including, providing a catheter defining a drainage lumen and including a sensor and a valve configured to control a fluid flow through the drainage lumen, inserting the catheter into a bladder, wherein a distal opening of the drainage lumen is in fluid communication with the bladder, transitioning the valve from a closed position to an open position when the sensor detects a first pressure level, and transitioning the valve from an open position to a closed position when the sensor detects a second pressure level, the second pressure level being less than the first pressure level.

[0007] In some embodiments, inserting the catheter into the bladder further includes placing one of the valve and the sensor within the bladder. In some embodiments, the method further includes placing the sensor on a skin surface of the patient to detect the first pressure level by sending and receiving ultrasound waves through the skin surface of the patient. The valve and the sensor are communicatively coupled by one of wired or wireless communication. The sensor is disposed within the drainage lumen and is distal of the valve. The first pressure level is between 25% and 100% of a maximum capacity of the bladder.

[0008] Also disclosed is a tube configured to drain a fluid from a cavity within a patient including, an elongate body defining a lumen, a distal portion of the body configured to be disposed within the cavity, a valve disposed in the distal portion of the body and designed to transition between an open position and a closed position to control a fluid flow through the lumen, and a sensor designed receive an input and transition the valve between the open position and the closed position.

[0009] In some embodiments, the sensor is a pressure transducer disposed on the distal portion of the elongate body and the input includes a first pressure level. The sensor is a wireless switch communicatively coupled with the valve and configured to receive an input from a user to selectably transition the valve between the open position and the closed position. The sensor is an ultrasound pressure sensor secured to a skin surface of the patient and configured to transmit and receive ultrasonic waves to determine an amount of fluid disposed within the cavity. The tube further includes a sensor lumen providing fluid communication

between the cavity and the sensor, the sensor is disposed outside of the cavity and designed receive a pressure level input to transition the valve between the open position and the closed position. The tube further includes a sensor lumen and wherein the sensor is disposed on a stylet configured to be inserted through the sensor lumen to position the sensor within the cavity.

DRAWINGS

[0010] A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0011] FIG. 1 shows an exemplary catheter and fluid collection system, in accordance with embodiments disclosed herein.

[0012] FIG. 2 shows a schematic view of a catheter including a flow control system, in accordance with embodiments disclosed herein.

[0013] FIG. 3 shows a schematic view of a catheter including a flow control system, in accordance with embodiments disclosed herein.

[0014] FIG. 4 shows a schematic view of a catheter including a flow control system, in accordance with embodiments disclosed herein.

[0015] FIG. 5 shows a schematic view of a catheter including a flow control system, in accordance with embodiments disclosed herein.

DESCRIPTION

[0016] Before some particular embodiments are disclosed in greater detail, it should be understood that the particular embodiments disclosed herein do not limit the scope of the concepts provided herein. It should also be understood that a particular embodiment disclosed herein can have features that can be readily separated from the particular embodiment and optionally combined with or substituted for features of any of a number of other embodiments disclosed herein.

[0017] Regarding terms used herein, it should also be understood the terms are for the purpose of describing some particular embodiments, and the terms do not limit the scope of the concepts provided herein. Ordinal numbers (e.g., first, second, third, etc.) are generally used to distinguish or identify different features or steps in a group of features or steps, and do not supply a serial or numerical limitation. For example, “first,” “second,” and “third” features or steps need not necessarily appear in that order, and the particular embodiments including such features or steps need not necessarily be limited to the three features or steps. Labels such as “left,” “right,” “top,” “bottom,” “front,” “back,” and the like are used for convenience and are not intended to imply, for example, any particular fixed location, orientation, or direction. Instead, such labels are used to reflect, for example, relative location, orientation, or directions. Singular forms of “a,” “an,” and “the” include plural references unless the context clearly dictates otherwise.

[0018] With respect to “proximal,” a “proximal portion” or a “proximal end portion” of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near a clinician when the catheter is used on a patient. Likewise, a “proximal length” of, for example, the catheter includes a length of the catheter intended to be near the clinician when the catheter is used on the patient. A “proximal end” of, for example, the catheter includes an end of the catheter intended to be near the clinician when the catheter is used on the patient. The proximal portion, the proximal end portion, or the proximal length of the catheter can include the proximal end of the catheter; however, the proximal portion, the proximal end portion, or the proximal length of the catheter need not include the proximal end of the catheter. That is, unless context suggests otherwise, the proximal portion, the proximal end portion, or the proximal length of the catheter is not a terminal portion or terminal length of the catheter.

[0019] With respect to “distal,” a “distal portion” or a “distal end portion” of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near or in a patient when the catheter is used on the patient. Likewise, a “distal length” of, for example, the catheter includes a length of the catheter intended to be near or in the patient when the catheter is used on the patient. A “distal end” of, for example, the catheter includes an end of the catheter intended to be near or in the patient when the catheter is used on the patient. The distal portion, the distal end portion, or the distal length of the catheter can include the distal end of the catheter; however, the distal portion, the distal end portion, or the distal length of the catheter need not include the distal end of the catheter. That is, unless context suggests

otherwise, the distal portion, the distal end portion, or the distal length of the catheter is not a terminal portion or terminal length of the catheter.

[0020] To assist in the description of embodiments described herein, a longitudinal axis extends substantially parallel to an axial length of the catheter 110. A lateral axis extends normal to the longitudinal axis, and a transverse axis extends normal to both the longitudinal and lateral axes. Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by those of ordinary skill in the art.

[0021] FIG. 1 shows an exemplary fluid collection system 100, which generally includes a catheter 110, a drainage tube (“tube”) 120, and a collection container (“container”) 130. Exemplary catheters 110 include indwelling catheters, Foley catheters, balloon catheters, peritoneal drainage catheters, or the like, and are configured to be inserted into an orifice within the body of a patient to drain a fluid therefrom. In an embodiment, the catheter 110 can be inserted through the urethra and into a bladder of a patient. The catheter 110 includes an eyelet 112 that provides fluid communication with a lumen of the catheter 110, and is configured to drain a fluid, e.g. urine.

[0022] The tube 120 extends from a distal end 128 to a proximal end 126 to define an axial length, and defines a lumen 124. The distal end 128 of the tube 120 is configured to engage a proximal 116 end of the catheter 110. The tube 120 provides fluid communication between the lumen 114 of the catheter 110 and the collection container 130. The tube 120 can be formed of rubber, plastic, polymer, silicone, or similar suitable material. The collection container 130 can include a rigid container, a flexible collection bag, or similar suitable container for receiving a fluid, e.g. urine, drained from the catheter 110. In an embodiment, the container 130 includes graduated markings 102 for measuring a fluid disposed therein.

[0023] As shown in FIG. 1, the elasticity of the drainage tube 120 allows dependent loops 122 to form, which can lead to urine pooling within the tube 120. Urine pooling within the tube 120 can be a source of CAUTI causing agents, e.g. microbes, bacteria, etc. Embodiments disclosed herein are directed to a catheter 110 including a flow control system 148 to control a flow of fluid through the catheter 110 and through the fluid collection system 100. The flow control system 148 allows a fluid to accumulate and before releasing the fluid, allowing the fluid to flush through the catheter 110 and collection system 100. This cycle of accumulating and flushing prevents pockets of fluid from stagnating either within the patient

or within dependent loops 122 that can form within the collection system 100. Further, the cycle of accumulating and flushing maintains a natural cycle of filling and emptying, preventing muscle atrophy and catheter induced incontinence, which is common side effect of indwelling catheters.

[0024] FIG. 2 shows a catheter 110 placed within a patient, for example placed through a urethra with a distal portion disposed within a bladder 30 of the patient. In an embodiment, the catheter 110 extends from a distal end 118 to a hub 108 disposed at a proximal end 116. The hub 108 can be configured to couple with various tubes or medical lines, e.g. drainage tube 120, inflation line, and the like. In an embodiment, the hub 108 can include one or more extension legs 104 that can be configured to provide fluid communication between one or more lumens of the catheter 110 and various tubes or medical lines. In an embodiment, the catheter 110 defines a drainage lumen 114 that provides fluid communication between an eyelet 112, disposed at a distal end of the catheter 110, and the tube lumen 124 coupled to the hub 108.

[0025] In an embodiment, the catheter 110 further includes a balloon 140 disposed at a distal end of the catheter 110. The balloon 140 is disposed annularly about the catheter 110 and is in fluid communication with an inflation lumen 144 that extends between the balloon 140 and the hub 108. Once disposed within the bladder 30, the balloon 140 can be inflated, to retain a distal portion of the catheter 110 within the bladder 30. The catheter 110 can include a valve to maintain the balloon in an inflated or deflated state.

[0026] In an embodiment, the catheter 110 includes a flow control system 148, which includes a valve 150 and a sensor 160. The valve 150 can be selectively opened and closed, and is designed to control a fluid flow through the drainage lumen 114. In an embodiment, the valve 150 can operate as a binary switch, i.e. selectively transitioning between either a fully open state or a fully closed state. In an embodiment, the valve 150 can operate as a graduated switch, i.e. progressively transitioning between a fully open state and a fully closed state. In an embodiment, the valve 150 can include various mechanical or electrical flow control valves such as piston valves, ball valves, magnetic valves, solenoid valves, and the like.

[0027] In an embodiment, a sensor 160 is functionally coupled with the valve 150 and is designed to receive an input and transition the valve 150 between the open state and the closed state. In an embodiment, the sensor 160 is a pressure transducer that detects a change in fluid pressure level and sends a signal to the valve 150 to transition the valve 150 between

the open and closed states. In an embodiment, the sensor 160 is a switch that can be operated by a user to open or close the valve 150. In an embodiment, the sensor 160 is a timer that actuates the valve 150 at a predetermined time interval or within a predetermined time window. In an embodiment, the sensor 160 can receive two or more inputs and can detect inputs from various different modalities, including acoustic, magnetic, electromagnetic, or kinetic modalities, temperature changes, chemical changes, temporal changes, combinations thereof and the like.

[0028] In an embodiment, the flow control system 148 can further include additional mechanisms, circuitry, communication modules, power source(s), and the like to enable the sensor 160 and valve 150 to detect and respond to the input(s), and modify a fluid flow through the drainage tube 114. In an embodiment, the valve 150 and the sensor 160 can be formed as a single unit. In an embodiment, the valve 150 and the sensor 160 can be communicatively coupled by wired or wireless communications. Exemplary wireless communications include WiFi, Bluetooth, Near Field Communication (NFC), and the like.

[0029] In an embodiment, the flow control system 148 includes a passive valve 150 that can open and close in a cyclical manner, as described herein, without the need for a sensor 160. For example, the valve 150 can include a passive spring valve that is configured to open when a fluid pressure acting on the valve overcomes the force of the spring.

[0030] As described in more detail herein, the valve 150 can be situated in various positions within the fluid collection system 100. In an embodiment, the valve 150A and the sensor 160A are disposed within a distal portion of the catheter 110 such that the valve 150A and the sensor 160A are disposed within the bladder 30 when the catheter 110 is deployed. In an embodiment, the sensor 160A can be disposed on an outer surface of the catheter 110. In an embodiment, the sensor 160B can be disposed within an entrance of the drainage lumen 114, upstream of the valve 150.

[0031] In an embodiment, the valve 150B can be disposed within a shaft portion of the catheter 110, between a proximal end 116 and a distal end 118, such that the valve is disposed outside of the bladder 30 but still within the body of the patient, when the catheter is placed within the patient. In an embodiment, the valve 150C can be disposed within a proximal portion of the catheter 110, e.g. a catheter hub, such that the valve is disposed outside of the

body of the patient, when the catheter is placed within the patient. In an embodiment, the valve 150D can be disposed within a tube 120 or sample port of the fluid collection system 110.

[0032] It will be appreciated that the valve 150 positioned at each of the positions 150A, 150B, 150C, 150D can be functionally coupled with the sensor 160A, disposed at a distal tip 118 of the catheter 110. For example, in an embodiment, the sensor 160 can be a transducer that detects a pressure input and sends an electrical signal, by way of a wire disposed within a wall of the catheter, to operate the valve 150. In an embodiment, the sensor 160 can be wirelessly coupled with the valve 150, as described herein. In an embodiment, the sensor 160E can be placed externally to the patient and can detect an internal pressure level through the skin surface 20. For example, the sensor 160E can be an ultrasound sensor that can be placed on the stomach area to detect a pressure level of the bladder 30. In an embodiment, the sensor 160E can send and receive ultrasound waves and can determine an amount of fluid disposed within the bladder 30. In an embodiment, the sensor 160E can determine an amount fluid disposed within the bladder, and determine a maximum capacity of the bladder, to determine a fluid level as a percentage of maximum capacity of the bladder. In an embodiment, the sensor 160E can be secured to the skin surface 20 using an adhesive or the like.

[0033] As shown in FIG. 3, the catheter 110 can include a sensor lumen 164 extending axially, and provides fluid communication between the sensor 160 and the bladder 30. As such, a fluid can enter the sensor lumen 164 from a distal end and travel therethrough to the location of the sensor 160, e.g. within the bladder, outside of the bladder, outside of the body, or within the tube 120, as described herein. A fluid pressure within the bladder can then be transferred through the sensor lumen 164 and detected by the sensor 160. In an embodiment, the valve 150 and the sensor 160 can be provided as a single flow control unit 148 and can be disposed at either of the internally, e.g. at positions 148A, 148B, or external, e.g. at positions 148C, 148D, as described herein.

[0034] In an embodiment, as shown in FIG. 4, the sensor lumen 164 can be a sealed volume within the wall of the catheter 110, i.e. a distal end is not in fluid communication with the bladder 30. Optionally, the sealed sensor lumen 164 can be filled with a gas or a liquid. A fluid pressure within the bladder 30 can compress a distal end of the sensor lumen 164. The pressure can be transferred through the sensor lumen 164 to the sensor 160 disposed at a distal end of the sensor lumen 164, e.g. sensor 160C. The sensor 160 can then actuate the valve 150, as described herein. It will be appreciated that the sensor 160 can be positioned either

internally, within the bladder, or externally, as described herein, and the sealed sensor lumen can extend between the distal portion of the catheter and the sensor 160.

[0035] As shown in FIG. 5, the sensor 160 can be disposed on a stylet 158. The stylet 158 can be urged distally through the sensor lumen 164 to position the sensor 160 within catheter 110, e.g. either externally, within the hub 108, or internally within the shaft portion of the catheter 110 or within the bladder 30. The sensor 160 can then communicate with the valve 150, as described herein. Advantageously, this allows the fluid control system 148 to be used with existing standard multi-lumen catheters, or be applied or removed from the catheter without requiring the re-catheterization of the patient unnecessarily.

[0036] In an embodiment, the sensor 160 includes a pressure sensor and is responsive to a predetermined pressure level. In an embodiment the pressure level can be between 25% and 100% of a maximum bladder capacity. In an embodiment, the flow control system 148 can be configured to open at a first pressure level and close at a second pressure level, the first pressure level being greater than the second pressure level.

[0037] In an exemplary method of use a catheter 110 is placed within a patient such that distal portion is disposed within a bladder 30. A balloon 140 can be inflated to retain the distal portion within the bladder 30. A flow control system 148, including a valve 150 and a sensor 160, is disposed within a distal portion of the catheter 110 such that the flow control system 148 is disposed within the bladder 30. It will be appreciated, however, that other configurations and positions of the valve 150 and the sensor 160 are also contemplated, as described herein.

[0038] The valve 150 is configured to remain in a closed position to prevent a fluid flow through the drainage lumen 114. As fluid collects within the bladder 30 the pressure within the bladder increases. The pressure within the bladder is detected by the sensor 160 and can activate the valve 150 when the intra-bladder pressure reaches a threshold level. In an embodiment, the threshold pressure level is between 25% and 100% of maximum capacity of the bladder. In an embodiment, the threshold pressure level is between 60% and 80% of maximum capacity of the bladder.

[0039] When the threshold pressure level is reached, the valve is opened and the bladder is allowed to evacuate through the drainage lumen 114. In an embodiment, the valve remains open for a predetermined amount of time to allow the bladder to fully evacuate. In an

embodiment, the valve remains open until a second pressure threshold is reached. The second pressure threshold being less than the first pressure threshold.

[0040] Advantageously, the flow control system 148 allows the bladder to maintain a typical cycle of filling and emptying. This allows the bladder to build up a pressure that is then released, forcing fluid through the collection system 100 and preventing fluid from stagnating within dependent loops 122 within the tube 120. Further, the catheterized bladder typically collects a residual fluid 40 within the bladder 30 that is below the height of the eyelet 112, e.g. as shown in FIG. 2. Typical indwelling catheters that allow a continuous flow never fully drain the residual fluid 40, allowing the fluid to stagnate and concentrate, becoming a source of CAUTI causing agents. By contrast, embodiments disclosed herein allow the bladder to fill, diluting the residual fluid 40 with each cycle, and preventing a buildup of CAUTI causing agents.

[0041] Further, prolonged catheterization that allows a continuous flow removes the need to withhold and evacuate urine. This leads to muscle atrophy and induced urinary incontinence requiring a “retraining” of bladder control after the catheter is removed. Advantageously, embodiments disclosed herein maintain the cyclical filling and emptying of the bladder, preventing muscle atrophy and urinary incontinence.

[0042] Advantageously, the cycle of filling and emptying provides an increased fluid pressure within the bladder. This fluid pressure can overcome a higher flow resistance within the drainage lumen 114. As such the drainage lumen 114 can define a thinner inner diameter compared with traditional unrestricted flow catheters. This in turn provide a thinner outer diameter to the catheter 110 that is more comfortable and more discrete for the user. A smaller inner diameter of the drainage lumen 114 also allows for a more consistent laminar flow. Further, the smaller inner diameter of the drainage lumen 114, and/or the tube lumen 124 employs a capillary action to draw the fluid through the tube and into the collection container 130. For example, referring to FIG. 1, the force of a bolus of fluid flushing through the collection system 100 is sufficient to urge the fluid up a positive incline and pass through the dependent loop 122. The thinner internal diameter of the tube lumen 124 then provides a capillary action that siphons or “pulls” the remaining fluid through the dependent loop 122 and into the container 130.

[0043] In an embodiment, a user can manually override the operation of the flow control system 148 by selectively opening or closing the valve 150, for example, by way of a second sensor 160F disposed externally. In an embodiment, the second sensor 160F can be a physical or virtual sensor configured to receive an input from the user and can be included with a handheld device, for example a smartphone, tablet, laptop, or similar device. Advantageously, a nurse can selectively release a bolus of fluid and observe an amount of fluid. This allows the nurse to detect low fluid output more readily compare with other continuous, low flow systems.

[0044] In an embodiment, the catheter 110 including a flow control system 148, can extend proximally until an outlet is disposed proximate to the external urethral orifice. As such, the device can be discretely positioned within the patient's body and can be operated as described herein to provide a natural cycle filling and emptying. This can resolve permanent or temporary urinary incontinence and provides a user with an improved quality of life by circumventing any external equipment.

[0045] While some particular embodiments have been disclosed herein, and while the particular embodiments have been disclosed in some detail, it is not the intention for the particular embodiments to limit the scope of the concepts provided herein. Additional adaptations and/or modifications can appear to those of ordinary skill in the art, and, in broader aspects, these adaptations and/or modifications are encompassed as well. Accordingly, departures may be made from the particular embodiments disclosed herein without departing from the scope of the concepts provided herein.

CLAIMS

What is claimed is:

1. A catheter configured to drain a fluid from a bladder of a patient, comprising:
an elongate body defining a drainage lumen; and
a flow control system including:
a valve configured to transition between an open position and a closed position to control a fluid flow through the drainage lumen; and
a pressure sensor disposed within the bladder and configured to actuate the valve between the open position and the closed position when a pressure within the bladder reaches a first pressure level.
2. The catheter according to claim 1, wherein the valve is disposed within the bladder when the catheter is placed within the patient.
3. The catheter according to any of the preceding claims, wherein the valve and the pressure sensor are communicatively coupled by one of wired or wireless communication.
4. The catheter according to any of the preceding claims, wherein the pressure sensor actuates the valve to transition from a closed position to an open position when the first pressure level reaches between 25% and 100% of a maximum capacity of the bladder.
5. The catheter according to any of the preceding claims, wherein the pressure sensor transitions the valve from an open position to a closed position when a second pressure level is reached, the second pressure level being less than the first pressure level.
6. The catheter according to any of the preceding claims, wherein the catheter further includes a sensor lumen extending parallel to the drainage lumen, and providing fluid communication between the bladder and the pressure sensor.
7. The catheter according to any of the preceding claims, wherein a proximal outlet of the drainage lumen is disposed adjacent a urethral opening.
8. A method of catheterizing a patient, comprising:
providing a catheter defining a drainage lumen and including a sensor and a valve configured to control a fluid flow through the drainage lumen;

inserting the catheter into a bladder, wherein a distal opening of the drainage lumen is in fluid communication with the bladder;
transitioning the valve from a closed position to an open position when the sensor detects a first pressure level; and
transitioning the valve from an open position to a closed position when the sensor detects a second pressure level, the second pressure level being less than the first pressure level.

9. The method according to claim 8, wherein inserting the catheter into the bladder further includes placing one of the valve and the sensor within the bladder.

10. The method according to either claim 8 or claim 9, further including placing the sensor on a skin surface of the patient to detect the first pressure level by sending and receiving ultrasound waves through the skin surface of the patient.

11. The method according to any claim of claims 8-10, wherein the valve and the sensor are communicatively coupled by one of wired or wireless communication.

12. The method according to any claim of claims 8-11, wherein the sensor is disposed within the drainage lumen and is distal of the valve.

13. The method according to any claim of claims 8-12, wherein the first pressure level is between 25% and 100% of a maximum capacity of the bladder.

14. A catheter tube configured to drain a fluid from a cavity within a patient, comprising:

an elongate body defining a lumen, a distal portion of the body configured to be disposed within the cavity;
a valve disposed in the distal portion of the body and designed to transition between an open position and a closed position to control a fluid flow through the lumen; and
a sensor designed receive an input and transition the valve between the open position and the closed position.

15. The catheter tube according to claim 14, wherein the sensor is a pressure transducer disposed on the distal portion of the elongate body and the input includes a first pressure level.

16. The catheter tube according to claim 14, wherein the sensor is a wireless switch communicatively coupled with the valve and configured to receive an input from a user to selectably transition the valve between the open position and the closed position.

17. The catheter tube according to claim 14, wherein the sensor is an ultrasound pressure sensor secured to a skin surface of the patient and configured to transmit and receive ultrasonic waves to determine an amount of fluid disposed within the cavity.

18. The catheter tube according to claim 14, wherein the catheter tube further includes a sensor lumen providing fluid communication between the cavity and the sensor, and wherein the sensor is disposed outside of the cavity and designed receive a pressure level input to transition the valve between the open position and the closed position.

19. The catheter tube according to claim 14, wherein the catheter tube further includes a sensor lumen, and wherein the sensor is disposed on a stylet configured to be inserted through the sensor lumen to position the sensor within the cavity.

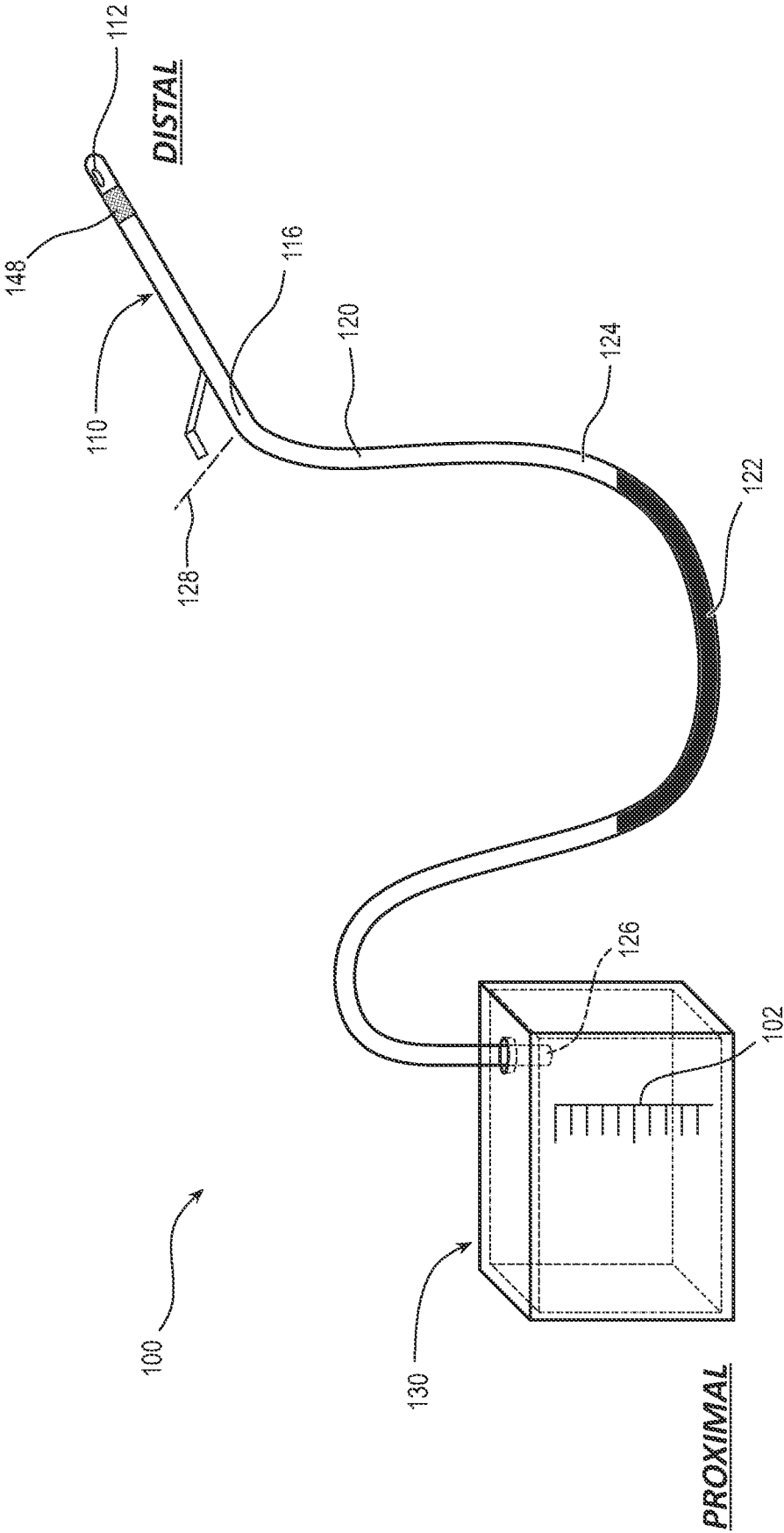


FIG. 1

2/5

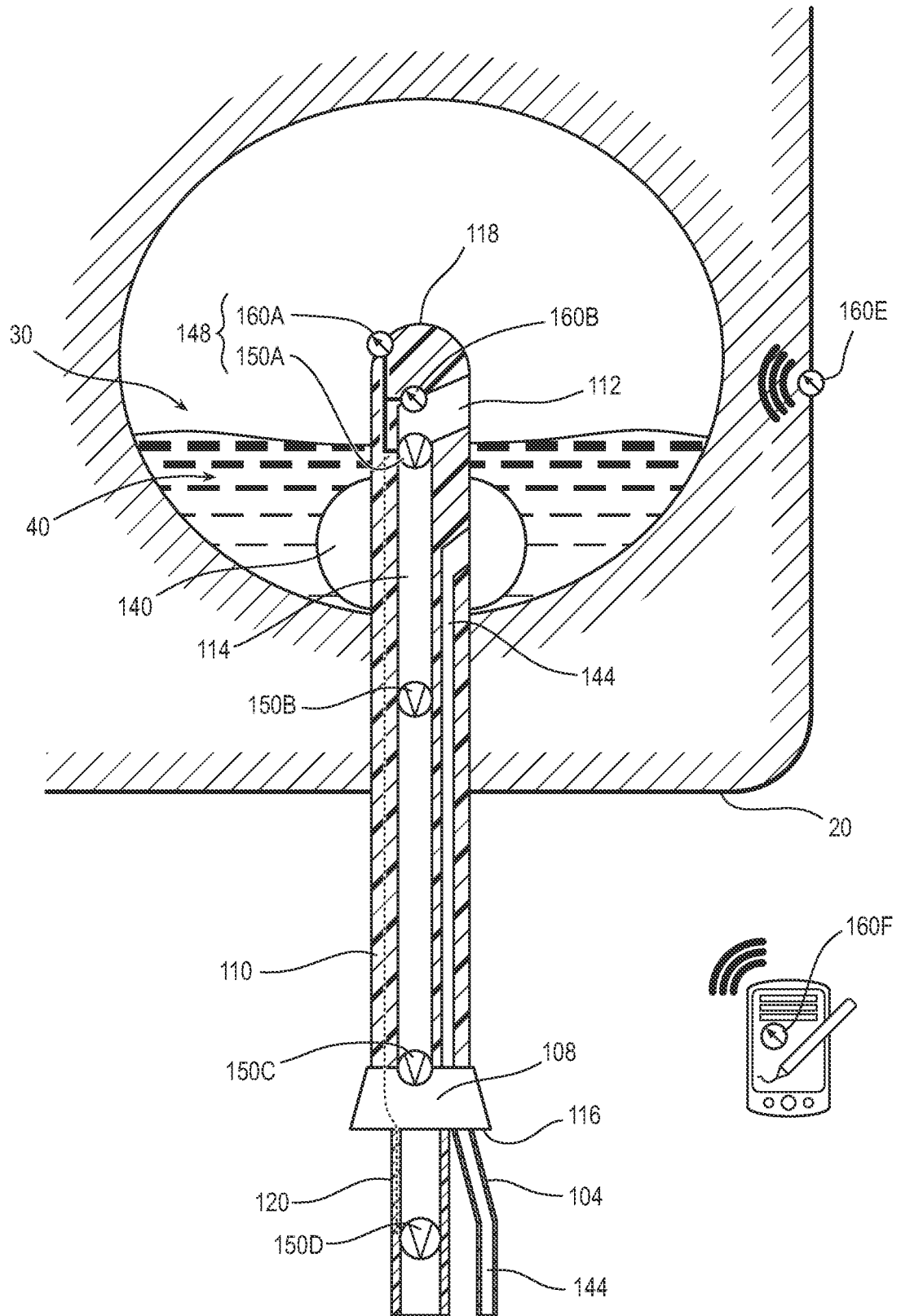


FIG. 2

3/5

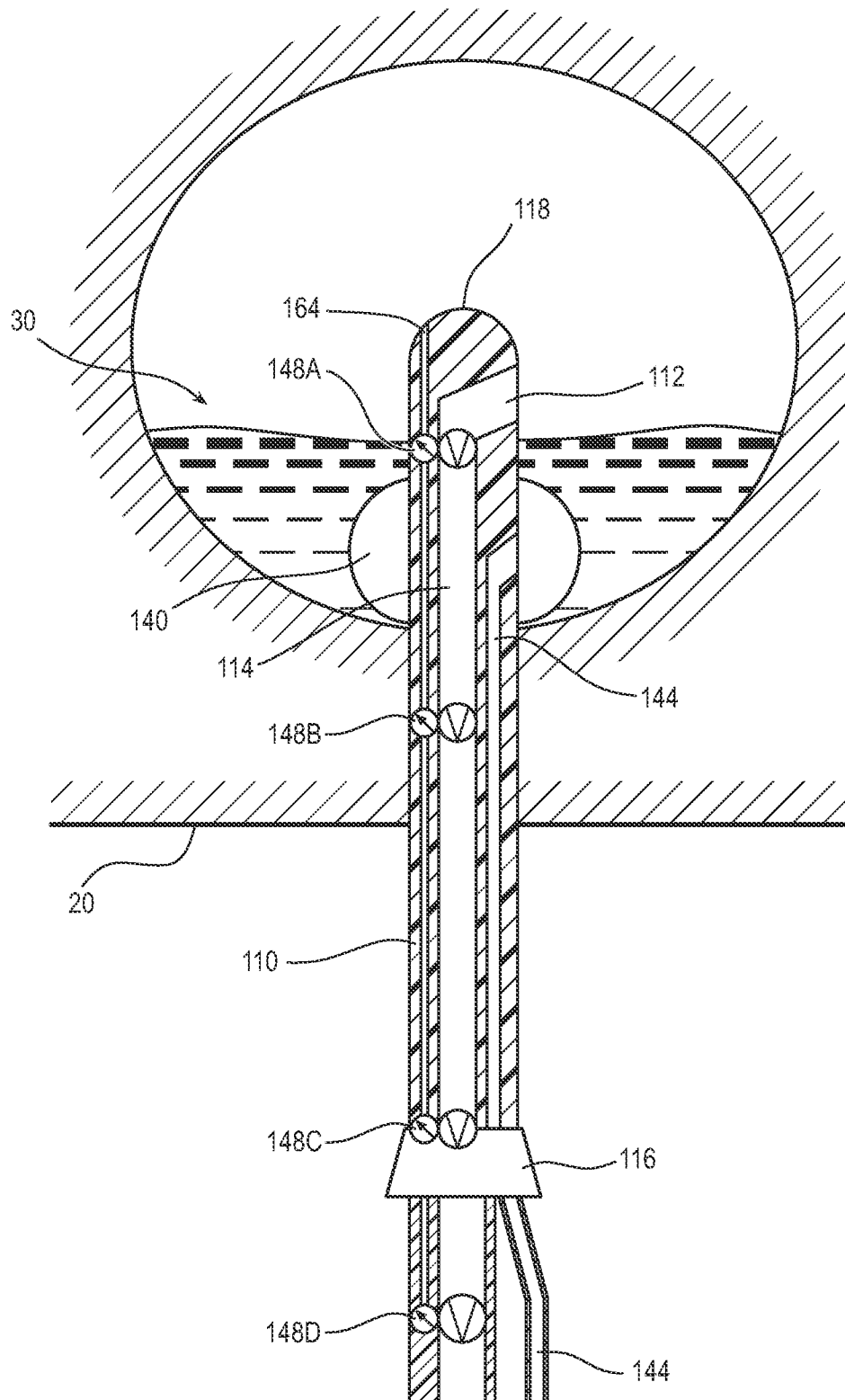


FIG. 3

4/5

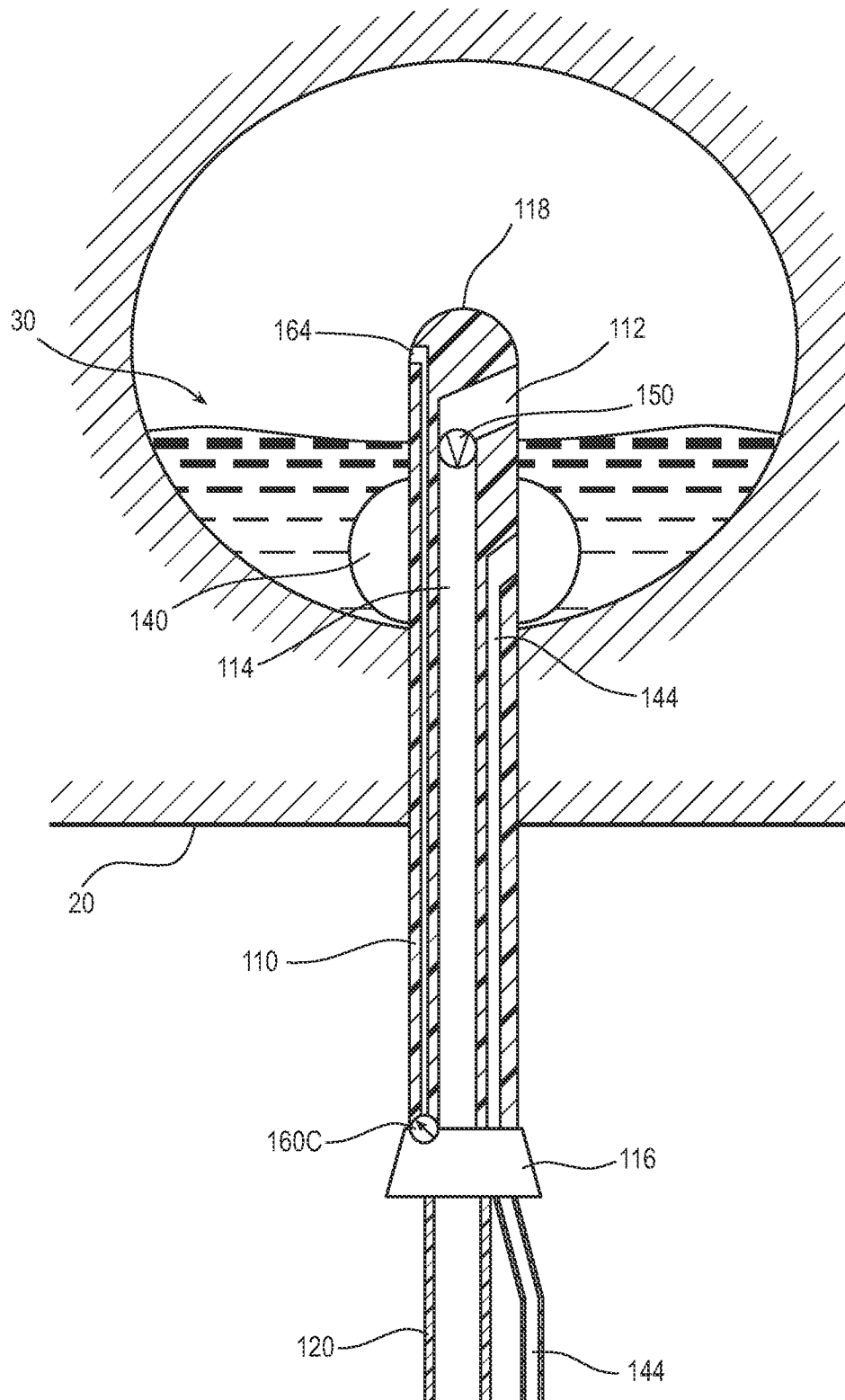


FIG. 4

5/5

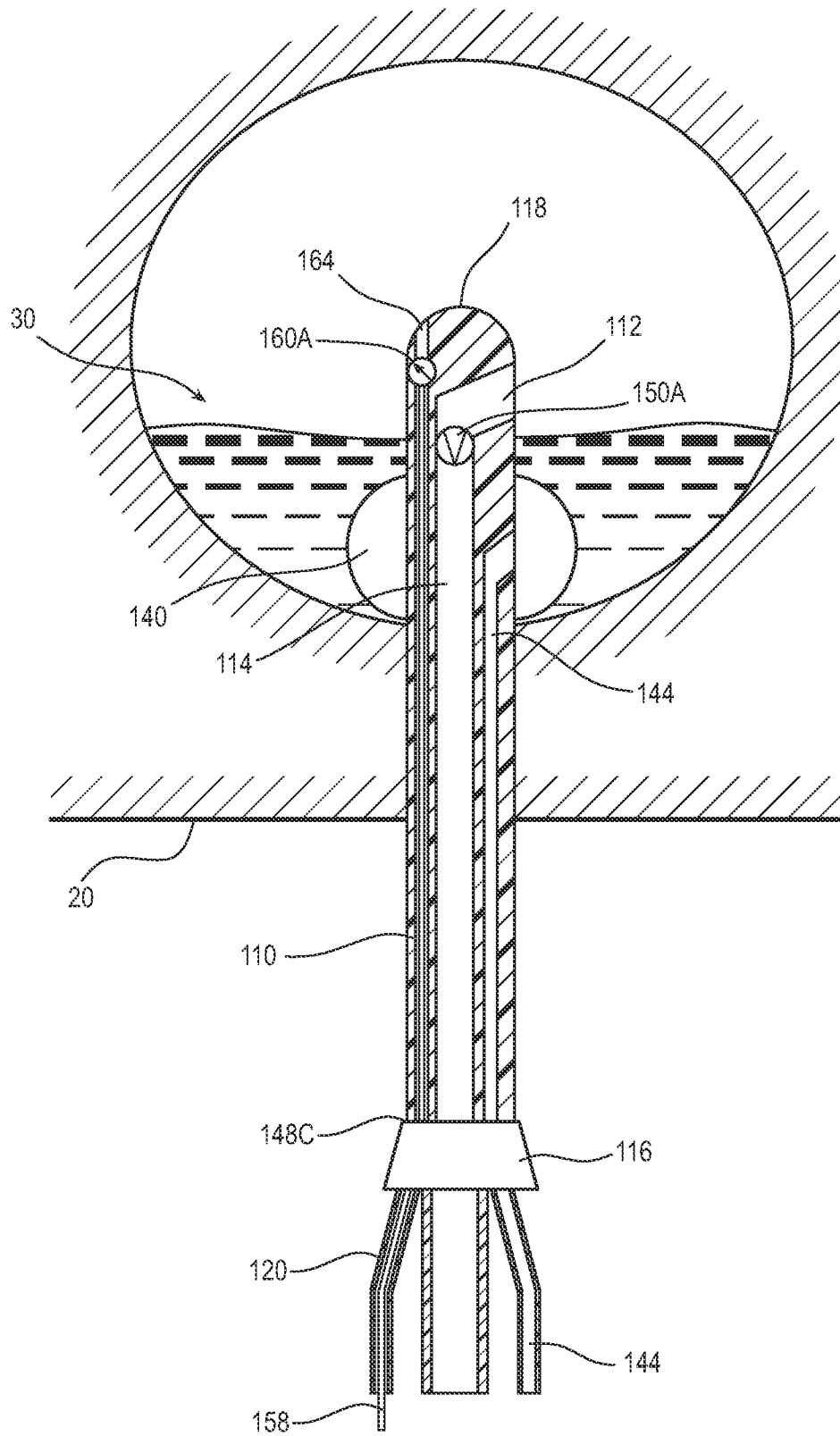


FIG. 5