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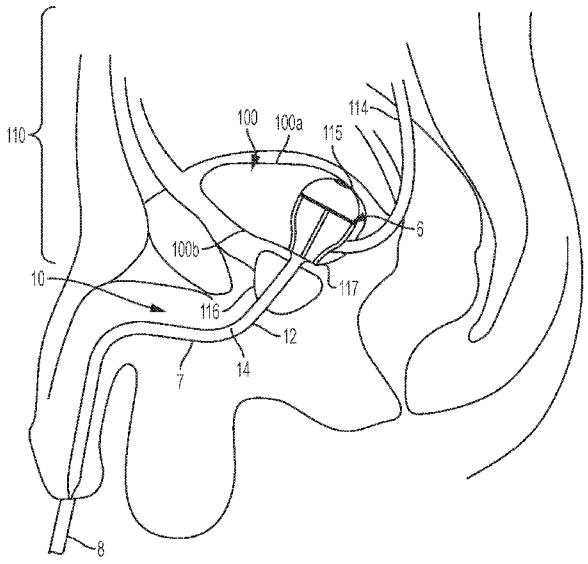

FIG. 1

(57) Abstract: A urine collection catheter is provided. The catheter includes: a conduit having an open distal end; a drainage tube positioned at least partially within the conduit; and a bladder superior wall support. The drainage tube includes one or more fluid ports or perforations for permitting fluid flow into a drainage lumen defined by the drainage tube. The bladder superior wall support includes a support cap and a plurality of support members extending from a proximal surface of the support cap through the open distal end of the conduit. The support cap is capable of being moved between a retracted position and a deployed position. In the deployed position, the distal end of the drainage tube is spaced apart from the support cap, such that the support cap supports portions of the superior wall of the bladder from occluding the one or more fluid ports or perforations of the drainage tube.

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CATHETER DEVICE AND METHOD FOR INDUCING NEGATIVE PRESSURE IN A PATIENT'S BLADDER

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to United States Provisional Application No. 62/194,585, filed July 20, 2015, United States Provisional Application No. 62/260,966, filed November 30, 2015, United States Provisional Application No. 62/278,721, filed January 14, 2016, and United States Provisional Application No. 62/300,025 filed February 25, 2016, each of which is incorporated herein by reference in its entirety.

BACKGROUND

Technical Field

[0002] The present disclosure relates to devices and methods for treating impaired renal function across a variety of disease states and, in particular, to devices and methods for collection of urine and inducement of negative pressure in the bladder.

Background

[0003] The renal or urinary system includes a pair of kidneys, each kidney being connected by a ureter to the bladder, and a urethra for draining urine produced by the kidneys from the bladder. The kidneys perform several vital functions for the human body including, for example, filtering the blood to eliminate waste in the form of urine. The kidneys also regulate electrolytes (e.g., sodium, potassium and calcium) and metabolites, blood volume, blood pressure, blood pH, fluid volume, production of red blood cells, and bone metabolism. Adequate understanding of the anatomy and physiology of the kidneys is useful for understanding the impact that altered hemodynamics other fluid overload conditions have on their function.

[0004] In normal anatomy, the two kidneys are located retroperitoneally in the abdominal cavity. The kidneys are bean-shaped encapsulated organs. Urine is formed by nephrons, the functional unit of the kidney, and then flows through a system of converging tubules called collecting ducts. The collecting ducts join together to form minor calyces, then major calyces, which ultimately join near the concave portion of the kidney (renal pelvis). A major function of the renal pelvis is to direct urine flow to the ureter. Urine flows from the renal pelvis into the ureter, a tube-like structure that carries the urine from the kidneys into the bladder. The

outer layer of the kidney is called the cortex, and is a rigid fibrous encapsulation. The interior of the kidney is called the medulla. The medulla structures are arranged in pyramids.

[0005] Each kidney is made up of approximately one million nephrons. Each nephron includes the glomerulus, Bowman's capsule, and tubules. The tubules include the proximal convoluted tubule, the loop of Henle, the distal convoluted tubule, and the collecting duct. The nephrons contained in the cortex layer of the kidney are distinct from the anatomy of those contained in the medulla. The principal difference is the length of the loop of Henle. Medullary nephrons contain a longer loop of Henle, which, under normal circumstances, allows greater regulation of water and sodium reabsorption than in the cortex nephrons.

[0006] The glomerulus is the beginning of the nephron, and is responsible for the initial filtration of blood. Afferent arterioles pass blood into the glomerular capillaries, where hydrostatic pressure pushes water and solutes into Bowman's capsule. Net filtration pressure is expressed as the hydrostatic pressure in the afferent arteriole minus the hydrostatic pressure in Bowman's space minus the osmotic pressure in the efferent arteriole.

Net Filtration Pressure = Hydrostatic Pressure (Afferent Arteriole) - Hydrostatic Pressure (Bowman's Space) - Osmotic Pressure (Efferent Arteriole) (Equation 1)

[0007] The magnitude of this net filtration pressure defined by Equation 1 determines how much ultra-filtrate is formed in Bowman's space and delivered to the tubules. The remaining blood exits the glomerulus via the efferent arteriole. Normal glomerular filtration, or delivery of ultra-filtrate into the tubules, is about 90 ml/min/1.73m^2.

[0008] The glomerulus has a three-layer filtration structure, which includes the vascular endothelium, a glomerular basement membrane, and podocytes. Normally, large proteins such as albumin and red blood cells, are not filtered into Bowman's space. However, elevated glomerular pressures and mesangial expansion create surface area changes on the basement membrane and larger fenestrations between the podocytes allowing larger proteins to pass into Bowman's space.

[0009] Ultra-filtrate collected in Bowman's space is delivered first to the proximal convoluted tubule. Re-absorption and secretion of water and solutes in the tubules is performed by a mix of active transport channels and passive pressure gradients. The proximal convoluted tubules normally reabsorb a majority of the sodium chloride and water, and nearly all glucose and amino acids that were filtered by the glomerulus. The loop of Henle has two components that are designed to concentrate wastes in the urine. The descending limb is highly water

permeable and reabsorbs most of the remaining water. The ascending limb reabsorbs 25% of the remaining sodium chloride, creating a concentrated urine, for example, in terms of urea and creatinine. The distal convoluted tubule normally reabsorbs a small proportion of sodium chloride, and the osmotic gradient creates conditions for the water to follow.

[0010] Under normal conditions, there is a net filtration of approximately 14 mmHg. The impact of venous congestion can be a significant decrease in net filtration, down to approximately 4 mmHg. *See* Jessup M., *The cardiorenal syndrome: Do we need a change of strategy or a change of tactics?*, JACC 53(7):597-600, 2009 (hereinafter "Jessup"). The second filtration stage occurs at the proximal tubules. Most of the secretion and absorption from urine occurs in tubules in the medullary nephrons. Active transport of sodium from the tubule into the interstitial space initiates this process. However, the hydrostatic forces dominate the net exchange of solutes and water. Under normal circumstances, it is believed that 75% of the sodium is reabsorbed back into lymphatic or venous circulation. However, because the kidney is encapsulated, it is sensitive to changes in hydrostatic pressures from both venous and lymphatic congestion. During venous congestion the retention of sodium and water can exceed 85%, further perpetuating the renal congestion. *See* Verbrugge et al., *The kidney in congestive heart failure: Are natriuresis, sodium, and diruetucs really the good, the bad and the ugly?* European Journal of Heart Failure 2014:16,133-42 (hereinafter "Verbrugge").

[0011] Venous congestion can lead to a prerenal form of acute kidney injury (AKI). Prerenal AKI is due to a loss of perfusion (or loss of blood flow) through the kidney. Many clinicians focus on the lack of flow into the kidney due to shock. However, there is also evidence that a lack of blood flow out of the organ due to venous congestion can be a clinically important sustaining injury. *See* Damman K, *Importance of venous congestion for worsening renal function in advanced decompensated heart failure*, JACC 17:589-96, 2009 (hereinafter "Damman").

[0012] Prerenal AKI occurs across a wide variety of diagnoses requiring critical care admissions. The most prominent admissions are for sepsis and Acute Decompensated Heart Failure (ADHF). Additional admissions include cardiovascular surgery, general surgery, cirrhosis, trauma, burns, and pancreatitis. While there is wide clinical variability in the presentation of these disease states, a common denominator is an elevated central venous pressure. In the case of ADHF, the elevated central venous pressure caused by heart failure leads to pulmonary edema, and, subsequently, dyspnea in turn precipitating the admission. In the case of sepsis, the elevated central venous pressure is largely a result of aggressive fluid

resuscitation. Whether the primary insult was low perfusion due to hypovolemia or sodium and fluid retention, the sustaining injury is the venous congestion resulting in inadequate perfusion.

[0013] Hypertension is another widely recognized state that creates perturbations within the active and passive transport systems of the kidney(s). Hypertension directly impacts afferent arteriole pressure and results in a proportional increase in net filtration pressure within the glomerulus. The increased filtration fraction also elevates the peritubular capillary pressure, which stimulates sodium and water re-absorption. *See* Verbrugge.

[0014] Because the kidney is an encapsulated organ, it is sensitive to pressure changes in the medullary pyramids. The elevated renal venous pressure creates congestion that leads to a rise in the interstitial pressures. The elevated interstitial pressures exert forces upon both the glomerulus and tubules. *See* Verburgge. In the glomerulus, the elevated interstitial pressures directly oppose filtration. The increased pressures increase the interstitial fluid, thereby increasing the hydrostatic pressures in the interstitial fluid and peritubular capillaries in the medulla of the kidney. In both instances, hypoxia can ensue leading to cellular injury and further loss of perfusion. The net result is a further exacerbation of the sodium and water re-absorption creating a negative feedback. *See* Verbrugge, 133-42. Fluid overload, particularly in the abdominal cavity is associated with many diseases and conditions, including elevated intra-abdominal pressure, abdominal compartment syndrome, and acute renal failure. Fluid overload can be addressed through renal replacement therapy. *See* Peters, C.D., *Short and Long-Term Effects of the Angiotensin II Receptor Blocker Irbesartanon Intradialytic Central Hemodynamics: A Randomized Double-Blind Placebo-Controlled One-Year Intervention Trial (the SAFIR Study)*, PLoS ONE (2015) 10(6): e0126882. doi:10.1371/journal.pone.0126882 (hereinafter "Peters"). However, such a clinical strategy provides no improvement in renal function for patients with the cardiorenal syndrome. *See* Bart B, *Ultrafiltration in decompensated heart failure with cardiorenal syndrome*, NEJM 2012;367:2296-2304 (hereinafter "Bart").

[0015] In view of such problematic effects of fluid retention, devices and methods for improving removal of urine from the urinary tract and, specifically for increasing quantity and quality of urine output from the kidneys, are needed.

SUMMARY

[0016] The present disclosure improves upon previous systems by providing a specialized (non-Foley) catheter for deployment within the bladder. The catheter of the present disclosure comprises an indwelling portion to be positioned within the bladder having restraints or anchors for passive fixation with superior and/or inferior portions of the bladder wall. A proximal restraint or anchor, within the bladder, can be designed to seal the urethra from air and fluid leaks. A distal anchor within the bladder can be designed to restrain the superior bladder wall as it collapses, allowing obstruction free delivery of negative pressure, collection of the urine produced, and avoidance of mucosal trauma. Further, a urine collection system comprising the catheter includes sensing devices for monitoring urine flow and for using urine flow and conductivity assessment to guide the negative pressure delivered by the system to optimize sodium and water excretion.

[0017] Non-limiting examples, aspects, or embodiments of the present invention will now be described in the following numbered clauses:

[0018] Clause 1: A urine collection catheter configured to be deployed in a patient's bladder, the catheter comprising: a conduit comprising a proximal end and an open distal end; a drainage tube positioned at least partially within the conduit, the drainage tube comprising a proximal end, a distal end, and one or more fluid ports or perforations for permitting fluid flow into a drainage lumen defined by the drainage tube; and a bladder superior wall support comprising a support cap and a plurality of support members extending from a proximal surface of the support cap through the open distal end of the conduit, and being capable of being moved between a retracted position and a deployed position, wherein, in the deployed position, the distal end of the drainage tube is spaced apart from the support cap, such that the support cap supports portions of the superior wall of the bladder from occluding the one or more fluid ports or perforations of the drainage tube.

[0019] Clause 2: The catheter of clause 1, wherein the support cap is configured to inhibit the superior bladder wall from occluding the one or more ports or perforations upon delivery of negative pressure to the bladder and/or kidneys through the drainage tube.

[0020] Clause 3: The catheter of clause 1 or clause 2, wherein the support cap is configured to inhibit the superior bladder wall from contacting ureteral orifices of the bladder upon delivery of negative pressure to the bladder and/or kidneys through the drainage lumen.

[0021] Clause 4: The catheter of any of clauses 1 to 3, wherein the support members comprise flexible tines, and wherein the support cap comprises a flexible cover mounted to and supported by the plurality of tines.

[0022] Clause 5: The catheter of clause 4, wherein the flexible tines comprise a shape-memory alloy configured to move to the deployed position at a temperature above ambient room temperature.

[0023] Clause 6: The catheter of clause 5, wherein the flexible cover is formed from a material that does not appreciably abrade, irritate, or damage a mucosal lining of the bladder walls or of a urethra when positioned adjacent to the mucosal lining of the bladder walls or the urethra.

[0024] Clause 7: The catheter of any of clauses 1 to 6, wherein the bladder superior wall support is configured to maintain its form when in contact with the superior wall of the bladder.

[0025] Clause 8: The catheter of any of clauses 1 to 3, wherein the support cap comprises an inflatable balloon.

[0026] Clause 9: The catheter of clause 8, further comprising an inflation lumen at least partially disposed within the conduit and configured to conduct a fluid or gas into an interior of the balloon for inflation of the balloon.

[0027] Clause 10: A urine collection catheter configured to be deployed in a patient's bladder, the catheter comprising: at least one tubular body comprising a proximal end, a distal end, a sidewall extending therebetween, and one or more fluid ports or perforations for permitting fluid flow into a drainage lumen defined by the tubular body; and a bladder superior wall support comprising a support cap connected to and extending radially from a portion of the distal end of the at least one tubular body, the support cap comprising a curved distal surface, the support cap being capable of being moved between a retracted position and a deployed position to support a superior wall of the bladder thereby inhibiting the superior bladder wall from occluding the one or more fluid ports or perforations.

[0028] Clause 11: The catheter of clause 10, wherein the bladder superior wall support is configured to inhibit the superior bladder wall from occluding the one or more ports or perforations upon delivery of negative pressure to the bladder and/or kidneys through the drainage lumen.

[0029] Clause 12: The catheter of clause 10, wherein the bladder superior wall support is configured to inhibit the superior bladder wall from contacting ureteral orifices of the bladder upon delivery of negative pressure to the bladder and/or kidneys through the drainage lumen.

[0030] Clause 13: The catheter of any of clauses 10 to 13, wherein the bladder superior wall support comprises a plurality of support members extending radially from the tubular body, and wherein the support cap comprises a flexible cover mounted to and supported by the plurality of support members.

[0031] Clause 14: The catheter of clause 13, wherein the support members comprise flexible tines formed from a shape-memory alloy, the flexible tines being configured to extend to the deployed position at a temperature above ambient room temperature.

[0032] Clause 15: The catheter of clause 13 or clause 14, wherein the flexible cover is formed from a material that does not appreciably abrade, irritate, or damage a mucosal lining of the bladder walls or of a urethra when positioned adjacent to the mucosal lining of the bladder walls or the urethra.

[0033] Clause 16: The catheter of any of clauses 10 to 15, wherein the bladder superior wall support comprises an inflatable balloon.

[0034] Clause 17: The catheter of clause 16, further comprising an inflation lumen configured to conduct a fluid or gas into an interior of the balloon for inflation of the balloon.

[0035] Clause 18: The catheter of clause 16 or clause 17, wherein the inflatable balloon comprises a bulbous portion and a plurality of lobes extending proximally therefrom, and wherein the one or more ports or perforations are positioned between adjacent lobes.

[0036] Clause 19: The catheter of any of clauses 10 to 18, further comprising a filter positioned over the one or more ports or perforations.

[0037] Clause 20: The catheter of any of clauses 10 to 19, further comprising an absorbent sponge positioned over the one or more ports or perforations.

[0038] Clause 21: The catheter of any of clauses 10 to 20, further comprising a bladder inferior wall support configured to contact an inferior wall of the bladder.

[0039] Clause 22: The catheter of clause 21, wherein the bladder inferior wall support comprises one or more support members extending radially from the tubular body and a cover to the one or more support members.

[0040] Clause 23: The catheter of clause 22, wherein the cover of the bladder inferior wall support comprises a material that does not appreciably abrade, irritate, or damage a mucosal lining of the bladder walls or of a urethra when positioned adjacent to the mucosal lining of the bladder walls or the urethra.

[0041] Clause 24: A system for drawing urine from the bladder of a patient, the system comprising: a urine collection catheter comprising: at least one tubular body comprising a

proximal end, a distal end, a sidewall extending therebetween, and one or more fluid ports or perforations for permitting fluid flow into a drainage lumen defined by the tubular body; and a bladder superior wall support comprising a support cap defining a curved distal surface connected to and extending radially from a portion of the distal end of the at least one tubular body, the support cap being capable of being moved between a retracted position and a deployed position to support a superior wall of the bladder to inhibit portions of the superior wall of the bladder from occluding the one or more fluid ports or perforations; and a pump in fluid connection with the drainage lumen of the tubular body, wherein the pump is configured to introduce negative pressure through the tubular body to the bladder to draw urine from the bladder.

[0042] Clause 25: The system of clause 24, further comprising one or more sensors in fluid communication with the drainage lumen of the tubular body for measuring information representative of a physiological condition of the patient.

[0043] Clause 26: The system of clause 25, wherein the one or more sensors are configured to measure one or more of capacitance, analyte concentration, and temperature of urine within the tubular body.

[0044] Clause 27: The system of clause 25 or clause 26, wherein the pump comprises: a processor comprising computer readable memory including programming instructions that, when executed, cause the processor to: receive the information from the one or more sensors, and adjust an operating parameter of the pump based, at least in part, on the information received from the one or more sensors to increase or decrease the negative pressure in the tubular body to adjust flow of urine therethrough.

[0045] Clause 28: The system of clause 27, wherein the pump further comprises a data transmitter in communication with the processor, the data transmitter being configured to provide the information from the one or more sensors to an external source.

[0046] Clause 29: The system of any of clauses 24 to 28, wherein the pump is capable of continuous operation for between 8 and 24 hours.

[0047] Clause 30: The system of any of clauses 24 to 29, wherein the pump provides a sensitivity of 10 mmHg or less.

[0048] Clause 31: The system of any of clauses 24 to 30, wherein the pump is configured to provide intermittent negative pressure.

[0049] Clause 32: The system of any of clauses 24 to 31, wherein the pump is configured to alternate between providing negative pressure and providing positive pressure.

[0050] Clause 33: The system of any of clauses 24 to 31, wherein the pump is configured to alternate between providing negative pressure and equalizing pressure to atmosphere.

[0051] Clause 34: A urine collection catheter configured to be deployed within a patient's bladder, the catheter comprising: a tubular body comprising a proximal portion configured to be positioned in at least a portion of a patient's urethra and a distal portion configured to be positioned in a patient's bladder, the distal portion comprising a coiled retention portion, wherein the retention portion comprises at least a first coil having a first diameter, a second coil having a second diameter, the first diameter being less than the second diameter, and a plurality of perforations disposed on a radially inwardly facing side of a sidewall of the retention portion.

[0052] Clause 35: The catheter of clause 34, wherein the first coil is proximal to the second coil.

[0053] Clause 36: The catheter of clause 34 or clause 35, wherein, prior to insertion into a patient's urinary tract, a portion of the tubular body that is proximal to the retention portion defines a straight or curvilinear central axis, and wherein the first coil and the second coil of the retention portion extend about an axis that is at least partially coextensive with the straight or curvilinear central axis of the portion of the drainage lumen.

[0054] Clause 37: The catheter of clause 36, wherein, in the retention portion, a total surface area for the perforations on the radially inwardly facing side of the sidewall of the tubular body is greater than a total surface area of perforations on the radially outwardly facing side of the sidewall of the tubular body.

[0055] Clause 38: The catheter of any of clauses 34 to 38, wherein, in the retention portion, a radially outwardly facing side of the sidewall of the tubular body is free from perforations.

[0056] Clause 39: A urine catheter comprising: a tubular body comprising a proximal end, a distal end, and a sidewall extending therebetween; and an indwelling portion adjacent to the distal end of the tubular body, the indwelling portion comprising a first surface configured to support a superior wall of a bladder, a second surface configured to contact an inferior wall of the bladder, and a linear portion of the sidewall extending between the first surface and the second surface, wherein the first surface and the second surface each comprise a flexible material, and wherein the first surface and the second surface are supported by a plurality of support members.

[0057] Clause 40: The catheter of clause 39, wherein the flexible material does not appreciably abrade, irritate, or damage a mucosal lining of the bladder walls or of a urethra when positioned adjacent to the mucosal lining of the bladder walls or the urethra.

[0058] Clause 41: The catheter of clause 39 or clause 40, wherein the indwelling portion insulates the superior wall of the bladder from a trigone region of the bladder.

[0059] Clause 42: The catheter of any of clauses 39 to 41, wherein the first surface and the second surface of the indwelling portion are transitionable between a contracted position and a deployed position.

[0060] Clause 43: The catheter of clause 42, wherein, in the deployed position, the first surface and the second surface maintain their form when in contact with the respective superior and inferior walls of the bladder.

[0061] Clause 44: The catheter of clause 42 or clause 43, wherein the flexible material contracts when the first surface and the second surface are in the contracted position and expands when the first surface and the second surface are in the deployed position.

[0062] Clause 45: The catheter of any of clauses 42 to 44, wherein the second surface of the indwelling portion provides a seal for an opening of a urethra of the bladder when in the deployed position.

[0063] Clause 46: The catheter of any of clauses 42 to 45, wherein the first surface of the indwelling portion contacts the superior wall of the bladder when in the deployed position so as to avoid obstruction of one or more ureter openings of the bladder.

[0064] Clause 47: The catheter of any of clauses 42 to 46, wherein a section of the indwelling portion between the first surface and the second surface is not covered with the flexible material at least when the first surface and the second surface are in the deployed position.

[0065] Clause 48: The catheter of any of clauses 42 to 47, further comprising a release mechanism configured to activate the first surface and the second surface from the contracted position to the deployed position.

[0066] Clause 49: The catheter of any of clauses 39 to 48, wherein the flexible material covers at least a portion of the plurality of support members.

[0067] Clause 50: The catheter of any of clauses 39 to 49, wherein the plurality of support members is drawn against the tube in the contracted position, and the plurality of support members extends outward from the tube in the deployed position.

[0068] Clause 51: The catheter of any of clauses 39 to 50, wherein the plurality of support members are formed of a shape-memory alloy.

[0069] Clause 52: The catheter of any of clauses 39 to 51, wherein the linear portion of the sidewall extending between the first surface and the second surface comprises one or more perforations extending through the sidewall to permit fluid flow therethrough into a fluid receiving portion of the tube.

[0070] Clause 53: A method of inducing a negative pressure to a bladder of a patient for enhancing urine excretion therefrom, the method comprising: inserting a distal portion of a tubular body of a urine collection catheter into the patient's bladder; deploying a support cap connected to and extending radially from a portion of the distal end of the tubular body, such that the support cap is in contact with the bladder superior wall; and inducing a negative pressure through a drainage lumen of the tubular body to draw urine from the bladder into the drainage lumen.

[0071] Clause 54: The method of clause 53, further comprising positioning a bladder inferior wall support in contact with an inferior wall of the patient's bladder.

[0072] Clause 55: The method of clause 54, wherein positioning the bladder inferior wall support comprises positioning the support over an opening of a urethra to seal the bladder.

[0073] Clause 56: The method of clause 54 or clause 55, wherein the bladder inferior wall support is separate from the support cap and is supported by a plurality of support members extending radially from the tubular body.

[0074] Clause 57: The method of any of clauses 53 to 56, wherein deploying the support cap comprises preventing the distal surface structure from occluding ureteral openings of the bladder.

[0075] Clause 58: The method of any of clauses 53 to 57, wherein inducing the negative pressure in the tubular body comprises coupling a mechanical pump in fluid communication with a proximal end of the tubular body to draw urine from the bladder into the tubular body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0076] These and other features and characteristics of the present disclosure, as well as the methods of operation and functions of the related elements of structures and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the

drawings are for the purpose of illustration and description only and are not intended as a definition of the limit of the invention.

[0077] Further features and other examples and advantages will become apparent from the following detailed description made with reference to the drawings in which:

[0078] FIG. 1 is a schematic drawing of a urine collection catheter device deployed within the bladder of a male patient according to an example of the disclosure;

[0079] FIG. 2 is a schematic drawing of another exemplary urine collection catheter device deployed within a patient's bladder according to an example of the disclosure;

[0080] FIG. 3A is a perspective view of an indwelling retention portion the urine collection catheter device of FIG. 1;

[0081] FIG. 3B is a cross-sectional view taken along line B-B of the indwelling retention portion of the urine collection catheter device of FIG. 3A;

[0082] FIG. 3C is a cross-sectional view taken along line C-C of the indwelling retention portion of FIG. 3A;

[0083] FIG. 4 is a perspective view of an indwelling retention portion of a urine collection catheter according to another example of the disclosure;

[0084] FIG. 5 is a perspective view of an indwelling retention portion of a urine collection catheter according to another example of the disclosure;

[0085] FIG. 6 is a perspective view of an indwelling retention portion of a urine collection catheter according to another example of the disclosure;

[0086] FIG. 7A is a schematic drawing of an indwelling retention portion of the catheter device of FIG. 2 in a contracted state;

[0087] FIG. 7B is a schematic drawing of the indwelling portion of the catheter device of FIG. 2 in a deployed state;

[0088] FIG. 8A is a schematic drawing of an indwelling retention portion of another exemplary urine collection catheter device in a contracted state, according to an embodiment of the disclosure;

[0089] FIG. 8B is a schematic drawing of the indwelling retention portion of the catheter device of FIG. 8A in a deployed state;

[0090] FIG. 9A is a perspective view of an indwelling retention portion of another exemplary urine collection catheter device according to an example of the disclosure;

[0091] FIG. 9B is a partial cross-sectional view of a portion of the indwelling retention portion of the catheter device of FIG. 9A;

[0092] FIG. 10A is a perspective view of an indwelling retention portion of another exemplary urine collection catheter device according to an example of the disclosure;

[0093] FIG. 10B is a partial cross-sectional view of a portion of the urine collection catheter of FIG. 10A;

[0094] FIG. 11A is a perspective view of an indwelling portion of another exemplary urine collection catheter according to an example of the disclosure;

[0095] FIG. 11B is a cross-sectional view of the urine collection catheter of FIG. 11A;

[0096] FIG. 12 is a front view of an indwelling retention portion of another exemplary urine collection device according to an example of the disclosure;

[0097] FIG. 13 is a schematic drawing of a urine collection device including both an indwelling portion and an external portion according to an example of the disclosure;

[0098] FIG. 14 is a system for inducing a negative pressure in the bladder of a patient including a urine collection catheter device configured to be deployed in a patient's bladder according to an example of the disclosure;

[0099] FIGS. 15A and 15B are schematic drawings of a pump for use with the system of FIG. 14; and

[00100] FIG. 16 is a flow chart of a process for inducing a negative pressure in a patient's bladder according to an example of the disclosure.

DETAILED DESCRIPTION OF THE INVENTION

[00101] As used herein, the singular form of "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

[00102] As used herein, the terms "right", "left", "top", and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. The term "proximal" refers to the portion of the catheter device that is manipulated or contacted by a user. The term "distal" refers to the opposite end of the catheter device that is configured to be inserted into a patient. However, it is to be understood that the invention can assume various alternative orientations and, accordingly, such terms are not to be considered as limiting. Also, it is to be understood that the invention can assume various alternative variations and stage sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are examples. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[00103] Unless indicated to the contrary, the numerical parameters set forth in the following specification and attached claims are approximations that can vary depending upon the desired properties sought to be obtained by the present disclosure.

[00104] Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical value, however, inherently contain certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

[00105] Also, it should be understood that any numerical range recited herein is intended to include all sub-ranges subsumed therein. For example, a range of "1 to 10" is intended to include any and all sub-ranges between and including the recited minimum value of 1 and the recited maximum value of 10, that is, all sub-ranges beginning with a minimum value equal to or greater than 1 and ending with a maximum value equal to or less than 10, and all sub-ranges in-between, e.g., 1 to 6.3, or 5.5 to 10, or 2.7 to 6.1.

[00106] As used herein, the terms "communication" and "communicate" refer to the receipt or transfer of one or more signals, messages, commands, or other type of data. For one unit or component to be in communication with another unit or component means that the one unit or component is able to directly or indirectly receive data from and/or transmit data to the other unit or component. This can refer to a direct or indirect connection that can be wired and/or wireless in nature. Additionally, two units or components can be in communication with each other even though the data transmitted can be modified, processed, routed, and the like, between the first and second unit or component. For example, a first unit can be in communication with a second unit even though the first unit passively receives data and does not actively transmit data to the second unit. As another example, a first unit can be in communication with a second unit if an intermediary unit processes data from one unit and transmits processed data to the second unit. It will be appreciated that numerous other arrangements are possible.

[00107] Fluid retention and venous congestion are central problems in the progression to advanced renal disease. Excess sodium ingestion coupled with relative decreases in excretion leads to isotonic volume expansion and secondary compartment involvement. In some examples, the present invention is generally directed to devices and methods for facilitating drainage of urine or waste from the bladder, ureter, and/or kidney(s) of a patient. In some examples, the present invention is generally directed to devices and methods for inducing a

negative pressure in the bladder of a patient. While not intending to be bound by any theory, it is believed that applying a negative pressure to the bladder can offset the medullary nephron tubule re-absorption of sodium and water in some situations. Offsetting re-absorption of sodium and water can increase urine production, decrease total body sodium, and improve erythrocyte production. Since the intra-medullary pressures are driven by sodium and, therefore, volume overload, the targeted removal of excess sodium enables maintenance of volume loss. Removal of volume restores medullary hemostasis. Normal urine production is 1.48-1.96 L/day (or 1-1.4 ml/min).

[00108] Fluid retention and venous congestion are also central problems in the progression of prerenal AKI. Specifically, AKI can be related to loss of perfusion or blood flow through the kidney(s). Accordingly, in some examples, the present invention facilitates improved renal hemodynamics and increases urine output for the purpose of relieving or reducing venous congestion. Further, it is anticipated that treatment and/or inhibition of AKI positively impacts and/or reduces the occurrence of other conditions, for example, reduction or inhibition of worsening renal function in patients with NYHA Class III and/or Class IV heart failure. Classification of different levels of heart failure are described in *The Criteria Committee of the New York Heart Association*, (1994), Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels, (9th ed.), Boston: Little, Brown & Co. pp. 253–256, the disclosure of which is incorporated by reference herein in its entirety. Reduction or inhibition of episodes of AKI and/or chronically decreased perfusion may also be a treatment for Stage 4 or Stage 5 chronic kidney disease. Chronic kidney disease progression is described in National Kidney Foundation, K/DOQI *Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification*. Am. J. Kidney Dis. 39:S1-S266, 2002 (Suppl. 1), the disclosure of which is incorporated by reference herein in its entirety.

[00109] With reference to FIGS. 1 and 2, a urinary tract or urinary system 110 comprises a patient's right and left kidneys 112 (shown in FIG. 2). The kidneys 112 are responsible for blood filtration and clearance of waste compounds from the body through urine. Urine produced by the kidneys 112 is drained into a patient's bladder 100 through tubules referred to as ureters 114. For example, urine may be conducted through the ureters 114 by peristalsis of the ureter walls as well as by gravity. The ureters 114 enter the bladder 100 through a ureter orifice or opening 115. The bladder 100 is a flexible and substantially hollow structure adapted to collect urine until the urine is excreted from the body. The bladder 100 is transitionable from an empty position (shown in FIG. 2) to a full position (signified by reference line F in

FIG. 2). Normally, when the bladder 100 reaches a substantially full state, urine is permitted to drain from the bladder 100 to a urethra 116 through a urethral sphincter or opening 117 located at a lower portion of the bladder 100. Contraction of the bladder 100 can be responsive to stresses and pressure exerted on the trigone region 113 of the bladder 100, which is the triangular region extending between the ureteral openings 115 and the urethral opening 117. The trigone region 113 is sensitive to stress and pressure, such that as the bladder 100 begins to fill, pressure on the trigone region 113 increases. When a threshold pressure on the trigone region is exceeded, sphincter or opening 117 relaxes and allows the bladder 100 to contract to expel collected urine through the urethra 116. The ureter orifice or openings 115 are covered by soft tissue which essentially forms a one-way flap valve. When the bladder 100 is collecting urine, the soft tissue is able to accommodate pressure from the peristalsis so that urine can pass from the ureters 114 into the bladder 100. When the bladder 100 contracts to expel urine therefrom, the soft tissue is restrained against the ureter openings 115 to prevent backflow of urine from the bladder 100 back into the ureters 114. The restraints are positioned to allow the ureter openings 115 to remain open during therapy so that negative pressure can draw urine into the bladder 100 and into catheter devices positioned in the bladder.

Example catheter devices:

[00110] With continued reference to FIGS. 1 and 2, exemplary disposable catheter devices 10 for inducing negative pressure in the bladder 100 of a patient are illustrated. As described herein, the bladder 100 is capable of contracting between the full position, denoted by dashed line F in FIG. 2, and the empty position. Desirably, the bladder 100 is prevented from collapsing completely by the catheter device 10. The exemplary catheter devices 10 can be a urine catheter (non-Foley) that can seal the bladder 100 and upper urinary system 110 under a guided negative pressure. The devices 10 generally comprise an elongated conduit or tubular body, referred to herein as a tube 12, having an external diameter or circumference which is generally within a range of about 8 to 16 Fr, the interior of which defines one or more drainage channel(s) or lumen(s) 14 or multiple lumens. The tube 12 can be formed from any suitable flexible material including, for example, biocompatible polymers, polyvinyl chloride, polytetrafluoroethylene (PTFE) such as Teflon®, silicon coated latex, or silicon. At least a portion or all of the catheter device 10, particularly the tube 12, can be coated with a hydrophilic coating to facilitate insertion and/or removal and/or to enhance comfort. In some examples, the coating is a hydrophobic and/or lubricious coating. For example, suitable coatings can comprise ComfortCoat® hydrophilic coating which is available from Koninklijke DSM N.V.

or hydrophilic coatings comprising polyelectrolyte(s) such as are disclosed in United States Patent No. 8,512,795, which is incorporated herein by reference.

[00111] In some examples, the tube 12 comprises an indwelling portion 6 configured to be positioned in the bladder 100 and a second or middle indwelling portion 7 configured to extend through the urethra 116. Generally, the second portion 7 of the tube 12 is the same diameter as the indwelling portion 6 of the tube 12 described above, although the diameter may increase to facilitate flow. Alternatively, all or part of the second portion 7 of the tube 12 can be a separate tubing that is connected to the retention or indwelling portion 6 of the tube 12. The second portion 7 of the tube 12 does not include perforations, such as are described in the indwelling portion 6 of the tube 12, so as to prevent leakage from the side of the tube 12. The tube 12 further comprises an external portion 8 (shown in FIG. 1) which extends from the indwelling portions 6, 7 to an external fluid collection container or device, such as a pump 410 (shown in FIG. 14).

[00112] The catheter device 10 and, in particular, the tube 12, can be available in different lengths to accommodate anatomical differences for gender and/or patient size. For example, the average female urethra length is only a few inches, so the length of the tube 12 can be rather short. The average urethra length for males is longer due to the penis and can be variable. It is possible that woman can use catheter devices 10 with longer length tubes 12 provided that the excess tubing does not increase difficulty in manipulating or positioning the device 10. In some examples, the sterile portion of the catheter 10 can range from about 1 in to 3 inches, for women, to about 20 inches, for men. The total length of the tube 12 including sterile and non-sterile portions is about several feet.

[00113] In some examples, the external portion 8 of the tube 12 comprises a deployment mechanism 44 and port 54 (shown in FIG. 13) for connection to the pump 410 (shown in FIG. 14). The connection between the tube 12 and the pump 410 or another fluid collection container can be a standard connection mechanism, such as a luer lock or snap fit connection. In other examples, a dedicated or customized connector or connection device can be used for connecting the proximal end of the catheter device 10 or port 54 to other elements of the fluid collection system. In some examples, the customized connector can be structured to prevent a user from connecting the catheter device 10 to unsuitable pressure sources. For example, the customized connector may be sized to prevent a user from connecting the catheter device 10 to sources of wall suction or other sources of elevated vacuum pressures.

Exemplary single-stage fixation retention portions

[00114] An exemplary indwelling portion 6 of a catheter device 10 is shown in FIGS. 3A-3C. The exemplary indwelling portion 6 of the catheter device 10 comprises a basket shaped structure, referred to as a bladder superior wall support 210 (shown in FIGS. 3A and 3B), configured to be disposed within a distal portion of the tube 12 in a retracted position and to extend from the distal end of the tube 12 in a deployed position. The bladder superior wall support 210 comprises a support cap 212 configured to support a superior wall 100a of the bladder 100 (shown in FIGS. 1 and 2) and a plurality of support members, such as legs 214, connected to a proximal surface of the support cap 212. The legs 214 can be positioned so that the cap 212 is spaced apart from an open distal end of the tube 12. For example, the legs 214 can be configured to maintain a gap, cavity, or space of distance D1 between an open distal end 30 of the tube 12 and the support cap 212. The distance D1 can be about 1.0 cm to about 2.0 cm. The height D2 of the bladder superior wall support 210 can about 1.5 cm to about 3.0 cm. The support cap 212 can be about 12 to 32 Fr in the deployed state, and preferably between about 8 mm and 10 mm.

[00115] In some examples, the legs 214 comprises flexible tines, which can be formed from a shape memory material, such as a nickel titanium. The support cap 212 can be a flexible cover 216 mounted to and supported by the legs 214. The flexible cover 216 can be formed from a soft and resilient material, such as silicone or Teflon®, for preventing air and/or fluid from passing through the cover 216. In some examples, the flexible material is formed from a material which does not appreciably abrade, irritate, or damage the mucosal lining of the bladder wall or the urethra when positioned adjacent to the mucosal lining, such as silicone or Teflon® materials. The thickness of the cover 216 can range from about 0.05 mm to about 0.5 mm. In some examples, the flexible cover 216 and legs 214 are sufficiently structurally rigid so that the cover 216 and legs 214 maintain their form when contacted by the superior wall 100a of the bladder 100 (shown in FIGS. 1 and 2). Accordingly, the legs 214 and flexible cover 216 prevent the bladder from collapsing and occluding perforations on the retention portion 6 and/or an open distal end 30 of the tube 12. In addition, the legs 214 and flexible cover 216 effectively keep the trigone region and ureteral orifices open so that negative pressure can draw urine into the bladder and lumen defined by or enclosed in the tube 12. As discussed herein, if the bladder were permitted to contract, flaps of tissue would extend over the ureter openings, thereby preventing negative pressure from drawing urine into the bladder.

[00116] In some examples, the support cap 212 is sized to be positioned within the bladder and to contact the superior wall of the bladder without occluding the ureteral openings. For

example, the bladder superior wall support 210 may be appropriately sized to span the trigone region such that the trigone region and other portions of the bladder are restricted from contracting. By spanning and avoiding contact with the trigone region, the support cap 212 can be positioned away from the ureteral openings to prevent occlusion of the openings, which would inhibit or prevent urine flow from the ureters to the bladder.

[00117] In some examples, the catheter device 10 further comprises a drainage tube 218 defining a drainage lumen disposed at least partially within the tube 12. As shown in FIGS. 3A-3C, the drainage tube 218 can comprise an open distal end 220 positioned adjacent to or extending from the open distal end 30 of the tube 12. In some examples, the open distal end 220 of the drainage tube 218 is the only opening for drawing urine from the bladder into the interior of the drainage tube 218. In other examples, a distal portion of the drainage tube 218 may comprise perforations (not shown in FIGS. 3A-3C) or holes on a sidewall 222 thereon. The perforations can provide additional spaces for drawing urine into the interior of the drainage tube 218, thereby ensuring that fluid collection can continue even if the open distal end 220 of the drainage tube 218 is occluded. In addition, perforations can increase surface area available for drawing fluid into the drainage tube 218, thereby increasing efficiency and/or fluid collection yield.

[00118] In some examples, a distal most portion of the support cap 212 can comprise a sponge or pad 224, such as a gel pad. The pad 224 can be positioned to contact and press against the superior bladder wall 100a for the purpose of preventing drainage, aspiration, or other trauma to the bladder 100a during negative pressure treatment.

[00119] With reference to FIG. 4, an indwelling portion of another exemplary bladder catheter 10 including a bladder superior wall support 210 is illustrated. The bladder superior wall support 210 comprises a support cap 212 and a plurality of legs 214. As in previously described examples, the bladder superior wall support 210 is capable of being moved between a retracted position, in which the support 210 is at least partially retracted in a conduit or tube 12, and a deployed position to support the superior wall of the bladder. In some examples, the catheter device 10 also includes a drainage tube 218 extending from the open distal end 30 of the conduit or tube 12. Unlike in the previously-described examples, the support cap 212 shown in FIG. 4 comprises an inflatable balloon 226. The inflatable balloon 226 can be a substantially semi-spherical and can comprise a curved distal surface 228 configured to contact the superior bladder wall 100a when deployed.

[00120] In some examples, the drainage tube 218 comprises a perforated portion 230 extending between the open distal end 30 of the tube 12 and the support structure 212. The perforated portion 230 is positioned to draw fluid into an interior of the drainage tube 218 so that it can be removed from the bladder 100. Desirably, the perforated portion 230 is positioned so as not to be occluded either by the deployed support cap 212 or the bladder wall when negative pressure is applied thereto. The drainage tube 218 can comprise or be positioned adjacent to an inflation lumen 232 for providing fluid or gas to an interior 234 of the balloon 226 for inflating the balloon 226 from its contracted position to the deployed position. For example, as shown in FIG. 4, the inflation lumen 232 can be disposed within the drainage tube 218.

[00121] With reference to FIG. 5, an indwelling portion 6 of another exemplary urine collection catheter device 10 configured to be disposed in the patient's bladder is illustrated. The indwelling portion 6 comprises a coiled retention portion disposed at a distal end portion of the tube 12. In some examples, the retention portion 6 can be a separate structure that is connected to the distal end 30 of the tube 12. In other examples, coils can be imparted to the distal end portion of the tube 12, thereby forming the coiled retention portion 6. In some examples, the coiled retention portion 6 comprises at least a first coil 236 having a first diameter D1 and at least one second coil 238 having a second diameter D2. In some examples, the first diameter D1 is less than the second diameter D2, giving the retention portion 6 a tapered appearance. For example, the second diameter D2 can be about 4 mm to about 26 mm. The first diameter D1 can be about 2 mm to 13 mm. In other examples, the arrangement of coils in the coiled retention portion can be reversed, such that the distal-most coil has a larger diameter than one or more of the proximal coils.

[00122] The retention portion 6 of the tube 12 can further comprise a plurality of perforations 230 disposed on a radially inwardly facing side 240 of a sidewall of the retention portion 6. The diameter of the perforations 230 can range from about 0.005 mm to about 1.0 mm. The spacing between the perforations 230 can range from about 1.5 mm to about 15 mm. The perforations 230 can be spaced in any arrangement, for example, linear or offset. In some examples, the perforations 230 can be non-circular, and can have a surface area of about .00002 to 0.79 mm^2. Placing perforations 230 on the radially inwardly facing side 240 of the coiled retention portion 6 is intended to prevent the bladder from occluding the perforations 230 when negative pressure is applied through the catheter device 10. For example, in response to application of negative pressure to the bladder, portions of the bladder wall can be drawn

against radially outwardly facing portions of the retention portion 6. Therefore, any perforations on radially outwardly facing side 242 of the retention portion 6 may be occluded by the bladder wall. However, perforations 230 on the radially inwardly facing side 240 of the retention portion 6 are protected. In other examples, a total surface area of perforations on the radially inwardly facing side 240 of the sidewall of the retention portion 6 can be greater than a total surface area of any perforations on radially outwardly facing side 242 of the retention portion 6.

[00123] With reference to FIG. 6, an exemplary retention portion 6 of a urine collection catheter device 10 including multiple coiled drainage lumens, generally denoted as lumens 218, is illustrated. The retention portion 6 comprises the tube 12 having a distal open end 30. The drainage lumens 218 are positioned partially within the tube 12. In a deployed position, the draining lumens 218 are configured to extend from the open distal end 30 of the tube 12 and to conform to a coiled orientation. The drainage lumens 218 can be separate for the entire length of the catheter device 10, or may empty into a single drainage lumen defined by the tube 12. In some examples, as shown in FIG. 6, the drainage lumens 218 can be pigtail coils having one or more coils 244. Unlike in the previously described example, the pigtail coils 244 are coiled about an axis that is not coextensive with an axis C of an uncoiled portion of the tube. Instead, as shown in FIG. 6, the pigtail coils can be coiled about an axis D that is approximately perpendicular to the axis C of the tube 12. In some examples, the drainage lumens 218 can comprise perforations (not shown in FIG. 6), similar to perforations 230 in FIG. 5, for drawing fluid from the bladder into an interior of the drainage lumens 218. In some examples, the perforations can be positioned on a radially inwardly facing side 240 of the coiled portions of the drainage lumens. As previously described, perforations positioned on radially inwardly facing sides of the drainage lumens 218 or tube 12 are less likely to be occluded by the bladder walls during application of negative pressure to the bladder. Urine can also be drawn directly into one or more drainage lumens defined by the tube 12. For example, rather than being drawing into the drainage lumen(s) 218 through the perforations 230, urine can be drawn directly through the open distal end 30 and into a drainage lumen defined by the tube 12.

Exemplary retention portions with two-stage fixation

[00124] With reference to FIGS. 7A and 7B, an exemplary retention or indwelling portion 6, which is adapted to provide a two-stage passive temporary fixation within the bladder, is illustrated. The retention portion 6 is configured to be transitionable between a contracted position (as shown, for example, in FIG. 7A), during insertion to the bladder, and a deployed

position (as shown in FIG. 7B) within the patient's bladder. As described herein, the indwelling portion 6 of the catheter device 10 comprises bracing, retaining, and/or sealing structures extending from the tube 12 for maintaining the bladder in a substantially expanded position through contact with the superior distal wall, in a similar manner to previously described examples. The two-stage fixation catheter device 10 also includes structures for sealing or partially sealing the urethral sphincter to prevent urine from passing through the urethra and for maintaining the trigone in an expanded position in which the ureteral orifices or openings are unobstructed.

[00125] In some examples, the indwelling portion 6 of the catheter device 10 comprises a bladder superior wall support, such as a distal anchor 20, and a bladder inferior wall support, such as a proximal anchor 22, each providing respective surfaces 20a, 22a for contacting the interior mucosal wall of the bladder. For example, the proximal anchor 22 can be positioned adjacent to the urethral sphincter to enhance suction when negative pressure is applied for drawing urine from the bladder. Desirably, the proximal anchor 22 is large enough to substantially or effectively seal the bladder and to stabilize the distal end 30 of the tube 12 within the bladder. For example, desirably, the proximal anchor 22 entirely seals the bladder with minimal leakage. It is noted that an 8 mm anchor is at least two times larger than the opening of the urethra. Accordingly, when correctly or substantially correctly positioned, the proximal anchor 22 covers the urethra opening with room to spare. In some examples, the proximal anchor 22 should not be so large that it completely covers the trigone and/or seals the ureter openings when positioned within the bladder. Furthermore, the distal anchor 20 also acts to maintain spacing between the superior bladder wall and the trigone so as to inhibit the superior bladder wall from contacting the trigone 113 (shown in FIG. 2).

[00126] While not intending to be bound by theory, it is believed that introducing negative pressure to the bladder 100 essentially collapses the bladder 100. Sealing the bladder 100 by positioning the proximal anchor 22 over the urethra opening may prevent the bladder 100 from collapsing completely, thereby ensuring that perforations or drainage holes 28 of the catheter 10, as well as the trigone and ureteral orifices or openings, are open, accessible, and free of obstruction. In some examples, pressure from the superior wall 100b holds the proximal anchor 22 in place against the inferior wall 100a, thereby creating the seal over the urethra opening.

[00127] For a catheter device 10 including an 8 to 16 Fr elongated tube 12, the anchors 20, 22 can have a diameter equivalent to about 4 mm to 10.7 mm (12 to 32 Fr) in the deployed state, and preferably between about 8 mm and 10 mm (24 Fr and 30 Fr). It is believed that an

8 mm diameter anchor 20, 22 would be a single size suitable for all or most patients. For a catheter device 10 with 24 Fr anchors, the length L (shown in FIG. 7B) between the anchors 20, 22 is about 1.5 cm to about 2.3 cm, and preferably about 1.9 cm (0.75 in). Thus, in some examples, in the contracted state, the opposing anchors 20, 22 have a total non-overlapping length of about 1.6 cm (0.8 cm per anchor). To account for end padding and other spacing, the anchors 20, 22 can be separated by an additional small amount, such as an additional twenty percent (e.g. about 0.3 cm). Thus, the length L (shown in FIGS. 7B and 8B) between the anchors 20, 22 is preferably about 1.9 cm.

[00128] In some examples, the anchors 20, 22 are controlled by a release mechanism, such as a biasing member that, when actuated, causes the anchors 20, 22 to transition from the contracted position to the deployed position. When deployed, the anchors 20, 22 are positioned and configured to form an essentially or fully airtight seal with the bladder walls 100a, 100b and, in particular, to prevent air and/or urine from exiting the bladder 100 through the urethra 116. In some examples, when deployed, anchors 20, 22 of the indwelling portion 6 have sufficient integrity or rigidity to support the superior wall 100b of the bladder 100 and maintain a space between the superior wall and the trigone and/or inferior wall of the bladder. In some examples, when deployed, anchors 20, 22 substantially maintain their configuration upon deployment and do not collapse due to contact with bladder walls and/or trigone. In some examples, when deployed, the indwelling portion 6 maintains its orientation such that central axis thereof extends between the superior wall of the bladder and the trigone. Desirably, the indwelling portion 6 does not appreciably collapse along the central axis, or shift or tilt from its axial position upon deployment from pressure exerted on the indwelling portion 6 by the bladder walls.

[00129] In some examples, the distal end 30 of the catheter body or tube 12 extends through the distal anchor 20 and is in contact with the superior wall 100b of the bladder 100 (shown in FIGS. 1 and 2). In that case, the distal end 30 of the catheter body or tube 12 can include a sponge or pad 40, such as a gel pad, mounted to the catheter body or tube 12 and positioned to contact and press against the superior bladder wall 100b for the purpose of preventing drainage, aspiration, or other trauma.

[00130] The tube 12 can further comprise a fluid receiving portion, e.g., the drainage channel(s) or lumen(s) 14. The drainage lumen 14 can include one or more perforations, such as drainage ports, eyelets, or holes 28 for draining fluid (e.g. urine or air) from the bladder 100 into the lumen 14 of the tube 12 for removal from the bladder 100. The drainage holes 28 can

be arranged in any suitable pattern, such as linearly along the length of the catheter body or tube 12, at various positions around the tube 12 or in a helical pattern extending along the tube 12. Desirably, the drainage holes 28 are arranged in a pattern that ensures stability and rigidity of the distal end 30 in the deployed position. In some examples, the drainage lumen 14 comprises about one to twenty drainage holes 28. The drainage holes 28 can have a diameter of about 0.005 mm to about 0.5 mm. The holes 28 can be generally circular or oval shaped, and can be arranged in a straight line along the tube 12 or can be offset.

[00131] In some examples, as shown in FIGS. 7A and 7B, the anchors 20, 22 can comprise a basket or umbrella shaped frame structure. For example, the anchors 20, 22 can comprise flexible supports, such as flexible support members 32, extending radially from the tube 12. For example, each flexible member 32 can include one end that is fixedly connected to the tube 12 and a free end that, in the deployed position, extends radially outward from the tube 12. The flexible members 32 can be slightly bowed, curved, or biased to better absorb contracting forces from the superior bladder wall. The flexible members 32 can be any suitable length and width to correspond with the anatomy of the bladder 100. For example, the flexible members 32 can be formed from a shape-memory alloy, such as nickel titanium, can be generally cylindrical or columnar in shape, and can have a diameter of between about 0.05 mm and 1 mm. In some examples, the flexible members 32 can also include one or more hinges for imparting sufficient flexibility thereto.

[00132] The support members 32 can be covered by a support cap, such as a cover 38 or membrane, formed from a flexible and non-porous material or fabric, such as silicone or Teflon®, for preventing air and/or fluid from passing through the cover or membrane. In some examples, the cover 38 is formed from a material which does not appreciably abrade, irritate, or damage the mucosal lining of the bladder wall or the urethra when positioned adjacent to the mucosal lining, such as silicone or Teflon® materials. The thickness of the cover 38 can range from about 0.05 mm to about 0.5 mm. In some examples, the cover 38 of the proximal anchor 22 defines an annular seal extending around a central opening 34 thereof for sealing the inferior bladder wall. In some examples, portions of the cover 38 can comprise include an elastomeric material or other flexible material, such as silicone or Teflon®, for ensuring tight contact with the inferior bladder wall.

[00133] In some examples, the catheter device 10 can further comprise one or more posts 26 extending substantially parallel and/or concentric to the tube 12 between the proximal anchor 22 and the distal anchor 20 for providing additional support for the tube 12. In some examples,

the posts 26 can be substantially rigid members that are connected to, enclosed within, or integrally formed with other portions of the tube 12. For example, the posts 26 can include one or more nickel titanium or plastic tines. The posts 26 are provided so that the distal end 30 of the tube 12 can withstand forces exerted on the anchors 20, 22 by the bladder wall(s). For example, the posts 26 can be formed from a rigid material that does not bend from a central axis of the tube 12 and ensures even distribution of downward bladder wall pressure. The length L (shown in FIG. 7B) of the post 26 can be a fixed length, and is selected such that, when deployed in the bladder 100, the anchors 20, 22 and the post 26 create sufficient space so that drainage functions of the catheter 10 are not inhibited. For example, the length L of the post 26 can be between about 1.0 cm and 3.0 cm. The posts 26 can prevent the bladder 100 from collapsing and obstructing drainage holes or anatomical structures of the bladder 100, such as the ureters 114. For anchors 20, 22 having a deployed diameter of about 8 mm, the posts 26 can have a diameter of about 0.3 mm to about 1.0 mm (e.g., 1 Fr to 3.3 Fr).

[00134] Alternatively, in some examples, the fluid receiving portion or distal end 30 of the tube 12 can be provided in different lengths L for different patients. In other arrangements, the distal end 30 can include a length adjustment mechanism, such as a telescoping arrangement, for adjusting the length L of the distal end 30 for a particular patient.

[00135] With reference to FIGS. 8A and 8B, an indwelling portion of another exemplary catheter device 10a is illustrated. A fluid receiving portion or distal end portion 30a of the catheter device 10a is shown in a contracted position in FIG. 8A, and in a deployed position in FIG. 8B. The distal end 30a includes opposing bladder wall supports for supporting the superior and inferior bladder walls. For example, the distal end portion 30a can comprise a proximal sheath 20a and a distal sheath 22a. Each sheath 20a, 22a extends between a slidable ring or collar 24a and stationary or mounted ring or collar 28a. The sheaths 20a, 22a are formed from a flexible, non-porous material, such as silicon. The sheaths 20a, 22a are held together by one or more flexible wires or cables 26a. The sheaths 20a, 22a can also be connected by one or more rigid members, such as supports 32a. In some examples, the supports 32a can be tines formed from a flexible, shape-memory material, such as nickel titanium. The supports 32a are positioned to provide support for the proximal sheath 20a and to prevent the distal end 30a from collapsing when it is in the deployed position. In the contracted position, the collars 24a, 28a are positioned apart from one another, such that the sheaths 20a, 22a are stretched or folded against the cable 26a and supports 32a. In the deployed position, the slidable collars

24a are moved toward the stationary collars 28a, allowing the sheaths 20a, 22a to unfold from the central cables 26a and to form a substantially flat disk-shaped structure.

[00136] In use, the distal end 30a of the catheter device 10a is inserted into the bladder of a patient in the contracted position. Once inserted in the bladder, the distal sheath 22a is released by sliding the slidable collar 24a in a distal direction toward the stationary collar 28a. Once the distal sheath 22a is deployed, the proximal sheath 20a is released or deployed in a similar manner by sliding the slidable collar 24a in the proximal direction toward the respective stationary collar 28a. At this point, the proximal sheath 20a is floating within the bladder, and is not positioned or sealed against the inferior wall of the bladder. Pressure against the distal sheath 22a caused by collapsing of the bladder is transferred to the proximal sheath 20a through the supports 32a and causes the proximal sheath 20a to move toward the desired position adjacent to the opening of the urethra. Once the proximal sheath 20a is in place, a seal over the urethra opening is created. The seal causes a negative pressure within the bladder and prevents air and/or urine from exiting the bladder through the urethra.

Exemplary retention portions with annular inflatable balloons

[00137] With reference to FIGS. 9A-11B, indwelling or retention portions 6 of additional exemplary urine collection catheter devices 10 comprising bladder superior wall supports 300 are illustrated. Unlike in previously described examples, the rigid or substantially rigid anchors 20, 22 (shown in FIGS. 7A and 7B) are replaced with an inflatable support cap, such as an annular balloon 310, positioned to contact the superior wall of the bladder to prevent the bladder from contracting and occluding either fluid port(s) 312 of the catheter device 10 or the ureteral openings of the bladder. In some examples, a distal end portion 30 of the tube 12 extends through a central opening 314 of the balloon 310. The distal end portion 30 of the tube 12 can also contact the superior bladder wall.

[00138] With specific reference to FIGS. 9A and 9B, in some examples, the tube 12 comprises a fluid access portion 316 positioned proximal to the balloon 310 and extending through a sidewall of the tube 12. The fluid access portion 316 can comprise a filter 318 (shown in FIG. 9B) disposed about a central lumen of the tube 12. In some examples, a sponge material 320 can be positioned over the filter 318 for increased absorbance of fluid within the bladder. For example, the sponge material 320 can be injection molded over the filter 318. In use, urine is absorbed by the sponge material 320 and, upon application of negative pressure through the tube 12, passes through the filter 318 and into the central lumen of the tube 12.

[00139] With specific reference to FIGS. 10A and 10B, in another exemplary embodiment, the support cap, such as the annular balloon 310, comprises a substantially bulbous distal portion 322 configured to contact and retain the superior bladder wall. The balloon 310 further comprises a plurality of proximally extending lobes 324. For example, the balloon 310 can comprise three lobes 324 spaced equidistantly around a portion of the tube 12 proximal to the balloon 310. As shown in FIG. 10B, the fluid ports 312 can be positioned between adjacent lobes 324. In this configuration, the lobes 324 and bulbous distal portion 322 contact the bladder wall, which prevents the bladder wall from blocking or occluding the fluid ports 312.

[00140] With specific reference to FIGS. 11A and 11B, in another exemplary embodiment, the annular balloon 310 is provided with a flattened and elongated shape. For example, the annular balloon 310 can have a substantially teardrop shaped radial cross section as shown in FIG. 11B, with a narrower portion 326 thereof positioned adjacent to the tube 12 and the enlarged or bulbous portion 328 positioned on the radially outwardly facing side thereof. The flatted annular balloon 310 is configured to span and seal the trigone region of the bladder such that when deployed in the bladder, the outer circumference of the balloon 310 extends radially beyond the ureteral openings. For example, when positioned in the patient's bladder, the central opening 314 of the balloon 310 can be configured to be positioned above the trigone region. Fluid port(s) 312 can be positioned proximal to the central portion balloon 310, as shown in FIG. 11B. Desirably, the fluid port(s) 312 are positioned between the central opening 314 of the balloon and the trigone region. When the bladder contracts from application of negative pressure, the bladder wall is supported by the outer circumference of the balloon 310 to avoid blocking the ureter openings. Accordingly, in this configuration, the balloon 310 contacts and prevents the bladder wall from blocking or occluding the fluid ports 312. In a similar manner, as discussed herein, the balloon 310 keeps the trigone region open so that urine can be drawn from the ureters into the bladder through the ureteral openings.

[00141] With reference to FIG. 12, another exemplary embodiment of an indwelling portion 6 of a urine collection catheter 10 comprising a bladder superior wall support 300 is illustrated. The bladder superior wall support 300 comprises a bulbous sponge 330 mounted to and extending from the open distal end 30 of the tube 12. The sponge 330 is substantially similar to the balloon 310 in previously-described examples and can be configured to contact the superior bladder wall to prevent or counteract contraction of the bladder. Desirably, the sponge 330 is formed from a soft, pliable material that does not appreciably abrade, irritate, or damage a mucosal lining of the bladder walls or of a urethra when positioned adjacent to a mucosal

lining of the bladder walls or the urethra. In use, upon application of negative pressure through the tube 12, fluid is drawn through the porous sponge 330, through the distal opening 30, and into a central lumen of the tube 12.

Exemplary external portions of the urine collection catheter

[00142] With reference to FIG. 13, elements of the external portion 8 of the tube 12 will be described in detail. As previously discussed, the external portion 8 comprises portions of the tube 12 external to the patient's body. A proximal end of the external portion 8 can be configured to be connected to a fluid container or pump 410 (shown in FIG. 14). In some examples, the external portion 8 can comprise a deployment guide 44 for advancing or inserting the catheter 10 through the urethra 116 (shown in FIGS. 1 and 2) and into the bladder. Desirably, the deployment guide 44 is easy to use for non-medical personnel so that, for example, the device 10 can be deployed independently by the patient (e.g., self-administration). The deployment guide 44 can be configured to accommodate different catheter lengths to accommodate the anatomy of a particular patient. The deployment guide 44 can include a mechanism for advancing the catheter 10 such as a trigger 46 or advancing knob. In some examples, the user extends or lengthens the catheter device 10 by pressing the trigger 46 in a distal direction. Similarly, the catheter device 10 is retracted by pulling the trigger 46 in the opposite direction to withdrawn the catheter 10 from the patient.

[00143] The deployment guide 44 can further comprise a release mechanism 48 for releasing the anchors 20, 22 to transition the catheter 10 from the contracted position (shown in FIGS. 7A and 8A) to the deployed position (shown, for example, in FIGS. 7B and 8B). For example, the release mechanism 48 can comprise a release button or switch located on or adjacent to the deployment guide 44 that, when actuated by a user, causes a corresponding structure on the distal end 30 of the catheter 10 to push or move the anchors 20, 22 from the contracted position to the deployed position. More specifically, the anchors 20, 22 naturally remain in the contracted position. The release mechanism 48 overcomes the bias toward the contracted position and temporarily holds or locks the anchors 20, 22 in the deployed position. In some examples, the release mechanism 48 can be configured to release the anchors 20, 22 simultaneously to avoid applying unequal pressure to opposite sides of the bladder 100, as would occur if one anchor was in a deployed state while the other anchor was in a contracted state. Similarly, the release mechanism 48 can be configured to automatically retract the proximal anchor 22 if the distal anchor 20 is forced to close from an excessive force exerted by the bladder wall 100a, 100b. The release mechanism 48 can also be configured to

automatically retract the anchors 20, 22 if, for example, the catheter device 10 is inadvertently or intentionally pulled out while the distal end 30 is in its deployed position.

[00144] With continued reference to FIG. 13, since the anchors 20, 22 are passively fixed and create an essentially airtight seal in the bladder 100 (shown in FIGS. 1 and 2), there is a risk that trauma to the bladder 100 or urethra 116 can occur if the catheter device 10 were pulled while the anchors 20, 22 were in the deployed state. Therefore, the external portion of the catheter 10 can comprise a breakaway valve 50 for releasing or separating a portion of the catheter 10 including the indwelling portion 6 of the catheter device 10 from the external portion of the catheter 10. The breakaway valve 50 is generally positioned along the tube 12 at a position that is proximal to the deployment guide 44 as shown, for example, in FIG. 13. The breakaway valve 50 can be configured such that, when the portions of the catheter device 10 are separated, the valve 50 transitions to a closed position to prevent fluid from leaking from the catheter 10. The external portions of the catheter 10 can be reattached to the breakaway valve 50 to continue therapy.

[00145] The catheter device 10 can further comprise sensors 52 for monitoring fluid characteristics of urine being excreted from the bladder. Information obtained from the sensors 52 can be transmitted to a central data collection module or processor and used, for example, to control operation of an external device, such as the pump 410 (shown in FIG. 14). The sensors 52 can be integrally formed with the tube 12 such as, for example, embedded in a wall of the tube 12 and in fluid communication with the one or more lumens 14 of the catheter 10. In other examples, one or more of the sensors 52 can be positioned in a fluid collection container (not shown) or in internal circuitry of an external device, such as a pump.

[00146] In some examples, the catheter device 10 further comprises one or more of the following types of sensors 52. For example, the catheter can include a conductance sensor or electrode that samples conductivity of urine in the catheter 10. The normal conductance of human urine is about 5-10 mS/m. Urine having a conductance outside of the expected range can indicate that the patient is experiencing a physiological problem, which requires further treatment or analysis. The catheter 10 can also include a flow meter for measuring a flow rate of urine through the catheter 10. Flow rate can be used to determine a total volume of fluid excreted from the body. The catheter 10 can also include a thermometer for measuring urine temperature. Urine temperature can be used to collaborate the conductance sensor. Urine temperature can also be used for monitoring purposes, as urine temperature outside of a physiologically normal range can be indicative of certain physiological conditions.

[00147] With continued reference to FIG. 13, the proximal end of the catheter body or tube 12 can comprise a port 54 configured to connect either to flexible tubing of a fluid collection system or directly to an external unit, such as a pump. The port 54 can comprise connectors, sealing members, and valves for forming a suitable fluid connection between the catheter 10 and the external unit. For example, the connector can be a bracket, luer connector, screw connector, clamp, or other suitable connection mechanism as is known in the art. In another example, the catheter body or tube 12 can be connected to a peristaltic pump connector. The peristaltic pump connector can be an inline catheter that is fed through arms of the pump, which are positioned to force fluid through the inline catheter. In other examples, the pump can be a diaphragm or piston pump, as are known in the art.

Exemplary system for inducing negative pressure

[00148] With reference to FIG. 14, a system 400 for inducing negative pressure including a catheter device 10 deployed in the bladder of a patient is illustrated. In some examples, the system 400 comprises the catheter device 10 connected to a fluid collection container 412 for collecting and storing expelled urine. The fluid collection container 412 can be placed under negative pressure by an external unit, such as the pump 410, connected thereto. The negative pressure generated by the pump 410 is provided to the patient's bladder through one or more drainage lumens of the catheter device 10. As discussed herein, negative pressure therapy can be provided for overcoming interstitial pressure in the kidneys to induce urine production. In some examples, the system 400 further comprises a controller 414, such as a microprocessor, having or associated with computer readable memory 416. The memory 416 can store instructions that, when executed, cause the controller 414 to receive information from sensors 52 located on, or associated with, the catheter device 10, determine information about the condition of the patient based on information from the sensors 52, and determine and implement operating parameters for the pump 410 based on information received from the sensors 52.

[00149] In some examples, the controller 414 is incorporated in a separate electronic device, such as a dedicated electronic device or a multipurpose electronic device, such as a computer, tablet PC, or smart phone. Alternatively, the controller 414 can be integral with and/or electronically coupled to the pump 410 and, for example, can control both a user interface for manually operating the pump 410, as well as system functions, such as receiving and processing information from the sensors 52.

[00150] The controller 414 can be configured to receive information from the one or more sensors 52, such as the conductance sensor, and to store the information in the associated computer-readable memory 416. For example, the controller 414 can be configured to receive information from the conductance sensor at a predetermined rate, such as once every second, and to determine a conductance based on the received information. In some examples, the algorithm for calculating conductance can also include other sensor measurements, such as urine temperature, to obtain a more robust determination of conductance.

[00151] The controller 414 can also be configured to calculate patient physical statistics or diagnostic indicators that illustrate changes in patient condition over time. For example, the system 400 can be configured to identify an amount of total sodium excreted. The total sodium excreted could be based, for example, on a combination of flow rate and conductance over a period of time.

[00152] With continued reference to FIG. 14, the system 400 can further comprise a feedback device 420, such as a visual display or audio system, for providing information to the user. In some examples, the feedback device 420 can be integrally formed with the pump 410. Alternatively, the feedback device 420 can be a separate dedicated or a multipurpose electronic device, such as a computer, laptop computer, tablet PC, smart phone, or other handheld electronic device. The feedback device 420 can be configured to receive the calculated or determined measurements from the controller 414 and to present the received information to a user via the feedback device 420. For example, the feedback device 420 can be configured to display current negative pressure (in mmHg) being applied to the urinary tract. The feedback device 420 can also display current flow rate of urine, temperature, current conductance in mS/m of urine, total urine produced during the session, total sodium excreted during the session, or any combination thereof.

[00153] The feedback device 420 can also include a user interface that allows the user to control operation of the pump 410. For example, the user can engage or turn off the pump 410 via the user interface. The user can also adjust pressure applied by the pump 410 to achieve a greater magnitude or rate of sodium excretion and fluid removal.

[00154] In some examples, the feedback device 420 and/or pump 410 further comprise a data transmitter 422 for sending information from the device 420 and/or pump 410 to other electronic devices or computer networks. The data transmitter 422 can utilize a short-range or long-range data communications protocol. An example of a short-range data transmission protocol is Bluetooth®. Long-range data transmission networks include, for example, Wi-Fi,

Zigbee, cellular transmissions protocols, and the like. The data transmitter 422 can send information to a patient's physician or caregiver to inform the physician or caregiver about the patient's current condition. Alternatively, or in addition, information can be sent from the data transmitter 422 to existing databases or information storage locations, such as, for example, to include the recorded information in a patient's electronic health record (EHR).

[00155] With reference to FIGS. 15A and 15B, an exemplary pump 410 for use with the system is illustrated. In some examples, the pump 410 is a micro-pump configured to draw fluid from the catheter device and having a sensitivity of about 0.5 mmHg. Desirably, the pump 410 is capable of providing a range of flow of urine between 0.05 ml/min and 3 ml/min for extended periods of time. At 0.2 ml/min it is anticipated that about 300 mL of urine per day is collected by the system 400. The pump 410 can be configured to provide a negative pressure to the bladder of the patient, the negative pressure ranging between about 0.1 mmHg and 20 mmHg (gauge pressure at the pump 410). For example, a micro-pump manufactured by Langer Inc. (Model BT100-2J), can be used with the presently disclosed system 400. Diaphragm aspirator pumps, as well as other types of commercially available pumps, can also be used for this purpose. Peristaltic pumps can also be used with the system 400.

[00156] In some examples, the pump 410 can be configured for extended use and, thus, is capable of maintaining precise suction for periods of between 8 and 24 hours. The pump 410 can be manually operated and, in that case, includes a control panel 418 that allows a user to set a desired suction value. The pump 410 can also include a controller or processor, which can be the same controller that operates the system 400, or can be a separate processor dedicated for operation of the pump 410. In either case, the processor is configured for both receiving instructions for manual operation of the pump and for automatically operating the pump 410 according to predetermined operating parameters. Alternatively, or in addition, operation of the pump 410 can be controlled by the processor based on feedback received from the plurality of sensors associated with the catheter.

Method of inducing negative pressure

[00157] Having described the catheter device and system, a process for inducing negative pressure in the bladder will now be discussed in detail. With reference to FIG. 16, a medical professional, caregiver, or the patient inserts the catheter through the urethra of the patient, as shown in box 510. The catheter is advanced through the urethra and enters the bladder at box 512. The user advances the catheter through the bladder until the pad or padding on the distal tip of the catheter comes into contact with the bladder wall immediately adjacent to the urethral

sphincter. At box 514, the user engages the release mechanism such that the proximal anchor and the distal anchor extend from the contracted state to the deployed state. In the deployed state, the distal anchor contacts the bladder wall immediately adjacent to the urethral sphincter. The proximal anchor contacts an opposing side of the bladder wall from the distal anchor and seals the opening to the urethra to maintain urine in the bladder. The anchors can be released simultaneously. In some examples, the distal anchor and the proximal anchor are also positioned simultaneously. Alternatively, the distal anchor can first be positioned adjacent to the urethral sphincter and the proximal anchor can float within the bladder. In that case, pressure from the superior wall of the bladder pushes against the distal anchor, which in turn guides the proximal anchor into position to seal the opening to the urethra.

[00158] Once the catheter is in place and transitioned to the deployed state, negative pressure is applied to the bladder at box 516. The negative pressure collapses the bladder, thereby holding the anchors against the mucosal wall to seal the urethra. Desirably, the negative pressure is evenly distributed across both ureters and both kidneys. Further, the negative pressure on the medulla counters congestion mediated interstitial hydrostatic pressures due to elevated intra-abdominal pressure and consequential or elevated renal venous pressure or renal lymphatic pressure. The applied negative pressure is therefore capable of increasing flow of filtrate through the medullary tubules and of decreasing water and sodium re-absorption.

[00159] As a result of the applied negative pressure, at box 518, urine is drawn into the catheter through the openings or eyelets. The urine is then drawn from the body through the catheter where it is collected in a collection container for disposal. As the urine is being drawn to the collection container, at box 520, the plurality of sensors provide a number of measurements about the urine that can be used to assess the volume of urine collected, as well as information about the physical condition of the patient and composition of the urine formed. For example, the sensors can be embedded in the catheter in fluid communication with the lumens extending therethrough. Information can be obtained by the sensors as urine passes through the catheter. The information obtained by the sensors can be processed, at box 522, by a processor associated with the pump or other device and, at box 524 is displayed to the user via the visual display of the feedback device.

[00160] The embodiments have been described with reference to various examples. Modifications and alterations will occur to others upon reading and understanding the foregoing examples. Accordingly, the foregoing examples are not to be construed as limiting the disclosure.

WHAT IS CLAIMED IS:

1. A urine collection catheter configured to be deployed in a patient's bladder, the catheter comprising:

a conduit comprising a proximal end and an open distal end;

a drainage tube positioned at least partially within the conduit, the drainage tube comprising a proximal end, a distal end, and one or more fluid ports or perforations for permitting fluid flow into a drainage lumen defined by the drainage tube; and

a bladder superior wall support comprising a support cap and a plurality of support members extending from a proximal surface of the support cap through the open distal end of the conduit, and being capable of being moved between a retracted position and a deployed position,

wherein, in the deployed position, the distal end of the drainage tube is spaced apart from the support cap, such that the support cap supports portions of the superior wall of the bladder from occluding the one or more fluid ports or perforations of the drainage tube.

2. The catheter of claim 1, wherein the support cap is configured to inhibit the superior bladder wall from occluding the one or more ports or perforations upon delivery of negative pressure to the bladder and/or kidneys through the drainage tube.

3. The catheter of claim 1 or claim 2, wherein the support cap is configured to inhibit the superior bladder wall from contacting ureteral orifices of the bladder upon delivery of negative pressure to the bladder and/or kidneys through the drainage lumen.

4. The catheter of any of claims 1 to 3, wherein the support members comprise flexible tines, and wherein the support cap comprises a flexible cover mounted to and supported by the plurality of tines.

5. The catheter of claim 4, wherein the flexible tines comprise a shape-memory alloy configured to move to the deployed position at a temperature above ambient room temperature.

6. The catheter of claim 5, wherein the flexible cover is formed from a material that does not appreciably abrade, irritate, or damage a mucosal lining of the bladder

walls or of a urethra when positioned adjacent to the mucosal lining of the bladder walls or the urethra.

7. The catheter of any of claims 1 to 6, wherein the bladder superior wall support is configured to maintain its form when in contact with the superior wall of the bladder.

8. The catheter of any of claims 1 to 3, wherein the support cap comprises an inflatable balloon.

9. The catheter of claim 8, further comprising an inflation lumen at least partially disposed within the conduit and configured to conduct a fluid or gas into an interior of the balloon for inflation of the balloon.

10. A urine collection catheter configured to be deployed in a patient's bladder, the catheter comprising:

at least one tubular body comprising a proximal end, a distal end, a sidewall extending therebetween, and one or more fluid ports or perforations for permitting fluid flow into a drainage lumen defined by the tubular body; and

a bladder superior wall support comprising a support cap connected to and extending radially from a portion of the distal end of the at least one tubular body, the support cap comprising a curved distal surface,

the support cap being capable of being moved between a retracted position and a deployed position to support a superior wall of the bladder thereby inhibiting the superior bladder wall from occluding the one or more fluid ports or perforations.

11. The catheter of claim 10, wherein the bladder superior wall support is configured to inhibit the superior bladder wall from occluding the one or more ports or perforations upon delivery of negative pressure to the bladder and/or kidneys through the drainage lumen.

12. The catheter of claim 10, wherein the bladder superior wall support is configured to inhibit the superior bladder wall from contacting ureteral orifices of the bladder upon delivery of negative pressure to the bladder and/or kidneys through the drainage lumen.

13. The catheter of any of claims 10 to 13, wherein the bladder superior wall support comprises a plurality of support members extending radially from the tubular body, and wherein the support cap comprises a flexible cover mounted to and supported by the plurality of support members.

14. The catheter of claim 13, wherein the support members comprise flexible tines formed from a shape-memory alloy, the flexible tines being configured to extend to the deployed position at a temperature above ambient room temperature.

15. The catheter of claim 13 or claim 14, wherein the flexible cover is formed from a material that does not appreciably abrade, irritate, or damage a mucosal lining of the bladder walls or of a urethra when positioned adjacent to the mucosal lining of the bladder walls or the urethra.

16. The catheter of any of claims 10 to 15, wherein the bladder superior wall support comprises an inflatable balloon.

17. The catheter of claim 16, further comprising an inflation lumen configured to conduct a fluid or gas into an interior of the balloon for inflation of the balloon.

18. The catheter of claim 16 or claim 17, wherein the inflatable balloon comprises a bulbous portion and a plurality of lobes extending proximally therefrom, and wherein the one or more ports or perforations are positioned between adjacent lobes.

19. The catheter of any of claims 10 to 18, further comprising a filter positioned over the one or more ports or perforations.

20. The catheter of any of claims 10 to 19, further comprising an absorbent sponge positioned over the one or more ports or perforations.

21. The catheter of any of claims 10 to 20, further comprising a bladder inferior wall support configured to contact an inferior wall of the bladder.

22. The catheter of claim 21, wherein the bladder inferior wall support comprises one or more support members extending radially from the tubular body and a cover to the one or more support members.

23. The catheter of claim 22, wherein the cover of the bladder inferior wall support comprises a material that does not appreciably abrade, irritate, or damage a mucosal lining of the bladder walls or of a urethra when positioned adjacent to the mucosal lining of the bladder walls or the urethra.

24. A system for drawing urine from the bladder of a patient, the system comprising:

a urine collection catheter comprising:

at least one tubular body comprising a proximal end, a distal end, a sidewall extending therebetween, and one or more fluid ports or perforations for permitting fluid flow into a drainage lumen defined by the tubular body; and

a bladder superior wall support comprising a support cap defining a curved distal surface connected to and extending radially from a portion of the distal end of the at least one tubular body,

the support cap being capable of being moved between a retracted position and a deployed position to support a superior wall of the bladder to inhibit portions of the superior wall of the bladder from occluding the one or more fluid ports or perforations; and

a pump in fluid connection with the drainage lumen of the tubular body, wherein the pump is configured to introduce negative pressure through the tubular body to the bladder to draw urine from the bladder.

25. The system of claim 24, further comprising one or more sensors in fluid communication with the drainage lumen of the tubular body for measuring information representative of a physiological condition of the patient.

26. The system of claim 25, wherein the one or more sensors are configured to measure one or more of capacitance, analyte concentration, and temperature of urine within the tubular body.

27. The system of claim 25 or claim 26, wherein the pump comprises:

a processor comprising computer readable memory including programming instructions that, when executed, cause the processor to:

receive the information from the one or more sensors, and

adjust an operating parameter of the pump based, at least in part, on the information received from the one or more sensors to increase or decrease the negative pressure in the tubular body to adjust flow of urine therethrough.

28. The system of claim 27, wherein the pump further comprises a data transmitter in communication with the processor, the data transmitter being configured to provide the information from the one or more sensors to an external source.

29. The system of any of claims 24 to 28, wherein the pump is capable of continuous operation for between 8 and 24 hours.

30. The system of any of claims 24 to 29, wherein the pump provides a sensitivity of 10 mmHg or less.

31. The system of any of claims 24 to 30, wherein the pump is configured to provide intermittent negative pressure.

32. The system of any of claims 24 to 31, wherein the pump is configured to alternate between providing negative pressure and providing positive pressure.

33. The system of any of claims 24 to 31, wherein the pump is configured to alternate between providing negative pressure and equalizing pressure to atmosphere.

34. A urine collection catheter configured to be deployed within a patient's bladder, the catheter comprising:

a tubular body comprising a proximal portion configured to be positioned in at least a portion of a patient's urethra and a distal portion configured to be positioned in a patient's bladder, the distal portion comprising a coiled retention portion,

wherein the retention portion comprises at least a first coil having a first diameter, a second coil having a second diameter, the first diameter being less than the second diameter, and a plurality of perforations disposed on a radially inwardly facing side of a sidewall of the retention portion.

35. The catheter of claim 34, wherein the first coil is proximal to the second coil.

36. The catheter of claim 34 or claim 35, wherein, prior to insertion into a patient's urinary tract, a portion of the tubular body that is proximal to the retention portion defines a straight or curvilinear central axis, and wherein the first coil and the second coil of the retention portion extend about an axis that is at least partially coextensive with the straight or curvilinear central axis of the portion of the drainage lumen.

37. The catheter of claim 36, wherein, in the retention portion, a total surface area for the perforations on the radially inwardly facing side of the sidewall of the tubular body is greater than a total surface area of perforations on the radially outwardly facing side of the sidewall of the tubular body.

38 The catheter of any of claims 34 to 38, wherein, in the retention portion, a radially outwardly facing side of the sidewall of the tubular body is free from perforations.

39. A urine catheter comprising:

a tubular body comprising a proximal end, a distal end, and a sidewall extending therebetween; and

an indwelling portion adjacent to the distal end of the tubular body, the indwelling portion comprising a first surface configured to support a superior wall of a bladder, a second surface configured to contact an inferior wall of the bladder, and a linear portion of the sidewall extending between the first surface and the second surface,

wherein the first surface and the second surface each comprise a flexible material, and wherein the first surface and the second surface are supported by a plurality of support members.

40. The catheter of claim 39, wherein the flexible material does not appreciably abrade, irritate, or damage a mucosal lining of the bladder walls or of a urethra when positioned adjacent to the mucosal lining of the bladder walls or the urethra.

41. The catheter of claim 39 or claim 40, wherein the indwelling portion insulates the superior wall of the bladder from a trigone region of the bladder.

42. The catheter of any of claims 39 to 41, wherein the first surface and the second surface of the indwelling portion are transitionable between a contracted position and a deployed position.

43. The catheter of claim 42, wherein, in the deployed position, the first surface and the second surface maintain their form when in contact with the respective superior and inferior walls of the bladder.

44. The catheter of claim 42 or claim 43, wherein the flexible material contracts when the first surface and the second surface are in the contracted position and expands when the first surface and the second surface are in the deployed position.

45. The catheter of any of claims 42 to 44, wherein the second surface of the indwelling portion provides a seal for an opening of a urethra of the bladder when in the deployed position.

46. The catheter of any of claims 42 to 45, wherein the first surface of the indwelling portion contacts the superior wall of the bladder when in the deployed position so as to avoid obstruction of one or more ureter openings of the bladder.

47. The catheter of any of claims 42 to 46, wherein a section of the indwelling portion between the first surface and the second surface is not covered with the flexible material at least when the first surface and the second surface are in the deployed position.

48. The catheter of any of claims 42 to 47, further comprising a release mechanism configured to activate the first surface and the second surface from the contracted position to the deployed position.

49. The catheter of any of claims 39 to 48, wherein the flexible material covers at least a portion of the plurality of support members.

50. The catheter of any of claims 39 to 49, wherein the plurality of support members is drawn against the tube in the contracted position, and the plurality of support members extends outward from the tube in the deployed position.

51. The catheter of any of claims 39 to 50, wherein the plurality of support members are formed of a shape-memory alloy.

52. The catheter of any of claims 39 to 51, wherein the linear portion of the sidewall extending between the first surface and the second surface comprises one or more perforations extending through the sidewall to permit fluid flow therethrough into a fluid receiving portion of the tube.

53. A method of inducing a negative pressure to a bladder of a patient for enhancing urine excretion therefrom, the method comprising:

inserting a distal portion of a tubular body of a urine collection catheter into the patient's bladder;

deploying a support cap connected to and extending radially from a portion of the distal end of the tubular body, such that the support cap is in contact with the bladder superior wall; and

inducing a negative pressure through a drainage lumen of the tubular body to draw urine from the bladder into the drainage lumen.

54. The method of claim 53, further comprising positioning a bladder inferior wall support in contact with an inferior wall of the patient's bladder.

55. The method of claim 54, wherein positioning the bladder inferior wall support comprises positioning the support over an opening of a urethra to seal the bladder.

56. The method of claim 54 or claim 55, wherein the bladder inferior wall support is separate from the support cap and is supported by a plurality of support members extending radially from the tubular body.

57. The method of any of claims 53 to 56, wherein deploying the support cap comprises preventing the distal surface structure from occluding ureteral openings of the bladder.

58. The method of any of claims 53 to 57, wherein inducing the negative pressure in the tubular body comprises coupling a mechanical pump in fluid communication with a proximal end of the tubular body to draw urine from the bladder into the tubular body.

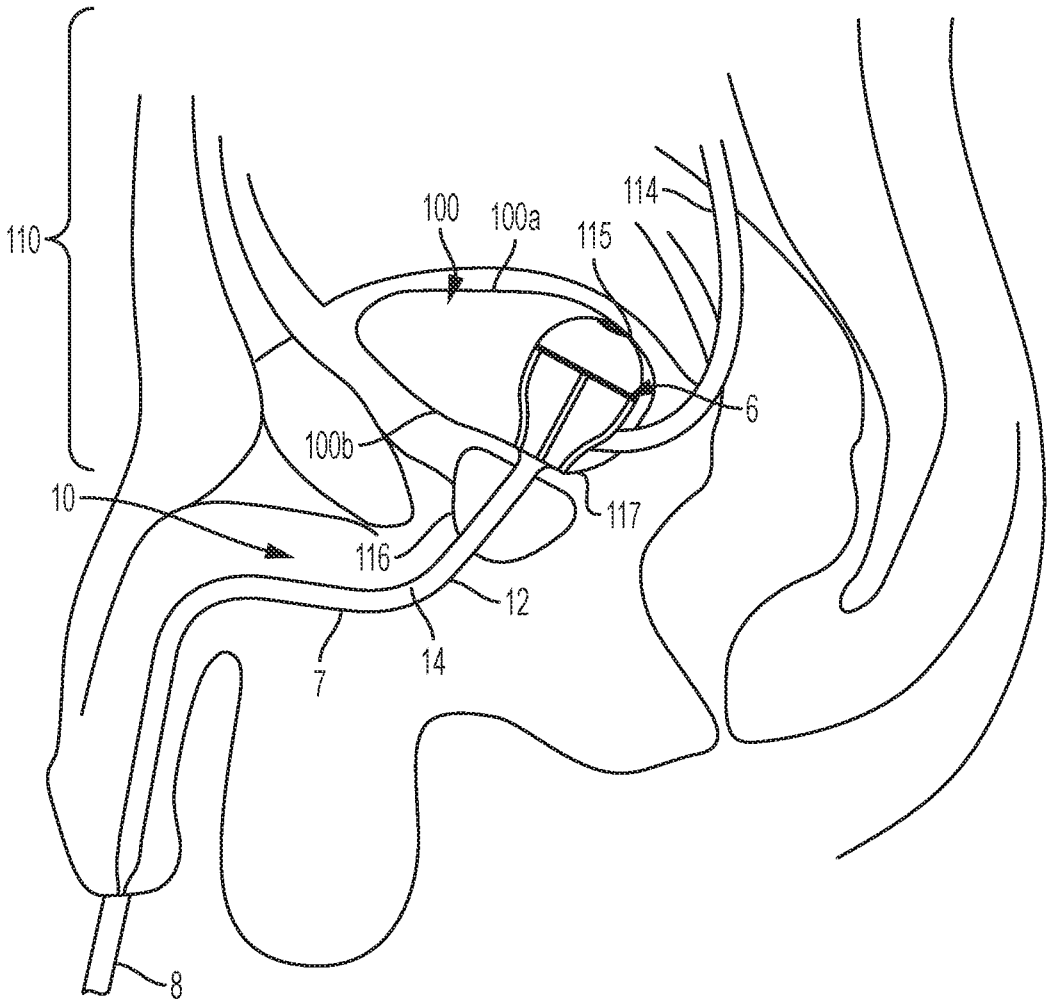

FIG. 1

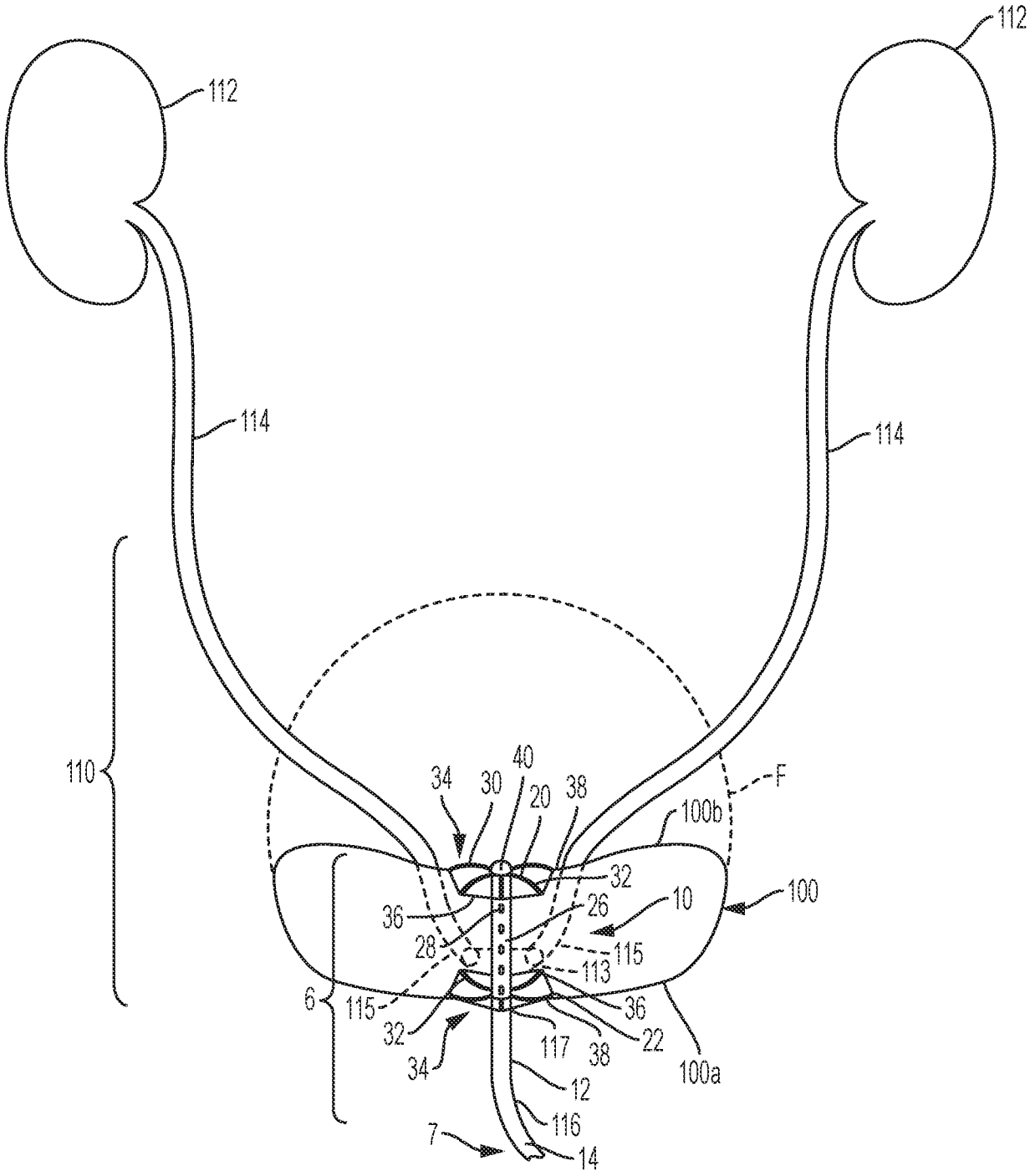
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FIG. 2

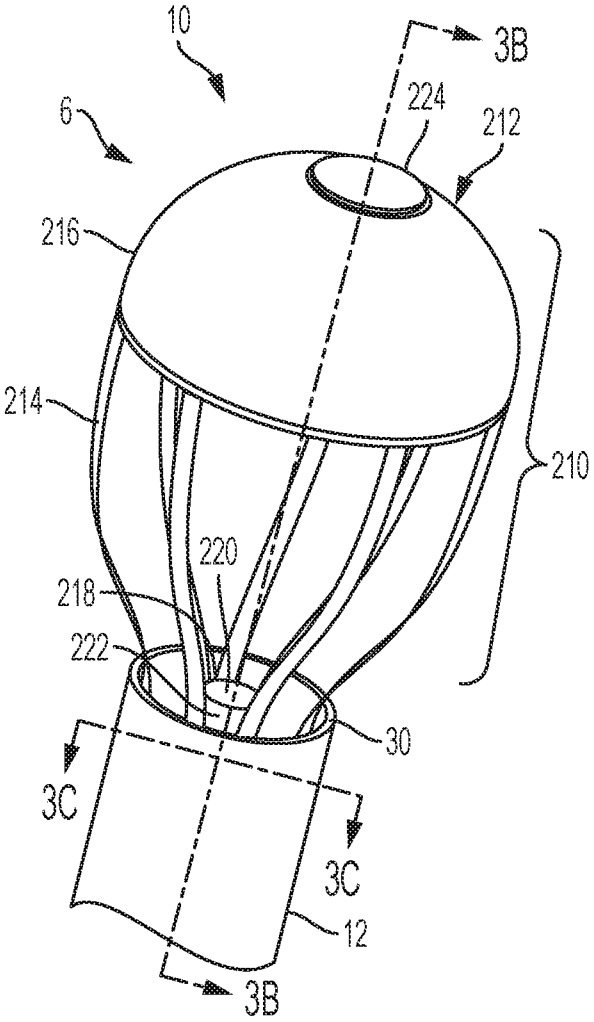


FIG. 3A

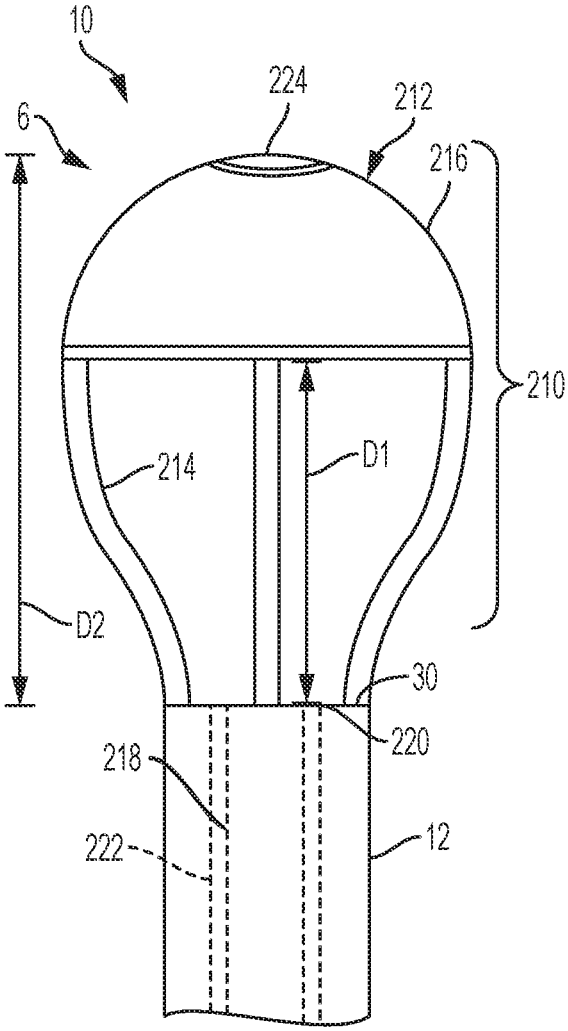


FIG. 3B

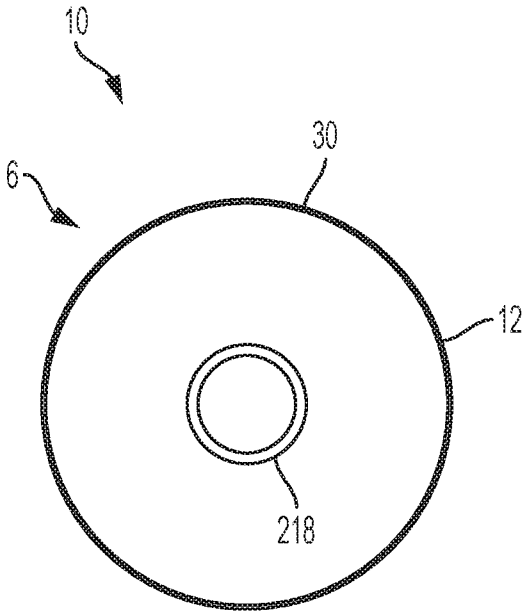


FIG. 3C

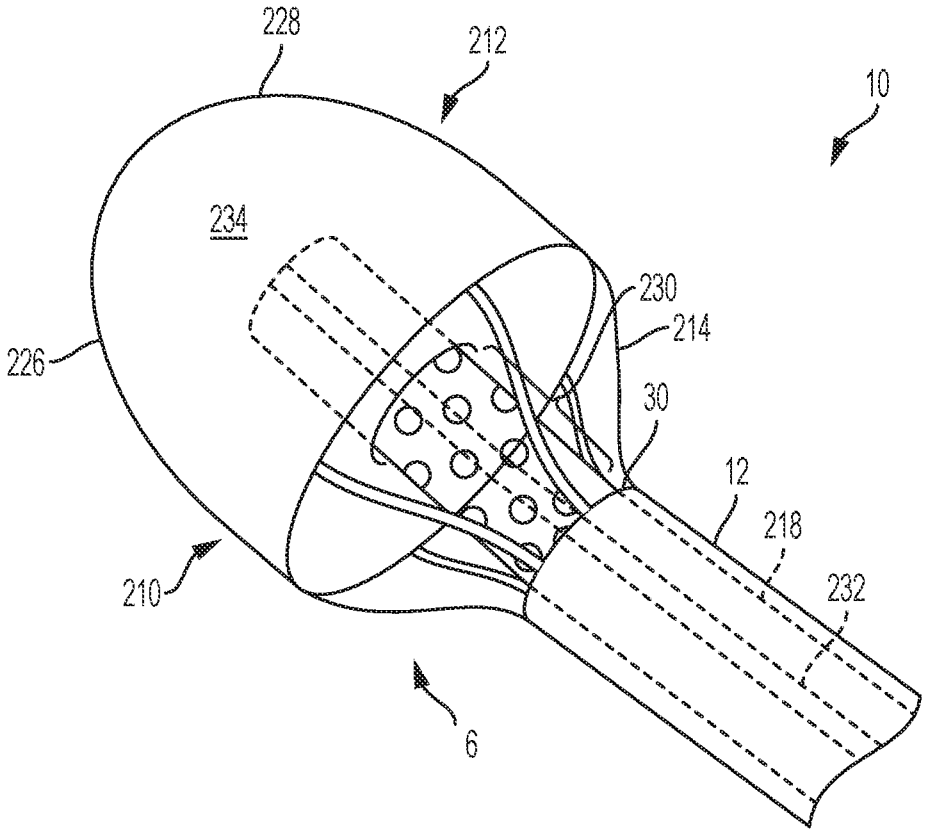
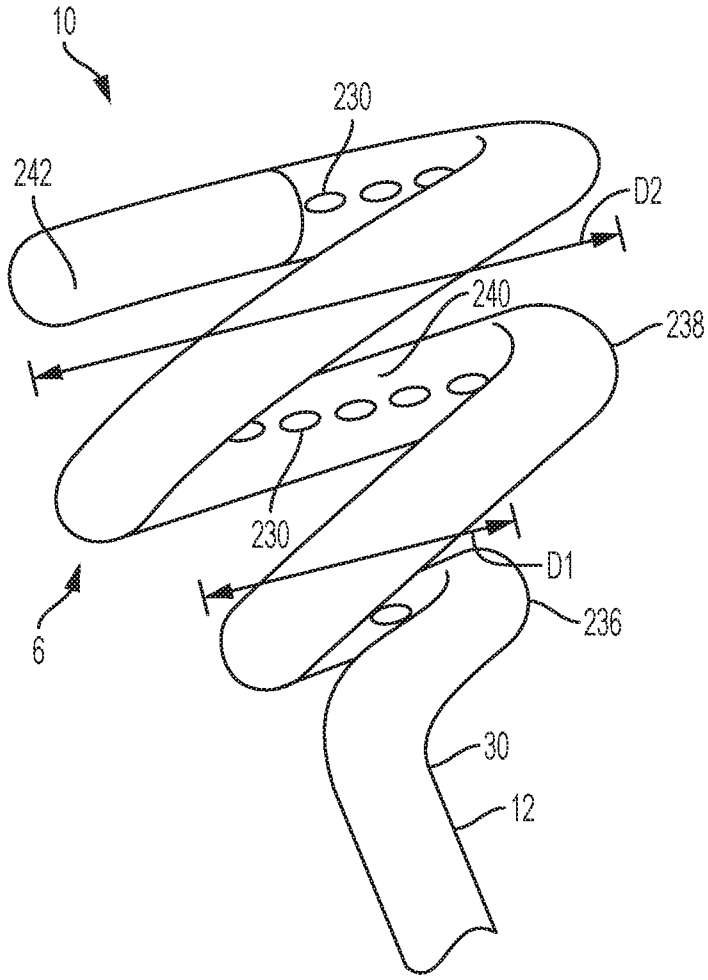


FIG. 4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238
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D1
236
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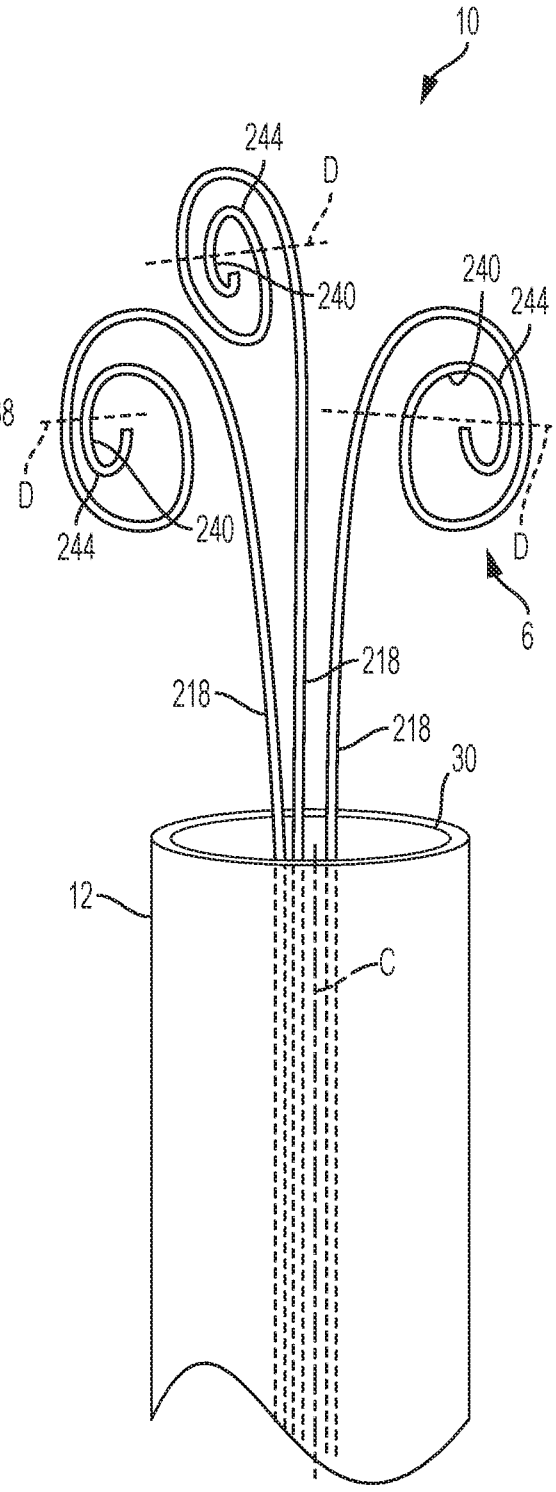
FIG. 5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240
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D
244
240
D
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218
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12
C

FIG. 6

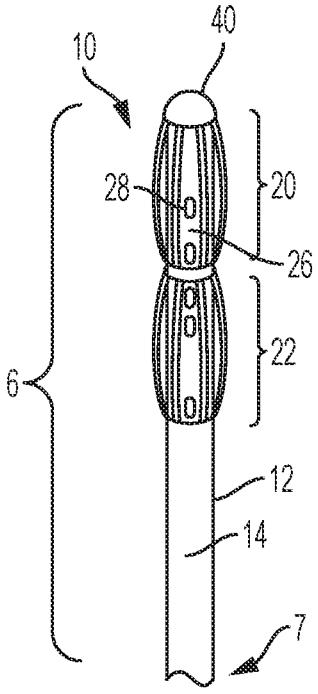
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FIG. 7A

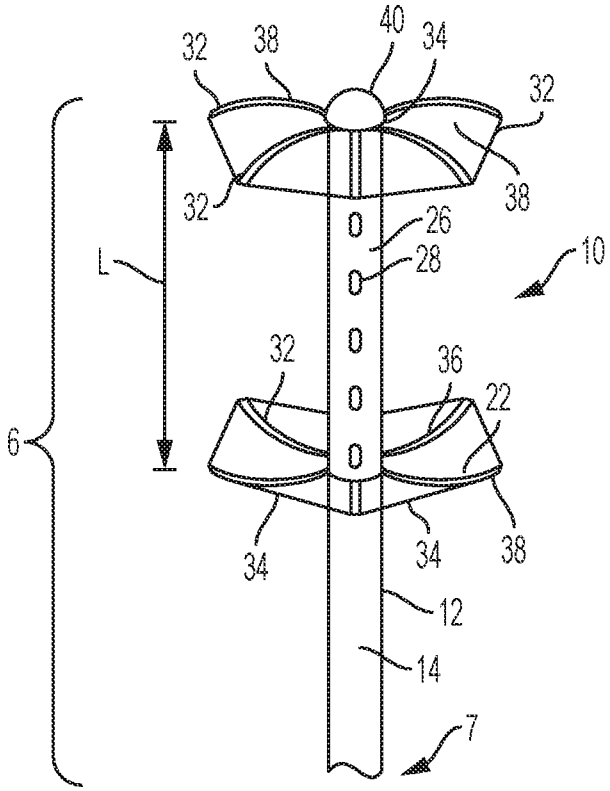
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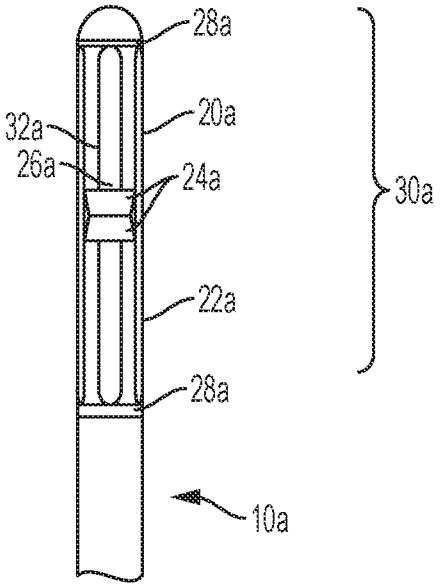
FIG. 7B


28a
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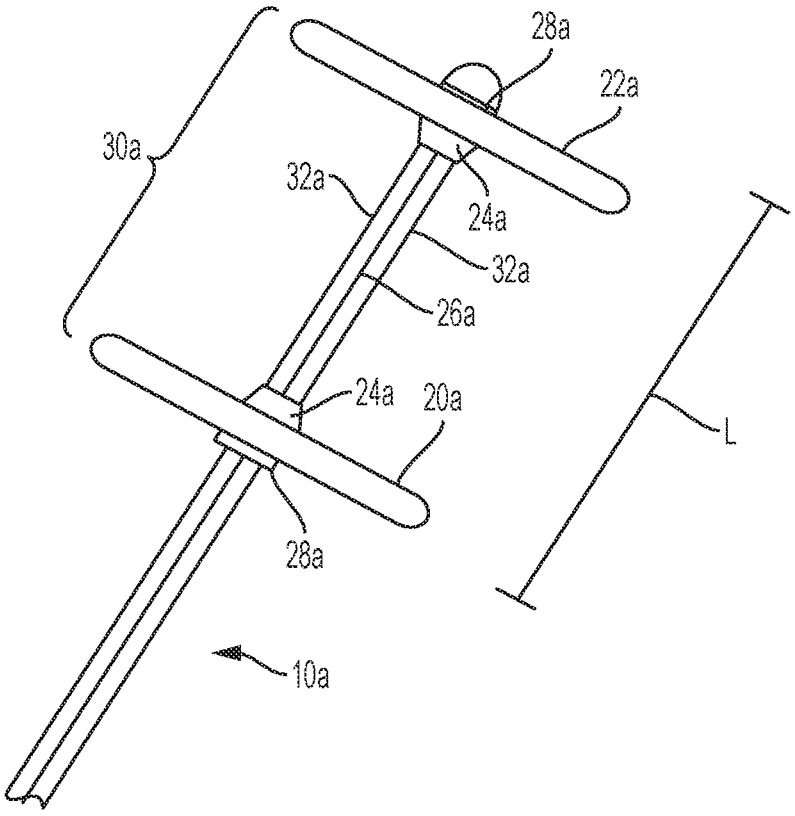
32a
26a
24a
30a
22a
28a
10a

FIG. 8A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24a
32a
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24a
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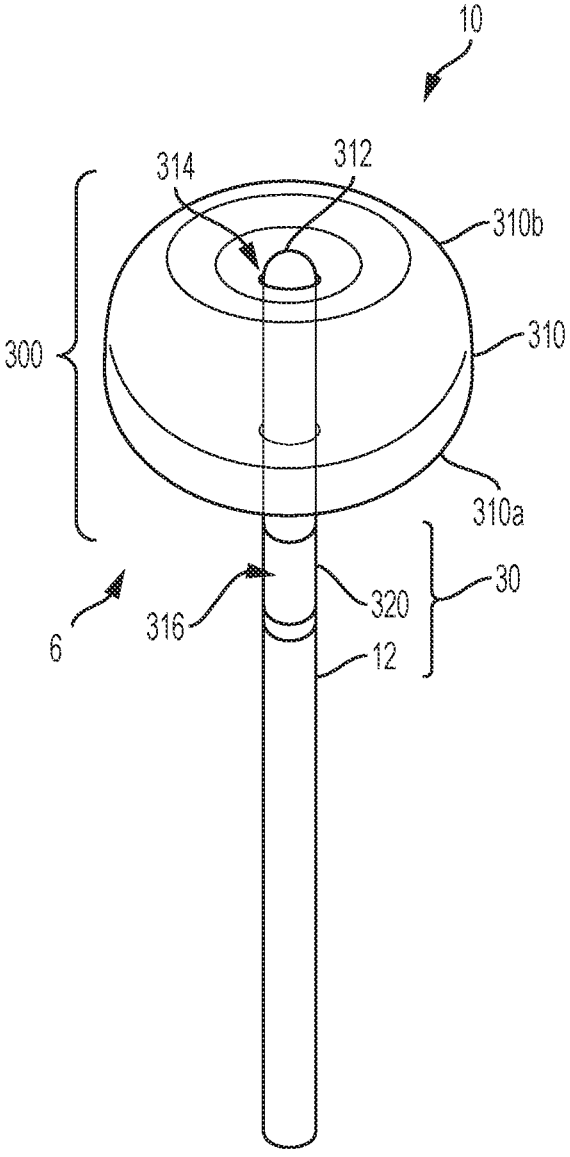
L
28a
10a

FIG. 8B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310b
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310a
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320
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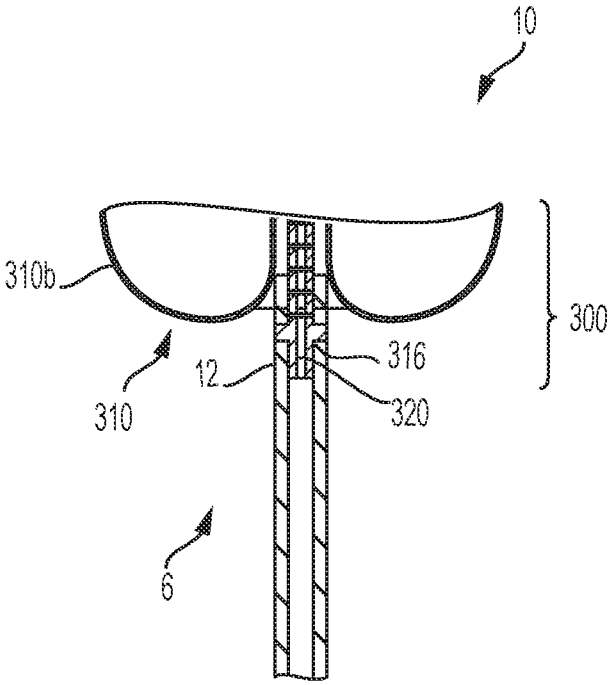
12

FIG. 9A


10
310b
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12
316
310
320
6

FIG. 9B

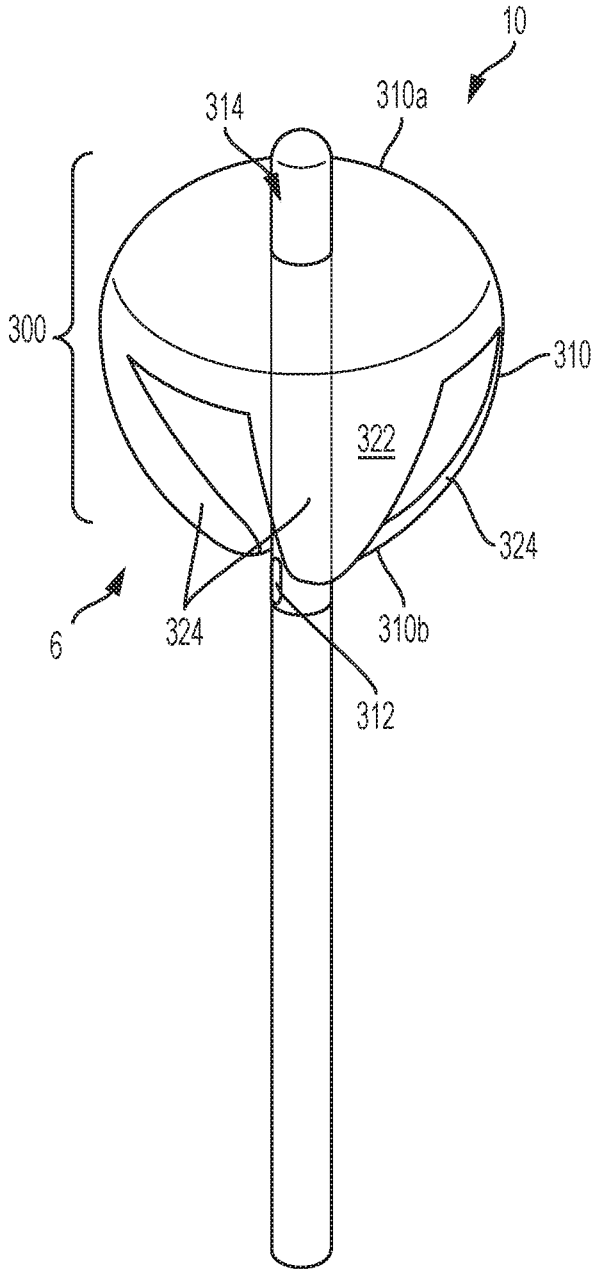

FIG. 10A

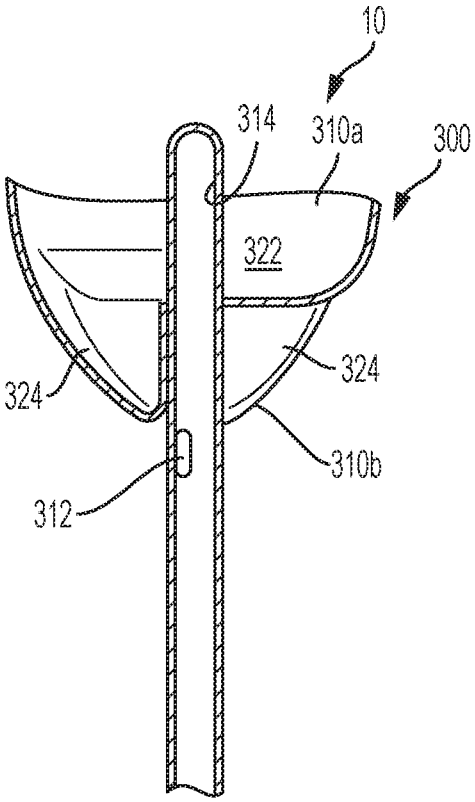

FIG. 10B

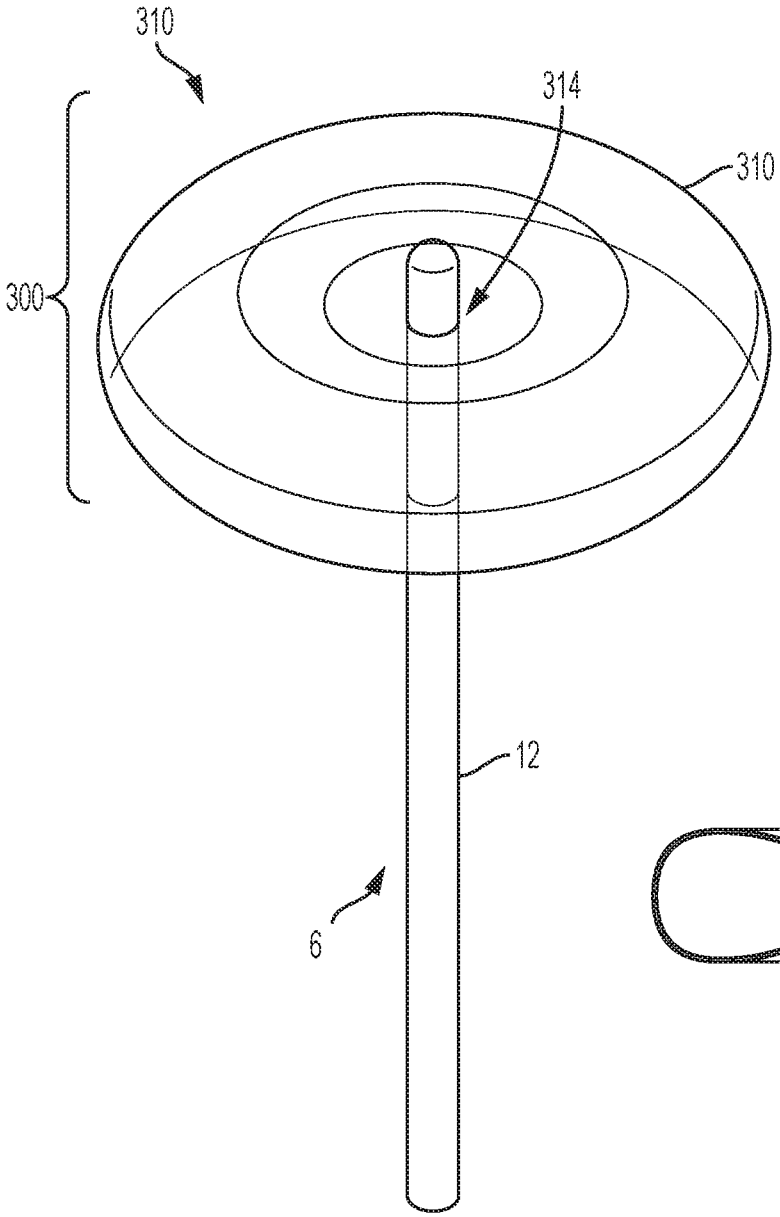

FIG. 11A

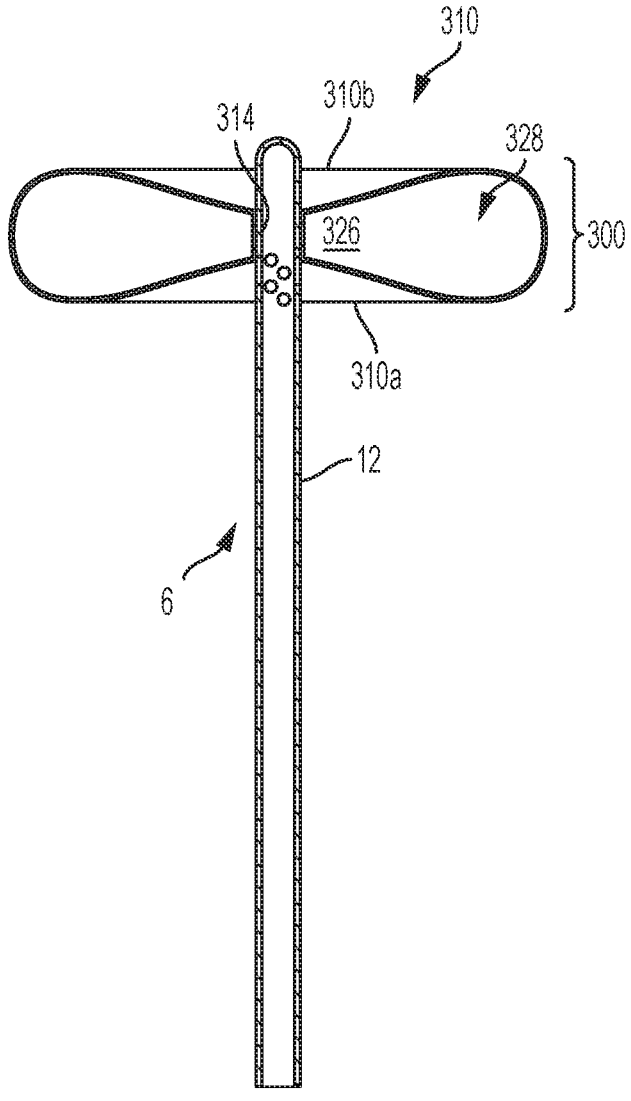

FIG. 11B

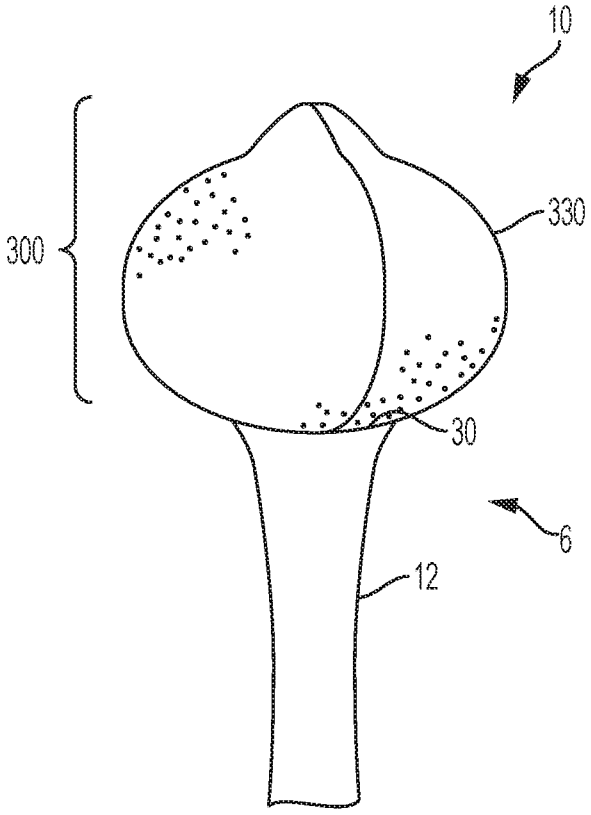

FIG. 12

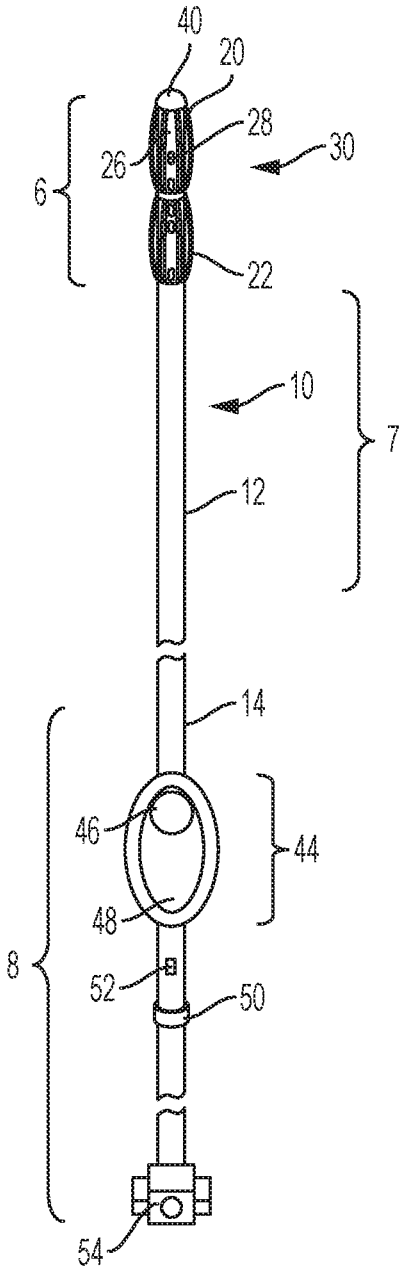

FIG. 13

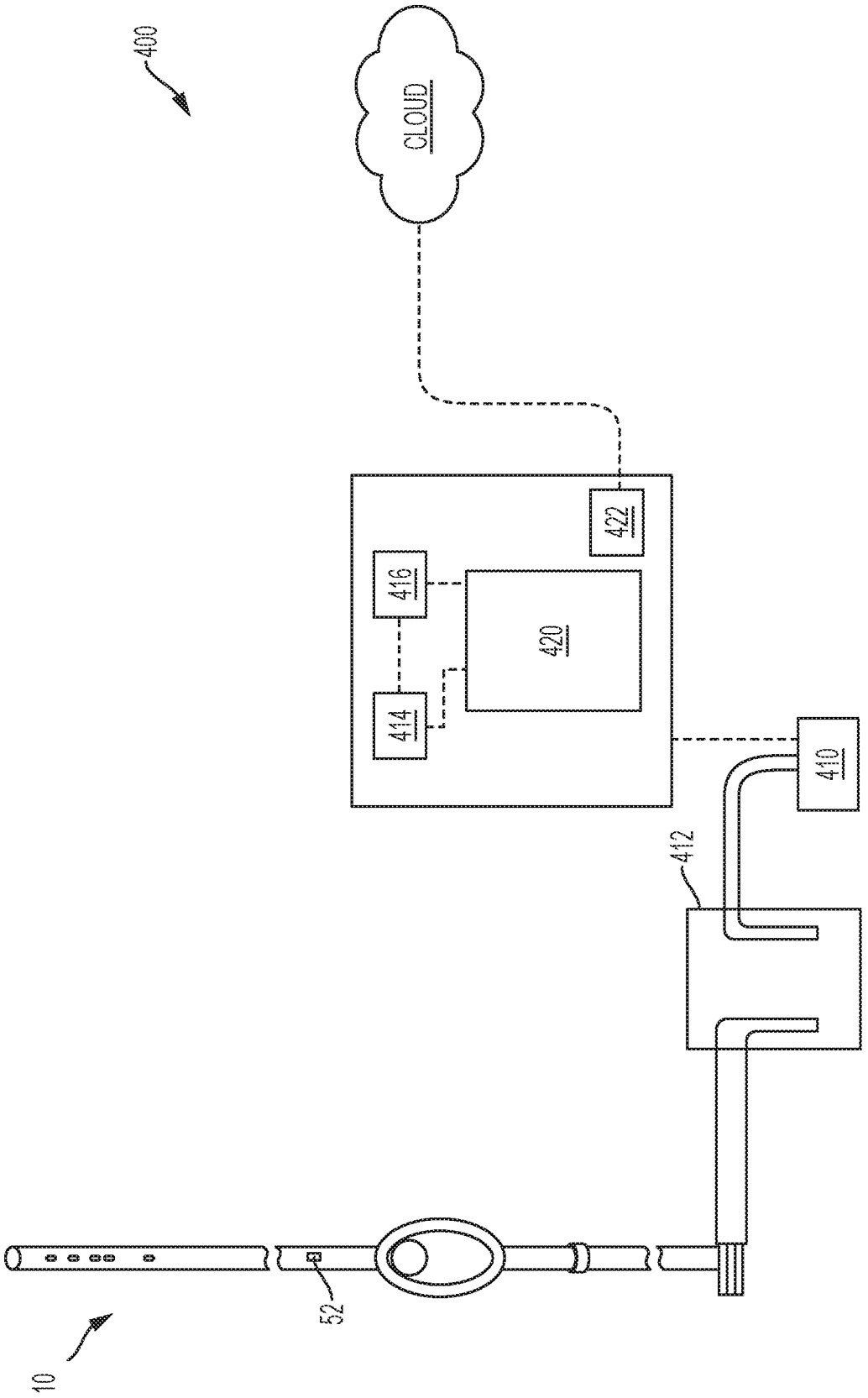

FIG. 14

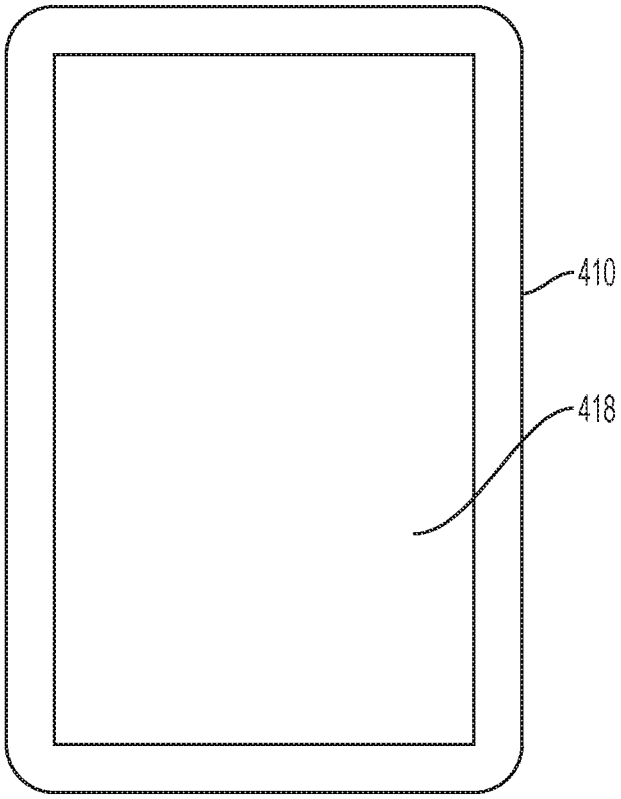

FIG. 15A

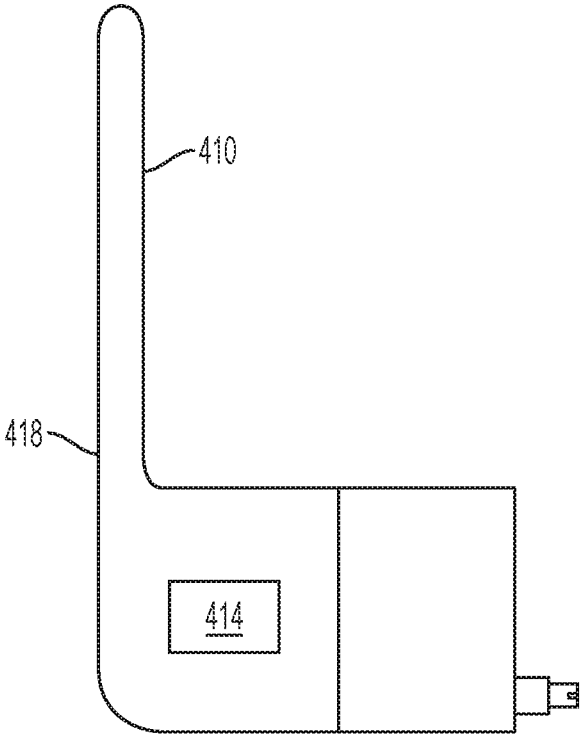

FIG. 15B

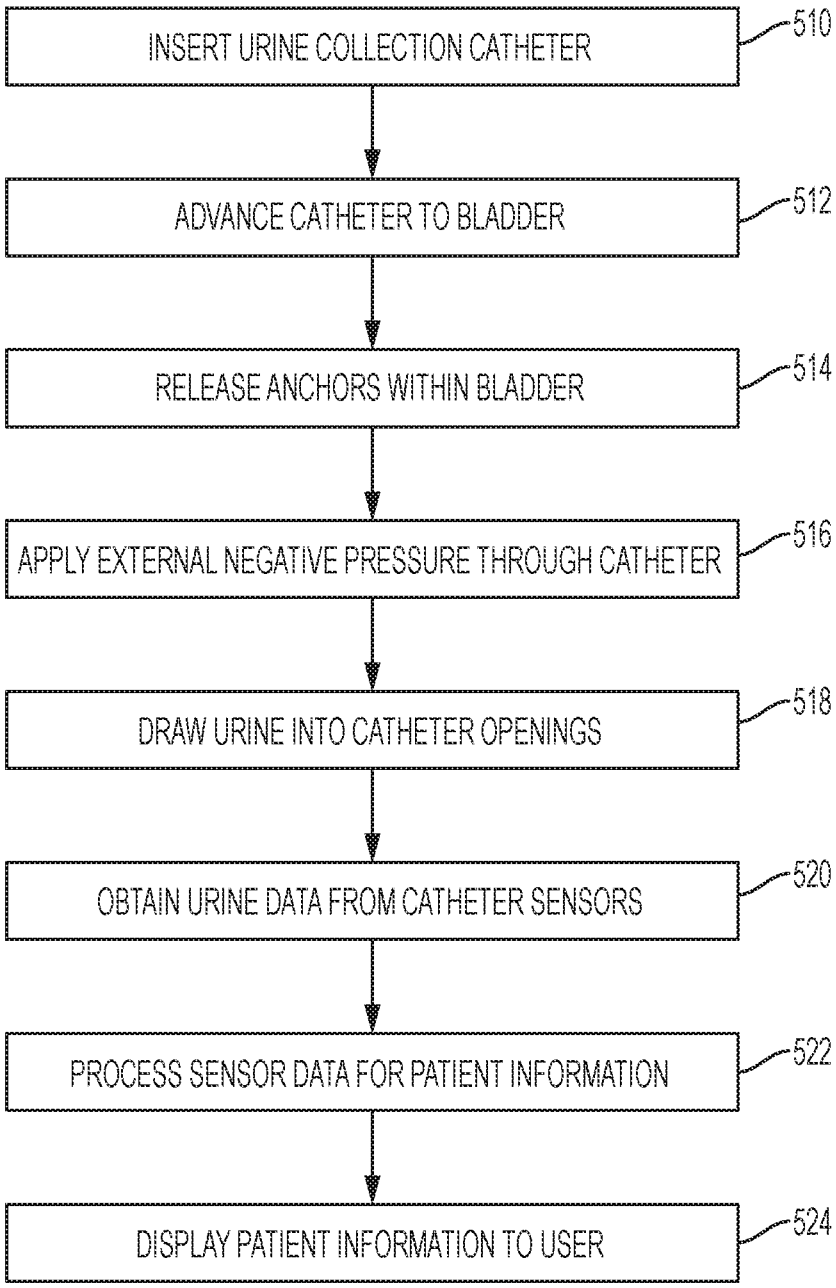
INSERT URINE COLLECTION CATHETER
510
ADVANCE CATHETER TO BLADDER
512
RELEASE ANCHORS WITHIN BLADDER
514
APPLY EXTERNAL NEGATIVE PRESSURE THROUGH CATHETER
516
DRAW URINE INTO CATHETER OPENINGS
518
OBTAIN URINE DATA FROM CATHETER SENSORS
520
PROCESS SENSOR DATA FOR PATIENT INFORMATION
522
DISPLAY PATIENT INFORMATION TO USER
524

FIG. 16

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(19) World Intellectual Property Organization
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26 January 2017 (26.01.2017)

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62/278,721	14 January 2016 (14.01.2016)	US
62/300,025	25 February 2016 (25.02.2016)	US

(71) Applicant: **STRATACA SYSTEMS, LLC** [US/US]; 145 Triple Crown Court, Milton, Georgia 30004 (US).

(72) Inventors: **ERBEY, John, R., II**; 145 Triple Crown Ct., Milton, Georgia 30004 (US). **UPPERCO, Jacob, L.**; 345 7th St NE, Apt 12, Atlanta, Georgia 30308 (US). **FISHER, Michael, Allen**; 1290 Thistle Gate Path, Lawrenceville, Georgia 30045 (US). **STRANE, Patrick, William**; 199 14th St NE, Atlanta, Georgia 30309 (US). **BLACK, Lance, Michael**; 2206 Rosemoore Walk, Marietta, Georgia 30062 (US).

(74) Agents: **CANNONI, Ann, M.** et al.; The Webb Law Firm, One Gateway Center, 420 Ft. Duquesne Blvd. Suite 1200, Pittsburgh, Pennsylvania 15222 (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, 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, 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,

[Continued on next page]

(54) Title: CATHETER DEVICE AND METHOD FOR INDUCING NEGATIVE PRESSURE IN A PATIENT'S BLADDER

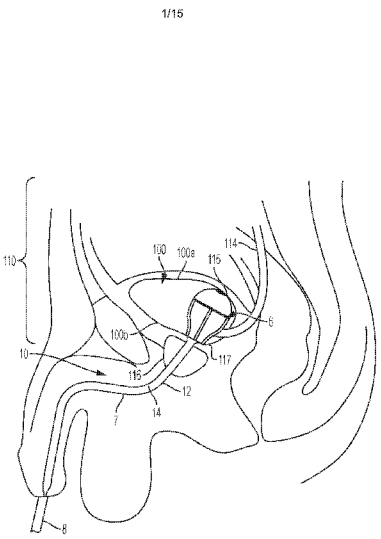

FIG. 1

(57) Abstract: A urine collection catheter is provided. The catheter includes: a conduit having an open distal end; a drainage tube positioned at least partially within the conduit; and a bladder superior wall support. The drainage tube includes one or more fluid ports or perforations for permitting fluid flow into a drainage lumen defined by the drainage tube. The bladder superior wall support includes a support cap and a plurality of support members extending from a proximal surface of the support cap through the open distal end of the conduit. The support cap is capable of being moved between a retracted position and a deployed position. In the deployed position, the distal end of the drainage tube is spaced apart from the support cap, such that the support cap supports portions of the superior wall of the bladder from occluding the one or more fluid ports or perforations of the drainage tube.

WO 2017/015345 A3

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, 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))*

(88) Date of publication of the international search report:
16 March 2017

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/43101

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 27/00 (2016.01)
CPC - A61M 27/008, 27/002
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) : A61M 27/00 (2016.01)
CPC : A61M 27/008, 27/002

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) : A61M 25/00, 25/01, 25/02, 25/04 (2016.01)
CPC: A61M 25/00, 25/0017, 25/0067, 25/0068, 25/0074, 25/01, 25/02, 25/04, 27/00

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Patbase, Google Patent, Google Scholar: bladder, urethra, urine, urological, catheter, drain, suction, suck, vacuum, negative pressure, wall, tissue, support, frame, scaffold, tine, prong, sma, shape memory, nitinol, expand, enlarge, deploy, shield, umbrella, retract, malecot, framework, superior, trigone, finger, anchor, retention, retain, dual, d

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,514,112 A (CHU et al) 7 May 1996 (07.05.1996) see especially col 1, ln 6-16, col 4, ln 59 to col 5, ln 16, col 5, ln 26-35, figs 6, 8	1 --- 2, 3/(1), 3/(2)
X --- Y	WO 2015/105916 A1 (CONSANO Inc) 16 July 2015 (16.07.2015) see especially para [0073], [0077], [0079], [0080], [0082], [0096], [0097], [0132], [0155], [0163], [0173], [0180], [0181], fig 1, 24A-B	10-12, 24-28, 53-55 --- 2, 3/(1), 3/(2), 13-14, 39-41, 56
X	US 2010/0241240 A1 (WILLARD et al) 23 September 2010 (23.09.2010) see especially para [0061], [0067], [0069], [0070], fig 3	34-37
Y	US 2006/0229553 A1 (HAMMACK et al) 12 October 2006 (12.10.2006) see especially para [0017]-[0020], [0022], [0027], [0028], [0029], fig 1A, 2, 3, 4	13-14, 39-41, 56
A	US 2007/0010798 A1 (STOLLER et al) 11 January 2007 (11.01.2007) see whole document	1-3, 10-14, 24-28, 34-37, 39-41, 53-56
A	US 2005/0177102 A1 (HART et al) 11 August 2005 (11.08.2005) see whole document	1-3, 10-14, 24-28, 34-37, 39-41, 53-56
A	US 2002/0177902 A1 (RIOUX et al) 28 November 2002 (28.11.2002) see whole document	1-3, 10-14, 24-28, 34-37, 39-41, 53-56
A	US 6,283,940 B1 (MULLHOLLAND) 4 September 2001 (04.09.2001) see whole document	1-3, 10-14, 24-28, 34-37, 39-41, 53-56

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
9 January 2017	03 FEB 2017
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/43101

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,813,935 A (HABER et al) 21 March 1989 (21.03.1989) see whole document	1-3, 10-14, 24-28, 34-37, 39-41, 53-56
A	US 4,710,169 A (CHISTOPHER) 1 Decemer 1987 (01.12.1987) see whole document	1-3, 10-14, 24-28, 34-37, 39-41, 53-56
A	US 3,108,595 A (OVERMENT) 29 October 1963 (29.10.1963) see whole document	1-3, 10-14, 24-28, 34-37, 39-41, 53-56

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/43101

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

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

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

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

3. ☒ Claims Nos.: 4-9, 15-23, 29-33, 38, 42-52, 57-58
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: claims 1-3 directed to a urine collection catheter having a support cap and a plurality of support members extending from a proximal surface of the cap.

Group II: claims 10-14, 24-28, 39-41, 53-56 directed to a urine collection catheter having a support cap connected to and extending radially from a portion of the distal end.

Group III: claims 34-37 directed to a urine collection catheter having a coiled retention portion.

--- see continuation sheet ---

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/43101

Box III - Observations where unity of invention is lacking (Continuation of item 3 of first sheet):

The groups of inventions above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special Technical Features:
The special technical feature of the Group I claims is a support cap and a plurality of support members extending from a proximal surface of the cap such that the cap is spaced from the distal end of the tube, which is not present in the claims of Group II-III.
The special technical feature of the Group II claims is a support cap connected to and extending radially from a portion of the distal end support members extending radially, which is not present in the claims of Group I, III
The special technical feature of the Group III claims is a coiled retention portion, which is not present in the claims of Group I-II.

Common Technical Features
Groups I-III share the technical feature of a urine collection catheter having a tubular body with one or more fluid ports and a support cap being capable of being moved between a retracted position and a deployed position such that it may support the bladder wall. This generic feature does not avoid the prior art, as evinced by US US 5,514,112 A to Chu et al (hereinafter Chu) which notably teaches a urinary catheter having a cap capable of being deployed such that it may support the bladder wall (col 1, ln 6-16, col 4, ln 59 to col 5, ln 16, col 5, ln 26-35, fig 6, 8, catheter 50 with end 66 supported and deployed by segments 61).

Therefore, the listed inventions lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.

Claims 4-9, 15-23, 29-33, 38, 42-52, 57-58 are improper multiple dependent claims not in compliance with PCT Rule 6.4 (a) and have not been included in any of the above groups.

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(71)申请人 斯卓特凯系统有限责任公司
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代理人 陈燕娴

(51)Int.Cl.
A61M 25/00(2006.01)

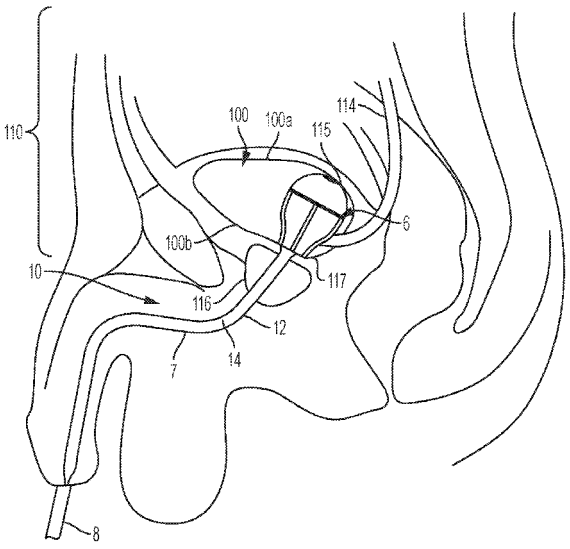
权利要求书4页 说明书18页 附图20页

(54)发明名称

在患者膀胱中引起负压的导管装置和方法

(57)摘要

提供尿液收集导管。导管包括:具有开放远端的管道;至少部分置于管道内的导液管;和膀胱上壁支承。导液管包括用于允许流体流入由导液管限定的导液腔的一个或多个流体口或穿孔。膀胱上壁支承包含支承帽和从支承帽的近端表面通过管道的开放远端延伸的多个支承构件。支承帽能够在回缩位置和展开位置之间移动。在展开位置处,导液管的远端远离支承帽,使得支承帽支撑膀胱上壁的部分免于堵塞导液管的一个或多个流体口或穿孔。



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1.一种配置成在患者膀胱中展开的尿液收集导管,所述导管包含:

包含近端和开放远端的管道;

至少部分置于管道内的导液管,所述导液管包含近端、远端和允许流体流进由导液管限定的导液腔的一个或多个流体口或穿孔;和

膀胱上壁支承,其包含支承帽和从支承帽的近端表面通过管道的开放远端延伸的多个支承构件,且能够在回缩位置和展开位置之间移动,

其中在展开位置处,导液管的远端远离支承帽,使得支承帽支撑膀胱上壁的部分免于堵塞导液管的一个或多个流体口或穿孔。

2.权利要求1的导管,其中所述支承帽配置成在将负压通过导液管传送至膀胱和/或肾时阻止膀胱上壁堵塞一个或多个口或穿孔。

3.权利要求1或权利要求2的导管,其中所述支承帽配置成在将负压通过导液腔传送至膀胱和/或肾时阻止膀胱上壁与膀胱的输尿管孔接触。

4.权利要求1-3中任一项的导管,其中所述支承构件包含柔性尖齿,且其中所述支承帽包含安装在多个尖齿上并受其支撑的柔性罩。

5.权利要求4的导管,其中所述柔性尖齿包含配置成在高于环境室温的温度下移动至展开位置的形状记忆合金。

6.权利要求5的导管,其中所述柔性罩用当置于膀胱壁或尿道的粘膜内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬的材料形成。

7.权利要求1-6中任一项的导管,其中所述膀胱上壁支承配置成当与膀胱上壁接触时保持其形状。

8.权利要求1-3中任一项的导管,其中所述支承帽包含可充气气囊。

9.权利要求8的导管,其进一步包含至少部分放置在管道内并配置成引导流体或气体进入气囊内部用于气囊充气的充气腔。

10. 一种配置成在患者膀胱中展开的尿液收集导管,所述导管包含:

至少一个小管体,其包含近端、远端、在其间延伸的侧壁和允许流体流进由小管体限定的导液腔的一个或多个流体口或穿孔;和

包含与至少一个小管体的远端的一部分连接并从中径向延伸的支承帽的膀胱上壁支承,所述支承帽包含弧形远端表面,

所述支承帽能够在回缩位置和展开位置之间移动以支撑膀胱上壁因而阻止膀胱上壁堵塞一个或多个流体口或穿孔。

11.权利要求10的导管,其中所述膀胱上壁支承配置成在将负压通过导液腔传送至膀胱和/或肾时阻止膀胱上壁堵塞一个或多个口或穿孔。

12.权利要求10的导管,其中所述膀胱上壁支承配置成在将负压通过导液腔传送至膀胱和/或肾时阻止膀胱上壁接触膀胱的输尿管孔。

13.权利要求10-13中任一项的导管,其中所述膀胱上壁支承包括从小管体径向延伸的多个支承构件,且其中所述支承帽包含安装在多个支承构件上并受其支撑的柔性罩。

14.权利要求13的导管,其中所述支承构件包含用形状记忆合金形成的柔性尖齿,所述柔性尖齿配置成在高于环境室温的温度下延伸到展开位置。

15.权利要求13或权利要求14的导管,其中所述柔性罩用当置于膀胱壁或尿道的粘膜

内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬的材料形成。

16.权利要求10-15中任一项的导管，其中所述膀胱上壁支承包含可充气气囊。

17.权利要求16的导管，其进一步包含配置成将流体或气体引入气囊内部用于气囊充气的充气腔。

18.权利要求16或权利要求17的导管，其中所述可充气气囊包括球状部分和由其近端伸展的多个气袋，且其中一个或多个口或穿孔位于相邻的气袋之间。

19.权利要求10-18中任一项的导管，进一步包含置于一个或多个口或穿孔之上的过滤器。

20.权利要求10-19中任一项的导管，进一步包含置于一个或多个口或穿孔之上的吸收海绵。

21.权利要求10-20中任一项的导管，进一步包括配置成接触膀胱下壁的膀胱下壁支承。

22.权利要求21的导管，其中所述膀胱下壁支承包含从小管体径向延伸的一个或多个支承构件和一个或多个支承构件的罩。

23.权利要求22的导管，其中所述膀胱下壁支承的罩包含当置于膀胱壁或尿道的粘膜内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬的材料。

24.一个从患者膀胱抽吸尿液的系统，所述系统包含：

包含以下的尿液收集导管：

至少一个小管体，其包括近端、远端、在其之间延伸的侧壁和允许流体流进由小管体限定的导液腔的一个或多个流体口或穿孔；和

膀胱上壁支承，其包含限定与至少一个小管体的远端的一部分连接并从中径向延伸的弧形远端表面的支承帽，

所述支承帽能够在回缩位置和展开位置之间移动以支撑膀胱上壁，以阻止膀胱上壁的部分堵塞一个或多个流体口或穿孔；和

与小管体的导液腔流体连接的泵，其中所述泵配置成将负压通过小管体引入膀胱以从膀胱抽吸尿液。

25.权利要求24的系统，进一步包含与小管体的导液腔流体连通的一个或多个传感器用于测量代表患者生理状况的信息。

26.权利要求25的系统，其中一个或多个传感器配置成测量小管体内尿液的电容、分析物浓度和温度的一项或多项。

27.权利要求25或权利要求26的系统，其中所述泵包含：

包含包括编程指令的计算机可读存储器的处理器，当执行所述编程指令时使处理器：

接收来自一个或多个传感器的信息，和

至少部分根据自一个或多个传感器接收的信息调节泵的操作参数来增加或降低小管体的负压以调节其中尿液的流量。

28.权利要求27的系统，其中所述泵进一步包含与处理器通讯的数据发送器，所述数据发送器配置成向外部源提供来自一个或多个传感器的信息。

29.权利要求24-28中任一项的系统，其中所述泵能够连续操作8-24小时。

30. 权利要求24-29中任一项的系统，其中所述泵提供10 mmHg或更小的灵敏度。

31.权利要求24-30中任一项的系统，其中所述泵配置成提供间歇性负压。

32.权利要求24-31中任一项的系统，其中所述泵配置成在提供负压和提供正压之间交替。

33.权利要求24-31中任一项的系统，其中所述泵配置成在提供负压和平衡压力至大气压之间交替。

34.一种配置成在患者膀胱内展开的尿液收集导管，所述导管包含：

包含配置成位于患者尿道的至少一部分中的近端部分和配置成位于患者膀胱中的远端部分的小管体，所述远端部分包含盘绕的固位部分，

其中所述固位部分至少包含具有第一直径的第一盘管、具有第二直径的第二盘管，该第一直径小于第二直径，和配置在固位部分侧壁的径向向内侧上的多个穿孔。

35.权利要求34的导管，其中所述第一盘管邻近第二盘管。

36.权利要求34或权利要求35的导管，其中在插入患者的泌尿道之前，邻近固位部分的小管体的一部分限定直的或曲线的中心轴，且其中所述固位部分的第一盘管和第二盘管在与导液腔的部分的直的或曲线的中心轴有至少部分同延的轴周围延伸。

37.权利要求36的导管，其中在固位部分中，小管体侧壁的径向向内侧上穿孔的总表面积大于小管体侧壁的径向向外侧上穿孔的总表面积。

38.权利要求34-38中任一项的导管，其中在固位部分中，小管体侧壁的径向向外侧没有穿孔。

39. 一种导尿管，其包含：

包含近端、远端和在其间延伸的侧壁的小管体；和

邻接小管体远端的留置部分，所述留置部分包含配置成支撑膀胱上壁的第一表面、配置成接触膀胱下壁的第二表面和在第一表面和第二表面之间延伸的侧壁的线性部分，

其中所述第一表面和第二表面各自包含柔性材料，且其中所述第一表面和第二表面被多个支承构件支撑。

40.权利要求39的导管，其中所述柔性材料当置于膀胱壁或尿道的粘膜内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬。

41.权利要求39或权利要求40的导管，其中所述留置部分将膀胱上壁与膀胱三角区隔离。

42.权利要求39-41中任一项的导管，其中所述留置部分的第一表面和第二表面在收缩位置和展开位置之间是可转换的。

43.权利要求42的导管，其中在展开位置处，所述第一表面和第二表面当与相应的膀胱的上壁和下壁接触时保持其形状。

44.权利要求42或权利要求43的导管，其中所述柔性材料在第一表面和第二表面位于收缩位置时收缩，而在第一表面和第二表面位于展开位置时伸展。

45.权利要求42-44中任一项的导管，其中所述留置部分的第二表面当在展开位置处时为膀胱的尿道口提供封闭。

46.权利要求42-45中任一项的导管，其中所述留置部分的第一表面当在展开位置处时接触膀胱上壁从而避免堵塞膀胱的一个或多个输尿管口。

47.权利要求42-46中任一项的导管，其中所述第一表面和第二表面之间的留置部分的

一段至少当第一表面和第二表面位于展开位置上时不被柔性材料覆盖。

48.权利要求42-47中任一项的导管，进一步包括配置成启动第一表面和第二表面从收缩位置到展开位置的释放机械装置。

49.权利要求39-48中任一项的导管，其中所述柔性材料覆盖多个支承构件的至少一部分。

50.权利要求39-49中任一项的导管，其中所述多个支承构件在收缩位置上倚靠管拉回，和所述多个支承构件在展开位置处从管向外伸出。

51.权利要求39-50中任一项的导管，其中所述多个支承构件用形状记忆合金形成。

52.权利要求39-51中任一项的导管，其中在第一表面和第二表面之间延伸的侧壁的线性部分包含通过侧壁延伸以允许流体流过进入管的流体接收部分的一个或多个穿孔。

53.一种将负压引入患者膀胱用于提高尿液自其中排泄的方法，所述方法包括：

将尿液收集导管的小管体的远端部分插入患者膀胱；

将与小管体远端的一部分连接并从中径向延伸的支承帽展开，使得支承帽与膀胱上壁接触；和

通过小管体的导液腔引起负压以将尿液从膀胱吸入导液腔。

54.权利要求53的方法，所述方法进一步包括放置膀胱下壁支承与患者膀胱的下壁接触。

55.权利要求54的方法，其中放置膀胱下壁支承包括在尿道口之上放置支承以封闭膀胱。

56.权利要求54或权利要求55的方法，其中所述膀胱下壁支承与支承帽分开，并由自小管体径向延伸的多个支承构件支撑。

57.权利要求53-56中任一项的方法，其中使支承帽展开包括防止远端表面结构堵塞膀胱的输尿管口。

58.权利要求53-57中任一项的方法，其中在小管体中引起负压包括使机械泵与小管体近端流体连通连接，以将尿液从膀胱吸入小管体。

在患者膀胱中引起负压的导管装置和方法

[0001] 相关申请的交叉引用

本申请要求2015年7月20日提交的美国临时申请号62/194,585、2015年11月30日提交的美国临时申请号62/260,966、2016年1月14日提交的美国临时申请号62/278,721和2016年2月25日提交的美国临时申请号62/300,025的优先权，其每一个通过引用以其整体结合到本文中。

[0002] 背景。

技术领域

[0003] 本公开内容涉及用于治疗波及多种疾病状态的肾功能受损的装置和方法，具体地说，涉及用于尿液收集和在膀胱中引起负压的装置和方法。

[0004] 背景

肾或泌尿系统包括一对肾(每个肾通过输尿管与膀胱连接)和用于将由肾产生的尿液从膀胱排出的尿道。肾执行人体的若干生命机能，包括例如过滤血液以排出呈尿液形式的废物。肾还调节电解质(例如钠、钾和钙)和代谢物、血量、血压、血pH、流体量、红细胞的产生和骨代谢。充分理解肾的解剖学和生理学对理解改变的血液动力学和其它流体过载条件对其功能产生的影响是有用的。

[0005] 在正常的解剖学中，两只肾在腹膜后位于腹腔中。肾是豆形包膜组织。尿液通过肾单位(肾的功能单位)形成，然后流经会聚小管(称为集尿管)系统。集尿管连接在一起形成肾小盏，然后形成肾大盏，其最终在肾的凹部(肾盂)附近连接。肾盂的主要功能是引导尿液流向输尿管。尿液从肾盂流入输尿管，一种将尿液从肾运送至膀胱的管状结构。肾的外层被称为皮质，是一种坚硬的纤维包裹。肾的内部被称为髓质。髓质结构呈锥体排列。

[0006] 每个肾由大约100万个肾单位组成。每个肾单位包括小球、肾小囊和小管。小管包括近曲小管、亨利袢、远曲小管和集合管。包含在皮质层中的肾单位不同于包含在髓质中的肾单位的解剖学。主要差异是亨利袢的长度。髓质肾单位含有较长的亨利袢，这在正常情况下允许比在皮质肾单位中更大地调节水和钠重吸收。

[0007] 小球是肾单位的起点，负责血液的初始滤过。入球微动脉使血液经过肾小球毛细血管，其中流体静力压将水和溶质推入肾小囊中。净滤过压表示为入球微动脉中的流体静力压减肾小囊腔中的流体静力压减出球微动脉中的渗透压。

[0008] *净滤过压= 流体静力压(入球微动脉) - 流体静力压(肾小囊腔) - 渗透压(出球微动脉)* (方程式1)

由方程式1确定的该净滤过压的量值决定了肾小囊腔中形成多少超滤液并递送至小管。剩余的血液通过出球微动脉离开小球。正常的肾小球滤过或向小管的超滤液递送约为90 ml/min/1.73m^2。

[0009] 小球具有三层滤过结构，其包括血管内皮、肾小球基膜和足细胞。通常，大的蛋白质例如白蛋白和红细胞不会渗入肾小囊腔。然而，肾小球压升高和系膜膨胀引起基膜上的表面积改变和足细胞间的较大穿孔使得较大蛋白质通过进入肾小囊腔。

[0010] 在肾小囊腔中收集的超滤液最先递送至近曲小管。小管中水和溶质的重吸收和排泄通过主动转运通道和被动压力梯度的混合进行。近曲小管通常重吸收大部分的氯化钠和水，以及通过小球滤过的几乎全部的葡萄糖和氨基酸。亨利袢具有被设计成浓缩尿液中的废物的两个组件。降支是高透水性的，并重吸收大多数剩余的水。升支重吸收25%的剩余氯化钠，产生浓缩尿液，例如就脲和肌酸酐而言。远曲小管通常重吸收少部分的氯化钠，且渗透梯度产生水跟进的条件。

[0011] 在正常情况下，有大约14 mmHg的净滤过。静脉充血的影响可为净滤过的显著下降，下至大约4 mmHg。参见Jessup M., *The cardiorenal syndrome: Do we need a change of strategy or a change of tactics?*, JACC 53(7):597-600, 2009 (下文亦为"Jessup")。第二滤过阶段发生在近端小管处。从尿液排泄和吸收的大部分发生在髓质肾单位的小管中。钠从小管主动转运至胞间隙启动了这个过程。然而，流体静力支配溶质和水的净交换。在正常情况下，认为75%的钠被重吸收回到淋巴或静脉循环。然而，因为肾被包裹着，所以对来自静脉和淋巴充血两者的流体静力压的变化敏感。在静脉充血期间，钠和水的潴留可超过85%，使肾充血进一步继续。参见Verbrugge et al., *The kidney in congestive heart failure: Are natriuresis, sodium, and diruetucs really the good, the bad and the ugly?*European Journal of Heart Failure 2014:16,133-42 (下文亦为"Verbrugge")。

[0012] 静脉充血可导致急性肾损伤(AKI)的肾前形式。肾前AKI由经过肾的灌注丧失(或血流丧失)所致。许多临床医生集中研究因休克所致注入肾的不足。然而，还存在因静脉充血引起血液流出该器官的缺乏可能是临床上重大持续性损伤的证据。参见Damman K, *Importance of venous congestion for worsening renal function in advanced decompensated heart failure*, JACC 17:589-96, 2009 (下文亦为"Damman")。

[0013] 肾前AKI出现在需要危重症入院的多种诊断中。最主要的入院是由于脓毒症和急性失代偿性心力衰竭(ADHF)。其它入院包括心血管手术、普通手术、肝硬化、创伤、烧伤和胰腺炎。虽然在这些疾病状态的呈现中有宽泛的临床变化性，但共同点是中心静脉压升高。在ADHF的情况下，由心力衰竭引起的中心静脉压升高导致肺水肿，随后呼吸困难进而促成入院。在脓毒症的情况下，中心静脉压升高大多是激进液体复苏的结果。不论最初的损伤是因血容量减少所致的低灌注还是钠和流体潴留，持续损伤是引起不当灌注的静脉充血。

[0014] 高血压是另一种在肾的主动和被动转运系统中造成扰动的广泛公认的状态。高血压直接影响入球微动脉压，并导致小球内净滤过压成比例的增加。滤过分数的提高还升高小管周毛细血管血压，这刺激钠和水重吸收。参见Verbrugge。

[0015] 因为肾是包膜器官，所以对髓质锥体中的压力变化敏感。肾静脉压升高造成充血，导致间质压力升高。间质压力升高把力施加于小球和小管两者。参见Verburgge。在小球中，间质压力升高直接对抗滤过。压力升高增加间质液，因而增加间质液中的流体静力压和肾髓质中的小管周毛细血管。在两种情况下，缺氧接着可引起细胞损伤和灌注的进一步丧失。最终结果是产生负反馈的钠和水重吸收进一步加重。参见Verbrugge，133-42。流体过载，特别在腹腔中的流体过载与许多疾病和病况有关，包括腹内压升高、腹腔室隔综合征和急性肾衰竭。流体过载可通过肾替代疗法克服。参见Peters, C.D., *Short and Long-Term Effects of the Angiotensin II Receptor Blocker Irbesartanon Intradialytic*

Central Hemodynamics: A Randomized Double-Blind Placebo-Controlled One-Year Intervention Trial (the SAFIR Study), PLoS ONE (2015) 10(6): e0126882. doi: 10.1371/journal.pone.0126882 (下文亦为"Peters")。然而,这种临床策略不为患有心肾综合征的患者提供肾功能改善。参见Bart B, *Ultrafiltration in decompensated heart failure with cardiorenal syndrome*, NEJM 2012;367:2296-2304 (下文亦为"Bart")。

[0016] 鉴于流体潴留的这种成问题的作用,需要用于改善将尿液从泌尿道排出,具体地说用于提高自肾的尿液输出的数量和质量的装置和方法。

[0017] 发明概述

本公开内容通过提供用于在膀胱内展开的专用(非Foley)导管对之前的系统加以改进。本公开内容的导管包含待置于膀胱内、具有与膀胱壁的上部和/或下部被动固定的限动器或锚钩的留置部分。膀胱内的近端限动器(restraint)或锚钩(anchor)可设计成封闭尿道免遭气体和流体渗漏。膀胱内的远端锚钩可设计成在膀胱壁萎陷时限制膀胱上壁,允许无阻碍传送负压、收集所产生的尿液和避免粘膜创伤。此外,包含导管的尿液收集系统包括用于监测尿流和使用尿流和指导由系统传送的负压以使钠和水排泄优化的传导性评价的传感装置。

[0018] 现将在下列编号项目中描述本发明的非限制性实例、方面或实施方案:

第1项:配置成在患者膀胱中展开的尿液收集导管,该导管包括:包含近端和开放远端的管道;至少部分置于管道内的导液管(drainage tube),该导液管包含近端、远端和允许流体流进由导液管限定的导液腔的一个或多个流体口(fluid port)或穿孔;和膀胱上壁支承(support),其包含支承帽(support cap)和从支承帽的近端表面通过管道的开放远端延伸且能够在回缩位置和展开位置之间移动的多个支承构件(support member),其中,在展开位置上,导液管的远端远离支承帽,使得支承帽支持膀胱上壁的部分免于堵塞导液管的一个或多个流体口或穿孔。

[0019] 第2项:第1项的导管,其中支承帽配置成在将负压通过导液管传送至膀胱和/或肾时阻止膀胱上壁堵塞一个或多个口或穿孔。

[0020] 第3项:第1项或第2项的导管,其中支承帽配置成在将负压通过导液腔传送至膀胱和/或肾时阻止膀胱上壁与膀胱的输尿管孔接触。

[0021] 第4项:第1-3项中任一项的导管,其中支承构件包含柔性尖齿,且其中支承帽包含安装在多个尖齿上并受尖齿支撑的柔性罩。

[0022] 第5项:第4项的导管,其中柔性尖齿包含配置成在高于环境室温的温度下移动至展开位置的形状记忆合金。

[0023] 第6项:第5项的导管,其中柔性罩用当置于膀胱壁或尿道的粘膜内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬的材料形成。

[0024] 第7项:第1-6项中任一项的导管,其中膀胱上壁支承配置成当与膀胱上壁接触时保持其形状。

[0025] 第8项:第1-3项中任一项的导管,其中支承帽包含可充气气囊。

[0026] 第9项:第8项的导管,进一步包含至少部分放置在管道内并配置成引导流体或气体进入气囊内部用于气囊充气的充气腔。

[0027] 第10项:配置成在患者膀胱中展开的尿液收集导管,该导管包含:至少一个小管

体，其包含近端、远端、在其间延伸的侧壁和允许流体流进由小管体限定的导液腔的一个或多个流体口或穿孔；和膀胱上壁支承，其包含与至少一个小管体的远端的一部分连接并从中径向延伸出来的支承帽，支承帽包含弧形远端表面，支承帽能够在回缩位置和展开位置之间移动以支撑膀胱上壁因而阻止膀胱上壁堵塞一个或多个流体口或穿孔。

[0028] 第11项：第10项的导管，其中膀胱上壁支承配置成在将负压通过导液腔传送至膀胱和/或肾时阻止膀胱上壁堵塞一个或多个口或穿孔。

[0029] 第12项：第10项的导管，其中膀胱上壁支承配置成阻止膀胱上壁在将负压通过导液腔传送至膀胱和/或肾时接触膀胱的输尿管孔。

[0030] 第13项：第10-13项中任一项的导管，其中膀胱上壁支承包括从小管体径向延伸的多个支承构件，且其中支承帽包含安装在多个支承构件上并受其支撑的柔性罩。

[0031] 第14项：第13项的导管，其中支承构件包含用形状记忆合金形成的柔性尖齿，柔性尖齿配置成在高于环境室温的温度下延伸到展开位置。

[0032] 第15项：第13项或第14项的导管，其中柔性罩用当置于膀胱壁或尿道的粘膜内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬的材料形成。

[0033] 第16项：第10-15项中任一项的导管，其中膀胱上壁支承包含可充气气囊。

[0034] 第17项：第16项的导管，进一步包含配置成将流体或气体引入气囊内部用于气囊充气的充气腔。

[0035] 第18项：第16项或第17项的导管，其中可充气气囊包括球状部分和由其近端伸展的多个气袋，且其中一个或多个口或穿孔位于相邻的气袋之间。

[0036] 第19项：第10-18项中任一项的导管，进一步包含置于一个或多个口或穿孔之上的过滤器。

[0037] 第20项：第10-19项中任一项的导管，进一步包含置于一个或多个口或穿孔之上的吸收海绵。

[0038] 第21项：第10-20项中任一项的导管，进一步包括配置成接触膀胱下壁的膀胱下壁支承。

[0039] 第22项：第21项的导管，其中膀胱下壁支承包含从小管体径向延伸的一个或多个支承构件和一个或多个支承构件的罩。

[0040] 第23项：第22项的导管，其中膀胱下壁支承的罩包含当置于膀胱壁或尿道的粘膜内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬的材料。

[0041] 第24项：一个从患者膀胱抽吸尿液的系统，该系统包含：包括的以下尿液收集导管：至少一个小管体，其包含近端、远端、在其间延伸的侧壁和允许流体流进由小管体限定的导液腔的一个或多个流体口或穿孔；和膀胱上壁支承，其包含限定与至少一个小管体的远端的一部分连接并从中径向延伸的弧形远端表面的支承帽，支承帽能够在回缩位置和展开位置之间移动以支撑膀胱上壁阻止膀胱上壁的部分堵塞一个或多个流体口或穿孔；和与小管体的导液腔流体连接的泵，其中泵配置成将负压通过小管体引入膀胱以从膀胱抽吸尿液。

[0042] 第25项：第24项的系统，进一步包含与小管体的导液腔流体连通的一个或多个传感器用于测量患者生理状况的代表性信息。

[0043] 第26项：第25项的系统，其中一个或多个传感器配置成测量小管体内尿液的电容、

分析物浓度和温度的一个或多个。

[0044] 第27项:第25项或第26项的系统,其中泵包含:包含包括编程指令的计算机可读存储器的处理器,当执行编程指令时使处理器:接收来自一个或多个传感器的信息,至少部分根据自一个或多个传感器接收的信息调节泵的操作参数来增加或降低小管体的负压以调节其中尿液的流量。

[0045] 第28项:第27项的系统,其中泵进一步包含与处理器通讯的数据发送器,数据发送器配置成向外部源提供来自一个或多个传感器的信息。

[0046] 第29项:第24-28项中任一项的系统,其中泵能够在8和24小时之间连续操作。

[0047] 第30项:第24-29项中任一项的系统,其中泵提供10 mmHg或更小的灵敏度。

[0048] 第31项:第24-30项中任一项的系统,其中泵配置成提供间歇性负压。

[0049] 第32项:第24-31项中任一项的系统,其中泵配置成在提供负压和提供正压之间交替。

[0050] 第33项:第24-31项中任一项的系统,其中泵配置成在提供负压和平衡压力至大气压之间交替。

[0051] 第34项:配置成在患者膀胱内展开的尿液收集导管,该导管包含:包含配置成位于患者尿道的至少一部分的近端部分和配置成位于患者膀胱中的远端部分的小管体,所述远端部分包含盘绕的固位部分(retention portion),其中固位部分至少包含具有第一直径的第一盘管,具有第二直径的第二盘管,该第一直径小于第二直径,且配置在固位部分侧壁的径向向内侧上的多个穿孔。

[0052] 第35项:第34项的导管,其中第一盘管是第二盘管的近端。

[0053] 第36项:第34项或第35项的导管,其中在插入患者的泌尿道之前,是固位部分的近端的小管体的一部分限定直的或曲线的中心轴,且其中固位部分的第一盘管和第二盘管在与导液腔的部分的直的或曲线的中心轴有至少部分同延的轴周围延伸。

[0054] 第37项:第36项的导管,其中在固位部分中,小管体侧壁的径向向内侧上穿孔的总表面积大于小管体侧壁的径向向外侧上穿孔的总表面积。

[0055] 第38项:第34-38项中任一项的导管,其中在固位部分中,小管体侧壁的径向向外侧没有穿孔。

[0056] 第39项:尿液导管包含:包含近端、远端和在其间延伸的侧壁的小管体;和邻接小管体远端的留置部分,该留置部分包含配置成支撑膀胱上壁的第一表面、配置成接触膀胱下壁的第二表面和在第一表面和第二表面之间延伸的侧壁的线性部分,其中第一表面和第二表面各自包含柔性材料,且其中第一表面和第二表面被多个支承构件支撑。

[0057] 第40项:第39项的导管,其中柔性材料当置于膀胱壁或尿道的粘膜内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬。

[0058] 第41项:第39项或第40项的导管,其中留置部分将膀胱上壁与膀胱三角区隔离。

[0059] 第42项:第39-41项中任一项的导管,其中留置部分的第一表面和第二表面在收缩位置和展开位置之间是可转换的。

[0060] 第43项:第42项的导管,其中在展开位置处,第一表面和第二表面当与相应的膀胱的上壁和下壁接触时保持其形状。

[0061] 第44项:第42项或第43项的导管,其中柔性材料在第一表面和第二表面位于收缩

位置时收缩，而在第一表面和第二表面位于展开位置时伸展。

[0062] 第45项：第42-44项中任一项的导管，其中留置部分的第二表面当在展开位置上时为膀胱的尿道口提供封闭。

[0063] 第46项：第42-45项中任一项的导管，其中留置部分的第一表面当在展开位置上时接触膀胱上壁从而避免堵塞膀胱的一个或多个输尿管口。

[0064] 第47项：第42-46项中任一项的导管，其中第一表面和第二表面之间的留置部分的一段至少当第一表面和第二表面位于展开位置上时不被柔性材料覆盖。

[0065] 第48项：第42-47项中任一项的导管，进一步包括配置成启动第一表面和第二表面从收缩位置到展开位置的释放机械装置。

[0066] 第49项：第39-48项中任一项的导管，其中柔性材料覆盖多个支承构件的至少一部分。

[0067] 第50项：第39-49项中任一项的导管，其中多个支承构件在收缩位置上倚靠管拉回，多个支承构件在展开位置上从管中向外伸出。

[0068] 第51项：第39-50项中任一项的导管，其中多个支承构件用形状记忆合金形成。

[0069] 第52项：第39-51项中任一项的导管，其中在第一表面和第二表面之间延伸的侧壁的线性部分包含通过侧壁延伸以允许流体流过进入管的流体接收部分的一个或多个穿孔。

[0070] 第53项：一种将负压引入患者膀胱用于提高尿液自其中排泄的方法，所述方法包括：将尿液收集导管的小管体的远端部分插入患者膀胱；将与小管体远端的一部分连接并从中径向延伸的支承帽展开，使得支承帽与膀胱上壁接触；通过小管体的导液腔引起负压以将尿液从膀胱吸入导液腔。

[0071] 第54项：第53项的方法，所述方法进一步包括放置膀胱下壁支承与患者膀胱的下壁接触。

[0072] 第55项：第54项的方法，其中放置膀胱下壁支承包括在尿道口之上放置支承以封闭膀胱。

[0073] 第56项：第54项或第55项的方法，其中膀胱下壁支承与支承帽分开，并由自小管体径向延伸的多个支承构件支撑。

[0074] 第57项：第53-56项中任一项的方法，其中使支承帽展开包括防止远端表面结构堵塞膀胱的输尿管口。

[0075] 第58项：第53-57项中任一项的方法，其中在小管体中引起负压包括使机械泵与小管体近端流体连通连接，以将尿液从膀胱吸入小管体。

[0076] 附图简述

本公开内容的这些和其它特征和性质，以及操作方法和结构的相关元件的功能和部件的组合和制造的经济性，在参照附图考虑以下描述和随附权利要求书时将变得更明显，其全部构成本说明书的一部分，其中相同的参考号表示不同图中的相应部件。然而，要明确了解附图仅用于说明和描述目的，无意作为界定本发明的限制。

[0077] 更多的特征和其它实例和优势从以下参考附图所做详细描述来看将变得显而易见，其中：

图1是按照本公开内容的一个实例在男性患者膀胱内展开的尿液收集导管装置的示意图；

图2是按照本公开内容的一个实例在患者膀胱内展开的另一个示例性尿液收集导管装置的示意图；

图3A是图1的尿液收集导管装置的留置固位部分的透视图；

图3B是沿图3A的尿液收集导管装置留置固位部分的线路B-B截取的剖视图；

图3C是沿图3A的留置固位部分的线路C-C截取的剖视图；

图4是按照本公开内容的另一个实例尿液收集导管的留置固位部分的透视图；

图5是按照本公开内容的另一个实例尿液收集导管的留置固位部分的透视图；

图6是按照本公开内容的另一个实例尿液收集导管的留置固位部分的透视图；

图7A是处于收缩状态的图2的导管装置的留置固位部分的示意图；

图7B是处于展开状态的图2的导管装置的留置部分的示意图；

图8A是按照本公开内容的实施方案处于收缩状态的另一示例性尿液收集导管装置的留置固位部分的示意图；

图8B是处于展开状态的图8A的导管装置的留置固位部分的示意图；

图9A是按照本公开内容的一个实例另一示例性尿液收集导管装置的留置固位部分的透视图；

图9B是图9A的导管装置留置固位部分的一部分的部分剖视图；

图10A是按照本公开内容的一个实例另一示例性尿液收集导管装置的留置固位部分的透视图；

图10B是图10A的尿液收集导管的部分的部分剖视图；

图11A是按照本公开内容的一个实例另一示例性尿液收集导管的留置部分的透视图；

图11B是图11A的尿液收集导管的剖视图；

图12是按照本公开内容的一个实例另一示例性尿液收集装置的留置固位部分的正视图；

图13是按照本公开内容的一个实例包括留置部分和外面部分两者的尿液收集装置的示意图；

图14是按照本公开内容的一个实例用于将负压引入患者膀胱的系统，其包括配置成在患者膀胱中展开的尿液收集导管装置；

图15A和15B是与图14的系统一起使用的泵的示意图；和

图16是按照本公开内容的一个实例将负压引入患者膀胱的过程的流程图。

[0078] 发明详述

如本文所用，“a”、“an”和“the”的单数形式包括复数指代物，除非文中另有明确规定。

[0079] 本文所用术语“右”、“左”、“上”及其派生词因在绘图中的取向可将本发明联系起来。术语“近端”是指由使用者操作或接触的导管装置的部分。术语“远端”是指配置成插入患者中的导管装置的相对端。然而，要了解本发明可采取不同的替代取向，因此，这类术语不得视为限制性的。此外，要了解本发明可采取不同的替代变化和阶段顺序，其中明确说明情况相反的除外。还要了解附图说明的以及以下说明书描述的具体装置和过程是实例。因此，与本文公开的实施方案有关的具体尺寸和其它物理性质不被视为限制性的。

[0080] 除非说明与之相反，否则以下说明书和随附权利要求书列出的数字参数是近似值，可随所寻求的通过本公开内容获得的所需性质而变化。

[0081] 尽管列出本发明广大范围的数字范围和参数是近似值，但尽可能精确地报告在具体实例中列出的数值。然而，任何数值内在含有必然产生于其各自的测试测量法中存在的标准差的某种误差。

[0082] 此外，应了解，本文引用的任何数值范围欲包括其中所归入的所有子范围。例如，“1-10”的范围欲包括所列举的最小值1和所列举的最大值10之间的任何和全部子范围并包括所列举的最小值1和所列举的最大值10，即，始于等于或大于1的最小值和止于等于或小于10的最大值的全部子范围及中间的全部子范围，例如1-6.3，或5.5-10，或2.7-6.1。

[0083] 本文所用术语“通讯”和“与……通讯”是指一个或多个信号、信息、指令或其它数据类型的接收或传送。对于与另一个单元或组件通讯的一个单元或组件意指一个单元或组件能够直接或间接接收来自另一个单元或组件的数据和/或将数据传送至另一个单元或组件。这可指在性质上可以是有线和/或无线的直接或间接连接。或者，两个单元或组件可彼此通讯，但是所传送的数据可在第一和第二单元或组件之间修改、处理或发送等。例如，即使第一单元被动接收数据且不主动将数据传送至第二单元，第一单元也可与第二单元通讯。作为另一个实例，如果中间单元处理来自一个单元的数据并将处理的数据传送至第二单元，则第一单元可与第二单元通讯。应认识到，多种其它的安排是可行的。

[0084] 流体潴留和静脉充血是晚期肾病进展中的首要问题。过量的钠摄入外加排泄的相对降低导致等渗体积膨胀和二级区室连累。在一些实例中，本发明一般涉及用于促进从患者的膀胱、输尿管和/或肾中排出尿液或废物的装置和方法。在一些实例中，本发明一般涉及用于将负压引入患者膀胱的装置和方法。虽然无意受任何理论的束缚，但是认为将负压施加于膀胱在某些情况下可抵销钠和水的髓质肾单位小管重吸收。抵销钠和水的重吸收可增加尿液产生，降低体内总钠，并提高红细胞产生。由于髓内压力受钠驱动，因此，容量过载、过量钠的定向去除使得能够维持容量丢失。容量的去除恢复髓质稳态(hemostasis)。正常的尿液产生为1.48-1.96 L/天(或1-1.4 ml/min)。

[0085] 流体潴留和静脉充血还是肾前AKI进展中的首要问题。具体地讲，AKI可能与通过肾的灌注或血流量的损失有关。因此，在一些实例中，本发明促进肾血液动力学改进并增加尿液输出用于缓解或减轻静脉充血的目的。此外，预期AKI的治疗和/或抑制积极影响和/或减少其它病况的发生，例如，减轻或抑制患有NYHA III类和/或IV类心力衰竭的患者中的肾功能恶化。不同心力衰竭水平的分类描述于*The Criteria Committee of the New York Heart Association*, (1994), Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels, (9th ed.), Boston: Little, Brown & Co. pp. 253-256，其公开内容通过引用以其整体结合到本文。减轻或抑制AKI的发作和/或长期灌注减少还可以是4期或5期慢性肾病的治疗法。慢性肾病进展描述于National Kidney Foundation, K/DOQI *Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification*. Am. J. Kidney Dis. 39:S1-S266, 2002 (Suppl. 1)，其公开内容通过引用以其整体结合到本文。

[0086] 参照图1和2，泌尿道或泌尿系统110包含患者的右肾和左肾112 (图2中所示)。肾112负责血液滤过和来自体内的废弃化合物经尿液清除。由肾112产生的尿液通过称为输尿管114的小管流入患者膀胱100。例如，尿液可通过输尿管壁的蠕动以及通过重力经由输尿管114引导。输尿管114经由输尿管孔或口115进入膀胱100。膀胱100是柔软的且基本上是空

心结构，适于收集尿液直到尿液从体内排泄。膀胱100从清空位置(图2中所示)到充满位置(图2参考线F所示)是可转换的。通常，当膀胱100达到基本满的状态时，允许尿液从膀胱100经由位于膀胱100的较低部分的尿道括约肌或口117流向尿道116。膀胱100的收缩可以是对膀胱100的三角区113 (其是在输尿管口115和尿道口117之间延伸的三角区)施加的应力和压力有反应的。三角区113对应力和压力是敏感的，使得在膀胱100开始充满时，对三角区113的压力增加。当超过三角区的阈值压力时，括约肌或口117松驰，并允许膀胱100收缩，将所收集的尿液通过尿道116排出。输尿管孔或口115由基本上形成单向片状瓣膜的软组织覆盖。当膀胱100收集尿液时，软组织能够容纳来自蠕动的压力，使得尿液可从输尿管114通过进入膀胱100。当膀胱100收缩以从中排出尿液时，软组织倚靠输尿管口115而受限制，防止尿液从膀胱100回流到输尿管114中。使限动器定位以允许输尿管口115在治疗期间保持开放，使得负压可将尿液吸进膀胱100和置于膀胱中的导管装置。

[0087] 实例导管装置：

继续参照图1和2，说明了用于将负压引入患者的膀胱100的示例性一次性导管装置10。如本文所述，膀胱100能够在图2中短划线F标示的充满位置和清空位置之间收缩。适宜的是，用导管装置10防止膀胱100完全萎陷。示例性导管装置10可以是可在导入的负压下封闭膀胱100和上泌尿系统110的导尿管(非Foley)。装置10通常包含长形管道或小管体，在此称为管12，具有一般范围约8-16 Fr的外径或圆周，其内部限定一个或多个排水槽或腔14或多个腔。管12可用任何合适的柔性材料形成，包括例如生物相容性聚合物、聚氯乙烯、聚四氟乙烯(PTFE)例如Teflon®、涂硅胶乳或硅。导管装置10，尤其管12的至少一部分或全部可涂上亲水涂料以便于插入和/或取出和/或提高舒适性。在一些实例中，涂料是疏水和/或润滑涂料。例如，合适的涂料可包括ComfortCoat®亲水涂料(可获自Koninklijke DSM N.V.)或例如公开于美国专利号8,512,795 (通过引用结合到本文)的包含聚电解质的亲水涂料。

[0088] 在一些实例中，管12包括配置成置于膀胱100中的留置部分6和配置成通过尿道116延伸的第二或中部留置部分7。一般来说，管12的第二部分7的直径与上述管12的留置部分6相同，然而可增加该直径以利于流动。或者，管12的第二部分7的全部或部分可以是与管12的固位或留置部分6连接的单独的管。管12的第二部分7不包括例如描述于管12的留置部分6的穿孔，以防止从管12的侧面渗漏。管12还包括外面部分8 (图1中所示)，其从留置部分6、7延伸至外部流体收集容器或装置，例如泵410 (图14中所示)。

[0089] 可获得不同长度的导管装置10，尤其管12以适应性别和/或患者尺寸的解剖差异。例如，平均女性尿道长度只有几英寸，因此管12的长度可以相当短。男性的平均尿道长度因阴茎而较长，并且可以是可变的。有可能女性可使用具有较长的管12的导管装置10，条件是超过的管不增加操作或放置装置10的难度。在一些实例中，导管10的无菌部分的范围对于女性可为约1英寸-3英寸，对于男性可为约1英寸-约20英寸。包括无菌和非无菌部分的管12的总长度为约几英尺。

[0090] 在一些实例中，管12的外面部分8包含展开机械装置44和用于连接泵410 (图14中所示)的口54 (图13中所示)。管12和泵410或另一个流体收集容器间的连接可以是标准连接机械装置，例如路厄锁(luer lock)或扣合连接。在其它实例中，可使用专用或定制连接器或连接装置将导管装置10的近端或口54与流体收集系统的其它元件连接。在一些实例中，可将定制连接器制备成形以防止使用者将导管装置10与不合适的压力源连接。例如，可

确定定制连接器的大小以防止使用者将导管装置10与吸壁来源或真空压力升高的其它来源连接。

[0091] *示例性一阶段固定固位部分*

图3A-3C显示导管装置10的示例性留置部分6。导管装置10的示例性留置部分6包含篮状结构，称为膀胱上壁支承210 (图3A和3B中所示)，配置成在回缩位置置于管12的远端部分内并在展开位置从管12的远端伸展。膀胱上壁支承210包含配置成支撑膀胱100的上壁100a (图1和2中所示)的支承帽212和多个支承构件，例如与支承帽212的近端表面连接的支柱214。支柱214可如此放置使得帽212远离管12的开放远端。例如，可配置支柱214以保持管12的开放远端30和支承帽212之间的距离D1的间隙、空腔或空隙。距离D1可为约1.0 cm-约2.0 cm。膀胱上壁支承210的高度D2可为约1.5 cm-约3.0 cm。支承帽212在展开状态可为约12-32 Fr，优选介于约8 mm和10 mm之间。

[0092] 在一些实例中，支柱214包含柔性尖齿，其可用形状记忆材料例如镍钛形成。支承帽212可以是安装在支柱214上并能受其支撑的柔性罩216。柔性罩216可用软的弹性材料例如硅酮或Teflon®形成，用于防止气体和/或流体流过罩216。在一些实例中，柔性材料用当置于粘膜内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬的材料(例如硅酮或Teflon®材料)形成。罩216的厚度的范围可为约0.05 mm-约0.5 mm。在一些实例中，柔性罩216和支柱214在结构上是充分刚性的，以致于罩216和支柱214当被膀胱100的上壁100a接触时保持其形状(图1和2中所示)。因此，支柱214和柔性罩216防止膀胱萎陷和堵塞管12的固位部分6和/或开放远端30的穿孔。此外，支柱214和柔性罩216有效地保持三角区和输尿管孔张开，使得负压可将尿液吸入由管12限定或围绕的膀胱和腔内。如本文所述，即使允许膀胱收缩，组织瓣膜可在输尿管口之上延展，因而防止负压将尿液吸入膀胱。

[0093] 在一些实例中，确定支承帽212的大小以定位于膀胱内并接触膀胱上壁而不堵塞输尿管口。例如，可适当确定膀胱上壁支承210的大小以跨越三角区使得三角区和膀胱的其它部分受限制免于收缩。通过跨越和避免与三角区接触，可将支承帽212远离输尿管口放置以防止口被阻塞，这可阻止或防止尿液从输尿管流向膀胱。

[0094] 在一些实例中，导管装置10进一步包含限定至少部分置于管12内的导液腔的导液管218。如图3A-3C中所示，导液管218可包含位于管12的开放远端30附近或从中延伸的开放远端220。在一些实例中，导液管218的开放远端220只是将尿液从膀胱吸入导液管218的内部的管口。在其它实例中，导液管218的远端部分可包含穿孔(图3A-3C中未显示)或在侧壁222上的洞口。穿孔可提供用于将尿液吸入导液管218的内部的额外空间，因而确保流体收集可继续，即使导液管218的开放远端220被阻塞。此外，穿孔可增加可用于将流体吸入导液管218的表面积，因而提高效率和/或流体收集量。

[0095] 在一些实例中，支承帽212的最远端部分可包含海绵或护垫224，例如凝胶垫。可放置护垫224以接触和贴着膀胱上壁100a用于在负压治疗期间防止排出、吸入或对膀胱100a的其它创伤。

[0096] 参照图4，显示了包括膀胱上壁支承210的另一示例性膀胱导管10的留置部分。膀胱上壁支承210包含支承帽212和多个支柱214。正如之前描述的实例，膀胱上壁支承210能够在回缩位置间移动，其中支承210至少部分缩进管道或管12中，展开位置支撑膀胱上壁。在一些实例中，导管装置10还包括从管道或管12的开放远端30延伸的导液管218。与前述实

例不同，图4所示支承帽212包含可充气气囊226。可充气气囊226基本上可以是半球形的，并可包含在展开时配置成接触膀胱上壁100a的弧形远端表面228。

[0097] 在一些实例中，导液管218包含在管12的开放远端30和支承结构212之间延伸的穿孔部分230。放置穿孔部分230以将流体吸入导液管218的内部，使得它可从膀胱100中排出。适宜的是，穿孔部分230如此放置，以便在向其施加负压时不被展开的支承帽212或膀胱壁堵塞。导液管218可包含充气腔232或置于其附近，充气腔232用于向气囊226的内部234提供流体或气体使气囊226从其收缩位置向展开位置膨胀。例如，如图4所示，可将充气腔232配置在导液管218中。

[0098] 参照图5，说明了配置成放置在患者膀胱中的另一示例性尿液收集导管装置10的留置部分6。留置部分6包含在管12的远端部分展开的盘绕的固位部分。在一些实例中，固位部分6可以是与管12的远端30连接的单独结构。在其它实例中，可使管12的远端部分成为盘管，因而形成盘绕的固位部分6。在一些实例中，盘绕的固位部分6包含具有第一直径D1的至少一个第一盘管236和具有第二直径D2的至少一个第二盘管238。在一些实例中，第一直径D1小于第二直径D2，得到锥形外观的固位部分6。例如，第二直径D2可为约4 mm-约26 mm。第一直径D1可为约2 mm-13 mm。在其它实例中，盘绕的固位部分中盘管的排列可以翻转，使得最远端的盘管具有比一个或多个近端盘管大的直径。

[0099] 管12的固位部分6可进一步包含布置在固位部分的侧壁6的径向向内侧240的多个穿孔230。穿孔230的直径的范围可为约0.005 mm-约1.0 mm。穿孔230的间距的范围可为约1.5 mm-约15 mm。穿孔230可按任何排列分隔开，例如线性或偏置。在一些实例中，穿孔230可以是非圆形的，并可具有约.00002-0.79 mm^2的表面积。将穿孔230置于盘绕的固位部分6的径向向内侧240旨在当通过导管装置10施加负压时防止膀胱堵塞穿孔230。例如，在响应向膀胱施加负压时，可倚靠固位部分6的径向向内部分吸入膀胱壁的一部分。因此，固位部分6的径向向外侧上的任何穿孔可被膀胱壁堵塞。然而，固位部分6的径向向内侧240的穿孔230被保护。在其它实例中，固位部分的侧壁6的径向向内侧240上穿孔的总表面积可大于固位部分6的径向向外侧242上任何穿孔的总表面积。

[0100] 参照图6，说明了包括多个盘绕导液腔(一般标示为腔218)的尿液收集导管装置10的示例性固位部分6。固位部分6包含具有远端开口端30的管12。导液腔218部分置于管12内。在展开位置处，导液腔218配置成从管12的开放远端30延伸并与盘绕方向一致。导液腔218可与导管装置10的整个长度分开，或可流入由管12限定的单个导液腔。在一些实例中，如图6所示，导液腔218可以是具有一个或多个盘管244的螺旋盘管。与前述实例不同，螺旋盘管244在与管的非盘绕部分轴C没有同延的轴周围盘绕。相反地，如图6所示，螺旋盘管可以在与管12的轴C大致垂直的轴D周围盘绕。在一些实例中，导液腔218可包含穿孔(图6中未显示)，与图5中的穿孔230相似，用于将流体从膀胱吸入导液腔218的内部。在一些实例中，穿孔可位于导液腔盘绕部分的径向向内侧240上。如前所述，在向膀胱施加负压期间，位于导液腔218或管12的径向向内侧的穿孔不太可能被膀胱壁堵塞。也可将尿液直接吸入由管12限定的一个或多个导液腔。例如，与其说通过穿孔230被吸入导液腔218，倒不如说尿液可通过开放远端30直接吸入并进入被管12限定的导液腔。

[0101] *有两阶段固定的示例性固位部分*

参照图7A和7B，说明了经适应以提供膀胱内两阶段被动临时固定的示例性固位或留置

部分6。固位部分6配置成在插入膀胱期间在收缩位置(如例如图7A中所示)和患者膀胱内的展开位置(如图所示7B)间可转换。如本文所述，按与前述实例类似的方式，导管装置10的留置部分6包括支撑、保持和/或封闭自管12延伸的结构用于通过与远端上壁接触保持膀胱在基本展开的位置。两阶段固定导管装置10还包括结构用于封闭或部分封闭尿道括约肌以防止尿液通过尿道并用于保持三角区在其中输尿管开口或口未被堵塞的扩展位置上。

[0102] 在一些实例中，导管装置10的留置部分6包含膀胱上壁支承，例如远端锚钩20，以及膀胱下壁支承，例如近端锚钩22，各自提供各自的表面20a，用于接触膀胱内部粘膜壁的22a。例如，近端锚钩22可置于尿道括约肌附近以在施加负压用于将尿液从膀胱吸出时提高吸力。适宜的是，近端锚钩22大到足以充分或有效地封闭膀胱并将管12的远端30在膀胱内稳固。例如，适宜的是，近端锚钩22以最小的渗漏完全封闭膀胱。注意，8 mm锚钩是尿道口的至少两倍。因此，当正确或基本正确定位时，近端锚钩22留有余地地覆盖尿道口。在一些实例中，近端锚钩22不应如此大使得当置于膀胱内时它完全覆盖三角区和/或封闭输尿管口。此外，远端锚钩20还起保持膀胱上壁和三角区之间的间距的作用以便阻止膀胱上壁接触三角区113 (图2中所示)。

[0103] 虽无意受理论束缚，但认为将负压引入膀胱100基本上使膀胱100萎陷。通过将近端锚钩22置于尿道口之上封闭膀胱100可防止膀胱100全萎陷，因而确保导管10的穿孔或导液孔28以及三角区和输尿管孔或口是开放的、可进入的和无阻碍的。在一些实例中，来自上壁100b的压力将近端锚钩22保持在依靠下壁100a的合适位置上，因而在尿道口之上造成封盖层。

[0104] 对于包括8-16 Fr长形管12的导管装置10，锚钩20、22在展开状态可具有等于约4 mm-10.7 mm (12-32 Fr)、优选介于约8 mm和10 mm (24 Fr和30 Fr)之间的直径。认为8 mm直径锚钩20、22是适于所有或大部分患者的单一尺寸。对于具有24 Fr锚钩的导管装置10，锚钩20与22间的长度L (图7B中所示)为约1.5 cm-约2.3 cm，优选约1.9 cm (0.75 in)。因此，在一些实例中，在收缩状态，相对锚钩20、22具有共约1.6 cm的不重叠的长度(0.8 cm/锚钩)。为了构成末端衬垫和其它间距，可将锚钩20、22以额外的少量，例如额外20% (例如约0.3 cm)间隔开来。因此，锚钩20、22间的长度L (图7B和8B中所示)优选约1.9 cm。

[0105] 在一些实例中，锚钩20、22受释放机械装置控制，例如偏置构件(biasing member)在启动时，引起锚钩20、22从收缩位置向展开位置转换。在展开时，锚钩20、22被定位并配置成以膀胱壁100a、100b形成基本上或完全空气密封，尤其防止气体和/或尿液通过尿道116排出膀胱100。在一些实例中，在展开时，留置部分6的锚钩20、22具有足够的完整性或刚性支撑膀胱100的上壁100b，并在上壁和三角区和/或膀胱内壁之间保持间隙。在一些实例中，在展开时，锚钩20、22在展开时基本保持其配置，并且不因与膀胱壁和/或三角区接触而萎陷。在一些实例中，在展开时，留置部分6保持其取向使得其中心轴在膀胱上壁和三角区之间延伸。适宜的是，在因由膀胱壁施加在留置部分6上的压力展开时，留置部分6沿中心轴没有可观的萎陷，或自其轴向位置移动或倾斜。

[0106] 在一些实例中，导管主体或管12的远端30通过远端锚钩20延伸，并与膀胱100的上壁100b接触(图1和2中所示)。在此情况下，导管主体或管12的远端30可包括海绵或护垫40，例如凝胶垫，其装在导管主体或管12上，并定位以接触并压在膀胱上壁100b上用于防止排出、吸入或其它创伤的目的。

[0107] 管12可进一步包含流体接收部分，例如导液槽或腔14。导液腔14可包括一个或多个穿孔，例如导液口、小孔或洞口28用于将流体(例如尿液或气体)从膀胱100排入管12的腔14以从膀胱100排出。导液孔28可以任何方式排列，例如沿导管主体或管12的长度线性排列、在管12周围的不同位置或以沿管12延伸的螺旋方式排列。适宜的是，将导液孔28以在展开位置上确保远端30的稳定性和刚性的方式排列。在一些实例中，导液腔14包含约1-20个导液孔28。导液孔28可具有约0.005 mm-约0.5 mm的直径。洞口28一般可为圆形的或卵圆形的，并可沿管12直线排列或可偏移。

[0108] 在一些实例中，如图7A和7B所示，锚钩20、22可包含篮状或伞状框架结构。例如，锚钩20、22可包含从管12径向延伸的柔性支承，例如柔性支承构件32。例如，各柔性构件32可包括与管12固定连接的一端和在展开位置上从管12径向向外延伸的活动端。柔性构件32可以是稍微弯曲的、弧形的或有偏向的以更好地从膀胱上壁吸收收缩力。柔性构件32可以是任何合适的长度和宽度以与膀胱100的解剖学一致。例如，柔性构件32可用形状记忆合金(例如镍钛)形成，形状一般可为圆柱状或柱状，并可具有介于约0.05 mm和1 mm之间的直径。在一些实例中，柔性构件32还包括一个或多个铰链用于向其赋予足够的柔性。

[0109] 支承构件32可被由柔性和无孔材料或织物(例如硅酮或Teflon®)形成的支承帽(例如罩38或膜)覆盖用于防止气体和/或流体流过该罩或膜。在一些实例中，罩38用当置于粘膜内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬的材料(例如硅酮或Teflon®材料)形成。罩38厚度的范围可为约0.05 mm-约0.5 mm。在一些实例中，近端锚钩22的罩38限定在其中心口34周围延伸的环状密封罩以封闭膀胱下壁。在一些实例中，罩38的部分可包含弹性体材料或其它柔性材料(例如硅酮或Teflon®)，用于确保与膀胱下壁紧密接触。

[0110] 在一些实例中，导管装置10可进一步包含在近端锚钩22和远端锚钩20之间与管12基本平行和/或同轴延伸的一个或多个杆26用于提供对管12的额外支撑。在一些实例中，杆26可以是基本刚性的构件，与管12的其它部分连接、被封入其中或与之整体成型。例如，杆26可包括一个或多个镍钛或塑料尖齿。如此提供杆26以便管12的远端30可承受由膀胱壁施加在锚钩20、22上的力。例如，杆26可用刚性材料形成，其不会偏离管12的中心轴弯曲并确保向下的膀胱壁压力的均匀分布。杆26的长度L (图7B中所示)可以是固定长度，经过选择使得在膀胱100中展开时，锚钩20、22和杆26造成足够的空间使得导管10的排水功能不受阻。例如，杆26的长度L可介于约1.0 cm和3.0 cm之间。杆26可防止膀胱100萎陷和堵塞导液孔或膀胱100的解剖结构，例如输尿管114。对于展开直径为约8 mm的锚钩20、22，杆26可具有约0.3 mm-约1.0 mm (例如1 Fr-3.3 Fr)的直径。

[0111] 或者，在一些实例中，可为不同患者提供不同长度L的流体接收部分或管12的远端30。在其它排列中，远端30可包括长度调整装置，例如伸缩装置，用于调节远端30的长度L用于具体患者。

[0112] 参照图8A和8B，说明了另一示例性导管装置10a的留置部分。图8A中显示了呈收缩位置的导管装置10a的流体接收部分或远端部分30a，图8B显示了展开位置。远端30a包括相对的膀胱壁支承用于支撑上和下膀胱壁。例如，远端部分30a可包含近端护套20a和远端护套22a。各护套20a、22a在滑动环或套环24a和静止或镶嵌环或套环28a之间延伸。护套20a、22a用柔性的无孔材料(例如硅)形成。护套20a、22a被一个或多个柔性金属丝或钢丝26a保

持在一起。护套20a、22a也可通过一个或多个刚性构件(例如支承32a)连接。在一些实例中，支承32a可以是由柔性的形状记忆材料(例如镍钛)形成的尖齿。使支承32a定位以提供近端护套20a的支撑并防止当其在展开位置上时远端30a萎陷。在收缩位置处，使套环24a、28a彼此相隔定位，使得护套20a、22a拉伸或依靠钢丝26a和支承32a折叠。在展开位置处，滑动套环24a向静止套环28a移动，允许护套20a、22a从中心钢丝26a展开，并形成基本平的盘状结构。

[0113] 在使用中，将呈收缩位置的导管装置10a的远端30a插入患者膀胱中。一旦插入膀胱，通过将滑动套环24a按朝向静止套环28a的远端方向滑动张开远端护套22a。一旦远端护套22a展开，通过将滑动套环24a按朝向各自的静止套环28a的近端方向滑动，以类似方式张开或展开近端护套20a。此时，近端护套20a在膀胱内漂浮，且不定位或靠着膀胱内壁封闭。由膀胱萎陷引起的针对远端护套22a的压力通过支承32a转移至近端护套20a，并引起近端护套20a向接近尿道口的所需位置移动。一旦近端护套20a就位，便在尿道口之上造成封闭。封闭引起膀胱内的负压，并防止气体和/或尿液通过尿道排出膀胱。

[0114] *具有环状可充气气囊的示例性固位部分*

参照图9A-11B，说明了包含膀胱上壁支承300的其它示例性尿液收集导管装置10的留置或固位部分6。与前述实例不同，刚性或大致刚性锚钩20、22 (图7A和7B中所示)用可充气支承帽例如环状气囊310代替，定位以接触膀胱上壁防止膀胱收缩和堵塞导管装置10的流体口312或膀胱的输尿管口。在一些实例中，管12的远端部分30通过气囊310的中心口314延伸。管12的远端部分30还可接触膀胱上壁。

[0115] 具体参考图9A和9B，在一些实例中，管12包含位于气囊310近端并从管12侧壁延伸的流体入口部分316。流体入口部分316可包含置于管12的中心腔周围的过滤器318 (图9B中所示)。在一些实例中，可将海绵材料320放置在过滤器318之上以提高膀胱内流体的吸收。例如，可将海绵材料320注模在过滤器318之上。在使用中，尿液被海绵材料320吸附，且在通过管12施加负压时，流过过滤器318，进入管12的中心腔。

[0116] 具体参考图10A和10B，在另一示例性实施方案中，支承帽，例如环状气囊310，包含配置成接触并留在膀胱上壁的基本球状的远端部分322。气囊310进一步包含多个从近端延伸的气袋324。例如，气囊310可包含在气囊310近端管12的一部分周围等距离间隔的3个气袋324。如图10B中所示，流体口312可置于相邻的气袋324之间。在这种配置中，气袋324和球状远端部分322接触膀胱壁，这防止膀胱壁阻断或堵塞流体口312。

[0117] 具体参考图11A和11B，在另一示例性实施方案中，提供扁平和长形的环状气囊310。例如，环状气囊310可具有如图11B中所示的基本水珠状的径向横截面，其较窄的部分326位于管12的附近，长形或球状部分328位于其径向向外侧。扁平的环状气囊310配置成跨越并封闭膀胱三角区，使得在膀胱中展开时，气囊310的外周缘径向超过输尿管口地延伸。例如，当置于患者膀胱中时，气囊310的中心口314可配置成位于三角区之上。流体口312可置于中心部分气囊310的近端，如图11B中所示。适宜的是，将流体口312置于气囊的中心口314和三角区之间。当膀胱因施加负压收缩时，膀胱壁被气囊310的外周缘支撑以避免阻断输尿管口。因此，在这种配置中，气囊310接触并防止膀胱壁阻断或堵塞流体口312。如本文所述，气囊310以类似方式保持三角区张开，使得尿液可从输尿管通过输尿管口吸入膀胱。

[0118] 参照图12，说明了包含膀胱上壁支承300的尿液收集导管10的留置部分6的另一个

示例性实施方案。膀胱上壁支承300包含安装在管12的开放远端30并从中延伸的球状海绵330。海绵330与前述实例中的气囊310基本相似，可配置成接触膀胱上壁以防止或对抗膀胱的收缩。适宜的是，海绵330用软的可塑材料形成，所述材料当置于膀胱壁或尿道的粘膜内衬附近时不会可观地磨损、刺激或损伤膀胱壁或尿道的粘膜内衬。在使用中，当通过管12施加负压时，流体通过多孔海绵330，经由远端口30，吸入管12的中心腔。

[0119] *尿液收集导管的示例性外面部分*

参照图13，详细描述了管12的外面部分8的元件。如前所述，外面部分8包含患者身体外部的管12的部分。外面部分8的近端可配置成与流体容器或泵410连接(图14中所示)。在一些实例中，外面部分8可包含展开导杆44用于将导管10推进或插入尿道116 (图1和2中所示)并进入膀胱。适宜的是，对非医务人员，展开导杆44容易使用，使得例如由患者独立布置装置10 (例如自我实施)。展开导杆44可配置成调节不同的导管长度以适应特定患者的解剖学。展开导杆44可包括用于推进导管10的机械装置，例如扳柄46或推进旋钮。在一些实例中，使用者通过向远端方向按压扳柄46来延伸或伸长导管装置10。类似地，通过向相反方向拉扳柄46使导管装置10缩回以从患者中收回导管10。

[0120] 展开导杆44可进一步包含释放机械装置48用于释放锚钩20、22以将导管10从收缩位置(图7A和8A中所示)转换成展开位置(例如图7B和8B中所示)。例如，释放机械装置48可包含位于展开导杆44上或附近的释放按钮或开关，当被使用者中启动时，引起导管10的远端30的相应结构将锚钩20、22从收缩位置推向或移动至展开位置。更具体地讲，锚钩20、22自然保持在收缩位置处。释放机械装置48克服向收缩位置的偏倚，临时将锚钩20、22保持或锁在展开位置处。在一些实例中，释放机械装置48可配置成同时释放锚钩20、22以避免将不均匀的力施加在膀胱100的相对侧，正如如果一个锚钩处于展开状态，而另一个锚钩处于收缩状态可能发生的一样。类似地，释放机械装置48可配置成如果因由膀胱壁100a、100b施加的过度的力迫使远端锚钩20关闭，则自动缩回近端锚钩22。释放机械装置48还可配置成如果例如导管装置10非有意或有意拉出同时远端30处于展开位置则自动缩回锚钩20、22。

[0121] 继续参照图13，由于锚钩20、22是被动固定的并在膀胱100中造成基本不透气的密封(图1和2中所示)，因此如果锚钩20、22在展开状态时拉动导管装置10，则有可能发生对膀胱100或尿道116造成创伤的风险。因此，导管10的外面部分可包含分离阀50用于将包括导管装置10的留置部分6的导管10的一部分从导管10的外面部分释放或分离出。如例如图13中所示，分离阀50通常沿管12位于是展开导杆44的近端的位置处。分离阀50可如此配置，使得当导管装置10的部分被分开时，阀50转换到关闭位置以防止流体从导管10中渗漏。导管10的外面部分可与分离阀50再次连接以继续治疗。

[0122] 导管装置10可进一步包含传感器52用于监测从膀胱排泄的尿液的流体性质。获自传感器52的信息可传送至中央数据收集模块或处理器，并用来例如控制外部装置(例如泵410)的操作(图14中所示)。传感器52例如可与管12一起整体成型，例如，嵌入管12的壁中并与导管10的一个或多个腔14流体连通。在其它实例中，一个或多个传感器52可位于流体收集容器(未显示)或外部装置的内部线路(例如泵)中。

[0123] 在一些实例中，导管装置10还包括一个或多个以下类型的传感器52。例如，导管可包括抽样检查导管10中尿液的电导性的电导率传感器或电极。人尿液的正常电导率为约5-10 mS/m。预期范围以外的尿液电导率可表示患者遇到生理问题，这需要进一步治疗或分

析。导管10还包括流量计用于测量尿液通过导管10的流速。流速可用来确定自体内排泄的流体的总体积。导管10还包括温度计用于测量尿液温度。尿液温度还可用来与电导率传感器合作。尿液温度还可用于监测目的，因为生理正常范围以外的尿液温度可表明某些生理病况。

[0124] 继续参照图13，导管主体或管12的近端可包含配置成与流体收集系统的柔性管连接或与外部单元(例如泵)直接连接的口54。口54可包含连接器、密封件和在导管10和外部单元间形成合适的流体连接的阀。例如，连接器可以是托架、luer连接器、螺旋式连接器、夹钳或本领域已知的其它合适的连接机械装置。在另一个实例中，导管主体或管12可与蠕动泵连接器连接。蠕动泵连接器可以是通过泵臂流入的内置导管，可定位以迫使流体通过内置导管。在其它实例中，泵可以是本领域已知的隔膜或活塞泵。

[0125] 用于引入负压的示例性系统

参照图14，说明了包括在患者膀胱中展开的导管装置10、用于引入负压的系统400。在一些实例中，系统400包含与用于收集和储存排出的尿液的流体收集容器412连接的导管装置10。流体收集容器412可置于在其中连接的外部单元(例如泵410)产生的负压下。通过导管装置10的一个或多个导液腔向患者膀胱提供由泵410产生的负压。如本文所述，可提供负压疗法以克服肾中的间质压力以诱导尿液产生。在一些实例中，系统400进一步包含具有或与计算机可读存储器416连接的控制器414，例如微处理器。存储器416可存储指令，当执行指令时，引起控制器414接收位于导管装置10或与之连接的传感器52的信息，根据来自传感器52的信息确定有关患者状况的信息，并根据自传感器52接收的信息确定并执行泵410的操作参数。

[0126] 在一些实例中，控制器414整合到单独的电子器件中，例如专用电子器件或多用途电子器件，例如计算机、平板PC或智能手机。或者，控制器414可与泵410整合和/或电子连接，例如可控制用户界面以手工操作泵410以及系统功能，例如接收并处理来自传感器52的信息。

[0127] 控制器414可配置成接收来自一个或多个传感器52 (例如电导率传感器)信息，并在相关计算机可读存储器416中存储信息。例如，控制器414可配置成以预定的速率(例如每秒一次)接收来自电导率传感器的信息，并根据所接受的信息确定电导率。在一些实例中，计算电导率的算法还包括其它传感器测量(例如尿液温度)，以获得更稳固的电导率测定结果。

[0128] 控制器414还可配置成计算说明患者状况随时间变化的患者身体统计资料或诊断指示物。例如，系统400可配置成鉴定所排出的钠的总量。所排出的总钠可基于例如一段时间内流速和电导率的组合。

[0129] 继续参照图14，系统400可进一步包含反馈装置420，例如直观显示设备或音频系统，以向使用者提供信息。在一些实例中，反馈装置420可与泵410一起整体成型。或者，反馈装置420可以是单独的专用或多用途电子器件，例如计算机、便携式计算机、平板PC、智能手机或其它手持电子器件。反馈装置420可配置成接收来自的控制器414经计算或求出的测量值，并通过反馈装置420向使用者提供信息。例如，反馈装置420可配置成显示正施加至泌尿道的当前负压(单位mmHg)。反馈装置420还可显示当前尿液流速、温度、尿液的当前电导率(单位mS/m)、在测定时段产生的总尿量、在测定时段排出的总钠或其任何组合。

[0130] 反馈装置420还包括允许使用者控制泵410的操作的用户界面。例如，使用者可通过用户界面占用或关掉泵410。使用者还可调节通过泵410施加的压力以达到钠排泄和流体排出的较大值或速率。

[0131] 在一些实例中，反馈装置420和/或泵410进一步包含数据发送器422用于将来自装置420和/或泵410的信息发送至其它电子器件或计算机网络。数据发送器422可利用短程或远程数据通信协议。短程数据传输协议的一个实例是Bluetooth®。远程数据传输网络包括例如Wi-Fi、Zigbee、蜂窝传输协议等。数据发送器422可向患者的医生或护理人员发送信息，知会医生或护理人员有关患者的现有状况。备选地或此外，可将信息从数据发送器422发送到现有数据库或信息存储单元，例如以将记录的信息纳入患者的电子健康记录(EHR)中。

[0132] 参照图15A和15B，说明了与系统一起使用的示例性泵410。在一些实例中，泵410是配置成从导管装置吸出液体和具有约0.5 mmHg的灵敏度的微型泵。适宜的是，泵410能够提供介于0.05 ml/min和3 ml/min之间的尿液流速范围持续一段长时间。按0.2 ml/min，预期系统400每天收集约300 mL的尿液。泵410可配置成向患者的膀胱提供负压，负压的范围为约0.1 mmHg和20 mmHg (在泵410上的表压力)。例如，由Langer Inc.生产的微型泵(Model BT100-2J)可与本文公开的系统400一起使用。隔膜抽气泵以及其它类型的商购泵也可用于此目的。蠕动泵也可与系统400一起使用。

[0133] 在一些实例中，泵410可配置用于长期使用，因此，能够保持介于8和24小时时间的准确抽吸。泵410可手工操作，在此情况下，包括允许使用者设定所需抽吸值的控制面板418。泵410还包括控制器或处理器，所述处理器可以是操作系统400的同一控制器，或可以是专用于操作泵410的单独的处理器。在任一情况下，把处理器配置成即接受手工操作泵的指令又用于按照操作参数自动操作泵410。备选地或此外，可根据自与导管相连的多个传感器接收的反馈通过处理器控制泵410的操作。

[0134] 引入负压的方法

已描述了导管装置和系统，现将详细论述将负压引入膀胱的过程。参照图16，医学专家、护理人员或患者将导管穿过患者尿道插入，如框510中所示。在框512中，将导管通过尿道推进并进入膀胱。使用者将导管推进整个膀胱直到导管远端顶端的护垫或衬垫与紧邻尿道括约肌的膀胱壁接触。在框514中，使用者使用释放机械装置使得近端锚钩和远端锚钩从收缩状态延伸成展开状态。在展开状态，远端锚钩接触紧邻尿道括约肌的膀胱壁。近端锚钩接触与远端锚钩相隔的膀胱壁的相对侧并封闭尿道口以将尿液保留在膀胱中。锚钩可同时释放。在一些实例中，还将远端锚钩和近端锚钩同时定位。或者，可将远端锚钩选定位于尿道括约肌附近，并可使近端锚钩在膀胱内漂浮。在此情况下，来自膀胱上壁的压力推向远端锚钩，这进而引导近端锚钩就位以封闭尿道口。

[0135] 在框516中，一旦导管就位，并转换成展开状态，便将负压施加于膀胱。负压使膀胱萎陷，因而使锚钩挂住粘膜壁以封闭尿道。适宜的是，负压在两个输尿管和两个肾间均匀分布。此外，髓质中的负压对抗由腹内压升高和必然的或升高的肾静脉压或肾淋巴压所致的充血介导的间质流体静力压。所施负压因此能够增加渗出液流过髓质小管，并且能够降低水和钠重吸收。

[0136] 在框518中，作为所施负压的结果，通过口或小孔将尿液吸入导管。然后通过导管

从身体抽吸尿液，其中将其收集在收集容器中待清除。在框520中，随着尿液被吸入收集容器中，多个传感器提供有关可用于评价所收集的尿液的体积的尿液的多个测量值以及有关患者的身体状况和所形成的尿液组成的信息。例如，传感器可嵌入与从其中延伸的腔有流体连通的导管中。在尿流过导管时，可通过传感器获得信息。通过传感器获得的信息可通过在框522中与泵或其它装置连接的处理器处理，并在框524中通过反馈装置的直观显示设备向使用者显示。

[0137] 参照不同的实例描述了实施方案。在阅读和理解前述实例时，可以想到修改和变动。因此，前述实例不得解释为限制本公开内容。

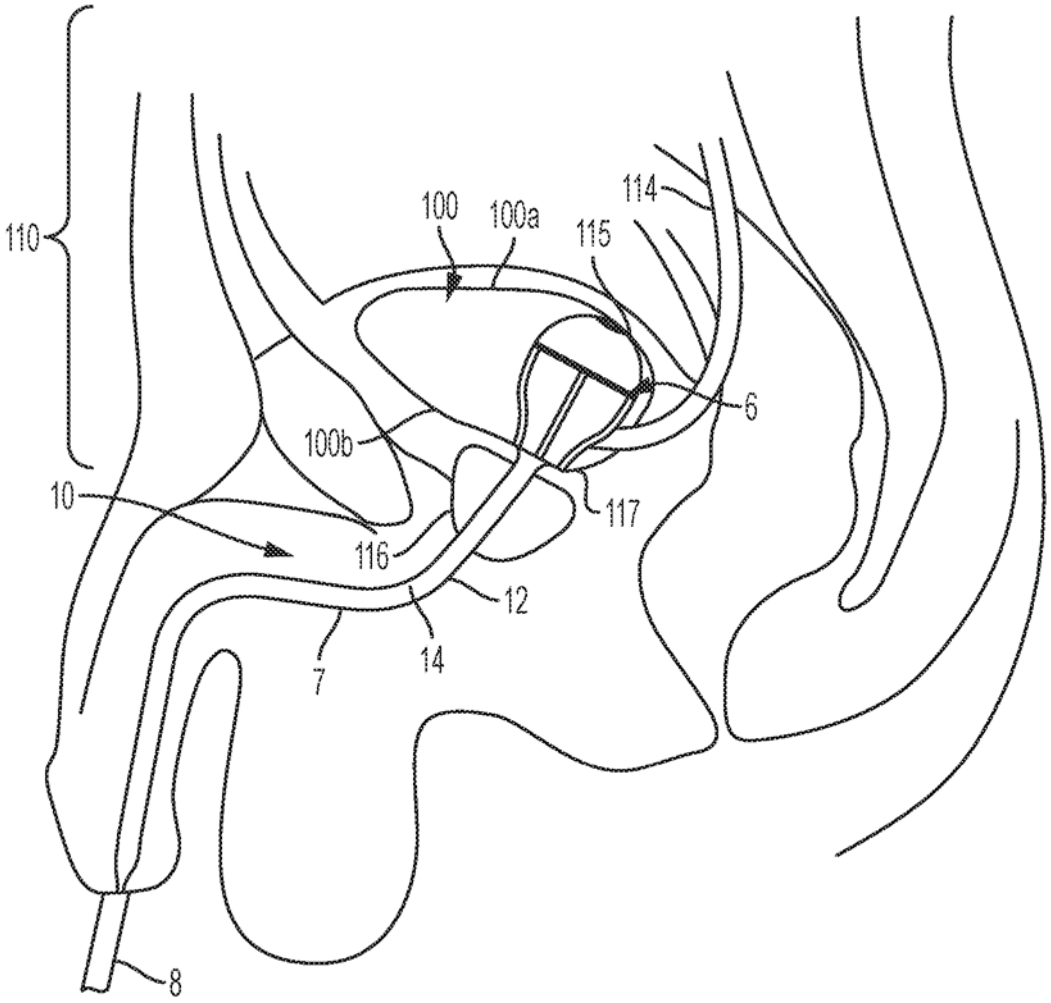

图 1

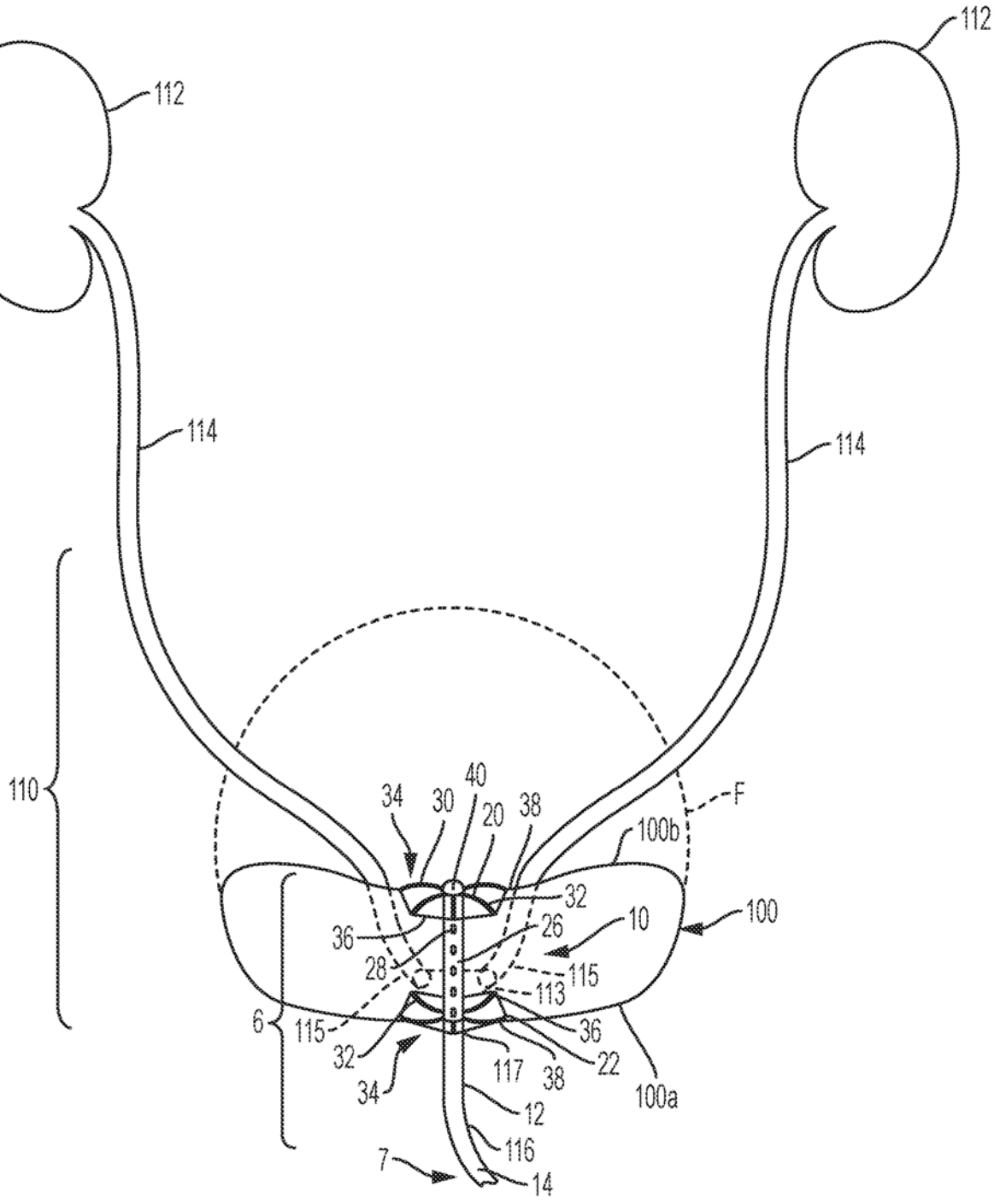
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图 2

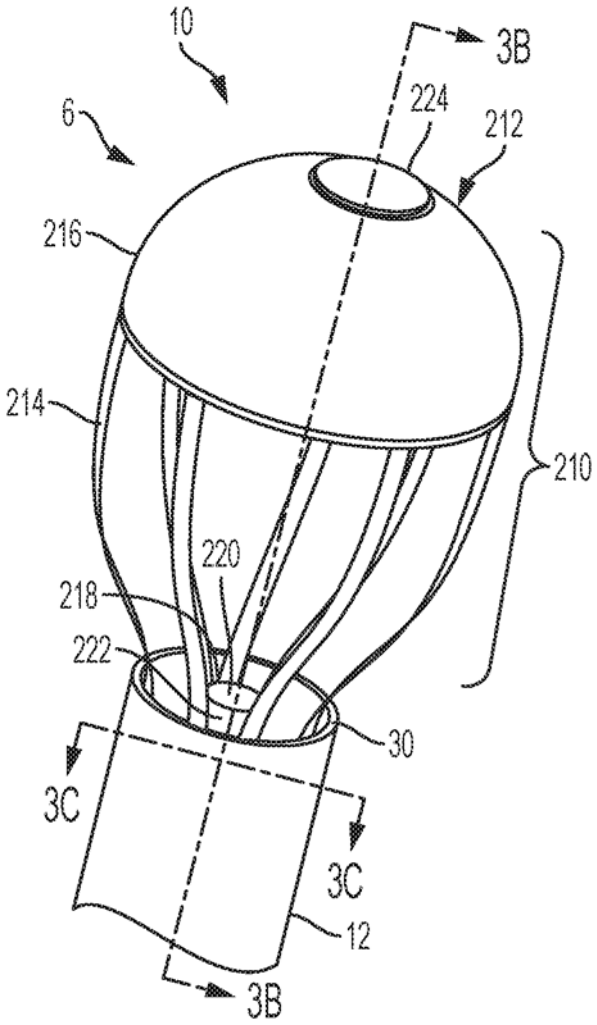

图 3A

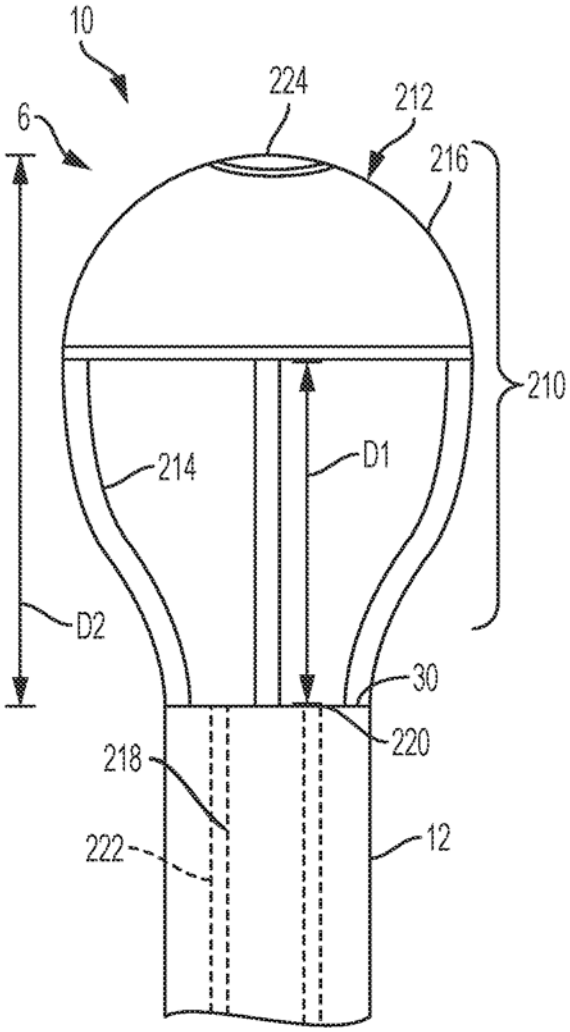

图 3B

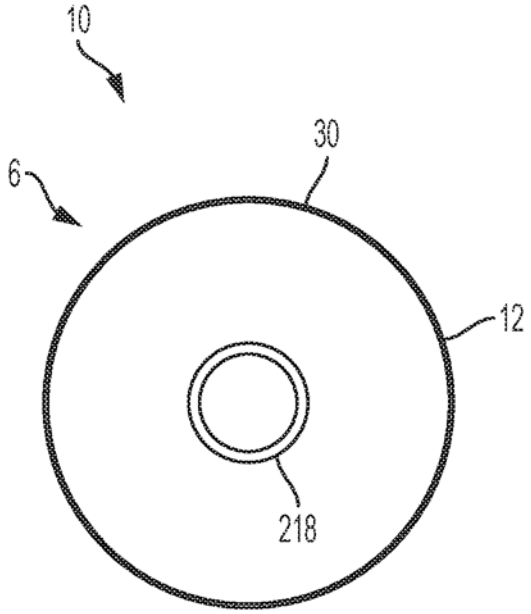

图 3C

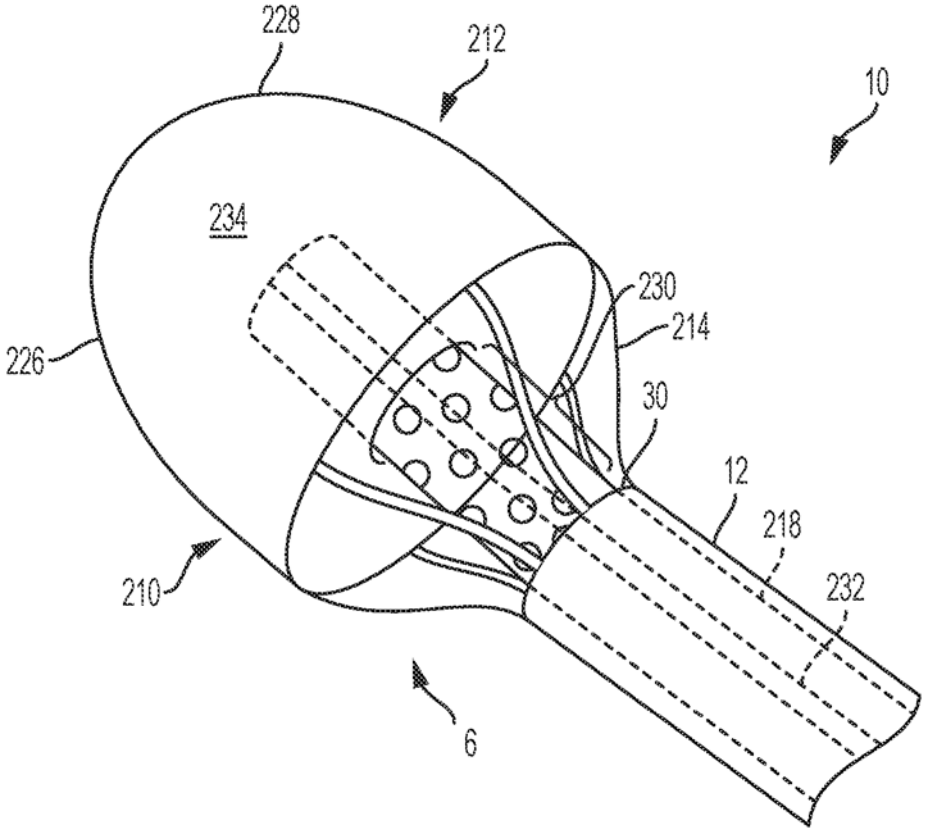

图 4

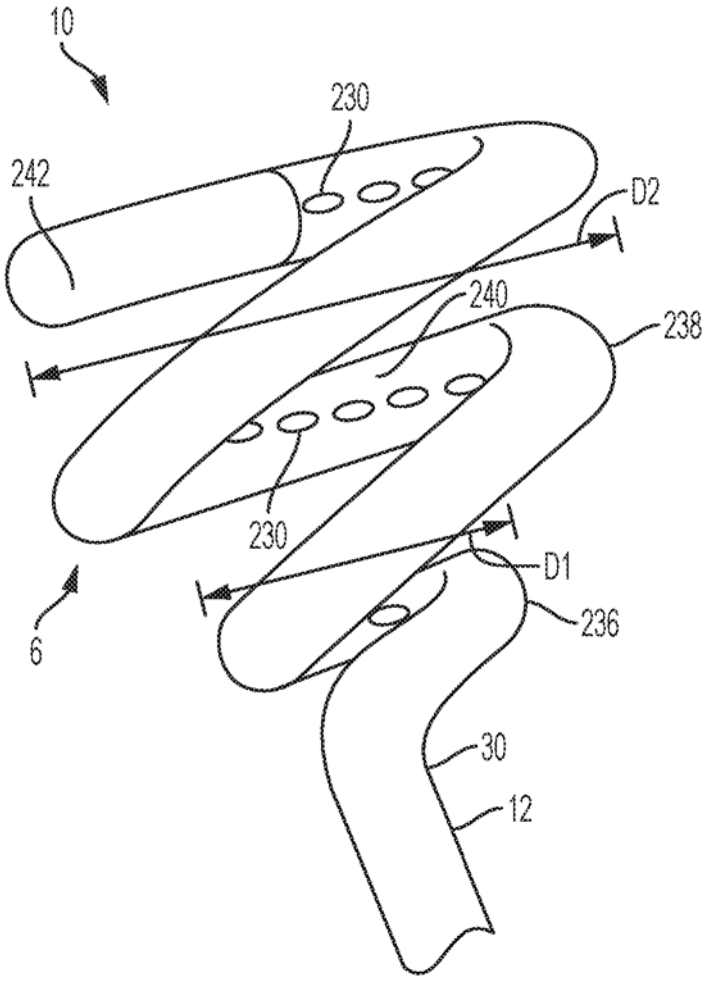

图 5

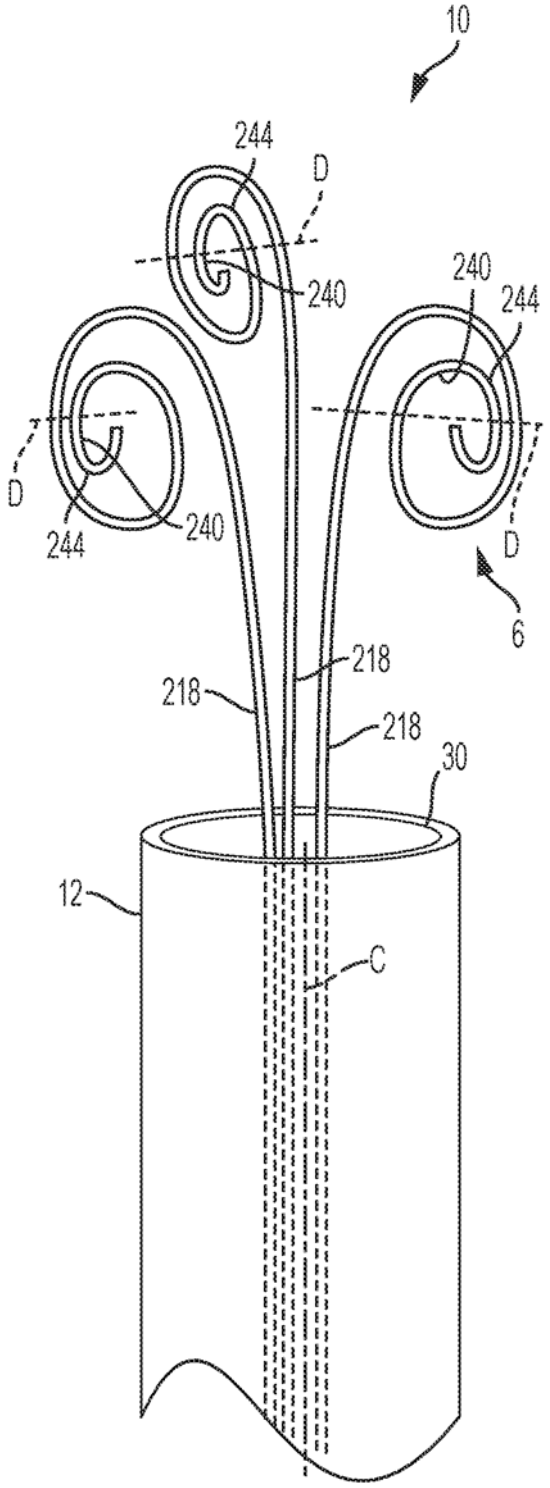

图 6

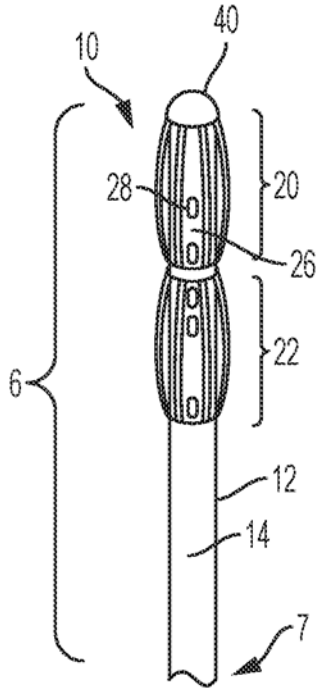
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图 7A

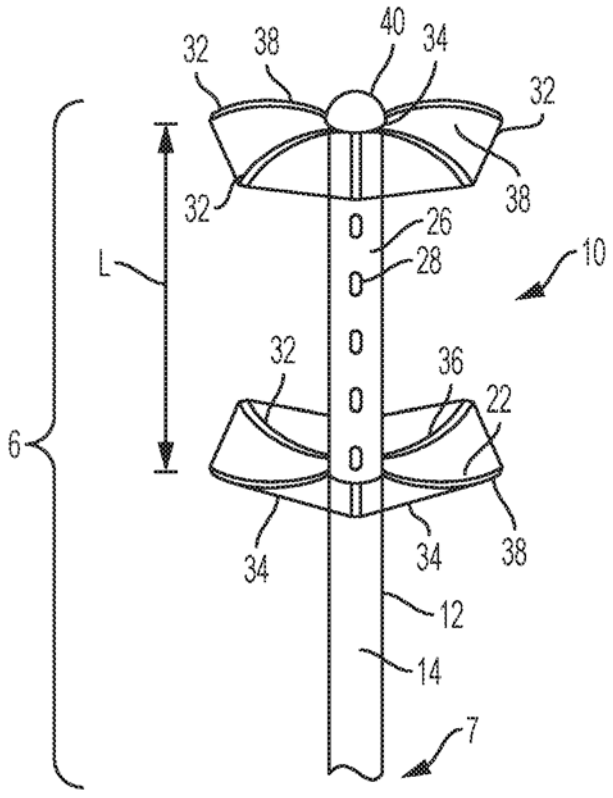
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图 7B

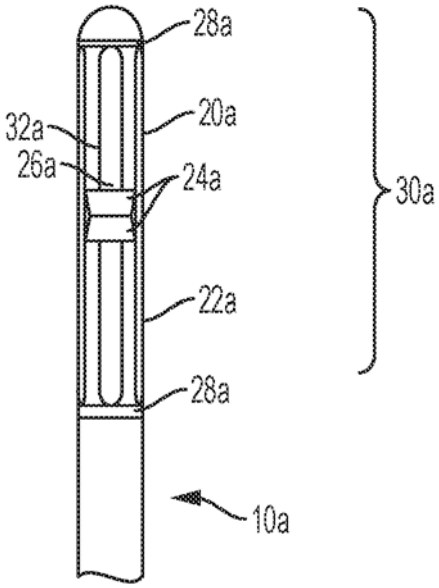
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图 8A

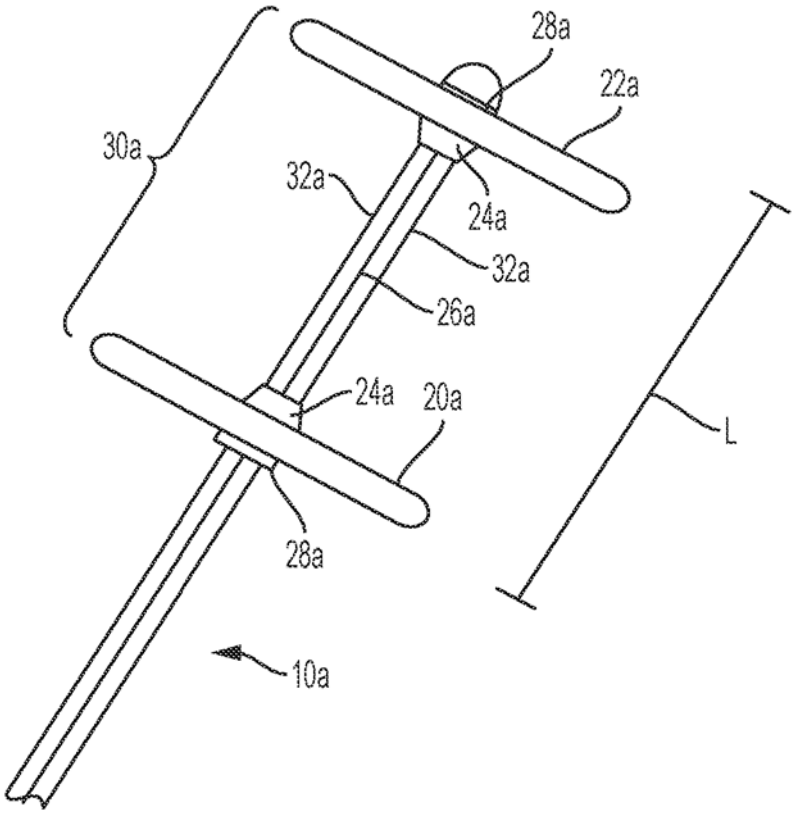
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图 8B

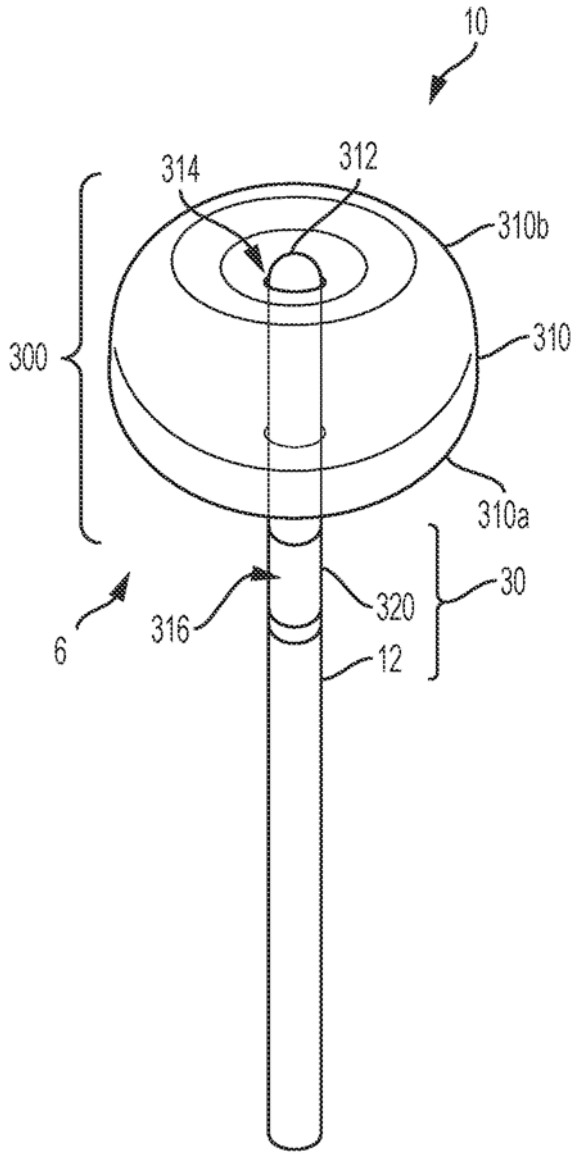

图 9A

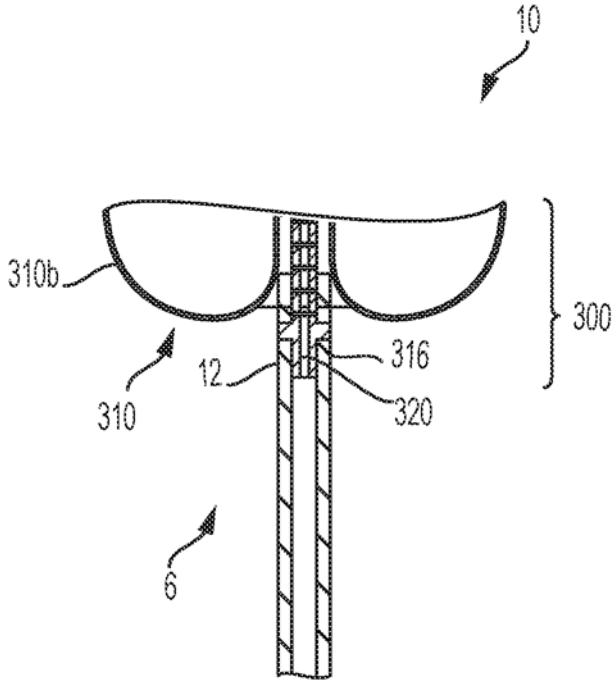

图 9B

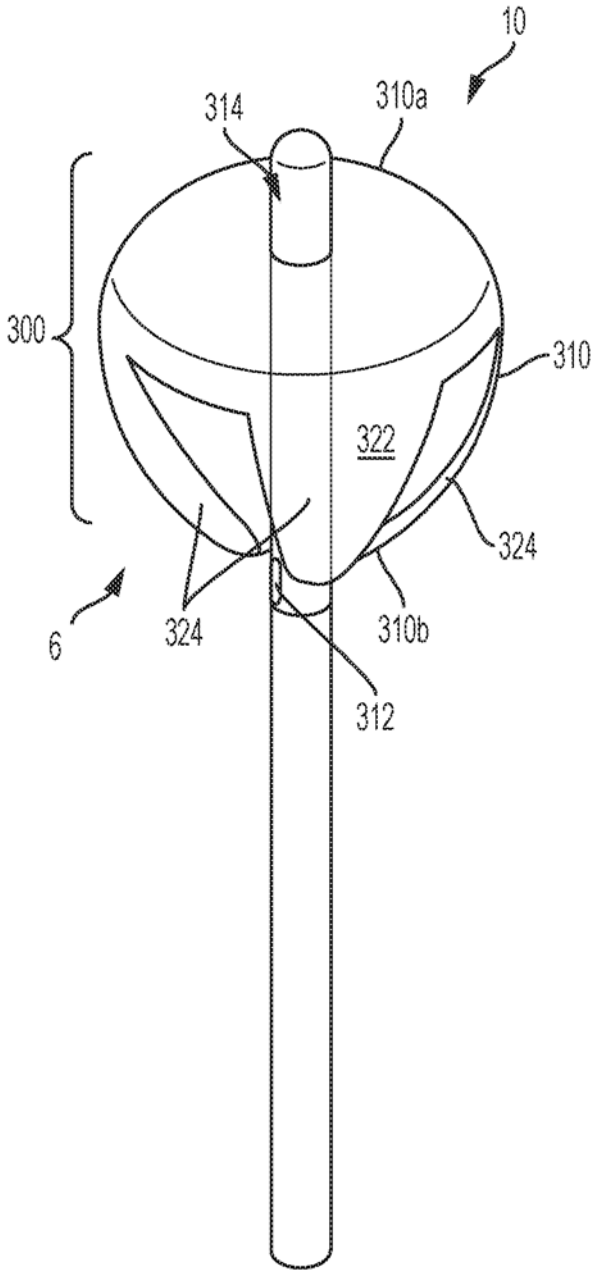

图 10A

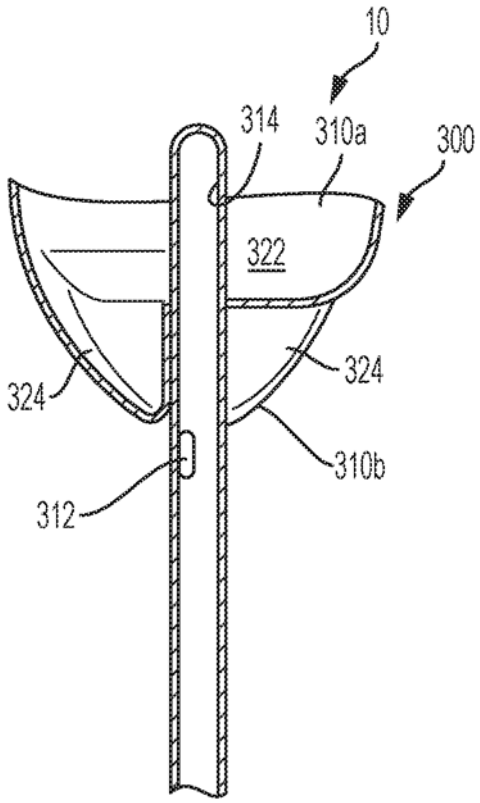

图 10B

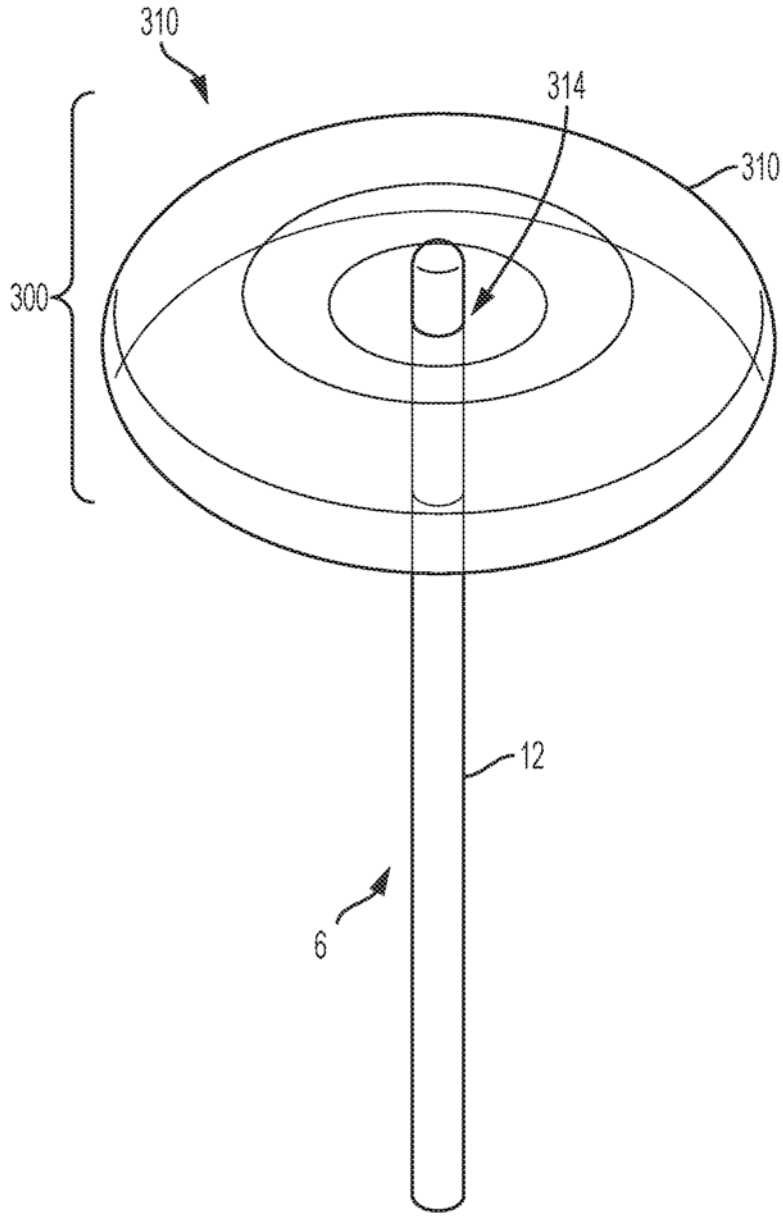

图 11A

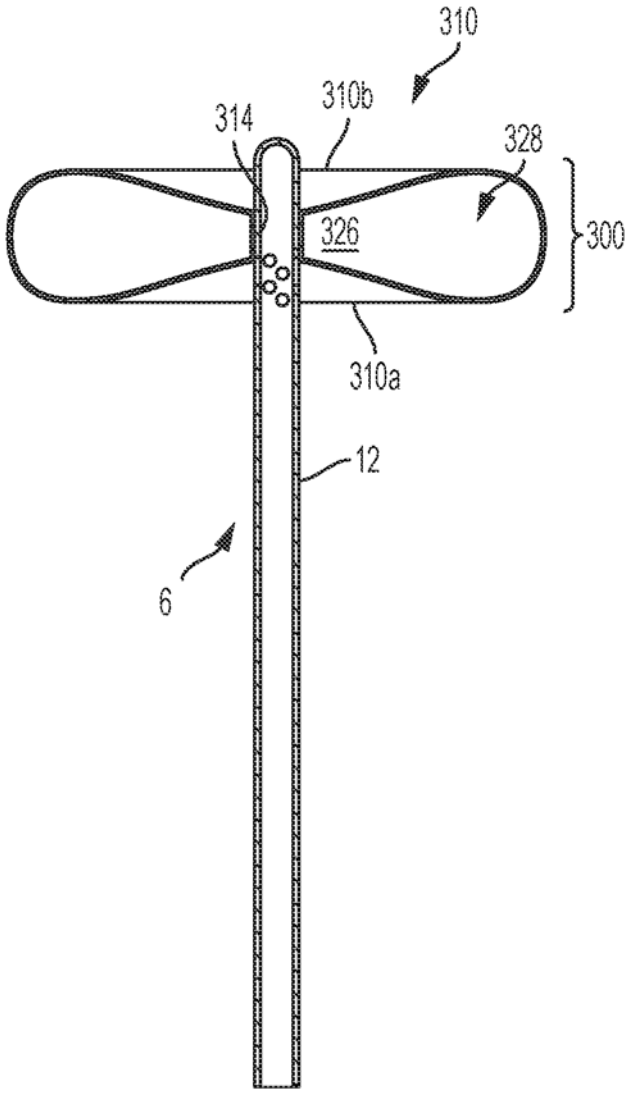

图 11B

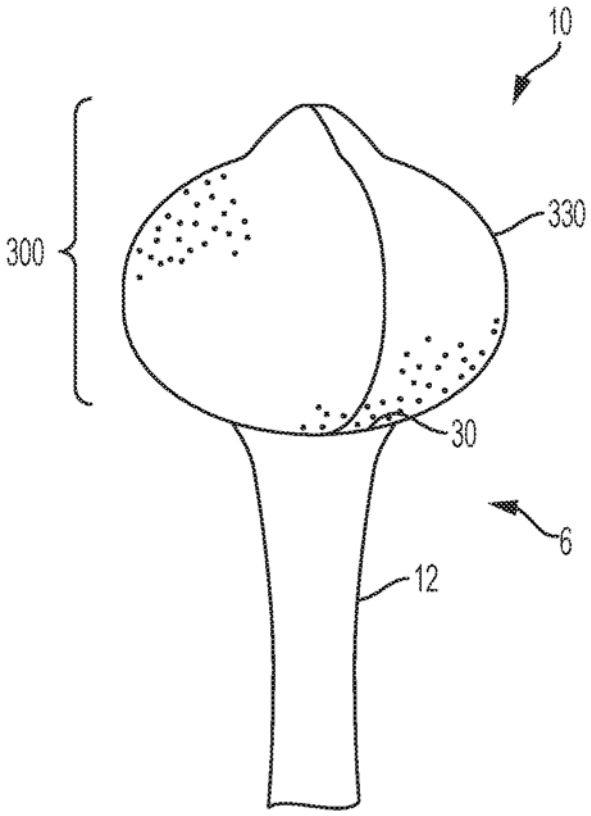

图 12

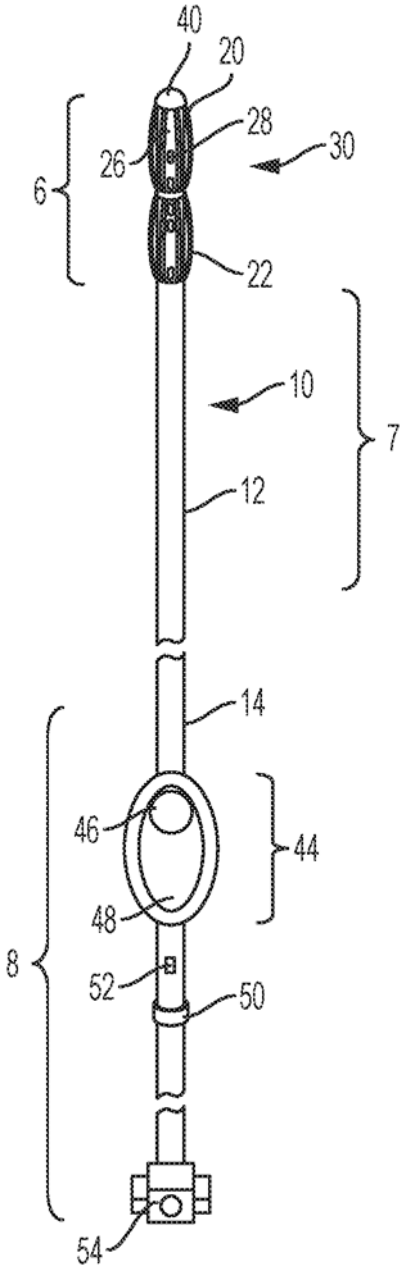

图 13

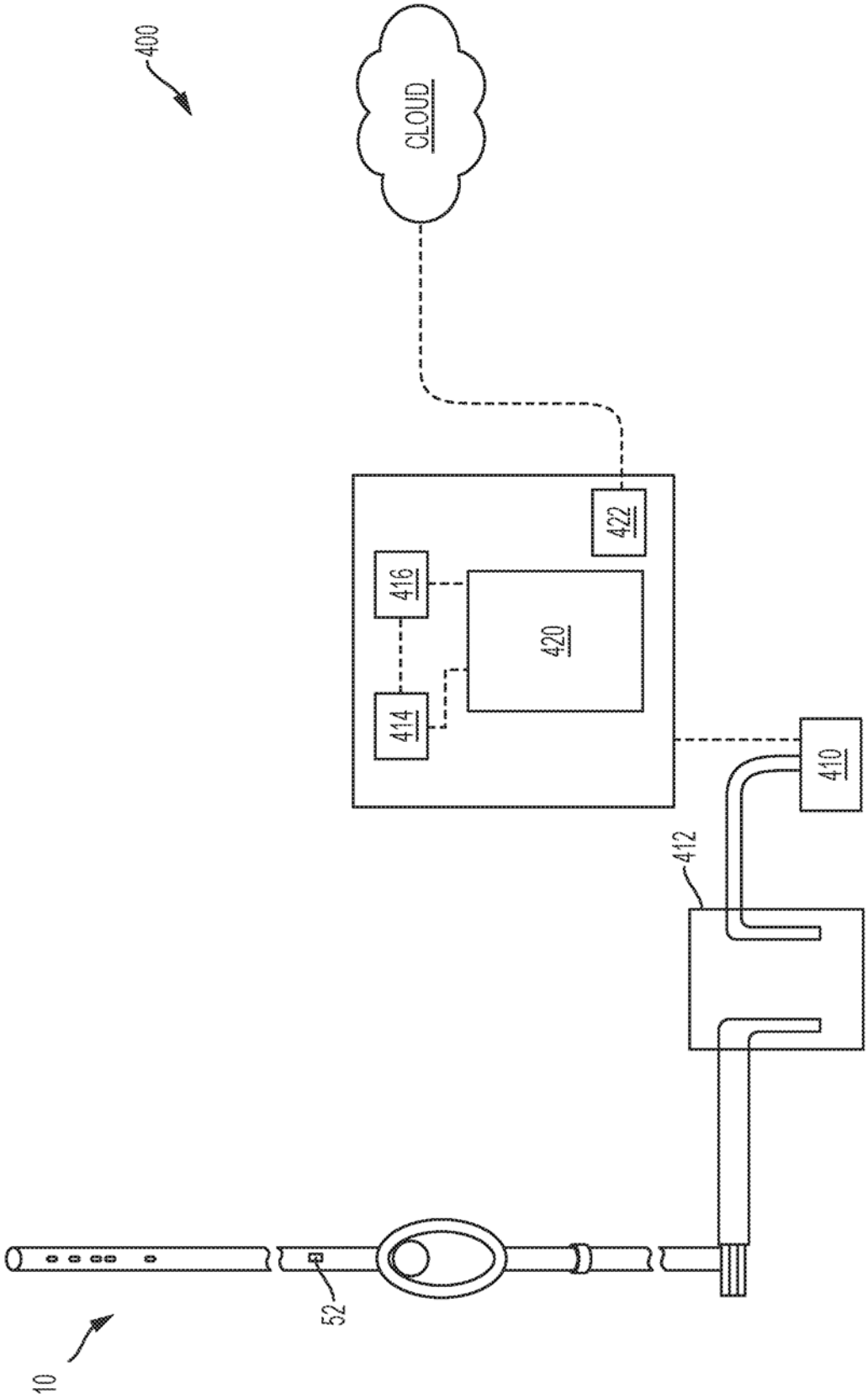

图 14

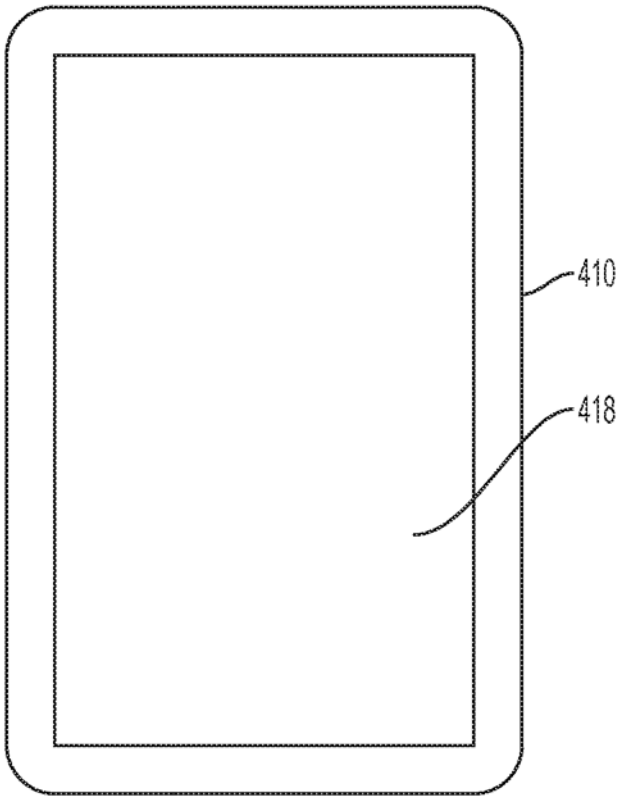

图 15A

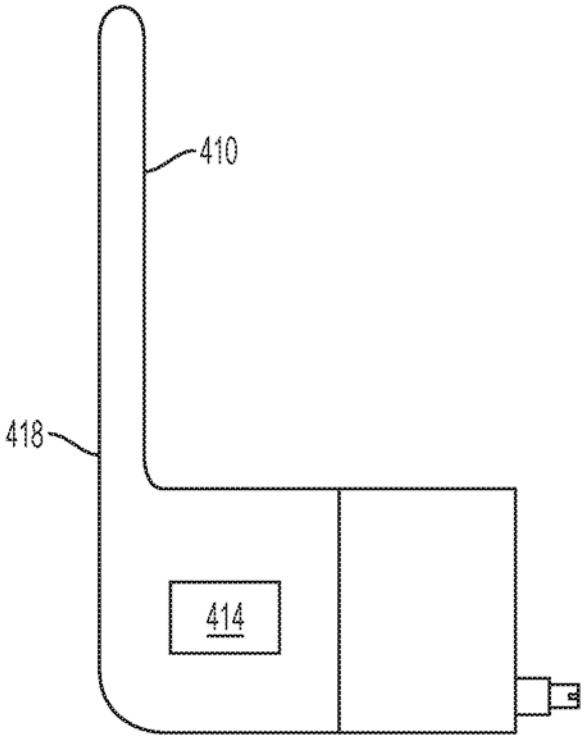

图 15B

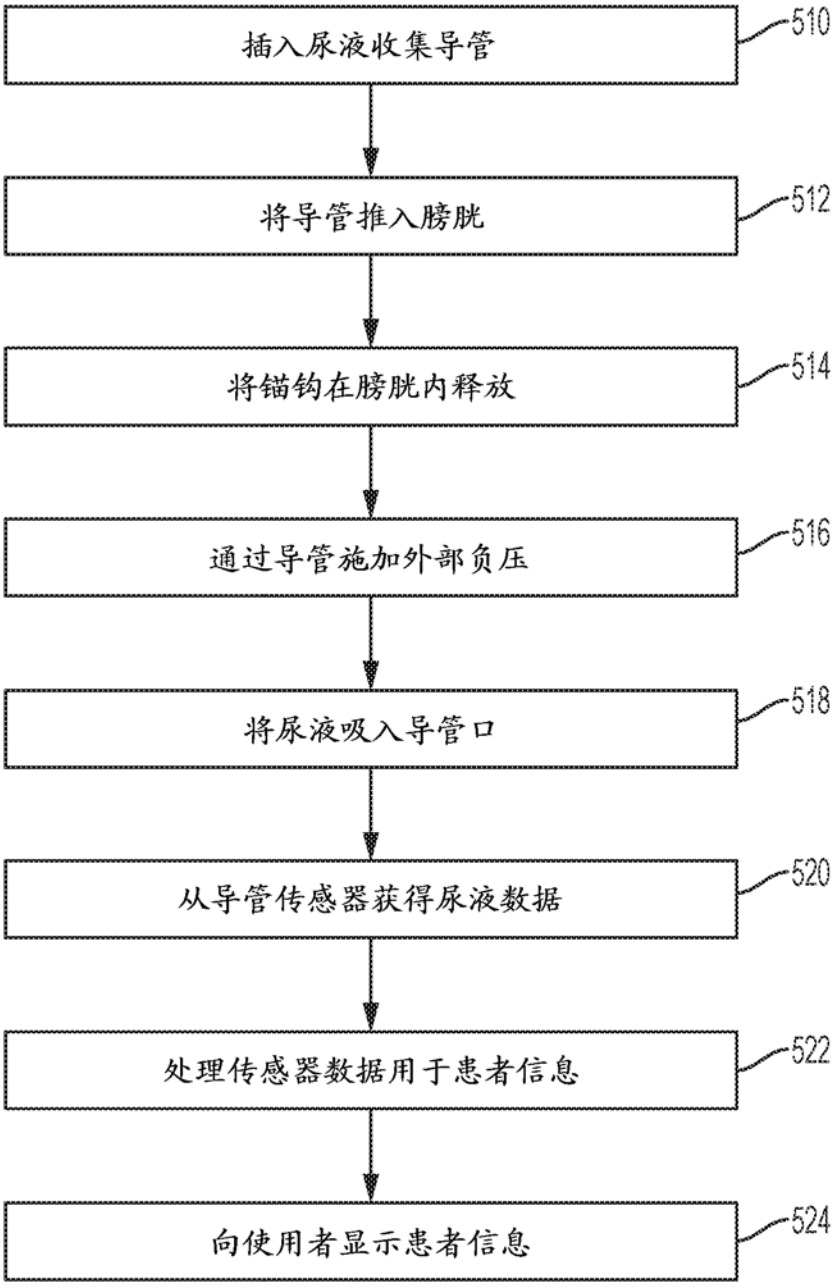
插入尿液收集导管
510
将导管推入膀胱
512
将锚钩在膀胱内释放
514
通过导管施加外部负压
516
将尿液吸入导管口
518
从导管传感器获得尿液数据
520
处理传感器数据用于患者信息
522
向使用者显示患者信息
524

图 16