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(54) Title: DRUG DELIVERY DEVICES AND METHODS FOR USE WITH A URINARY CATHETER

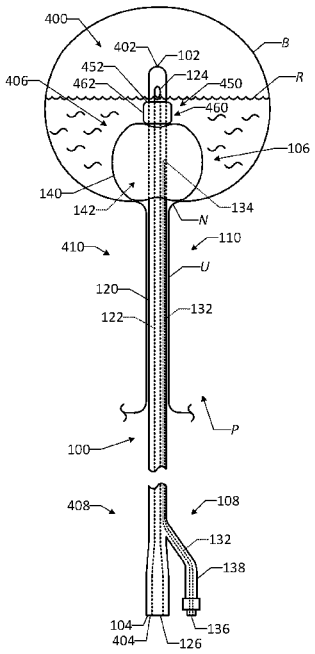

FIG. 4E

(57) Abstract: Drug delivery devices (200) and methods of their use are provided. In one embodiment, a drug delivery device (200) for use with a urinary catheter (100) includes a drug reservoir configured to be disposed outside of a patient's body, and a flexible elongate body (220) attached to the drug reservoir (230) and configured to traverse the patient's urethra to reach the bladder. The drug reservoir (230) includes a drug chamber (234) containing a drug therein, a fluid chamber (236) containing a fluid therein, and an osmotic barrier (238) separating the drug chamber (234) and the fluid chamber (236). The body includes a drug delivery lumen (222) extending therethrough and in fluid communication with the drug chamber (234).

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DRUG DELIVERY DEVICES AND METHODS FOR USE WITH A URINARY CATHETER

Cross-Reference to Related Applications

[0001] This application claims priority benefit to U.S. Provisional Patent Application No. 62/584,006, filed November 9, 2017, which is incorporated herein by reference.

Technical Field

[0002] This application relates generally to medical devices and methods, and more particularly to drug delivery devices and related methods of using such devices for controlled delivery of a drug to a selected region of the lower urinary tract, such as the bladder, of a catheterized patient.

Background

[0003] Various types of drug delivery devices and methods have been developed for delivering a drug to the lower urinary tract of a patient. For example, certain drug delivery devices may be implanted and retained in the patient's urinary bladder and configured to controllably release a drug therein over an extended period of time to treat a number of conditions. However, use of such drug delivery devices may not be practical, or even possible, when the patient is catheterized. Urinary catheters, such as Foley catheters, are often used in both acute (e.g., post-surgical) and chronic (e.g., spinal cord injury) settings to maintain continuous urethral patency. Because urinary catheters allow urine to drain freely from the bladder and thus keep the bladder continuously empty (aside from minimal residual urine), use of intravesical drug delivery devices which benefit from or require the presence of a substantial amount of urine in the bladder may not be optimal or feasible for catheterized patients. Additionally, a distal end portion of the urinary catheter residing in the bladder may interfere with desired interaction between the drug delivery device and the bladder and/or may inhibit desired movement of the drug delivery device within the bladder. Furthermore, the presence of the intravesical drug delivery device within the bladder, along with the distal end portion of the urinary catheter, may interfere with the desired function of the catheter and/or may result in issues of patient tolerability.

[0004] It therefore would be desirable to provide new and improved drug delivery devices and methods for controlled delivery of a drug to a selected region of the lower urinary tract, such as the bladder, of a catheterized patient. Such drug delivery devices

should be configured to be easily inserted into and removed from the bladder, either along with or separately from a urinary catheter, such as a Foley catheter. It would be advantageous for such devices to include a sufficiently large drug payload in order to provide drug delivery over an extended period of time, without interfering with the desired function of the urinary catheter and without occupying such a significant portion of the bladder that would result in patient tolerability issues. It also would be advantageous for such devices and methods to prevent or inhibit microbial infections that otherwise may develop from continued catheterization.

Brief Summary

[0005] Drug delivery devices, systems, and methods for controlled delivery of a drug to a selected region of the lower urinary tract, such as the bladder, of a catheterized patient are provided. According to one aspect, a drug delivery device for use with a urinary catheter is provided. In one embodiment, the drug delivery device includes a drug reservoir configured to be disposed outside of a patient's body, and a flexible elongate body attached to the drug reservoir and configured to traverse the patient's urethra to reach the bladder. The drug reservoir includes a drug chamber containing a drug therein, a fluid chamber containing a fluid therein, and an osmotic barrier separating the drug chamber and the fluid chamber. The body includes a drug delivery lumen extending therethrough and in fluid communication with the drug chamber.

[0006] In another aspect, a urinary catheter and drug delivery system is provided. In one embodiment, the system includes (i) a urinary catheter configured to allow urine to drain from a patient's bladder, and (ii) a drug delivery device configured for use with the urinary catheter. The urinary catheter includes a flexible elongate catheter body configured to traverse the patient's urethra to reach the bladder, and the catheter body includes a drainage lumen extending therethrough. The drug delivery device includes a drug reservoir configured to be disposed outside of the patient's body, and a flexible elongate device body attached to the drug reservoir and configured to traverse the patient's urethra to reach the bladder. The drug reservoir includes a drug chamber containing a drug therein, a fluid chamber containing a fluid therein, and an osmotic barrier separating the drug chamber and the fluid chamber. The body includes a drug delivery lumen extending therethrough and in fluid communication with the drug chamber.

[0007] In still another aspect, a method of administering a drug to a patient in need thereof is provided. In one embodiment, the method includes inserting distal end portions of

a drug delivery device and a urinary catheter through the patient's urethra and positioning the distal end portions within the bladder, while maintaining proximal end portions of the drug delivery device and the urinary catheter positioned outside of the patient's body; allowing urine to drain from the bladder through the urinary catheter; and delivering a drug, via osmotic pressure, from the proximal end portion of the drug delivery device into the bladder.

[0008] In another aspect, a urinary catheter and drug delivery system is provided. In one embodiment, the system includes (i) a urinary catheter configured to allow urine to drain from a patient's bladder, and (ii) a drug delivery device attached to the urinary catheter. The urinary catheter includes a flexible elongate catheter body configured to traverse the patient's urethra to reach the bladder, and the catheter body includes a drainage lumen extending therethrough from a distal opening to proximal opening defined in the catheter body. The drug delivery device includes a drug reservoir positioned near the distal opening of the drainage lumen and configured to be disposed within the patient's bladder, and the drug reservoir includes a drug chamber containing a drug therein.

[0009] In still another aspect, a method of administering a drug to a patient in need thereof is provided. In one embodiment, the method includes inserting a drug delivery device and a distal end portion of a urinary catheter through the patient's urethra and positioning the drug delivery device and the distal end portion of the urinary catheter within the bladder, wherein the urinary catheter includes a flexible elongate catheter body including a drainage lumen extending therethrough from a distal opening to proximal opening defined in the catheter body, and wherein the drug delivery device includes a drug reservoir positioned near the distal opening of the drainage lumen and including a drug chamber containing a drug therein; allowing urine to drain from the bladder through the drainage lumen; and delivering the drug from the drug chamber into the bladder.

[00010] These and other aspects and embodiments of the present disclosure will be apparent or will become apparent to one of ordinary skill in the art upon review of the following detailed description when taken in conjunction with the drawings and the appended claims.

Brief Description of the Drawings

[00011] The detailed description is set forth with reference to the accompanying drawings. The use of the same reference numerals may indicate similar or identical items. Various embodiments of the disclosure may utilize components and/or features other than those illustrated in the drawings, and the illustrated components and/or features may not be present

in various embodiments. Components and/or features illustrated in the drawings are not necessarily drawn to scale. In some figures, the relative size of certain components and/or features may be exaggerated for ease of illustration. Throughout this disclosure, depending on context, singular and plural terminology may be used interchangeably.

[00012] **FIG. 1A** is a plan view of a urinary catheter in accordance with one or more embodiments of the disclosure, showing a balloon of the catheter in a collapsed configuration.

[00013] **FIG. 1B** is a plan view of the urinary catheter of **FIG. 1A**, showing the balloon in an expanded configuration.

[00014] **FIG. 1C** is a detailed plan view of a distal end portion of the urinary catheter of **FIG. 1A**, showing the balloon in the collapsed configuration.

[00015] **FIG. 1D** is a detailed plan view of the distal end portion of the urinary catheter of **FIG. 1A**, showing the balloon in the expanded configuration.

[00016] **FIG. 1E** is a plan view of the urinary catheter of **FIG. 1A** positioned partially within a patient, showing the distal end portion of the urinary catheter positioned within the patient's bladder and a proximal end portion of the urinary catheter positioned outside of the patient's body.

[00017] **FIG. 2A** is a plan view of a drug delivery device in accordance with one or more embodiments of the disclosure, which may be used with the urinary catheter of **FIG. 1A**.

[00018] **FIG. 2B** is a side view of the drug delivery device of **FIG. 2A**.

[00019] **FIG. 2C** is a cross-sectional top view of the drug delivery device of **FIG. 2A**, taken along line 2C-2C in **FIG. 2B**.

[00020] **FIG. 2D** is a cross-sectional top view of the drug delivery device of **FIG. 2A**, taken along line 2D-2D in **FIG. 2B**.

[00021] **FIG. 3A** is a plan view of a urinary catheter and drug delivery system in accordance with one or more embodiments of the disclosure including the urinary catheter of **FIG. 1A** and the drug delivery device of **FIG. 2A**, showing the balloon of the catheter in the collapsed configuration.

[00022] **FIG. 3B** is a plan view of the urinary catheter and drug delivery system of **FIG. 3A**, showing the balloon of the catheter in the expanded configuration.

[00023] **FIG. 3C** is a detailed plan view of a distal end portion of the urinary catheter and drug delivery system of **FIG. 3A**, showing the balloon of the catheter in the collapsed configuration.

[00024] **FIG. 3D** is a detailed plan view of a distal end portion of the urinary catheter and drug delivery system of **FIG. 3A**, showing the balloon of the catheter in the expanded configuration.

[00025] **FIG. 3E** is a plan view of the urinary catheter and drug delivery system of **FIG. 3A** positioned partially within a patient, showing the distal end portion of the system positioned within the patient's bladder and a proximal end portion of the system positioned outside of the patient's body.

[00026] **FIG. 3F** is a detailed plan view of a distal end portion of a urinary catheter and drug delivery system in accordance with one or more embodiments of the disclosure including the urinary catheter of **FIG. 1A** and the drug delivery device of **FIG. 2A**, showing the balloon of the catheter in the collapsed configuration.

[00027] **FIG. 3G** is a detailed plan view of the distal end portion of the urinary catheter and drug delivery system of **FIG. 3F**, showing the balloon of the catheter in the expanded configuration.

[00028] **FIG. 3H** is a detailed plan view of a distal end portion of a urinary catheter and drug delivery system in accordance with one or more embodiments of the disclosure including the urinary catheter of **FIG. 1A** and the drug delivery device of **FIG. 2A**, showing the balloon of the catheter in the collapsed configuration.

[00029] **FIG. 3I** is a detailed plan view of the distal end portion of the urinary catheter and drug delivery system of **FIG. 3H**, showing the balloon of the catheter in the expanded configuration.

[00030] **FIG. 3J** is a detailed plan view of a distal end portion of a urinary catheter and drug delivery system in accordance with one or more embodiments of the disclosure including the urinary catheter of **FIG. 1A** and the drug delivery device of **FIG. 2A**, showing the balloon of the catheter in the collapsed configuration.

[00031] **FIG. 3K** is a detailed plan view of the distal end portion of the urinary catheter and drug delivery system of **FIG. 3J**, showing the balloon of the catheter in the expanded configuration.

[00032] **FIG. 4A** is a plan view of a urinary catheter and drug delivery system in accordance with one or more embodiments of the disclosure including the urinary catheter of **FIG. 1A** and a drug delivery device, showing the balloon of the catheter in the collapsed configuration.

[00033] **FIG. 4B** is a plan view of the urinary catheter and drug delivery system of **FIG. 4A**, showing the balloon of the catheter in the expanded configuration.

[00034] **FIG. 4C** is a detailed plan view of a distal end portion of the urinary catheter and drug delivery system of **FIG. 4A**, showing the balloon of the catheter in the collapsed configuration.

[00035] **FIG. 4D** is a detailed cross-sectional plan view of a distal end portion of the urinary catheter and drug delivery system of **FIG. 4A**, showing the balloon of the catheter in the collapsed configuration.

[00036] **FIG. 4E** is a plan view of the urinary catheter and drug delivery system of **FIG. 4A** positioned partially within a patient, showing the distal end portion of the system positioned within the patient's bladder and a proximal end portion of the system positioned outside of the patient's body.

[00037] **FIG. 5A** is a plan view of a urinary catheter and drug delivery system in accordance with one or more embodiments of the disclosure including a urinary catheter and a drug delivery device, showing the balloon of the catheter in the collapsed configuration.

[00038] **FIG. 5B** is a plan view of the urinary catheter and drug delivery system of **FIG. 5A**, showing the balloon of the catheter in the expanded configuration.

[00039] **FIG. 5C** is a detailed plan view of a distal end portion of the urinary catheter and drug delivery system of **FIG. 5A**, showing the balloon of the catheter in the collapsed configuration.

[00040] **FIG. 5D** is a detailed cross-sectional plan view of a distal end portion of the urinary catheter and drug delivery system of **FIG. 5A**, showing the balloon of the catheter in the collapsed configuration.

[00041] **FIG. 5E** is a plan view of the urinary catheter and drug delivery system of **FIG. 4A** positioned partially within a patient, showing the distal end portion of the system positioned within the patient's bladder and a proximal end portion of the system positioned outside of the patient's body.

Detailed Description

[00042] Improved drug delivery devices, systems, and methods have been developed for controlled delivery of a drug to a selected region of the lower urinary tract, such as the bladder, of a catheterized patient. The drug delivery devices may be used with a urinary catheter, such as a Foley catheter, which collectively form a urinary catheter and drug delivery system. The drug delivery devices advantageously include a drug reservoir that resides outside of the patient's body during use of the device and is configured to operate as an osmotic pump to push a drug from the reservoir through a flexible elongate luminal body

(e.g., a capillary tube) extending along or through the catheter for release of the drug into the bladder. The positioning of the drug reservoir outside of the patient's body advantageously allows the drug delivery device to include a sufficiently large drug payload for drug delivery over an extended period of time, while minimizing interference with the desired function of the urinary catheter and reducing the likelihood of patient tolerability issues. The drug delivery devices, systems, and methods may be used to controllably release a drug into the patient's bladder over an extended period of time to treat a number of bladder conditions, while also preventing or inhibiting microbial infections that otherwise may develop from continued catheterization.

[00043] The drug delivery device may be provided along with a urinary catheter, such as a Foley catheter, to collectively form a urinary catheter and drug delivery system. The system may be provided with the device and the catheter pre-assembled and permanently attached to one another, or the device and the catheter may be provided separately and configured for releasable attachment to one another. Alternatively, the drug delivery device may be configured for use in conjunction with a conventional urinary catheter, such as a commercially available Foley catheter.

[00044] As used herein, the term "patient" refers primarily to a human adult or child, but also may include other suitable mammalian animals, for example in a pre-clinical trial or in veterinary care.

[00045] Urinary Catheter

[00046] **FIGS. 1A-1E** illustrate a urinary catheter **100** (which also may be referred to as a "Foley catheter" or simply a "catheter") configured to allow urine to drain freely from a patient's bladder, in accordance with one or more embodiments of the disclosure. During use, a portion of the catheter **100** may be inserted through the patient's urethra and into the bladder to maintain continuous urethral patency. Although the illustrated embodiment of the catheter **100** is configured as a Foley catheter, other types of catheters may be used in accordance with other embodiments of the disclosure. As described below, the urinary catheter **100** may be used with a drug delivery device **200** to form a urinary catheter and drug delivery system **300** which allows for continuous urine drainage in addition to controlled delivery of a drug to a selected region of the patient's lower urinary tract, such as the bladder, over an extended period of time.

[00047] As shown in **FIG. 1A**, the urinary catheter **100** has an elongated shape including a distal end **102** (which also may be referred to as a "bladder end") and a proximal end **104** (which also may be referred to as an "external end") positioned along a longitudinal axis *A* of

the catheter **100**. The urinary catheter **100** includes a distal end portion **106** (which also may be referred to as a "bladder end portion") extending from the distal end **102** toward the proximal end **104** along the longitudinal axis *A*, a proximal end portion **108** (which also may be referred to as an "external end portion") extending from the proximal end **104** toward the distal end **102** along the longitudinal axis *A*, and an intermediate portion **110** (which also may be referred to as a "urethral portion") extending axially from the distal end portion **106** to the proximal end portion **108**. When the catheter **100** is used to allow urine to drain from the patient's bladder, the distal end portion **106** may be inserted through the urethra and into the bladder, while the intermediate portion **110** resides within the urethra and the proximal end portion **108** resides outside of the patient's body.

[00048] The urinary catheter **100** includes a flexible elongate body **120** (which also may be referred to as a "catheter body" or a "catheter tube") and an inflatable balloon **140** attached to the body **120**, as shown. The body **120** may extend axially from the distal end **102** to the proximal end **104** of the catheter **100** and may be configured to traverse the patient's urethra to reach the bladder. As shown, the body **120** may have an elongated tubular shape and a circular cross-sectional shape, although other shapes of the body **120** may be used. As shown, a longitudinal axis of the body **120** may be coaxial with the longitudinal axis *A* of the catheter **100**. The body **120** may include a drainage lumen **122** (which also may be referred to as a "primary lumen") extending axially through the catheter **100** and configured to allow urine to flow therethrough from the bladder to a collection bag attached to the proximal end **104** of the catheter **100**. In particular, the drainage lumen **122** may extend from a distal opening **124** (which also may be referred to as a "drainage entry opening") defined in the body **120** to a proximal opening **126** (which also may be referred to as a "drainage exit opening") defined in the body **120**. As shown, the distal opening **124** may be defined in a sidewall of the body **120** and positioned near but spaced apart from the distal end **102** of the catheter **100**, and the proximal opening **126** may be defined in or near the proximal end **104** of the catheter **100**. In some embodiments, as shown, the drainage lumen **122** has a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the drainage lumen **122** may be used. In some embodiments, as shown, a longitudinal axis of the drainage lumen **122** is coaxial with the longitudinal axis of the body **120** and the longitudinal axis A_L of the catheter **100**.

[00049] The body **120** also may include an inflation lumen **132** (which also may be referred to as a "secondary lumen") extending axially through the catheter **100** and configured to allow a fluid, such as sterile water, to be delivered therethrough from a fluid

source attached to the proximal end **104** of the catheter **100** for inflation of the balloon **140**. In particular, the inflation lumen **132** may extend from a distal opening **134** (which also may be referred to as a "inflation exit opening") defined in the body **120** to a proximal opening **136** (which also may be referred to as a "inflation entry opening") defined in the body **120**. As shown, the distal opening **134** may be defined in a sidewall of the body **120** and spaced apart from the distal end **102** of the catheter **100**, and the proximal opening **136** may be defined in or near the proximal end **104** of the catheter **100**. For example, the proximal opening **136** may be defined in the proximal end of an inflation arm **138** of the body **120**. In some embodiments, as shown, the inflation lumen **132** has a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the inflation lumen **132** may be used. In some embodiments, as shown, a longitudinal axis of the inflation lumen **132** is offset from the longitudinal axis of the body **120** and the longitudinal axis *A* of the catheter **100**.

[00050] The balloon **140** may be attached to body **120** and configured to be inflated from a collapsed configuration (which also may be referred to as a "deflated configuration"), as shown in **FIG. 1A**, to an expanded configuration (which also may be referred to as an "inflated configuration"), as shown in **FIG. 1B**. As shown, the balloon **140** may be positioned near but proximally spaced apart from the distal end **102** of the catheter **100**. The balloon **140** also may be positioned near but proximally spaced apart from the distal opening **124** of the drainage lumen **122**. The balloon **140** may be positioned over the distal opening **134** of the inflation lumen **132** and may include an internal cavity **142** in fluid communication with the inflation lumen **132**. In this manner, the fluid may be passed through the inflation lumen **132** and fill the cavity **142** to inflate the balloon **140** from the collapsed configuration to the expanded configuration.

[00051] **FIG. 1E** illustrates use of the urinary catheter **100** to allow urine to drain from the bladder *B* of a patient *P*. With the balloon **140** in the collapsed configuration, the distal end portion **106** of the catheter **100** may be inserted through the urethra *U* and into the bladder *B*, such that the balloon **140** is disposed within the bladder *B* adjacent the bladder neck *N*, while the intermediate portion **110** of the catheter **100** is disposed within the urethra *U* and the proximal end portion **108** is disposed outside of the body of the patient *P*. Fluid, such as sterile water, then may be passed through the inflation lumen **132** and into the cavity **142** to inflate the balloon **140** to the expanded configuration, such that the balloon **140** forms a seal against the bladder neck *N*. With the catheter **100** positioned as shown in **FIG. 1E**, urine may freely enter the distal opening **124** of the drainage lumen **122**, pass through the drainage lumen **122**, and be collected in a collection bag attached to the proximal end **104** of the

catheter **100**. As shown, some residual urine ***R*** may remain in the bladder ***B*** due to the position of the distal opening **124** of the drainage lumen **122** relative to the bladder neck *N*.

[00052] Although the urinary catheter **100** is shown and described as being a Foley catheter including the body **120** and the balloon **140**, it will be appreciated that other configurations of the catheter **100**, with or without a balloon, may be used according to various embodiments of the disclosure. Further, the catheter **100** may include other components and/or features in addition to those shown in the figures and described herein.

[00053] Drug Delivery Device

[00054] **FIGS. 2A-2E** illustrate a drug delivery device **200** (which also may be referred to as a "therapeutic agent delivery device" or simply a "device") in accordance with one or more embodiments of the disclosure. The drug delivery device **200** may be configured to controllably release a drug to a selected region of the lower urinary tract, such as the bladder, of a catheterized patient. During use, a portion of the drug delivery device **200** may be inserted through the patient's urethra and into the bladder to provide a pathway for delivering the drug to the selected region. As described below, the drug delivery device **200** may be used with the urinary catheter **100** to form a urinary catheter and drug delivery system **300** which allows for continuous urine drainage in addition to controlled delivery of a drug to a selected region of the patient's lower urinary tract, such as the bladder, over an extended period of time.

[00055] As shown in **FIG. 2A**, the drug delivery device **200** has an elongated shape including a distal end **202** (which also may be referred to as a "bladder end") and a proximal end **204** (which also may be referred to as an "external end"). The device **200** includes a distal end portion **206** (which also may be referred to as a "bladder end portion") extending from the distal end **202** toward the proximal end **204**, a proximal end portion **208** (which also may be referred to as an "external end portion") extending from the proximal end **204** toward the distal end **202**, and an intermediate portion **210** (which also may be referred to as a "urethral portion") extending from the distal end portion **206** to the proximal end portion **208**. When the drug delivery device **200** is used to deliver a drug to a selected region of the lower urinary tract, such as the patient's bladder, the distal end portion **206** may be inserted through the urethra and into the bladder, while the intermediate portion **210** resides within the urethra and the proximal end portion **208** resides outside of the patient's body.

[00056] The drug delivery device **200** includes a flexible elongate body **220** (which also may be referred to as a "drug delivery body" or a "drug delivery tube") and a drug reservoir **230** (which also may be referred to as an "external drug reservoir") attached to the body **220**,

as shown. The body **220** may extend axially from the distal end **202** toward the proximal end **204** of the device **200** and may be configured to traverse the patient's urethra to reach the bladder. As shown, the body **220** may have an elongated tubular shape and a circular cross-sectional shape, although other shapes of the body **220** may be used. In some embodiments, the body **220** is formed as a capillary tube. The body **220** may include a drug delivery lumen **222** (which also may be referred to as a "primary lumen") extending axially through the body **220** and configured to allow a drug to pass therethrough from the drug reservoir **230** to the patient's bladder. In particular, the drug delivery lumen **222** may extend from a distal opening **224** (which also may be referred to as a "drug exit opening") defined in the body **220** to a proximal opening **226** (which also may be referred to as a "drug entry opening") defined in the body **220**. As shown, the distal opening **224** may be defined in or near the distal end of the body **220** and positioned at or near the distal end **202** of the device **200**, and the proximal opening **226** may be defined in or near the proximal end of the body **220** and positioned at or near the proximal end **204** of the device **200**. In some embodiments, as shown, the drug delivery lumen **222** has a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the drug delivery lumen **222** may be used.

[00057] The drug reservoir **230** may include a housing **232** having a plurality of chambers defined therein. In particular, the drug reservoir **230** may include a drug chamber **234** (which also may be referred to as a "therapeutic agent chamber") and a fluid chamber **236** (which also may be referred to as a "water chamber") defined therein. The drug chamber **234** may be configured to contain a drug therein, and the fluid chamber **236** may be configured to contain a fluid therein. As shown, the drug chamber **234** and the fluid chamber **236** may be separated by an osmotic barrier **238** (which also may be referred to as a "semi-permeable barrier"). In this manner, the drug chamber **234** may be defined by (i.e., bounded by) a portion of the housing **232** and the osmotic barrier **238**, and the fluid chamber **236** may be defined by another portion of the housing **232** and the osmotic barrier **238**. As shown, the drug chamber **234** and the fluid chamber **236** may be separated by only the osmotic barrier **238**. In other words, a first surface of the osmotic barrier **238** may extend along and define a portion of the drug chamber **234**, and an opposite second surface of the osmotic barrier **238** may extend along and define a portion of the fluid chamber **236**.

[00058] The drug reservoir **230** may include a drug **244** disposed within the drug chamber **234**, and a fluid **246** disposed within the fluid chamber **236**. In some embodiments, the drug **244** fills or substantially fills the drug chamber **234**, and the fluid **246** fills or substantially fills the fluid chamber **236**. In some embodiments, the drug **244** is in a solid form. For

example, the drug **244** may be in the form of a unitary block that fills or substantially fills the drug chamber **234** or a plurality of tablets, capsules, particles, microparticles, or other solid drug units that fill or substantially fill the drug chamber **234**. In other embodiments, the drug **244** is in a semi-solid form or a liquid form that fills or substantially fills the drug chamber **234**. In some embodiments, the fluid **246** is sterile water or an aqueous solution (e.g., saline), although other suitable fluids may be used. The term "fluid" as used herein refers to incompressible fluids, i.e., liquids, not gases.

[00059] The osmotic barrier **238** may be a semi-permeable wall that is configured to allow the fluid **246** to pass therethrough but to prevent the drug **244** from passing therethrough. For example, the osmotic barrier **238** may be a water-permeable wall. In this manner, the osmotic barrier **238** may allow the fluid **246** to pass therethrough and into the drug chamber **234**. In embodiments in which the drug **244** is in a solid or semi-solid form, the fluid **246** may solubilize the drug **244** within the drug chamber **234**. The passage of the fluid **246** through the osmotic barrier **238** and into the drug chamber **234** may create osmotic pressure within the drug chamber **234**. As shown, the drug delivery lumen **222** of the body **220** may be in fluid communication with the drug chamber **234** via the distal opening **224** of the lumen **222** and a corresponding opening defined in the housing **232** of the drug reservoir **230** adjacent the drug chamber **234**. Accordingly, the osmotic pressure created within the drug chamber **234** may drive the drug **244** out of the drug chamber **234**, through the drug delivery lumen **222**, and out of the drug delivery device **200**. In this manner, the drug reservoir **230** may be configured to operate as an osmotic pump to controllably release the drug **244** from the drug delivery device **200** and into a selected region of the lower urinary tract, such as the bladder.

[00060] In embodiments, the proximal portion and drug reservoir of the drug delivery device, in use, may be configured to be secured to the patient, particularly for ambulatory patients. For example, the drug reservoir may be strapped to the patient, e.g., about one of the thighs of the patient. For instance, the drug reservoir may be secured within a soft fabric pouch that is connected to a pair of fabric straps connectable to one another by hook-and-loop fasteners or other adjustable fasteners.

[00061] Flexible Elongate Body

[00062] The flexible elongate body **220** of the drug delivery device **200** is sized and shaped to extend through the urethra of a patient and into the bladder. The body **220** is elastic/flexible such that the body **220** may be easily maneuvered for deployment and positioning within the urethra without undue complications and with minimal discomfort to

the patient. When the device **200** is inserted into the patient, the distal end portion **206** is positioned within the bladder, the intermediate portion **210** is positioned within the urethra, and the proximal end portion **208** is positioned outside of the patient's body. In this manner, the drug delivery lumen **222** of the body **220** extends from outside of the patient's body, through the urethra, and into the bladder to facilitate delivery of the drug **244** from outside of the patient's body to the bladder.

[00063] The flexible elongate body **220** is generally made of biocompatible polymeric materials known in the art. In some embodiments, the biocompatible polymeric material is silicone or other non-resorbable polymers known in the art. Examples of suitable materials of construction include poly(ethers), poly(acrylates), poly(methacrylates), poly(vinyl pyrolidones), poly(vinyl acetates), poly(urethanes), celluloses, cellulose acetates, poly(siloxanes), poly(ethylene), poly(tetrafluoroethylene) and other fluorinated polymers, poly(siloxanes), copolymers thereof, and combinations thereof. In some embodiments, the body **220** defining the drug delivery lumen **222** is or includes a capillary tube or similar structure. The tube forming the drug delivery lumen **222** may be configured to have suitable wall strength and resistance to compression such that it resists collapse or constriction when deployed in the urethra.

[00064] Drug Reservoir

[00065] The drug reservoir **220** of the drug delivery device **200** includes the housing **232** and the osmotic barrier **238** which define the chambers of the reservoir **220**. As described above, the drug reservoir **220** remains outside of the patient's body during use of the device **200**. The drug chamber **234** is defined by (i.e., bounded by) a portion of the housing **232** and the osmotic barrier **238**, and the fluid chamber **236** similarly is defined by a portion of the housing **232** and the osmotic barrier **238**. The housing **232** includes one or more outer walls that are impermeable to the drug **244** contained within the drug chamber **234** and the fluid **246** contained within the fluid chamber **236**. The wall or walls of the housing **232** may be formed of any suitable material, such as a biocompatible polymeric material. In some embodiments, the wall or walls of the housing **232** are formed of the same material as the flexible elongate body **220**, although the housing **232** and the body **220** may be formed of different materials in other embodiments. In some embodiments, the wall or walls of the housing **232** are integrally formed with the body **220**. For example, the housing **232** and the body **220** may be integrally molded as a unitary structure. In other embodiments, the wall of walls of the housing **232** and the body **220** are separately formed and attached to one another. For example, the housing **232** and the body **220** may be separately formed by extrusion,

molding, or a combination thereof, and then attached to other another by a biocompatible adhesive, ultrasonic welding, or other means of attachment.

[00066] The osmotic barrier **238** may be a semi-permeable wall, as described above. In particular, the osmotic barrier **238** may be formed of a semi-permeable material that is effective to permit the fluid **246** in the fluid chamber **236** to permeate therethrough and enter the drug chamber **234**. The osmotic barrier **238** may be semi-permeable in that, while it is permeable to the fluid **246**, such as water, it is substantially or completely impermeable to the drug **244** in the drug chamber **234** and/or an excipient. In this manner, the solubilized drug **244** and excipients cannot diffuse through the osmotic barrier **238** and into the fluid chamber **236**. Accordingly, during use of the device **200**, the fluid **246** enters the drug chamber **234**, solubilizes the drug **244** as well as any excipient (e.g., an osmotic excipient) contained in the drug chamber **234**, creating osmotic pressure in the drug chamber **234**. The osmotic pressure causes the solubilized drug **244** to be pumped from the drug chamber **234** into and through the drug delivery lumen **222** of the body **220**, and directly into the bladder via the distal opening **224**. Non-limiting examples of suitable, semi-permeable materials of construction for the osmotic barrier **238** include silicones and polyurethanes known in the art.

[00067] Drug

[00068] The drug **244** can be any suitable therapeutic, prophylactic, or diagnostic agent. The drug **244** stored in and released from the device **200** may consist only of the pharmaceutically active ingredient (API) or other agent of interest, or the drug **244** may be formulated with one or more pharmaceutically acceptable excipients. The drug **244** may be a biologic. The drug **244** may be a metabolite. As used herein, the term "drug" with reference to any specific drug described herein includes its alternative forms, such as salt forms, free acid forms, free base forms, and hydrates. In some embodiments, the drug is a high solubility drug. As used herein, the term "high solubility" refers to a drug having a solubility above about 10 mg/mL water at 37 °C. In other embodiments, the drug is a low solubility drug. As used herein, the term "low solubility" refers to a drug having a solubility from about 0.001 mg/mL to about 10 mg/mL water at 37 °C. The solubility of the drug may be affected at least in part by its form and dissolution medium pH. For example, a drug in the form of a water soluble salt may have a high solubility, while the same drug in base form may have a low solubility.

[00069] Pharmaceutically acceptable excipients are known in the art and may include lubricants, viscosity modifiers, surface active agents, osmotic agents, diluents, and other non-active ingredients of the formulation intended to facilitate handling, stability, dispersibility,

wettability, and/or release kinetics of the drug. The excipient may facilitate loading of solid drug units into the drug reservoir of the device. The excipient also may facilitate forming a therapeutic agent into a solid drug tablet that can be loaded into the drug reservoir. The excipients also may affect the kinetics of drug release from the device, such as by increasing or retarding the solubility or dissolution rate of the drug. In some embodiments, however, the drug release rate is predominately controlled by characteristics of the drug reservoir, such as the thickness and water permeability of the semi-permeable wall.

[00070] The drug **244** is to be released from the drug delivery device **200** at a therapeutically effective rate. For some drugs, this may require the addition of one or more excipients, e.g., an osmotic agent to increase water flux, solubilizing or solubility enhancing agent, pH adjusting agent, or stability enhancing agent. Generally, the combination of the solubility of the selected drug in the presence or absence of functional agents, if any, and osmotic pressure flux will determine the release rate and duration, and such combination can be configured for the rate and duration to be within a therapeutically effective range. In embodiments in which the drug is a low solubility drug, the drug may be formulated with an osmotic agent having a higher solubility than the drug, such that the osmotic agent expedites solubilization, causes osmotic pressure flux, and/or subsequent release of the drug. This beneficially allows for the delivery of low solubility or other drugs typically only delivered via diffusion, from osmotic delivery-based devices as described herein.

[00071] The drug **244** can be loaded and stored in the device **200** in any suitable form. In some embodiments, the drug **244** is in a solid or semi-solid drug formulation in order to reduce the overall volume of the drug chamber **234** and the overall drug reservoir **230**. The semi-solid form may be, for example, an emulsion or suspension; a gel or a paste. The solid form may be, for example, tablets, mini-tablets, pellets, beads, granules, or a powder. In an alternative embodiment, the drug **244** is loaded into the drug chamber **234** in a liquid form. In some embodiments, the drug **244** is preloaded into the drug chamber **234** during manufacture of the drug delivery device **200**. In other embodiments, the drug **244** is loaded into the drug chamber **234** by a clinician just prior to use of the device **200**.

[00072] In some embodiments, the drug **244** includes an antimicrobial agent, such as an antibiotic, antifungal, or antiseptic agent. In this manner, the drug delivery device **200** may be effective in the treatment or prevention of catheter-associated urinary tract infections. In some embodiments, the drug **244** includes an antifibrotic or other agent configured to promote wound healing. In this manner, the drug delivery device **200** may be effective in the prevention of scar tissue formation in a post-surgical setting. In some embodiments, the drug

244 includes an antimuscarinic agent. In this manner, the drug delivery device **200** may be effective in the treatment patients with bladder overactivity (e.g., spinal cord injury patients) who have chronic indwelling catheters. In some embodiments, the drug **244** includes an agent which catalyzes or re-dissolves stones or breaks down biofilms, which may include pharmacological or nonpharmacological agents. In this manner, the drug delivery device **200** may be effective in the prevention of encrustation, stone, or biofilm formation. It will be appreciated that the above-described embodiments of the drug **244** and uses of the drug delivery device **200** are merely examples, as the device **200** may be used to treat or prevent various conditions using various formulations of the drug **244**.

[00073] In one embodiment, the devices provide pain relief to the patient. A variety of anesthetic agents, analgesic agents, and combinations thereof may be used as the drug **244**. In embodiments, the device delivers one or more anesthetic agents. Representative examples of aminoamides or amide-class anesthetics include articaine, bupivacaine, carticaine, cinchocaine, etidocaine, levobupivacaine, lidocaine, mepivacaine, prilocaine, ropivacaine, and trimecaine. Representative examples of aminoesters or ester-class anesthetics include amylocaine, benzocaine, butacaine, chloroprocaine, cocaine, cyclomethycaine, dimethocaine, hexylcaine, larocaine, meprylcaine, metabutoxycaine, orthocaine, piperocaine, procaine, proparacaine, propoxycaine, proxymetacaine, risocaine, and tetracaine. The anesthetic agent may be formulated as a salt, such as a hydrochloride salt, to render them water-soluble, although the anesthetic agent also can be used in free base or hydrate form. Other anesthetics, such as lontocaine, may be used. The drug may be an antimuscarinic compound that exhibits an anesthetic effect, such as oxybutynin or propiverine.

[00074] In one embodiment, the analgesic agent includes an opioid. Representative examples of opioid agonists include alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, desomorphine, dextromoramide, dezocine, diampromide, diamorphone, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levorphanol, levophenacylmorphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metopon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, nalorphine, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phenomorphan, phenazocine, phenoperidine, piminodine, piritramide, proheptazine, promedol, properidine,

propiram, propoxyphene, sufentanil, tilidine, tramadol, pharmaceutically acceptable salts thereof, and mixtures thereof. Other opioid drugs, such as mu, kappa, delta, and nociception opioid receptor agonists, are contemplated.

[00075] Representative examples of other suitable pain relieving agents include such agents as salicyl alcohol, phenazopyridine hydrochloride, acetaminophen, acetylsalicylic acid, flufenisal, ibuprofen, indoprofen, indomethacin, and naproxen.

[00076] In one embodiment, the drug delivery device includes a drug **244** which is used to treat inflammatory conditions such as interstitial cystitis (IC), radiation cystitis, painful bladder syndrome, prostatitis, urethritis, post-surgical pain, and kidney stones. Non-limiting examples of drugs for these conditions include lidocaine, glycosaminoglycans (e.g., chondroitin sulfate, sulodexide), pentosan polysulfate sodium (PPS), dimethyl sulfoxide (DMSO), oxybutynin, mitomycin C, heparin, flavoxate, ketorolac, or a combination thereof. For kidney stones, the drug(s) may be selected to treat pain and/or to promote dissolution of renal stones. Other non-limiting examples of drugs that may be used in the treatment of IC include nerve growth factor monoclonal antibody (MAB) antagonists, such as Tanezumab, and calcium channel alpha-2-delta modulators, such as PD-299685 or gabepentin.

[00077] In one embodiment, the drug delivery device includes a drug **244** which is used to treat urinary incontinence, frequency, or urgency, including urge incontinence and neurogenic incontinence, as well as trigonitis. Drugs that may be used include anticholinergic agents, antispasmodic agents, anti-muscarinic agents, β-2 agonists, alpha adrenergics, anticonvulsants, norepinephrine uptake inhibitors, serotonin uptake inhibitors, calcium channel blockers, potassium channel openers, and muscle relaxants. Representative examples of drugs for the treatment of incontinence include oxybutynin, S-oxybutytin, emepronium, verapamil, imipramine, flavoxate, atropine, propantheline, tolterodine, rociverine, clenbuterol, darifenacin, terodiline, trospium, hyoscyamin, propiverine, desmopressin, vamicamide, clidinium bromide, dicyclomine HCl, glycopyrrolate aminoalcohol ester, ipratropium bromide, mepenzolate bromide, methscopolamine bromide, scopolamine hydrobromide, iotropium bromide, fesoterodine fumarate, YM-46303 (Yamanouchi Co., Japan), lanperisone (Nippon Kayaku Co., Japan), inaperisone, NS-21 (Nippon Shinyaku Orion, Formenti, Japan/Italy), NC-1800 (Nippon Chemiphar Co., Japan), Z D-6169 (Zeneca Co., United Kingdom), and stilonium iodide.

[00078] In one embodiment, the drug delivery device includes a drug **244** which is used to treat urinary tract cancer, such as bladder cancer and prostate cancer. Drugs that may be used include antiproliferative agents, cytotoxic agents, chemotherapeutic agents, or a combination

thereof. Representative examples of drugs which may be suitable for the treatment of urinary tract cancer include Bacillus Calmette Guerin (BCG) vaccine, cisplatin, doxorubicin, valrubicin, gemcitabine, mycobacterial cell wall-DNA complex (MCC), methotrexate, vinblastine, thiotepa, mitomycin, fluorouracil, leuprolide, diethylstilbestrol, estramustine, megestrol acetate, cyproterone, flutamide, a selective estrogen receptor modulators (i.e. a SERM, such as tamoxifen), botulinum toxins, and cyclophosphamide. The drug may be a biologic, and it may comprise a monoclonal antibody, a TNF inhibitor, an anti-leukin, or the like. The drug also may be an immunomodulator, such as a TLR agonist, including imiquimod or another TLR7 agonist. The drug also may be a kinase inhibitor, such as a fibroblast growth factor receptor-3 (FGFR3)-selective tyrosine kinase inhibitor, a phosphatidylinositol 3 kinase (PI3K) inhibitor, or a mitogen-activated protein kinase (MAPK) inhibitor, among others or combinations thereof. Other examples include celecoxib, erolotinib, gefitinib, paclitaxel, polyphenon E, valrubicin, neocarzinostatin, apaziquone, Belinostat, Ingenol mebutate, Urocidin (MCC), Proxinium (VB 4845), BC 819 (BioCancell Therapeutics), Keyhole limpet haemocyanin, LOR 2040 (Lorus Therapeutics), urocanic acid, OGX 427 (OncoGenex), and SCH 721015 (Schering-Plough). The drug treatment may be coupled with a conventional radiation or surgical therapy targeted to the cancerous tissue.

[00079] In another embodiment, the drug **244** for intravesical cancer treatment may include small molecules, such as Apaziquone, adriamycin, AD-32, doxorubicin, doxetaxel, epirubicin, gemcitabine, HTI-286 (hemiasterlin analogue), idarubicin, γ-linolenic acid, mitozantrone, meglumine, and thiotepa; large molecules, such as Activated macrophages, activated T cells, EGF-dextran, HPC-doxorubicin, IL-12, IFN-a2b, IFN-γ, α-lactalbumin, p53 adenovector, TNFα; combinations, such as Epirubicin + BCG, IFN + farmarubicin, Doxorubicin + 5-FU (oral), BCG + IFN, and Pertussis toxin + cystectomy; activated cells, such as macrophages and T cells; intravesical infusions such as IL-2 and Doxorubicin; chemosensitizers, such as BCG+antifirinolytics (paramethylbenzoic acid or aminocaproic acid) and Doxorubicin + verapimil; diagnostic/imaging agents, such as Hexylaminolevulinate, 5-aminolevulinic acid, Iododexyuridine, HMFG1 Mab+Tc99m; and agents for the management of local toxicity, such as Formaline (hemorrhagic cystitis).

[00080] In one embodiment, the drug delivery device includes a drug **244** which is used to treat infections involving the bladder, the prostate, and the urethra. Antibiotics, antibacterial, antifungal, antiprotozoal, antiseptic, antiviral and other antiinfective agents can be administered for treatment of such infections. Representative examples of drugs for the

treatment of infections include mitomycin, ciprofloxacin, norfloxacin, ofloxacin, methanamine, nitrofurantoin, ampicillin, amoxicillin, nafcillin, trimethoprim, sulfonamides trimethoprimsulfamethoxazole, erythromycin, doxycycline, metronidazole, tetracycline, kanamycin, penicillins, cephalosporins, and aminoglycosides.

[00081] In one embodiment, the drug delivery device includes a drug **244** which is used to treat fibrosis of a genitourinary site, such as the bladder or uterus. Representative examples of drugs for the treatment of fibroids include pentoxphylline (xanthine analogue), antiTNF, antiTGF agents, GnRH analogues, exogenous progestins, antiprogestins, selective estrogen receptor modulators, danazol and NSAIDs.

[00082] In one embodiment, the drug delivery device includes a drug **244** which is used to treat neurogenic bladder. Representative examples of drugs for the treatment of neurogenic bladder include analgesics or anaesthetics, such as lidocaine, bupivacaine, mepivacaine, prilocaine, articaine, and ropivacaine; anticholinergics; antimuscarinics such as oxybutynin or propiverine; a vanilloid, such as capsaicin or resiniferatoxin; antimuscarinics such as ones that act on the M3 muscarinic acetylcholine receptor (mAChRs); antispasmodics including GABAB agonists such as baclofen; botulinum toxins; capsaicins; alpha-adrenergic antagonists; anticonvulsants; serotonin reuptake inhibitors such as amitriptyline; and nerve growth factor antagonists. In various embodiments, the drug may be one that acts on bladder afferents or one that acts on the efferent cholinergic transmission, as described in Reitz et al., Spinal Cord 42:267-72 (2004).

[00083] In one embodiment, the drug **244** is selected from those known for the treatment of incontinence due to neurologic detrusor overactivity and/or low compliant detrusor. Examples of these types of drugs include bladder relaxant drugs (e.g., oxybutynin (antimuscarinic agent with a pronounced muscle relaxant activity and local anesthetic activity), propiverine, impratroprium, tiotropium, trospium, terodiline, tolterodine, propantheline, oxyphencyclimine, flavoxate, and tricyclic antidepressants; drugs for blocking nerves innervating the bladder and urethra (e.g., vanilloids (capsaicin, resiniferatoxin), botulinum-A toxin); or drugs that modulate detrusor contraction strength, micturition reflex, detrusor sphincter dyssynergia (e.g., GABAb agonists (baclofen), benzodiazapines). The drug may be selected from those known for the treatment of incontinence due to neurologic sphincter deficiency. Examples of these drugs include alpha adrenergic agonists, estrogens, beta-adrenergic agonists, tricyclic antidepressants (imipramine, amitriptyline). The drug may be selected from those known for facilitating bladder emptying (e.g., alpha adrenergic antagonists (phentolamine) or cholinergics). The drug may be selected from among

anticholinergic drugs (e.g., dicyclomine), calcium channel blockers (e.g., verapamil) tropane alkaloids (e.g., atropine, scopolamine), nociceptin/orphanin FQ, and bethanechol (e.g., m3 muscarinc agonist, choline ester).

[00084] Urinary Catheter and Drug Delivery System

[00085] **FIGS. 3A-3I** illustrate a urinary catheter and drug delivery system **300** (which also may be referred to as simply a "system") in accordance with one or more embodiments of the disclosure. As shown, the system **300** includes the urinary catheter **100** and the drug delivery device **200**, which each may provide the functions described above. The drug delivery device **200** may be permanently or removably attached to the urinary catheter **100**. In this manner, the urinary catheter **100** may serve as a support structure for positioning and supporting the drug delivery device **200** relative to the patient for drug delivery. Ultimately, the urinary catheter and drug delivery system **300** may allow for continuous urine drainage in addition to controlled delivery of a drug to a selected region of the patient's lower urinary tract, such as the bladder, over an extended period of time.

[00086] As shown in **FIG. 3A**, the urinary catheter and drug delivery system **300** has an elongated shape including a distal end **302** (which also may be referred to as a "bladder end") and a proximal end **304** (which also may be referred to as an "external end"). The system **300** includes a distal end portion **306** (which also may be referred to as a "bladder end portion") extending from the distal end **302** toward the proximal end **304**, a proximal end portion **308** (which also may be referred to as an "external end portion") extending from the proximal end **304** toward the distal end **302**, and an intermediate portion **310** (which also may be referred to as a "urethral portion") extending from the distal end portion **306** to the proximal end portion **308**. As shown, the distal end portion **306** includes the distal end portion **106** of the urinary catheter **100** and the distal end portion **206** of the drug delivery device **200**, the proximal end portion **308** includes the proximal end portion **108** of the catheter **100** and the proximal end portion **208** of the device **200**, and the intermediate portion **310** includes the intermediate portion **110** of the catheter **100** and the intermediate portion **210** of the device **200**. When the urinary catheter and drug delivery system **300** is used for urine drainage from a patient's bladder and drug delivery to the bladder, the distal end portion **306** may be inserted through the urethra and into the bladder, while the intermediate portion **310** resides within the urethra and the proximal end portion **308** resides outside of the patient's body.

[00087] In some embodiments, the drug delivery device **200** is permanently attached to the urinary catheter **100** such that the system **300** is a permanent assembly. As shown in **FIGS.**

3A-3D, the device **200** may extend along at least a portion of the length of the catheter **100** and be attached thereto. In particular, the device body **220** may extend along at least a portion of the catheter **100** and be attached thereto. In some embodiments, as shown, the device body **220** extends along the external surface of the catheter body **120** and is attached thereto. For example, the device body **220** may be attached to the external surface of one or more, or all, of the distal end portion of the catheter body **120** (i.e., distally with respect to the balloon **140**), the intermediate portion of the catheter body **120** (i.e., proximally with respect to the balloon **140**), and the proximal end portion of the catheter body **120**. In some embodiments, the device body **220** extends along the external surface of the balloon **140** and is attached thereto, either in addition to or instead of being attached to one or more portions of the catheter body **120**. In some embodiments, as shown, at least part of the proximal end portion of the device body **220** is separate from (i.e., not attached to) a respective part of the proximal end portion of the catheter body **120**. In this manner, such parts of the catheter body **120** and the device body **220**, as well as the drug reservoir **230**, may be separately manipulated during use of the system **300**. The attached portions of the drug delivery device **200** and the urinary catheter **100** may be permanently attached to one another by a biocompatible adhesive, ultrasonic welding, or other suitable means of attachment.

[00088] In other embodiments, the drug delivery device **200** is removably attached to the urinary catheter **100** such that the system **300** is a separable assembly. In this manner, the device **200** may be attached to the catheter **100** when drug delivery is desired and removed from the catheter **100** when drug delivery is not needed. In such embodiments, the drug delivery device **200** may include one or more releasable fasteners, such as caps, clips, bands, straps, or other types of mechanical fasteners configured for releasably attaching the device **200** to the catheter **100**. Alternatively, the catheter **100** may include one or more releasable fasteners, such as caps, clips, bands, straps, or other types of mechanical fasteners configured for releasably attaching the device **200** to the catheter **100**. According to various embodiments, the releasable fasteners may attach the device body **220** to the catheter body **120** and/or the balloon **140** along one or more, or all, of the distal end portion **306**, the proximal end portion **308**, and the intermediate portion **310** of the system **300**.

[00089] When the drug delivery device **200** is attached, either permanently or removably, to the urinary catheter **100**, the distal opening **224** of the drug delivery lumen **222** may be positioned along the distal end portion **306** of the system **300**. In some embodiments, as shown in **FIGS. 3A-3D**, the distal opening **224** is positioned at the distal end **302** of the system **300**. In other embodiments, the distal opening **224** is positioned near but proximally

spaced apart from the distal end **302** of the system **300**. In some embodiments, the distal opening **224** of the drug delivery lumen **222** is positioned adjacent the distal opening **124** of the drainage lumen **122**. In other embodiments, the distal opening **224** of the drug delivery lumen **222** is distally or proximally spaced apart from the distal opening **124** of the drainage lumen **122**. In some embodiments, as shown, the distal opening **224** of the drug delivery lumen **222** faces a first direction, and the distal opening **124** of the drainage lumen **122** faces a second direction that is different from the first direction. For example, the first direction may be transverse to the second direction or may be opposite the second direction. In other embodiments, the distal opening **224** of the drug delivery lumen **222** and the distal opening **124** of the drainage lumen **122** face the same direction. In some embodiments, as shown, the distal opening **224** of the drug delivery lumen **222** is distally spaced apart from the balloon **140**. In other embodiments, the distal opening **224** of the drug delivery lumen **222** is positioned along the external surface of the balloon **140**.

[00090] **FIG. 3E** illustrates use of the urinary catheter and drug delivery system **300** to allow urine to drain from the bladder ***B*** of a patient ***P*** and also deliver a drug into the bladder ***B***. With the drug delivery device **200** attached, either permanently or removably, to the urinary catheter **100** and the balloon **140** in the collapsed configuration, the distal end portion **306** of the system **300** may be inserted through the urethra ***U*** and into the bladder ***B***. In particular, distal end portion **306** of the system **300** may be inserted such that the balloon **140** is disposed within the bladder ***B*** adjacent the bladder neck ***N***, while the intermediate portion **310** of the system **300** is disposed within the urethra ***U*** and the proximal end portion **308** of the system **300** is disposed outside of the body of the patient ***P***. Fluid, such as sterile water, then may be passed through the inflation lumen **132** and into the cavity **142** to inflate the balloon **140** to the expanded configuration, such that the balloon **140** forms a seal against the bladder neck ***N***.

[00091] With the catheter **100** positioned as shown in **FIG. 3E**, urine may freely enter the distal opening **124** of the drainage lumen **122**, pass through the drainage lumen **122**, and be collected in a collection bag attached to the proximal end **104** of the catheter **100**. As shown, some residual urine ***R*** may remain in the bladder ***B*** due to the position of the distal opening **124** of the drainage lumen **122** relative to the bladder neck ***N***. With the drug delivery device **200** positioned as shown in **FIG. 3E**, the fluid **246** within the fluid chamber **236** may permeate through the osmotic barrier **238** and into the drug chamber **234**. In this manner, the fluid **246** may solubilize the drug **244** within the drug chamber **234** and create osmotic pressure within the drug chamber **234**. The osmotic pressure created may drive the drug **244**

out of the drug chamber **234**, through the drug delivery lumen **222**, and out of the drug delivery device **200** into the bladder ***B***. In particular, the drug **244** may be released from the drug delivery lumen **222**, via the distal opening **224**, directly into the bladder ***B***. In other words, the distal opening **224** may be in direct fluid communication with the bladder ***B***, such the drug **244** passes directly from the drug delivery lumen **222** into the bladder ***B***. In this manner, in reaching the bladder ***B***, the drug **244** does not pass through any additional components or features positioned between the distal opening **224** and the bladder ***B***. As described above, the drug reservoir **230** may operate as an osmotic pump to controllably release the drug **244** from the drug delivery device **200** and into the bladder over an extended period of time, such as multiple days, weeks, or months, depending on the drug payload of the reservoir **230**. Because the drug reservoir **230** is disposed outside of the patient's body, the drug chamber **234** may be sufficiently large to accommodate the drug payload necessary for controlled drug delivery over such an extended period of time.

[00092] **FIGS. 3F** and **3G** illustrate another version of the urinary catheter and drug delivery system **300**, which includes the drug delivery device **200** and the urinary catheter **100**. As shown, the device body **220** may extend between the balloon **140** and the external surface of the catheter body **120**, instead of running along the outside of the balloon **140** as illustrated in **FIGS. 3C** and **3D**. In this manner, the balloon **140** may help secure the distal end portion **206** of the drug delivery device **200** to the urinary catheter **100**. In some embodiments, the balloon **140** includes a passageway defined therein and configured to allow a portion of the device body **220** to be positioned therein. In other embodiments, the body **120** of the urinary catheter **100** includes a passageway defined therein and configured to allow a portion of the device body **220** to be positioned therein. In still other embodiments, a passageway may be defined between the balloon **140** and the body **120** of the urinary catheter **100** and configured to allow a portion of the device body **220** to be positioned therein. In some embodiments, the drug delivery device **200** is removably attached to the urinary catheter **100** to provide the arrangement shown in **FIGS. 3F** and **3G**. For example, the device body **220** may be slid through the passageway defined by the balloon **140** and/or the body **120** and secured therewithin, e.g., by frictional engagement. In other embodiments, the drug delivery device **200** is permanently attached to the urinary catheter **100** to provide the illustrated arrangement. For example, the device body **220** may be positioned through the passageway defined by the balloon **140** and/or the body **120** and permanently secured to the balloon **140** and/or the body **120** by one or more suitable means of attachment.

[00093] **FIGS. 3H** and **3I** illustrate yet another version of the urinary catheter and drug delivery system **300**, which includes the drug delivery device **200** attached to the urinary catheter **100** via a cap **320**. In some embodiments, the cap **320** is a part of the drug delivery device **200** and is configured for removable attachment to the urinary catheter **100**. For example, the cap **320** may be permanently attached to the distal end portion of the device body **220** and configured for removable attachment to the distal end portion of the catheter body **120**, as shown. In this manner, the drug delivery device **200** may be removably attached to the catheter **100**, via the cap **320**, when desired for drug delivery. In such embodiments, the cap **320** may be press-fitted onto the distal end of the catheter body **120**, adhered to the distal end of the catheter body **120** via a releasable biocompatible adhesive, or otherwise removably attached to the distal end of the catheter body **120**. In other embodiments, the cap **320** is permanently attached to both the device body **220** and the catheter body **120**.

[00094] **FIGS. 3J** and **3K** illustrate still another version of the urinary catheter and drug delivery system **300**, which includes the drug delivery device **200** and the urinary catheter **100**. As shown, the device body **220** may extend through the drainage lumen **122** of the catheter body **120**, such that the distal opening **224** of the drug delivery lumen **222** is positioned outside of the drainage lumen **122**. In some embodiments, the drug delivery device **200** is removably attached to the urinary catheter **100** to provide the arrangement shown in **FIGS. 3J** and **3K**. In other embodiments, the drug delivery device **200** is permanently attached to the urinary catheter **100** to provide the illustrated arrangement. For example, the device body **220** may be permanently attached to the wall of the drainage lumen **122**. In still other embodiments, the drug delivery device **200** is not attached to the urinary catheter **100** at all, as the device body **220** is merely inserted through the drainage lumen **122**. In this manner, the relative position of the distal opening **224** of the drug delivery lumen **222** with respect to the distal opening **124** of the drainage lumen **122** may be adjusted, as desired.

[00095] **FIGS. 4A-4E** illustrate a urinary catheter and drug delivery system **400** (which also may be referred to as simply a "system") in accordance with one or more embodiments of the disclosure. As shown, the system **400** includes the urinary catheter **100**, which may provide the functions described above, and a drug delivery device **450** (which also may be referred to as a "therapeutic agent delivery device" or simply a "device") attached to the urinary catheter **100**. The drug delivery device **450** may be permanently or removably attached to the urinary catheter **100**. In this manner, the urinary catheter **100** may serve as a support structure for positioning and supporting the drug delivery device **450** relative to the

patient for drug delivery. Ultimately, the urinary catheter and drug delivery system **400** may allow for continuous urine drainage in addition to controlled delivery of a drug to a selected region of the patient's lower urinary tract, such as the bladder, over an extended period of time.

[00096] As shown in **FIG. 4A**, the urinary catheter and drug delivery system **400** has an elongated shape including a distal end **402** (which also may be referred to as a "bladder end") and a proximal end **404** (which also may be referred to as an "external end") positioned along a longitudinal axis *A* of the system **400**. The system **400** includes a distal end portion **406** (which also may be referred to as a "bladder end portion") extending from the distal end **402** toward the proximal end **404** along the longitudinal axis *A*, a proximal end portion **408** (which also may be referred to as an "external end portion") extending from the proximal end **404** toward the distal end **402** along the longitudinal axis *A*, and an intermediate portion **410** (which also may be referred to as a "urethral portion") extending axially from the distal end portion **406** to the proximal end portion **408**. As shown, the distal end portion **406** includes the distal end portion **106** of the urinary catheter **100** and the drug delivery device **450**, the proximal end portion **408** includes the proximal end portion **108** of the catheter **100**, and the intermediate portion **410** includes the intermediate portion **110** of the catheter **100**. When the urinary catheter and drug delivery system **400** is used for urine drainage from the a patient's bladder and drug delivery to the bladder, the distal end portion **406** may be inserted through the urethra and into the bladder, while the intermediate portion **410** resides within the urethra and the proximal end portion **408** resides outside of the patient's body.

[00097] The drug delivery device **450** may be configured to controllably release a drug to a selected region of the lower urinary tract, such as the bladder, of a catheterized patient. During use, the entire drug delivery device **450** may be inserted through the patient's urethra and into the bladder to provide a mechanism for delivering the drug to the selected region. As shown in **FIG. 4A**, the drug delivery device **450** has an annular shape extending around and coaxial with the longitudinal axis *A* of the system **400**. In this manner, the drug delivery device **450** may extend entirely around a distal end portion of the body **120** of the catheter **100**. Although the drug delivery device **450** is illustrated as having an annular or toroidal shape, it will be appreciated that other shapes of the device **450** may be used in other embodiments. As shown, the drug delivery device **450** includes a distal end **452** and a proximal end **454** opposite the distal end **452**. When the drug delivery device **450** is used to deliver a drug to a selected region of the lower urinary tract, such as the patient's bladder, the

entire device **450** may be inserted through the urethra, such that the distal end **452** and the proximal end **454** both reside in the bladder.

[00098] As shown, the drug delivery device **450** may include, or may be formed as, a drug reservoir **460** attached to the distal end portion of the catheter body **120**. In some embodiments, the drug reservoir **460** is permanently attached to the catheter body **120**. In other embodiments, the drug reservoir **460** is removably attached to the catheter body **120**, for example, by one or more releasable fasteners. The drug reservoir **460** may have an annular or toroidal shape, although other shapes of the drug reservoir **460** may be used.

[00099] As shown, the drug reservoir **460** may be positioned axially between the distal opening **124** of the drainage lumen **122** and the balloon **140**. In other words, the distal end of the drug reservoir **460** may be positioned proximally with respect to the distal opening **124**, and the proximal end of the drug reservoir **460** may be positioned distally with respect to the balloon **140**. In some embodiments, as shown, the distal end of the drug reservoir **460** is axially spaced apart from the distal opening **124**, and the proximal end of the drug reservoir **460** is axially spaced apart from the balloon **140**. Alternatively, the distal end of the drug reservoir **460** may abut the distal opening **124**, and/or the proximal end of the drug reservoir **460** may abut the balloon **140**. By locating the drug delivery device below the distal opening **124** and above the balloon **140**, the drug delivery device advantageously will be positioned in, or in contact with, the residual volume of urine in the bladder, which tends to remain below the drainage opening, as the drug delivery device **450** relies on the urine the medium for transfer of the drug from the device to the tissues of the patient's bladder.

[000100] The drug reservoir **460** may include a housing **462** having one or more chambers defined therein. In particular, the drug reservoir **460** may include a drug chamber **464** (which also may be referred to as a "therapeutic agent chamber") defined therein. Although the illustrated embodiment includes only a single drug chamber **464**, the drug reservoir **460** may include two or more drug chambers **464** in other embodiments. The drug chamber **464** may be configured to contain a drug therein. In some embodiments, as shown, the drug chamber **464** is defined by (i.e., bounded by) a portion of the housing **462** and a portion of the catheter body **120**. In particular, the drug chamber **464** may be defined by an internal surface of the outer circumferential wall of the housing **462** and an external surface of the sidewall of the catheter body **120**, as shown. In other embodiments, the drug chamber **464** is defined entirely by the housing **462**. For example, the housing **462** may include an inner circumferential wall extending along and around the external surface of the sidewall of the catheter body **120**, such that the drug chamber **464** is defined by and between the internal surface of the outer

circumferential wall and the external surface of the inner circumferential wall of the housing **462**.

[000101] As shown in **FIG. 4D**, the drug reservoir **460** may include a drug **474** disposed within the drug chamber **464**. In some embodiments, the drug **474** fills or substantially fills the drug chamber **464**. In some embodiments, the drug **474** is in a solid form. For example, the drug **474** may be in the form of a unitary block that fills or substantially fills the drug chamber **464** or a plurality of tablets, mini-tablets, pellets, beads, granules, a powder, or other solid drug units that fill or substantially fill the drug chamber **464**. In other embodiments, the drug **474** is in a semi-solid form or a liquid form that fills or substantially fills the drug chamber **464**. The semi-solid form may be, for example, an emulsion or suspension; a gel or a paste. In some embodiments, the drug **474** is preloaded into the drug chamber **464** during manufacture of the drug delivery device **450**. In other embodiments, the drug **474** is loaded into the drug chamber **464** by a clinician just prior to use of the drug delivery device **450**. The drug **474** may be any suitable therapeutic, prophylactic, or diagnostic agent. According to various embodiments, the drug **474** may be or may include any of the agents described above with respect to the drug **244**, although still other agents may be used in other embodiments.

[000102] The wall or walls of the housing **462** may be formed of any suitable material, such as a biocompatible polymeric material. In some embodiments, the wall or walls of the housing **462** are formed of the same material as the catheter body **120**, although the housing **462** and the catheter body **120** may be formed of different materials in other embodiments. In some embodiments, the wall or walls of the housing **462** are integrally formed with the catheter body **120**. For example, the housing **462** and the catheter body **120** may be integrally molded as a unitary structure. In other embodiments, the wall of walls of the housing **462** and the catheter body **120** are separately formed and attached to one another. For example, the housing **462** and the catheter body **120** may be separately formed by extrusion, molding, or a combination thereof, and then attached to other another by a biocompatible adhesive, ultrasonic welding, or other means of attachment. In some embodiments, the housing **462** is formed of an elastomeric or flexible material to permit some deformation of the housing **462**, which may ease insertion of the drug delivery device **450** through the patient's urethra and into the bladder. The material used to form the housing **462** also may be water permeable or porous so that solubilizing fluid (e.g., urine) can enter the drug chamber **464** to solubilize the drug **474** once the drug delivery device **450** is positioned in the bladder. For example, silicone or another biocompatible elastomeric

material may be used. In various embodiments, depending at least in part on the selected mechanism of drug release for the selected drug, the housing wall(s) may be formed of a thermoplastic elastomeric material, such as one or more suitable thermoplastic polyurethanes known in the art. Examples of such materials include Tecophilic™, HydroThane™, Hydromed™, Dryflex™, Carbothane™, Tecoflex™, Isoplast™, Pellethane™, Tecoplast™, Tecothane™, or a combination thereof.

[000103] The housing **462** is configured to allow the drug **474** to be released from the drug chamber **464** and into the patient's bladder. The drug release mechanism may be osmosis or diffusion through orifice(s) or permeation through the reservoir membrane with or without an orifice. The release rate of the drug **474** from the drug chamber **464** generally is controlled by the design of the combination of the device components, including but not limited to the materials, dimensions, surface area, and apertures of the housing **462**, as well as the particular drug formulation and total mass of drug load, among others.

[000104] In some embodiments, the housing **462** includes one or more apertures **466** extending through the wall or walls of the housing **462** and in fluid communication with the drug chamber **464**. In some embodiments in which an aperture **466** is provided, the aperture **466** may be temporarily closed by a degradable or dissolvable timing membrane, which may control the initiation of release of the drug **474** from the drug chamber **464**.

[000105] In some embodiments, the drug reservoir **460** operates as an osmotic pump. In such embodiments, the housing **462** may be formed from a water permeable material, such as a silicone, which may act as a semi-permeable membrane, permeable to water but not to the selected drug in solubilized form. Following positioning of the drug delivery device **460** within the bladder, urine diffuses through a wall of the housing **462**, enters the drug chamber **464**, and solubilizes the drug **474**. Solubilized drug **474** then is dispensed at a controlled rate out of the drug chamber **464** through the one or more apertures **466**, driven by osmotic pressure in the drug chamber **464**. The delivery rate and overall performance of the osmotic pump is affected by device parameters, such as the surface area of the housing **462**; the permeability to liquid of the material used to form the housing **462**; the size and placement of the apertures **466**; and the drug formulation dissolution profile, among other factors.

[000106] In other embodiments, the drug delivery device **450** may operate essentially by diffusion of the drug **474** from the housing **462** through (i) one or more discrete apertures **466** formed in the wall or walls of the housing **462**, (ii) through the wall or walls of the housing **462** itself, which may be permeable to the drug **474**, or (iii) a combination thereof. In embodiments in which diffusion occurs through the wall or walls of the housing **462**, the

apertures **466** or passing pores may not be included. In still other embodiments, the drug delivery device **450** may operate by a combination of osmosis and diffusion.

[000107] In some embodiments, the housing **462** is non-resorbable. For example, the housing **462** may be formed of a medical grade silicone. In another example, the housing may be formed of a thermoplastic elastomer, as described above. Other examples of suitable non-resorbable materials include synthetic polymers selected from poly(ethers), poly(acrylates), poly(methacrylates), poly(vinyl pyrolidones), poly(vinyl acetates), poly(urethanes), celluloses, cellulose acetates, poly(siloxanes), poly(ethylene), poly(tetrafluoroethylene) and other fluorinated polymers, poly(siloxanes), copolymers thereof, and combinations thereof.

[000108] In some embodiments, the housing **462** is bioerodible. In one embodiment of a bioerodible housing **462**, the housing **462** is formed of a biodegradable or bioresorbable polymer. Examples of suitable such materials include synthetic polymers selected from poly(amides), poly(esters), poly(ester amides), poly(anhydrides), poly(orthoesters), polyphosphazenes, pseudo poly(amino acids), poly(glycerol-sebacate)(PGS), copolymers thereof, and mixtures thereof.

[000109] The size, number, and placement of the apertures **466** may be selected to provide a controlled rate of release of the drug **474**. A drug delivery device **450** that operates primarily as an osmotic pump may have one or more apertures **466** sized small enough to reduce diffusion of the drug **474** through the aperture(s) **466**, yet large enough and spaced appropriately along the housing **462** to manage the buildup of hydrostatic pressure in the housing **462**. Within these constraints, the size and number of apertures **466** for a single drug delivery device **450** can be varied to achieve a selected release rate. In an exemplary embodiment, the device includes a single aperture having a diameter between about 20 μm and about 500 μm. In embodiments where the drug delivery device **450** operates primarily by diffusion, the apertures **466,** if present, may be in this range or larger.

[000110] In some embodiments, the housing **462** may not have any apertures, in which case the drug **474** may be released via a release mechanism other than osmosis, such as diffusion through the wall or walls of the housing **462**. Similarly, a drug delivery device **450** having multiple discrete drug chambers **464** may have apertures **466** associated with all, some, or none of the drug chambers **464**, in which cases release from the different drug chambers **464** may occur via different release mechanisms.

[000111] **FIG. 4E** illustrates use of the urinary catheter and drug delivery system **400** to allow urine to drain from the bladder ***B*** of a patient ***P*** and also deliver a drug into the bladder ***B***. With the drug delivery device **450** attached, either permanently or removably, to the urinary catheter **100** and the balloon **140** in the collapsed configuration, the distal end portion **406** of the system **400** may be inserted through the urethra ***U*** and into the bladder ***B***. In particular, distal end portion **406** of the system **400** may be inserted such that the balloon **140** is disposed within the bladder ***B*** adjacent the bladder neck ***N***, while the intermediate portion **410** of the system **400** is disposed within the urethra ***U*** and the proximal end portion **408** of the system **400** is disposed outside of the body of the patient ***P***. Fluid, such as sterile water, then may be passed through the inflation lumen **132** and into the cavity **142** to inflate the balloon **140** to the expanded configuration, such that the balloon **140** forms a seal against the bladder neck ***N***.

[000112] With the catheter **100** positioned as shown in **FIG. 4E**, urine may freely enter the distal opening **124** of the drainage lumen **122**, pass through the drainage lumen **122**, and be collected in a collection bag attached to the proximal end **104** of the catheter **100**. The urine flows by gravity. As shown, some residual urine ***R*** may remain in the bladder ***B*** due to the position of the distal opening **124** of the drainage lumen **122** relative to the bladder neck ***N***. With the drug delivery device **450** positioned between the distal opening **124** of the drainage lumen **122** and the balloon **140**, as shown in **FIG. 4E**, the device **450** may reside within the residual urine ***R***. In embodiments in which the housing **462** is formed of a water permeable material, some of the residual urine ***R*** may permeate through the wall or walls of the housing **462** and solubilize the drug **474** within the drug chamber **464**. Ultimately, the drug delivery device **450** may controllably release the drug **474** into the bladder ***B*** via one or more apertures **466** or pores or through the wall or walls of the housing **462**, according to one or more of the release mechanisms described above. In particular, the drug delivery device **450** may release the drug **474** directly into the bladder ***B***. The drug **474** may be released from the drug delivery device **450** and into the bladder ***B*** over an extended period of time, such as multiple days, weeks, or months, depending on the drug payload of the drug reservoir **460**. If the drug **474** present in the drug chamber **464** becomes depleted, the drug chamber **464** may be refilled, a new drug delivery device **450** may be attached to the urinary catheter **100** upon removal of the urinary catheter and drug delivery system **400**, or a new system **400** may be used for further drug delivery.

[000113] **FIGS. 5A-5E** illustrate a urinary catheter and drug delivery system **500** (which also may be referred to as simply a "system") in accordance with one or more embodiments

of the disclosure. As shown, the system **500** includes the urinary catheter **100**, which may provide the functions described above, and the drug delivery device **450** attached to the urinary catheter **100**. The drug delivery device **450** may be permanently or removably attached to the urinary catheter **100**. In this manner, the urinary catheter **100** may serve as a support structure for positioning and supporting the drug delivery device **450** relative to the patient for drug delivery. Ultimately, the urinary catheter and drug delivery system **500** may allow for continuous urine drainage in addition to controlled delivery of a drug to a selected region of the patient's lower urinary tract, such as the bladder, over an extended period of time.

[000114] As shown in **FIG. 5A**, the urinary catheter and drug delivery system **500** has an elongated shape including a distal end **502** (which also may be referred to as a "bladder end") and a proximal end **504** (which also may be referred to as an "external end") positioned along a longitudinal axis *A* of the system **500**. The system **500** includes a distal end portion **506** (which also may be referred to as a "bladder end portion") extending from the distal end **502** toward the proximal end **504** along the longitudinal axis *A*, a proximal end portion **508** (which also may be referred to as an "external end portion") extending from the proximal end **504** toward the distal end **502** along the longitudinal axis *A*, and an intermediate portion **510** (which also may be referred to as a "urethral portion") extending axially from the distal end portion **506** to the proximal end portion **508**. As shown, the distal end portion **506** includes the distal end portion **106** of the urinary catheter **100** and the drug delivery device **450**, the proximal end portion **508** includes the proximal end portion **108** of the catheter **100**, and the intermediate portion **510** includes the intermediate portion **110** of the catheter **100**. When the urinary catheter and drug delivery system **500** is used for urine drainage from the a patient's bladder and drug delivery to the bladder, the distal end portion **506** may be inserted through the urethra and into the bladder, while the intermediate portion **510** resides within the urethra and the proximal end portion **508** resides outside of the patient's body.

[000115] The urinary catheter **100** illustrated in **FIGS. 5A-5E** is generally similar to the catheter **100** described above with respect to **FIGS. 1A-1E** but may include additional features described herein below. According to the embodiment of the urinary catheter **100** illustrated in **FIGS. 5A-5E**, the body **120** includes a drug delivery lumen **152** (which also may be referred to as a "tertiary lumen") extending axially through the catheter **100** and configured to allow a drug or drug solution to be delivered therethrough from a drug source attached to the proximal end **104** of the catheter **100**. In particular, the drug delivery lumen **152** may extend from a distal opening **154** (which also may be referred to as a "drug exit

opening") defined in the body **120** to a proximal opening **156** (which also may be referred to as a "drug entry opening") defined in the body **120**. As shown, the distal opening **154** may be defined in a sidewall of the body **120** and positioned adjacent the drug delivery device **450**, and the proximal opening **156** may be defined in or near the proximal end **104** of the catheter **100**. For example, the proximal opening **156** may be defined in the proximal end of a drug delivery arm **158** of the body **120**. In some embodiments, as shown, the drug delivery lumen **152** has a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the drug delivery lumen **152** may be used. In some embodiments, as shown, a longitudinal axis of the drug delivery lumen **152** is offset from the longitudinal axis of the body **120** and the longitudinal axis *A* of the system **500**. In some embodiments, as shown, a valve **160** is positioned within the distal opening **154**, between the drug delivery lumen **152** and the drug delivery device **450**.

[000116] The drug delivery device **450** illustrated in **FIGS. 5A-5E** is generally similar to the drug delivery device **450** described above with respect to **FIGS. 4A-4E** but may include additional features described herein below. According to the embodiment of the drug delivery device **450** illustrated in **FIGS. 5A-5E**, the housing **462** of the drug reservoir **460** includes an opening **478** positioned adjacent the distal opening **154** of the drug delivery lumen **152**. In this manner, the drug delivery lumen **152** of the catheter **100** may be in fluid communication with the drug chamber **464** of the drug reservoir **460**, although such fluid communication may be controlled by the valve **160** in some embodiments. In particular, the valve **160** may be a one-way valve configured to allow fluid to flow from the drug delivery lumen **152** into the drug chamber **464** but to prevent fluid from flowing from the drug chamber **464** into the drug delivery lumen **152**.

[000117] In some embodiments in which the drug **474** is not pre-loaded within the drug chamber **464**, the drug delivery lumen **152** may be used to fill the drug chamber **464** with the drug **474** (in a liquid form) prior to use of the system **500** (i.e., prior to insertion of the distal end portion **506** of the system **500** through the patient's urethra and into the bladder). According to this approach, a clinician may choose to load the drug delivery device **450** with a particular drug formulation just prior to use of the system **500**. In other embodiments in which the drug **474** is not pre-loaded within the drug chamber **464**, the drug delivery lumen **152** may be used to fill the drug chamber **464** with the drug **474** (in a liquid form) after insertion of the distal end portion **506** of the system **500** through the patient's urethra and into the bladder. According to this approach, the reduced volume of the drug delivery device **450** (i.e., when the drug chamber **464** is empty) may ease insertion of the distal end portion **506**

through the urethra and into the bladder. In these embodiments and others in which the drug **474** is pre-loaded within the drug chamber **464**, the drug delivery lumen **152** also may be used to refill the drug chamber **464** with additional drug **474** (in a liquid form) after depletion of the initial drug payload.

[000118] **FIG. 5E** illustrates use of the urinary catheter and drug delivery system **500** to allow urine to drain from the bladder ***B*** of a patient ***P*** and also deliver a drug into the bladder ***B***. With the drug delivery device **450** attached, either permanently or removably, to the urinary catheter **100** and the balloon **140** in the collapsed configuration, the distal end portion **506** of the system **500** may be inserted through the urethra ***U*** and into the bladder ***B***. In particular, distal end portion **506** of the system **500** may be inserted such that the balloon **140** is disposed within the bladder ***B*** adjacent the bladder neck ***N***, while the intermediate portion **510** of the system **500** is disposed within the urethra ***U*** and the proximal end portion **508** of the system **500** is disposed outside of the body of the patient ***P***. Fluid, such as sterile water, then may be passed through the inflation lumen **132** and into the cavity **142** to inflate the balloon **140** to the expanded configuration, such that the balloon **140** forms a seal against the bladder neck ***N***.

[000119] In some embodiments, the drug chamber **464** may be filled with the drug **474** either before or after insertion of the distal end portion **506** of the system **500** through the urethra ***U*** and into the bladder ***B***. In particular, a fluid source, such as a syringe or a pump, may be attached to the proximal opening **156** of the drug delivery lumen **152** and used to deliver the drug **474** through the drug delivery lumen **152** and into the drug chamber **464**. In other embodiments, the drug chamber **464** may be pre-loaded with the drug **474** during manufacture of the system **500**.

[000120] With the catheter **100** positioned as shown in **FIG. 5E**, urine may freely enter the distal opening **124** of the drainage lumen **122**, pass through the drainage lumen **122**, and be collected in a collection bag attached to the proximal end **104** of the catheter **100**. As shown, some residual urine ***R*** may remain in the bladder ***B*** due to the position of the distal opening **124** of the drainage lumen **122** relative to the bladder neck ***N***. With the drug delivery device **450** positioned between the distal opening **124** of the drainage lumen **122** and the balloon **140**, as shown in **FIG. 5E**, the device **450** may reside within the residual urine ***R***. In embodiments in which the housing **462** is formed of a water permeable material, some of the residual urine ***R*** may permeate through the wall or walls of the housing **462** and solubilize the drug **474** within the drug chamber **464**. Ultimately, the drug delivery device **450** may controllably release the drug **474** into the bladder ***B*** via one or more apertures **466** or pores or

through the wall or walls of the housing **462**, according to one or more of the release mechanisms described above. In particular, the drug delivery device **450** may release the drug **474** directly into the bladder ***B***. The drug **474** may be released from the drug delivery device **450** and into the bladder ***B*** over an extended period of time, such as multiple days, weeks, or months, depending on the drug payload of the drug reservoir **460**.

[000121] If the drug **474** present in the drug chamber **464** becomes depleted, the drug chamber **464** may be refilled. In particular, a fluid source, such as a syringe or a pump, may be attached to the proximal opening **156** of the drug delivery lumen **152** and used to deliver new drug **474** through the drug delivery lumen **152** and into the drug chamber **464**. The one-way valve **160** may maintain the new drug **474** within the drug chamber **464**, preventing the new drug **474** from flowing back into the drug delivery lumen **152**. The drug delivery lumen **152** advantageously may allow the drug chamber **464** to be refilled as many times as necessary to provide continued drug delivery over a desired treatment period.

[000122] Publications cited herein and the materials for which they are cited are specifically incorporated by reference. Modifications and variations of the devices, systems, and methods described herein will be obvious to those skilled in the art from the foregoing detailed description. Such modifications and variations are intended to come within the scope of the appended claims.

CLAIMS

We claim:

1. A drug delivery device for use with a urinary catheter, the drug delivery device comprising:

a drug reservoir configured to be disposed outside of a patient's body, the drug reservoir comprising:

a drug chamber containing a drug therein;

a fluid chamber containing a fluid therein; and

an osmotic barrier separating the drug chamber and the fluid chamber; and

a flexible elongate body attached to the drug reservoir and configured to traverse the patient's urethra to reach the bladder, the body comprising a drug delivery lumen extending therethrough and in fluid communication with the drug chamber.

2. The drug delivery device of claim 1, wherein the drug reservoir further comprises a housing, wherein the drug chamber is defined by a portion of the housing and the osmotic barrier, and wherein the fluid chamber is defined by a portion of the housing and the osmotic barrier.

3. The drug delivery device of claim 1, wherein the drug is in a solid form.

4. The drug delivery device of claim 3, wherein the drug is in the form of tablets, pellets, beads, granules, or powder.

5. The drug delivery device of claim 1, wherein the drug comprises an antimicrobial agent, an antifibrotic agent, an antimuscarinic agent, an anesthetic agent, an antinociceptive agent, or a combination thereof.

6. The drug delivery device of claim 1, wherein the drug comprises an agent which dissolves stones or breaks down biofilms.

7. The drug delivery device of claim 1, wherein the fluid substantially fills the fluid chamber.

8. The drug delivery device of claim 1, wherein the fluid comprises water.

9. The drug delivery device of claim 1, wherein the osmotic barrier comprises a semi-permeable wall.

10. The drug delivery device of claim 1, wherein the osmotic barrier is formed of a semi-permeable polymeric material which allows the fluid to pass therethrough but prevents the drug from passing therethrough.

11. The drug delivery device of claim 1, wherein the drug reservoir is configured to operate as an osmotic pump to drive the drug out of the drug chamber and through the drug delivery lumen.

12. The drug delivery device of claim 1, wherein the body is permanently attached to the drug reservoir.

13. The drug delivery device of claim 1, wherein the body has a tubular shape.

14. The drug delivery device of claim 1, wherein the body comprises a capillary tube.

15. The drug delivery device of claim 1, further comprising one or more releasable fasteners configured to removably attach the drug delivery device to the urinary catheter.

16. The drug delivery device of any one of claims 1 to 15, wherein the urinary catheter is a Foley catheter.

17. A urinary catheter and drug delivery system comprising:

a urinary catheter configured to allow urine to drain from a patient's bladder, the urinary catheter comprising a flexible elongate catheter body configured to traverse the patient's urethra to reach the bladder, the catheter body comprising a drainage lumen extending therethrough; and

a drug delivery device configured for use with the urinary catheter, the drug delivery device comprising:

a drug reservoir configured to be disposed outside of the patient's body, the drug reservoir comprising:

a drug chamber containing a drug therein;

a fluid chamber containing a fluid therein; and

an osmotic barrier separating the drug chamber and the fluid chamber; and

a flexible elongate device body attached to the drug reservoir and configured to traverse the patient's urethra to reach the bladder, the device body comprising a drug delivery lumen extending therethrough and in fluid communication with the drug chamber.

18. The urinary catheter and drug delivery system of claim 17, wherein the urinary catheter is a Foley catheter.

19. The urinary catheter and drug delivery system of claim 17, wherein the urinary catheter further comprises a balloon attached to the catheter body and comprising an internal cavity, and wherein the catheter body further comprises an inflation lumen extending therethrough and in fluid communication with the internal cavity.

20. The urinary catheter and drug delivery system of claim 19, wherein the drug delivery lumen extends between catheter body and the balloon.

21. The urinary catheter and drug delivery system of claim 17, wherein the drug delivery device is attached to the urinary catheter.

22. The urinary catheter and drug delivery system of claim 21, wherein the drug delivery device is permanently attached to the urinary catheter.

23. The urinary catheter and drug delivery system of claim 21, wherein the drug delivery device is removably attached to the urinary catheter.

24. The urinary catheter and drug delivery system of claim 23, wherein the drug delivery device is removably attached to the urinary catheter by one or more releasable fasteners.

25. The urinary catheter and drug delivery system of claim 17, wherein the device body extends along an external surface of the catheter body.

26. The urinary catheter and drug delivery system of claim 25, wherein the device body is attached to the external surface of the catheter body.

27. The urinary catheter and drug delivery system of claim 17, wherein the drainage lumen extends from a distal opening to a proximal opening of the catheter body, and wherein the drug delivery lumen extends from a distal opening to a proximal opening of the device body.

28. The urinary catheter and drug delivery system of claim 27, wherein the distal opening of the drug delivery lumen is distally spaced apart from the distal opening of the drainage lumen.

29. The urinary catheter and drug delivery system of claim 28, wherein the distal opening of the drug delivery lumen is adjacent the distal opening of the drainage lumen.

30. The urinary catheter and drug delivery system of claim 17, wherein the device body extends through the drainage lumen.

31. The urinary catheter and drug delivery system of claim 17, wherein the drug is in the form of tablets, pellets, beads, granules, or powder.

32. The urinary catheter and drug delivery system of claim 17, wherein the drug substantially fills the drug chamber.

33. The urinary catheter and drug delivery system of claim 17, wherein the drug comprises an antimicrobial agent, an antifibrotic agent, an antimuscarinic agent, an anesthetic agent, an antinociceptive agent, or a combination thereof.

34. The urinary catheter and drug delivery system of claim 17, wherein the drug comprises an agent which dissolves stones or breaks down biofilms.

35. The urinary catheter and drug delivery system of claim 17, wherein the fluid substantially fills the fluid chamber.

36. The urinary catheter and drug delivery system of claim 17, wherein the fluid comprises water.

37. The urinary catheter and drug delivery system of claim 17, wherein the osmotic barrier comprises a semi-permeable wall.

38. The urinary catheter and drug delivery system of claim 17, wherein the osmotic barrier is formed of a semi-permeable polymeric material which allows the fluid to pass therethrough but prevents the drug from passing therethrough.

39. The urinary catheter and drug delivery system of claim 17, wherein the drug reservoir is configured to operate as an osmotic pump to drive the drug out of the drug chamber and through the drug delivery lumen.

40. The urinary catheter and drug delivery system of claim 17, wherein the device body is permanently attached to the drug reservoir.

41. The urinary catheter and drug delivery system of claim 17, wherein the device body has a tubular shape.

42. The urinary catheter and drug delivery system of claim 17, wherein the device body comprises a capillary tube.

43. A method of administering a drug to a patient in need thereof, the method comprising:

inserting distal end portions of a drug delivery device and a urinary catheter through the patient's urethra and positioning the distal end portions within the bladder, while maintaining proximal end portions of the drug delivery device and the urinary catheter positioned outside of the patient's body;

allowing urine to drain from the bladder through the urinary catheter; and

delivering a drug, via osmotic pressure, from the proximal end portion of the drug delivery device into the bladder.

44. The method of claim 43, wherein inserting the distal end portions of the drug delivery device and the urinary catheter through the patient's urethra comprises simultaneously inserting the distal end portions of the drug delivery device and the urinary catheter through the patient's urethra.

45. The method of claim 43, wherein the drug delivery device is attached to the urinary catheter.

46. The method of claim 45, wherein the drug delivery device is permanently attached to the urinary catheter.

47. The method of claim 45, wherein the drug delivery device is removably attached to the urinary catheter.

48. The method of claim 47, wherein the proximal end portion of the drug delivery device comprises a drug reservoir comprising:

a drug chamber containing the drug therein;

a fluid chamber containing a fluid therein; and

an osmotic barrier separating the drug chamber and the fluid chamber.

49. The method of claim 48, wherein the drug delivery device further comprises a flexible elongate device body attached to the drug reservoir, the device body comprising a drug delivery lumen extending therethrough and in fluid communication with the drug chamber.

50. The method of claim 49, wherein inserting the distal end portion of the drug delivery device through the patient's urethra comprises inserting a distal end portion of the device body through the patient's urethra, while maintaining a proximal end portion of the device body positioned outside of the patient's body.

51. The method of claim 48, wherein the device body is a capillary tube.

52. The method of claim 48, wherein the osmotic barrier comprises a semi-permeable wall.

53. The method of claim 48, wherein the osmotic barrier is formed of a semi-permeable polymeric material which allows the fluid to pass therethrough but prevents the drug from passing therethrough.

54. The method of claim 53, wherein the drug is in a solid form and/or the fluid comprises water.

55. The method of claim 43, wherein the drug comprises an antimicrobial agent, an antifibrotic agent, an antimuscarinic agent, an anesthetic agent, an antinociceptive agent, or a combination thereof.

56. The method of claim 43, wherein the drug comprises an agent which re-dissolves stones or breaks down biofilms.

57. The method of claim 43, wherein the urinary catheter comprises a drainage lumen having a distal opening positioned along the distal end portion of the urinary catheter, and wherein the drug delivery device comprises a drug delivery lumen having a distal opening positioned along the distal end portion of the drug delivery device.

58. The method of claim 57, wherein positioning the distal end portions of the drug delivery device and the urinary catheter within the bladder comprises positioning the distal opening of the drug delivery lumen distally with respect to the distal opening of the drainage lumen.

59. The method of claim 57, wherein delivering the drug into the bladder comprises releasing the drug from the distal opening of the drug delivery lumen directly into the bladder.

60. The method of claim 57, wherein the drug delivery device extends through the drainage lumen of the urinary catheter.

61. The method of any one of claims 43 to 60, wherein the urinary catheter is a Foley catheter.

62. A urinary catheter and drug delivery system comprising:

a urinary catheter configured to allow urine to drain from a patient's bladder, the urinary catheter comprising a flexible elongate catheter body configured to traverse the patient's urethra to reach the bladder, the catheter body comprising a drainage lumen extending therethrough from a distal opening to proximal opening defined in the catheter body; and

a drug delivery device attached to the urinary catheter, the drug delivery device comprising a drug reservoir positioned near the distal opening of the drainage lumen and configured to be disposed within the patient's bladder, the drug reservoir comprising a drug chamber containing a drug therein.

63. The urinary catheter and drug delivery system of claim 62, wherein the urinary catheter is a Foley catheter.

64. The urinary catheter and drug delivery system of claim 62, wherein the urinary catheter further comprises a balloon attached to the catheter body and comprising an internal cavity, and wherein the catheter body further comprises an inflation lumen extending therethrough and in fluid communication with the internal cavity.

65. The urinary catheter and drug delivery system of claim 64, wherein the drug reservoir is positioned axially between the distal opening of the drainage lumen and the balloon.

66. The urinary catheter and drug delivery system of claim 65, wherein the drug reservoir is axially spaced apart from each of the distal opening of the drainage lumen and the balloon.

67. The urinary catheter and drug delivery system of claim 62, wherein the drug delivery device is permanently attached to the urinary catheter.

68. The urinary catheter and drug delivery system of claim 62, wherein the drug delivery device is removably attached to the urinary catheter.

69. The urinary catheter and drug delivery system of claim 68, wherein the drug delivery device is removably attached to the urinary catheter by one or more releasable fasteners and/or by one or more releasable adhesives.

70. The urinary catheter and drug delivery system of claim 62, wherein the drug reservoir extends along an external surface of the catheter body.

71. The urinary catheter and drug delivery system of claim 70, wherein the drug reservoir is attached to the external surface of the catheter body.

72. The urinary catheter and drug delivery system of claim 62, wherein the drug reservoir has an annular shape extending around the catheter body.

73. The urinary catheter and drug delivery system of claim 62, wherein the drug reservoir comprises one or more apertures extending through a wall of the drug reservoir and in fluid communication with the drug chamber.

74. The urinary catheter and drug delivery system of claim 62, wherein the drug reservoir is formed of a water-permeable material.

75. The urinary catheter and drug delivery system of claim 62, wherein the drug reservoir is configured to release the drug into the patient's bladder via diffusion.

76. The urinary catheter and drug delivery system of claim 62, wherein the drug reservoir is configured to release the drug into the patient's bladder via osmotic pressure.

77. The urinary catheter and drug delivery system of claim 62, wherein the drug is in a solid or semi-solid form.

78. The urinary catheter and drug delivery system of claim 62, wherein the drug is in a liquid form.

79. The urinary catheter and drug delivery system of claim 62, wherein the drug comprises an antimicrobial agent, an antifibrotic agent, an antimuscarinic agent, an anesthetic agent, an antinociceptive agent, or a combination thereof.

80. The urinary catheter and drug delivery system of claim 62, wherein the drug comprises an agent which dissolves stones or breaks down biofilms.

81. The urinary catheter and drug delivery system of claim 62, wherein the catheter body further comprises a drug delivery lumen extending therethrough from a distal opening to a proximal opening defined in the catheter body, and wherein the drug delivery lumen is in fluid communication with the drug chamber.

82. The urinary catheter and drug delivery system of claim 81, wherein the distal opening of the drug delivery lumen is positioned adjacent the drug reservoir.

83. The urinary catheter and drug delivery system of claim 81, further comprising a valve positioned between the drug delivery lumen and the drug chamber.

84. The urinary catheter and drug delivery system of claim 83, wherein the valve comprises a one-way valve configured to allow fluid to flow from the drug delivery lumen into the drug chamber but to prevent fluid from flowing from the drug chamber into the drug delivery lumen.

85. A method of administering a drug to a patient in need thereof, the method comprising:

inserting a drug delivery device and a distal end portion of a urinary catheter through the patient's urethra and positioning the drug delivery device and the distal end portion of the urinary catheter within the bladder, wherein the urinary catheter comprises a flexible elongate catheter body comprising a drainage lumen extending therethrough from a distal opening to proximal opening defined in the catheter body, and wherein the drug delivery device comprises a drug reservoir positioned near the distal opening of the drainage lumen and comprising a drug chamber containing a drug therein;

allowing urine to drain from the bladder through the drainage lumen; and

delivering the drug from the drug chamber into the bladder.

86. The method of claim 85, wherein inserting the drug delivery device and the urinary catheter through the patient's urethra comprises simultaneously inserting the drug delivery device and the urinary catheter through the patient's urethra.

87. The method of claim 85, wherein the drug delivery device is attached to the urinary catheter.

88. The method of claim 85, wherein the urinary catheter further comprises a balloon attached to the catheter body and comprising an internal cavity, and wherein the method further comprises inflating the balloon within the bladder.

89. The method of claim 88, wherein the drug reservoir is positioned axially between the distal opening of the drainage lumen and the balloon.

90. The method of claim 89, wherein the drug reservoir is axially spaced apart from each of the distal opening of the drainage lumen and the balloon.

91. The method of claim 85, further comprising allowing urine to enter the drug chamber.

92. The method of claim 85, wherein delivering the drug from the drug chamber into the bladder comprises releasing the drug into the bladder via diffusion.

93. The method of claim 85, wherein delivering the drug from the drug chamber into the bladder comprises releasing the drug into the bladder via osmotic pressure.

94. The method of claim 85, wherein the catheter body further comprises a drug delivery lumen extending therethrough from a distal opening to a proximal opening defined in the catheter body, and wherein the drug delivery lumen is in fluid communication with the drug chamber.

95. The method of claim 94, further comprising delivering the drug through the drug delivery lumen and into the drug chamber.

96. The method of claim 95, wherein the drug is delivered through the drug delivery lumen and into the drug chamber prior to inserting the drug delivery device through the patient's urethra.

97. The method of claim 95, wherein the drug is delivered through the drug delivery lumen and into the drug chamber after inserting the drug delivery device through the patient's urethra.

98. The method of any one of claims 85 to 97, wherein the urinary catheter is a Foley catheter.

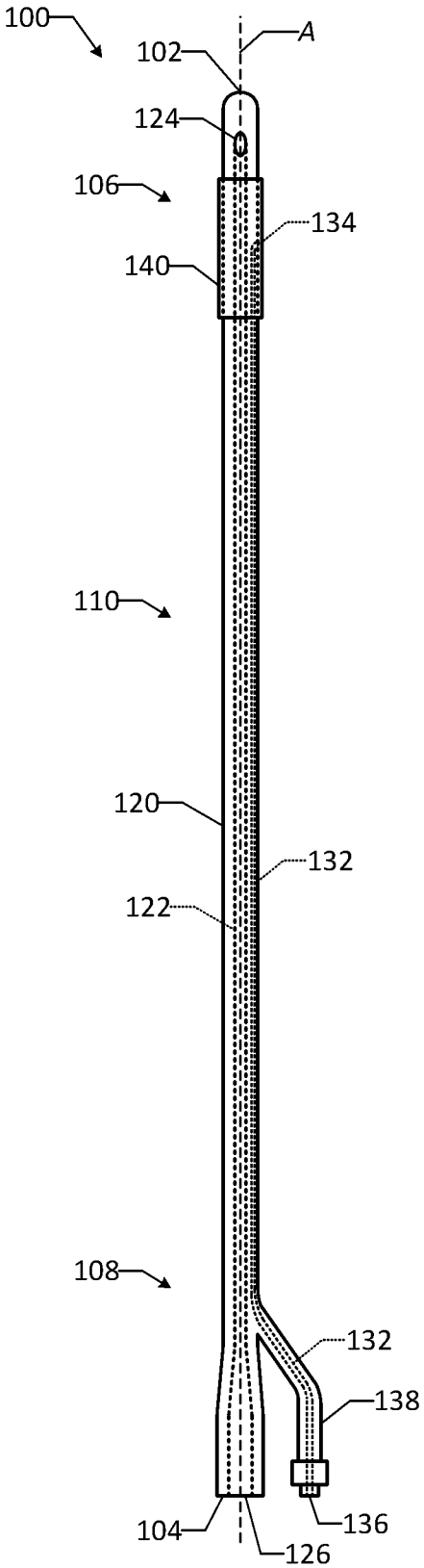
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FIG. 1A

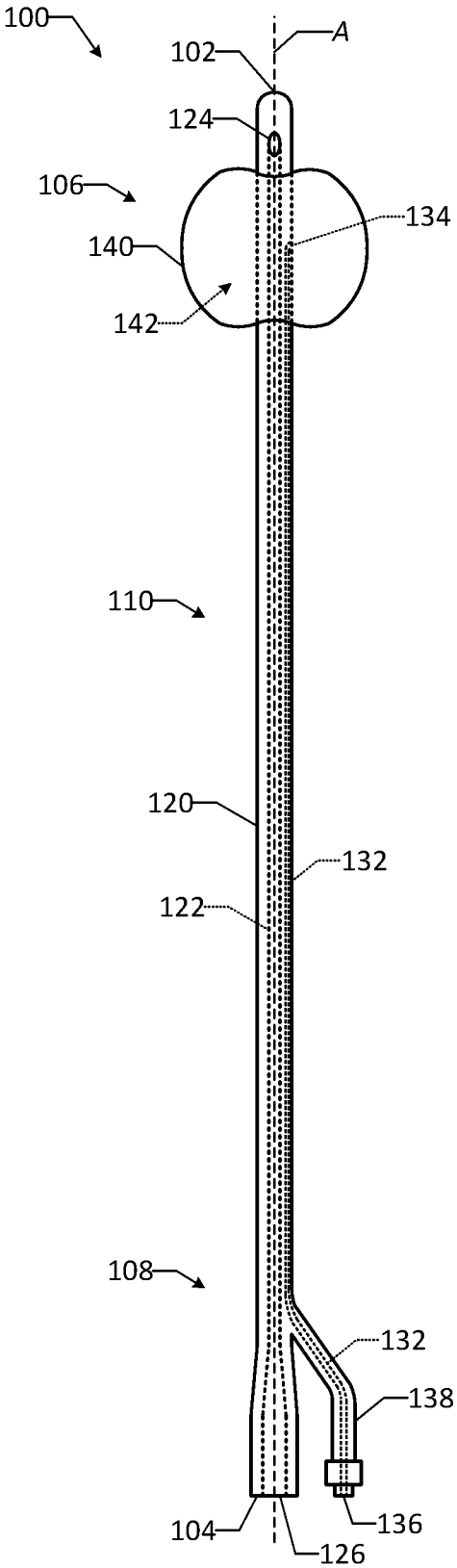
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FIG. 1B

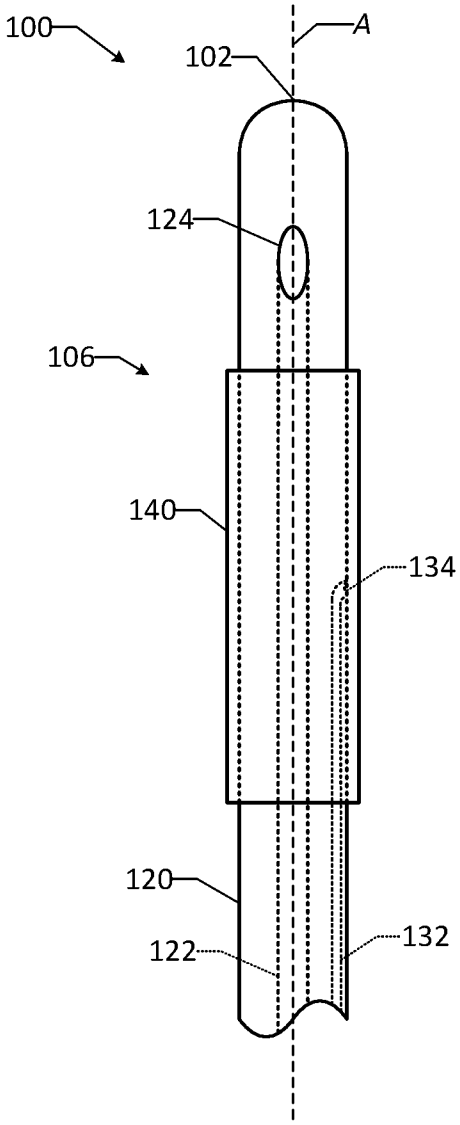
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FIG. 1C

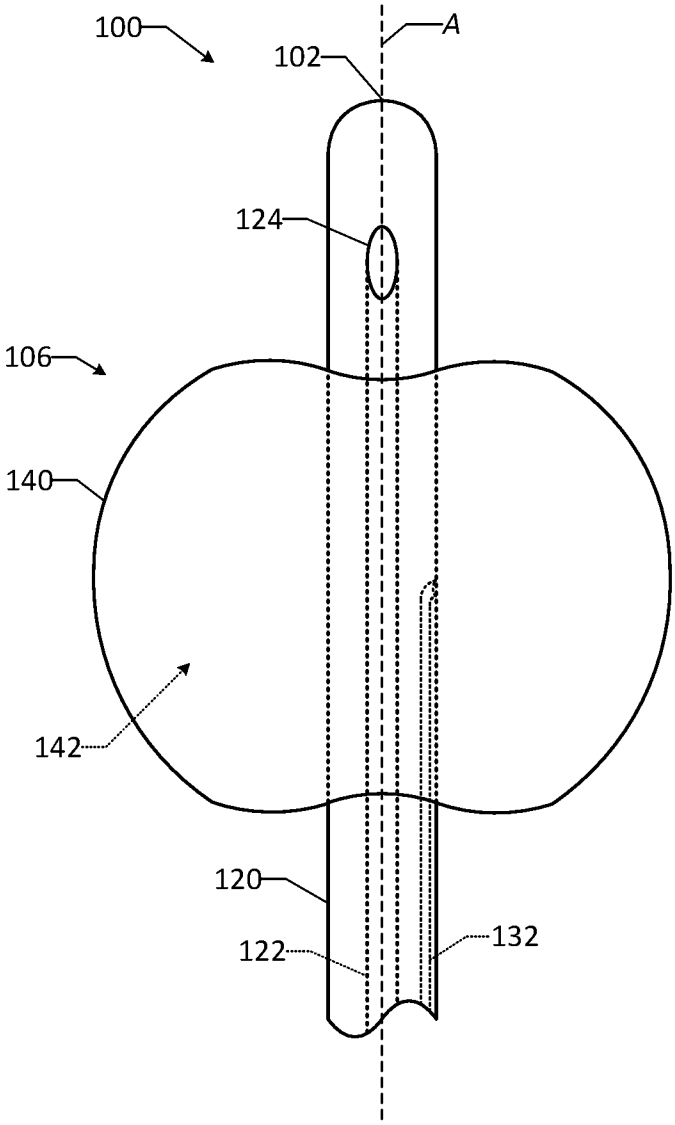
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FIG. 1D

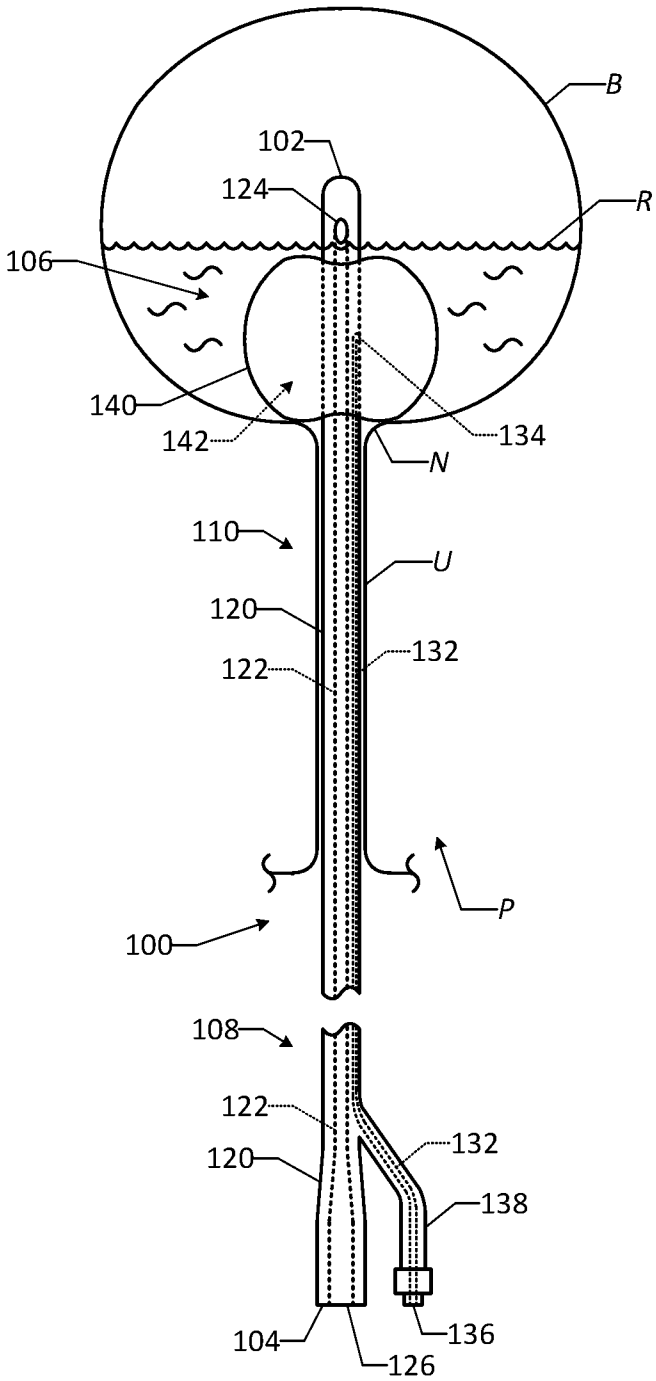
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FIG. 1E

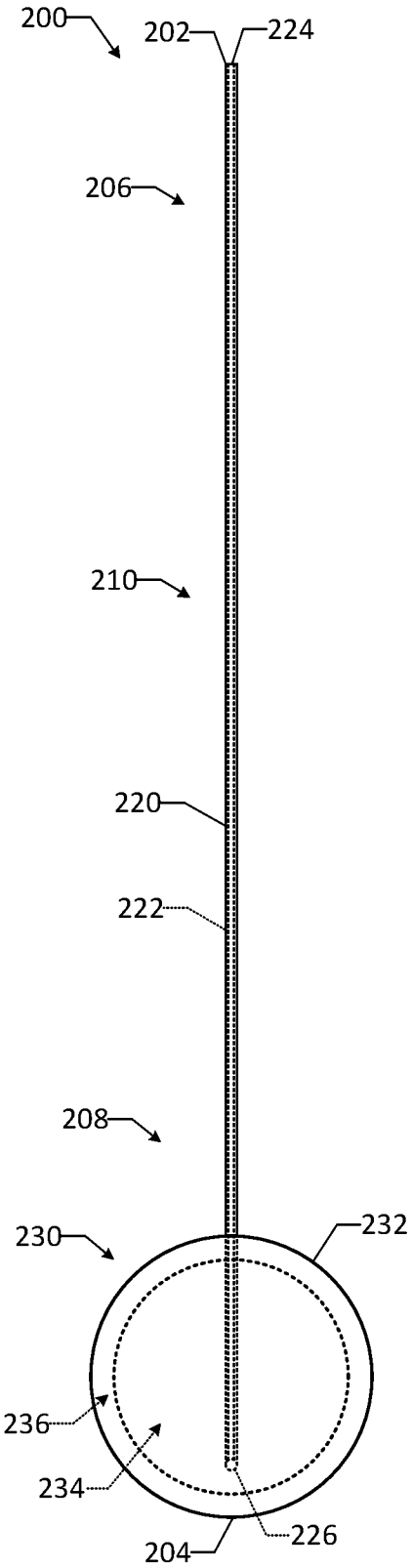

FIG. 2A

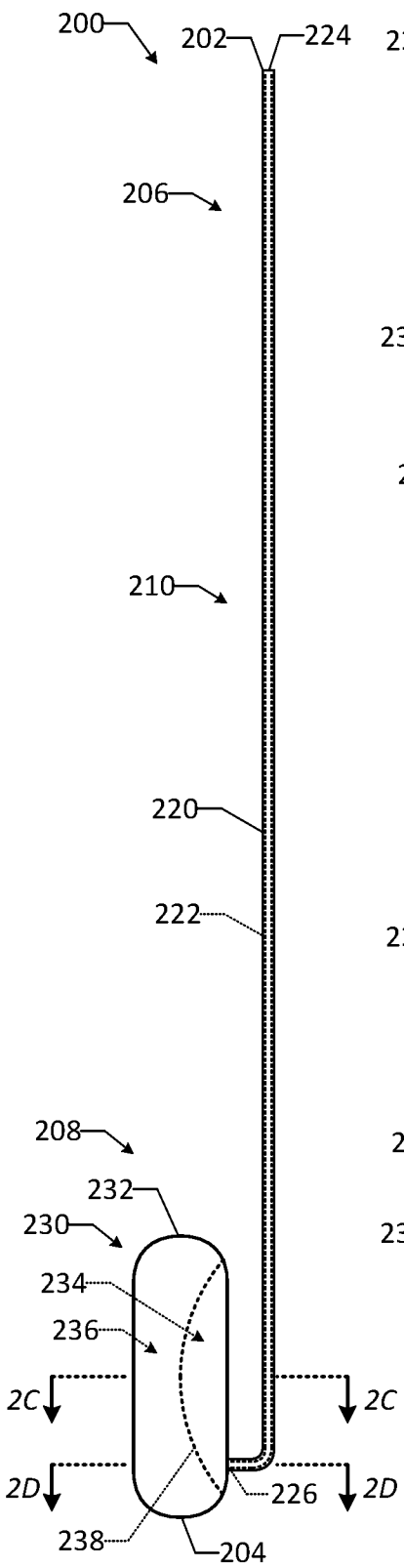

FIG. 2B

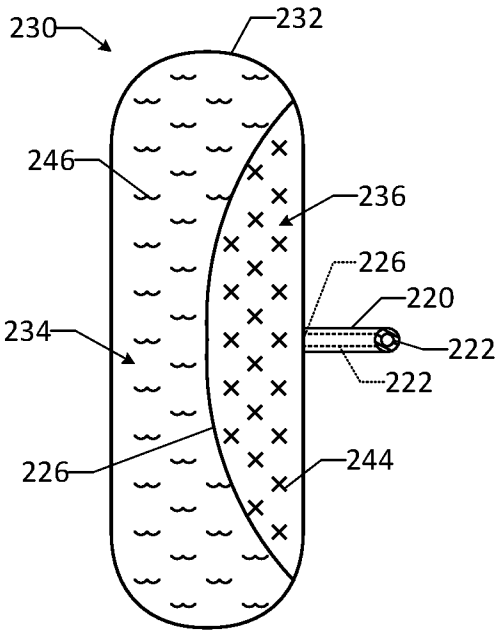

FIG. 2C

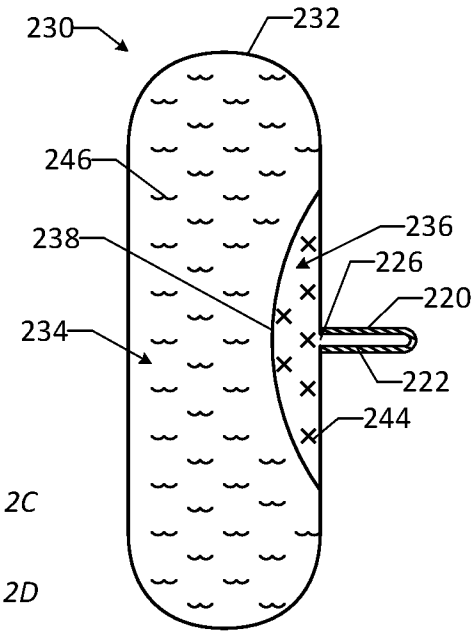

FIG. 2D

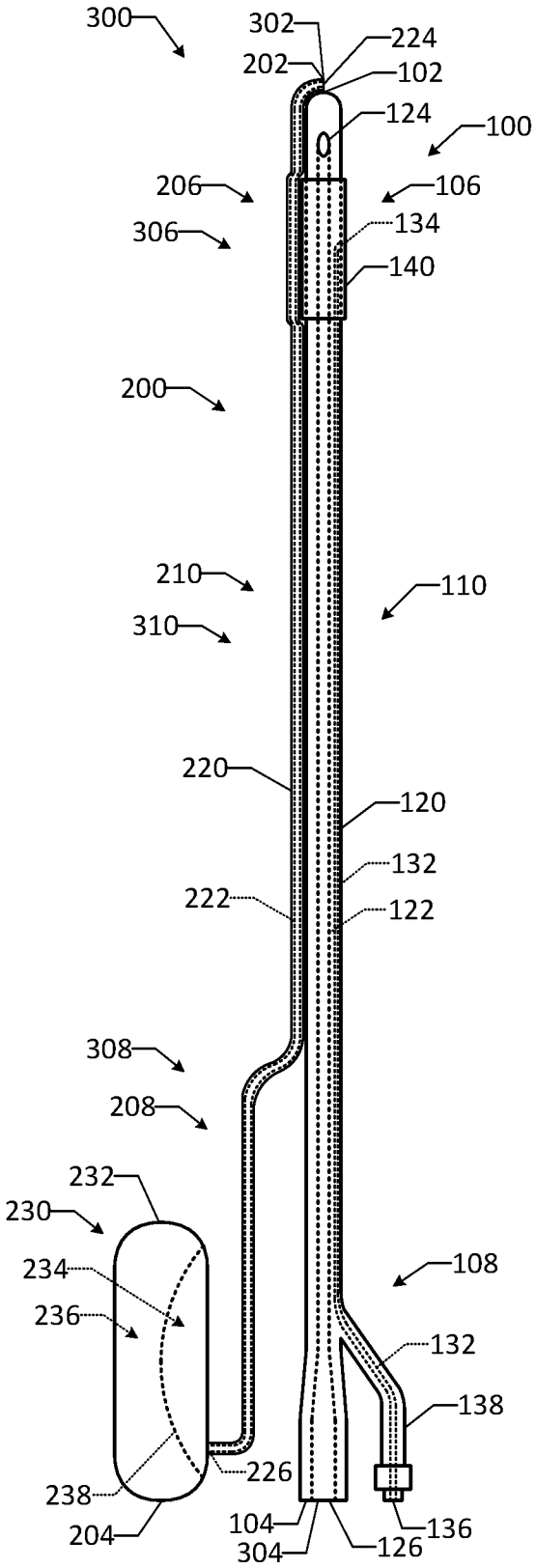
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FIG. 3A

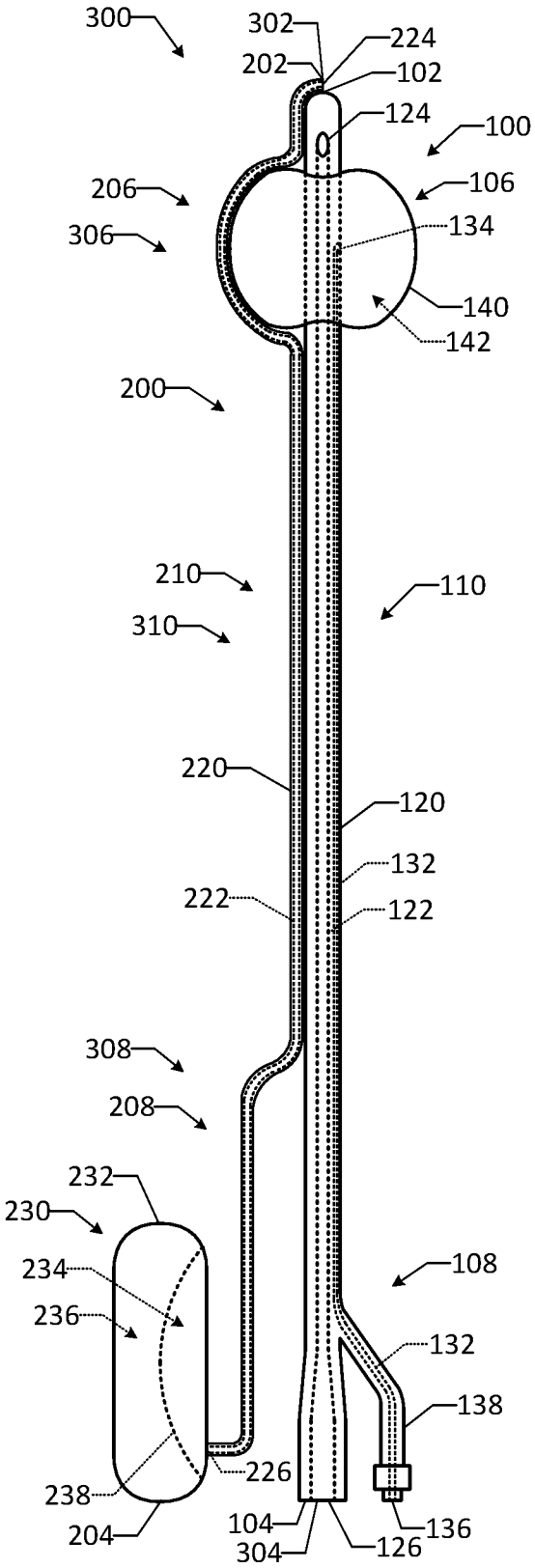
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FIG. 3B

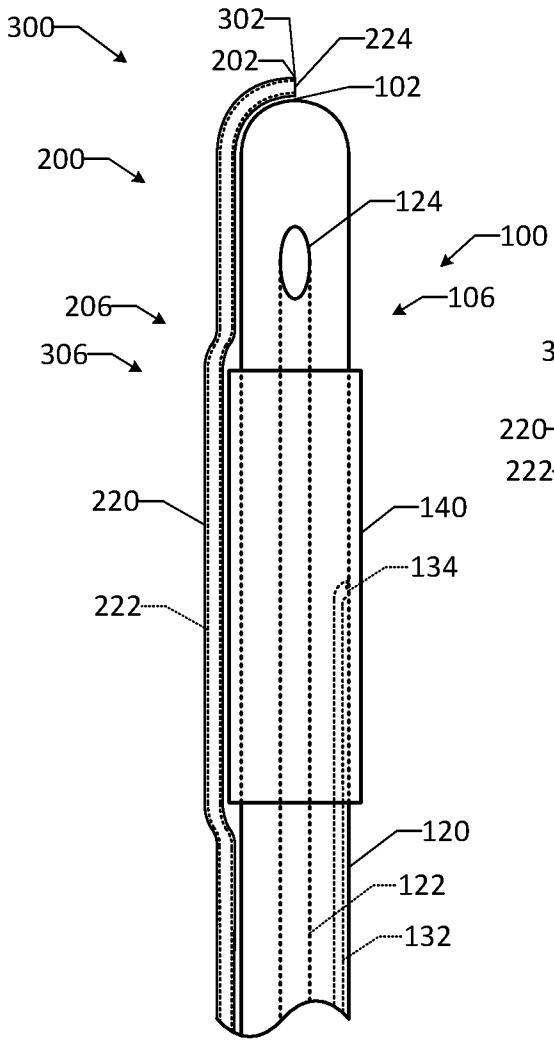
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FIG. 3C

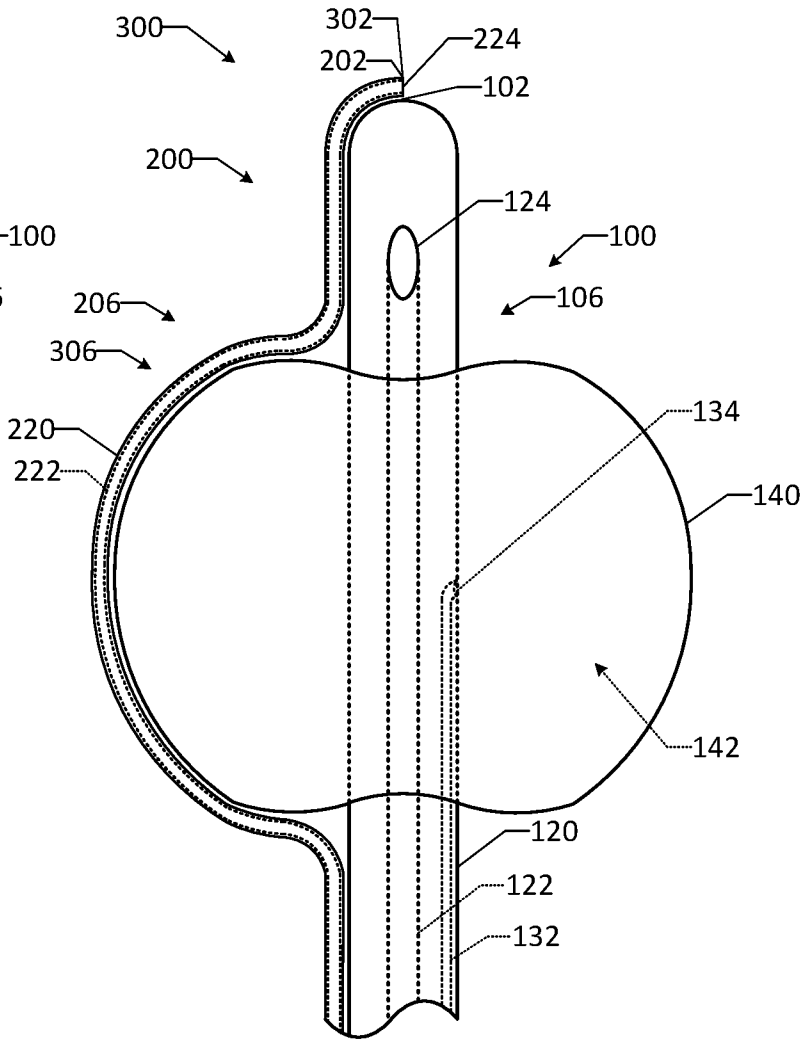
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FIG. 3D

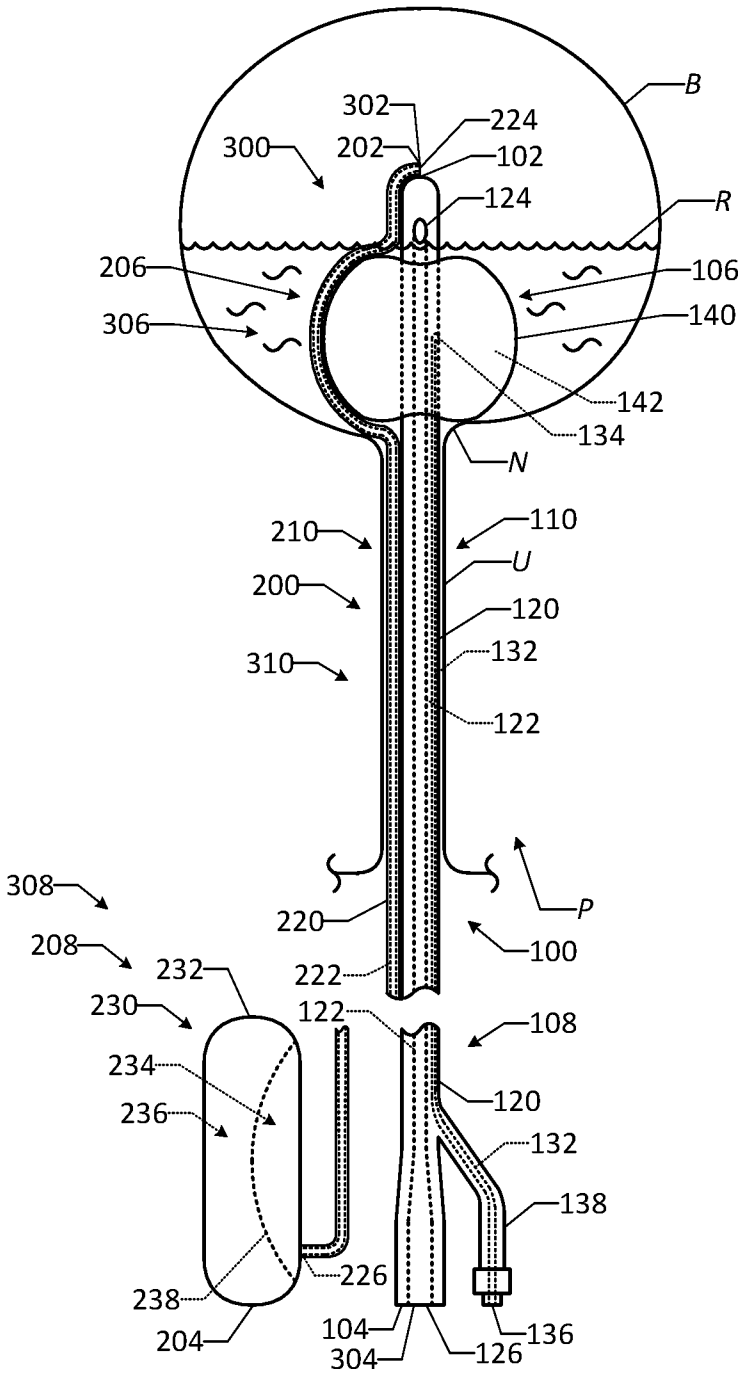
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FIG. 3E

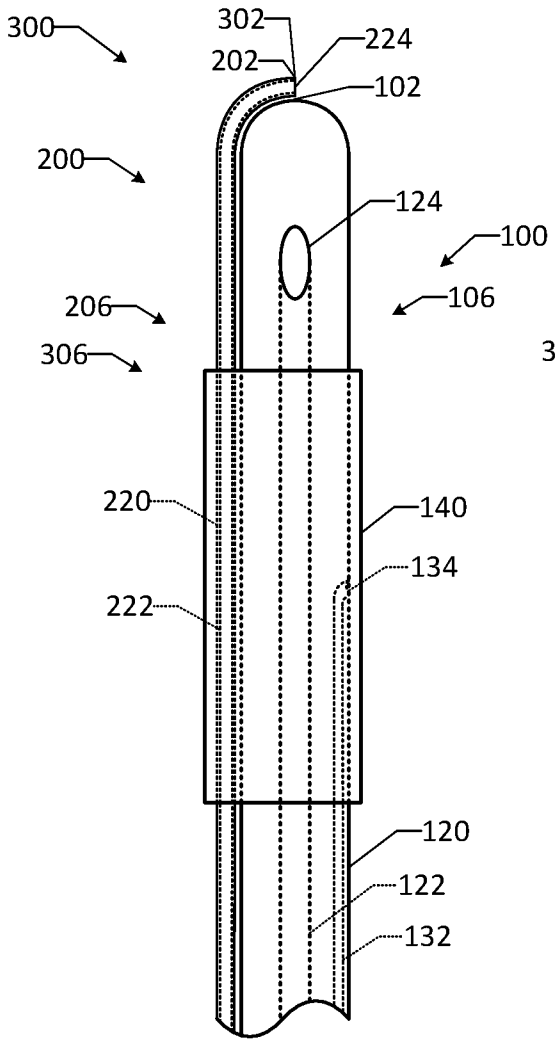
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FIG. 3F

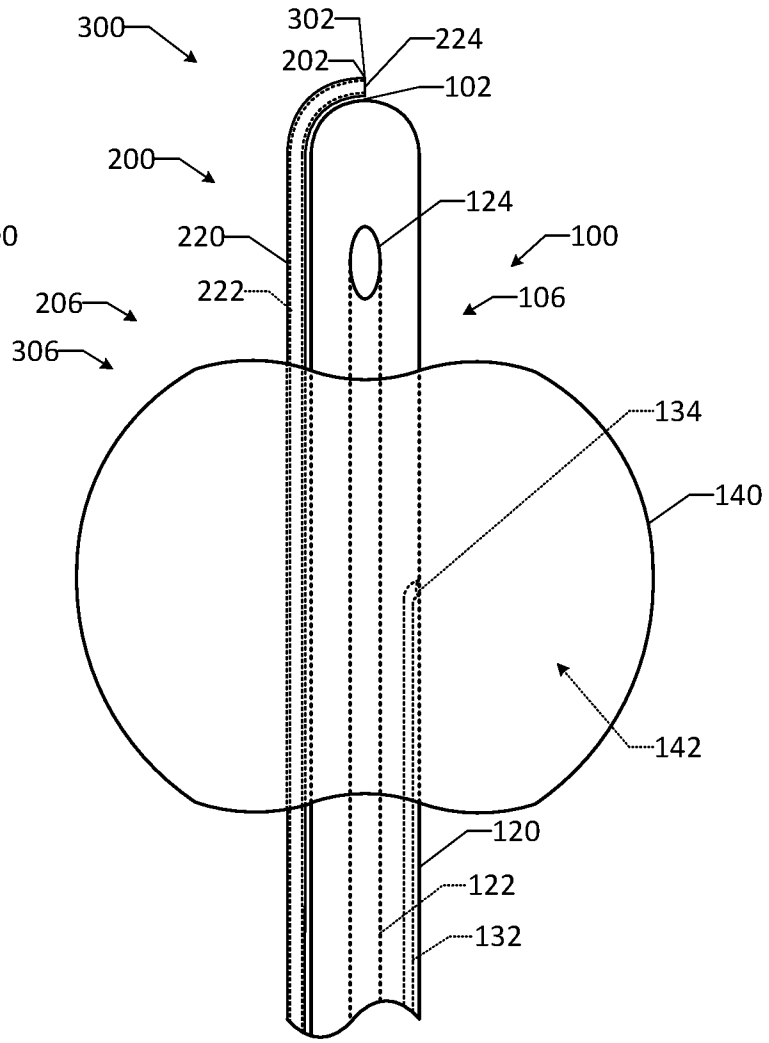
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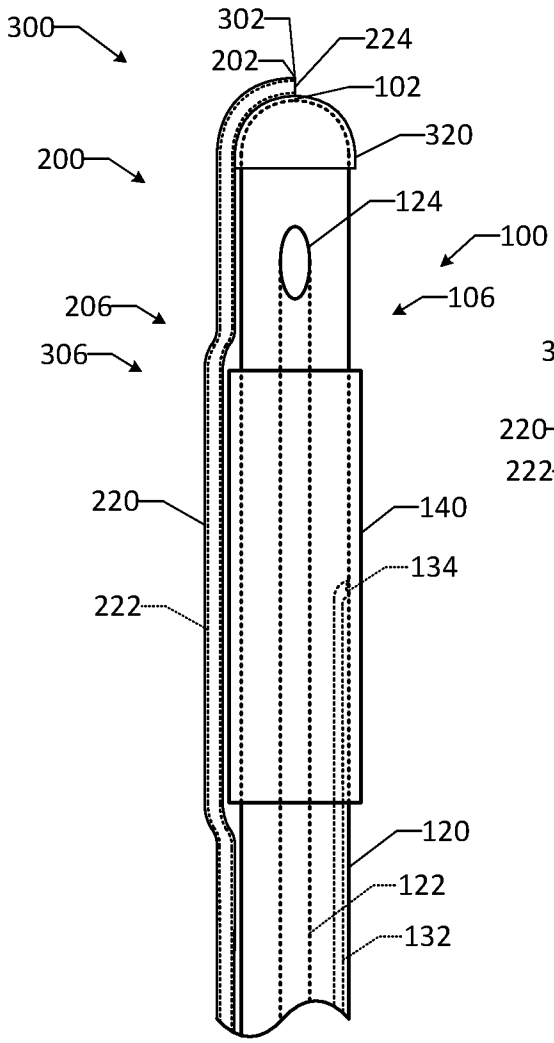
FIG. 3G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106
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306
220
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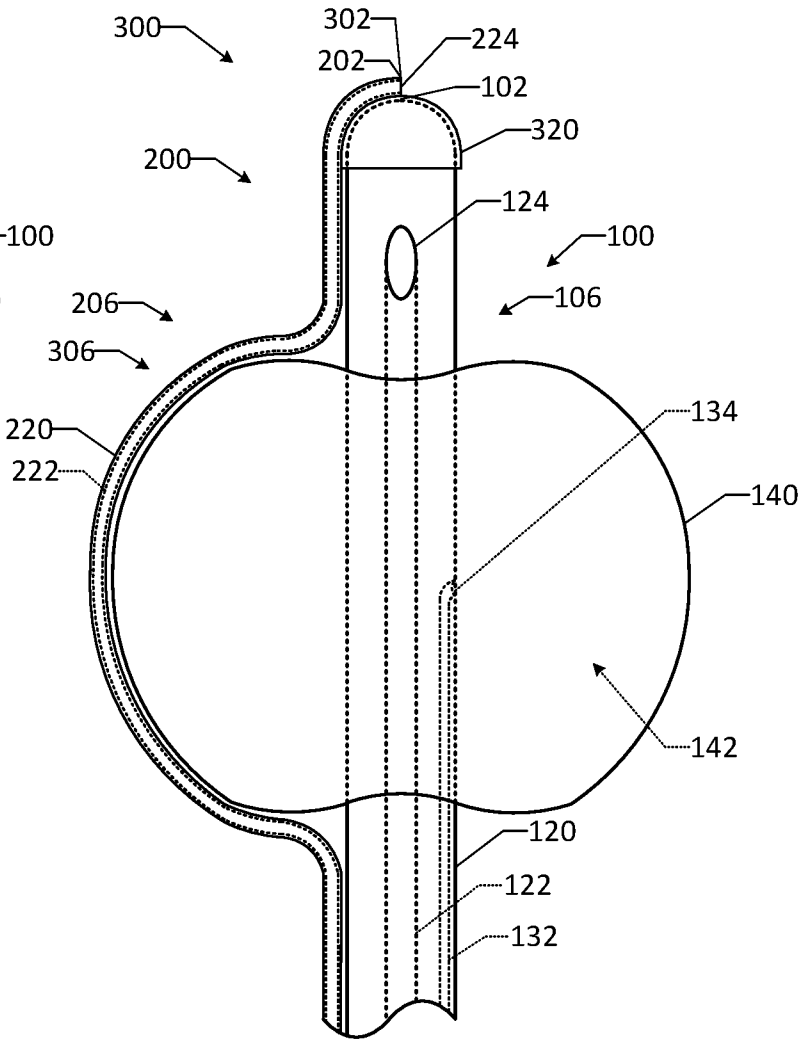
134
222
120
122
132

FIG. 3H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132

FIG. 3I

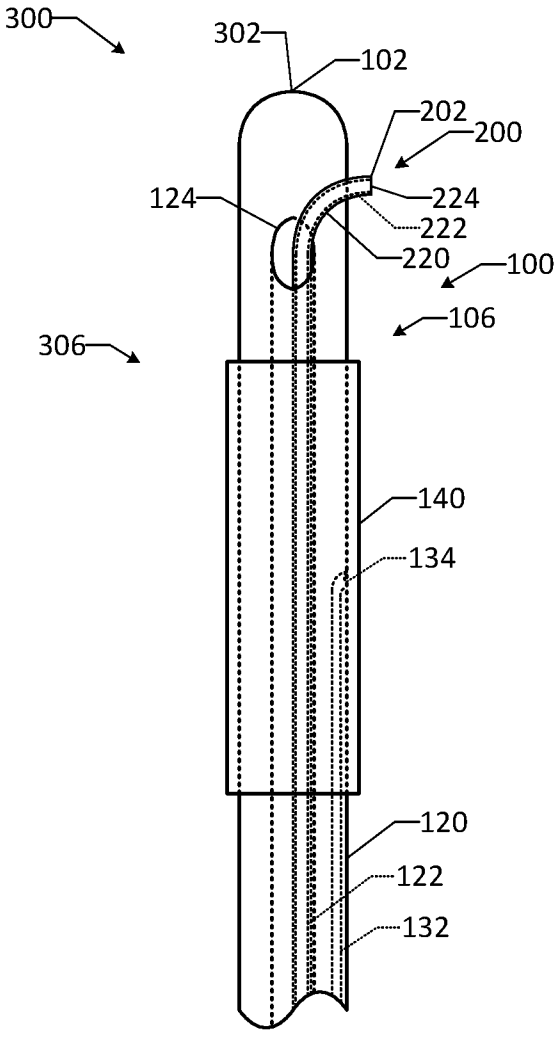
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FIG. 3J

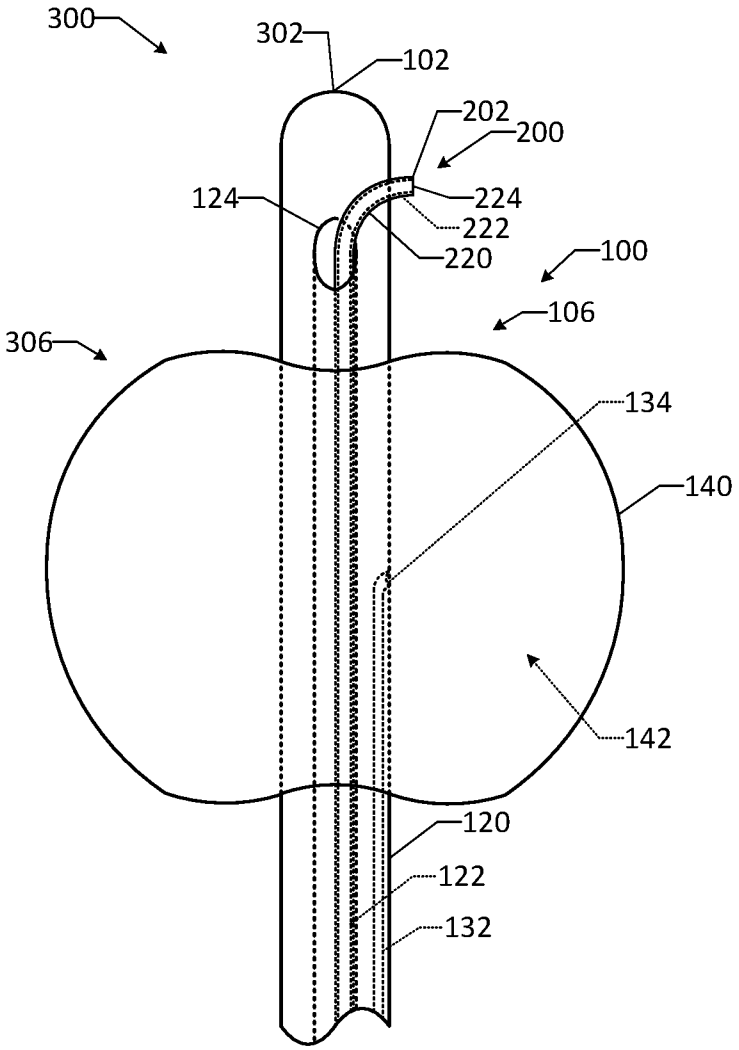
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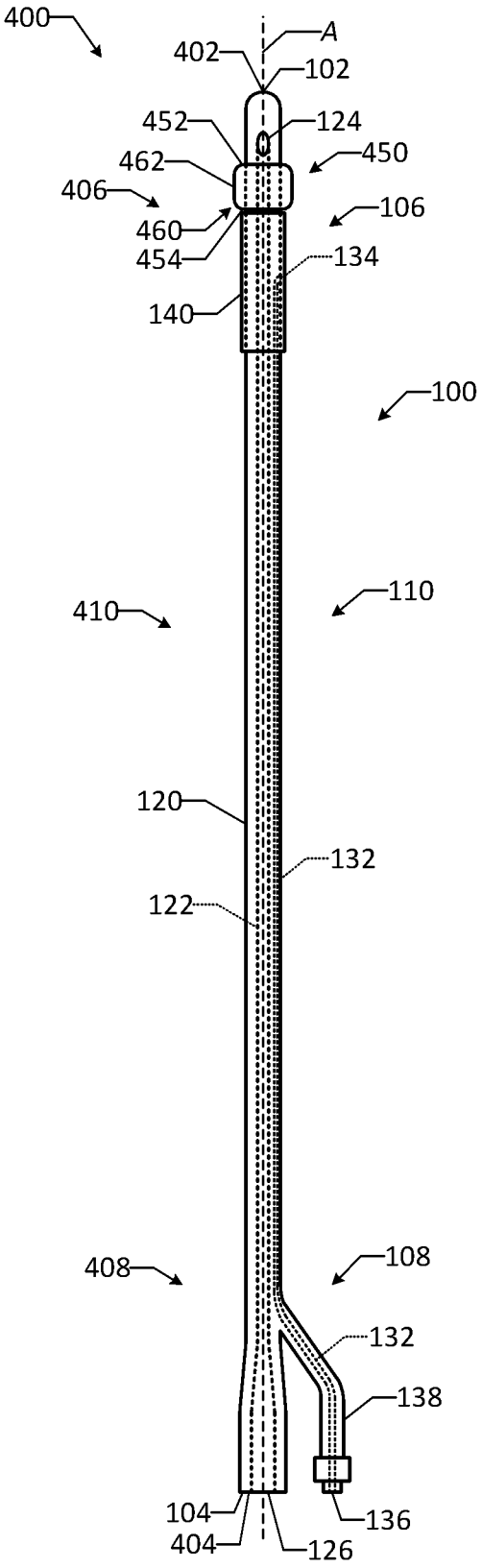
FIG. 3K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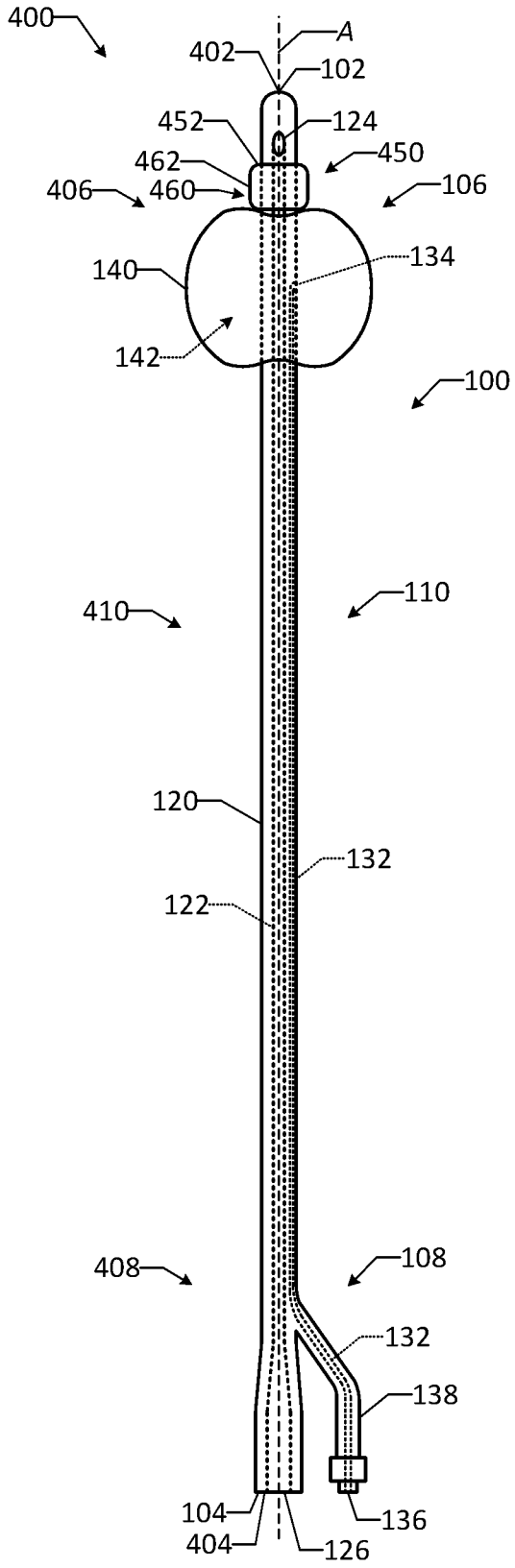
120
132
122
408
108
132
138
104
404
136
126

FIG. 4A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132
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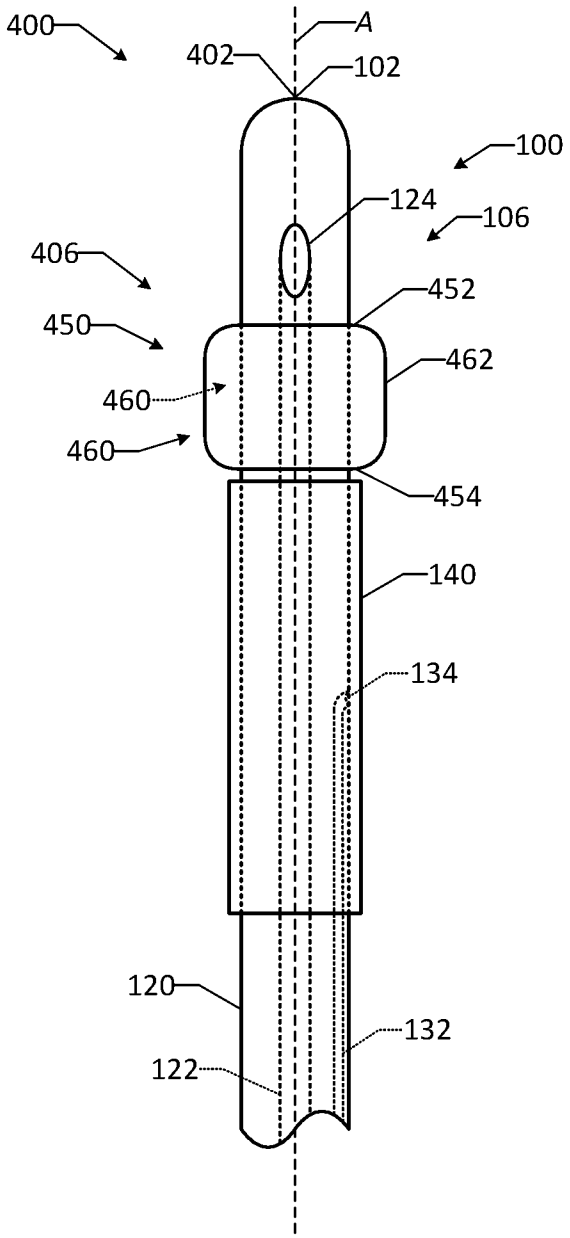
104
404
136
126

FIG. 4B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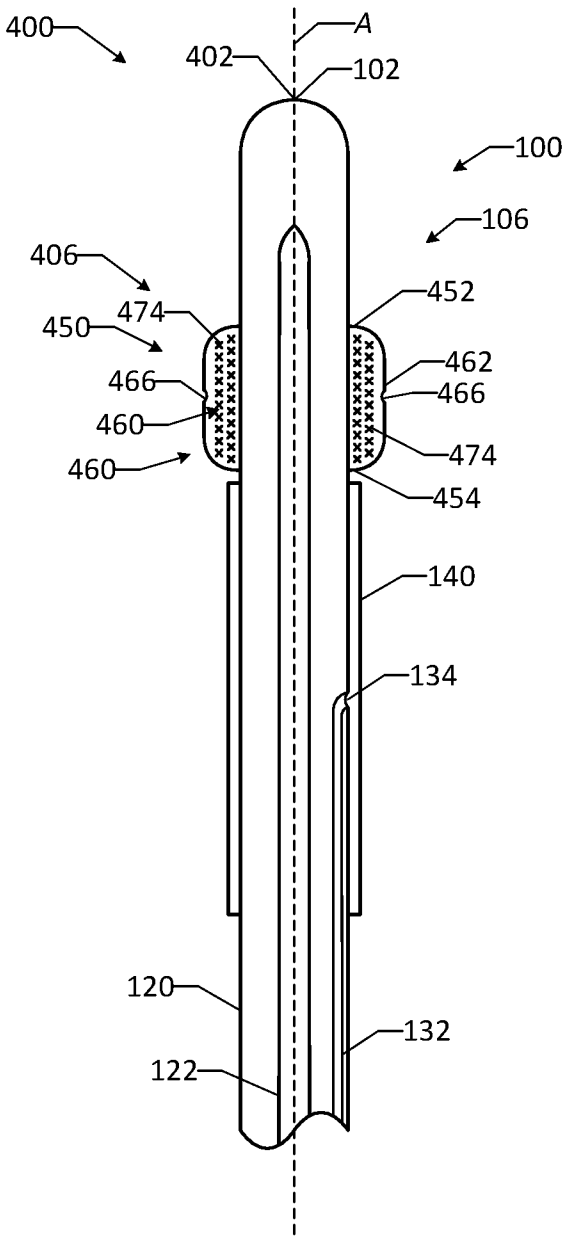
122

FIG. 4C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454
140
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120
132
122

FIG. 4D

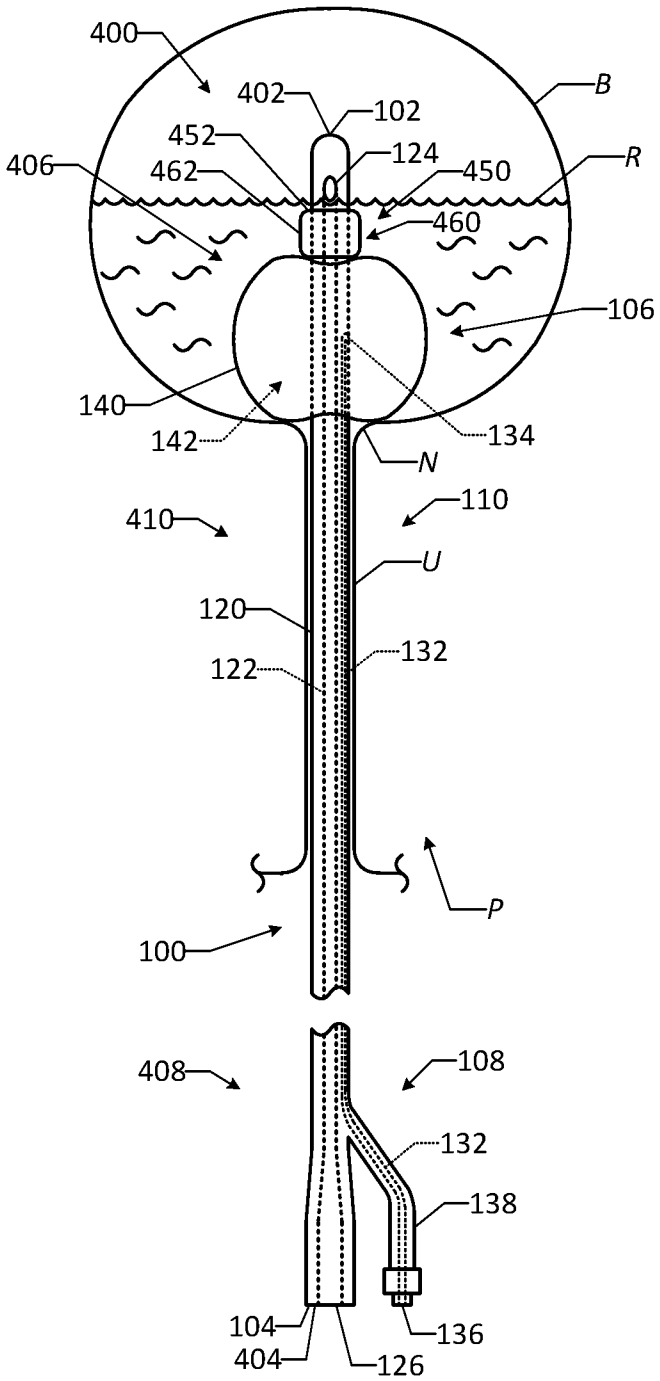
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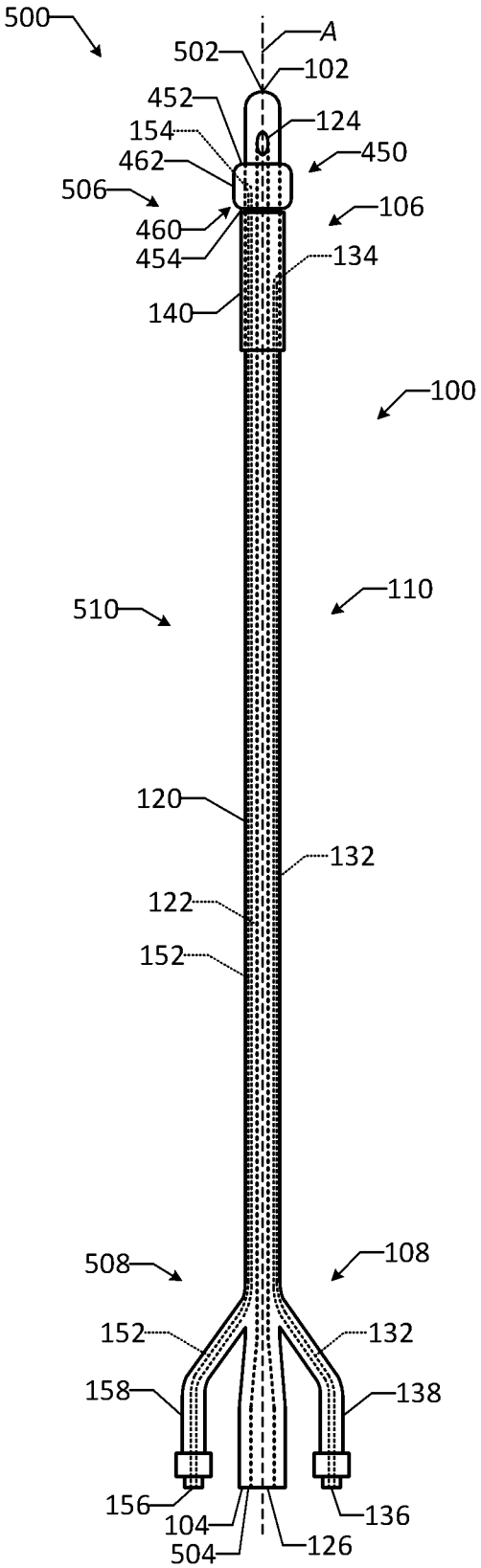
FIG. 4E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138
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FIG. 5A

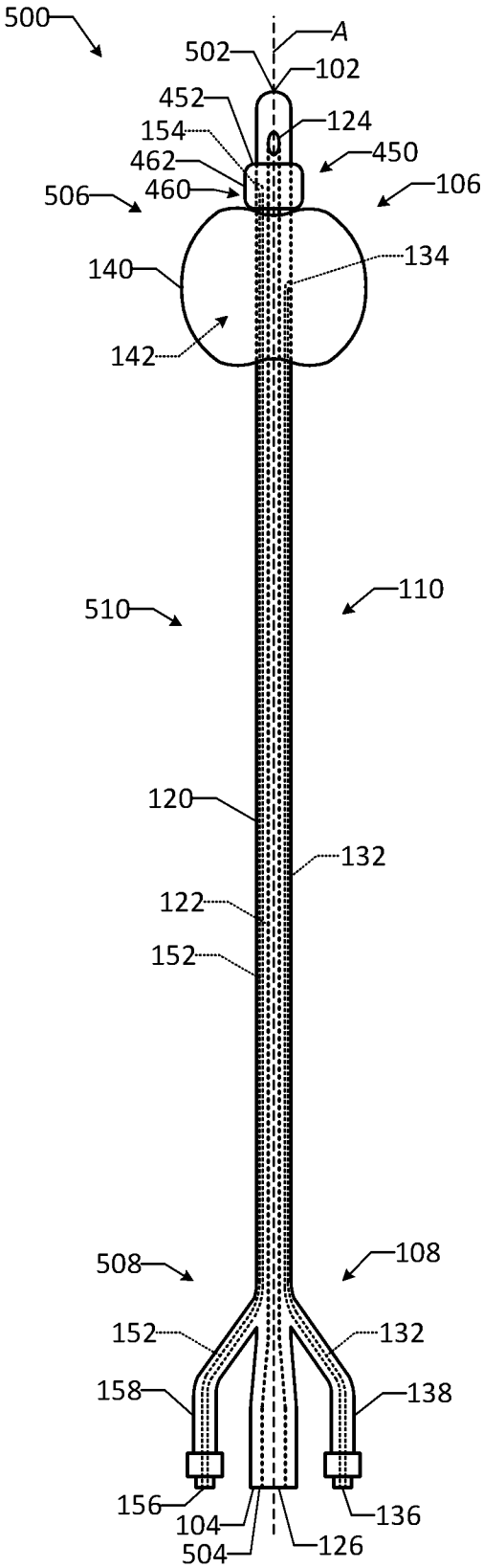
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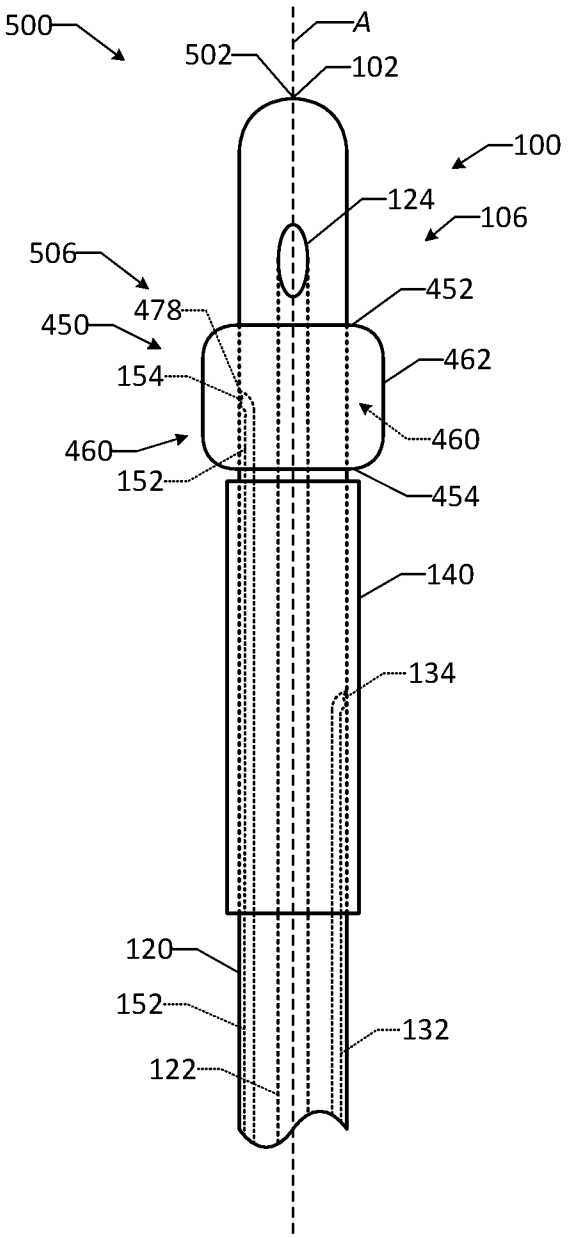
FIG. 5B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454
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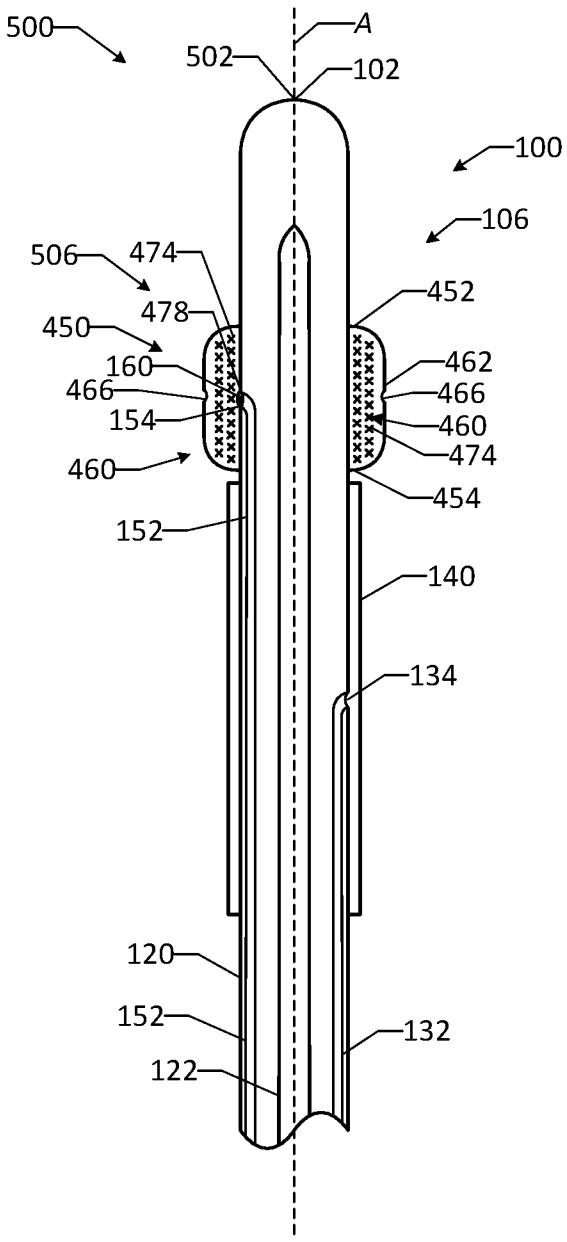
122

FIG. 5C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152
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122

FIG. 5D

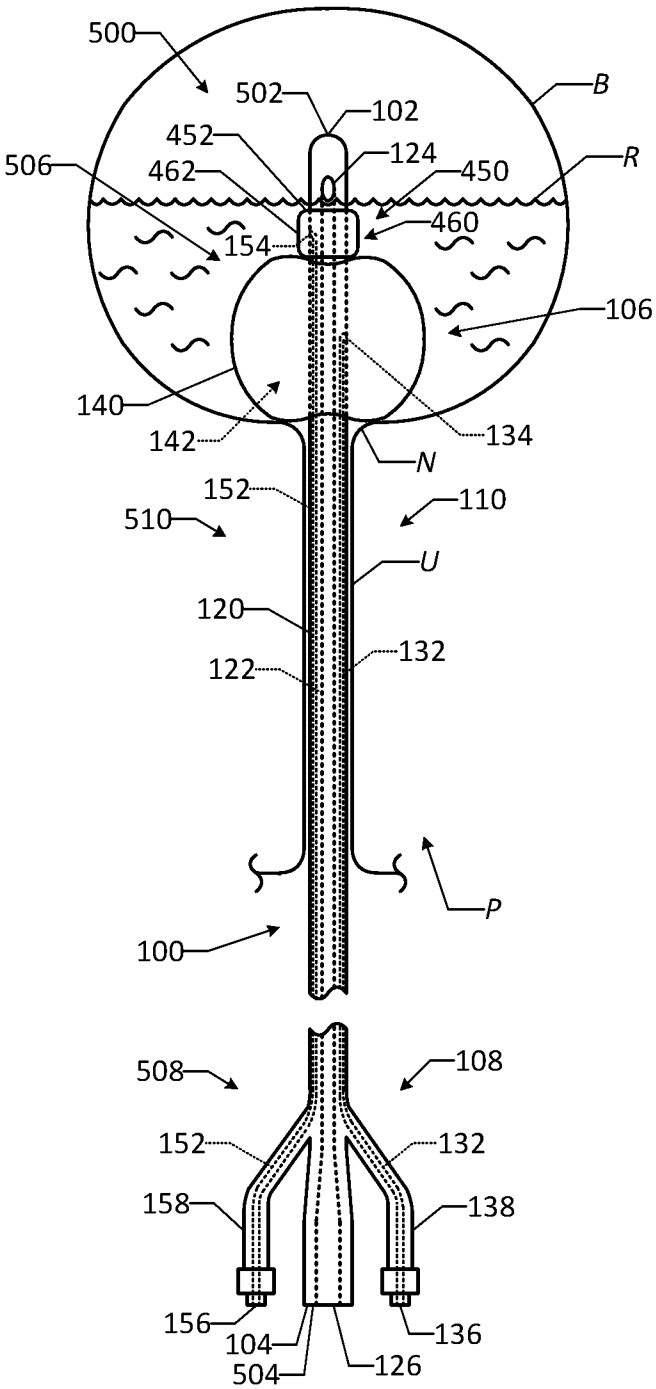
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FIG. 5E