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(54) **Title:** TRANSURETHRAL CATHETER DEVICE FOR BLEEDING CONTROL IN PELVIC FRACTURES

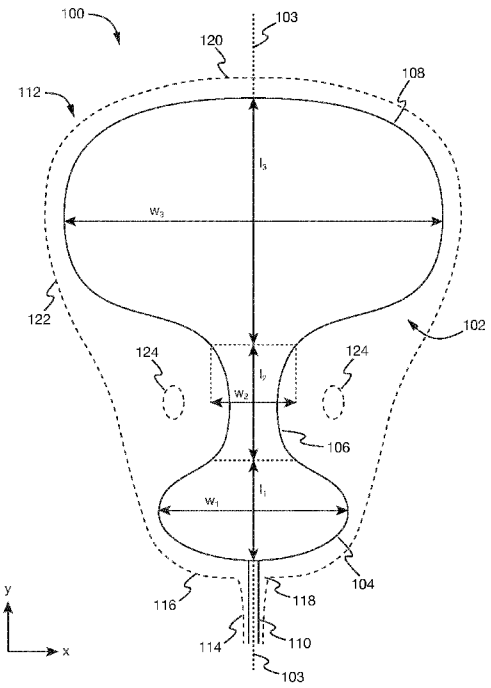

Fig. 1a

(57) **Abstract:** The inventions relates to a transurethral catheter device for bleeding control in pelvic fractures. The catheter device comprises an expandable body assembly with at least one expandable body. The expandable body assembly comprises a proximal portion, a center portion and a distal portion. The expandable body assembly is configured to be expanded from a collapsed state to an expanded state by expanding the at least one expandable body. The expandable body assembly is further configured to be inserted into the urinary bladder of a patient via the urethra in the collapsed state. In the expanded state, the proximal portion has a length l_1 and a width w_1, the center portion a length l_2 and a width w_2, the distal portion a length l_3 and a width w_3, and the expandable body assembly a total length l. A displacement volume V of the expandable body assembly in the expanded state is larger than 0.5 liters. The width w_2 is smaller than 50% of the width w_3. The width w_1 is larger than a width w_1 of the proximal portion in the collapsed state and the width w_3 is larger than a width w_3 of the distal portion in the collapsed state. The length l_1 is smaller than 25% of the total length l. This allows for arranging the expandable body assembly in the expanded state in the urinary bladder such that the proximal portion is adjacent to the internal urethral orifice of the urinary bladder and the center portion is adjacent to the ureter orifices of the urinary bladder, but not in contact with the ureter orifices.

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Transurethral catheter device for bleeding control in pelvic fractures

FIELD OF THE INVENTION

[0001] The present invention is in the field of medical technology. In particular, the invention relates to a transurethral catheter device for bleeding control in pelvic fractures.

BACKGROUND

[0002] Blood loss from internal bleeding constitutes a major challenge in the treatment of patients with pelvic fractures. The stability of the pelvis may be reduced due to the fracture, which may lead to an increase in the intrapelvic volume and may thereby complicate controlling the bleeding, see e.g. *M. C. Moss and M. D. Bircher, Injury 27, Suppl 1:S-A21-3 (1996).* During emergency treatment of patients, the main goal is thus to reduce the intrapelvic volume to minimize the available volume and to increase the pressure on the wound in order to stop the bleeding, see e.g. *D. Köhler et al., J. Trauma 71, 585 (2011).*

[0003]For this, a number of methods are currently being used. These include external compression, e.g. by placing a belt around the patient's pelvis, as well as a plurality of surgical methods to reduce the intrapelvic volume, e.g. by inserting a tamponade in the intrapelvic volume. External compression may often not be sufficient to control the bleeding. Surgical methods, on the other hand, require a high level of expertise and special equipment and in general cannot be performed by first responders. In some cases, it may not be possible to reach an appropriately equipped hospital in time, resulting in a considerable mortality rate among patients with internal bleeding in combination with a pelvic fracture.

SUMMARY OF THE INVENTION

[0004] The object of the invention is thus to provide a device that facilitates an effective emergency treatment of patients with internal bleeding, particularly by first responders.

[0005] This object is met by a transurethral catheter device according to claim 1. Embodiments of the present invention are detailed in the dependent claims.

[0006]The transurethral catheter device for bleeding control in pelvic fractures comprises an expandable body assembly with at least one expandable body. The expandable body assembly

comprises a proximal portion, a center portion and a distal portion and is configured to be expanded from a collapsed state to an expanded state by expanding the at least one expandable body. In the collapsed state, the expandable body assembly is configured to be inserted into the urinary bladder of a patient via the urethra. In the expanded state, the proximal portion has a length l_1 and a width w_1, the center portion has a length l_2 and a width w_2, the distal portion has a length l_3 and a width w_3, and the expandable body assembly has a total length l. A displacement volume V of the expandable body assembly in the expanded state is larger than 0.5 liters. Furthermore, the width w_2 is smaller than 50% of the width w_3, the width w_1 is larger than a width $\tilde{w}_1$ of the proximal portion in the collapsed state and the width w_3 is larger than a width $\tilde{w}_3$ of the distal portion in the collapsed state. The length l_1 is smaller than 25% of the total length l. This shape of the expandable body assembly allows for arranging the expandable body assembly in the expanded state in the urinary bladder such that the proximal portion is adjacent to the internal urethral orifice of the urinary bladder and the center portion is adjacent to the ureter orifices of the urinary bladder, but not in contact with the ureter orifices.

[0007]The catheter device may for example be used for the treatment of internal bleeding in patients with a pelvic fracture, e.g. by inserting the expandable body assembly in the collapsed state into the urinary bladder of the patient via the urethra and subsequently expanding the expandable body assembly to the expanded state. The displacement volume of the expandable body assembly in the expanded state is larger than in the collapsed state. Thereby, the volume of the urinary bladder may be increased, thus reducing the intrapelvic volume and increasing the pressure in the abdomen. This may help to stop the internal bleeding. Inserting the expandable body assembly into the urinary bladder may not require additional equipment and may thus already be performed by first responders. Furthermore, urinary catheterization is often performed as a standard procedure in the treatment of patients with severe injuries and hence the catheter device according to the invention may be employed without complicating the treatment. In addition, the catheter device may be used in combination with known methods, e.g. external compression of the pelvis.

[0008]The expandable body assembly comprises at least one expandable body that is configured to be expanded to increase the displacement volume of the expandable body assembly. The displacement volume is defined as the volume of an incompressible fluid that is displaced by the expandable body assembly when fully immersing the expandable body assembly in the fluid. In the expanded state, the proximal portion, the center portion and the distal portion of the expandable body assembly are arranged along a longitudinal axis of the expandable body assembly such that the center portion is located between the proximal portion and the distal portion. The longitudinal axis extends from the proximal portion to the distal

portion and may e.g. be defined as the axis around which the expandable body assembly has the smallest moment of inertia in the expanded state. The length of a portion is defined as the largest extent of the respective portion in the direction of the longitudinal axis. Accordingly, the total length of the expandable body assembly is the largest extent of the expandable body assembly in the direction of the longitudinal axis. The width of a portion is defined as the largest radially averaged width of the respective portion perpendicular to the longitudinal axis, wherein radial averaging of the width corresponds to taking the average of the width in a plane perpendicular to the longitudinal axis. Correspondingly, the total width w of the expandable body assembly is the largest width of widths of the individual portions.

[0009] In the collapsed state, the proximal portion has a length $\tilde{l}_1$ and the width $\tilde{w}_1$, the center portion a length $\tilde{l}_2$ and a width $\tilde{w}_2$, the distal portion a length $\tilde{l}_3$ and the width $\tilde{w}_3$, and the expandable body assembly a total length $\tilde{l}$ and a total width $\tilde{w}$, wherein the lengths and widths may differ from the respective values in the expanded state. To facilitate inserting the expandable body assembly into the urinary bladder, the total width $\tilde{w}$ may be less than 10 mm, preferably less than 5 mm. Preferably, the expandable body assembly comprises or consists of flexible materials.

[0010] The transurethral catheter device may further comprise a catheter tube assembly, which may e.g. be attached to or connected to the proximal portion and may extend outwards from the expandable body assembly, e.g. in proximal direction. Alternatively, the catheter device may comprise a connector configured to receive an external catheter tube assembly, wherein the connector may for example be arranged in the proximal portion. The catheter tube assembly may facilitate inserting the expandable body assembly into the urinary bladder and may extend through the urethra when the expandable body assembly is arranged in the urinary bladder.

[0011] In the expanded state, the expandable body assembly has a displacement volume V of more than 0.5 liters to allow for a substantial reduction of the intrapelvic volume. The width w_2 of the center portion is smaller than 50% of the width w_3. The length l_1 is smaller than 25% of the total length l. With this shape, the expandable body assembly may for example be arranged in the urinary bladder such that the proximal portion is adjacent to the internal urethral orifice and the center portion is adjacent to the ureter orifices. The reduced width of the center portion allows for preventing the expandable body assembly from coming in contact with the ureter orifices, thereby allowing urine to flow into the urinary bladder. This may allow for leaving the expandable body assembly inside the urinary bladder for an extended amount of time, e.g. for more than 24 hours or for more than 48 hours. The widths w_1 and w_3 in the expanded state are larger than the corresponding width $\tilde{w}_1$ and $\tilde{w}_3$, respectively, in the

collapsed state, i.e. both the proximal portion and the distal portion expand when expanding the at least one expandable body. Increasing the width of the proximal portion may e.g. be advantageous to prevent the expandable body assembly from accidentally being retracted into the urethra after expanding the at least one expandable body. In a preferred embodiment, the displacement volume V of the expandable body assembly in the expanded state is larger than 0.8 liters, preferably larger than 1.2 liters. In one example, the displacement volume of the expandable body assembly in the expanded state may for example be 1.5 liters. As detailed below, the catheter device may in some examples be configured to adjust a volume of the expandable body assembly in the expanded state. Alternatively or additionally, the width w_2 may be smaller than 20% of the width w_3, e.g. in order to reduce the probability that the expandable body assembly blocks the ureter orifices. Preferably, the width w_1 is at least two times as large as the width $\tilde{w}_1$. The width w_3 may also be at least two times as large as the width $\tilde{w}_3$, in some examples at least four times as larger as the width $\tilde{w}_3$. Furthermore, the length l_1 may be smaller than 15% of the total length l, e.g. to more reliably ensure that the center portion is located adjacent to the ureter orifices when the proximal portion is adjacent to the internal urethral orifice.

[0012] The width w_2 may be smaller than 50% of the width w_1, preferably smaller than 30% of the width w_1 such that the expandable body assembly has a dumbbell-like or hourglass-like shape in the expanded state. This may further reduce the probability of the center portion coming in contact with the ureter orifices.

[0013] To facilitate arranging the expandable body assembly within the urinary bladder, the catheter device may be configured to adjust at least one parameter selected from a group consisting of the widths w_1, w_2, w_3 and w, the lengths l_1, l_2, l_3 and l and the displacement volume V. In one example, the catheter device is configured to adjust the total length l such that, when the expandable body assembly is arranged in the urinary bladder in the expanded state, the proximal portion is in contact with a bottom portion of the wall of the urinary bladder and the distal portion is in contact with an upper portion of the wall of the urinary bladder. This may be advantageous to prevent the expandable body assembly from moving within the urinary bladder. The catheter device may for example be configured to adjust the total length l by changing at least one of the lengths l_1, l_2, and l_3.

[0014] The catheter device may also be configured to adjust the width w_3 such that, when the expandable body assembly is arranged in the urinary bladder in the expanded state, the distal portion is in contact with a lateral portion of the wall of the urinary bladder. Preferably, the catheter device is configured to adjust the total length l, the width w_1 and/or the width w_3 such that, when the expandable body assembly is arranged in the urinary bladder in the ex-

panded state, the expandable body assembly is in contact with at least 50%, preferably with at least 75% of a surface area of the wall of the urinary bladder.

[0015] In a preferred embodiment, the width w_2 is smaller than 2 cm, preferably smaller than 1 cm and/or the length l_2 is between 10% and 30% of the total length l. In one example, the width of the center portion may be uniform over the entire center portion or may deviate by less than 30%, preferably by less than 15% from the width w_2. The total length l may for example be between 10 cm and 20 cm, preferably between 12.5 cm and 17.5 cm. In some examples, the catheter device may be configured to adjust the total length l over a range between 12.5 cm and 17.5 cm, preferably between 10 cm and 20 cm. The width w_3 may be larger than the width w_1, preferably at least twice as large as the width w_1, e.g. to adapt a shape of the expandable body assembly to the shape of the urinary bladder. The width w_1 may for example be between 2 cm and 8 cm and the width w_3 may for example be larger than 10 cm, e.g. between 10 cm and 20 cm.

[0016] An outer surface of the proximal portion and/or an outer surface of the distal portion may have positive principal curvatures over at least 50%, preferably over at least 75% of the surface area of the respective portion in the expanded state, wherein the principal curvatures at a given point on a surface are the minimum and maximum values of the curvature of the surface at this point. Accordingly, positive principal curvatures correspond to a convex surface and negative principal curvatures correspond to a concave surface. In one example, the outer surface of the proximal portion and/or the outer surface of the distal portion may be an ellipsoid. In other examples, the outer surface of the proximal portion may be a cylinder or a partial cylinder as detailed below. Additionally or alternatively, an outer surface of the center portion may have at least one principle curvature equal to or smaller than zero over at least 50%, preferably over at least 75% of the surface area of the center portion in the expanded state. In one example, the outer surface of the center portion may be a cylinder or a partial cylinder. In another example, the outer surface of the center portion may have a negative curvature in the direction of the longitudinal axis.

[0017] In some examples, the outer surface of the proximal portion and/or the outer surface of the center portion may comprise a recess or cut-out, e.g. for arranging an opening of a urine extraction tube as described below. The proximal portion and/or the center portion may for example be a partial cylinder with a recess or cut-out, e.g. a cylinder whose radial cross-section is a circular sector. The circular sector may for example have a central angle between 210° and 330°, in one example a central angle of 270°.

[0018] In some embodiments, the expandable body assembly is rotationally symmetric around the longitudinal axis extending from the proximal portion to the distal portion. The expandable body assembly may e.g. exhibit a discrete rotational symmetry, i.e. may be symmetric with respect to a rotation around the longitudinal axis by 360°/n with integer n > 1. The expandable body assembly may in particular exhibit a continuous rotational symmetry around the longitudinal axis, i.e. may be symmetric with respect to a rotation around the longitudinal axis by any angle. This may facilitate arranging the expandable body assembly in the urinary bladder.

[0019] Preferably, the catheter device further comprises an urine extraction tube, wherein the urine extraction tube has at least one distal opening arranged in the center portion of the expandable body assembly. The urine extraction tube may e.g. be part of a catheter tube assembly attached to or connected to the proximal portion. The at least one distal opening of the urine extraction tube may be arranged such that the urine extraction tube provides a connection to the interior of the urinary bladder for fluids, e.g. to drain urine from the urinary bladder via the urine extraction tube. The at least one distal opening may e.g. be arranged on the outer surface of the center portion. In some examples, the at least one distal opening of the urine extraction tube may be located within a recess in the outer surface of the center portion, e.g. a recess formed by a partial cylinder. In one example, the urine extraction tube may have a plurality of distal openings distributed over the center portion.

[0020]The expandable body assembly may comprise an expandable body extending from the proximal portion to the distal portion, e.g. to adjust the widths w_1, w_2, and w_3 simultaneously by expanding the expandable body. In one example, the expandable body assembly comprises a single expandable body, e.g. a single expandable body extending from the proximal portion to the distal portion. In other examples, the expandable body assembly comprises a plurality of expandable bodies, e.g. a distal expandable body arranged in the distal portion of the expandable body assembly and a proximal expandable body arranged in the proximal portion of the expandable body assembly.

[0021] In a preferred embodiment, the at least one expandable body comprises an inflatable balloon comprising a flexible material enclosing an inner volume that is configured to receive an inflation medium. The inflatable balloon may for example comprise latex, polyurethane, silicone and/or a combination thereof. An inner surface and/or an outer surface of the inflatable balloon may be coated, wherein the coating may e.g. include a silicone elastomer, a hydrogel, polytetrafluoroethylene or a combination thereof.

[0022]Additionally or alternatively, the at least one expandable body may comprise other expandable elements, e.g. an element comprising a mechanically extendable element like a spring. In one example, the catheter device may comprise an insertion tube that is configured to be arranged in the urethra, wherein the expandable body assembly may be configured to be inserted into the urinary bladder through said insertion tube. The insertion tube may be configured to compress the mechanically extendable elements and the mechanically extendable elements may extend upon leaving the insertion tube.

[0023]The catheter device may further comprise an inflation tube, wherein the inflatable balloon is configured to receive the inflation medium through the inflation tube. The inflation tube may for example be part of a catheter tube assembly. The inflation tube may e.g. have a distal opening in communication with the inner volume of the inflatable balloon to supply the inflation medium to the inner volume. The opening may for example be arranged in a wall of the inflatable balloon or within its inner volume.

[0024]The center portion of the expandable body assembly may comprise at least one constraining element configured to limit a width of the center portion. In one example, the inflatable balloon may extend from the proximal portion to the distal portion. The constraining element may be configured to limit an expansion of the inflatable balloon in the center portion. The constraining element may for example comprise or consist of a material with smaller elasticity than a material of the inflatable balloon. The constraining element may for example be a ring or cylinder surrounding the inflatable balloon in the center portion. In other examples, the constraining element may be integrated into the inflatable balloon, e.g. a portion of the inflatable balloon with a larger wall thickness and/or comprising a different material than other portions of the inflatable balloon.

[0025]In a preferred embodiment, the inflation medium is a fluid, in particular an incompressible fluid like a liquid. The inflation medium may for example be water or a physiological salt solution. This may e.g. be advantageous in case of a leak in the inflatable balloon. Furthermore, it may facilitate adjusting a volume of the inflatable balloon by controlling the amount of liquid supplied to inflatable balloon as detailed below. In other examples, the inflation medium may be a gas or may be supplied to the inflatable balloon in a liquid phase and a phase transition to a gas phase may be induced to expand the expandable body assembly.

[0026]The catheter device may also comprise a volume control unit configured to adjust the volume of the inflatable balloon by adjusting a pressure in the inner volume of the inflatable balloon and/or by adjusting an amount of inflation medium supplied to the inner volume of

the inflatable balloon. In other examples, the catheter device may comprise a connector to connect the catheter device to a volume control unit configured to adjust the volume of the inflatable balloon. The volume control unit may be configured to inject and/or extract inflation medium into/from the inner volume, e.g. by controlling a supply unit supplying the inflation medium. The volume control unit may be configured to control the amount of inflation medium supplied to the inner volume by injecting and/or extracting inflation medium, e.g. to supply a predefined volume of an incompressible inflation medium such as a liquid. Alternatively or additionally, the volume control unit may be configured to control the pressure in the inner volume of the inflatable balloon by injecting and/or extracting inflation medium, e.g. to reach a predefined pressure in the inner volume. The volume control unit may be configured to adjust the volume of the inflatable balloon in the expanded state at least within a range between 1 liter and 1.5 liters, preferably at least within a range between 0.5 liters and 2 liters, most preferably at least within a range between 0.5 liters and 3 liters.

[0027] The catheter device may further comprise a pressure sensor configured to determine a pressure in the inner volume of the inflatable balloon and/or a pressure on an outer surface of the expandable body assembly. The pressure sensor may for example be a piezoresistive, piezoelectric, inductive or capacitive pressure sensor. The pressure sensor may e.g. be arranged in the inner volume, in or adjacent to the wall of the inflatable balloon or on an outer surface of the expandable body assembly. In other examples, the pressure sensor may be integrated into the inflation tube or another element of the catheter device exposed to the inflation medium, e.g. a pump or a tube in the supply unit.

[0028] As mentioned above, the expandable body assembly may comprise more than one expandable body. The expandable body assembly may for example comprise a distal expandable body arranged in the distal portion of the expandable body assembly and a proximal expandable body arranged in the proximal portion of the expandable body assembly. The catheter device may be configured such that the expandable bodies may be expanded independently of one another, e.g. to expand the proximal expandable body prior to expanding the distal expandable body or to expand the proximal and distal expandable bodies to different volumes and/or pressures. In some examples, the proximal expandable body may extend from the proximal portion to the center portion. A distal end of the proximal inflatable body may e.g. be directly adjacent to a proximal end of the distal inflatable body. The proximal expandable body may for example be an ellipsoid, a cylinder or a partial cylinder. The expandable body assembly may also comprise a central expandable body arranged in the center portion.

[0029]The proximal expandable body and the distal expandable body may each comprise an inflatable balloon configured to receive an inflation medium. The catheter device may further comprise a proximal inflation tube and a distal inflation tube, wherein the inflatable balloon in the proximal portion is configured to receive an inflation medium through the proximal inflation tube and the inflatable balloon in the distal portion is configured to receive an inflation medium through the distal inflation tube. The catheter device may be configured such that there is no connection between the proximal inflation tube and the distal inflation tube to exchange inflation medium. In other examples, the catheter device may comprise a single inflation tube to supply inflation medium to both the inflatable balloon in the proximal portion and the inflatable balloon in the distal portion.

[0030]In a preferred embodiment, the catheter device comprises an insertion tube extending through the proximal portion and the center portion of the expandable body assembly. The distal portion of the expandable body assembly may be configured to be inserted into the urinary bladder through the insertion tube in the collapsed state. The distal portion may in particular be part of an independent catheter assembly. The insertion tube may e.g. be part of the catheter tube assembly, which may also comprise the urine extraction tube and/or the proximal inflation tube. In this way, the proximal portion and the center portion of the expandable body assembly may first be inserted into the urinary bladder via the urethra, e.g. to provide access to the urinary bladder via the urine extraction tube similar to a conventional urinary catheter. If needed, the distal portion may subsequently be inserted through the insertion tube, e.g. using the distal inflation tube to thread the distal portion through the insertion tube. This may be advantageous to increase the flexibility when employing the catheter device. The distal portion may in particular be inserted after expanding the proximal portion and/or the center portion to the expanded state, while the distal portion is in the collapsed state.

LIST OF FIGURES

[0031] In the following, a detailed description of the invention and exemplary embodiments thereof is given with reference to the figures. The figures show schematic illustrations of

[0032] Fig. 1a: a transurethral catheter device in an expanded state according to an exemplary embodiment of the invention;

[0033] Fig. 1b: the transurethral catheter device of Fig. 1a in a collapsed state;

[0034] Fig. 2: a transurethral catheter device with an inflatable balloon and a constraining element in accordance with an embodiment of the invention;

[0035] Fig. 3: a transurethral catheter device with two expandable bodies according to an exemplary embodiment of the invention;

[0036] Fig. 4: a transurethral catheter device with a supply unit in accordance with an embodiment of the invention;

[0037] Fig. 5: a flow diagram illustrating a method for using a transurethral catheter device according to an exemplary embodiment of the invention;

[0038] Fig. 6a: a transurethral catheter device with two expandable bodies and an insertion tube in a partially expanded state in accordance with an embodiment of the invention;

[0039] Fig. 6b: a cross section of the center portion of the catheter device of Fig. 6a in an expanded state;

[0040] Fig. 6c: the transurethral catheter device of Fig. 6a in the expanded state; and

[0041] Fig. 7: a flow diagram illustrating a method for using a transurethral catheter device with two independent catheter assemblies according to an exemplary embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0042] Figs. 1a and 1b depict a schematic illustration (not to scale) of a sectional view of a transurethral catheter device 100 in accordance with an embodiment of the invention. The catheter device 100 comprises an expandable body assembly 102 with at least one expandable body. By expanding the at least one expandable body, the expandable body assembly 102 can be expanded from a collapsed state to an expanded state. The catheter device 100 is shown with the expandable body assembly 102 in the expanded state in Fig. 1a and with the expandable body assembly 102 in the collapsed state in Fig. 1b.

[0043]The expandable body assembly 102 has a proximal portion 104, a center portion 106 and a distal portion 108. In the expanded state, the portions 104, 106, and 108 are arranged

along a longitudinal axis 103 of the expandable body assembly 102 such that the proximal portion 104 is directly adjacent to the center portion 106 and the center portion 106 is directly adjacent to the distal portion 108. The longitudinal axis 103 may e.g. be defined as the axis around which the expandable body assembly has the smallest moment of inertia in the expanded state and is aligned with the y-axis in the example shown in Fig. 1a. The portions 104, 106, and 108 differ in their physical dimensions as detailed below. In some examples, the portions 104, 106, and 108 may have an identical internal structure, e.g. comprise or consist of the same materials. The portions 104, 106, and 108 may in particular be virtual axial segments of the expandable body assembly 102 along the longitudinal axis 103 as in the example shown in Figs. 1a and 1b, in which the virtual borders between the portions 104, 106, and 108 are indicated by horizontal dotted lines. In other examples, the portions 104, 106 and 108 may have different internal structures, e.g. comprise or consist of different materials.

[0044]The at least one expandable body may for example comprise one or more expandable elements, e.g. an inflatable balloon as described below with reference to Figs. 2 and 3. Additionally or alternatively, the at least one expandable body may comprise other expandable elements, e.g. an element comprising a mechanically extendable element like a spring as detailed below.

[0045]The at least one expandable body may be arranged in the proximal portion 104, the center portion 106 and/or the distal portion 108. In one example, the expandable body assembly 102 may comprise an expandable body that extends from the proximal portion 104 through the center portion 106 to the distal portion 108. The expandable body assembly 102 may comprise a plurality of expandable bodies, each being configured to be expanded, e.g. one expandable body arranged in the distal portion 108 and another expandable body arranged in the proximal portion 104. In some examples, the catheter device 100 may be configured such that each of the expandable bodies may be expanded independently of the other expandable bodies.

[0046]The catheter device 100 further comprises a catheter tube assembly 110 that is attached to the proximal portion 104. In one example, the catheter tube assembly 110 may be formed integrally with the expandable body assembly 102. In another example, the catheter tube assembly 110 may be detachably connected to the expandable body assembly 102 through a connector. The catheter tube assembly 110 may for example be similar to the catheter tube assembly of the catheter device 200 of Fig. 2 or the catheter device 300 of Fig. 3 described below. Preferably, the catheter tube assembly 110 comprises an urine extraction tube that is in communication with the inner volume of the urinary bladder 112, e.g. similar to the urine extraction tube 214 of the catheter device 200. In the example shown in Figs. 1a and 1b,

the expandable body assembly 102 has been inserted into the urinary bladder 112 of a patient via the urethra 114. Correspondingly, the catheter tube assembly 110 may extend through the urethra 114 and may provide a connection to the expandable body assembly 102 and/or to the urinary bladder 112 from the outside. The catheter tube assembly 110 may furthermore facilitate arranging the extendable body assembly 102 in the urinary bladder 112 as detailed below.

[0047] In one example, the catheter device 100 may comprise an insertion tube (not shown) that is configured to be arranged in the urethra 114, wherein the expandable body assembly 102 or a part thereof may be configured to be inserted into the urinary bladder 112 through said insertion tube. The insertion tube may e.g. be configured to compress a mechanically extendable element of the expandable body assembly 102 when the expandable body assembly 102 is inside the insertion tube. When the expandable body assembly 102 leaves the insertion tube and enters the urinary bladder 112, the mechanically extendable element may extend, thereby expanding the expandable body assembly 102. In one example, a mechanically extendable element may be arranged in the proximal portion 104, wherein the mechanically extendable element extends when entering the urinary bladder 112, thereby increasing the width of the proximal portion 104. This may e.g. be advantageous to prevent the proximal portion 104 from accidentally being retracted into the urethra 114 again as a force exceeding a certain threshold may be required to compress the mechanically extendable element in order to pull the proximal portion 104 into the urethra 114.

[0048]The proximal portion 104 has a length l_1 and a width w_1 in the expanded state and a length $\tilde{l}_1$ and a width $\tilde{w}_1$ in the collapsed state. The center portion 106 has a length l_2 and a width w_2 in the expanded state and a length $\tilde{l}_2$ and a width $\tilde{w}_2$ in the collapsed state. The distal portion 108 has a length l_3 and a width w_3 in the expanded state and a length $\tilde{l}_3$ and a width $\tilde{w}_3$ in the collapsed state. The length of a portion is defined as the largest extent of the respective portion in the direction of the longitudinal axis 103. The width of a portion is defined as the largest radially averaged width of the respective portion perpendicular to the longitudinal axis 103, wherein radial averaging of the width corresponds to taking the average of the width in a plane perpendicular to the longitudinal axis 103. In some examples, the expandable body assembly 102 may be rotationally symmetric around the longitudinal axis 103 and may e.g. exhibit a continuous rotational symmetry such that the width of the expandable body assembly 102 is the same in every direction perpendicular to the longitudinal axis 103 at a given point along the longitudinal axis 103. In other examples, at least one of the portions 104, 106, and 108 may be rotationally symmetric with respect to the longitudinal axis 103.

[0049] In the example shown in Figs. 1a and 1b, a total length l of the expandable body assembly 102 in the expanded state is given by $l = l_1 + l_2 + l_3$ and a total length $\tilde{l}$ of the expandable body assembly 102 in the collapsed state is given by $\tilde{l} = \tilde{l}_1 + \tilde{l}_2 + \tilde{l}_3$, wherein the total length of the expandable body assembly 102 is the largest extent of the expandable body assembly 102 in the direction of the longitudinal axis 103. The total widths w and $\tilde{w}$ of the expandable body assembly are the largest width among the widths of the individual portions, i.e. equal to w_3 and $\tilde{w}_3$, respectively, in the example shown in Figs 1a and 1b.

[0050] The lengths and widths in the expanded state are larger than the respective quantities in the collapsed state such that a displacement volume V of the expandable body assembly 102 in the expanded state is larger than a displacement volume $\tilde{V}$ of the expandable body assembly 102 in the collapsed state. Thereby, a volume of the urinary bladder 112 may be increased by expanding the expandable body assembly 102 from the collapsed state to the expanded state. Furthermore, the dimensions of the expandable body assembly 102 in the collapsed state are sufficiently small in order to insert the expandable body assembly 102 into the urinary bladder 112 through the urethra 114. The displacement volume in the collapsed state $\tilde{V}$ may therefore be much smaller than the displacement volume V, e.g. less than 5%, preferably less than 1% of V. In one example, the total width $\tilde{w}$ of the expandable body in the collapsed state may be less than 10 mm, preferably less than 5 mm.

[0051] The displacement volume V may for example be in the range between 0.5 liters and 3 liters, e.g. 1.5 liters. The width w_2 is smaller than 50%, preferably smaller than 20% of the width w_3. As shown in Fig. 1a, the width w_2 may also be smaller than 50%, preferably smaller than 30% of the width w_1. In one example, the width w_1 may be 5 cm, the width w_2 may be 1.5 cm and the width w_3 may be 15 cm. The length l_1 is smaller than 25%, preferably smaller than 15% of the total length l. The total length l may for example be 15 cm and the length l_1 may e.g. be 2 cm. The length l_2 may be between 10% and 30% of the total length l, e.g. 3 cm. Correspondingly, the length l_3 may for example be 10 cm. The displacement volume of the distal portion 108 may be more than 75%, in some examples more than 90% of the displacement volume V.

[0052] In the example shown in Fig. 1a, the expandable body assembly 102 is arranged such that the proximal portion 104 is adjacent to a bottom portion 116 of the wall of the urinary bladder 112 that is in the vicinity of the internal urethral orifice 118, and the distal portion 108 is adjacent to an upper portion 120 and a lateral portion 122 of the wall of the urinary bladder 112. In some cases, the proximal portion 104 may even be in contact with the bottom portion 116 and the distal portion 108 may be in contact with the upper portion 120 and/or the lateral portion 122. The catheter tube assembly 110 may facilitate arranging the expanda-

ble body assembly 102 in the urinary bladder 112 into the configuration shown in Fig. 1a since the catheter tube assembly 110 is connected to the proximal portion 104 and thus may ensure that the proximal portion 104 is located adjacent to the internal urethral orifice 118.

[0053] The shape of the expandable body assembly 102 in the expanded state is such that the center portion 106 is located adjacent to the ureter orifices 124 of the urinary bladder 112 when the expandable body assembly 102 is arranged in the urinary bladder 112 as shown in Fig. 1a. Due to the smaller width w_2 of the center portion 106, which is preferably smaller than the typical distance between the ureter orifices 124, the center portion 106 is not in contact with the ureter orifices 124. In this way, an uninterrupted flow of urine through the ureters into the urinary bladder 112 may be ensured. A rotationally symmetric shape of the center portion 106 and/or of the expandable body assembly 102 around the longitudinal axis 103 may facilitate arranging the expandable body assembly 102 in the urinary bladder 112 such that the ureter orifices 124 are not blocked by the expandable body assembly 102 irrespective of the orientation of the expandable body assembly 102 around the longitudinal axis 103.

[0054] The catheter device 100 may be configured to adjust at least one of the parameters comprising the widths w_1, w_2, w_3 and w, the lengths l_1, l_2, l_3 and l and the displacement volume V, e.g. in order to facilitate arranging the expandable body assembly 102 within the urinary bladder 112. The catheter device 100 may for example be configured to adjust the at least one parameter such that the proximal portion 104 is in contact with the bottom portion 116 of the wall of the urinary bladder 112 and/or such that the distal portion 108 is in contact with the upper portion 120 and/or the lateral portion 122 of the wall of the urinary bladder 112, e.g. by changing the lengths l_1 and l_3 and/or the width w_3. In one example, the catheter device 100 may be configured to adjust the at least one parameter such that expandable body assembly 102 is in contact with at least 50%, preferably with at least 75% of the surface area of the wall of the urinary bladder 112.

[0055] The shape of the expandable body assembly 102 may be adapted to the shape of the urinary bladder 112 of a human, e.g. in order to reduce the mechanical stress on the urinary bladder 112 when expanding the expandable body assembly 102 and/or to ensure that the expandable body assembly 102 is securely fitted in the urinary bladder 112. An outer surface of the proximal portion 104 and/or an outer surface of the distal portion 108 may for example have positive principle curvatures over at least 50%, preferably over at least 75% of the surface area of the respective portion in the expanded state, e.g. as in the example shown in Fig. 1a. In other examples, the proximal portion 104 may have a cylindrical shape, e.g. a cylinder with an axis parallel to the longitudinal axis 103, or may be a partial cylinder. Preferably, the proximal portion 104, the distal portion 108, and/or the expandable body assembly

102 comprises or consists of a flexible material, e.g. such that the shape of the expandable body assembly 102 adapts to the shape of the urinary bladder 112 when expanding the expandable body assembly 102.

[0056] In the expanded state, an outer surface of the center portion 106 may have at least one principle curvature equal to or smaller than zero over at least 50%, preferably over at least 75% of the surface area of the center portion 106. In the example shown in Fig. 1a, the center portion 106 has a negative principle curvature, i.e. a concave shape, along the longitudinal axis 103, which may e.g. be advantageous to increase the distance to the ureter orifices 124. In other examples, the center portion 106 may be a cylinder, i.e. exhibit a principle curvature of zero along the longitudinal axis 103.

[0057] Fig. 2 shows a schematic illustration (not to scale) of a sectional view of a transurethral catheter device 200 according to an exemplary embodiment of the invention. Similar to the catheter device 100, the catheter device 200 comprises an expandable body assembly 102 having a proximal portion 104, a center portion 106 and a distal portion 108 and a catheter tube assembly 110. In Fig. 2, the catheter device 200 is shown with the expandable body assembly 102 in the expanded state.

[0058] In the example shown in Fig. 2, the expandable body assembly 102 comprises an inflatable balloon 202 as an expandable body and the portions 104, 106, and 108 are virtual axial segments of the inflatable balloon 202 that differ in their physical dimensions as detailed above with reference to Fig. 1a. The inflatable balloon 202 comprises a wall 204 that consists of a flexible material and encloses an inner volume 206. The wall 204 may for example be made of latex, polyurethane, silicone and/or a combination thereof. An inner surface and/or an outer surface of the wall 204 may be coated, e.g. to reduce friction or to decrease the hydrophobicity of the respective surface. The coating may for example include a silicone elastomer, a hydrogel, polytetrafluoroethylene or a combination thereof.

[0059] The inner volume 206 is configured to receive an inflation medium, wherein a volume of the inflatable balloon 202 may e.g. be adjusted by adding inflation medium to the inner volume 206 or extracting inflation medium from the inner volume 206. The flexible material of the wall 204 may allow for changing V, l_1, l_2, l_3, l, w_1, w_2, w_3 and/or w in the expanded state by adjusting the amount of inflation medium supplied to the inner volume 206. Preferably, the inflation medium is a fluid, in particular an incompressible fluid like a liquid, for example a physiological salt solution. In other examples, the inflation medium may be a gas. In one example, the inflation medium may be supplied to the inner volume 206 in a liquid phase

and a phase transition to a gas phase may be induced to expand the expandable body assembly, e.g. through a chemical reaction and/or a change in temperature.

[0060]The inflatable balloon 202 may be configured to be expanded up to a volume of at least 150%, preferably of at least 200% of the displacement volume V by supplying inflation medium to the inner volume 206 without creating leaks in the wall 204 or otherwise damaging the inflatable balloon 202, e.g. by choosing an appropriate thickness and/or material composition of the wall 204. This may provide a safety margin when expanding the expandable body assembly 102 to the expanded state. The inflatable balloon 202 may e.g. be configured to be expanded up to a volume of at least 2.5 liters without creating leaks in the wall 204 or otherwise damaging the inflatable balloon 202. A minimum thickness of the wall 204 in the expanded state may for example be larger than 0.5 mm, preferably larger than 1 mm.

[0061] The shape of the inflatable balloon 202 in the expanded state may for example be determined by a surface area of the wall 204, a thickness of the wall 204 and/or a material composition of the wall 204 in the collapsed state in different parts of the inflatable balloon 202. In the example shown in Fig. 2, the inflatable balloon 202 extends from the proximal portion 104 through the center portion 106 to the distal portion 108. In one example, the thickness of the wall 204 may be larger in the center portion 106 than in the proximal portion 104 and/or in the distal portion 108 in order to achieve a smaller width w_2 in the center portion 106 than in the proximal portion 104 and in the distal portion 108. Alternatively or additionally, the surface area of the wall 204 may be larger in the distal portion 108 than in the center portion 106 and/or in the proximal portion 104. As the wall 204 consists of a flexible material, the shape of the inflatable balloon 202 may adapt to the shape of the urinary bladder 112, e.g. when the wall 204 comes in contact with the wall of the urinary bladder 112.

[0062]The expandable body assembly 102 of the catheter device 200 further comprises constraining elements 208 that are configured to limit the width w_2 of the center portion 106. In this example, the constraining elements 208 are ring-shaped reinforcements of the center portion 106. The constraining elements 208 may be integral parts of the center portion 106, e.g. regions with a thicker wall 204 and/or with a different material composition. The constraining elements 208 may for example comprise or consist of a material with a smaller elasticity than other parts of the center portion 106. In other examples, the constraining elements 208 may be separate from the center portion 106 and may for example be ring-shaped elements that are attached to the center portion 106 and surround the center portion 106.

[0063]The catheter device 200 may further comprise a removable cover (not shown), which may cover at least a part of the expandable body assembly 102, e.g. an outer surface of the

distal portion 108. The cover may for example be removed after inserting the expandable body assembly 102 into the urinary bladder 112 and prior to expanding the expandable body assembly 102. A surface of the cover may be coated, wherein the coating may e.g. include a silicone elastomer, a hydrogel, polytetrafluoroethylene or a combination thereof.

[0064]The catheter tube assembly 110 comprises an inflation tube 210 with a distal opening 212 that is in communication with the inner volume 206, i.e. opens towards the inner volume 206. In the example shown in Fig. 2, the distal opening 212 is arranged inside the inner volume 206 of the inflatable balloon 202. Thereby, inflation medium can be supplied to the inner volume 206 through the inflation tube 210. In other examples, the distal opening 212 may be arranged in the outer wall 204 of the inflatable balloon 202. In some examples, the inflation tube 210 may comprise a plurality of openings in communication with the inner volume 206 (not shown). The inflation tube 210 may e.g. comprise or consist of latex, polyurethane, silicone and/or a combination thereof. The material composition and/or the wall thickness of the inflation tube 210 may be chosen such that a diameter of the inflation tube 210 outside of the expandable body assembly 102 changes by less than 50%, preferably by less than 25% when expanding the inflatable balloon 202 from the collapsed state to the expanded state. When the inflatable balloon 202 is in the expanded state, a diameter of the inflation tube 210 outside of the expandable body assembly 102 may for example be less than 2 mm, preferably less than 1 mm. The inflation tube 210 may further comprises a valve, which may e.g. be opened to inject inflation medium into the inflatable balloon 202 and subsequently be closed to prevent the inflation medium from leaving the inflatable balloon 202.

[0065]The catheter tube assembly 110 further comprises an urine extraction tube 214 with a distal opening 216 that is arranged in the center portion 106 of the expandable body assembly 102. The distal opening 216 may for example be arranged on an outer surface of the wall 204 as shown in Fig. 2 such that the distal opening 216 is in communication with the inner volume of the urinary bladder 112 when the expandable body assembly 102 is arranged in the urinary bladder 112. In this way, the urine extraction tube 214 may be used to drain urine from the urinary bladder 112 as well as to inject a substance into the urinary bladder 112, e.g. for treatment or diagnostic purposes. In some examples, the urine extraction tube 214 may comprise a plurality of distal openings arranged in the center portion 106 (not shown). The urine extraction tube 214 may be made of the same material as the inflation tube 210 and may have the same diameter. In one example, the urine extraction tube 214 may enclose at least a part of the inflation tube 210 or vice versa, i.e. the inflation tube 210 may e.g. be arranged within the urine extraction tube 214.

[0066] In the example shown in Fig. 2, the catheter tube assembly 110 is attached to the proximal portion 104 and extends outwards from the proximal portion 104. The catheter tube assembly 110 may for example have a length between 0.5 m and 2 m such that the catheter tube can extend through the urethra 114 and can be connected to an external supply unit, e.g. as detailed below with reference to Fig. 4. In other examples, the catheter tube assembly 110 may terminate at a connector arranged on or adjacent to an outer wall of the expandable body assembly 102, e.g. in the proximal portion 104, wherein the connector is configured to receive an external catheter tube assembly and to connect the external catheter tube assembly to the catheter tube assembly 110.

[0067] Fig. 3 depicts a schematic illustration (not to scale) of a sectional view of a transurethral catheter device 300 in accordance with an embodiment of the invention. Similar to the catheter devices 100 and 200, the catheter device 300 comprises an expandable body assembly 102 having a proximal portion 104, a center portion 106 and a distal portion 108 and a catheter tube assembly 110. In Fig. 3, the catheter device 300 is shown with the expandable body assembly 102 in the expanded state.

[0068] The expandable body assembly 102 of the catheter device 300 comprises two expandable bodies, namely a proximal inflatable balloon 302 and a distal inflatable balloon 304. The proximal inflatable balloon 302 is arranged in the proximal portion 104 of the expandable body assembly 102 and the distal inflatable balloon 304 is arranged in the distal portion 108 of the expandable body assembly 102. The center portion 106 of the expandable body assembly 102 on the other hand does not comprise an expandable body, but only comprises a part of the catheter tube assembly 110. Correspondingly, the width w_2 of the center portion 106 in the expanded state may be comparable to the width $\tilde{w}_2$ of the center portion 106 in the collapsed state, e.g. less than 150% of $\tilde{w}_2$. In other embodiments, the proximal inflatable balloon 302 may extend from the proximal portion 104 to the center portion 106 (not shown), e.g. similar to the embodiment described below with reference to Figs. 6a-6c. A distal end of the proximal inflatable balloon 302 may e.g. be directly adjacent to a proximal end of the distal inflatable balloon 304.

[0069] Similar to the inflatable balloon 202 of the catheter device 200, each of the proximal and distal inflatable balloons 302 and 304 comprises an outer wall surrounding an inner volume that is configured to receive an inflation medium. To supply the inflation medium, the catheter tube assembly 110 comprises a proximal inflation tube 306 and a distal inflation tube 310 in addition to an urine extraction tube 214. The proximal inflation tube 306 has a distal opening 308 that is in communication with the inner volume of the proximal inflatable balloon 302. The distal inflation tube 310 has a distal opening 312 that is in communication

with the inner volume of the distal inflatable balloon 304. In this way, the inflation medium may be supplied to the balloons 302 and 304 independently, e.g. to expand the balloons 302 and 304 to different volumes and/or pressures or to use different inflation media for the balloons 302 and 304. In particular, the balloons 302 and 304 may be expanded at different points in time when expanding the expandable body assembly 102 to the expanded state, e.g. as detailed below with reference to Fig. 5.

[0070]The proximal inflatable balloon 302 and/or the distal inflatable balloon 304 may have an ellipsoidal shape, in particular a spherical shape in the expanded state. In other examples, the proximal inflatable balloon 302 may have a cylindrical shape or the shape of a partial cylinder, e.g. as detailed below with reference to Figs. 6a-6c. In some examples, the volume of the distal inflatable balloon 304 in the expanded state may be at least five times as large, in one example at least ten times as large as the volume of the proximal inflatable balloon 302 in the expanded state. The catheter device 300 may further comprise a removable cover (not shown), which may cover at least a part of the expandable body assembly 102, e.g. an outer surface of the distal inflatable balloon 304.

[0071] Fig. 4 schematically illustrates a transurethral catheter device 400 in accordance with an embodiment of the invention. The catheter device 400 comprises an expandable body assembly 102, which may for example be similar to the expandable body assembly of the catheter device 100, 200 or 300 described above. In Fig. 4, the expandable body assembly 102 is arranged in the urinary bladder 112 of a patient such that a catheter tube assembly 110 attached to or connected to the expandable body assembly 102 extends through the urethra 114 of the patient to the outside. The catheter tube assembly 110 may for example comprise an urine extraction tube similar to the urine extraction tube 214 shown in Figs. 2 and 3 and at least one inflation tube similar to the inflation tube 210 or 310 shown in Fig. 2 and 3, respectively, to supply an inflation medium to the expandable body assembly 102. The catheter tube assembly 110 is connected to an urine reservoir 402 that is configured to receive urine drained from the urinary bladder 112 via the catheter tube assembly 110, e.g. through the urine extraction tube 214.

[0072] The catheter tube assembly 110 is furthermore connected to a supply unit 404 that is configured to provide the inflation medium, e.g. through the at least one inflation tube 210. The supply unit 404 comprises a pump 406 that is connected with a supply reservoir 408. The supply reservoir 408 is configured to store a certain amount of inflation medium, for example 3 liters to 5 liters of inflation medium. In some examples, the supply reservoir 408 may be an infusion bag connected to the supply unit 404 and/or to the pump 406. The pump 406 may for example be configured to pump inflation medium from the supply reservoir 408

into the expandable body assembly 102. Additionally, the pump 406 may be configured to pump inflation medium from the expandable body assembly 102 into the supply reservoir 408 through the catheter tube assembly 110.

[0073] The supply unit 404 further comprises a control unit 410 that is configured to control operation of the pump 406. The supply unit 404 may for example be connected to a control panel of the supply unit 404, e.g. such that an operator of the supply unit 404 can pump inflation medium to/from the expandable body assembly 102 by pressing a button and/or control a set point value for the displacement volume V, a pressure and/or an amount of inflation medium to be supplied, e.g. by rotating a switch.

[0074] The catheter device 400 further comprises a flow meter 412 that is configured to measure an amount of the inflation medium transported through the catheter tube assembly 110, e.g. a volume of the transported inflation medium. The flow meter 412 may for example be a mechanical flow meter, a pressure-based flow meter, an optical flow meter or an electromagnetic flow meter. The flow meter 412 is coupled to the control unit 410. The control unit 410 may for example be configured to determine the amount of inflation medium supplied to the expandable body assembly 102 via the flow meter 412, e.g. by measuring the volume of the inflation medium injected into and/or extracted from the expandable body assembly 102. In other examples, the control unit 410 may determine the amount of inflation medium in the supply reservoir 408 to determine the amount of inflation medium supplied to the expandable body assembly 102. The control unit 410 may furthermore be configured to supply a predetermined amount of inflation medium to the expandable body assembly 102, wherein the predetermined amount may for example be set by an operator using the control panel.

[0075] The catheter device 400 also comprises a pressure sensor 414 that is arranged in the expandable body assembly 102. The pressure sensor 414 may for example be arranged on an outer surface of the expandable body assembly 102, e.g. an outer surface of the wall 204 of the inflatable balloon 202, and may be configured to measure a pressure in the vicinity of the expandable body assembly 102. In other examples, the pressure sensor 414 may be arranged on an inner surface of the wall 204 or within the inner volume 206 of the inflatable balloon 202, e.g. to measure the pressure in the inner volume 206. Alternatively, the pressure sensor 414 may be arranged in other elements of the catheter device 400 that are in contact with the inflation medium, e.g. in a sidewall of the at least one inflation tube 210 or within the supply unit 404. The control unit 410 is coupled to the pressure sensor 414 and may be configured to read-out the pressure measured by the pressure sensor 414. The control unit 410 may also be configured to control the pressure measured by the pressure sensor 414, e.g. to a predeter-

mined set point specified by the operator, by injecting and/or extracting inflation medium into/from the expandable body assembly 102 by the pump 406.

[0076] Fig. 5 depicts a flowchart of a method 500 to treat a patient using a transurethral catheter device in accordance with an embodiment of the invention. The method 500 may for example be performed with any one of the catheter devices 100, 200, 300 and 400 and will be described the following with reference to Figs. 2 to 4.

[0077] In a first step 502, the expandable body assembly 102 is prepared in the collapsed state and inserted into the urinary bladder 112 of the patient via the urethra 114. The expandable body assembly 102 may for example be inserted into the urethra 114 by first inserting the distal portion 108 of the expandable body assembly 102 into the urethra 114, subsequently inserting the center portion 106 and the proximal portion 104 and finally pushing the expandable body assembly 102 through the urethra 114 into the urinary bladder 112 using the catheter tube assembly 110.

[0078] Once the expandable body assembly 102 has been fully inserted into the urinary bladder 112, the expandable body assembly 102 is expanded from the collapsed state to the expanded state by expanding the at least one expandable body in step 504. In the examples of the catheter devices 200 and 300, the expandable body assembly 102 may be expanded by injecting inflation medium into the inflatable balloons 202 and 302/304, respectively. In some examples, the expandable body assembly 102 may be expanded to a predefined displacement volume V and/or pressure, e.g. using the control unit 410. The displacement volume V and/or the pressure that the expandable body assembly 102 is expanded to may be chosen depending on a weight, size, gender and/or condition of the patient. For example, a larger displacement volume V may be used for a taller and heavier patient than for a smaller and lighter patient. Additionally or alternatively, a different catheter device may be used depending on the weight, size, gender and/or condition of the patient, e.g. a catheter device with a displacement volume V of 1.5 liters for a male patient and a catheter device with a displacement volume V of 1.2 liters for a female patient.

[0079] In one example, a catheter device is used that comprises a plurality of expandable bodies which can be expanded independently, e.g. the catheter device 300 with the distal inflatable balloon 304 and the proximal inflatable balloon 302. In this case, the expandable bodies may be expanded at different points in time. For example, after inserting the expandable body assembly 102 into the urinary bladder 112, the proximal inflatable balloon 302 may be expanded first by injecting inflation medium through the proximal inflation tube 306. This may prevent the expandable body assembly 102 from entering the urethra 114 again. Subse-

quently, the distal inflatable balloon 304 may be expanded by injecting inflation medium through the distal inflation tube 310. The distal inflatable balloon 304 may also be expanded to a different pressure than the proximal inflatable balloon 302, e.g. to a higher pressure to reach a larger displacement volume for the distal inflatable balloon 304.

[0080]Subsequently, in step 506, the displacement volume V and/or the pressure is maintained, e.g. by injecting and/or extracting inflation medium to/from the expandable body assembly 102 using the supply unit 404 and/or by the pump 406. The control unit 410 of the supply unit 404 may for example be configured to regulate the displacement volume V and/or the pressure to the predefined set point. In one example, the control unit 410 is configured to regulate the pressure to the predefined set point and may thereby react to a pressure change in the patient's abdomen, e.g. resulting from a release of urine.

[0081] While the expandable body assembly 102 is arranged in the urinary bladder 112, urine may be drained from the urinary bladder 112 via the urine extraction tube 214 in step 508. Urine may for example be drained from the urinary bladder 112 as a result of the increased pressure created by the expansion of the expandable body assembly 102. To account for this, the control unit 410 may be configured to stabilize the pressure to the predefined set point as mentioned above. In other examples, urine may be actively drained from the urinary bladder 112, e.g. using a pump.

[0082]Figs. 6a-6c depict another example of a transurethral catheter device 600 according to an embodiment of the invention (not to scale). The catheter device 600 is similar to the catheter device 300 and also comprises an expandable body assembly 102 with two expandable bodies, namely a proximal inflatable balloon 302 and a distal inflatable balloon 304. In contrast to the catheter device 300, the proximal inflatable balloon 302 and the distal inflatable balloon 304 of the catheter device 600 are parts of independent catheter assemblies, wherein the distal inflatable balloon 304 is configured to be inserted through an insertion tube 602 extending through the proximal inflatable balloon 302 as detailed below. Fig. 6a schematically illustrates a sectional view of the catheter device 600 in a partially expanded state, in which the proximal inflatable balloon 302 is in an expanded state while the distal inflatable balloon 304 is in a collapsed state and is being inserted through the insertion tube 602. Fig. 6b shows a radial cross section 106r of the center portion 106 of the catheter device 600 in the expanded state, wherein the radial cross section 106r is the cross section in the x-z-plane perpendicular to the longitudinal axis 103, which may e.g. be aligned with the y-axis. Fig. 6c depicts the catheter device 600 in the expanded state. The expanded state of the catheter device 600 is the state in which both the proximal inflatable balloon 302 and the distal inflatable balloon 304 are expanded.

[0083]The proximal inflatable balloon 302 extends from the proximal portion 104 to the center portion 106. In the expanded state, a distal end of the proximal inflatable balloon 302 is directly adjacent to a proximal end of the distal inflatable balloon 304. The proximal inflatable balloon 302 may for example increase the rigidity of the center portion 106 and thereby may prevent excessive bending of the center portion 106.

[0084]In the example shown in Figs. 6a-6c, the proximal inflatable balloon 302 forms a partial cylinder in the expanded state, wherein the axis of the partial cylinder is aligned with the longitudinal axis 103. The proximal inflatable balloon 302 in particular forms a partial cylinder whose radial cross-section is a circular sector as shown in Fig. 6b. The circular sector may for example have a central angle between 210° and 330°, e.g. 270°. In other examples, the proximal inflatable balloon 302 may form a partial cylinder having a recess or cut-out with a different shape, e.g. a circular or rectangular cut-out. In some examples, the proximal inflatable balloon 302 may only be arranged in the proximal portion 104 and/or may have a different shape, e.g. an ellipsoidal shape, a cylindrical shape or a shape similar to the proximal inflatable balloon 302 of the catheter device 300 shown in Fig. 3. Furthermore, the catheter device 600 may comprise a central inflatable balloon (not shown) in addition to the proximal inflatable balloon 302, wherein the central inflatable balloon is arranged in the center portion 106 and may e.g. form a partial cylinder in the expanded state.

[0085]The proximal inflatable balloon 302 partially encloses the catheter tube assembly 110, which comprises the urine extraction tube 214 and the proximal inflation tube 306. The urine extraction tube 214 has a plurality of distal openings 216, which are located within the recess formed by the partial cylinder, i.e. within the circular sector that is not covered by the proximal inflatable balloon 302. In the example shown in Figs. 6a-6c, the catheter tube assembly 110 is located in the center of the proximal inflatable balloon 302. In other examples, the catheter tube assembly 110 may be located at a different position, e.g. in a cut-out adjacent to an outer edge of the proximal inflatable balloon 302.

[0086]The catheter tube assembly 110 further comprises the insertion tube 602, which extends through the proximal inflatable balloon 302, i.e. through the proximal portion 104 and the center portion 106. The insertion tube 602 comprises a distal opening 604, which is in communication with the inner volume of the urinary bladder 112 when the proximal inflatable balloon 302 is arranged in the urinary bladder 112. In some examples, the insertion tube 602 may be a trocar, i.e. may further comprise a removable obturator that is configured to block the distal opening 604 (not shown). An inner diameter of the insertion tube 602 is chosen such that the distal portion 108 of the expandable body assembly 102, i.e. the distal in-

flatable balloon 304, can be inserted through the insertion tube 602 in the collapsed state as shown in Fig. 6a.

[0087] In the example of Figs. 6a-6c, the distal inflatable balloon 304 and the distal inflation tube 310 are not attached or connected to the other elements of the catheter device 600, i.e. the remaining elements of the catheter device 600 and the distal inflatable balloon 304 with the distal inflation tube 310 are independent catheter assemblies. This allows for first inserting the proximal inflatable balloon 302 into the urinary bladder 112 and expanding the proximal inflatable balloon 302, e.g. to provide access to the interior of the urinary bladder 112 via the urine extraction tube 214 similar to a conventional urinary catheter, and subsequently inserting and expanding the distal inflatable balloon 304 if needed. A method 700 for treating a patient with such a catheter device with two independent catheter assemblies is illustrated as a flowchart in Fig. 7.

[0088] At first, in step 702, the proximal expandable body, i.e. the proximal inflatable balloon 302, of the catheter device 600 is prepared in the collapsed state and is inserted into the urinary bladder 112 of the patient via the urethra 114, e.g. by pushing the proximal inflatable balloon 302 through the urethra 114 into the urinary bladder 112 using the catheter tube assembly 110.

[0089]Subsequently, in step 704, the proximal inflatable balloon 302 is expanded from the collapsed state to the expanded state such that the catheter device 600 is in the partially expanded state. This may prevent the proximal inflatable balloon 302 from entering the urethra 114 again and may thus secure the proximal inflatable balloon 302 within the urinary bladder 112. At this point, the catheter device 600 may be used similar to a conventional urinary catheter. The urine extraction tube 214 with the openings 216 is in communication with the inner volume of the urinary bladder 112 and may e.g. be used to drain urine from the urinary bladder 112 in 706.

[0090]Depending on the state of the patient, the distal expandable body, i.e. the distal inflatable balloon 304, may be inserted into the urinary bladder 112 in 708, either directly after step 702 or 704 or at a later point in time should the need arise. The distal inflatable balloon 304 may be inserted by threading the distal inflatable balloon 304 in the collapsed state through the insertion tube 602 using the distal inflation tube 310 as illustrated in Fig. 6a. After the distal inflatable balloon 304 has been arranged in the urinary bladder 112, the distal inflatable balloon 304 may be expanded as well in step 710 via the distal inflation tube 310, see Fig. 6c.

[0091] If the distal inflatable balloon 304 with the distal inflation tube 310 is an independent catheter assembly, the distal inflatable balloon 304 may also be removed independently from the other elements of the catheter device 600, e.g. after a bleeding has been stopped successfully. The proximal inflatable balloon 304 may for example remain in the urinary bladder 112 to provide the functionality of a conventional urinary catheter.

[0092] In other examples, the urine extraction tube 214 may be used as an insertion tube to insert the distal inflatable balloon 304 into the urinary bladder 112 (not shown). In this case, the distal opening 602 of the insertion tube may be one of the distal openings 216 of the urine extraction tube 214. Preferably, an outer diameter of the distal inflation tube 314 is less than 75%, in one example less than 50% of an inner diameter of the urine extraction tube 214, e.g. such as to not block the flow of urine through the urine extraction tube 214 when distal inflation tube 314 is arranged in the urine extraction tube 214.The embodiments of the present invention disclosed herein only constitute specific examples for illustration purposes. The present invention can be implemented in various ways and with many modifications without altering the underlying basic properties. Therefore, the present invention is only defined by the claims as stated below.

LIST OF REFERENCE SIGNS

100 – transurethral catheter device
102 – expandable body assembly
103 – longitudinal axis
104 – proximal portion of the expandable body assembly 102
106 – center portion of the expandable body assembly 102
108 – distal portion of the expandable body assembly 102
110 – catheter tube assembly
112 – urinary bladder
114 – urethra
116 – bottom portion of the wall of the urinary bladder 112
118 – internal urethral orifice
120 – upper portion of the wall of the urinary bladder 112
122 – lateral portion of the wall of the urinary bladder 112
124 – ureter orifices

l_1 – length of the proximal portion 104 in the expanded state
w_1 – width of the proximal portion 104 in the expanded state
l_2 – length of the center portion 106 in the expanded state
w_2 – width of the center portion 106 in the expanded state
l_3 – length of the distal portion 108 in the expanded state
w_3 – width of the distal portion 108 in the expanded state

$\tilde{l}_1$ – length of the proximal portion 104 in the collapsed state
$\tilde{w}_1$ – width of the proximal portion 104 in the collapsed state
$\tilde{l}_2$ – length of the center portion 106 in the collapsed state
$\tilde{w}_2$ – width of the center portion 106 in the collapsed state
$\tilde{l}_3$ – length of the distal portion 108 in the collapsed state
$\tilde{w}_3$ – width of the distal portion 108 in the collapsed state

200 – transurethral catheter device
202 – inflatable balloon
204 – wall of the inflatable balloon 202
206 – inner volume of the inflatable balloon 202
208 – constraining element
210 – inflation tube

212 – distal opening of the inflation tube 210
214 – urine extraction tube
216 – distal opening of the urine extraction tube 214

300 – transurethral catheter device
304 – distal inflatable balloon
302 – proximal inflatable balloon
306 – proximal inflation tube
308 – distal opening of the proximal inflation tube 306
310 – distal inflation tube
312 – distal opening of the distal inflation tube 310

400 – transurethral catheter device
402 – urine reservoir
404 – supply unit
406 – pump
408 – supply reservoir
410 – control unit
412 – flow meter
414 – pressure sensor

500 – method of using a transurethral catheter device
502 – step of inserting the expandable body assembly 102 into the urinary bladder 112
504 – step of expanding the expandable body assembly 102 to the expanded state
506 – step of maintaining the displacement volume and/or pressure
508 – step of draining urine from urinary bladder 112

600 – transurethral catheter device
602 – insertion tube
604 – distal opening of the insertion tube 602
106r – radial cross section of the center portion 106 of the transurethral catheter device 600

700 – method of using a transurethral catheter device
702 – step of inserting the proximal expandable body into the urinary bladder 112
704 – step of expanding the proximal expandable body to the expanded state
706 – step of draining urine from urinary bladder 112
708 – step of inserting the distal expandable body into the urinary bladder 112

710 – step of expanding the distal expandable body to the expanded state

Claims

1. Transurethral catheter device (100) for bleeding control in pelvic fractures, the catheter device (100) comprising an expandable body assembly (102) with at least one expandable body, wherein

the expandable body assembly (102) comprises a proximal portion (104), a center portion (106) and a distal portion (108);

the expandable body assembly (102) is configured to be expanded from a collapsed state to an expanded state by expanding the at least one expandable body;

the expandable body assembly (102) is configured to be inserted into the urinary bladder (112) of a patient via the urethra (114) in the collapsed state;

in the expanded state, the proximal portion (104) has a length l_1 and a width w_1, the center portion (106) a length l_2 and a width w_2, the distal portion (108) a length l_3 and a width w_3, and the expandable body assembly (102) a total length l;

a displacement volume V of the expandable body assembly (102) in the expanded state is larger than 0.5 liters;

the width w_2 is smaller than 50% of the width w_3;

the width w_1 is larger than a width $\tilde{w}_1$ of the proximal portion (104) in the collapsed state and the width w_3 is larger than a width $\tilde{w}_3$ of the distal portion (108) in the collapsed state; and

the length l_1 is smaller than 25% of the total length l,

thereby allowing for arranging the expandable body assembly (102) in the expanded state in the urinary bladder (112) such that the proximal portion (104) is adjacent to the internal urethral orifice (118) of the urinary bladder (112) and the center portion (106) is adjacent to the ureter orifices (124) of the urinary bladder (112), but not in contact with the ureter orifices (124).

2. The catheter device (100) of claim 1, wherein

the displacement volume V of the expandable body assembly (102) in the expanded state is larger than 0.8 liters, preferably larger than 1.2 liters; and/or

the width w_2 is smaller than 20% of the width w_3; and/or

the width w_1 is at least two times as large as the width $\tilde{w}_1$; and/or

the length l_1 is smaller than 15% of the total length l.

3. The catheter device (100) of claim 1 or 2, wherein the width w_2 is smaller than 50% of the width w_1, preferably smaller than 30% of the width w_1.

4. The catheter device (100) of any one of the preceding claims, wherein the catheter device (100) is configured to adjust the total length l such that, when the expandable body assembly (102) is arranged in the urinary bladder (112) in the expanded state, the proximal portion (104) is in contact with a bottom portion (116) of the wall of the urinary bladder (112) and the distal portion (108) is in contact with an upper portion (120) of the wall of the urinary bladder (112).

5. The catheter device (100) of any one of the preceding claims, wherein the catheter device (100) is configured to adjust the width w_3 such that, when the expandable body assembly (102) is arranged in the urinary bladder (112) in the expanded state, the distal portion (108) is in contact with a lateral portion (122) of the wall of the urinary bladder (112).

6. The catheter device (100) of any one of the preceding claims, wherein the catheter device (100) is configured to adjust the total length l, the width w_1 and/or the width w_3 such that, when the expandable body assembly (102) is arranged in the urinary bladder (112) in the expanded state, the expandable body assembly (102) is in contact with at least 50%, preferably with at least 75% of a surface area of the wall of the urinary bladder (112).

7. The catheter device (100) of any one of the preceding claims, wherein the width w_2 is smaller than 2 cm, preferably smaller than 1 cm.

8. The catheter device (100) of any one of the preceding claims, wherein the length l_2 is between 10% and 30% of the total length l.

9. The catheter device (100) of any one of the preceding claims, wherein the total length l is between 10 cm and 20 cm, preferably between 12.5 cm and 17.5 cm.

10. The catheter device (100) of any one of the preceding claims, wherein the width w_3 is larger than, preferably at least twice as large as the width w_1.

11. The catheter device (100) of any one of the preceding claims, wherein an outer surface of the proximal portion (104) and/or an outer surface of the distal portion (108) has positive principal curvatures over at least 50%, preferably over at least 75% of the surface area of the respective portion in the expanded state.

12. The catheter device (100) of any one of the preceding claims, wherein an outer surface of the center portion (106) has at least one principle curvature equal to or smaller than zero over at least 50%, preferably over at least 75% of the surface area of the center portion (106) in the expanded state.

13. The catheter device (100) of any one of the preceding claims, wherein the expandable body assembly (102) is rotationally symmetric around a longitudinal axis extending from the proximal portion (104) to the distal portion (108).

14. The catheter device (200) of any one of the preceding claims, further comprising an urine extraction tube (214), wherein the urine extraction tube (214) has at least one distal opening (216) arranged in the center portion (106) of the expandable body assembly (102).

15. The catheter device (200) of any one of the preceding claims, wherein the expandable body assembly (102) comprises an expandable body extending from the proximal portion (104) to the distal portion (108).

16. The catheter device (200) of any one of the preceding claims, wherein the at least one expandable body comprises an inflatable balloon (202) comprising a flexible material (204) enclosing an inner volume (206) that is configured to receive an inflation medium.

17. The catheter device (200) of claim 16, further comprising an inflation tube (210), wherein the inflatable balloon (202) is configured to receive the inflation medium through the inflation tube (210).

18. The catheter device (200) of claim 16 or 17, wherein the center portion (106) of the expandable body assembly (102) comprises at least one constraining element (208) configured to limit a width of the center portion (106).

19. The catheter device (200) of any one of claims 16 to 18, wherein the inflation medium is a fluid.

20. The catheter device (400) of any one of claims 16 to 19, further comprising a volume control unit (410) configured to adjust the volume of the inflatable balloon (202) by adjusting a pressure in the inner volume (206) of the inflatable balloon (202) and/or by adjusting an amount of inflation medium supplied to the inner volume (206) of the inflatable balloon (202).

21. The catheter device (400) of claim 20, wherein the volume control unit (410) is configured to adjust the volume of the inflatable balloon (202) in the expanded state at least within a range between 1 liter and 1.5 liters, preferably at least within a range between 0.5 liters and 3 liters.

22. The catheter device (400) of any one of claims 16 to 21, further comprising a pressure sensor (414) configured to determine a pressure in the inner volume (406) of the inflatable balloon (202) and/or a pressure on an outer surface of the expandable body assembly (102).

23. The catheter device (300) of any one of the preceding claims, wherein the expandable body assembly (102) comprises a distal expandable body arranged in the distal portion (108) of the expandable body assembly (102) and a proximal expandable body arranged in the proximal portion (104) of the expandable body assembly (102).

24. The catheter device (300) of claim 23, wherein the proximal expandable body and the distal expandable body each comprise an inflatable balloon configured to receive an inflation medium, the catheter device (300) further comprising a proximal inflation tube (306) and a distal inflation tube (310), wherein the inflatable balloon (302) in the proximal portion (104) is configured to receive an inflation medium through

the proximal inflation tube (306) and the inflatable balloon (304) in the distal portion (108) is configured to receive an inflation medium through the distal inflation tube (310).

25. The catheter device (600) of claim 23 or 24, further comprising an insertion tube (602) that extends through the proximal portion (104) and the center portion (106) of the expandable body assembly (102), wherein the distal portion (108) of the expandable body assembly (102) is configured to be inserted into the urinary bladder (112) through the insertion tube (602) in the collapsed state.

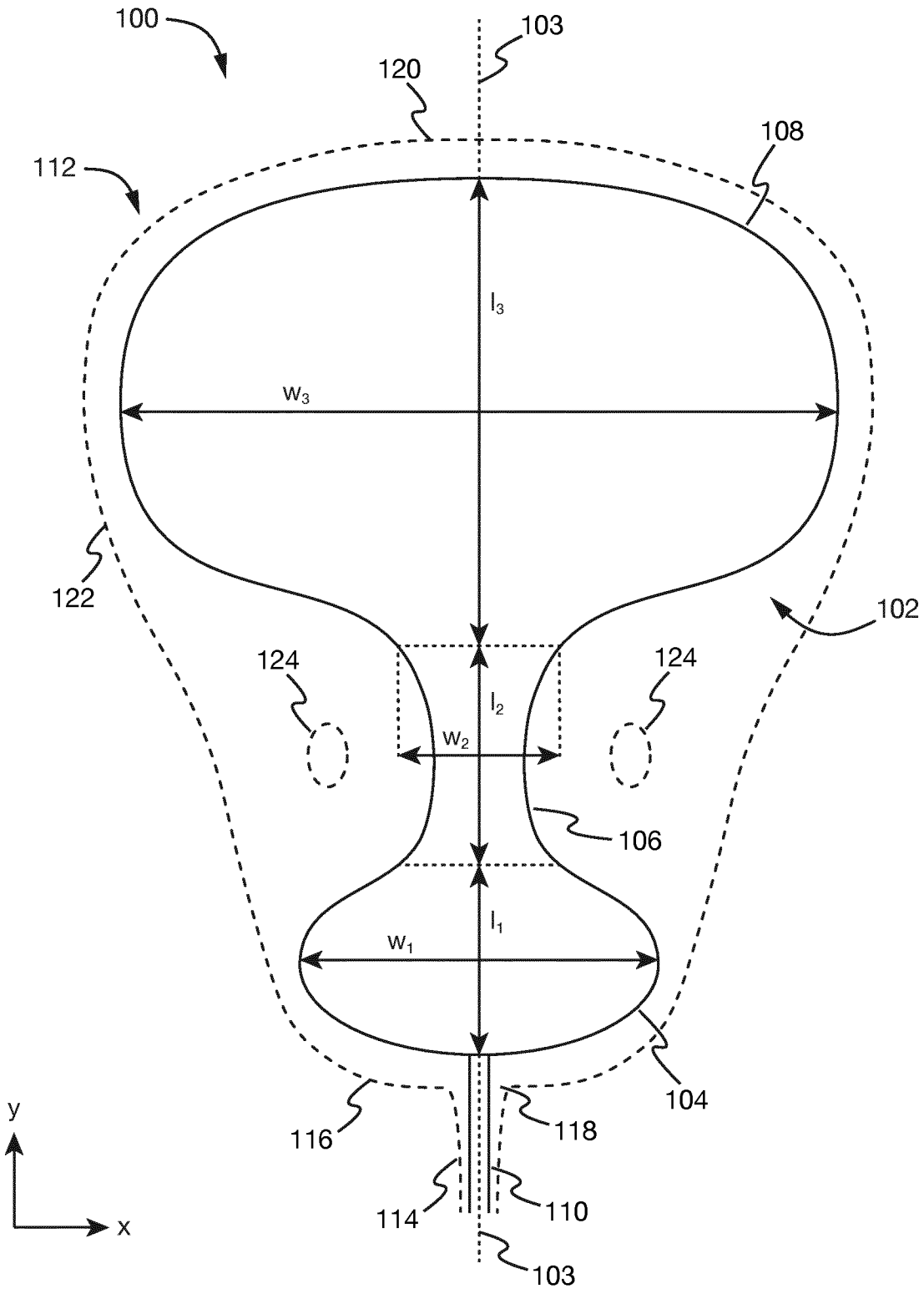
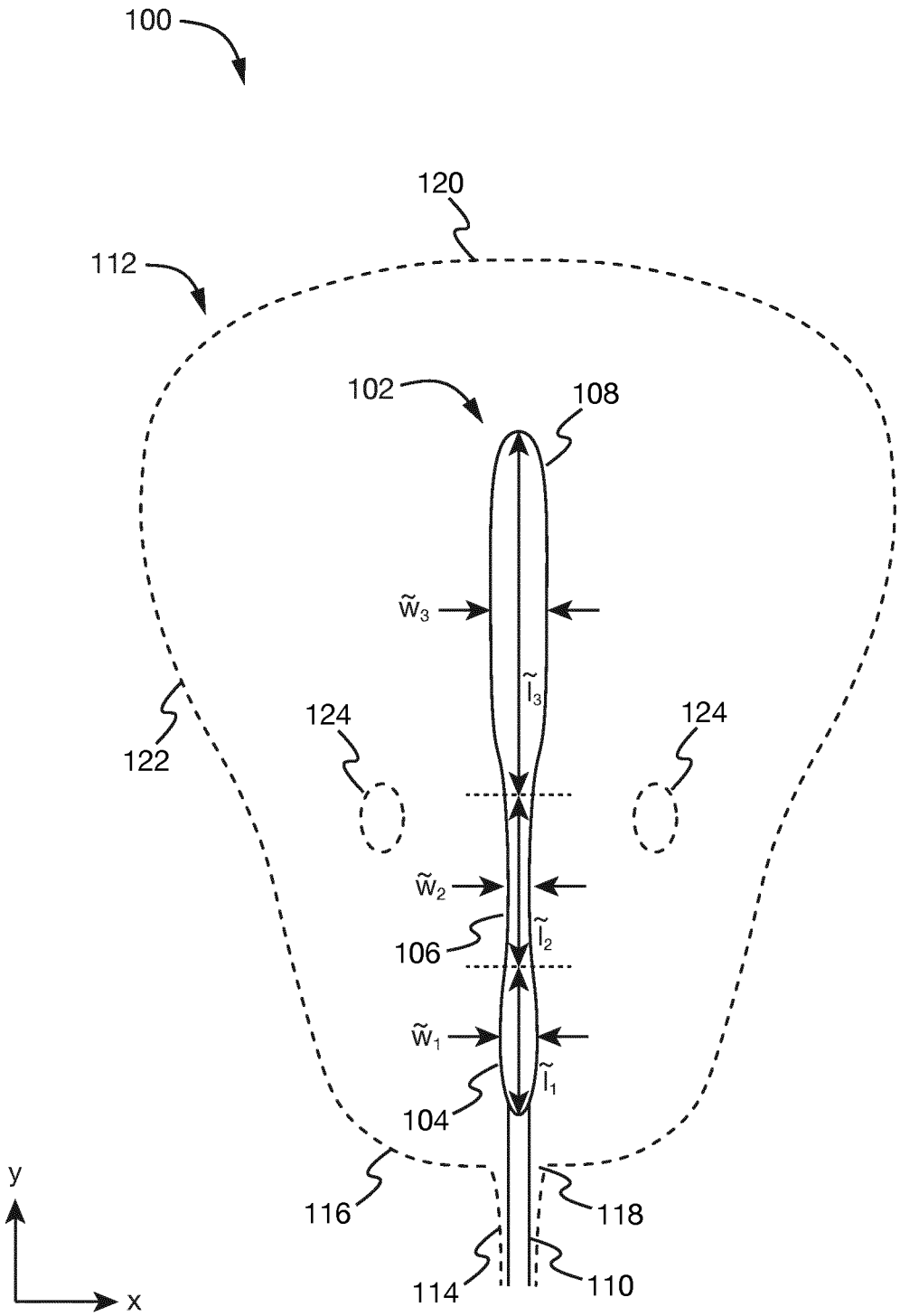

100
103
120
108
112
l_3
w_3
122
102
124
124
l_2
w_2
106
l_1
w_1
104
116
118
114
110
103
y
x

Fig. 1a


100
120
112
102
108
$\tilde{w}_3$
$\tilde{l}_3$
124
124
122
$\tilde{w}_2$
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106
$\tilde{w}_1$
$\tilde{l}_1$
104
116
118
114
110
y
x

Fig. 1b

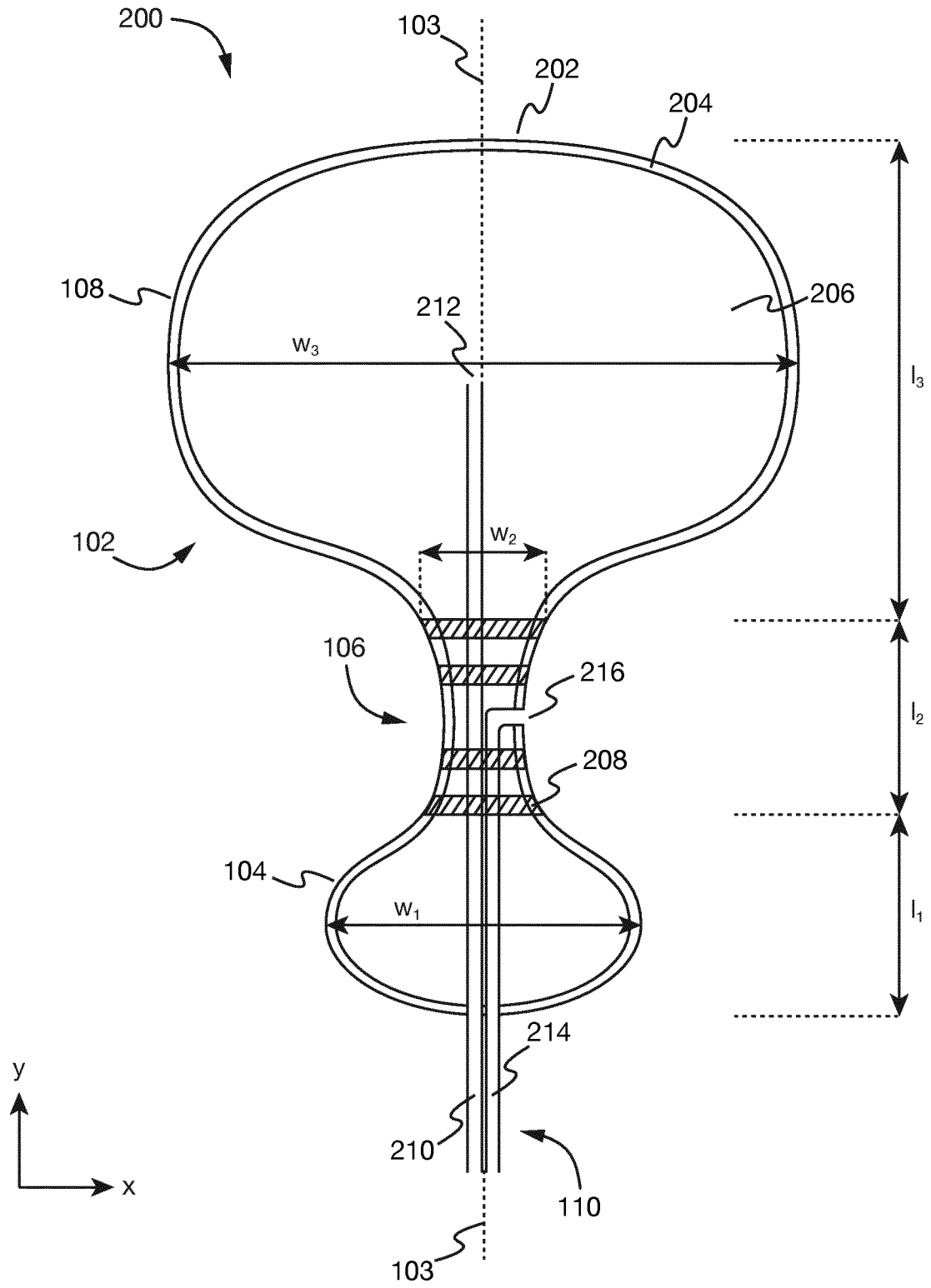
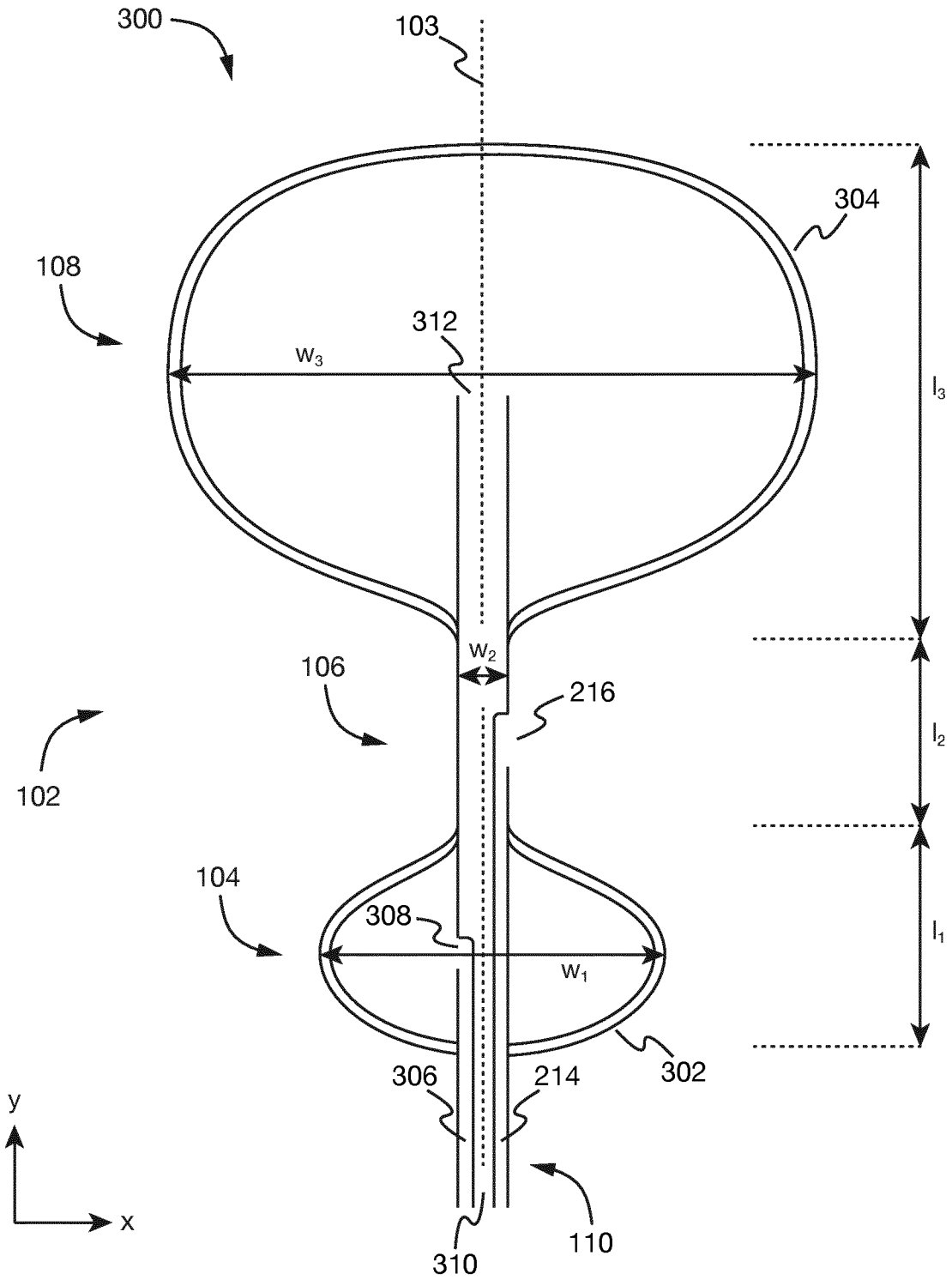

200
103
202
204
108
206
212
w_3
l_3
102
w_2
106
216
l_2
208
104
w_1
l_1
214
y
210
x
110
103

Fig. 2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103
304
108
312
w_3
l_3
w_2
106
216
l_2
102
104
308
w_1
l_1
306
214
302
y
x
310
110

Fig. 3

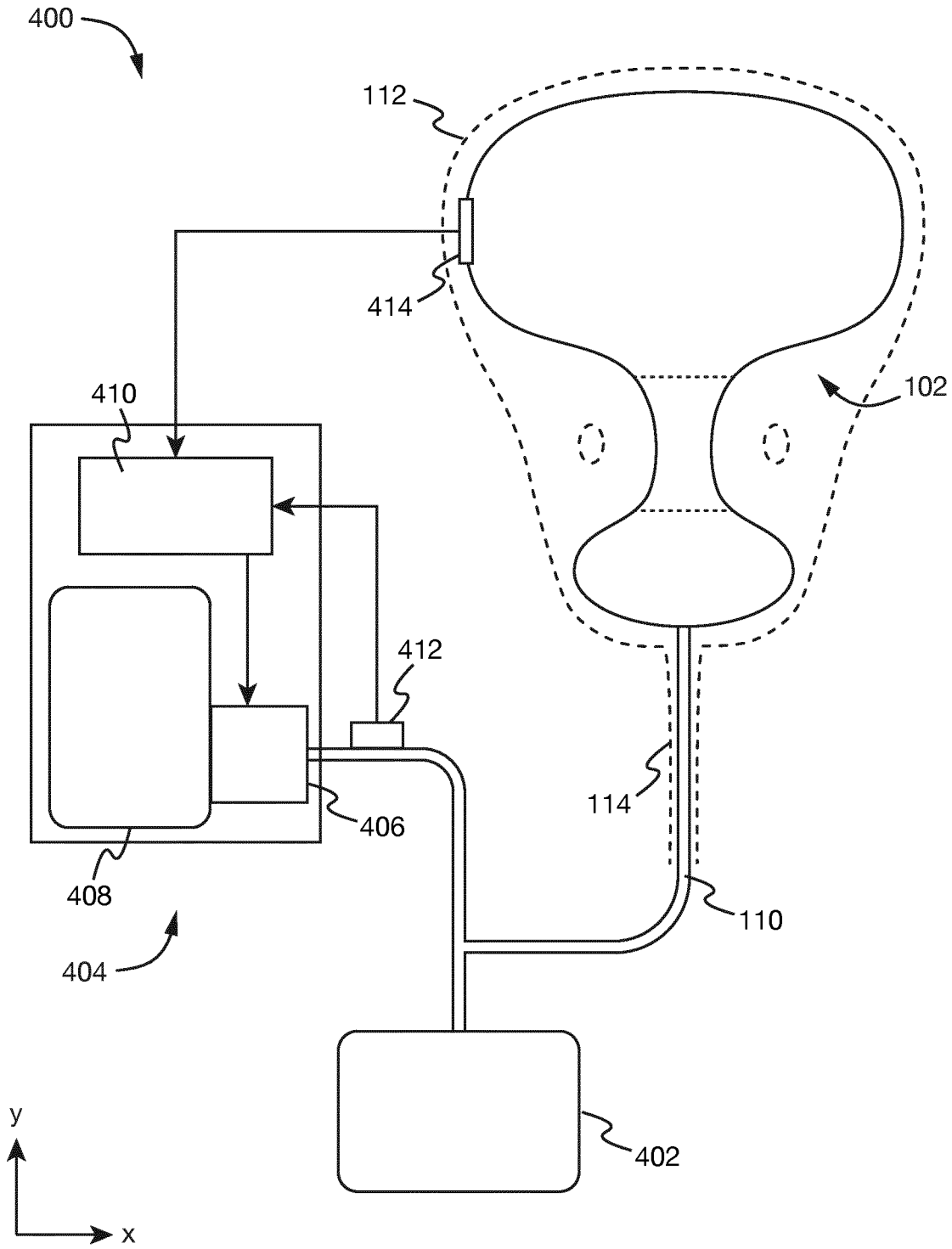

Fig. 4

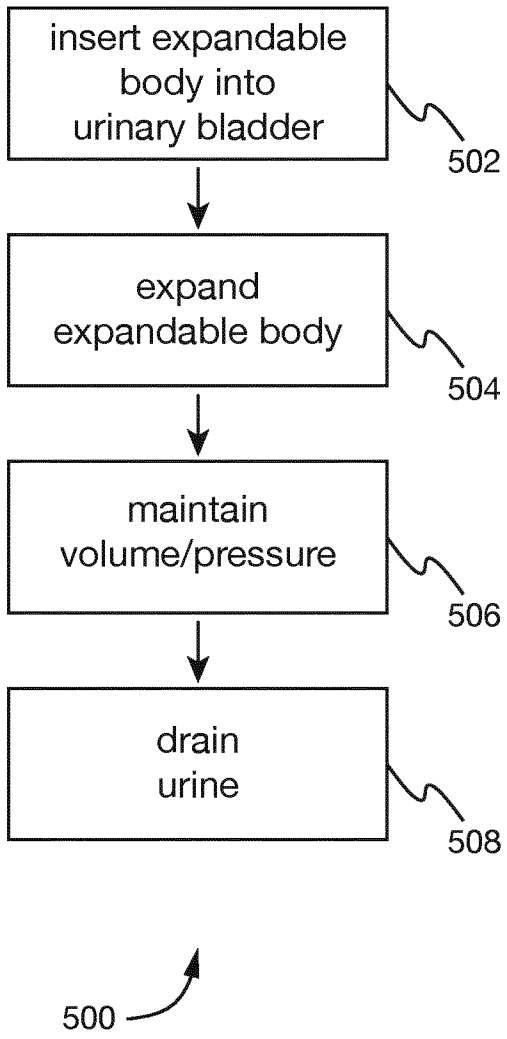
insert expandable body into urinary bladder
502
expand expandable body
504
maintain volume/pressure
506
drain urine
508
500

Fig. 5

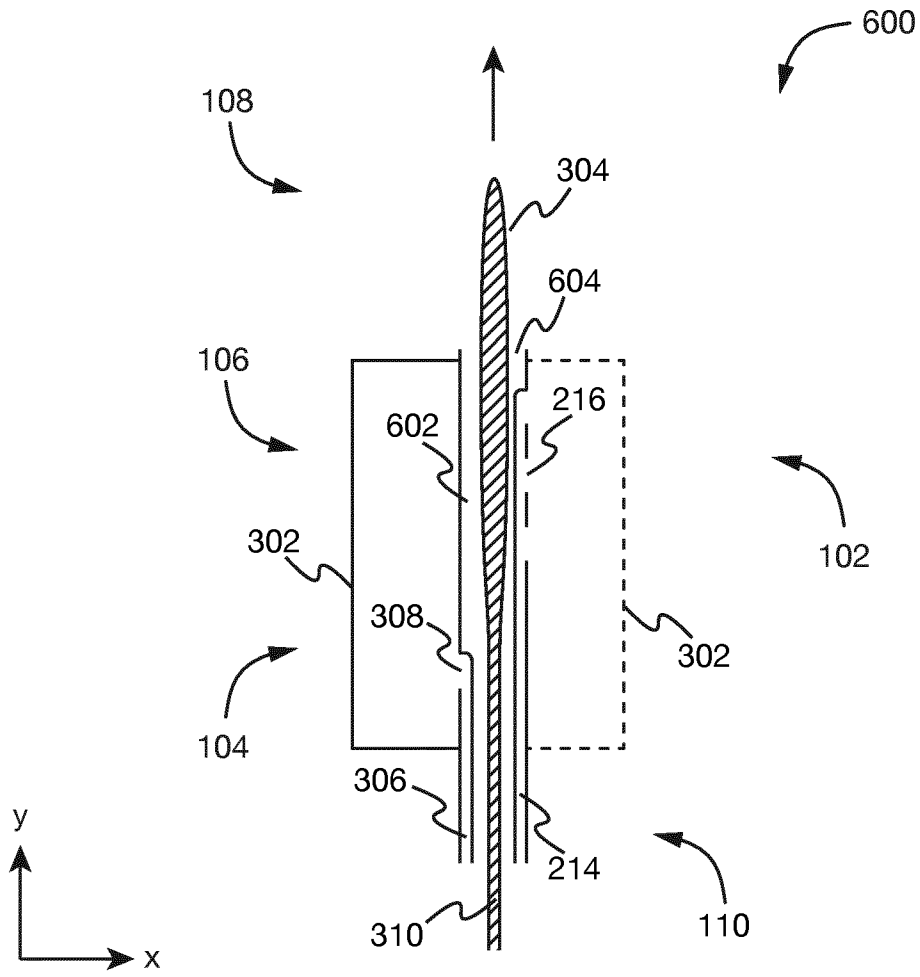
600
108
304
604
106
602
216
102
302
308
302
104
306
214
310
110
y
x

Fig. 6a

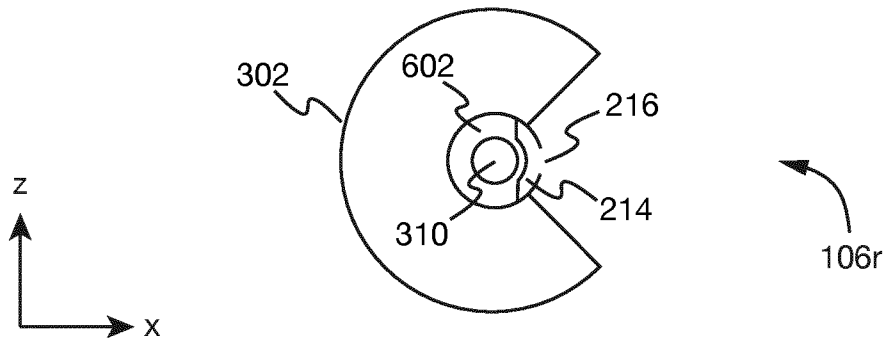
302
602
216
214
310
106r
z
x

Fig. 6b

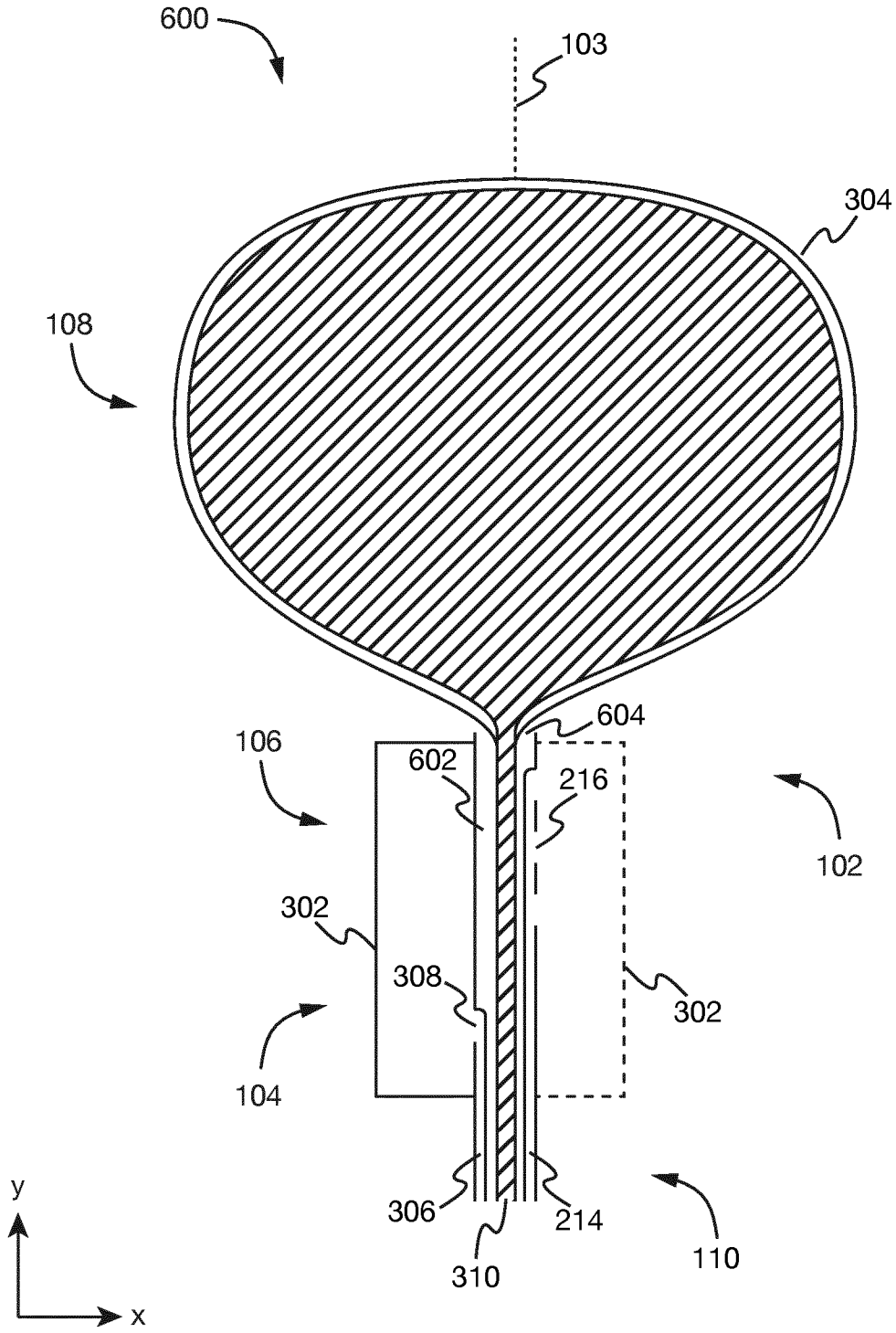
600
103
304
108
604
106
602
216
102
302
308
302
104
306
214
310
110
y
x

Fig. 6c

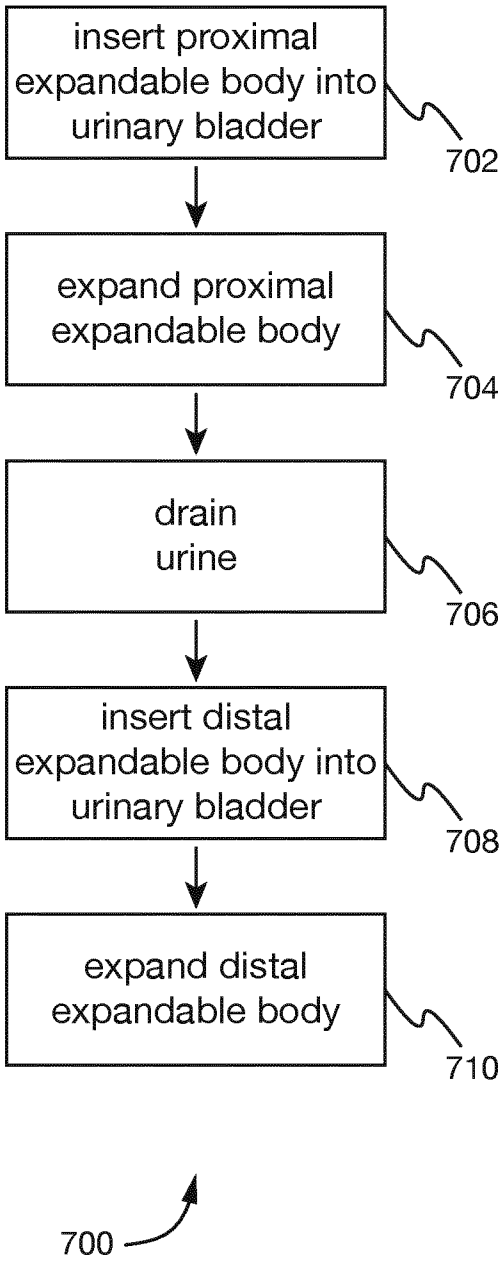
insert proximal expandable body into urinary bladder
702
expand proximal expandable body
704
drain urine
706
insert distal expandable body into urinary bladder
708
expand distal expandable body
710
700

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/058458

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/10 A61B17/12 A61F2/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 34 25 437 A1 (SACHSE HANS E) 23 January 1986 (1986-01-23) abstract page 1, line 38 - line 49 page 6, last paragraph figures 1,2	1
A	DE 34 28 536 A1 (SACHSE HANS E) 13 February 1986 (1986-02-13) abstract page 3, line 15 - line 30 figures 1-3	1
A	US 2017/325927 A1 (GÖBEL FRED [DE]) 16 November 2017 (2017-11-16) paragraph [0065] - paragraph [0066]	1

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 June 2020	01/07/2020

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Amaro, Henrique

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/058458

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

International application No
PCT/EP2020/058458

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2020/058458

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