US 20250256073A1

(19) United States
(12) Patent Application Publication
(10) Pub. No.: US 2025/0256073 A1
(43) Pub. Date: Aug. 14, 2025
Degaga

(54) **EXPANDABLE CATHETER**

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(21) Appl. No.: **19/048,722**

(22) Filed: **Feb. 7, 2025**

Related U.S. Application Data

(60) Provisional application No. 63/551,363, filed on Feb. 8, 2024.

Publication Classification

(51) **Int. Cl.**

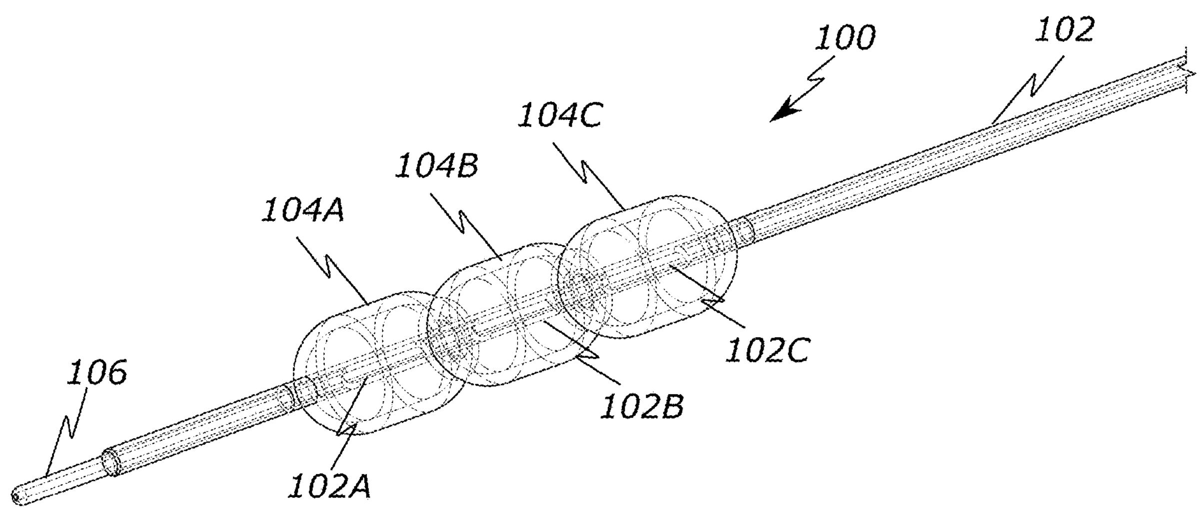
A61M 25/10	(2013.01)
A61F 2/24	(2006.01)
A61F 2/958	(2013.01)

(52) **U.S. Cl.**

CPC ***A61M 25/1011*** (2013.01); ***A61F 2/2427*** (2013.01); ***A61F 2/958*** (2013.01); *A61M 2025/1013* (2013.01); *A61M 2025/1061* (2013.01)

(57) **ABSTRACT**

An expandable catheter system includes a catheter body and a plurality of expansile elements connected at a distal region of the catheter body. The system further comprises an expansion mechanism capable of independently adjusting the radial size of each expansile element when in an actuated state. This independent adjustment allows for precise control over the expansion of each element, facilitating targeted treatment or intervention within a body lumen. The system is designed to enhance the adaptability and effectiveness of catheter-based procedures by providing customizable expansion capabilities tailored to specific anatomical or procedural requirements.



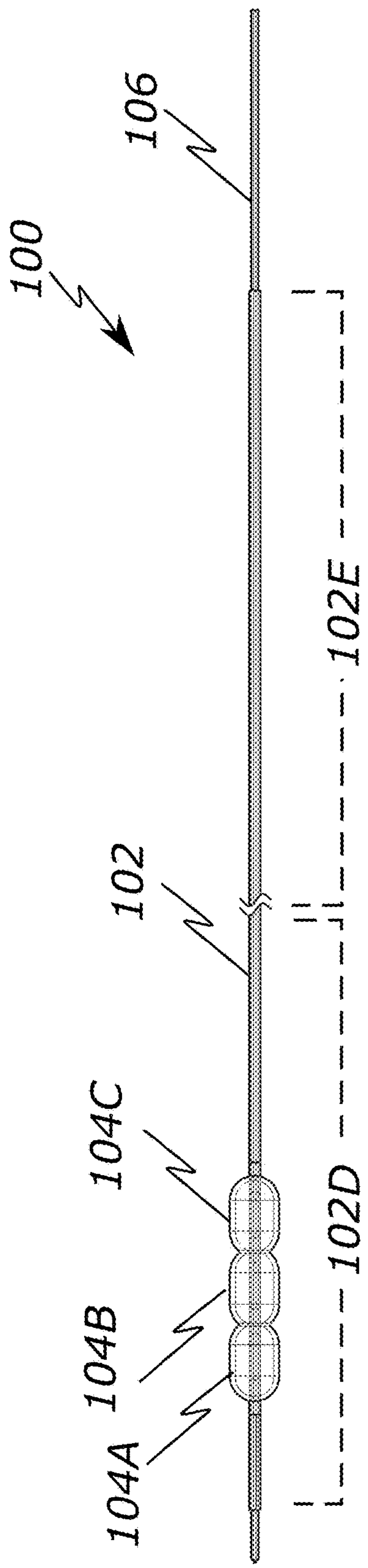

100
106
102
102E
102D
104C
104B
104A

FIG.1

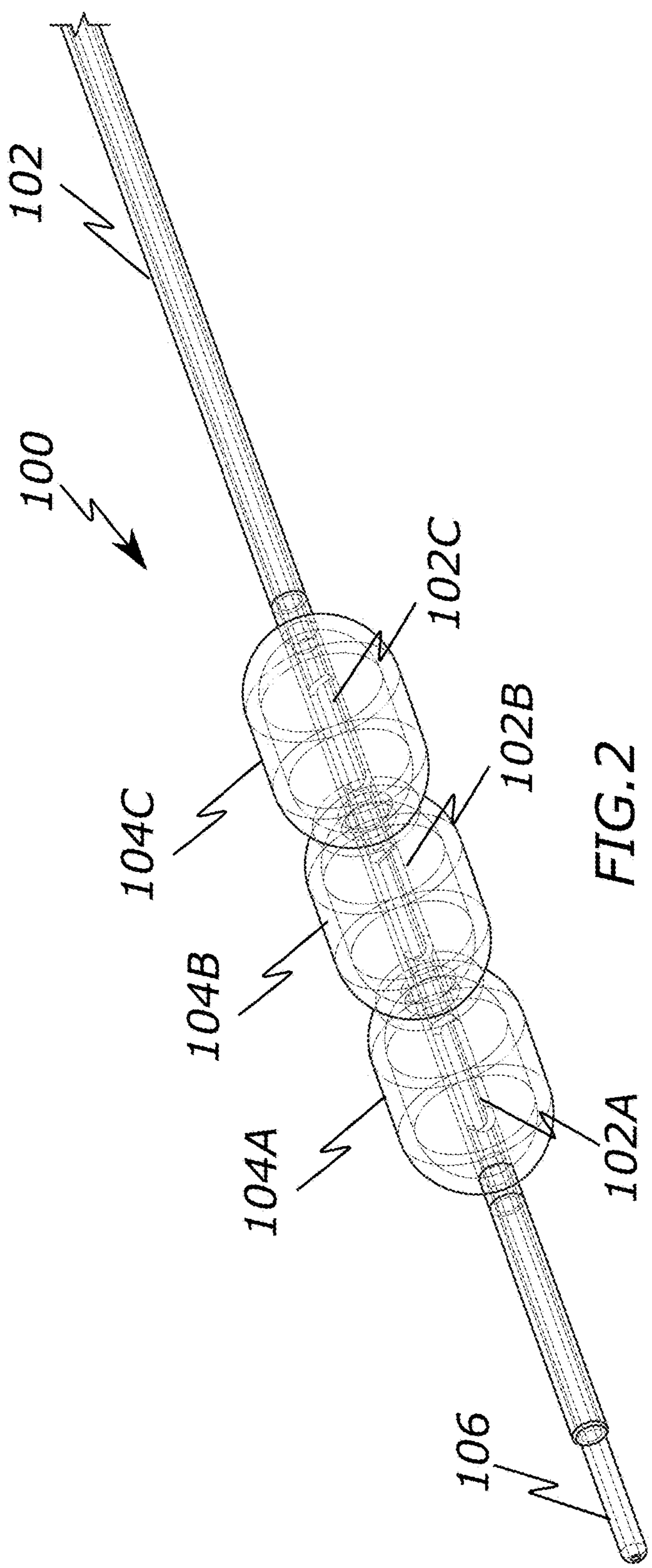

102
100
102C
102B
104C
104B
104A
102A
106

FIG.2

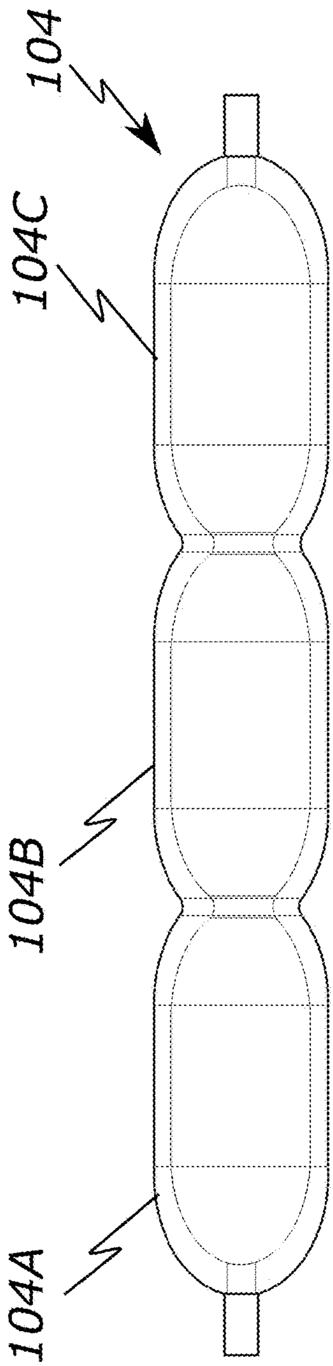


FIG.3

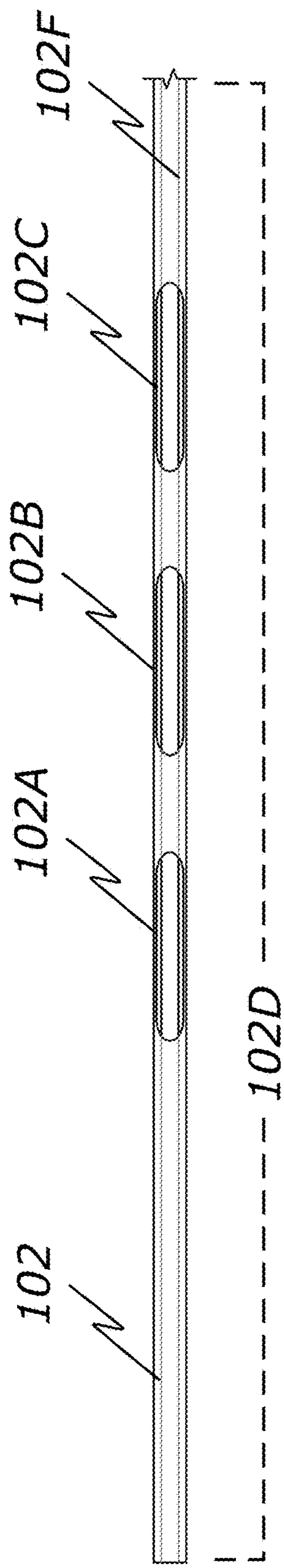


FIG.4

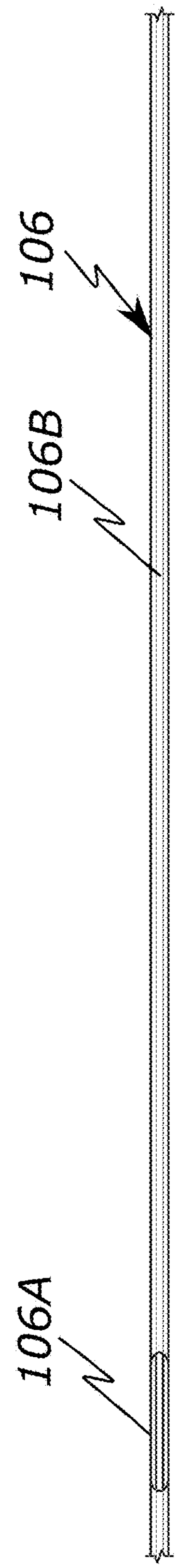


FIG.5

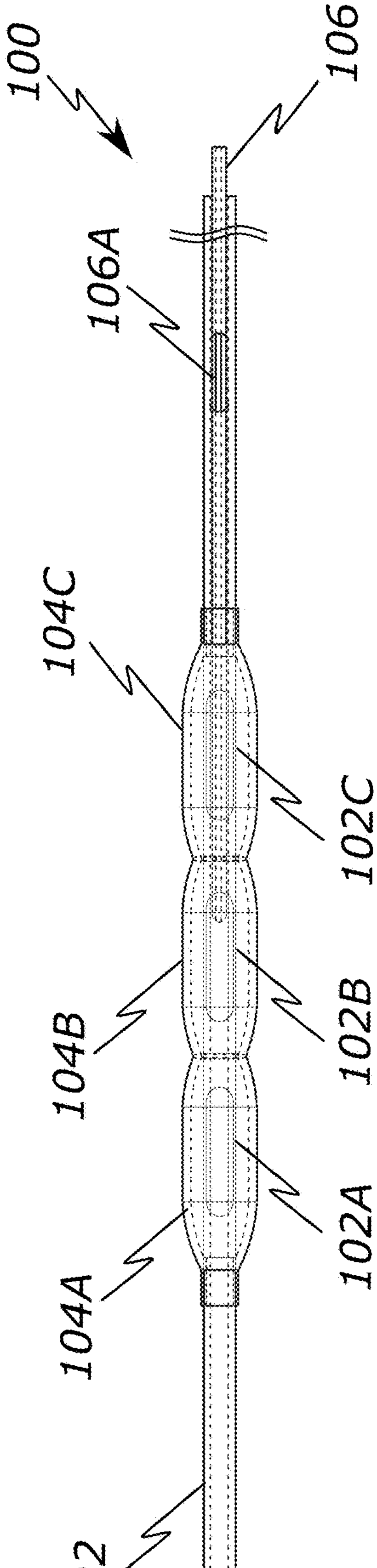

100
106
106A
104C
102C
104B
102B
104A
102A
102

FIG.6

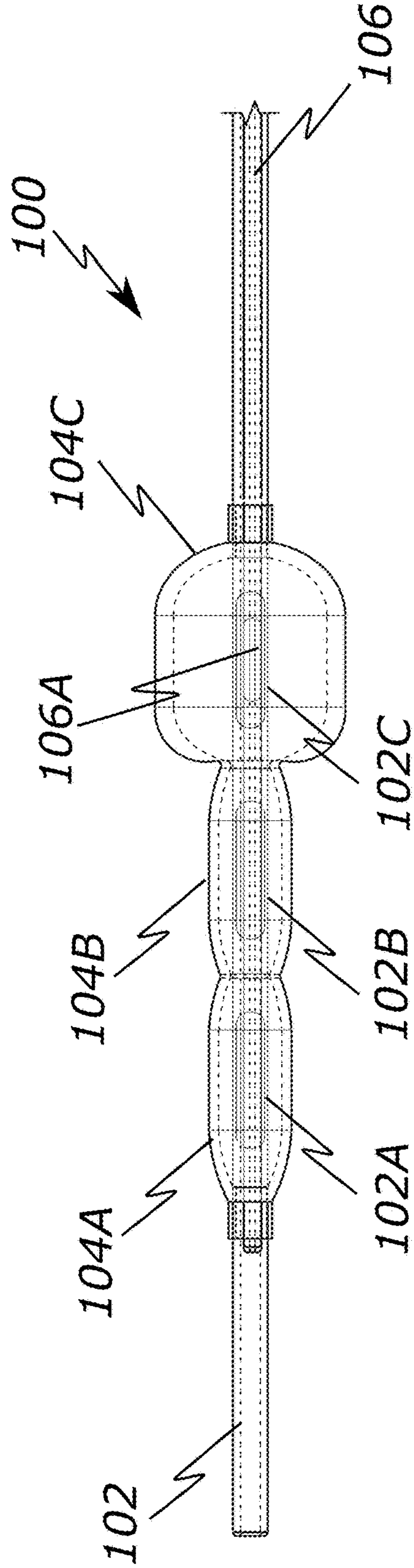

106
100
104C
106A
102C
104B
102B
104A
102A
102

FIG.7

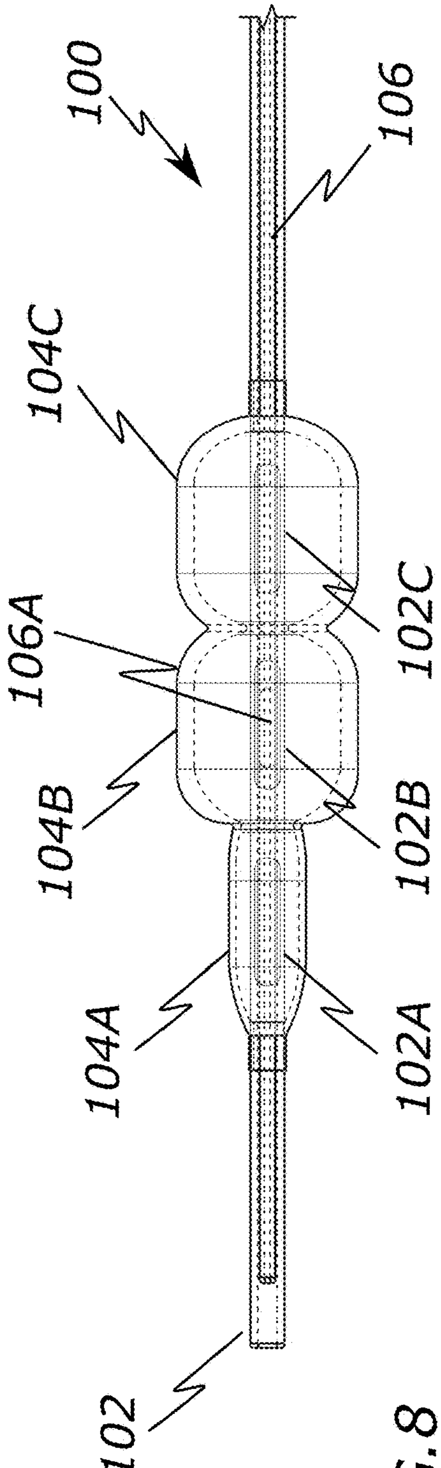

100
106
104C
102C
106A
104B
102B
104A
102A
102

FIG.8

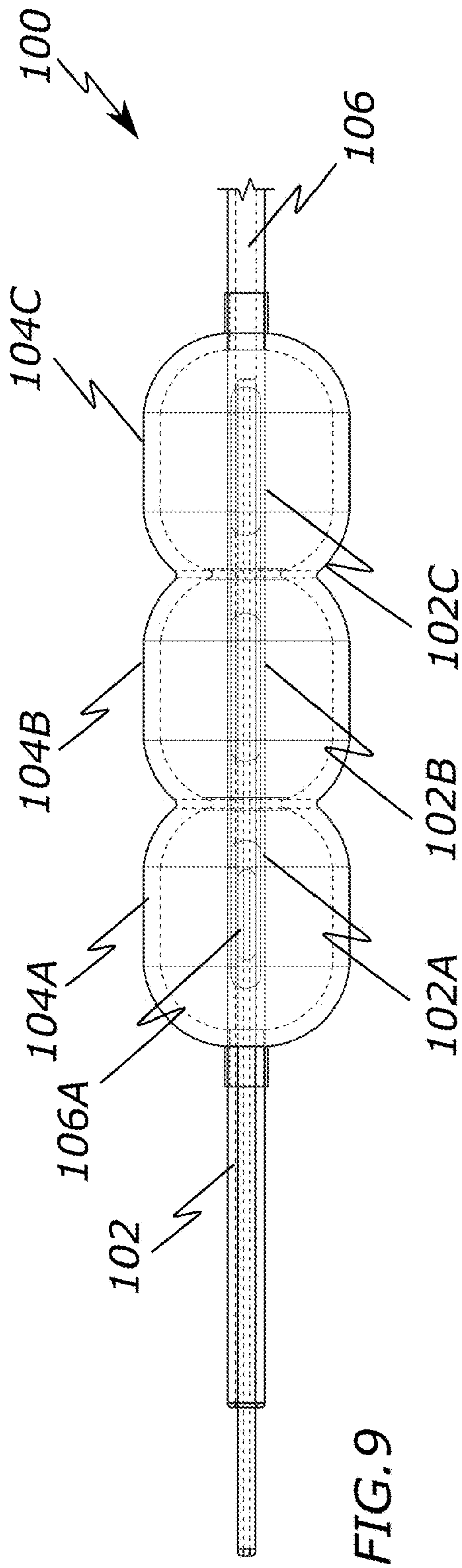

100
106
104C
102C
104B
102B
104A
102A
106A
102

FIG.9

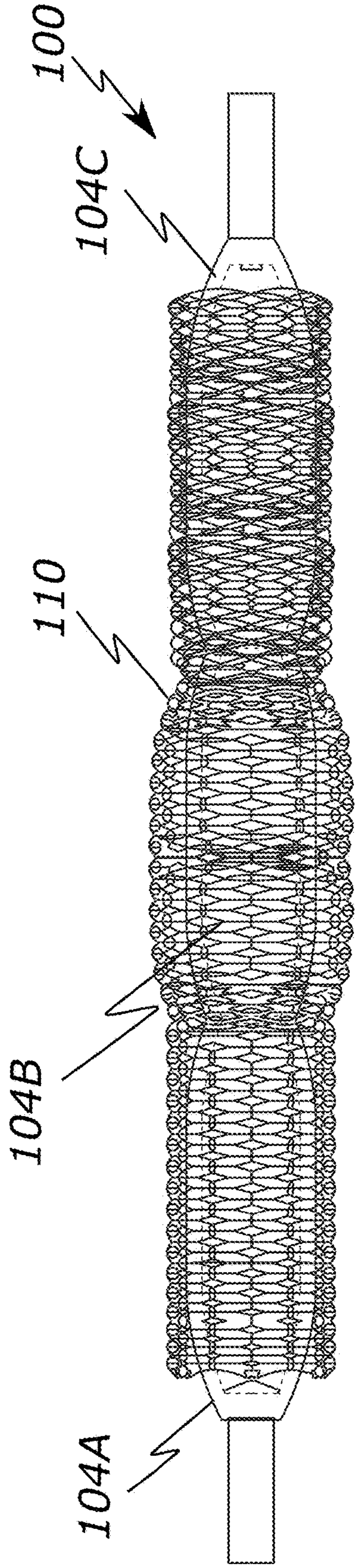


FIG.10A

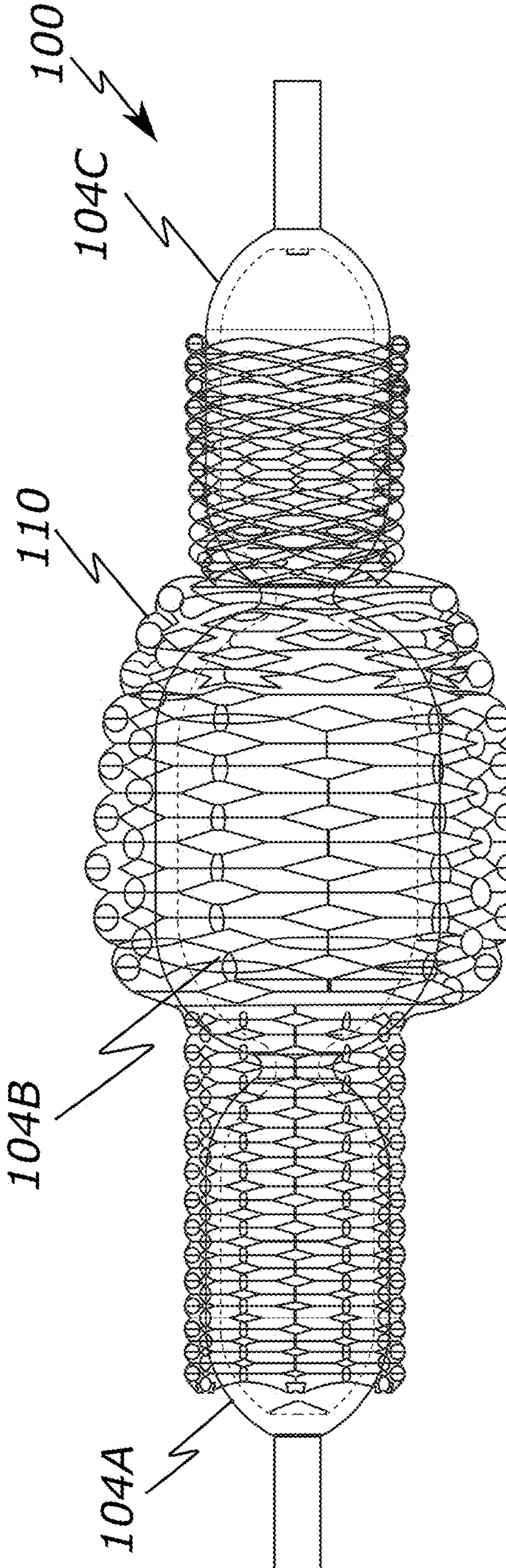


FIG.10B

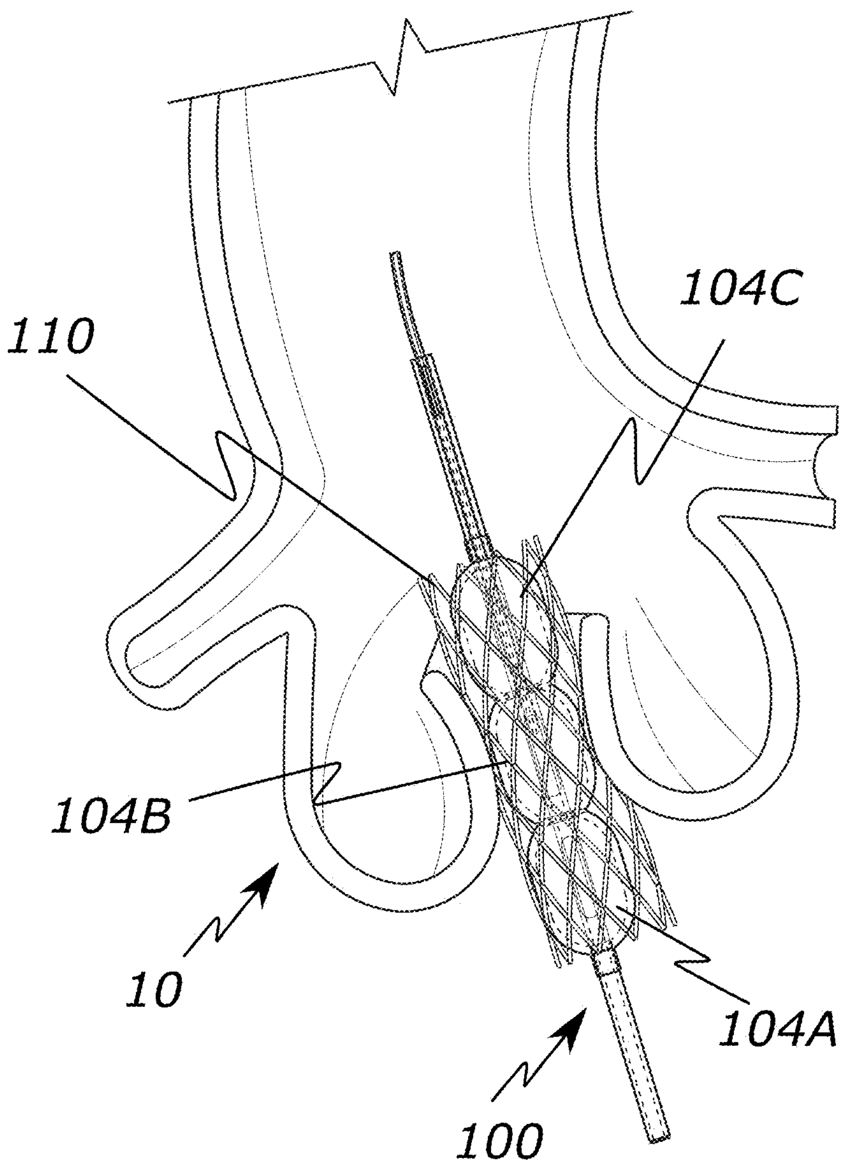


FIG.11A

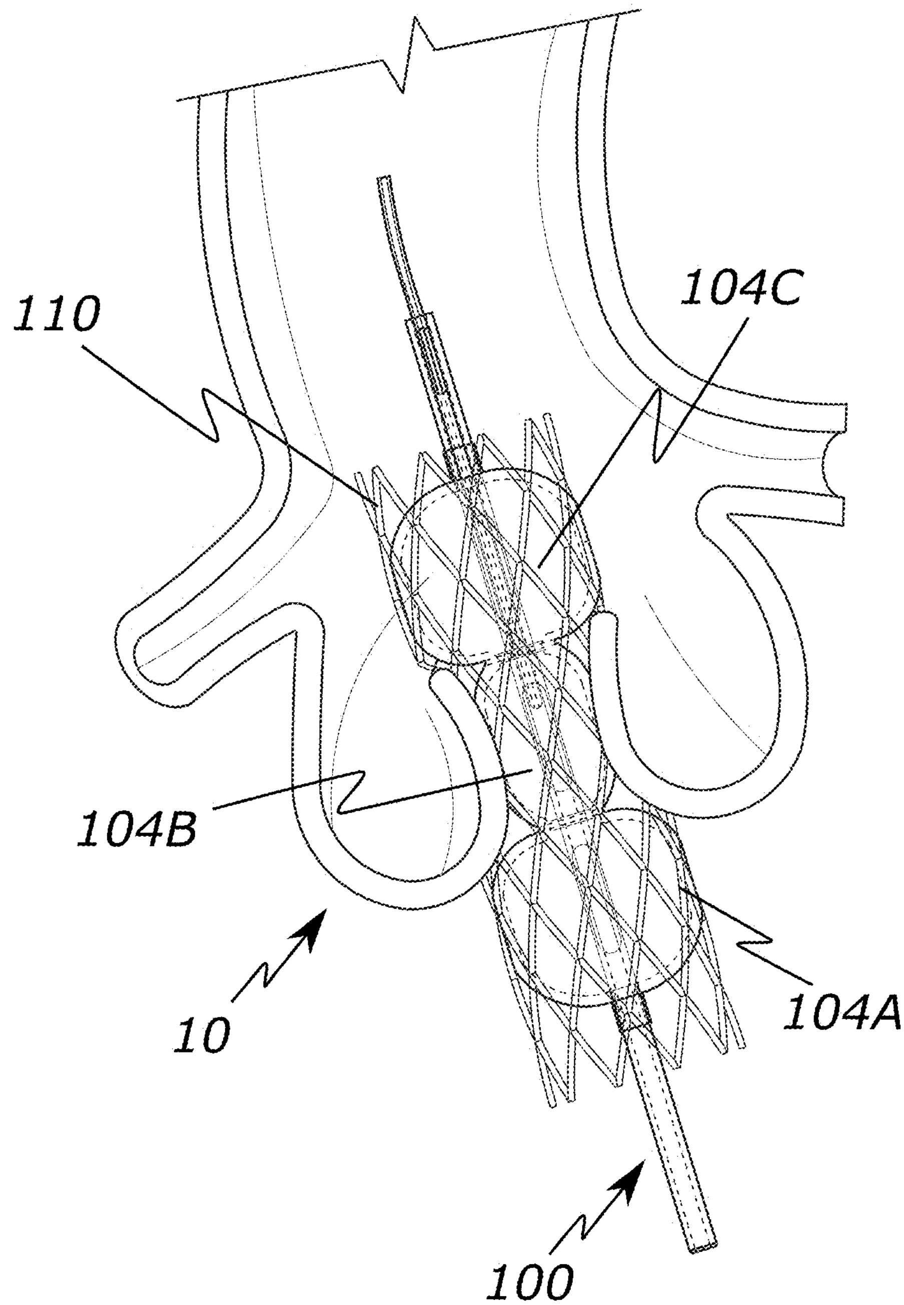


FIG.11B

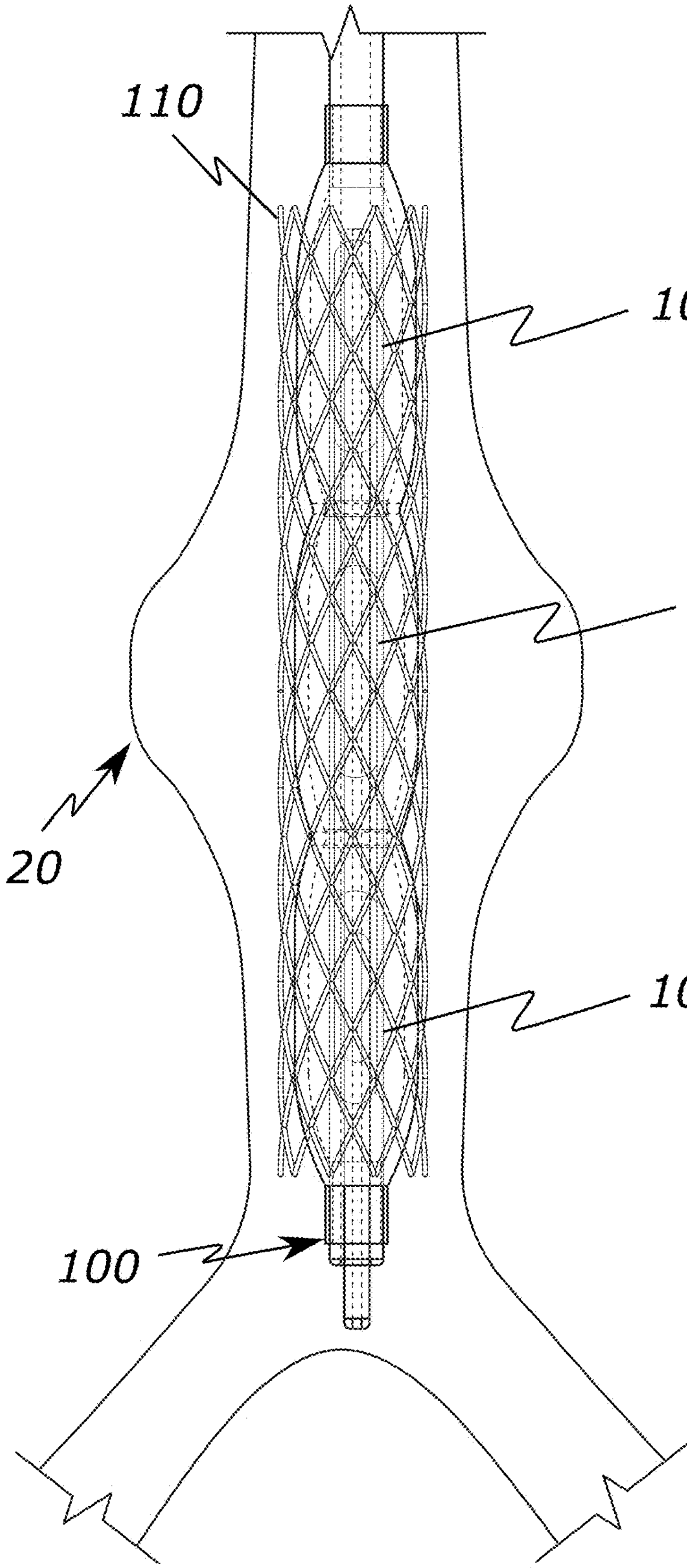


FIG.12A

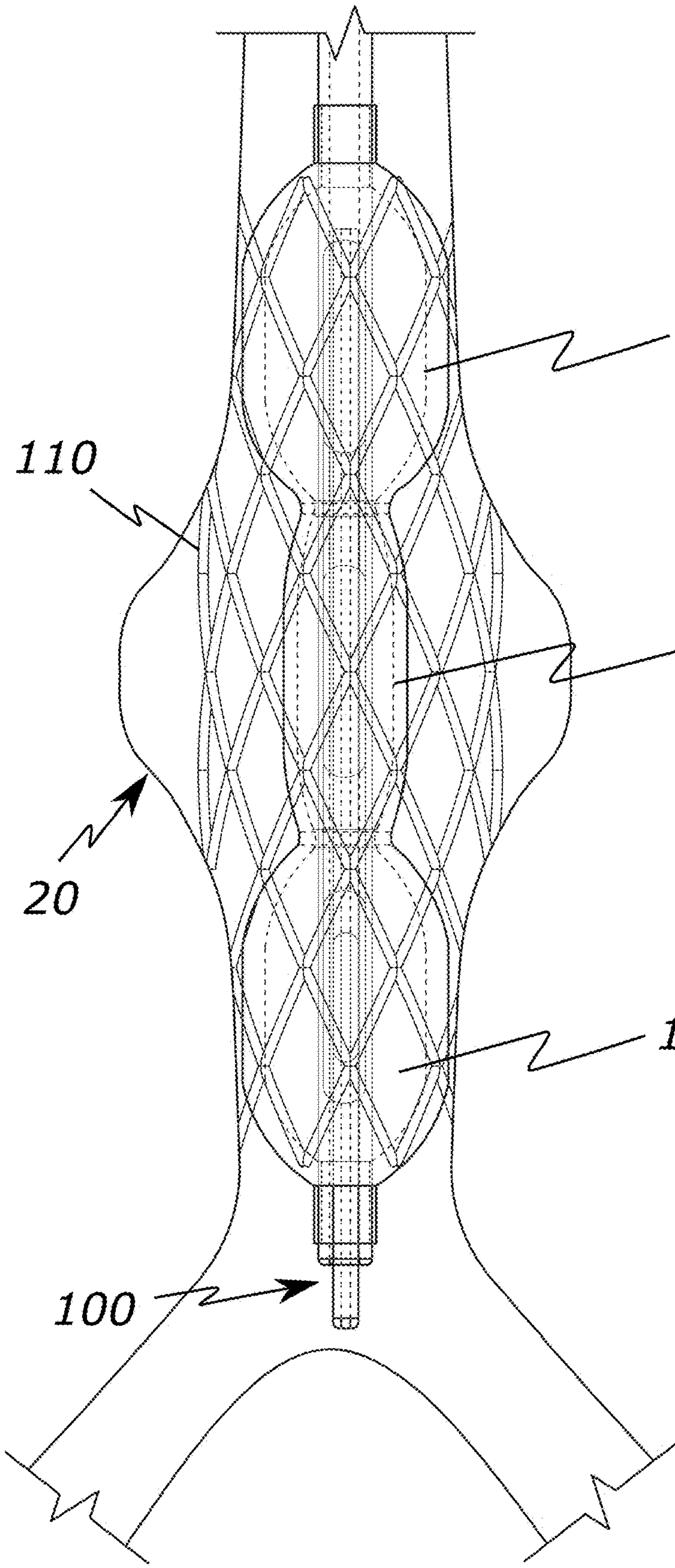


FIG.12B

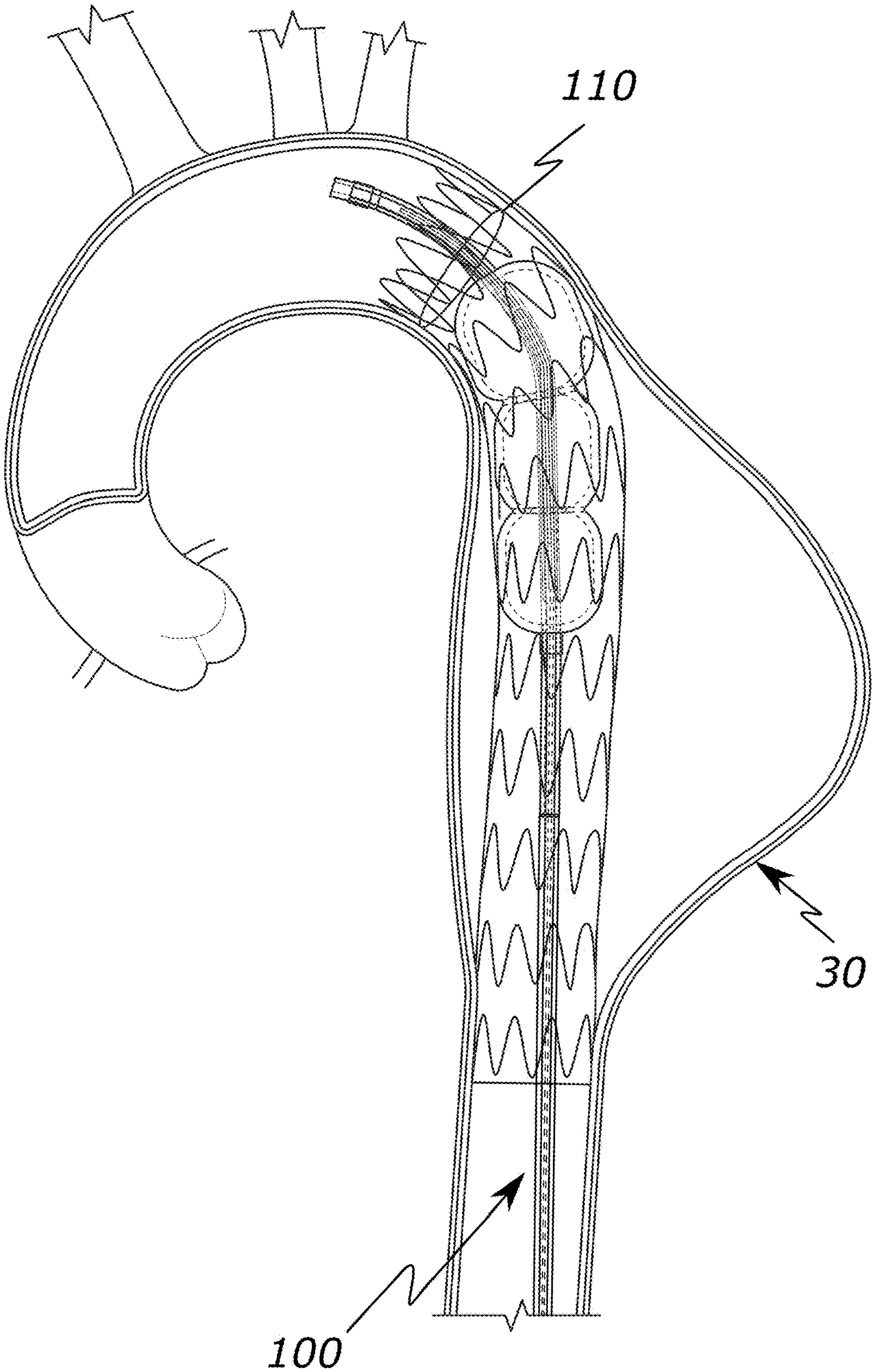


FIG.13

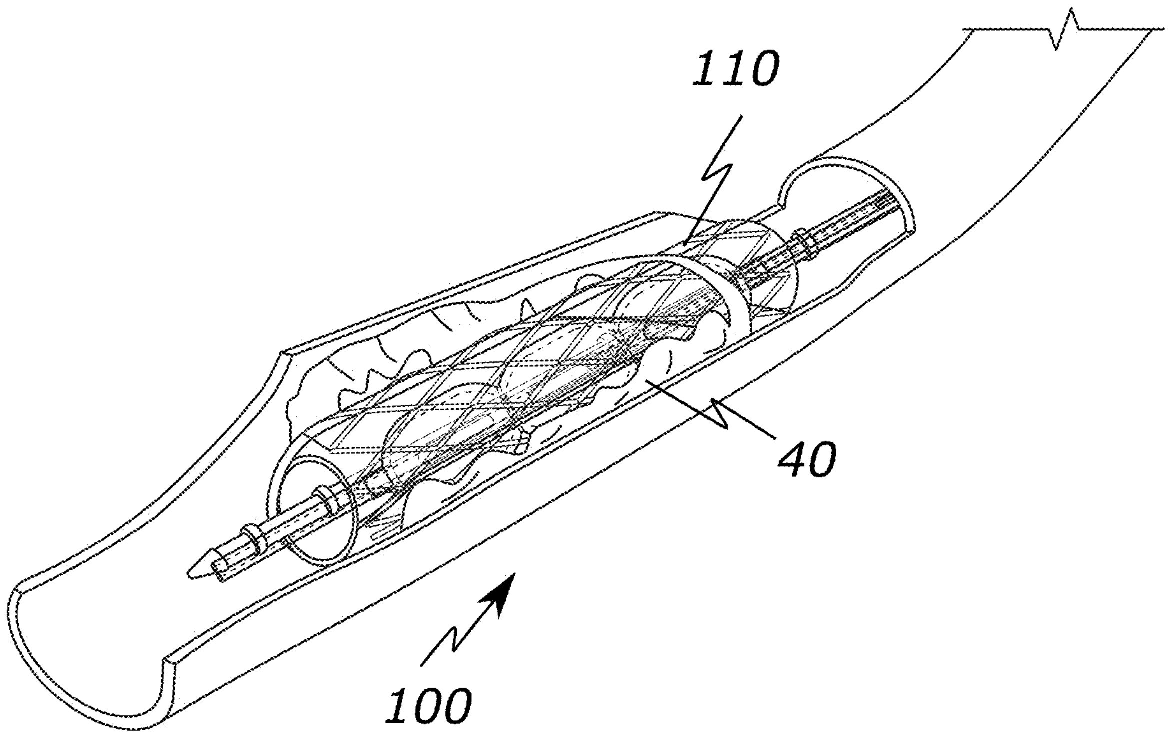


FIG.14

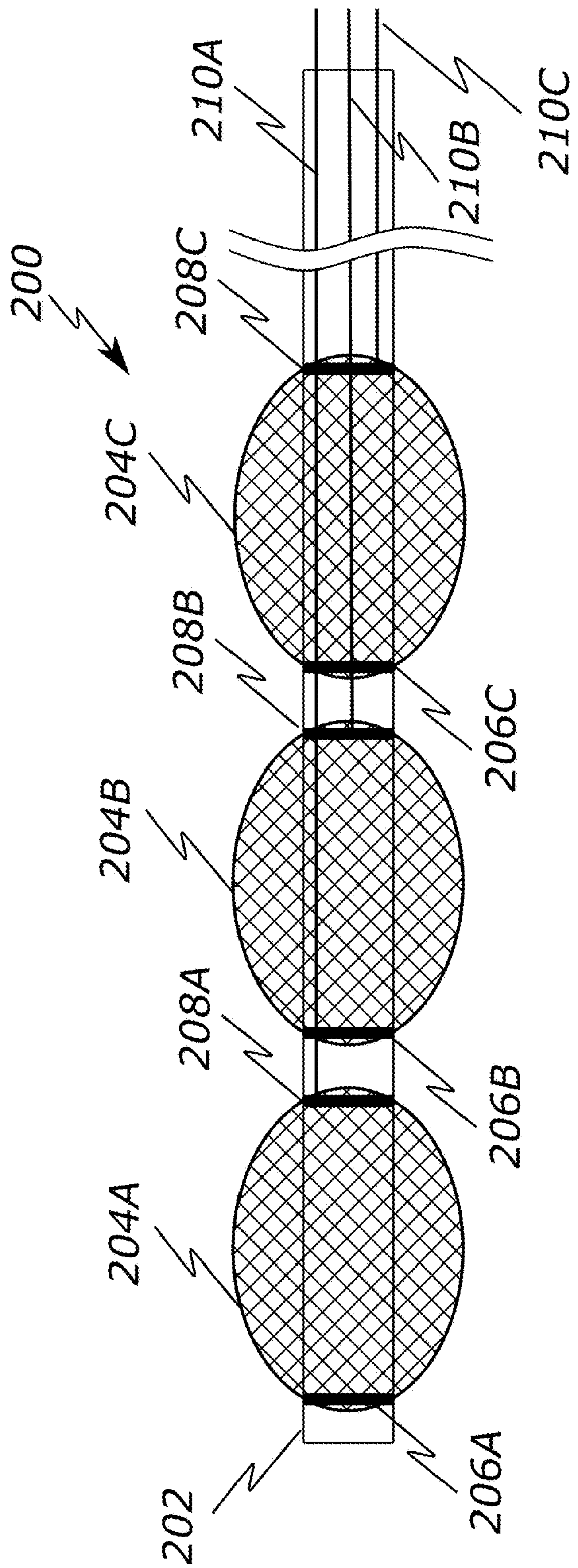

200
202
204A
204B
204C
206A
206B
206C
208A
208B
208C
210A
210B
210C

FIG.15

EXPANDABLE CATHETER

RELATED APPLICATIONS

[0001] This application claims benefit of and priority to U.S. Provisional Application Ser. No. 63/551,363 filed Feb. 8, 2024, entitled Balloon Catheter, which is hereby incorporated herein by reference in its entirety.

BACKGROUND

[0002] Stents, artificial heart valves, and similar implantable devices are often expanded within a patient by inflating a balloon catheter within the device. Similarly, narrowed vessels, such as those narrowed by vascular plaque, are often treated by angioplasty in which a balloon catheter is inflated at the narrowed region.

[0003] Balloon catheters typically include an elongated catheter body, a balloon at or near a distal end of the balloon body, and an inflation lumen within catheter body that is in communication with an interior of the balloon. Inflation media may be delivered through the inflation lumen to inflate the balloon during a procedure. As the balloon expands, it radially expands the device and/or vessel to a desired size.

SUMMARY

[0004] In some aspects, the techniques described herein relate to an expandable catheter system, including: a catheter body; a plurality of expansile elements connected at a distal region of the catheter body; and, an expansion mechanism having an actuated state that independently adjusts a radial size of each of the plurality of expansile elements.

[0005] In some aspects, the techniques described herein relate to an expandable catheter system, wherein the plurality of expansile elements include balloons and wherein the expansion mechanism includes an inflation tube longitudinally movable within the catheter body between at least a first position in communication with a first balloon of the plurality of balloons, and a second position in communication with a second balloon of the plurality of balloons.

[0006] In some aspects, the techniques described herein relate to an expandable catheter system, wherein the catheter body includes an interior body passage extending between a proximal region and a distal region of the catheter body; and wherein the inflation tube is longitudinally movable within the interior body passage between the at least first position and second position.

[0007] In some aspects, the techniques described herein relate to an expandable catheter system, wherein of all of the plurality of balloons, the inflation tube is only in communication with the first balloon when in the first position.

[0008] In some aspects, the techniques described herein relate to an expandable catheter system, wherein of all of the plurality of balloons, the inflation tube is only in communication with the second balloon when in the second position.

[0009] In some aspects, the techniques described herein relate to an expandable catheter system, wherein of all of the plurality of balloons, the inflation tube is only in communication with the first balloon when in the first position and wherein the inflation tube is only in communication with the first balloon and the second balloon when in the second position.

[0010] In some aspects, the techniques described herein relate to an expandable catheter system, wherein the first balloon and the second balloon each include inflation chambers that are completely isolated from each other, partially in communication with each other, or selectively in communication with each other.

[0011] In some aspects, the techniques described herein relate to an expandable catheter system, wherein the catheter body includes a first catheter body port located underneath the first balloon and a second catheter body port located underneath the second balloon.

[0012] In some aspects, the techniques described herein relate to an expandable catheter system, wherein the inflation tube further includes an inflation port opening through a sidewall of the inflation tube and into an inflation passage of the inflation tube.

[0013] In some aspects, the techniques described herein relate to an expandable catheter system, further including rotational orientation lock that maintains a rotational orientation of the inflation tube relative to the catheter body.

[0014] In some aspects, the techniques described herein relate to an expandable catheter system, further including one or more seals located around 1) the inflation port opening and/or located around 2) the first catheter body port and the second catheter body port.

[0015] In some aspects, the techniques described herein relate to an expandable catheter system, further including a stent positioned over the plurality of balloons.

[0016] In some aspects, the techniques described herein relate to an expandable catheter system, further including a replacement valve framework positioned over the plurality of balloons.

[0017] In some aspects, the techniques described herein relate to an expandable catheter system, wherein at least some of the plurality of balloons have inflated diameters that are different from each other.

[0018] In some aspects, the techniques described herein relate to an expandable catheter system, wherein the plurality of balloons includes the first balloon, the second balloon, and a third balloon, and wherein the second balloon is positioned between the first balloon and the third balloon, and wherein an inflated diameter of the second balloon is larger or smaller than inflated diameters of the first balloon and the third balloon.

[0019] In some aspects, the techniques described herein relate to an expandable catheter system, wherein the plurality of balloons includes the first balloon, the second balloon, and a third balloon, and wherein the inflation tube is moved between the first position, the second position, and a third position to sequentially inflate the first balloon first, the second balloon second, and the third balloon third.

[0020] In some aspects, the techniques described herein relate to an expandable catheter system, wherein the inflation tube is movable to a third position to remove inflation fluid from the plurality of balloons.

[0021] In some aspects, the techniques described herein relate to an expandable catheter system, wherein the plurality of expansile elements include a plurality of mesh structures and wherein the expansion mechanism includes one or more control wires connected to the plurality of mesh structures.

[0022] In some aspects, the techniques described herein relate to a balloon catheter system, including: a catheter body including an interior body passage extending between a proximal region and a distal region of the catheter body; a plurality of balloons connected at the distal region of the catheter body; wherein each balloon is separately in communication with the interior body passage; and, an inflation tube including a distal inflation opening; wherein the inflation tube is longitudinally movable between at least a first position in communication with a first balloon of the plurality of balloons, and a second position in communication with a second balloon of the plurality of balloons.

[0023] In some aspects, the techniques described herein relate to a balloon catheter system, including: a catheter body; a plurality of balloons connected at a distal region of the catheter body; and, an inflation tube means for longitudinally moving between positions within the catheter body and establishing an inflation passage between only one of the plurality of balloons at a time.

[0024] In some aspects, the techniques described herein relate to a method of using a balloon catheter system, including: longitudinally aligning a distal inflation opening of an inflation tube with a first port of an interior body passage of a catheter body; inflating a first balloon in communication with the first port; longitudinally aligning the distal inflation opening of the inflation tube with a second port of an interior body passage of the catheter body; and, inflating a second balloon in communication with the second port.

[0025] In some aspects, the techniques described herein relate to a method, further including longitudinally aligning the distal inflation opening of the inflation tube with a third port of the interior body passage of the catheter body, and inflating a third balloon in communication with the third port.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] The following figures are included to illustrate certain example aspects of the present disclosure and should not be viewed as exclusive or limiting. The subject matter disclosed is capable of considerable modifications, alterations, combinations, and equivalents in form and function, as will occur to one having ordinary skill in the art and having the benefit of this disclosure. The present disclosure references the drawings as follows:

[0027] FIG. **1** illustrates a side view of an example balloon catheter system **100** with a plurality of balloons **104**A, **104**B, and **104**C located within a distal region **102**D of a catheter body **102** that may be separately and independently inflated relative to each other, according to some examples.

[0028] FIG. **2** illustrates a perspective view of a portion of the distal region **102**D of the catheter body **102**, according to some examples.

[0029] FIG. **3** illustrates a side view of a balloon assembly **104** comprising the plurality of balloons **104**A, **104**B, and **104**C, according to some examples.

[0030] FIG. **4** illustrates a side view of the distal region **102**D of the catheter body **102** comprising catheter body ports **102**A, **102**B, and **102**C, according to some examples.

[0031] FIG. **5** illustrates a side view of the inflation tube **106**, according to some examples.

[0032] FIG. **6** illustrates balloons **104**A, **104**B, and **104**C in a deflated state, according to some examples.

[0033] FIG. **7** illustrates balloon **104**C at an inflated state in response to injecting inflation media when the inflation opening **106**A is aligned with catheter body port **102**C, according to some examples.

[0034] FIG. **8** illustrates balloons **104**C and **104**B in an inflated state, according to some examples.

[0035] FIG. **9** illustrates balloons **104**C, **104**B, and **104**C in an inflated state, according to some examples.

[0036] FIG. **10**A illustrates a side view of a balloon catheter system **100** with a stent-like structure **110** positioned over balloons **104**A, **104**B, and **104**C in an uninflated state, according to some examples.

[0037] FIG. **10**B illustrates a side view of the balloon catheter system **100** in which the balloons **104**A, **104**B, and **104**C are in various states of inflation, depending on how the operator actuates inflation, according to some examples.

[0038] FIGS. **11**A and **11**B illustrate a side view of the balloon catheter system **100** deploying a stent-like structure **110** (e.g., a replacement valve framework) within a heart valve **10**, according to some examples.

[0039] FIGS. **12**A and **12**B illustrate side views of the balloon catheter system **100** deploying a stent-like structure **110** within an aortic aneurysm **20**, according to some examples.

[0040] FIG. **13** illustrates a side view of the balloon catheter system **100** deploying a stent-like structure **110** within a thoracic aortic aneurysm **30**, according to some examples.

[0041] FIG. **14** illustrates a side view of the balloon catheter system **100** deploying a stent-like structure **110** within a vessel containing plaque **40**, according to some examples.

[0042] FIG. **15** illustrates a side view of a catheter **200** comprising mesh structures **204**A, **204**B, and **204**C that may be selectively and individually expanded in diameter, according to some examples.

DETAILED DESCRIPTION

[0043] It will be appreciated by persons skilled in the art that the present disclosure is not limited to what has been particularly shown and described herein. A variety of modifications and variations are possible in view of the teachings herein without departing their scope, spirit, or intent.

[0044] While different examples may be described in this specification, it is specifically contemplated that any of the features from the different examples can be used and brought together in any combination. In other words, the features of different examples can be mixed and matched with each other. Hence, while every permutation of features from different examples may not be explicitly shown or described, it is the intention of this disclosure to cover any such combinations, especially as may be appreciated by one of skill in the art.

[0045] The terminology used in this disclosure should be interpreted in a permissive manner and is not intended to be limiting. In the drawings, like numbers refer to like elements. Unless otherwise noted, all of the accompanying drawings are not to scale. Unless otherwise noted, the term "about" is defined to mean plus-or-minus 5% of a stated value.

[0046] The terms distal or distally generally refer to a direction or area towards an end of a device within a patient (e.g., away from a physician/clinician), while the terms proximal or proximally refer to a direction or area toward an end of a device that remains outside of a patient (e.g., toward or closer to a physician/clinician or handle/hub of a device).

[0047] Typically, balloon catheters comprise a single balloon on the end of a catheter body that inflates to a generally cylindrical shape with a mostly uniform diameter. These balloon catheters can be used for delivering stents, artificial valves, or similar devices, as well as expanding areas within a patient, such as for angioplasty or valvuloplasty.

[0048] However, some areas of use within a patient may have an irregular shape. For example, locations near an aneurysm, near a large plaque deposit, or within an annulus of a valve often include shapes that vary in diameter and/or have non-symmetrical shapes. These uniformity variations can increase the difficulty of adequately expanding a device or a target portion of anatomy.

[0049] Aspects of a catheter are described in this specification which may improve delivery, expansion, or other therapy at areas having irregular shapes, variations in diameter, or both. The catheter may include a plurality of independently expandable expansile elements. Expansile elements may include balloons, mesh structures, strut frameworks, hydrogel, or similar structures.

[0050] The catheter may also include an expansion mechanism that, when adjusted by a user to an actuated state, selectively expands some or all of the expansile elements at various times and to different various diameters. Expansion mechanisms may include one or more expansion mechanism members, including a longitudinally movable inflation tube that may individually direct inflation media into individual balloons, elongated control wires that are longitudinally movable to expand mesh expansile members, longitudinally movable outer sheaths that selectively expose individual self-expanding expansile members, electrically activated hydrogel that selectively expands when current is directed to it, or similar variations.

[0051] An example balloon catheter may include a plurality of independently inflatable balloons or a plurality of independently inflatable chambers of a single balloon. Each of these balloons/chambers may expand to a different desired diameter to accommodate any irregular shapes or diameters of the target anatomy. Additionally or alternatively, each of these balloons/chambers may be individually inflated in a desired sequence which may be further helpful during certain procedures.

[0052] For simplicity, the terms "balloon" or "balloons" may be used in this specification. However, these terms should be understood to include discrete, physically separate balloons, physically touching or connected balloons, or a single balloon structure with multiple inflation chambers. Further, these balloons may have balloon chambers that are completely isolated from each other, partially in communication with each other, or only selectively/periodically in communication with each other.

[0053] In some examples, a distal region of the balloon catheter may include two or more balloons that can be independently inflated. Each balloon may be disposed over at least one catheter body opening or port which opens into an interior body passage extending from the distal region to a proximal end of the catheter body. Inflation media is directed to each of the catheter body ports by an elongated inflation tube. The inflation tube is movable (e.g., longitudinally slidable and/or rotatable) within the interior body passage of the catheter body and may be optionally removable from the catheter body.

[0054] A distal portion of the inflation tube may have an inflation port (e.g., on its side) which may be longitudinally and rotationally aligned with one of the ports of the catheter body into one of the plurality of balloons. When inflation media is injected into a proximal end of the inflation tube, the chamber of the balloon the inflation tube is aligned with inflates. The inflation tube may be longitudinally moved and aligned with other ports of the catheter body so that other balloons may be subsequently inflated.

[0055] Specific example uses of the balloon catheters of this specification may include stent delivery on a thoracic aortic aneurysm, stent delivery for an abdominal aortic aneurysm, trans aortic valve repair or replacement, superior vena cava stenosis, angioplasty, valvuloplasty, and similar treatments.

[0056] FIG. **1** illustrates a side view of an example balloon catheter system **100** with a plurality of balloons **104**A, **104**B, and **104**C located within a distal region **102**D of a catheter body **102** that may be separately and independently inflated relative to each other. FIG. **2** illustrates a perspective view of a portion of the distal region **102**D of the catheter body **102**. FIG. **3** illustrates a side view of a balloon assembly **104** comprising the plurality of balloons **104**A, **104**B, and **104**C. FIG. **4** illustrates a side view of the distal region **102**D of the catheter body **102**. FIG. **5** illustrates a side view of the inflation tube **106**. These figures will be discussed concurrently below.

[0057] As best illustrated in FIGS. **1** and **4**, the balloon catheter system **100** may include an elongated catheter body **102**. The catheter body **102** may include at least one interior body passage **102**F that extends from an opening at a proximal end of a proximal region **102**E (FIG. **1**) of the catheter body **102** (e.g., a catheter hub) to a distal region **102**D (FIG. **2**, **4**) of the catheter body **102**. The distal region **102**D of the catheter body may have a variety of different lengths, depending on the use, target location, and the approach to the target location. However, in one example, the distal region **102**D of the catheter body **102** may have a length from a distal end of the catheter body **102** within an inclusive range of 0 mm to 50 mm. In another example, the distal region **102**D of the catheter body **102** may have a length from the distal end of the catheter body **102** within an inclusive range of 10 mm to 40 mm.

[0058] As further illustrated in FIG. **4**, the catheter body **102** also includes a plurality of catheter body ports **102**A, **102**B, and **102**C that open into the at least one interior body passage **102**F of the catheter body **102**. The catheter body ports **102**A, **102**B, **102**C form openings or passages through the wall of the catheter body **102** to connect the interior body passage **102**F with the interior chambers of a respective balloon **104**A, **104**B, and **104**C. The catheter body ports **102**A, **102**B, **102**C are longitudinally spaced apart from each other and may be generally located within the distal region of the catheter body **102** or near a distal end of the catheter body **102**. In the illustrated example, the catheter body ports **102**A, **102**B, and **102**C are illustrated as being located generally at the same radial or circumferential position relative to each other, however, the ports **102**A, **102**B, and **102**C may also be located at different radial or circumferential positions relative to each other.

[0059] Referring to FIG. **2**, each balloon **104**A, **104**B, and **104**C is located over a corresponding catheter body port **102**A, **102**B, **102**C so that each catheter body port may open into only one of the balloons (e.g., there is a one-to-one relationship such that each catheter body port is in fluid communication with only one balloon). Aside from the catheter body ports **102**A, **102**B, **102**C, the chamber within each balloon may be sealed from an outside atmosphere, as well as sealed from adjacent balloons **104**A, **104**B, and **104**C. Alternatively, the chambers of each balloon may have a relatively small passage into adjacent balloon chambers.

[0060] The example balloon catheter system **100** is illustrated with three balloons in these figures, however, two or more balloons may alternatively be included (e.g., 2, 3, 4, 5, 6, 7, 8, 9, or 10). Each of the plurality of balloons **104**A, **104**B, **104**C may be the same length as each other or have different lengths (e.g., lengths within an inclusive range of about 2 mm to 20 mm each). Each of the balloons may be physically touching or directly connected to each other, or may be longitudinally spaced apart or physically separated from each other.

[0061] An inflation tube **106** may be used to inflate each of the balloons **104**A, **104**B, and **104**C. As seen in FIG. **5**, the inflation tube **106** may be an elongated tube with an internal inflation passage **106**B extending between a proximal region and a distal region. At the proximal region, the internal inflation passage is in communication with an inflation device (e.g., a syringe). At the distal region, the internal inflation passage **106**B is in communication with an inflation opening **106**A (e.g., distal inflation port). The inflation opening **106**A may be located along a side or through a sidewall of the inflation tube **106** and may have a size smaller, larger, or about the same size as one of the catheter body ports **102**A, **102**B, **102**C.

[0062] The inflation tube **106** may be positioned within the interior body passage **102**F of the catheter body **102** and the inflation opening **106**A may be longitudinally and rotationally positioned to align with one of the catheter body ports **102**A, **102**B, **102**C. The inflation tube **106** may have a length such that a proximal end of the inflation tube **106** is positioned proximally outside of the catheter body **102** during use, allowing a user to grasp and move the inflation tube **106** relative to the catheter body **102**. When media is injected into the internal inflation passage **106**B of the inflation tube **106**, the media passes through the inflation opening **106**A. If the inflation opening **106**A is positioned under or aligned with one of the catheter body ports **102**A, **102**B, **102**C, the media passes through one of those aligned catheter body ports **102**A, **102**B, **102**C and into the chamber of one of the corresponding balloons **104**A, **104**B, or **104**C.

[0063] Optionally the inflation tube **106** and the interior body passage of the catheter body **102** may include a feature that maintains only a specific rotational orientation between the inflation tube **106** and catheter body **102** so that the inflation opening **106**A always maintains a rotational orientation that aligns with the catheter body ports **102**A, **102**B, **102**C. For example, the inflation tube **106** and/or the catheter body **102** may include mating grooves, ridges, diameter shapes, and similar features may lock rotational orientation of the inflation tube **106** relative to the catheter body **102**.

[0064] One or more seals or gaskets may also be included in the inflation tube **106** and/or the catheter body **102** to prevent unwanted leakage of the inflation media. For example, areas surrounding the catheter body ports **102**A, **102**B, **102**C (e.g., within the interior body passage of the catheter body **102**) may include seals/gaskets, and/or an area on the outer surface of the inflation tube **106** surrounding the inflation opening **106**A may also include a seal/gasket.

[0065] The balloon catheter system **100** may also include one or more features that indicate a position of the inflation opening **106**A and/or the catheter body ports **102**A, **102**B, **102**C to that the user may move and align the inflation opening **106**A as needed to inflate a desired balloon **104**A, **104**B, **104**C.

[0066] In one example, one or more radiopaque markers may be positioned immediately proximally, immediately distally, and/or circumferentially relative to the inflation opening **106**A, allowing the location of the inflation opening **106**A to be visualized during a procedure. Additionally or alternatively, radiopaque markers may be positioned immediately proximally, immediately distally, and/or circumferentially relative to each of the catheter body ports **102**A, **102**B, **102**C, allowing the location of these ports to be visualized during a procedure.

[0067] Additionally or alternatively, the proximal portion of the inflation tube **106** may include a plurality of visual markers (e.g., ink, engraving, etc.) that are spaced to align with a proximal end of the catheter body **102** when the inflation opening **106**A is at a predetermined position (e.g., longitudinally aligned with a catheter body port **102**A, **102**B, **102**C). Hence, the inflation tube **106** may have a first proximal marker indicating alignment with the catheter body port **102**A, a second proximal marker indicating alignment with the catheter body port **102**B, and a third proximal marker indicating alignment with the catheter body port **102**C.

[0068] FIGS. **6-9** illustrate a side view of the balloon catheter system **100** in various inflation states or configurations and also an example method of inflating the balloon catheter system **100**, as discussed further below.

[0069] FIG. **6** illustrates balloons **104**A, **104**B, and **104**C in a deflated state. As shown in FIG. **6**, the inflation opening **106**A is positioned proximally of catheter body ports **102**A, **102**B, **102**C. In such a configuration where the inflation opening **106**A is not aligned with catheter body ports **102**A, **102**B, or **102**C, if inflation media is injected into the internal inflation passage **106**B of the inflation tube **106**, balloons **104**A, **104**B, and **104**C may maintain a deflated state because inflation fluid is unable to enter within them. In other words, the inflation opening **106**A is sealed off from the catheter body ports **102**A, **102**B, and **102**C when not respectively aligned.

[0070] However, some positions of the inflation opening **106**A within the interior body passage of the catheter body **102** may allow for all of the balloons **104**A, **104**B, and **104**C to be simultaneously inflated. In some examples, this may be achieved by including regions of the interior body passage **102**F with two different diameters. A first region of the interior body passage **102**F may have a diameter that closely fits or is about the same size as the outer diameter of the inflation tube **106**. In that respect, the inflation opening **106**A may remain blocked when positioned in this closely fitting first diameter region since the inflation opening **106**A is located on a side of the inflation tube **106**.

[0071] A second region of the interior body passage **102**F may have a diameter that is larger than the first region and provides space (e.g., a gap) between the interior body passage **102**F and the outer surface of the inflation tube **106**. When the inflation opening **106**A is positioned within this larger diameter second region, the inflation opening **106**A remains open to and in communication with the interior body passage **102**F, allowing media to pass out of the inflation opening **106**A between the gap between the interior body passage **102**F and the inflation tube **106**, down the interior body passage **102**F, into each of the catheter body ports **102**A, **102**B, and **102**C, and finally into the chambers of each of the balloons **104**A, **104**B, and **104**C.

[0072] In one specific example seen in FIG. **1**, the closely fitting first diameter region of the interior body passage **102**F may be located along the distal region **102**D of the catheter body **102**. The larger diameter second region of the interior body passage **102**F may be located along the proximal region **102**E. In that respect, if the user positions the inflation opening **106**A of the inflation tube **106** within the proximal region **102**E, inflation media will pass distally into each of the catheter body ports **102**A, **102**B, and **102**C, and finally into the chambers of each of the balloons **104**A, **104**B, and **104**C. If the user positions the inflation opening **106**A of the inflation tube **106** within the distal region **102**D, the smaller diameter of the interior body passage **102**F in that region either prevents any inflation media from escaping from the inflation tube **106** or only allows the inflation media to pass into one of the catheter body ports **102**A, **102**B, and **102**C, and balloons **104**A, **104**B, and **104**C.

[0073] FIG. **7** illustrates balloon **104**C at an inflated state in response to injecting inflation media when the inflation opening **106**A is aligned with catheter body port **102**C. The inflation tube **106** may be distally advanced within the catheter body **102** from the position in FIG. **6** so that the inflation opening **106**A aligns with catheter body port **102**C. When inflation media is injected into the inflation passage of the inflation tube **106**, the inflation media causes only the balloon **104**C to inflate because the inflation opening **106**A is aligned with catheter body port **102**C.

[0074] FIG. **8** illustrates balloons **104**C and **104**B in an inflated state. The inflation tube **106** may be further advanced from the position in FIG. **7** distally within the catheter body **102** so that the inflation opening **106**A aligns with catheter body port **102**B. When inflation media is injected into the inflation passage of the inflation tube **106**, the inflation media causes only the balloon **104**B to inflate because the inflation opening **106**A is aligned with catheter body port **102**B.

[0075] FIG. **9** illustrates balloons **104**C, **104**B, and **104**C in an inflated state. The inflation tube **106** can be further advanced from the position in FIG. **8** distally within the catheter body **102** so that the inflation opening **106**A aligns with catheter body port **102**A. When inflation media is injected into the inflation passage of the inflation tube **106**, the inflation media causes only the balloon **104**A to inflate because the inflation opening **106**A is aligned with catheter body port **102**A.

[0076] An operator may choose to fill the balloons **104**A, **104**B, and **104**C in any order. For example, the middle balloon **104**B may be inflated first or last, the distal balloon **104**A may be inflated first or last, or the proximal balloon **104**C may be inflated first or last. This may be beneficial to an operator from an ease of use or patient safety perspective if the vasculature surrounding the balloons is not uniform (e.g., blocked, stenosis, abnormal anatomy, arterial lesion, etc.).

[0077] Additionally, an operator may choose to fill the balloons **104**A, **104**B, and **104**C to different inflation diameters relative to each other. For example, the middle balloon **104**B may be inflated larger or smaller than the adjacent balloons **104**A and **104**C. In another example the distal balloon **104**A may be inflated larger or smaller than the balloons **104**B and **104**C. In another example the proximal balloon **104**C may be inflated larger or smaller than the balloons **104**A and **104**B.

[0078] The balloons **104**A, **104**B, and **104**C may be individually deflated in a similar manner as the inflation process, either partially or completely. For example, the inflation opening **106**A of the inflation tube **106** may be moved to align with one of the catheter body ports **102**A, **102**B, and **102**C. A proximal end of the inflation tube **106** may be adjusted to remove media from the internal inflation passage **106**B, for example, by using a syringe to withdraw media or by opening a valve that releases the media.

[0079] If the interior body passage **102**F with different diameter regions are present, all of the balloons **104**A, **104**B, and **104**C may be simultaneously deflated by moving the inflation opening **106**A to the proximal region **102**E having the larger diameter which creates a pathway in communication with all of the interior chambers of the balloons **104**A, **104**B, and **104**C. Hence, removing media from the inflation tube **106** (e.g., via syringe or valve) may simultaneously remove media from all of the balloons **104**A, **104**B, and **104**C at once.

[0080] FIG. **10**A illustrates a side view of a balloon catheter system **100** with a stent-like structure **110** positioned over balloons **104**A, **104**B, and **104**C in an uninflated state. This uninflated state may be used when the balloon catheter system **100** is advanced to a desired location within a patient. Alternatively, the stent-like structure **110** may be first delivered to a target location within the patient and the balloons **104**A, **104**B, and **104**C may be positioned within the lumen of the stent-like structure **110**.

[0081] FIG. **10**B illustrates a side view of the balloon catheter system **100** in which the balloons **104**A, **104**B, and **104**C are in various states of inflation, depending on how the operator actuates inflation. In this example, the balloon **104**B is inflated to a much larger diameter than the balloons **104**A and **104**C, at least initially. However, any combination of larger and smaller diameters, as previously disclosed, may be possible. Additionally, such combinations also apply if more or less than three balloons are included on the balloon catheter system **100**.

[0082] Having the ability to choose different diameter sizes and sequences for the balloons **104**A, **104**B, and **104**C may be beneficial to an operator from an ease of use or patient safety perspective if the vasculature surrounding the balloons is not uniform (e.g., blocked, stenosis, abnormal anatomy, arterial lesion, etc.). There may also be additional benefits, for example, a single pre-loaded stent-like structure **110** on a balloon (as described herein) may provide the operator with the option of selecting from two different methods of inflating the balloon(s) and expanding the stent-like structure **110**, either individually (by inflating balloons **104**A, **104**B, and **104**C sequentially, individually, and/or independently) or as a group (simultaneous inflation of all balloons). This may benefit the operator by providing a single intravascular device that can accommodate various anatomies and/or disease states, and if unexpected anatomies and disease states are encountered during a procedure, the operator may be able to expand the balloon(s) and/or deploy the stent-like structure without having to remove the device from the patient. This one-size-fits-all type approach may provide reduced operation times, reduced waste, improved patient outcomes, and cost savings. Additional benefits may include improved deployment accuracy of the stent-like structure **110**, improved anchoring (and/or initial anchoring) of the stent-like structure **110** to the targeted vessel wall, and improved wall apposition of the stent (and corresponding improvements in patient outcomes related to aneurysm occlusion).

[0083] FIGS. **11**A and **11**B illustrate a side view of the balloon catheter system **100** deploying a stent-like structure **110** (e.g., a replacement valve framework) within a heart valve **10**.

[0084] In FIG. **11**A, the balloon catheter system **100** and stent-like structure **110** are positioned between leaflets of the heart valve **10**.

[0085] In FIG. **11**B, the balloons are inflated such that balloons **104**A and **104**C are greatly increased in diameter on each side of the leaflets relative to the middle balloon **104**B. Since many valves tend to have a somewhat hourglass shape, the stent-like structure **110** may be expanded in a way that better conforms to the underlying structure of the heart valve **10**. specifically, the balloons **104**A and **104**C can better expand the stent-like structure **110** against the upper and lower shapes of the heart valve **10**, while the middle balloon **104**B can better accommodate the leaflets and annulus of the heart valve **10**. Again, depending on the desired positioning of the balloon catheter system **100** in the heart valve **10** and the shape of the heart valve **10**, other inflations profiles and sequences may be desirable.

[0086] FIGS. **12**A and **12**B illustrate side views of the balloon catheter system **100** deploying a stent-like structure **110** within an aortic aneurysm **20**.

[0087] In FIG. **12**A, the balloon catheter system **100** is positioned through the aortic aneurysm **20** so that the end balloons **104**A and **104**C are located beyond each side of the aortic aneurysm **20**.

[0088] In FIG. **12**B, the middle balloon **104**B may be inflated in size first to expand a middle of the stent-like structure **110** to a desired diameter and then deflated, followed by inflating the end balloons **104**A and **104**C to expand and anchor the stent-like structure **110**. Such sequential inflation, in addition to differential inflation sizes, may be helpful in various circumstances for a variety of purposes, such as improving anchoring force of the stent-like structure **110**, improving the expansion location of the stent-like structure **110** (e.g., if it foreshortens during expansion), or reducing stress on portions of a vessel wall.

[0089] FIG. **13** illustrates a side view of the balloon catheter system **100** deploying a stent-like structure **110** within a thoracic aortic aneurysm **30**. Note, the catheter system **100** is illustrated such that the length of the array of the balloons does not extend the entire length of the stent-like structure **110** and may be advantageous in certain circumstances, such as for incremental expansion of a relatively long stent-like structure **110**. However, the array of balloons may alternatively extend the length of the stent-like structure **110** or even beyond the length of the stent-like structure **110** in the FIG. **13** example. These length variations are applicable to any other examples or embodiments of the balloon catheter system **100** described in this specification.

[0090] FIG. **14** illustrates a side view of the balloon catheter system **100** deploying a stent-like structure **110** within a vessel containing plaque **40**. Depending on the shape of the plaque **40**, inflation of the balloons to different diameters may be helpful for expanding the vessel and securing the stent-like structure **110**. For example, the expansion profile of FIGS. **10**A and **10**B may be helpful to help compress the plaque **40** and open diameter of the vessel.

[0091] In some examples, the expansile element may include an expandable mesh structure. For example, FIG. **15** illustrates a side view of a catheter **200** comprising mesh structures **204**A, **204**B, and **204**C that may be selectively and individually expanded in diameter.

[0092] In some examples, the mesh structures **204**A, **204**B, and **204**C may comprise a tubular mesh shape that is located around the catheter body **202**. One end of each of the mesh structures **204**A, **204**B, and **204**C may be fixed in place relative to the catheter body **202** while the other may be longitudinally slidable relative to the catheter body **202**. For example, distal mounting fixtures **206**A, **206**B, and **206**C may fix the distal ends of the mesh structures **204**A, **204**B, and **204**C to the catheter body **202**, respectively. Proximal mounting fixtures **208**A, **208**B, and **208**C may be fixed to proximal ends of each of the mesh structures **204**A, **204**B, and **204**C respectively and may further be slidably connected to the catheter body **202**. For example, the proximal mounting fixtures **208**A, **208**B, and **208**C may be a ring on the outside of the catheter body **202** or on the inside of the catheter body **202**.

[0093] Each of the proximal mounting fixtures **208**A, **208**B, and **208**C may also be connected to control wires **210**A, **210**B, and **210**C respectively which allow a user to adjust the longitudinal position of each of the proximal mounting fixtures **208**A, **208**B, and **208**C along the catheter body **202**. Each of the control wires **210**A, **210**B, and **210**C may be located within the catheter body **202** or along an outer surface of the catheter body **202**. Each of the control wires **210**A, **210**B, and **210**C may extend proximally out of the proximal end of the catheter body **202** so that the user may grasp them directly or they may further connect to a handle mechanism that longitudinally moves the control wires **210**A, **210**B, and **210**C (e.g., via individual sliders on the handle).

[0094] As a user distally advances one of the control wires **210**A, **210**B, or **210**C, a respective proximal mounting fixture **208**A, **208**B, or **208**C is also moved distally causing the respective mesh structure **204**A, **204**B, or **204**C to radially expand to a desired diameter/size. Conversely, as a user proximally retracts one of the control wires **210**A, **210**B, or **210**C, a respective proximal mounting fixture **208**A, **208**B, or **208**C is also moved proximally causing the respective mesh structure **204**A, **204**B, or **204**C to radially contract to a desired diameter/size. As with the other examples discussed in this specification, the catheter **200** may be used to expand a stent, angioplasty, valvuloplasty, or other uses.

Claim Bank

[0095] Clause 1. An expandable catheter system, comprising: a catheter body; a plurality of expansile elements connected at a distal region of the catheter body; and, an expansion mechanism having an actuated state that independently adjusts a radial size of each of the plurality of expansile elements.

[0096] Clause 2. The expandable catheter system of clause 1, wherein the plurality of expansile elements include balloons and wherein the expansion mechanism includes an inflation tube longitudinally movable within the catheter body between at least a first position in communication with a first balloon of the plurality of balloons, and a second position in communication with a second balloon of the plurality of balloons.

[0097] Clause 3. The expandable catheter system of clause 2, wherein the catheter body comprises an interior body passage extending between a proximal region and a distal region of the catheter body; and wherein the inflation tube is longitudinally movable within the interior body passage between the at least first position and second position.

[0098] Clause 4. The expandable catheter system of clause 3, wherein of all of the plurality of balloons, the inflation tube is only in communication with the first balloon when in the first position.

[0099] Clause 5. The expandable catheter system of clause 4, wherein of all of the plurality of balloons, the inflation tube is only in communication with the second balloon when in the second position.

[0100] Clause 6. The expandable catheter system of clause 3, wherein of all of the plurality of balloons, the inflation tube is only in communication with the first balloon when in the first position and wherein the inflation tube is only in communication with the first balloon and the second balloon when in the second position.

[0101] Clause 7. The expandable catheter system of clause 2, wherein the first balloon and the second balloon each include inflation chambers that are completely isolated from each other, partially in communication with each other, or selectively in communication with each other.

[0102] Clause 8. The expandable catheter system of clause 3, wherein the catheter body comprises a first catheter body port located underneath the first balloon and a second catheter body port located underneath the second balloon.

[0103] Clause 9. The expandable catheter system of clause 8, wherein the inflation tube further comprises an inflation port opening through a sidewall of the inflation tube and into an inflation passage of the inflation tube.

[0104] Clause 10. The expandable catheter system of clause 9, further comprising rotational orientation lock that maintains a rotational orientation of the inflation tube relative to the catheter body.

[0105] Clause 11. The expandable catheter system of clause 9, further comprising one or more seals located around 1) the inflation port opening and/or located around 2) the first catheter body port and the second catheter body port.

[0106] Clause 12. The expandable catheter system of clause 2, further comprising a stent positioned over the plurality of balloons.

[0107] Clause 13. The expandable catheter system of clause 2, further comprising a replacement valve framework positioned over the plurality of balloons.

[0108] Clause 14. The expandable catheter system of clause 2, wherein at least some of the plurality of balloons have inflated diameters that are different from each other.

[0109] Clause 15. The expandable catheter system of clause 2, wherein the plurality of balloons comprises the first balloon, the second balloon, and a third balloon, and wherein the second balloon is positioned between the first balloon and the third balloon, and wherein an inflated diameter of the second balloon is larger or smaller than inflated diameters of the first balloon and the third balloon.

[0110] Clause 16. The expandable catheter system of clause 2, wherein the plurality of balloons comprises the first balloon, the second balloon, and a third balloon, and wherein the inflation tube is moved between the first position, the second position, and a third position to sequentially inflate the first balloon first, the second balloon second, and the third balloon third.

[0111] Clause 17. The expandable catheter system of clause 2, wherein the inflation tube is movable to a third position to remove inflation fluid from the plurality of balloons.

[0112] Clause 18. The expandable catheter system of clause 1, wherein the plurality of expansile elements include a plurality of mesh structures and wherein the expansion mechanism includes one or more control wires connected to the plurality of mesh structures.

[0113] Clause 19. A balloon catheter system, comprising: a catheter body comprising an interior body passage extending between a proximal region and a distal region of the catheter body; a plurality of balloons connected at the distal region of the catheter body; wherein each balloon is separately in communication with the interior body passage; and, an inflation tube comprising a distal inflation opening; wherein the inflation tube is longitudinally movable between at least a first position in communication with a first balloon of the plurality of balloons, and a second position in communication with a second balloon of the plurality of balloons.

[0114] Clause 20. A balloon catheter system, comprising: a catheter body; a plurality of balloons connected at a distal region of the catheter body; and, an inflation tube means for longitudinally moving between positions within the catheter body and establishing an inflation passage between only one of the plurality of balloons at a time.

[0115] Clause 21. A method of using a balloon catheter system, comprising: longitudinally aligning a distal inflation opening of an inflation tube with a first port of an interior body passage of a catheter body; inflating a first balloon in communication with the first port; longitudinally aligning the distal inflation opening of the inflation tube with a second port of an interior body passage of the catheter body; and, inflating a second balloon in communication with the second port.

[0116] Clause 22. The method of clause 21, further comprising longitudinally aligning the distal inflation opening of the inflation tube with a third port of the interior body passage of the catheter body, and inflating a third balloon in communication with the third port.

What is claimed is:

1. An expandable catheter system, comprising:

a catheter body;

a plurality of expansile elements connected at a distal region of the catheter body; and,

an expansion mechanism having an actuated state that independently adjusts a radial size of each of the plurality of expansile elements.

2. The expandable catheter system of claim **1**, wherein the plurality of expansile elements include a plurality of balloons and wherein the expansion mechanism includes an inflation tube longitudinally movable within the catheter body between at least a first position in communication with a first balloon of the plurality of balloons, and a second position in communication with a second balloon of the plurality of balloons.

3. The expandable catheter system of claim **2**, wherein the catheter body comprises an interior body passage extending between a proximal region and a distal region of the catheter body; and wherein the inflation tube is longitudinally movable within the interior body passage between the at least first position and second position.

4. The expandable catheter system of claim **3**, wherein of all of the plurality of balloons, the inflation tube is only in communication with the first balloon when in the first position.

5. The expandable catheter system of claim **4**, wherein of all of the plurality of balloons, the inflation tube is only in communication with the second balloon when in the second position.

6. The expandable catheter system of claim **3**, wherein of all of the plurality of balloons, the inflation tube is only in communication with the first balloon when in the first position and wherein the inflation tube is only in communication with the first balloon and the second balloon when in the second position.

7. The expandable catheter system of claim **2**, wherein the first balloon and the second balloon each include inflation chambers that are completely isolated from each other, partially in communication with each other, or selectively in communication with each other.

8. The expandable catheter system of claim **3**, wherein the catheter body comprises a first catheter body port located underneath the first balloon and a second catheter body port located underneath the second balloon.

9. The expandable catheter system of claim **8**, wherein the inflation tube further comprises an inflation port opening through a sidewall of the inflation tube and into an inflation passage of the inflation tube.

10. The expandable catheter system of claim **9**, further comprising rotational orientation lock that maintains a rotational orientation of the inflation tube relative to the catheter body.

11. The expandable catheter system of claim **9**, further comprising one or more seals located around 1) the inflation port opening and/or located around 2) the first catheter body port and the second catheter body port.

12. The expandable catheter system of claim **2**, further comprising a stent positioned over the plurality of balloons.

13. The expandable catheter system of claim **2**, further comprising a replacement valve framework positioned over the plurality of balloons.

14. The expandable catheter system of claim **2**, wherein at least some of the plurality of balloons have inflated diameters that are different from each other.

15. The expandable catheter system of claim **2**, wherein the plurality of balloons comprises the first balloon, the second balloon, and a third balloon, and wherein the second balloon is positioned between the first balloon and the third balloon, and wherein an inflated diameter of the second balloon is larger or smaller than inflated diameters of the first balloon and the third balloon.

16. The expandable catheter system of claim **2**, wherein the plurality of balloons comprises the first balloon, the second balloon, and a third balloon, and wherein the inflation tube is moved between the first position, the second position, and a third position to sequentially inflate the first balloon first, the second balloon second, and the third balloon third.

17. The expandable catheter system of claim **2**, wherein the inflation tube is movable to a third position to remove inflation fluid from the plurality of balloons.

18. The expandable catheter system of claim **1**, wherein the plurality of expansile elements include a plurality of mesh structures and wherein the expansion mechanism includes one or more control wires connected to the plurality of mesh structures.

19. A balloon catheter system, comprising:

a catheter body comprising an interior body passage extending between a proximal region and a distal region of the catheter body;

a plurality of balloons connected at the distal region of the catheter body; wherein each balloon is separately in communication with the interior body passage; and,

an inflation tube comprising a distal inflation opening; wherein the inflation tube is longitudinally movable between at least a first position in communication with a first balloon of the plurality of balloons, and a second position in communication with a second balloon of the plurality of balloons.

20. A balloon catheter system, comprising:

a catheter body;

a plurality of balloons connected at a distal region of the catheter body; and,

an inflation tube means for longitudinally moving between positions within the catheter body and establishing an inflation passage between only one of the plurality of balloons at a time.

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