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(54) Title: SHAFTS WITH PRESSURE RELIEF IN CRYOTHERAPEUTIC CATHETERS AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS

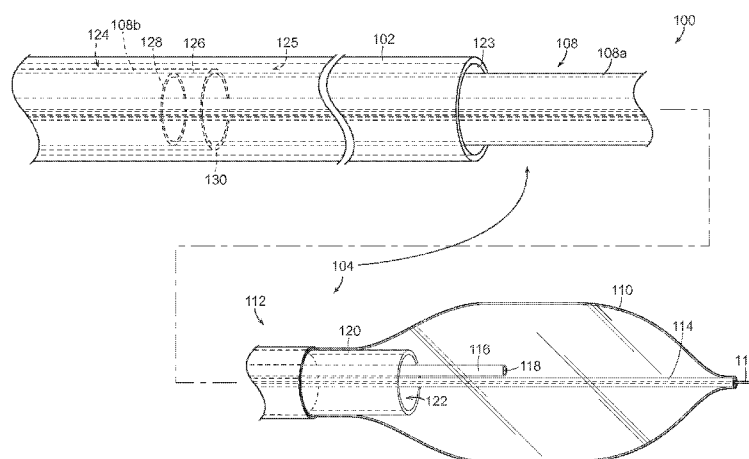


FIG. 1

(57) Abstract: Cryotherapeutic systems with features that can facilitate pressure relief in the event of exhaust-passage blockage and associated devices, systems, and methods are disclosed herein. A cryotherapeutic system configured in accordance with a particular embodiment can include an elongated shaft having a distal portion and a pressure-relief portion proximal to the distal portion. The cryotherapeutic system can further include a supply lumen, an exhaust passage, and a balloon configured to receive refrigerant from the supply lumen and to exhaust refrigerant to the exhaust passage. The pressure-relief portion can be configured to release refrigerant from the exhaust passage when a pressure of refrigerant in the exhaust passage exceeds a threshold pressure less than a pressure rating of the balloon. The pressure-relief portion, for example, can include a rupture element configured to rupture at about the threshold pressure.



SHAFTS WITH PRESSURE RELIEF IN CRYOTHERAPEUTIC CATHETERS AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS

TECHNICAL FIELD

[0001] The present technology relates generally to cryotherapeutic devices (e.g., cryotherapeutic catheters including balloons configured to expand within the vasculature of a patient). In particular, several embodiments are directed to shafts with pressure relief in cryotherapeutic catheters and associated devices, systems, and methods.

BACKGROUND

[0002] Cryotherapy can be a useful treatment modality in a wide range of catheter-based interventional procedures. For example, cryotherapeutic cooling can be used to modulate nerves or affect other tissue proximate anatomical vessels and other lumens or cavities in the body. This can reduce undesirable neural activity to achieve therapeutic benefits. Catheter-based neuromodulation utilizing cryotherapy can be used, for example, to modulate nerves and thereby reduce pain, local sympathetic activity, systemic sympathetic activity, associated pathologies, and other conditions. Cryotherapy can also be used for ablating tumors, treating stenosis, and other applications. In some cryotherapeutic procedures, it can be useful to deliver cryotherapy via a balloon that can be expanded within an anatomical vessel or lumen. Such balloons can be operatively connected to extracorporeal support components (e.g., refrigerant supplies). As the applicability of cryotherapy for surgical intervention continues to expand, there is a need for innovation in the associated devices, systems, and methods (e.g., with respect to efficacy, efficiency, and/or reliability). Such innovation has the potential to further expand the role of cryotherapy as a tool for improving the health of patients.

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] Many aspects of the present disclosure can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present technology.

Furthermore, components can be shown as transparent in certain views for clarity of illustration only and not to indicate that the illustrated component is necessarily transparent.

[0004] FIG. 1 is a perspective view illustrating a cryotherapeutic system configured in accordance with an embodiment of the present technology.

[0005] FIG. 2 is a cross-sectional view of the cryotherapeutic system of FIG. 1.

[0006] FIGS. 3-6 are cross-sectional views illustrating cryotherapeutic systems configured in accordance with additional embodiments of the present technology.

DETAILED DESCRIPTION

[0007] Specific details of several embodiments of the present technology are described herein with reference to FIGS. 1-6. Generally, unless the context indicates otherwise, the terms "distal" and "proximal" within this description reference a position relative to a refrigerant source, an operator, and/or an entry point into a patient. For ease of reference, throughout this disclosure identical reference numbers are used to identify similar or analogous components or features, but the use of the same reference number does not imply that the parts should be construed to be identical. Indeed, in many examples described herein, the identically numbered parts are distinct in structure and/or function.

[0008] In cryotherapeutic procedures, it can be desirable to apply cooling with high selectivity. Reducing cooling of non-targeted structures and tissue can enhance cooling efficiency and reduce complications. Although both high-pressure refrigerants and low-temperature refrigerants are potentially useful for cryotherapy, high-pressure refrigerants can be particularly well suited for delivering intense, targeted cooling to specific locations within the body, particularly in relatively small-diameter catheters. In many cases, the cooling potential of high-pressure refrigerants can be maintained more readily during transport through the catheter than low-temperature refrigerants. For example, a suitable strong-walled conduit can be used to convey a high-pressure refrigerant from an extracorporeal source to a delivery location at a distal end of a catheter with relatively little loss of cooling potential because the cooling action occurs upon expansion of the refrigerant at the distal end of the catheter. In contrast, as a low-temperature refrigerant moves along a catheter, it can be difficult to prevent the low-temperature refrigerant from absorbing heat from surrounding structures and tissue. Thermal insulation can be used to control such heat transfer to some

extent, but adequate thermal insulation can be excessively bulky for use in modern, small-diameter catheters.

[0009] While advantageous in many respects, the use of high-pressure refrigerants can place certain constraints on catheter construction. For example, tubes configured to carry refrigerant supplies typically are constructed of metal, hard polymers (e.g., polyimides), or other suitable materials, and have wall thicknesses that allow the tubes to have pressure ratings higher than the pressures of the refrigerants they are configured to transport. After a high-pressure refrigerant undergoes expansion and cooling, its pressure can decrease dramatically. Accordingly, the catheter components that contain the refrigerant after expansion are not limited to strong-walled tubes and similar high-strength structures with pressure ratings higher than the pressures of the refrigerant before expansion. Furthermore, some cryotherapeutic procedures use balloons because they can be relatively compact when not inflated, thereby allowing for delivery through narrow anatomical vessels and lumens, and they can expand to generally conform to the size and shape of the treatment location. Balloons also can have relatively thin walls well suited for cryotherapeutic heat transfer. Thin-walled cryotherapy balloons, however, typically have relatively low pressure ratings. For example, cryotherapeutic balloons typically have pressure ratings well below the supply pressures of suitable high-pressure refrigerants.

[0010] In some embodiments of the present technology, a high-pressure refrigerant can be transported along at least a portion of the length of a catheter and then expanded to a relatively low-temperature and low-pressure state via the Joule-Thomson effect alone or in combination with evaporative cooling. The catheter can be constructed such that the expansion can occur at or near a balloon. With a sufficient pressure drop, cooling from near ambient temperatures to cryogenic temperatures can be achieved. Suitable refrigerants for pressurization and expansion in cryotherapeutic devices include, for example, N₂O, CO₂, and hydrofluorocarbons (e.g., Freon® refrigerant, R-410A, etc.), among others. To maintain a pressure drop within a balloon, an exhaust passage can be provided from the balloon to the atmosphere or to a low-pressure containment vessel. Since expanded refrigerant has a lower density than high-pressure refrigerant, the exhaust passage can have a greater free-passage area than a corresponding supply lumen. During normal operation, evacuation of expanded refrigerant via the exhaust passage maintains the pressure in the balloon sufficiently below the high pressures associated with the refrigerant supply.

[0011] If the exhaust passage is blocked while the supply of high-pressure refrigerant to the balloon continues, the pressure in the balloon can build up until it equilibrates with the pressure of the supply lumen. Similarly, the pressure in the balloon can approach a lower, but still elevated, pressure if the exhaust passage becomes partially blocked. The exhaust passage can be partially or fully blocked, for example, due to an operator error (e.g., if an extracorporeal line carrying the exhaust passage becomes kinked or compressed or if a backpressure control valve is closed unexpectedly). In these and other such scenarios, it is possible that the pressure within the balloon can exceed the pressure rating of the balloon, which can be related to the pressure at which the balloon is likely to fail. Balloon failures can include, for example, bursting, leakage, excessive expansion (e.g., beyond the elastic tolerances of surrounding anatomical vessels or lumens), or combinations thereof. In some cases, the pressure rating of a balloon can correspond to a burst pressure of the balloon. It is undesirable for balloons to fail during a procedure for a number of reasons.

[0012] Cryotherapeutic devices, systems, and methods configured in accordance with embodiments of the present technology can include one or more features useful for reducing the likelihood of balloon failures (e.g., associated with excessive pressure build up within a balloon due to partial or complete blockage of an exhaust passage). For example, some embodiments can include one or more features configured to release pressure automatically when the pressure within the balloon is about to reach, reaches, or exceeds a predetermined threshold relative to the pressure rating of the balloon or another pressure level. These features can prevent or at least mitigate undesirable balloon failure.

[0013] FIGS. 1-2 are, respectively, perspective and cross-sectional views illustrating a cryotherapeutic system 100 configured in accordance with an embodiment of the present technology. The cryotherapeutic system 100 can include a guide catheter 102 and a treatment catheter 104. As shown in FIGS. 1-2, the treatment catheter 104 can be configured for insertion into and through the guide catheter 102. In some embodiments, the guide catheter 102 can be 8 French or smaller (e.g., 7 French, 6 French, or smaller). The guide catheter 102 can include a guide passage 125 through which the treatment catheter 104 can be axially advanced and retracted. The cryotherapeutic system 100 can further include a guide wire 113 that can facilitate introducing the guide catheter 102 and/or the treatment catheter 104 to a desired location within the vessel or lumen. For example, during a treatment procedure, the guide wire 113 can be introduced percutaneously or through a natural anatomical orifice of

the patient and advanced along a suitable catheterization path. Imaging (e.g., ultrasound, fluoroscopy, or another suitable imaging modality) can be used to aid in navigating the guide wire 113. Once in position, the guide catheter 102 can be advanced over the guide wire 113 and the treatment catheter 104 can subsequently be advanced through the guide passage 125 and over the guide wire 113. In other embodiments, the guide catheter 102 and the guide wire 113 can be introduced simultaneously. In still other embodiments, the guide catheter 102 and the treatment catheter 104 can be configured for use without a guide wire 113.

[0014] The treatment catheter 104 can include an elongated shaft 108 and a balloon 110 at a distal portion 112 of the shaft 108. The shaft 108 can be configured to locate the distal portion 112 within a vessel or lumen of a human patient. The treatment catheter 104 can further include a guide lumen 114 and a supply lumen 116 extending along at least a portion of the shaft 108, and the supply lumen 116 can have an orifice 118 within the balloon 110. The balloon 110 can extend from a stepped-down segment 120 of the distal portion 112 to an outer surface of the guide lumen 114. The supply lumen 116 can be configured to supply high-pressure refrigerant to the balloon 110 via the orifice 118. The high-pressure refrigerant can change phase from a liquid to a gas within the balloon 110, which can expand and cool the balloon 110. The treatment catheter 104 can also have an exhaust passage 122 extending proximally from the balloon 110 along at least a portion of the shaft 108 (e.g., around the guide lumen 114 and the supply lumen 116) to the atmosphere or an extracorporeal containment vessel (not shown). During operation, refrigerant flows to the balloon 110 through the supply lumen 116 and out of the balloon 110 via the exhaust passage 122. The exhaust passage 122 can have a greater free-passage area than the supply lumen 116 to accommodate the lower density of expanded refrigerant relative to the high-pressure refrigerant within the supply lumen 116.

[0015] As shown in FIGS. 1-2, the treatment catheter 104 can be configured to extend beyond a distal opening 123 of the guide catheter 102. For example, during a treatment procedure, at least a portion of the distal portion 112 of the shaft 108 can extend beyond the distal opening 123 to locate the balloon 110 at a desired treatment location spaced apart from the distal opening 123. When the balloon 110 is outside the guide passage 125 of the guide catheter 102, the balloon 110 can radially expand to a diameter greater than the diameter of the guide passage 125.

[0016] The shaft 108 can further include a pressure-relief portion 124 located proximally relative to the distal portion 112. In some embodiments, the distal portion 112 can extend along an entire length of the treatment catheter 104 between the pressure-relief portion 124 and the balloon 110. In other embodiments, the shaft 108 can include an intermediate portion (not shown) between the pressure-relief portion 124 and the distal portion 112. The pressure-relief portion 124 can be configured to release refrigerant from the exhaust passage 122 (e.g., to a space in the guide passage 125 between the treatment catheter 104 and the guide catheter 102) when a pressure of refrigerant in at least a portion of the exhaust passage 122 (e.g., a portion at or near the pressure-relief portion 124), the balloon 110, or both exceeds a threshold pressure. The threshold pressure, for example, can be less than a pressure rating of the balloon 110 (e.g., a pressure rating corresponding to a burst pressure of the balloon 110).

[0017] As shown in FIGS. 1-2, the distal portion 112 can include a first segment 108a of the shaft 108 and the pressure-relief portion 124 can include a second segment 108b of the shaft 108. The first and second segments 108a-b can be attached to one another at a lap joint 126 (e.g., via compression, adhesive bonding, thermal welding, or another suitable attachment mechanism). For example, a proximal end 128 of the first segment 108a can be within the second segment 108b at the lap joint 126. In other embodiments, a distal end 130 of the second segment 108b can be within the first segment 108a at the lap joint 126. As shown in FIGS. 1-2, the diameter of the first segment 108a can be less than the diameter of the second segment 108b. Correspondingly, the free-passage area of the first segment 108a can be less than the free-passage area of the second segment 108b. The free-passage area of the first segment 108a can define the free-passage area of the overall exhaust passage 122. Since refrigerant can warm and expand as it travels proximally along the exhaust passage 122, the smaller free-passage area of the first segment 108a relative to the free-passage area of the second segment 108b can have little or no effect on flow through the exhaust passage 122.

[0018] The lap joint 126 can provide a particularly strong connection between the first and second segments 108a-b, but other connections can also be used. For example, FIG. 3 is a cross-sectional view illustrating a cryotherapeutic system 300 configured in accordance with an embodiment of the present technology that is similar to the cryotherapeutic system 100 shown in FIGS. 1-2. The cryotherapeutic system 300 can include a treatment catheter 302 having an elongated shaft 304 with a distal first segment 304a connected to a proximal

second segment 304b by a butt joint 306 in place of the lap joint 126 shown in FIGS. 1-2. The shaft 304 can include a pressure-relief portion 308 defined by the second segment 304b which has a diameter at least approximately equal to the diameter of the first segment 304a. The first segment 304a can be a component of the distal portion 112. The butt joint 306 can be formed by adhesive bonding, thermal welding, or another suitable attachment mechanism between the first and second segments 304a-b.

[0019] With reference to FIGS. 1-3, in some embodiments, the distal portion 112 can have a wall strength (e.g., yield strength or ultimate tensile strength) greater than a wall strength of the pressure-relief portion 124, 308. For example, the first segment 108a, 304a can have a wall strength greater than a wall strength of the second segment 108b, 304b. The wall strength of all or a portion of the pressure-relief portion 124, 308 or the second segment 108b, 304b, for example, can be less than about 80% (e.g., less than about 60% or less than about 40%) of that of the distal portion 112 or the first segment 108a, 304a. Different constructions and/or compositions can cause the different wall strengths. For example, the pressure-relief portion 124, 308 or the second segment 108b, 304b can include walls that are thinner and/or made of weaker materials than walls of the distal portion 112 or the first segment 108a, 304a. In some embodiments, the pressure-relief portion 124, 308 or the second segment 108b, 304b can be made of polyamide and the distal portion 112 or the first segment 108a, 304a can be made of polyimide. In other embodiments, the pressure-relief portion 124, 308 or the second segment 108b, 304b can be made of a polyimide at a first thickness and the distal portion 112 or the first segment 108a, 304a can be made of a polyimide at a second thickness greater than the first thickness. When the pressure-relief portion 124, 308 or the second segment 108b, 304b is braided, the braid pattern or density can be selected to cause a wall strength lower than that of the distal portion 112 or the first segment 108a, 304a. Similarly, when the pressure-relief portion 124, 308 or the second segment 108b, 304b includes multiple layers, the number of layers can be selected to cause a wall strength lower than that of the distal portion 112 or the first segment 108a, 304a. A variety of other suitable materials and configurations are also possible.

[0020] The wall strength of the pressure-relief portion 124, 308 or the second segment 108b, 304b can be selected to cause the pressure-relief portion 124, 308 or the second segment 108b, 304b to rupture at about the threshold pressure. Accordingly, the pressure-relief portion 124, 308 or the second segment 108b, 304b can be sacrificial and/or otherwise

configured to fail before the balloon 110 fails during a malfunction in which the pressure in the balloon 110 increases unexpectedly. Failure of the pressure-relief portion 124, 308 or the second segment 108b, 304b can allow refrigerant to quickly flow into the space in the guide passage 125 between the shaft 108 and the guide catheter 102. At least a portion of the refrigerant in the space can then move proximally to a proximal opening (not shown) of the guide catheter 102. In some embodiments, the pressure-relief portion 124, 308 or the second segment 108b, 304b can be configured to rupture relatively rapidly. For example, the pressure-relief portion 124, 308 or the second segment 108b, 304b can include a relatively brittle material, such as a material having an elongation at break less than about 50% (e.g., less than about 30% or less than about 20%). In other embodiments, the pressure-relief portion 124, 308 or the second segment 108b, 304b can be configured to rupture more slowly.

[0021] In the cryotherapeutic systems 100, 300 shown in FIGS. 1-3, it may be difficult to predict where the pressure-relief portion 124, 308 or the second segment 108b, 304a will sacrificially release the pressure along the exhaust passage 122. As such, it may be desirable to control the release of refrigerant at specific locations along the device. FIG. 4 is a cross-sectional view illustrating one example of a cryotherapeutic system 400 configured in accordance with another embodiment of the present technology that includes a treatment catheter 402 having a shaft 404 with a relatively short pressure-relief portion 406. The shaft 404 can further include a proximal portion 408 proximal to the pressure-relief portion 406, a first lap joint 410 between the distal portion 112 and the pressure-relief portion 406, and a second lap joint 412 between the pressure-relief portion 406 and the proximal portion 408. In other embodiments, the first and second lap joints 410, 412 can be replaced with butt joints or other suitable connections. The pressure-relief portion 406 can have a lower pressure rating than the distal portion 112, the proximal portion 408, and the balloon 110 such that the pressure-relief portion 406 preferentially fails at a specific location along the device.

[0022] FIG. 5 is a cross-sectional view illustrating a cryotherapeutic system 500 configured in accordance with an embodiment of the present technology having another pressure-relief configuration. The cryotherapeutic system 500 can include a treatment catheter 502 having a shaft 504 with a pressure-relief portion 506 including a rupture element 508. In the embodiment shown in FIG. 5, the rupture element 508 does not extend around the entire circumference of the shaft 504. In other embodiments, the rupture element 508 can be annular and can extend around the entire circumference of the shaft 504. The rupture element

508 can include a membrane (e.g., embedded within a wall of the pressure-relief portion 506), a weakened (e.g., scored and/or thinned) portion of a wall of the pressure-relief portion 506, or another suitable structure configured to break predictably in response to pressure. The rupture element 508, for example, can be configured to rupture in response to a pressure in an adjacent portion of the exhaust passage 122 that is near or exceeds the threshold pressure. The size of the rupture element 508 can be selected to control the rate at which refrigerant is released from the exhaust passage 122 into the space in the guide passage 125.

[0023] With reference to FIGS. 1-5, the locations of the pressure-relief portions 124, 308, 406, 506 and/or portions thereof (e.g., the first segments 108a, 304a of the pressure-relief portions 124, 308 and the rupture element 508 of the pressure-relief portion 506) can be selected to control the locations where refrigerant is released into the space in the guide passage 125. In some embodiments, the release locations can be outside vessels or lumens of patients during treatment procedures. For example, such release locations can be proximal relative to entry points into the vessels or lumens and, in some cases, proximal to proximal openings of corresponding guide catheters 102. Such release locations can reduce the possibility that the refrigerant will be released into the vessels or lumens via the distal openings 123 of the guide catheters 102. Locations closer to the balloons 110, however, can be useful to decrease pressure differential and/or delay between the release point along the exhaust passages 122 and the balloon 110. This can improve the responsiveness of the pressure-relief portions 124, 308, 406, 506 to rapid increases in pressure within the balloon 110. Furthermore, in some cases, the pressure-relief portions 124, 308, 406, 506 may have limited effectiveness when blockages of the corresponding exhaust passages occur between the pressure-relief portions 124, 308, 406, 506 and the balloon 110. Decreasing the distance between the pressure-relief portions 124, 308, 406, 506 and the balloon 110 can decrease the likelihood of such blockages. In some embodiments, the pressure-relief portions 124, 308, 406, 506 can be proximally spaced apart from the balloon 110 such that the pressure-relief portions 124, 308, 406, 506 are just within the corresponding guide passage 125.

[0024] With reference again to FIG. 5, the cryotherapeutic system 500 can also include a guide catheter 510 having a flow restrictor 512 around a perimeter of the guide passage 125. In other embodiments, the treatment catheter 502 can include the flow restrictor 512 at a position distal to the pressure-relief portion 506. The flow restrictor 512 can be configured to reduce or prevent distal flow of released refrigerant within the guide passage 125 through the

distal opening 123 and into a vessel or lumen of a patient. Instead, the path of least resistance for the released refrigerant can extend proximally through the guide passage 125 to the proximal opening of the guide catheter 510 outside the vessel or lumen. In some embodiments, the flow restrictor 512 can be at least partially annular and/or compressible and configured to conform to the shaft 504. Furthermore, the flow restrictor 512 can be configured to reduce or prevent proximal blood flow within the guide catheter 510 in addition to reducing or preventing distal refrigerant flow. Other embodiments can include different features for reducing or preventing distal flow of released refrigerant. For example, the cryotherapeutic system 200 shown in FIG. 2 can be modified such that the second segment 108b is within the first segment 108a at the lap joint 126 and the distal portion 112 has a larger diameter than the pressure-relief portion 124. This can reduce the space in the guide passage 125 around the distal portion 112 and thereby encourage flow of released refrigerant in a proximal direction. In some embodiments, refrigerant released into a vessel or lumen of a patient through the distal opening 123 can be less problematic than refrigerant release resulting from a balloon failure, thereby reducing the usefulness of the flow restrictor 512. Furthermore, the pressure-relief portion 506 can be located closer to the proximal opening of the guide catheter 510 than to the distal opening 123 of the guide catheter 510, which can delay or prevent refrigerant release into a vessel or lumen of a patient through the distal opening 123.

[0025] In some embodiments the diameter of the treatment catheter 502 and/or the diameter of the guide catheter 510 can be selected to size the space therebetween in the guide passage 125. For example, a difference between the outer diameter of the shaft 504 at and the inner diameter of the guide passage 125 can be greater than about 0.2 mm (e.g., greater than about 0.3 mm or greater than about 0.4 mm) along at least about 100 cm of the shaft 504 extending proximally from the pressure-relief portion 506. In some cases, however, it can be useful to reduce the size of the space in the guide passage 125 in favor of increasing the size of the shaft 504. For example, larger-diameter shafts can support greater cooling. FIG. 6 is a cross-sectional view illustrating a cryotherapeutic system 600 configured in accordance with an embodiment of the present technology and including a treatment catheter 602 and a guide catheter 603. The treatment catheter 602 can include a shaft 604 having a pressure-relief portion 606 with a rupture element 608. The guide catheter 603 can be smaller and/or the shaft 604 can be larger than the embodiments shown in FIGS. 1-5 to provide a relatively close fit that restricts the distal flow of refrigerant along the space in the guide passage 125.

[0026] The pressure-relief portion 606 and portions of the shaft 604 proximal to the pressure-relief portion 606 can have a smaller diameter than the distal portion 112 such that there is more space between the proximal portion of the shaft 604 and the guide catheter 602. This can facilitate the proximal flow of refrigerant along the space within the guide passage 125 (e.g., from a release location proximate the rupture element 608 along a generally continuous path to a proximal opening of the guide catheter 603). The path, for example, can be greater than about 100 cm (e.g., greater than about 200 cm or greater than about 300 cm) in length and can extend proximally from the rupture element 608. In some embodiments, the pressure-relief portion 606 can be configured to deform from a first state (not shown) in which the pressure-relief portion 606 has a diameter similar to the diameter of the distal portion 112 to a second state (shown in FIG. 6) in which the rupture element 608 is ruptured and the pressure-relief portion 606 deforms inwardly. The pressure-relief portion 606 can deform, for example, in response to pressure within the space in the guide passage 125 exceeding a threshold pressure. As shown in FIG. 6, in some embodiments, the pressure-relief portion 606 can deform generally evenly. In other embodiments, the pressure-relief portion 606 and portions of the shaft 604 proximal to the pressure-relief portion 606 can be configured to selectively deform (e.g., along a channel). Deforming can occur, for example, as a result of reversible or irreversible compression or expansion of at least a portion of a wall of the shaft 604. For example, the shaft 604 can be at least partially elastic, folded, articulated, or otherwise configured to expand or contract in response to pressure within the guide passage 125. In other embodiments, the shaft 604 can have general or local wall strength sufficiently low to allow the shaft 604 to deform inwardly in response to pressure within the guide passage 125.

[0027] In some embodiments, the disclosed pressure-relief features can be redundant to other features intended to prevent balloon failures. For example, the cryotherapeutic systems shown in FIGS. 1-6 can include one or more pressure sensors (not shown) configured to monitor pressures within the balloon 110 and controllers (not shown) configured to stop refrigerant flow to the balloon 110 if the monitored pressures increase above threshold pressures. In other embodiments, the disclosed pressure-relief features can take the place of pressure monitoring. Furthermore, reducing the likelihood of balloon failure can allow for greater freedom in balloon constructions and compositions. In some embodiments, the balloon 110 can have a pressure rating less than about 400% (e.g., less than about 300% or less than about 200%) of a steady-state pressure within the balloon 110 during normal

operation. This can facilitate, for example, the use of balloons 110 having thinner walls and greater elasticity.

Examples

1. A cryotherapeutic system, comprising:
 - an elongated shaft including a distal portion and a pressure-relief portion, the shaft configured to locate the distal portion within a vessel or lumen of a human patient;
 - a supply lumen extending along at least a portion of the shaft and having a first free-passage area;
 - an exhaust passage extending along at least a portion of the shaft and having a second free-passage area; and
 - a balloon configured to receive refrigerant from the supply lumen and to exhaust refrigerant to the exhaust passage, the balloon having a pressure rating, wherein—
 - the balloon is proximate the distal portion, and
 - the pressure-relief portion is configured to release refrigerant from the exhaust passage when a pressure of refrigerant in the exhaust passage at or near the pressure-relief portion exceeds a threshold pressure.
2. The cryotherapeutic system according to example 1, wherein the distal portion extends along a length of the shaft between the pressure-relief portion and the balloon.
3. The cryotherapeutic system according to example 1 or example 2, wherein the threshold pressure is less than the pressure rating of the balloon.
4. The cryotherapeutic system according to any of examples 1-3, wherein the second free-passage area is greater than the first free-passage area.
5. The cryotherapeutic system according to any of examples 1-4, wherein the distal portion and the pressure-relief portion are configured to fit within a guide catheter that is 8 French or smaller.

6. The cryotherapeutic system according to any of examples 1-5, wherein the pressure rating corresponds to a burst pressure of the balloon.

7. The cryotherapeutic system according to any of examples 1-6, wherein the pressure-relief portion includes a rupture element configured to rupture at about the threshold pressure.

8. The cryotherapeutic system according to example 7, wherein the shaft is deformable along a path greater than about 100 cm in length and extending proximally from the rupture element.

9. The cryotherapeutic system according to any of examples 1-8, wherein—
the distal portion includes a first segment of the shaft having a first wall strength, and
the pressure-relief portion includes a second segment of the shaft having a second wall strength less than the first wall strength.

10. The cryotherapeutic system according to example 9, wherein the second wall strength is selected to cause the second segment to rupture at about the threshold pressure.

11. The cryotherapeutic system according to example 9 or example 10, wherein the first segment is attached to the second segment at a butt joint.

12. The cryotherapeutic system according to any of examples 9-11, wherein—
the first segment defines the second free-passage area, and
the second segment has a third free-passage area greater than the second free-passage area.

13. The cryotherapeutic system according to any of examples 9, 10 or 12, wherein the first segment is attached to the second segment at a lap joint.

14. The cryotherapeutic system according to example 13, wherein the first segment includes a proximal end within the second segment at the lap joint.

15. A cryotherapeutic system, comprising:
a guide catheter including a distal opening, a proximal opening, and a guide passage extending between the distal opening and the proximal opening;
an elongated shaft configured to move axially within the guide passage, and including a distal portion and a pressure-relief portion proximal to the distal portion, the shaft configured to locate the distal portion within a vessel or lumen of a human patient;
a supply lumen extending along at least a portion of the shaft;
an exhaust passage extending along at least a portion of the shaft; and
a balloon configured to receive refrigerant from the supply lumen and to exhaust refrigerant to the exhaust passage, the balloon having a pressure rating, wherein—
the distal portion extends between the pressure-relief portion and the balloon, and
the pressure-relief portion is configured to release refrigerant from the exhaust passage to a space between the shaft and the guide catheter when a pressure of refrigerant in at least a portion of the exhaust passage, the balloon, or both approaches and/or exceeds a threshold pressure related to the pressure rating of the balloon.
16. The cryotherapeutic system according to example 15, wherein the guide catheter is 8 French or smaller.
17. The cryotherapeutic system according to example 15 or example 16, wherein a difference between an outer diameter of the shaft and an inner diameter of the guide passage is greater than about 0.2 mm along at least about 100 cm of the shaft extending proximally from the pressure-relief portion.
18. The cryotherapeutic system according to any of examples 15-17, wherein—
the threshold pressure is a first threshold pressure, and
the shaft is at least partially deformable when a pressure in the space exceeds a second threshold pressure.

19. The cryotherapeutic system according to example 18, wherein the second threshold pressure is greater than the first threshold pressure.

20. The cryotherapeutic system according to any of examples 15-19, further comprising a flow restrictor configured to prevent flow of refrigerant distally from the space through the distal opening of the guide catheter.

21. The cryotherapeutic system according to example 20, wherein the flow restrictor is at least partially annular and compressible.

22. A method, comprising:

introducing a guide catheter into a vessel or lumen of a human patient;

moving a treatment catheter axially along a guide passage of the guide catheter, the treatment catheter including a supply lumen, an exhaust passage, and a balloon;

supplying refrigerant to the balloon through the supply lumen;

exhausting refrigerant from the balloon through the exhaust passage; and

releasing refrigerant into a space between the treatment catheter and the guide catheter when a pressure of refrigerant in at least a portion of the exhaust passage exceeds a threshold pressure less than a pressure rating of the balloon.

23. The method according to example 22, wherein releasing refrigerant into the space includes rupturing a rupture element configured to rupture at about the threshold pressure.

24. The method according to example 22 or example 23, wherein releasing refrigerant into the space includes—

releasing refrigerant into the space at a release location, and

exhausting refrigerant proximally through the space from the release location.

25. The method according to example 24, wherein the release location is within the vessel or lumen.

26. The method according to example 24, wherein the release location is outside the vessel or lumen.

27. The method according to any of examples 24-26, further comprising deforming the treatment catheter along a generally continuous path from the release location to a proximal opening of the guide catheter.

Conclusion

[0028] The above detailed descriptions of embodiments of the present technology are for purposes of illustration only and are not intended to be exhaustive or to limit the present technology to the precise form(s) disclosed above. Various equivalent modifications are possible within the scope of the present technology, as those skilled in the relevant art will recognize. For example, while stages may be presented in a given order, alternative embodiments may perform stages in a different order. The various embodiments described herein and elements thereof may also be combined to provide further embodiments. In some cases, well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of embodiments of the present technology.

[0029] Where the context permits, singular or plural terms may also include the plural or singular terms, respectively. Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the terms "comprising" and the like are used throughout the disclosure to mean including at least the recited feature(s) such that any greater number of the same feature(s) and/or additional types of other features are not precluded. It will also be appreciated that various modifications may be made to the described embodiments without deviating from the present technology. Further, while advantages associated with certain embodiments of the present technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the present technology. Accordingly, the

disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A cryotherapeutic system, comprising:
an elongated shaft including a distal portion and a pressure-relief portion, the shaft configured to locate the distal portion within a vessel or lumen of a human patient;
a supply lumen extending along at least a portion of the shaft and having a first free-passage area;
an exhaust passage extending along at least a portion of the shaft and having a second free-passage area; and
a balloon configured to receive refrigerant from the supply lumen and to exhaust refrigerant to the exhaust passage, the balloon having a pressure rating, wherein—
the balloon is proximate the distal portion, and
the pressure-relief portion is configured to release refrigerant from the exhaust passage when a pressure of refrigerant in the exhaust passage at or near the pressure-relief portion exceeds a threshold pressure.
2. The cryotherapeutic system according to claim 1, wherein the distal portion extends along a length of the shaft between the pressure-relief portion and the balloon.
3. The cryotherapeutic system according to claim 1, wherein the threshold pressure is less than the pressure rating of the balloon.
4. The cryotherapeutic system according to claim 1, wherein the second free-passage area is greater than the first free-passage area.
5. The cryotherapeutic system according to claim 1, wherein the distal portion and the pressure-relief portion are configured to fit within a guide catheter that is 8 French or smaller.

6. The cryotherapeutic system according to claim 1, wherein the pressure rating corresponds to a burst pressure of the balloon.

7. The cryotherapeutic system according to claim 1, wherein the pressure-relief portion includes a rupture element configured to rupture at about the threshold pressure.

8. The cryotherapeutic system according to claim 7, wherein the shaft is deformable along a path greater than about 100 cm in length and extending proximally from the rupture element.

9. The cryotherapeutic system according to claim 1, wherein—
the distal portion includes a first segment of the shaft having a first wall strength, and
the pressure-relief portion includes a second segment of the shaft having a second wall strength less than the first wall strength.

10. The cryotherapeutic system according to claim 9, wherein the second wall strength is selected to cause the second segment to rupture at about the threshold pressure.

11. The cryotherapeutic system according to claim 9, wherein the first segment is attached to the second segment at a butt joint.

12. The cryotherapeutic system according to claim 9, wherein—
the first segment defines the second free-passage area, and
the second segment has a third free-passage area greater than the second free-passage area.

13. The cryotherapeutic system according to claim 9, wherein the first segment is attached to the second segment at a lap joint.

14. The cryotherapeutic system according to claim 13, wherein the first segment includes a proximal end within the second segment at the lap joint.

15. A cryotherapeutic system, comprising:
a guide catheter including a distal opening, a proximal opening, and a guide passage extending between the distal opening and the proximal opening;
an elongated shaft configured to move axially within the guide passage, and including a distal portion and a pressure-relief portion proximal to the distal portion, the shaft configured to locate the distal portion within a vessel or lumen of a human patient;
a supply lumen extending along at least a portion of the shaft;
an exhaust passage extending along at least a portion of the shaft; and
a balloon configured to receive refrigerant from the supply lumen and to exhaust refrigerant to the exhaust passage, the balloon having a pressure rating, wherein—
the distal portion extends between the pressure-relief portion and the balloon, and
the pressure-relief portion is configured to release refrigerant from the exhaust passage to a space between the shaft and the guide catheter when a pressure of refrigerant in at least a portion of the exhaust passage, the balloon, or both approaches and/or exceeds a threshold pressure related to the pressure rating of the balloon.
16. The cryotherapeutic system according to claim 15, wherein the guide catheter is 8 French or smaller.
17. The cryotherapeutic system according to claim 15, wherein a difference between an outer diameter of the shaft and an inner diameter of the guide passage is greater than about 0.2 mm along at least about 100 cm of the shaft extending proximally from the pressure-relief portion.
18. The cryotherapeutic system according to claim 15, wherein—
the threshold pressure is a first threshold pressure, and
the shaft is at least partially deformable when a pressure in the space exceeds a second threshold pressure.

19. The cryotherapeutic system according to claim 18, wherein the second threshold pressure is greater than the first threshold pressure.

20. The cryotherapeutic system according to claim 15, further comprising a flow restrictor configured to prevent flow of refrigerant distally from the space through the distal opening of the guide catheter.

21. The cryotherapeutic system according to claim 20, wherein the flow restrictor is at least partially annular and compressible.

22. A method, comprising:

introducing a guide catheter into a vessel or lumen of a human patient;

moving a treatment catheter axially along a guide passage of the guide catheter, the treatment catheter including a supply lumen, an exhaust passage, and a balloon;

supplying refrigerant to the balloon through the supply lumen;

exhausting refrigerant from the balloon through the exhaust passage; and

releasing refrigerant into a space between the treatment catheter and the guide catheter when a pressure of refrigerant in at least a portion of the exhaust passage exceeds a threshold pressure less than a pressure rating of the balloon.

23. The method according to claim 22, wherein releasing refrigerant into the space includes rupturing a rupture element configured to rupture at about the threshold pressure.

24. The method according to claim 22, wherein releasing refrigerant into the space includes—

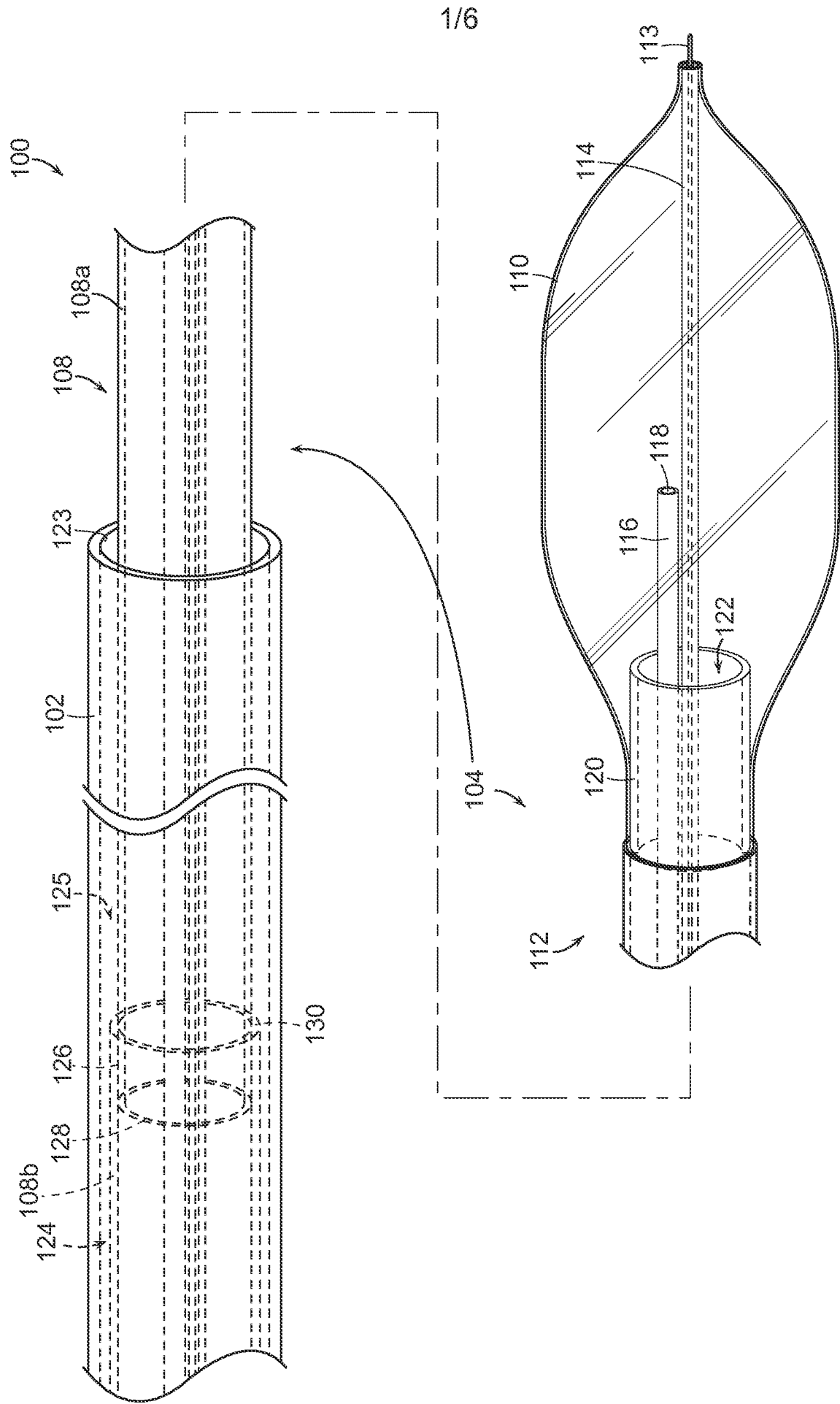
releasing refrigerant into the space at a release location, and

exhausting refrigerant proximally through the space from the release location.

25. The method according to claim 24, wherein the release location is within the vessel or lumen.

26. The method according to claim 24, wherein the release location is outside the vessel or lumen.

27. The method according to claim 24, further comprising deforming the treatment catheter along a generally continuous path from the release location to a proximal opening of the guide catheter.



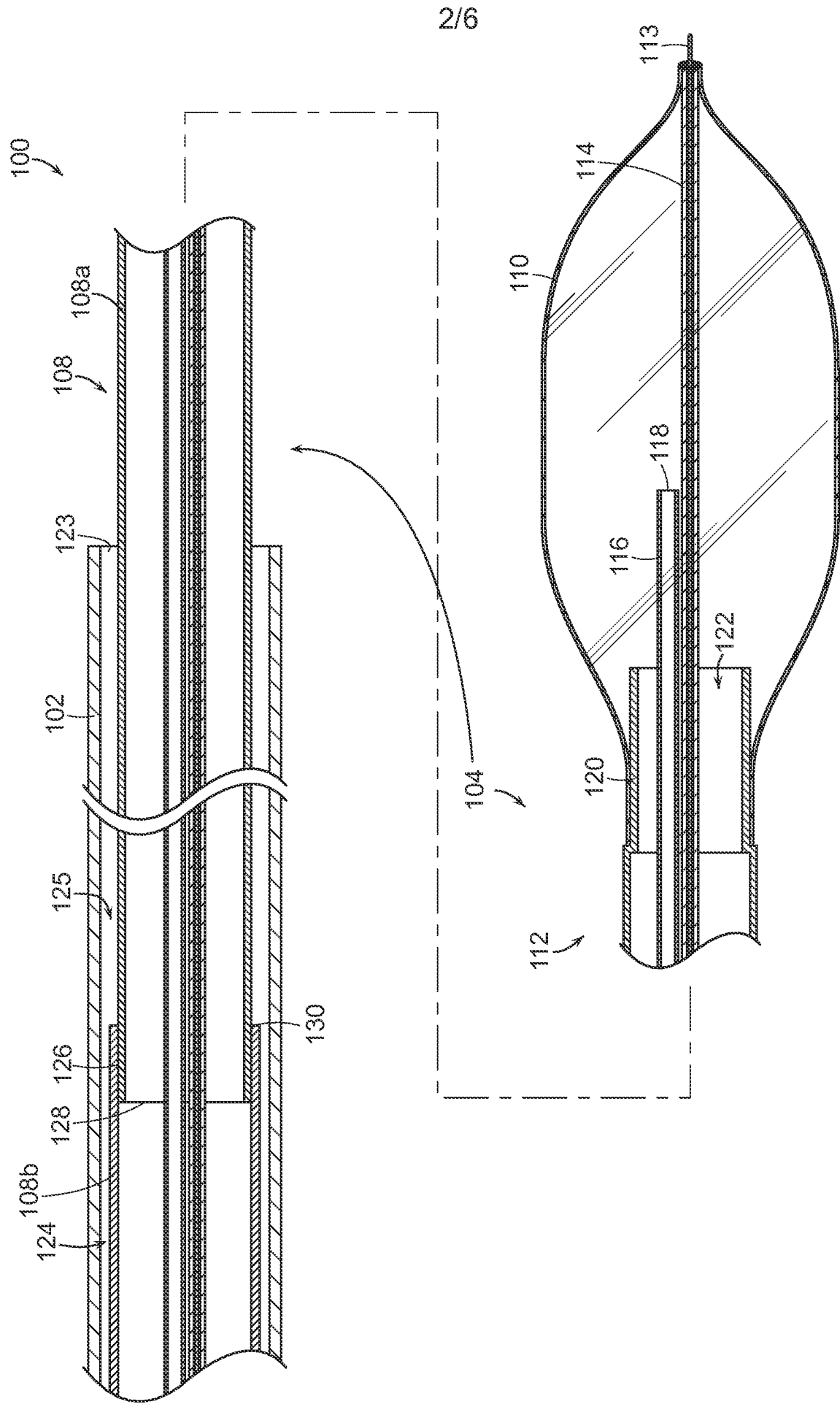
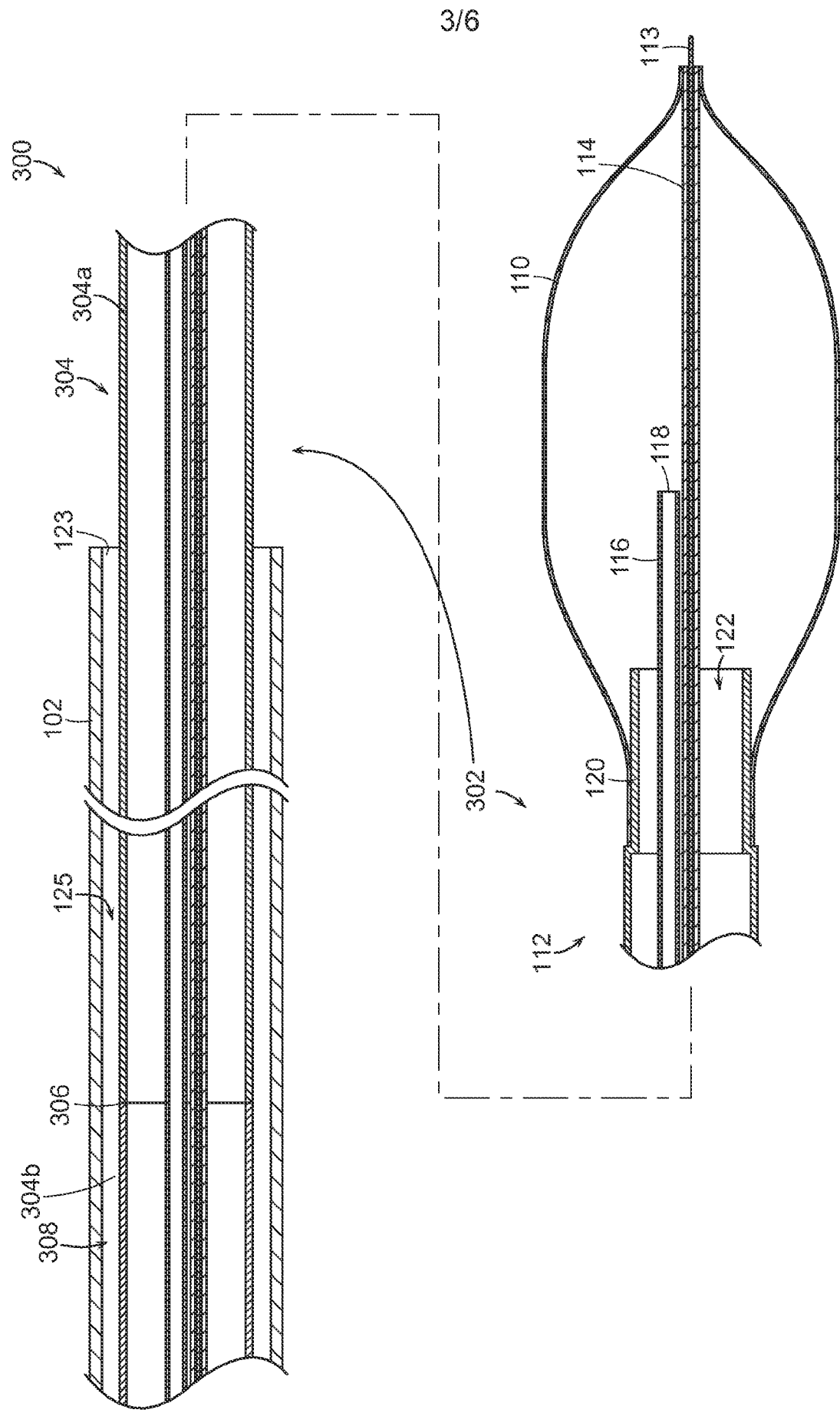


FIG. 2



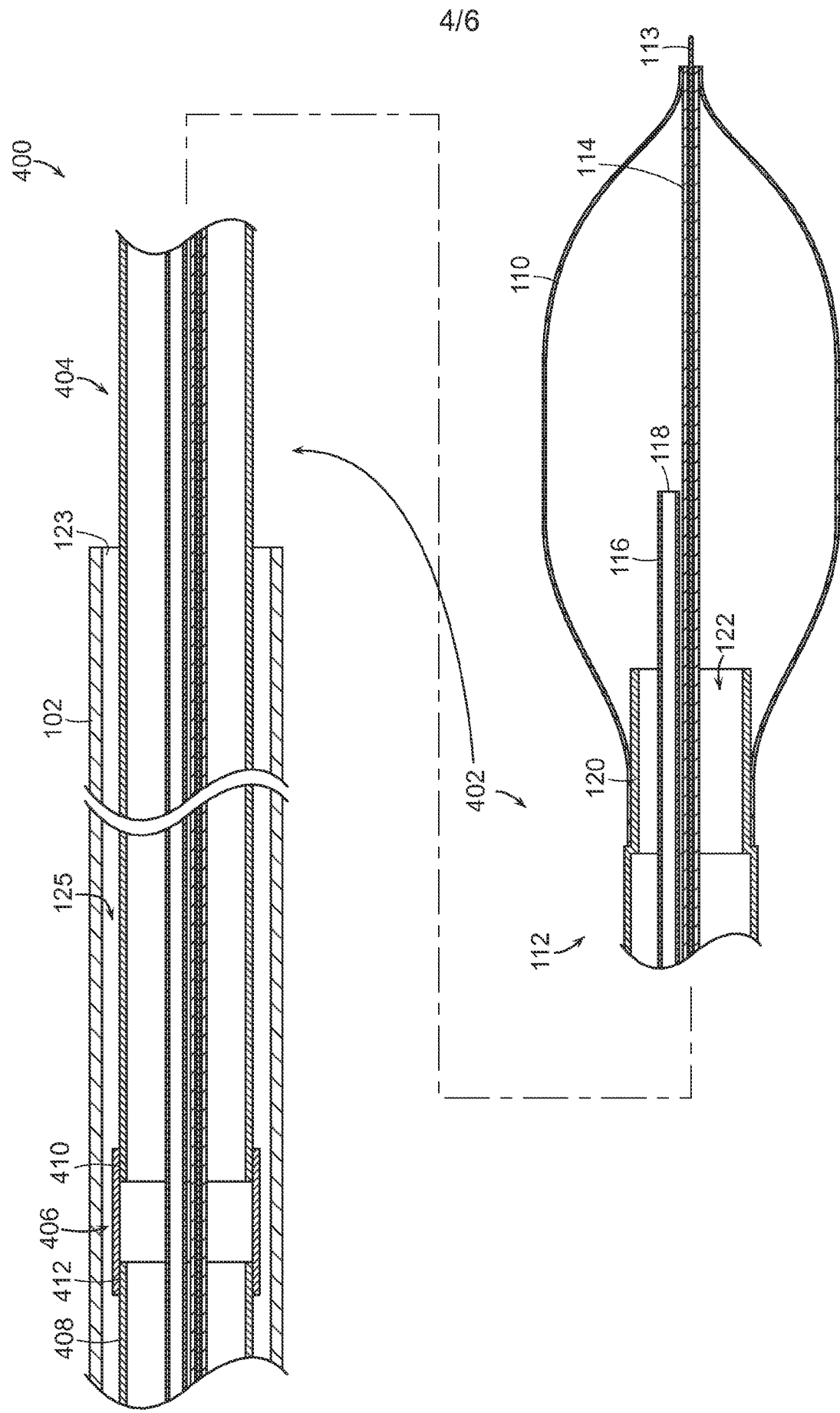
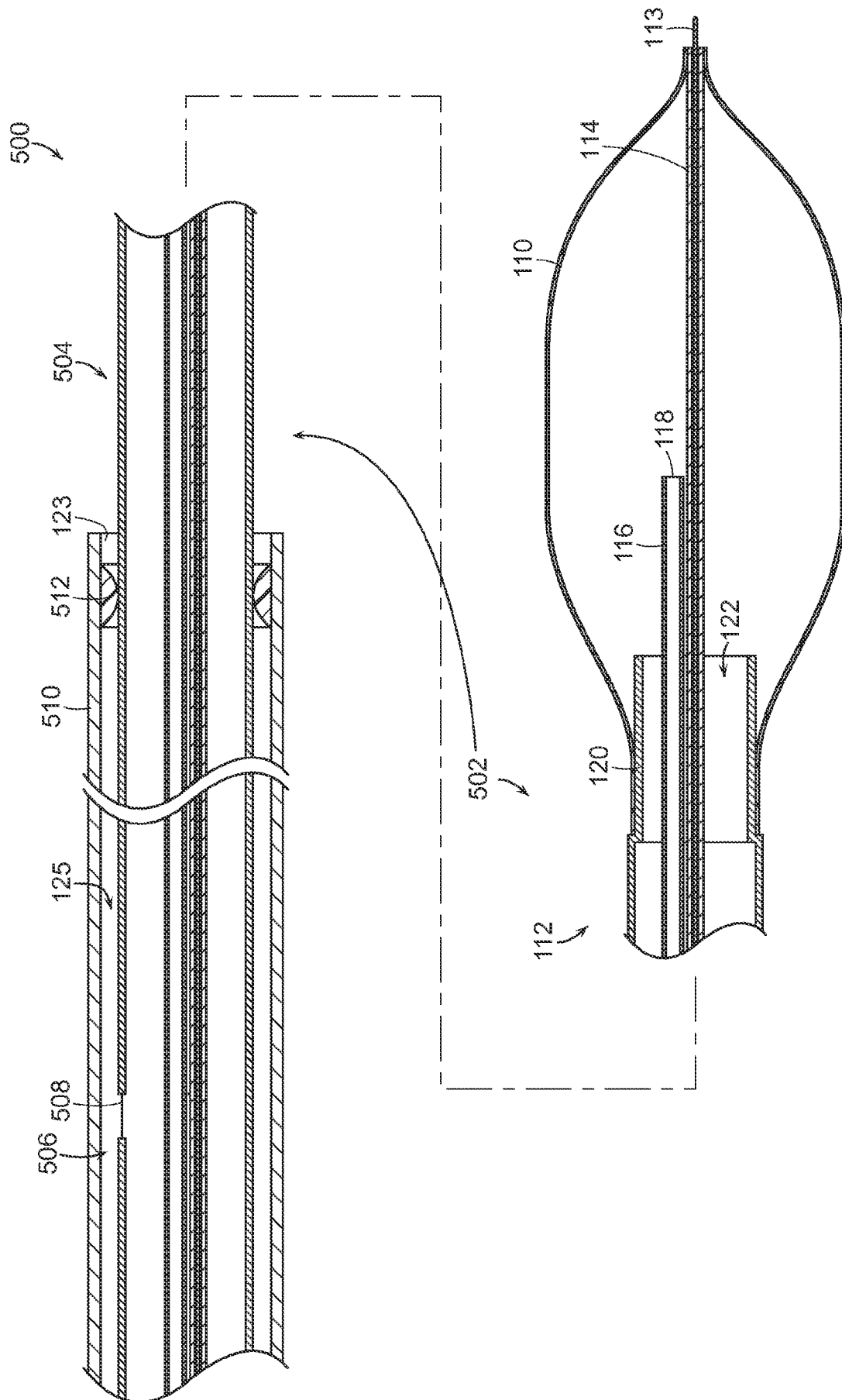


FIG. 4





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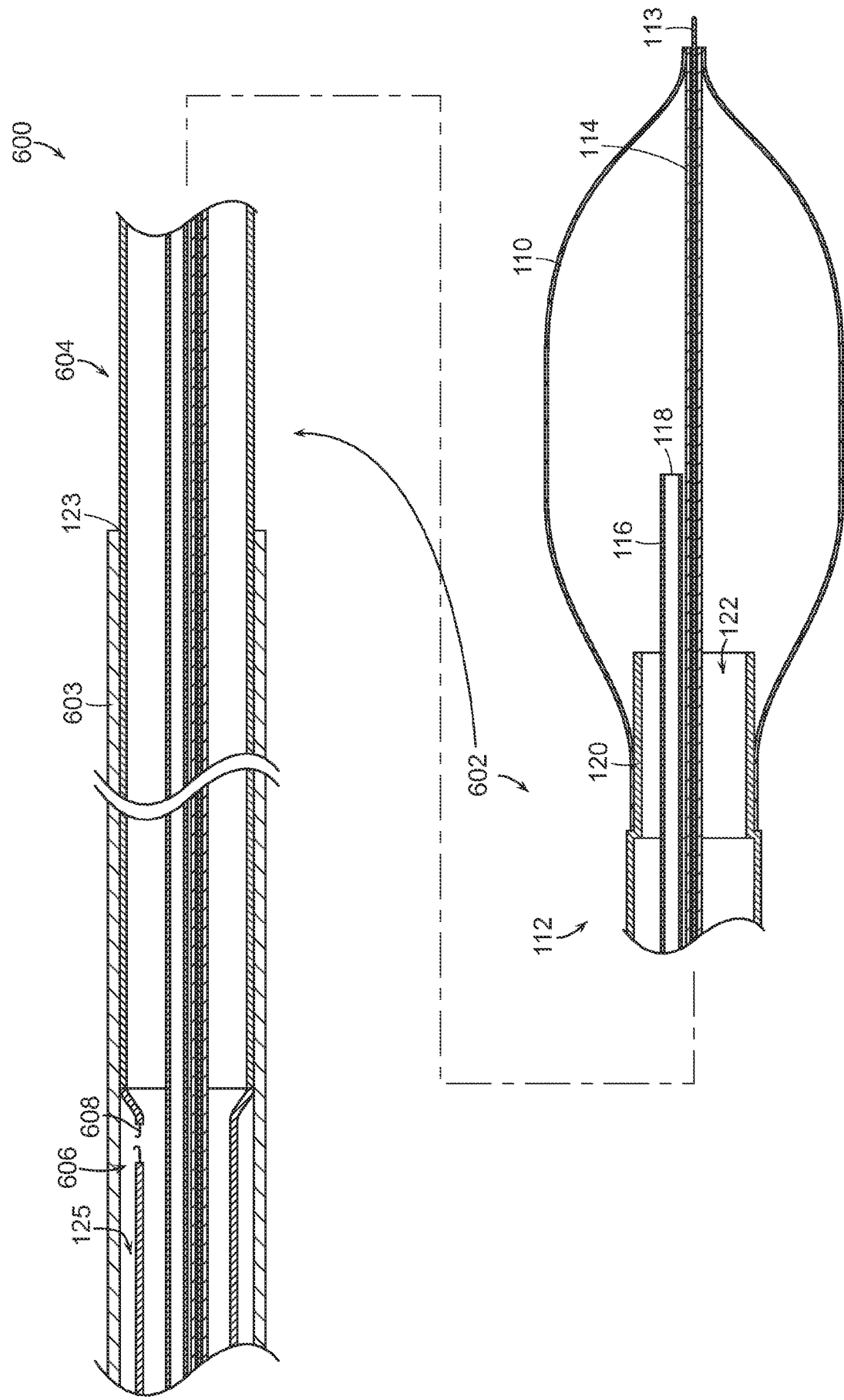


FIG. 6