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(54) Title: ENDOVASCULAR VARIABLE AORTIC CONTROL CATHETER

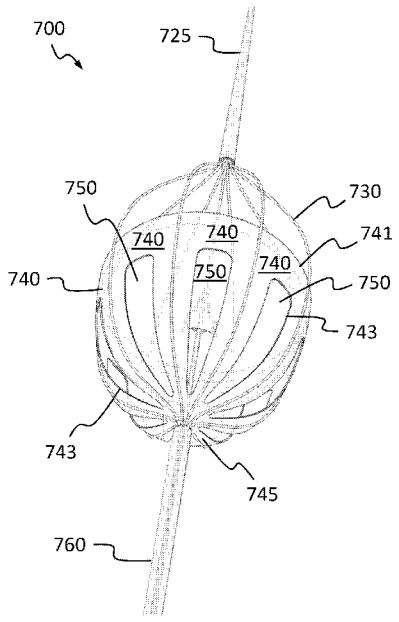


Fig. 42B

(57) Abstract: An endovascular variable aortic control catheter (EVACC) 10 is provided that is adapted to augment upstream blood pressure and regulate downstream blood flow for patients in shock. The EVACC device provide improved treatment for truncal wounds, which may be used for example on a battlefield, thereby increasing survivability of injured soldiers. The device 10 is a catheter-based system having a proximal hand piece 70 for controlled deployment of the device through a delivery sheath 60. A collapsible, wire framework 30 supports an expandable and collapsible occlusion barrier 40. The wire framework 30 and occlusion barrier 40 expand to fit within the lumen of the aorta. Various movable elements are used to adjust an adjustable passageway to regulate controlled anterograde blood flow.

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# ENDOVASCULAR VARIABLE AORTIC CONTROL CATHETER

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** The present application claims priority to U.S. Provisional Patent Application Serial Nos. 62/105,887 filed January 21, 2015, and 62/235,087 filed September 30, 2015, and U.S. Patent Application Serial No. 14/990,465 filed January 7, 2016, each of which is hereby incorporated herein by reference in its entirety.

## RIGHTS OF THE GOVERNMENT

**[0002]** The invention described herein may be manufactured and used by or for the Government of the United States for all governmental purposes without the payment of any royalty.

## FIELD OF THE INVENTION

**[0003]** This disclosure relates generally to endovascular aortic occlusion devices deployed within the aorta. More particularly, the invention relates to endovascular aortic occlusion devices adapted for augmenting blood pressure and controlling blood flow downstream of the occluded region.

## BACKGROUND

**[0004]** Death from the complications of truncal hemorrhage continues to exist as a high probability in an overwhelming number of cases in both the military and civilian medical spheres. Existing systems and procedures used to control truncal hemorrhage frequently contribute to a patient's ultimate death through inability to maintain adequate blood flow to vital organs. It is well recognized that without controlled distal reperfusion, hemodynamic collapse is common, particularly where open aortic cross-clamping is used to stop hemorrhage. The ability to rapidly deliver effective, variable and adaptive control of aortic flow for hemorrhaging patients will save innumerable lives.

**[0005]** Mitigation of battlefield injury and hemorrhage is a high priority of U.S. military trauma surgeons and researchers. Uncontrolled blood loss is recognized as the leading cause of death in 90 percent of the potentially survivable battlefield cases and in 80 percent of those who died in a military treatment facility. "Bleed-outs," especially those caused by groin or neck wounds, challenge medics, corpsmen and physicians who can do little to stop blood loss caused by major arterial injuries.

**[0006]** Two devices, the Combat Ready Clamp and Abdominal Aortic Tourniquet, have been built to treat truncal injuries. The Combat Ready Clamp is primarily for treating junctional hemorrhage (i.e. between the trunk and an extremity). The Combat Ready Clamp is ineffective

against wounds involving the genital region or the loss of both legs. The Abdominal Aortic Tourniquet functions as a large blood pressure cuff which wraps around the lower torso to minimize extremity bleeding.

**[0007]** Limiting or stopping blood flow through the major blood vessel of the body, the aorta, is an established method for slowing the rate of blood loss in a severely injured patient with ongoing bleeding. In the military, this aortic occlusion has traditionally been achieved using a large aortic clamp inserted into the chest cavity via a large incision between the ribs. This dramatic and extremely invasive maneuver is typically a "last ditch" effort. The clamping of the aorta excludes the systemic circulation, by definition, thus causing an ischemia. The goal of the aortic clamping procedure is to keep the patient's remaining blood circulating to the heart, lungs, and brain for precious minutes until bleeding below the aortic clamp is controlled and the patient can be resuscitated and systemic circulation restored. Because of the inherent morbidity of the aortic clamp maneuver, it is often reserved for only the sickest or moribund patients who have lost vital signs and are essentially already dead.

**[0008]** Recently, balloon catheters used in endovascular surgery have been repurposed to fully occlude the aorta by inflation of a balloon in the lumen of the aorta, as an alternative to aortic clamping. This procedure is referred to as Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA). REBOA has the potential to achieve effective aortic occlusion with less morbidity. Therefore, REBOA may be used earlier in the clinical course of the bleeding patient.

**[0009]** As with aortic clamping, REBOA can be used to increase blood pressure to vital organs while slowing ongoing blood loss. However, currently available FDA-approved balloon catheters used for REBOA can only reliably achieve complete occlusion or no occlusion. As such, attempting to wean a patient from complete balloon occlusion by slowly deflating the balloon is not achievable. When aortic occlusion is used in the course of treatment of a hemorrhaging patient, the physician must begin to wean the patient off complete occlusion as early as possible. Using REBOA, when the balloon is inflated, everything below the balloon quickly starts to die due to lack of blood flow. When the balloon is deflated to initiate flow, hemodynamic collapse is a possibility. Additionally, variation in patient size (height, weight, aortic diameter) limits the ability of a single REBOA catheter to effectively occlude aortic flow in all patients.

**[0010]** Currently, REBOA is performed utilizing devices largely intended for other purposes, specifically the FDA-approved CODA® balloon catheter (Cook Medical Technologies, LLC, Bloomington, IN) for occluding large blood vessels and molding of aortic endoprostheses.

While effective at complete aortic occlusion, the CODA® balloon catheter is not ideally suited for partial vessel occlusion or controlled distal reperfusion during gradual deflation based on its inherent design characteristics, particularly an inability to create a variable and sustained pressure gradient across the balloon. An example of this type of device is disclosed by Eliason et al., U.S. Patent Application Publication No. 2013/0102926, published April 25, 2013, which is incorporated by reference herein in its entirety. The invention of Eliason et al. is directed to a method for placing an aortic occlusion device without having to rely on fluoroscopy to ensure proper placement. The system of Eliason et al. relies on the use of an inflatable balloon to provide occlusion, and thus, has only marginal ability to control variability in flow from upstream to downstream of the occlusion device. Moreover, the system of Eliason et al. is unable to provide controlled anterograde blood flow (i.e., distal reperfusion).

**[0011]** It is well recognized that without controlled distal reperfusion, hemodynamic collapse is common. In particular, hemodynamic collapse has a high probability of occurrence when open aortic cross-clamping is used to staunch blood flow. Although complete occlusion can stop distal blood loss, complete occlusion also causes supraphysiologic blood pressure spikes to everything upstream of the occlusion balloon. These blood pressure spikes can worsen concomitant injuries to tissue beds proximal to the balloon (e.g. traumatic brain injury, pulmonary contusions and hemorrhage, or traumatic amputations of the upper extremities). Additionally, upon uncontrolled release of complete occlusion, the blood volume supplying the heart, lungs and brain is rapidly redistributed to the lower half of the body effectively reducing the circulating blood volume. Additionally, peripheral vasodilation and the washout of toxic metabolites, which have built up in the ischemic tissues, can result in myocardial suppression and further deterioration of hemodynamics. As a result, the growing clinical experience with REBOA in its current form reveals negative physiologic effects.

**[0012]** The current compliant balloon architecture poses technical challenges for incremental restoration of distal reperfusion necessary to prevent hemodynamic collapse following complete aortic occlusion. As an alternative to compliant balloon architectures, there exist fixed-diameter, non-compliant balloon catheter designs (e.g., ARMADA® by Abbott Laboratories Corp., North Chicago, IL). However, these catheters are intended and approved for vessel dilation (angioplasty), typically for narrowed vessels (e.g.,. atherosclerosis). Additionally, a fixed-diameter, non-compliant balloon catheter must be sized appropriately to properly occlude each patient's aorta. Consequently, although the non-compliant balloon is less susceptible to change in shape due to blood pressure spikes, the inability to change diameter outside of a narrow range impedes its ability to serve as an adaptable device to support both complete

occlusion and partial occlusion. Therefore, the relatively fixed diameter of non-compliant balloon catheters limits their real-world applicability across a range of normal aortic diameters.

**[0013]** Other efforts have been directed to development of potential alternative methods of providing aortic occlusion. For example, Barbut et al., U.S. Patent No. 6,743,196, issued June 1, 2004, describes a plurality of approaches to support aortic occlusion. Each approach described in Barbut et al. includes a catheter having a distally mounted constricting mechanism. Each constrictor is collapsed to facilitate insertion and then expanded once inserted to obstruct blood flow. Barbut et al. describes a constrictor comprising an outer conical shell and an inner conical shell, each having a distal open base and proximal apex. The outer shell further includes a pre-shaped ring to facilitate expansion. Both shells include ports or openings. Flow through the mechanism is controlled by rotating the inner conical shell such that the ports of each shell communicate.

**[0014]** More recently, VanCamp et al, in U.S. Patent No. 7,927,346, issued April 19, 2011, describes a device to provide temporary partial aortic occlusion to achieve diversion of blood flow to the brain in patients suffering from cerebral ischemia. The primary thrust of the VanCamp et al. invention is the provision of an occlusion device that does not require fluoroscopy to ensure proper placement. VanCamp's device includes an expandable frame with a planar membrane mounted on a first portion of the frame to occlude blood flow. In one embodiment disclosed in VanCamp et al., the membrane includes a fixed size opening in the center of the planar membrane to allow some blood to flow through the opening. Alternatively, VanCamp also discloses that the membrane itself may be somewhat permeable to blood flow to allow some flow. However, VanCamp is unable to provide variable control of blood flow during use.

**[0015]** In light of the aforementioned considerations and limitations of existing and proposed devices, there exists an urgent and unmet need for a viable solution to allow a physician to address hemorrhagic injuries and carefully regulate blood flow, from complete occlusion to sustained partial occlusion, with an ability to adjust the level of occlusion as the patient's vital signs dictate.

**SUMMARY**

**[0016]** The present invention, in its several embodiments, comprises a medical device to control blood flow and pressure in a patient having hemorrhagic blood loss from a traumatic truncal wound, hereinafter the endovascular variable aortic control catheter ("EVACC") or "EVAC device". The various embodiments of the EVACC enable adaptable and variable aortic occlusion for controlling anterograde blood flow and augmenting blood pressure to vital organs,

particularly in patients suffering from significant blood loss. A relevant example is a patient presenting with a traumatic hemorrhagic event, such as a gunshot wound to the abdomen. The EVAC device provides variable levels of aortic occlusion to control distal aortic blood flow and pressure on either side of an occlusion barrier established by the device.

**[0017]** As used herein, the terms "proximal" and "distal" are from the perspective of the physician or other medical professionals, such that "proximal" describes a direction away from a patient, while "distal" describes a direction toward the patient. For example, the end of a device that is inserted into a patient would be considered the "distal end"; the end held by the physician would be considered the "proximal end".

**[0018]** Further, as used herein, the terms "upstream" and "downstream" describe portions of the vascular system located on either side of the occlusion barrier. "Upstream" is in a direction away from the occlusion barrier toward the heart and associated vascularity; and "downstream" is away from the occlusion barrier to the remaining vascularity, i.e., systemic circulation, in communication with the site of hemorrhage.

**[0019]** Each of the various embodiments described herein is able to achieve more precise regulation of the degree of aortic occlusion and controlled incremental restoration of downstream reperfusion. Accordingly, one object of the various embodiments of the invention is to quickly staunch a source of bleeding. Another object is to reinitiate blood flow to deprived areas of the body while maintaining adequate flow and pressure in the vascularity serving the brain, lungs and other critical organs.

**[0020]** A further object of the various embodiments of the invention is to allow a physician to safely transition a patient from a state of complete aortic occlusion to a plurality of levels of partial aortic flow and back and forth between complete occlusion and a plurality of levels of partial flow. The invention will allow a physician to wean a patient between various states of partial aortic flow to promote a more effective process for promptly responding to the patient's varying physiologic and vascular conditions.

**[0021]** Yet another object of the various embodiments of the invention is to allow a physician to wean a patient dynamically in real-time to respond to a patient's changing physiologic conditions. A further object of the various embodiments of the invention is to allow controlled distal reperfusion as required to minimize the likelihood of reperfusion injury associated with tissue ischemia associated with aortic occlusion. Another object of the various embodiments of the invention is to support patients suffering from other non-hemorrhagic causes of shock including, but not limited to, sepsis, cardiogenic shock, and spinal shock.

**[0022]** Not all of the objects described above need be accomplished in aggregate by any one or more of the various embodiments of the invention. Each of the objects may be accomplished individually or in combination with other objects by any one of the embodiments according to the invention. Consequently, interpretation of the claims herein should not be limited by any one or more of the objects addressed above.

**[0023]** Thus, in accordance with embodiments of the present invention, an endovascular variable aortic occlusion device is provided that comprises a central guide wire; a distal end potion that includes a first wire framework and an occlusion barrier; a delivery sheath, and a proximal end portion that includes a hand piece having a stationary portion and a movable portion. The first wire framework of the distal end portion is radially expandable and collapsible. The wire framework is configured to radially expand to a sufficient radial circumference to engage with an aortic wall within a lumen of an aorta to secure the device within the aorta. The occlusion barrier surrounds at least a portion of the first wire framework and is attached thereto to provide a cup-shaped occlusion barrier, such that an upper perimeter of the occlusion barrier contacts the aortic wall when the wire framework is radially expanded. The occlusion barrier also includes at least one adjustable passageway therein to facilitate controlled anterograde blood flow. The delivery sheath is extensible and retractable, wherein a collapsed form of the first wire framework is contained therein during delivery of the device into the lumen of the aorta. The movable portion of the hand piece controls a translational movement of the delivery sheath relative to the wire framework to enable unsheathing and radial expansion of the first wire framework. The movable portion of the hand piece may also be configured to adjust the at least one adjustable passageway to regulate controlled anterograde blood flow.

**[0024]** Each of the various embodiments described herein have common elements that support the delivery of an effective occlusion barrier, but each of the embodiments has slightly different movable elements for controlling the adjustable passageway to regulate controlled anterograde blood flow. As appropriate, additional detail associated with each of the described embodiments will focus on the specific movable structural elements that provide control of anterograde (or downstream) blood flow rather than the common elements. Following is a listing of the various embodiments of the invention described herein, named in reference to their movable structural elements that enable flow control: 1) Fenestrated cylindrical conduit ("FCC") ; 2) Single aperture reduction ("SAR"); 3) Captive balloon ("CB"); 4) Fenestrated cone ("FC"); 5) Peripheral internal constriction ("PIC"); 6) Lasso aperture closure ("LAC"); 7) Rotating cup ("RC"); and 8) Deformable cup ("DC").

**[0025]** In a first embodiment, identified herein as a Fenestrated Cylindrical Conduit (FCC), the EVACC-FCC comprises a catheter-based system having a proximal hand piece for controlled deployment and operation of a distal portion of the device, wherein the distal portion is used to both partially and completely occlude the aorta. The distal portion of the EVACC-FCC comprises the components necessary to create an occlusion barrier within a targeted blood vessel, e.g., the aorta. In this first embodiment, a cylindrical conduit having a plurality of orifices (i.e., a fenestrated cylindrical conduit) extends proximally from a bottom of the occlusion barrier. Regulation of anterograde blood flow is achieved by translational movement of the delivery sheath relative to the occlusion barrier to change a number of orifices in an uncovered state to adjust an available flow area for blood flow. In one aspect, the occlusion barrier may comprise an expandable and collapsible impermeable membrane that is supported by an expandable and collapsible egg-shaped memory wire architecture. When deployed to occlude a blood vessel, the memory wire architecture expands the impermeable membrane to form a cup-shaped occlusion barrier. The conduit and the occlusion barrier may be formed as a unitary body or may be discreet components joined together (e.g., by glue, thermal fusion, or a mechanical mating arrangement, for example).

**[0026]** The collapsible membrane and associated memory wire architecture are deployed into a vessel through a delivery sheath. During use, when deployed out the end of the delivery sheath, the memory wire architecture and an upper perimeter of the cup of the collapsible membrane expand to the size of the lumen of the blood vessel, e.g., the aorta, creating a barrier or restriction to flow. The cup-shaped occlusion barrier funnels flow into the cylindrical fenestrated conduit. The fenestrated conduit has a plurality of orifices or perforations that can be exposed or covered to support variable downstream flow to systemic circulation. Linear translation of the delivery sheath causes the orifices in the fenestrated conduit to be exposed or covered. Thus, the EVACC-FCC is able to control the rate of blood flow through the orifices or fenestrations below the occlusion barrier as well as the blood pressure on either side of the occlusion barrier. Once the occlusion barrier is fully deployed within the aorta, the delivery sheath may be retracted in a controlled and graded fashion to uncover one or more orifices in the fenestrated conduit, thereby allowing blood to flow from a higher-pressure upstream vascular region to a lower pressure downstream systemic vascular region.

**[0027]** In a second embodiment of the invention, identified herein as a Singled Aperture Reduction (SAR), the movable elements for controlling the adjustable passageway to regulate controlled anterograde blood flow is based on aperture reduction and/or enlargement via linear translation of the delivery sheath over a neck of the wire basket architecture. From its top

perimeter, the cup of the occlusion barrier narrows to a single circular aperture whose size is variably adjusted by the advancement or retraction of the delivery sheath toward or away from the aperture. As the delivery sheath is moved towards the aperture, the wires of the supporting wire basket architecture are drawn close together to converge, and the diameter of the aperture is likewise reduced, restricting flow through the aperture and reducing downstream systemic circulation. To increase flow, the delivery sheath is moved away from the aperture, enlarging the aperture and hence, the flow area.

**[0028]** In a third embodiment, identified herein as Captive Balloon (CB), the movable elements for controlling the adjustable passageway to regulate controlled anterograde blood flow include an inflatable obstructive member (e.g., a captive balloon) extending into a single circular orifice, where inflation or deflation of the inflatable obstructive member adjusts a diameter of the portion of the inflatable obstructive member extending into the orifice to change an available flow area for anterograde blood flow. In one aspect, the single orifice may extend into an impermeable cylindrical conduit, such that the captive balloon is within the conduit. Rather than tapering down to a fenestrated conduit, the impermeable cylindrical conduit is internally occupied by a corresponding cylindrical balloon. The cylindrical conduit may have limited expansion. The balloon may be inflated to varying degrees within the conduit to variably occlude the lumen of the conduit, thus increasing resistance to flow and flow restriction. Complete occlusion is accomplished by full inflation of the balloon within the cylindrical conduit.

**[0029]** In a fourth embodiment, identified herein as Fenestrated Cone (FC), the movable elements for controlling the adjustable passageway to regulate controlled anterograde blood flow include a conical conduit having a plurality of orifices (i.e., a fenestrated cone) extends proximally from a bottom of the occlusion barrier. Regulation of anterograde blood flow is achieved by translational movement of the delivery sheath relative to the occlusion barrier to change a number of orifices in an uncovered state to adjust an available flow area for blood flow. The proximal region of the cup of the occlusion barrier tapers to a conically-shaped fenestrated conduit, rather than the cylindrical fenestrated conduit described above. As with the first embodiment, retraction or deployment of the conical portion out of the sheath regulates flow by causing the fenestrations to be covered or exposed and the diameter of the conical portion to be reduced as the sheath is linearly translated to cover more of the conically-shaped conduit.

**[0030]** In a fifth embodiment, identified herein as Peripheral Internal Constriction (PIC), movable elements for controlling the adjustable passageway to regulate controlled anterograde

blood flow include a conduit portion comprising an elastomeric wall that extends proximally from the occlusion barrier; and a wire mesh structure comprising a cylindrical, helically-wound braid that is surrounded by the elastomeric wall of the conduit portion. This configuration is akin to a "finger trap" design. The proximal region of the cup of the occlusion barrier tapers to this conduit portion, whose interior incorporates a wire mesh structure (e.g., a helically-wound braid) anchored to a central structural wire. The proximal portion of this conduit portion is open to allow downstream flow. The wire mesh structure or architecture may be constructed of a shape memory material, such that in its native state, the conduit portion is open. Retraction on the cylindrical conduit portion results in elongation and diameter reduction, but does not disrupt the upper perimeter of the occlusion barrier's apposition to the aortic wall. Instead, mechanical retraction of the conduit pulls against a point of fixation on a central structural wire. By elongating and narrowing the conduit portion, flow through the device is variably restricted.

**[0031]** In a sixth embodiment, identified herein as lasso aperture closure (LAC), the movable elements for controlling the adjustable passageway to regulate controlled anterograde blood flow include a lasso aperture constriction. The proximal region of the cup-shaped occlusion barrier narrows to an aperture or orifice that is variably restricted in diameter by the retraction of wires. In one embodiment, a lasso wire is provided that includes a distal end wire segment configured in a semi-circle having two end portions, and a wire portion extending from each end portion and terminating at the movable portion of the hand piece. The first wire framework passes through the semicircle of the distal end wire segment. An overlapping portion extending from the proximal terminal end of the occlusion barrier conforms to the distal end wire segment and thereby forms a single circular orifice at the proximal terminal end of the occlusion barrier. Retraction (or possibly rotation) of the wire portions extending from the end portions controls the size of the orifice. This function is similar to closing of a noose in a lasso.

**[0032]** In a seventh embodiment, identified herein as rotating cup (RC), movable elements for controlling the adjustable passageway to regulate controlled anterograde blood flow include two cup-shaped membranes where a first cup-shaped membrane has a first set of openings and a second cup-shaped membrane has a second set of openings. The adjustable passageway is formed by rotational alignment of the first and second set of openings to coincide, where at least one of the first or the second cup-shaped membrane is coupled to the movable portion of the hand piece. A rotational motion of the movable portion of the hand piece causes a relative rotation between the first and the second cup-shaped membrane to vary a degree of coincidence between the first and second set of openings. In one embodiment, the second (downstream) cup membrane includes a set of openings (e.g., two slots) to allow flow when the openings are

uncovered, and is supported by the first wire framework. The first (upstream) cup membrane also includes a set of openings, and is supported by a second wire framework and may be rotated in either direction to cover or uncover the openings in the second cup membrane to restrict or increase blood flow, respectively.

**[0033]** In an eighth embodiment, identified herein as deformable cup (DC), the movable elements for controlling the adjustable passageway to regulate controlled anterograde blood flow include two mating cup-shaped membranes, where an inner cup is deformable. The occlusion barrier includes a first cup-shaped membrane bonded to the first wire framework, where interstitial openings are present around a perimeter of the first cup-shaped membrane; and a second cup-shaped membrane positioned upstream relative to the first cup-shaped membrane. The second cup-shaped membrane includes a central aperture in a bottom portion, and the second cup-shaped membrane conforms to a distal surface of the first cup-shaped membrane, and wherein the central aperture in the second cup and the interstitial openings in the first cup do not coincide when mated together. In one aspect, the two mating cups may be supported by a single wire basket architecture. The second cup-shaped membrane may include a flexible impermeable membrane having a central aperture. The aperture may be linearly reciprocated back and forth, creating various toroidal shapes and uncovering or covering the interstitial openings within the downstream cup. In a fully closed state, the second (upstream) cup-shaped membrane adapts to the shape of the first (downstream) cup-shaped membrane, such that the interstitial openings are fully covered by the upstream membrane and flow is occluded. Flow is increased by linear translation of a center wire to lift the center aperture, and a portion of the surrounding circumferential area, of the upstream membrane off the downstream occluding element, causing the interstitial openings between the petals of the first occluding element to be uncovered, thereby allowing flow to occur.

## BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

**[0034]** These and other features, aspects and advantages of various embodiments of the present invention will become better understood with regard to the following description, appended claims, and accompanying drawings where:

**[0035]** FIG. 1 is a rear elevation view of an embodiment of the variable and adaptable aortic occlusion apparatus;

**[0036]** FIG. 2 is an enlarged front elevation view of the distal end portion of the apparatus shown in FIG. 1;

**[0037]** FIG. 3 is an enlarged front elevation view thereof;

**[0038]** FIG. 4 is an enlarged fragmentary view taken from the view of FIG. 1;

**[0039]** FIG. 5 is a top plan view thereof;

**[0040]** FIG. 6 is a bottom plan view thereof;

**[0041]** FIG. 7 shows the variable and adaptable aortic occlusion apparatus of FIG. 1 in use in a human body;

**[0042]** FIGS. 8A, 8B, and 8C show the variable and adaptable aortic occlusion apparatus of FIG. 1 in various stages of deployment inside an aorta;

**[0043]** FIGS. 9A, 9B, and 9C show side enlarged side views of an embodiment of the variable and adaptable aortic occlusion apparatus in use inside a major blood vessel of the body, wherein FIG. 9A shows the apparatus prior to deployment, FIG. 9B shows the apparatus deployed for full occlusion, and FIG. 9C shows the apparatus deployed for partial occlusion;

**[0044]** FIG. 10 is an enlarged front elevation view of an endovascular variable aortic control aperture device according to an embodiment of the present invention;

**[0045]** FIG. 11 is an enlarged front elevation view showing components of the device thereof;

**[0046]** FIG. 12 is an enlarged fragmentary view thereof;

**[0047]** FIG. 13 is a second enlarged fragmentary view thereof;

**[0048]** FIG. 14 is an enlarged front elevation view of an endovascular variable aortic control captive balloon device according to an embodiment of the present invention;

**[0049]** FIG. 15 is an enlarged front elevation view showing components of the device thereof;

**[0050]** FIG. 16 is an enlarged fragmentary view thereof;

**[0051]** FIG. 17 is a second enlarged fragmentary view thereof;

**[0052]** FIG. 18 is an enlarged front elevation view of an endovascular variable aortic control fenestrated cone device according to an embodiment of the present invention;

**[0053]** FIG. 19 is an enlarged front elevation view showing components of the device thereof;

**[0054]** FIG. 20 is an enlarged fragmentary view thereof;

**[0055]** FIG. 21 is a second enlarged fragmentary view thereof;

**[0056]** FIG. 22 is an enlarged front elevation view of an endovascular variable aortic control "finger trap" device according to an embodiment of the present invention;

**[0057]** FIG. 23 is an enlarged front elevation view showing components of the device thereof;

**[0058]** FIG. 24 is an enlarged fragmentary view thereof;

**[0059]** FIG. 25 is a second enlarged fragmentary view thereof;

**[0060]** FIG. 26 is an enlarged front elevation view of an endovascular variable aortic control lasso device according to an embodiment of the present invention;

**[0061]** FIG. 27 is an enlarged front elevation view showing components of the device thereof;

**[0062]** FIG. 28 is an enlarged fragmentary view thereof;

**[0063]** FIG. 29A is a second enlarged fragmentary view thereof;

**[0064]** FIG. 29B is a third enlarged fragmentary view thereof;

**[0065]** FIG. 30 is an enlarged front elevation view of an endovascular variable aortic control rotating cups device according to an embodiment of the present invention;

**[0066]** FIG. 31 is an enlarged front elevation view showing components of the device thereof;

**[0067]** FIG. 32A is an enlarged fragmentary view of the endovascular variable aortic control rotating cups device of FIG. 30 in a closed position;

**[0068]** FIG. 32B is the enlarged fragmentary view of the endovascular variable aortic control rotating cups device of FIG. 32A in an open position;

**[0069]** FIG. 33A is a second enlarged fragmentary view of the endovascular variable aortic control rotating cups device of FIG. 30 in a closed position;

**[0070]** FIG. 33B is the second enlarged fragmentary view of the endovascular variable aortic control rotating cups device of FIG. 32A in an open position;

**[0071]** FIG. 34A is a top plan view of the endovascular variable aortic control rotating cups device of FIG. 30 in a closed position;

**[0072]** FIG. 34B is a top plan view of the endovascular variable aortic control rotating cups device of FIG. 30 in an open position;

**[0073]** FIG. 35A is a bottom plan view of the endovascular variable aortic control rotating cups device of FIG. 30 in a closed position;

**[0074]** FIG. 35B is a bottom plan view of the endovascular variable aortic control rotating cups device of FIG. 30 in an open position;

**[0075]** FIG. 36A is an enlarged front elevation view of an endovascular variable aortic control tulip device in a closed position according to an embodiment of the present invention;

**[0076]** FIG. 36B is an enlarged front elevation view in an open position thereof;

**[0077]** FIG. 37 is an enlarged front elevation view showing components of the device thereof;

**[0078]** FIG. 38A is a top plan view in a closed position thereof;

**[0079]** FIG. 38B is a top plan view in an open position thereof;

**[0080]** FIG. 39A is a bottom plan in a closed position thereof;

**[0081]** FIG. 39B is a bottom plan view in an open position thereof;

**[0082]** FIG. 40A is a cross-section view of the endovascular variable aortic control tulip device in a closed position shown in FIG. 38A, taken along the cutting plane 3-3;

**[0083]** FIG. 40B is a cross-section view of the endovascular variable aortic control tulip device in an open position shown in FIG. 38B, taken along the cutting plane 4-4;

**[0084]** FIG. 41A is an enlarged fragmentary view of an endovascular variable aortic control tulip device in a closed position;

**[0085]** FIG. 41B is a second enlarged fragmentary view in an open position thereof;

**[0086]** FIG. 42A is a third enlarged fragmentary view in a closed position thereof; and

**[0087]** FIG. 42B is a fourth enlarged fragmentary view in an open position thereof.

**[0088]** The accompanying drawings numbered herein are given by way of illustration only and are not intended to be limitative to any extent. Commonly used reference numbers identify the same or equivalent parts of the claimed invention throughout the accompanying drawings.

**DETAILED DESCRIPTION**

**[0089]** Following is a listing of the various embodiments of the endovascular variable aortic control catheter (hereinafter, "EVACC") described herein, named in reference to movable elements used to control, regulate, and/or modulate anterograde blood flow and identified by their shortened acronym and associated reference numeral. Hereinafter, each of the various embodiments of the EVACC will be identified by the precursor, "EVACC", followed by additional initials describing the movable elements that enable anterograde blood flow control, e.g., "FCC" for "fenestrated cylindrical conduit", and then the appropriate reference numeral, e.g., "10".

1. Fenestrated Cylindrical Conduit (EVACC-FCC 10);
2. Single Aperture Reduction (EVACC-SAR 100);
3. Captive Balloon (EVACC-CB 200);
4. Fenestrated Cone (EVACC-FC 300);
5. Peripheral Internal Constriction(EVACC-PIC 400);
6. Lasso Aperture Closure (EVACC-LAC 500);
7. Rotating Cup (EVACC-RC 600); and
8. Deformable Cup (EVACC-DC 700).

**[0090]** Fenestrated Cylindrical Conduit Embodiment (EVACC-FCC 10): FIGS. 1-6

**[0091]** Turning now to FIG. 1, an endovascular variable aortic control catheter (EVACC) according to a first embodiment 10 of the present invention is illustrated, wherein anterograde blood flow is controlled or regulated using a fenestrated cylindrical cylinder configuration, hereinafter referred to as EVACC-FCC 10.

**[0092]** The EVACC-FCC 10 comprises a central guide wire 20, a supporting memory wire basket architecture 30, an occlusion barrier 40, a flow-regulating fenestrated cylindrical conduit 50 and an extensible and retractable delivery sheath 60. As indicated by segmentation symbol

62, the length of the delivery sheath 60 and central guide wire 20 may be varied to accommodate differing deployment requirements.

**[0093]** An exemplary version of a hand piece 70 used to manipulate and control the distal components of the EVACC-FCC 10 is shown. This same hand piece 70 may be used to manipulate the distal components of the additional embodiments described herein. The hand piece 70 comprises a stationary distal grip 71 and a rotatable proximal grip 72. Proximal grip 72 is rotatable on threaded guide 74 to manipulate the distal components of the EVACC-FCC 10 during and after deployment. Additional wire assemblies (not shown) may be threaded through a center lumen (not shown) of the threaded guide 74 to provide additional methods for actuating the distal components.

**[0094]** Now, in greater detail, FIG. 2 is an enlarged component view of the EVACC-FCC 10 of FIG. 1. The central guide wire 20 is a self-centering rigid endovascular guide wire 20 used to reach a target occlusion location within a patient's vascular system. After deployment, the EVACC-FCC 10 is slidably received on the central guide wire 20 and inserted in the patient via a delivery sheath 60. The endovascular guide wire 20 includes a J-tip 22 at a distal end 34 thereof. The J-tip 22 ensures that the distal components of the EVACC-FCC 10 can be smoothly advanced or retracted within the arterial complex to reach a desired location for occlusion. The J-tip 22 provides centering of the central guide wire 20 and the delivery sheath 60 within the lumen of the artery. A tapered nose cone 25 is positioned on the central guide wire 20 between the J-tip 22 and a distal end 34 of the wire framework or basket architecture 30 to ensure that the distal end 34 of the wire basket architecture 30 can likewise be smoothly advanced through the arterial tree during deployment. In addition, the tapered nose cone 25 may be radiopaque to allow tracking during use with appropriate medical imaging solutions.

**[0095]** The wire basket architecture 30 may be made of nitinol or other material having similar memory-shape properties. As illustrated, the wire basket architecture 30 assumes an approximate egg-shape when fully deployed and released from the delivery sheath 60. It should be appreciated that other shapes, e.g., spherical or cylindrical, are further contemplated. The wire basket architecture 30 expands when deployed out the end of the delivery sheath 60 and will collapse upon retraction back into the delivery sheath 60. The wire basket architecture 30 and its neck 32 are partially enveloped by and provide structural integrity to both the occlusion barrier 40 and a fenestrated cylindrical conduit 50, while ensuring adequate but not excessive apposition of the occlusion barrier 40 to the aortic wall.

**[0096]** The occlusion barrier 40 comprises a membrane, preferably made of expanded polytetrafluoroethylene (hereinafter, "ePTFE"). Other materials, such as polyester, may also be

used to form the occlusion barrier 40. When deployed, the occlusion barrier 40 expands to form a cup 42 having an upper perimeter edge 44. The cup 42 necks down to the fenestrated cylindrical conduit 50.

**[0097]** The fenestrated cylindrical conduit 50 includes a plurality of orifices or perforations 52 distributed along its length through which blood may flow when not covered by the delivery sheath 60. When complete occlusion of flow is desirable, the perforations 52 are covered by the delivery sheath 60. The perforations 52 may be uncovered and opened to varying degrees by linear retraction of the delivery sheath 60 from over the perforations 52, thereby allowing blood flow and pressure to be altered. Similar to the occlusion barrier 40, the fenestrated cylindrical conduit 50 is preferably made of ePTFE, but may be made of other materials to increase rigidity or elasticity during deployment. In one aspect, the occlusion barrier 40 comprising the cup 42 and fenestrated conduit 50 form one unitary piece. In another aspect, the occlusion barrier 40 may comprise a separate cup 42 and fenestrated conduit 50, which are joined or bonded by various means, such as glue, thermal fusion or a mechanical mating arrangement.

**[0098]** The EVACC-FCC 10 may be constructed using standard, commercial-grade endovascular components. The delivery sheath 60 is preferably deployed through a percutaneous introducer catheter directly into the femoral artery. The delivery sheath 60 is then advanced to the level of the thoracic or abdominal aorta and then the basket architecture 30 and occlusion barrier 40 are deployed.

**[0099]** Turning now to FIG. 3, a side elevation view of the distal components of the EVACC-FCC 10 in an assembled and deployed state is shown. The memory wire architecture 30 is fully deployed, expanding the occlusion barrier 40 to create a cup 42 having an upper perimeter 44. The distal tip 34 of the memory wire architecture 30 is secured within the conical tip 25. The neck 32 of the memory wire architecture 30 is deployed beyond the end of the delivery sheath 60 to expand the fenestrated cylindrical conduit 50 and the proximal end 54 of the neck 52 and uncover the perforations 52. In this configuration, while deployed in a blood vessel, the EVACC-FCC 10 would provide its maximum flow downstream of the occlusion barrier 40.

**[0100]** FIG. 4 is a perspective view of the view of FIG. 3. Although the perimeter 44 of the cup 42 of the occlusion barrier 40 is shown as being comprised of chords of membrane between each wire, in actual use, the perimeter 44 of the cup 42 will blossom to appose the interior wall of the aorta. The blossoming effect occurs as a result of blood flow and the associated pressure differential, which causes the occlusion barrier to expand in the manner of a wind sock.

**[0101]** FIG. 5 is a top plan view of the EVACC-FCC 10, emphasizing the view into the cup 42 of the occlusion barrier 40 in a fully deployed state and illustrating the J-tip 22, the conical tip 25 and the internal wire basket architecture 30. FIG. 6 is a bottom plan view of the EVACC-FCC 10, emphasizing a view of the proximal end of the collapsible occlusion barrier 40 and fenestrated channel 50 in a fully deployed state, extended out of the delivery sheath 60.

**[0102]** FIGS. 7 – 9 provide illustrations of the EVACC-FCC 10 in use and operation. The description provided regarding use and operation of this first embodiment, the EVACC-FCC 10, is applicable to the use and operation of the various additional embodiments described herein.

**[0103]** FIG. 7 is a simplified illustration of a method used to deploy the EVACC-FCC 10 in a subject B. The central guidewire 20 and delivery sheath 60 are inserted into an incision in the subject B femoral artery and guided through the vascular until reaching a targeted occlusion location within the aorta A.

**[0104]** The delivery sheath 60 of the EVACC-FCC 10 is preferably inserted into the arterial tree through a 7-French sheath or smaller. The degree to which the fenestrated cylindrical conduit 50 is opened to allow flow is controlled by the hand piece 70 connected to a proximal portion of the EVACC-FCC 10 (outside the patient). During initial insertion into the arterial tree and through advancement to the desired occlusion site within the aorta A, the central guide wire 20, the wire basket architecture 30, the collapsible occlusion barrier 40 and the fenestrated cylindrical conduit 50 are initially enclosed in the delivery sheath 60, in a manner similar to vena cava filter deployment catheters. Once deployed out the delivery sheath 60 and into the lumen of the aorta A, the wire basket architecture 30 will assume its natural opened position and appose the wall of the aorta, thereby creating a sealing portion buttressed by the unfurling of the occlusion barrier 40. The degree of occlusion and flow control may be manipulated by covering and exposing the perforations 52 of the fenestrated cylindrical conduit 50 via advancement and retraction of the delivery sheath 60. The advancement and retraction of the delivery sheath 60 may be accomplished by rotary manipulation of the rotatable grip 72 of hand piece 70 to advance a threaded guide 74 in either a proximal or a distal direction. The stationary distal grip 71 and rotatable proximate grip 72 of the hand piece 70 are rotated in opposite directions to linearly translate the threaded guide 74, which is attached via pull wires to the sheath 60 and/or the fenestrated cylindrical conduit 50.

**[0105]** The EVACC-FCC 10 and the additional embodiments described herein may be equipped with blood pressure measuring capabilities proximal and distal to the occlusion barrier 40 for measuring upstream and downstream blood pressure. The blood pressure measuring capabilities may comprise a manometer mounted on the EVACC-FCC 10 or a channel

communicating with a transducer at the proximal end and a port at the distal end of the EVACC 10. Blood pressure measuring may also be accomplished by use of a fiber optic in vivo pressure transducer as described in U.S. Pat. Nos. 5,392,117 and 5,202,939, each of which is incorporated herein by reference in its entirety, or a Radi pressure wire as described in U.S. Pat. Nos. Re 35,648; 5,085,223; 4,712,566; 4,941,473; 4,744,863; 4,853,669; and 4,996,082, each of which is incorporated herein by reference in its entirety.

**[0106]** With the inclusion of upstream and downstream pressure sensors, upstream and downstream blood pressure measurements may then be recorded and displayed via a monitor at a proximal end of the EVACC-FCC 10. A control device or module (not shown) may be programmed with various preferred treatment and operational parameters. The control device may then provide automated control of the operational parameters including: 1) blood pressure, upstream and downstream of the occlusion barrier 40, and 2) flow diversion through the uncovered perforations 52 of the fenestrated conduit 50. For example, the control device can include a set pressure threshold to maintain upstream blood pressure to a desired level.

**[0107]** Data communicated to the pressure monitor from pressure sensors may be transferred or transmitted to the control device, which then sends control signals to a separate electrically-powered rotary unit to linearly translate the threaded guide 74 and the delivery sheath 60. The translational movement of the delivery sheath 60 by the threaded guide 74 controls exposure of perforations 52 in the fenestrated cylindrical conduit 50. The threaded guide 74 retracts or extends the delivery sheath 60 to uncover or cover the perforations 52, thereby adjusting the diversion of flow from upstream to downstream and causing modification of blood pressure on each side of the occlusion barrier 40.

**[0108]** In the field, where a separate automated control device may not be available, the hand piece 70 can be manually rotated to obtain desired upstream and downstream blood pressures. An audible alarm may be incorporated into the pressure monitor to sound when blood pressures exceeds desired thresholds. In one aspect, the rotary unit, pressure monitor, and control device may be integrated into the hand piece 70 of the EVACC 10.

**[0109]** The EVACC-FCC 10, and the additional embodiments described herein, are configurable to provide adaptive control of the means for flow regulation. Adaptive control is described in the context of the EVACC-FCC 10, but is intended to extend to the functionality of the additional embodiments described herein. In each embodiment, adaptive control is accomplished via manipulation of the various movable elements used for anterograde blood flow control.

**[0110]** Hence, in the case of the EVACC-FCC 10, adaptive control may be accomplished via the exposure or covering of the perforations 52 based on continuous dual pressure measurements both upstream and downstream of the occlusion barrier 40. Estimates of systemic flow may be determined via algorithms correlated to each EVACC-FCC 10 based on the pressure measurements. The real-time availability of both flow measurments and pressure measurements may then be used to inform either physician decisions or automated adaptive control of the EVACC-FCC 10 according to specified operational parameters. For example, just as a tourniquet is periodically released to allow flow to avoid further tissue damage, the EVACC-FCC 10 may operate via the automated control device to periodically adjust flow downstream of the occlusion barrier 40 to avoid ischemia, or, to reduce downstream flow to divert flow to the brain and other vital organs upstream of the occlusion barrier 40.

**[0111]** Turning now to FIGS. 8A through 8C, the deployment of the occlusion barrier 40 and wire basket architecture 30 is shown. In FIG. 8A, the EVACC-FCC 10 has been positioned within the aorta A at a desired location. In FIG. 8B, the delivery sheath 60 has been retracted from over the wire basket architecture 30, allowing the wire basket architecture 30 and the cup 42 of the occlusion barrier 40 to expand slightly. In FIG. 8C, the entire occlusion barrier 40 has been deployed out the delivery sheath 60 within the aorta A and the fenestrated cylindrical conduit 50 has been exposed outside the delivery sheath 60 providing an initial level of flow wherein the occlusion barrier 40 is operating in a full open state.

**[0112]** Turning now to FIGS. 9A though 9C, the manipulation of flow using the EVACC-FCC 10 is illustrated. In FIG. 9A, the the wire basket architecture 30 and occlusion barrier 40 are both collapsed within the lumen tof the delivery sheath 60 while positioned at a desired occlusion location. Note that the various arrows indicate the general distribution of blood flow during each of the described states, where blood is indicated by the dotted markings.

**[0113]** In FIG. 9A, with the EVAC-FCC 10 positioned at a desired location, flow continues to the site of hemorrhage with no occlusion or regulation of flow. Now, in FIG. 9B, the wire basket architecture 30 and occlusion barrier 40 are fully deployed out the distal end of the delivery sheath 60. In this configuration, the occlusion barrier 40 is deployed to appose the interior wall of the aorta A, but the fenestrated cylindrical conduit 50 is still fully covered by the delivery sheath 60, thereby causing full occlusion of downstream blood flow, with all existing flow redirected to upstream portions of the vascular. Now, in FIG. 9C, the delivery sheath 60 has been retracted to expose a portion of the fenestrated cylindrical conduit 50 and the perforations 52, providing an adjusted level of flow through the occlusion barrier 40, through the fenestrated conduit 50 and out the perforations 52 and downstream to support

systemic circulation. Note that partial occlusion may distribute blood flow to other upstream elements of the vascular, while still allowing downstream flow.

**[0114]** The delivery sheath 60 may be advanced or retracted over the fenestrated cylindrical conduit 50 to continually adjust flow from fully occluded to various levels of partial occlusion. This ability to continually redistribute flow as required by a patient's physiologic status allows a surgeon to maximize the probability of survival and minimize potential negative outcomes, such as hemodyamic collapse, when weaning the patient off full or partial occlusion.

**[0115]** Now, several alternative embodiments are described in detail in the following paragraphs. In each alternative embodiment, the device is deployed and used in a similar fashion as described for the EVACC-FCC 10. However, in each alternative embodiment, the structure, configuration and operation of movable elements used for flow control will differ to varying degrees.

**[0116]** Single Aperture Reduction Embodiment (EVACC-SAR 100): FIGS. 10-13

**[0117]** Referring now to FIG. 10, a second embodiment 100 of the EVACC is illustrated. The second embodiment 100 comprises anterograde blood flow control based on a single aperture reduction. Therefore, we refer to this second embodiment 100 as the EVACC-SAR 100. An egg-shaped memory wire basket architecture 130 supporting a flexible cup-shaped occlusion barrier 140 and including a perimeter 144, narrows to a single aperture 150 having a maximum deployed diameter. The maximum deployed diameter of the single aperture 150 establishes the maximum flow rate through the occlusion barrier 140. The flow area of the single aperture 150 is reduced by the advancement of the delivery sheath 160 towards the single aperture 150, causing the supporting wires 132 of the wire basket 130 to converge closer together. As the supporting wires 132 converge, the diameter of the aperture 150 is reduced, thereby restricting flow through the aperture 150. As the delivery sheath 160 is retracted and the supporting wires 132 diverge to their memory state, the single aperture 150 is enlarged, thereby allowing increased flow. The EVACC-SAR 100 is fully occluded when the delivery sheath 160 is advanced to cover and envelop the single aperture 150.

**[0118]** Referring now to FIG. 11, an exploded view of the components of the distal portion of the EVACC-SAR 100 is shown. EVACC-SAR 100 comprises a central guide wire 120 having J-tip 122, a tapered nose cone 125 for receiving the distal end 134 of a wire basket architecture 130, an occlusion barrier 140 having an aperture 150, and a delivery sheath 160.

**[0119]** FIG. 12 is a perspective view of the EVACC-SAR 100 looking into the interior of the occlusion barrier 140 and wire basket architecture 130. The supporting wires 132 extend through the single aperture 150 to deploy the occlusion barrier 140 via the wire basket

architecture 130. The occlusion barrier 140 is extended by the wire basket architecture 130 to establish a perimeter 144 of the occlusion barrier 140. The wire basket architecture 130 converges to a distal end 134, which is captured within the base of the tapered conical tip 125.

**[0120]** FIG. 13 is another bottom or downstream perspective view of the EVACC-SAR 100. The aperture 150 is joined to the supporting wires 132 so that as the supporting wires 132 are retracted into the sheath 160, the aperture 150 reduces in size. Once the supporting wires 132 have been fully retracted into the sheath to up to the aperture 150, the aperture 150 is closed and flow is fully occluded. As with other embodiments, the amount of flow may be adjusted by reciprocating the sheath 160 back and forth over the closure supporting wires 132 from a fully occluded state to a partially occluded state, thereby causing the aperture 150 to vary in size. In other versions of the EVACC-SAR 100, the aperture 150 may have a different size, which would modify the total flow through the aperture 150 in a fully deployed state.

**[0121]** Captive Balloon Embodiment (EVACC-CB 200): FIGS. 14-17

**[0122]** Referring now to FIG. 14, in a third EVACC embodiment 200 of the invention, anterograde blood flow control employs a captive balloon concept, hereinafter, referred to as the EVACC-CB 200. The EVACC-CB 200 also comprises elements similar to those previously described in other embodiments including a central guide wire 220, a J-tip 222, a cone shaped tip 225, a wire basket architecture 230, an occlusion barrier 240 and a delivery sheath 260. The wire basket architecture 230 includes an extended throat 232 and the occlusion barrier 240 includes an extended occlusion barrier neck 242. The occlusion barrier neck 242 and extended throat 232 are sized to receive an inflatable balloon 250. The extended occlusion barrier neck 242 is sized to expand less than a perimeter 244 of the occlusion barrier 240. Consequently, the occlusion barrier neck 242 constrains expansion of the balloon 250 such that full expansion of the balloon within the extended wire structure 232 and occlusion barrier neck 242 causes the lumen within the occlusion barrier neck 242 to be fully occluded by the balloon 250. Flow may be adjusted by deflating or inflating the balloon 250 within the occlusion barrier neck 242; this changes the available flow area.

**[0123]** Referring now to FIG. 15, individual components of the EVACC-CB 200 are shown. The EVACC-CB 200 comprises the endovascular guide wire 220 having J-tip 222, a tapered nose cone 225 for receiving the distal end of the wire basket 230, the extended wire basket architecture 232, the occlusion barrier 240, the corresponding inflatable balloon 250, and the delivery sheath 260. The occlusion barrier 240 includes an extended neck 252 having a downstream end 254. The occlusion barrier 240 includes an upstream occluding cup 242, having a perimeter 244.

**[0124]** Referring now to FIG. 16, a perspective view of the EVACC-CB 200 in a fully deployed state, looking into the interior of the extended occlusion barrier 240 and extended wire basket architecture 230 is provided. The captive balloon 250 is fully inflated, creating full occlusion.

**[0125]** Likewise, FIG. 17 is another perspective view of the EVACC-CB 200 from the bottom or downstream side of the extended occlusion barrier 240. The balloon 250 extends into the cup 242 of the extended occlusion barrier 240. The balloon 250 resides within the extended wire structure 232, which resides within the extended occlusion barrier throat 252. Unlike other described embodiments, rather than adjusting flow by reciprocating the sheath 260 back and forth, flow is adjusted by inflating or deflating the balloon 250. Hence, flow may be adjusted from a fully occluded state to a partially occluded state, and back.

**[0126]** Fenestrated Cone Embodiment (EVACC-FC 300): FIGS. 18-21

**[0127]** Referring now to FIG. 18, a fourth EVACC embodiment 300, anterograde blood flow is controlled or regulated using a fenestrated cone concept hereinafter the EVACC-FC 300, which is a hybrid version of the EVACC-FCC 10 and the EVACC-SAR 100. The EVACC-FC 300 is substantially similar to the previously described EVACC-FCC 10 with the exception of the occlusion barrier 340, which tapers down to a conically-shaped fenestrated conduit 350, rather than a cylindrical fenestrated conduit 50. As with the EVACC-FCC 10 , retraction or deployment of the conically-shaped fenestrated conduit 350 out of the delivery sheath 360 regulates flow by causing perforations 352 to be covered or exposed and the diameter of the conical portion 350 to be enlarged or reduced as retracted into the delivery sheath 360.

**[0128]** FIG. 19 is a component view of the EVACC-FC 300, comprising an endovascular wire 320 having a J-tip 322, a tapered nose cone 325 for receiving the distal end 334 of a wire basket architecture 330, an occlusion barrier 340 having a conically-shaped fenestrated conduit 350 with perforations 352, and a delivery sheath 360. The occlusion barrier 340 comprises a cup-shaped barrier portion 342 having an upstream perimeter 344. The wire basket architecture 330 includes a throat wire assembly 332, which expands to deploy the fenestrated cone 350. The fenestrated cone 350 includes a downstream end orifice 354.

**[0129]** Referring now to FIG., 20, a perspective view of the occluding portion of the EVACC-FC 300 is illustrated, looking into the interior of the cup 342 of the occlusion barrier 340 and revealing the perforations 352. The occlusion barrier includes a cup-shaped diverter 342 having an upper perimeter 344.

**[0130]** In FIG. 21, a bottom perspective view is provided illustrating the conically-shaped fenestrated conduit 350 and associated perforations 352. Flow is adjustable from a fully

occluded state to a partially occluded state by advancing or retracting the delivery sheath 360 over the conically shaped fenestrated conduit 350.

**[0131]** Peripheral Internal Constriction Embodiment (EVACC-PIC 400): FIGS. 22-25

**[0132]** Referring now to FIG. 22, a side elevation view of a fifth EVACC embodiment 400 of the invention, where anterograde blood flow is controlled or regulated using a peripheral internal constriction (PIC) wire mesh structure 450, hereinafter referred to as the EVACC-PIC 400. The EVACC-PIC 400 comprises an central guide wire 420 for moving the EVACC-PIC 400 through the vascular to a targeted location. A distal tapered nose cone 425 is slidably received onto the central guide wire 420. At its base, the nose cone 425 is sized to receive a distal end 434 of an egg-shaped wire basket architecture 430 where each of the support wires converges to form a tip. The wire basket architecture 430 is partially enveloped by an occlusion barrier 440 made of appropriate collapsible and expandable material, such as ePTFE, polyester or other material having similar characteristics. Upon deployment within an artery, the memory wire architecture 430 and the occlusion barrier 440 expand to create a cup-shaped diverter 442. The diverter 442 expands to appose the arterial wall. The occlusion barrier 440 includes an upper perimeter 444 and an extended neck 446. The PIC wire structure 450, which is a wire mesh structure comprising a cylindrical, helically-wound braid, is positioned within the lumen of the extended neck 446 and the extended neck 446 and PIC wire structure 450 are joined to each other. The extended neck 446 includes a downstream orifice 454 that is deployed out the end of the delivery sheath 460 to allow flow when the occlusion barrier 440 is deployed and the extended neck 446 open.

**[0133]** Referring now to FIG. 23, the individual components of the EVACC-PIC 400 are illustrated and described in greater detail. The notable difference includes the PIC wire architecture 450 and the extended neck 446 of the occlusion barrier 440. In use, the PIC wire architecture is lengthened to reduce diameter; shortened to increase diameter. In one aspect, the extended neck 446 may be constructed of a version of ePTFE, polyester or other appropriate material having sufficient elasticity to accommodate the manipulation of the PIC wire architecture 450 from a closed to open state.

**[0134]** Referring now to FIG. 24, a top perspective view looking into the interior of the occlusion barrier 440 of the EVACC-PIC 400 is provided. The PIC wire architecture 450 is deployed within the lumen of the extended neck 446 of the occlusion barrier 440. The memory wire architecture 430 expands to deploy the occlusion barrier 440, creating the cup 442 and extended neck 446. The perimeter 444 of the occlusion barrier apposes and conforms to the shape of the interior of the blood vessel, thereby forming a cup to funnel flow into the extended

neck 446 and through the proximal orifice. The distal end 434 of the memory wire architecture 430 is captured within the conical tip 425.

**[0135]** Turning now to FIG. 25, a bottom perspective view of the EVACC-PIC 400 in a fully deployed state is provided, illustrating the bottom portion of the occlusion barrier 440 in greater detail. The means for flow control comprises the PIC wire architecture 450 in conjunction with the extended neck 446 and the occlusion barrier orifice 454.

**[0136]** In a fully deployed state, the EVACC-PIC 400 is actuated by the retraction or extension of an inner pull wire 456 that causes the PIC wire structure 450 to extend and reduce its diameter, or, shorten and expand its diameter. The proximal orifice 454 will increase or decrease in size as well, in correlation to the lengthening or shortening of the PIC wire structure 450. The individual wires of the PIC wire structure are threaded together in a manner similar to a finger trap toy, wherein extending the PIC wire structure causes the individual wires to rotate and mesh more closely together, thereby increasing resistance to flow caused by the restriction within the extended neck 446. Thus, upstream and downstream blood pressure and flow through the EVACC-PIC 400 may be adjusted and controlled. The material used to form the extended neck 446 will have sufficient elasticity to stretch and narrow in correlation with the PIC wire structure 450.

**[0137]** Lasso Aperture Embodiment (EVACC-LA 500): FIGS. 26-29

**[0138]** Referring now to FIG. 26, in a sixth embodiment 500 of the invention, where anterograde blood flow is controlled or regulated using a lasso aperture concept, hereinafter the EVACC-LA 500. A wire basket architecture 530 narrows to a throat 532 that may be variably occluded by the retraction of wires 550 configured to narrow the aperture 554 when tension is placed on the wires. The EVACC-LA further includes a central guidewire 520 having a J-tip 522 for guiding the device to a target location within a patient's vasculature. A distal end 534 of the wire basket architecture is captured within a tapered cone 525. The wire basket architecture 530, which may be constructed using shape memory materials, is enveloped by and bonded to an occlusion barrier 540 forming an expandable and collapsible cup 542. The occlusion barrier 540 may be made of ePTFE, polyester or other similar material. The cup 542, when deployed, includes a top edge 544, which will appose the interior wall of the blood vessel, and a proximal orifice 554, through which flow will be diverted when in an open state. A lasso wire arrangement 550 is slidably joined with the proximal orifice 554. Manipulation of the lasso wire arrangement 550 causes the proximal orifice 554 to either increase or decrease in diameter, thereby regulating flow through the proximal orifice 554 and establishing a pressure

differential across the proximal orifice 554. The occlusion barrier 540 and wire basket architecture 530 is delivered to a specific location in the vascular by the delivery sheath 560.

**[0139]** Referring now to FIG. 27, an enlarged exploded front elevation view of the individual distal components of the EVACC-PIC 500 is provided. The EVACC-LA 500 comprises an endovascular guide wire 520 having a J-tip 522, a tapered nose cone 525 for receiving a distal end 534 of the wire basket architecture 530, a central structural wire 550 serving as the lasso, an occlusion barrier 540 deployed to form a cup 542 having a perimeter edge 544 and a downstream orifice 554. A delivery sheath 560 serves as the means for transporting the occlusion barrier 540 to a targeted location.

**[0140]** Referring now to FIG. 28, a top perspective view into the interior of the cup 542 of the EVACC-LA 500 is provided. A lasso wire arrangement 550 extends to and is slidably bonded within a rim 552 of the proximal orifice 554. The throat 532 of the EVACC-LA 500 blossoms through the orifice 554 and continues to form the egg-shaped wire basket architecture 530.

**[0141]** Referring now to FIG. 29A, a bottom perspective view of the EVACC-LA 500 emphasizes the proximal orifice 554 of the occlusion barrier 540 in a fully deployed state, extended out of the delivery sheath 560.

**[0142]** Referring now to FIG. 29B, an enlarged view of the occluding portions of the EVACC-LA 500 in a fully deployed state is shown in greater detail. The cup 542 includes an orifice 554 at a downstream end. The throat wires 532 expand to fully deploy and open the proximal orifice 554 to allow flow. The lasso wires 550 extended into the orifice 554 such that retraction of the wires 550 cause the orifice 554 to be cinched down to a smaller size, thereby reducing flow through the proximal orifice 554.

**[0143]** Rotating Cups Embodiment (EVACC – RC 600): FIGS. 30-34B

**[0144]** Referring now to FIG. 30, in a sixth alternative embodiment 600 of the invention, where anterograde blood flow is controlled or regulated using a rotating mated cups concept, hereinafter, the EVACC-RC 600. The EVACC-RC 600 comprises two mating cup-shaped membranes supported by a dual wire basket structure 630, 652. A downstream (first) cup 640 is supported by and bonded to first wire framework 630. The downstream cup 640 includes a first set of openings 643 (e.g., two slots) that serve as passageways to allow blood flow when uncovered. An upstream (second) cup 650 is supported by and bonded to a separate (second) wire framework 652. The upstream cup 650, which includes a second set of openings 653 (e.g., two slots), is rotatable to cover the slots 643 to varying degrees to increase or restrict blood flow downstream of the occlusion barrier 640. When openings 653 coincide with openings 643, flow through the occlusion barrier 640 occurs.

**[0145]** Referring now to FIG 32A, an enlarged bottom perspective view of the EVACC-RC 600 fully deployed out the delivery sheath 660 illustrates the arrangement of the first wire framework 630 enveloping the downstream cup 640. In this state, the openings 643 are covered by the upstream cup 650. FIG. 32B is the same view but with the upstream cup 650 having been rotated such that the openings 643 are fully uncovered to allow anterograde flow through the openings 643 and to the downstream vasculature. FIG. 33A is equivalent to FIG. 32A in a closed state, but taken from a top or upstream perspective; FIG 33B is equivalent to FIG. 32B in an open state, but likewise taken from a top or upstream perspective

**[0146]** Referring now to FIG. 34A and FIG. 34B, a top plan view of the EVACC-RC 600 emphasizes the view into the two mating cup-shaped membranes and illustrates the J-tip 622 and first wire framework 630. FIG. 34A shows the EVACC-RC 600 in a fully closed state, whereby the flow is fully restricted. FIG. 34B shows the EVACC-RC 600 in a fully open state, whereby the upstream cup membrane 650 is in a rotated position such that the slots 643 of the downstream cup membrane 640 are fully uncovered, allowing maximum blood flow.

**[0147]** Referring now to FIG. 35A and FIG. 35B, a bottom plan view of the EVACC-RC 600 is provided. FIG. 35A shows the EVACC-RC 600 in a fully closed state. The slots 643 of the downstream cup membrane 640 are aligned such that flow is blocked by the upstream cup membrane 650. FIG. 35B shows the EVACC-RC 600 in a fully open state, where the slots 643 are uncovered from the upstream cup membrane 650 such that fluid may pass unrestricted through the EVACC-RC 600.

**[0148]** Deformable Cup Embodiment (EVACC-DC 700): FIGS. 36A-42B

**[0149]** Referring now to FIG. 36A, according to a seventh alternative embodiment 700 of the invention, where anterograde blood flow is controlled or regulated using a deformable mating cups concept, hereinafter, the EVACC-DC 700. The EVACC-DC 700 comprises two occluding barriers (e.g., cup-shaped membranes) 740, 750 supported by a wire basket architecture 730. The first cup-shaped membrane 740 is positioned downstream of the second cup-shaped membrane 750. The first cup-shaped membrane 740 has multiple interstitial openings 743 around its perimeter. The second cup-shaped membrane 750, which is positioned upstream of the first occluding element 740,comprises a flexible membrane that adapts to the shape of the wire basket architecture 730, and thus, the shape of the first cup-shaped membrane 740. In a closed state, the interstitial openings 743 of the first cup-shaped membrane 740 are covered by the second cup-shaped membrane 750 and anterograde blood flow through the EVACC-DC 700 is minimized or stopped.

**[0150]** Referring now to FIG. 36B, flow is increased by linear translation of a center wire 720 to lift a center portion 727 of the second cup-shaped membrane 750 off the first cup-shaped membrane 740, causing the interstitial openings 743 of the first cup-shaped membrane 740 to be uncovered. FIG. 36B shows the EVACC-DC 700 in an open state with interstitial openings 743 uncovered. The EVACC-DC 700 includes a central aperture 752 that acts as a choke or restriction on flow. The aperture 752 size may be varied to change the amount of flow. However, the size of the aperture 752 correlates with the size of a bottom center portion of the first cup-shaped membrane 740 such that flow may be effectively stopped when the second cup-shaped membrane 750 is laid flush against the interior of the first cup-shaped membrane 740.

**[0151]** Referring now to FIG. 37, a semi-exploded view of components of the EVACC-DC 700 is shown. Central guide wire 720 having J-tip 722 allows the EVACC-DC 700 to be carefully deployed through a patient's vascular to reach a desired occlusion location. Tapered cone 725 is slidably received on the central guide wire 720 and likewise is sized to receive the distal tip 734 of the wire framework 730. The second cup-shaped membrane 750 having a center wire structure 726 and orifice 727 is slidably received on the central guide wire 720. The first cup-shaped membrane 740 is likewise slidably received on the central guide wire 720 to mate with the second cup-shaped membrane 750. Both the first cup-shaped membrane 740 and the second cup-shaped membrane 750 are disposed within the interior of the wire framework 730. The assembly is delivered to a desired location for occlusion via the delivery sheath 760.

**[0152]** Referring now to FIG. 38A and FIG. 38B, a top plan view of the EVACC-DC 700 is provided. FIG. 38A shows the EVACC-DC 700 in a closed state, with interstitial openings 743 covered such that flow is restricted. FIG. 38B shows the EVACC-DC 700 in an open state, with the second cup-shaped membrane 750 lifted at its center such that the aperture 752 rises off the first cup-shaped membrane 740. As a result, the interstitial openings 743 are uncovered, allowing blood flow to pass through the orifice 752 and through the interstitial openings 743 to the remainder of the downstream vascular network.

**[0153]** Referring now to FIG. 39A and FIG. 39B, a bottom plan view of the EVACC-DC 700 is provided. FIG. 39A shows the EVACC-DC 700 in a fully closed state. The interstitial openings 743 of the first cup-shaped membrane 740 aligned with the second cup-shaped membrane 740 such that flow is blocked by the second cup-shaped membrane 750. FIG. 39B shows the device 700 in a fully open state, whereby the interstitial openings 743 are uncovered such that blood flow may occur, constrained by the size of the orifice 752.

**[0154]** Referring now to FIG. 40A, a cross-sectional view of the EVACC-DC 700 in FIG. 38A taken along section line 3-3 is shown. FIG. 40A shows the EVACC-DC 700 in a fully closed state, in which fluid flow is blocked. Referring now to FIG. 40B, a cross-sectional view of the EVACC-DC 700 in FIG. 38B taken along section line 4-4 is shown. FIG. 40B shows the EVACC-DC 700 in an open state. The center portion of the second cup-shaped membrane 750 is in a lifted position, causing the interstitial openings 743 between the petals 745 of the first cup-shaped membrane 740 to be uncovered and allowing blood to flow through the orifice 752 and the interstitial openings 743 to the remainder of the vascular.

**[0155]** Referring now to FIG. 41A, an enlarged perspective view of the interior of the EVACC-DC 700 in a fully closed state is shown. FIG. 41B is the same perspective view but with the second cup-shaped membrane 750 raised to allow flow. FIG. 42A and FIG. 42B correspond to FIG. 41A and 41B, but from a bottom perspective view.

**[0156]** Although not specifically shown, applicable to several embodiments described herein, the EVACC may include one or more pressure sensors that communicate blood pressure measurements to an external display, an external control device, or both. The display provides pressure readings to the surgeon to inform the surgeon's operational decisions. Alternatively, the pressure data may be processed by the external control device, and then used by the control device to determine a desired level of flow restriction. For example, the control device can operate a rotary unit, such as a small stepper motor, to operate the central threaded guide, which may be configured to a) linearly translate the sheath back and forth over perforations in a fenestrated conduit, b) linearly translate a tension wire to constrict or expand a lasso, or c) pressurize or depressurize a captive balloon, for exampl. Additionally, the EVACC may also incorporate and provide automated control of the degree of flow restriction via an active control algorithm that determines adjustments based on the patient's physiologic status as determined by blood pressure, other relevant metrics and the assessment of the surgeon. A visual display and associated operational dashboard provides an active touch interface for use by the surgeon or a surgeon's assistant to actively control the operation of the EVACC once deployed. Where an automated control system is provided, the display provides relevant operational parameters and allows automated control to be overridden by the surgeon or assistant. The display may include icons that are selectable by touch, keyboard, mouse, voice or gesture. The interactive features will allow the surgeon or assistant to quickly select various desired flow and pressure conditions to achieve certain physiologic objectives and set desired operating parameters.

**[0157]** Although driven by a need to address treatment of soldiers injured on the battlefield, the EVACC, in its several embodiments described herein, has applicability that extends beyond

military and civilian trauma victims. Any patient with significant risk of hemorrhage will benefit from use of the EVACC to support regulation of distal aortic flow to augment vital perfusion to critical organs. In addition, patients that require increased diversion of blood flow to other portions of their body, such as the brain, can use the device, initially deployed to allow full flow, to gradually restrict downstream flow, and increase flow and pressure to those targeted areas. This approach for augmenting central aortic pressure to perfuse the heart, lungs and brain would extend beyond hemorrhagic shock to include any patient with hypotension and shock that needed augmentation of pressure to keep vital organs alive while other therapeutic measures were undertaken or to support physiology during transport to definitive care.

**[0158]** In addition, although shown and described herein as applicable to use in human subjects, the EVACC is likewise adaptable to use in animal subjects.

**[0159]** The present invention has been particularly shown and described with respect to certain preferred embodiments and features thereof. However, it should be readily apparent to those of ordinary skill in the art that various changes and modifications in form and detail may be made without departing from the spirit and scope of the inventions as set forth herein and the appended claims.

WHAT IS CLAIMED IS:

1. An endovascular variable aortic occlusion device to modulate anterograde blood flow, comprising:

a central guide wire;

a distal end portion comprising

a first wire framework that is radially expandable and collapsible, wherein the first wire framework is configured to radially expand to a sufficient radial circumference to engage with an aortic wall within a lumen of an aorta to secure the device within the aorta; and

an occlusion barrier surrounding at least a portion of the first wire framework and attached thereto, wherein an upper perimeter of the occlusion barrier contacts the aortic wall when the wire framework is radially expanded, and wherein the occlusion barrier includes at least one adjustable passageway therein having an available flow area to modulate the anterograde blood flow;

a delivery sheath that is extensible and retractable, wherein a collapsed form of the first wire framework and the occlusion barrier of the distal end portion are contained therein during delivery of the device into the lumen of the aorta; and

a proximal end portion comprising a hand piece having a stationary portion and a movable portion, wherein the movable portion controls a translational movement of the delivery sheath relative to the wire framework to enable unsheathing and radial expansion of the first wire framework, and optionally wherein the movable portion adjusts the available flow area of the at least one adjustable passageway to modulate the anterograde blood flow.

2. The endovascular variable aortic occlusion device of claim 1, wherein the occlusion barrier comprises a conduit extending proximally therefrom, wherein the at least one adjustable passageway comprises a plurality of orifices in the conduit, and wherein the translational movement of the delivery sheath relative to the first wire framework changes a number of orifices in an uncovered state to adjust the available flow area for anterograde blood flow.

3. The endovascular variable aortic occlusion device of claim 2, wherein the conduit comprises a cylindrical conduit or a conical conduit.

4. The endovascular variable aortic occlusion device of claim 1, wherein the at least one adjustable passageway of the occlusion barrier comprises a single circular orifice at a proximal

terminal end of the occlusion barrier, and wherein the single circular orifice has a diameter that defines the available flow area for anterograde blood flow.

5. The endovascular variable aortic occlusion device of claim 4, wherein the translational movement of the delivery sheath relative to the first wire framework adjusts the diameter of the single circular orifice to adjust the available flow area for anterograde blood flow.

6. The endovascular variable aortic occlusion device of claim 4, further comprising:

a lasso wire comprising a distal end wire segment configured in a semi-circle having two end portions, and a wire portion extending from each end portion and terminating at the movable portion of the hand piece, wherein the first wire framework passes through the semicircle of the distal end wire segment; and

an overlapping portion extending from the proximal terminal end of the occlusion barrier that conforms to the distal end wire segment and thereby forms the single circular orifice at the proximal terminal end of the occlusion barrier,

wherein adjustment of the movable portion of the hand piece effects a translational motion of the wire portion and alters the diameter of the single circular orifice to adjust the available flow area for anterograde blood flow.

7. The endovascular variable aortic occlusion device of claim 4, further comprising:

an inflatable obstructive member positioned adjacent the single circular orifice, wherein a portion of the inflatable obstructive member extends into the single circular orifice, and wherein inflation or deflation of the inflatable obstructive member adjusts a diameter of the portion of the inflatable obstructive member extending into the orifice to change the available flow area for anterograde blood flow.

8. The endovascular variable aortic occlusion device of claim 4, further comprising:

a conduit portion comprising an elastomeric wall that extends proximally from the occlusion barrier; and

a wire mesh structure comprising a cylindrical, helically-wound braid that is surrounded by the elastomeric wall of the conduit portion, wherein application of an extension force reduces a circumference of the wire mesh structure and the conduit portion, which thereby reduces a diameter of the single circular orifice.

9. The endovascular variable aortic occlusion device of claim 1, wherein the occlusion barrier surrounding at least a portion of the first wire framework comprises:

a first cup-shaped membrane having a first set of openings; and

a second cup-shaped membrane having a second set of openings, wherein the at least one adjustable passageway is formed by rotational alignment of the first and second set of openings to coincide, wherein at least one of the first or the second cup-shaped membrane is coupled to the movable portion of the hand piece, and wherein a rotational motion of the movable portion of the hand piece causes a relative rotation between the first and the second cup-shaped membrane to vary a degree of coincidence between the first and second set of openings.

10. The endovascular variable aortic occlusion device of claim 9, further comprising:

a second wire framework that is radially expandable and collapsible, wherein the second wire framework is disposed within a cavity formed by the first wire framework,

wherein the second cup-shaped membrane is positioned upstream relative to the first cup-shaped membrane, and wherein the first cup-shaped membrane is supported by and bonded to the first wire framework and the second cup-shaped membrane is supported by and bonded to the second wire framework.

11. The endovascular variable aortic occlusion device of claim 1, wherein the occlusion barrier surrounding at least a portion of the first wire framework comprises:

a first cup-shaped membrane bonded to the first wire framework, comprising interstitial openings around a perimeter of the first cup-shaped membrane; and

a second cup-shaped membrane positioned upstream relative to the first cup-shaped membrane, comprising a central aperture in a bottom portion, wherein the second cup-shaped membrane conforms to a distal surface of the first cup-shaped membrane, and wherein the central aperture and the interstitial openings do not coincide when mated together.

12. The endovascular variable aortic occlusion device of claim 11, wherein the central aperture in the bottom portion of the second cup-shaped membrane is coupled to the movable portion of the hand piece, and wherein a translational motion in a distal direction lifts the aperture and its surrounding region away from the distal surface of the first cup-shaped membrane to uncover at least a portion of the interstitial openings and permit anterograde blood flow.

13. The endovascular variable aortic occlusion device of claim 1, wherein the first wire framework comprises a memory-shape material.

14. The endovascular variable aortic occlusion device of claim 13, wherein the memory-shape material selected from a metal alloy, a polymer, or a combination thereof.

15. The endovascular variable aortic occlusion device of claim 2, wherein the occlusion barrier and the conduit are formed into a unitary body.

16. The endovascular variable aortic occlusion device of claim 1, wherein the occlusion barrier and the conduit are joined by glue, thermal fusion, or a mechanical mating arrangement.

17. The endovascular variable aortic occlusion device of claim 1, further comprising:

one or more pressure sensors to measure or record upstream and/or downstream blood pressure measurements, or

one or more flow meters to measure or record anterograde blood flowrate,

either of which optionally may be visually displayed on a display unit near the proximal end portion of the device.

18. The endovascular variable aortic occlusion device of claim 17, further comprising:

a control module programmed with operational parameters to provide automated control of:

the translational movement of the delivery sheath relative to the wire framework to enable unsheathing and radial expansion of the first wire framework, or

the available flow area of the at least one adjustable passageway to modulate anterograde blood,

wherein the operational parameters are based on (a) the upstream and/or downstream blood pressure measurements; or (b) a determined flowrate of anterograde blood flow.

19. The endovascular variable aortic occlusion device of claim 18, further comprising:

an electrically-powered rotary unit positioned at the proximal end portion that is coupled to a movable element at the distal end potion, wherein upstream or downstream blood pressure data or anterograde blood flowrate data is transferred to the control module, and wherein the

control module sends control signals to the electrically-powered rotary unit to cause translational or rotational movement of the movable element that adjusts the at least one adjustable passageway to regulate controlled anterograde blood flow.

20. The endovascular variable aortic occlusion device of claim 19, wherein the electrically-powered rotary unit, the display unit, and the control module are integrated into the hand piece at the proximal end portion.

21. An endovascular variable aortic occlusion device to control anterograde blood flow, comprising:

a central guide wire;

a distal end portion comprising

a first wire framework that is radially expandable and collapsible, wherein the first wire framework is configured to radially expand to a sufficient radial circumference to engage with an aortic wall within a lumen of an aorta to secure the device within the aorta; and

an occlusion barrier surrounding at least a portion of the first wire framework and attached thereto, wherein an upper perimeter of the occlusion barrier contacts the aortic wall when the wire framework is radially expanded, and wherein the occlusion barrier includes at least one adjustable passageway therein;

a delivery sheath that is extensible and retractable, wherein a collapsed form of the first wire framework and the occlusion barrier of the distal end portion are contained therein during delivery of the device into the lumen of the aorta; and

a proximal end portion comprising a hand piece having a stationary portion and a movable portion, wherein the movable portion controls a translational movement of the delivery sheath relative to the wire framework to enable unsheathing and radial expansion of the first wire framework, and optionally wherein the movable portion adjusts the at least one adjustable passageway.

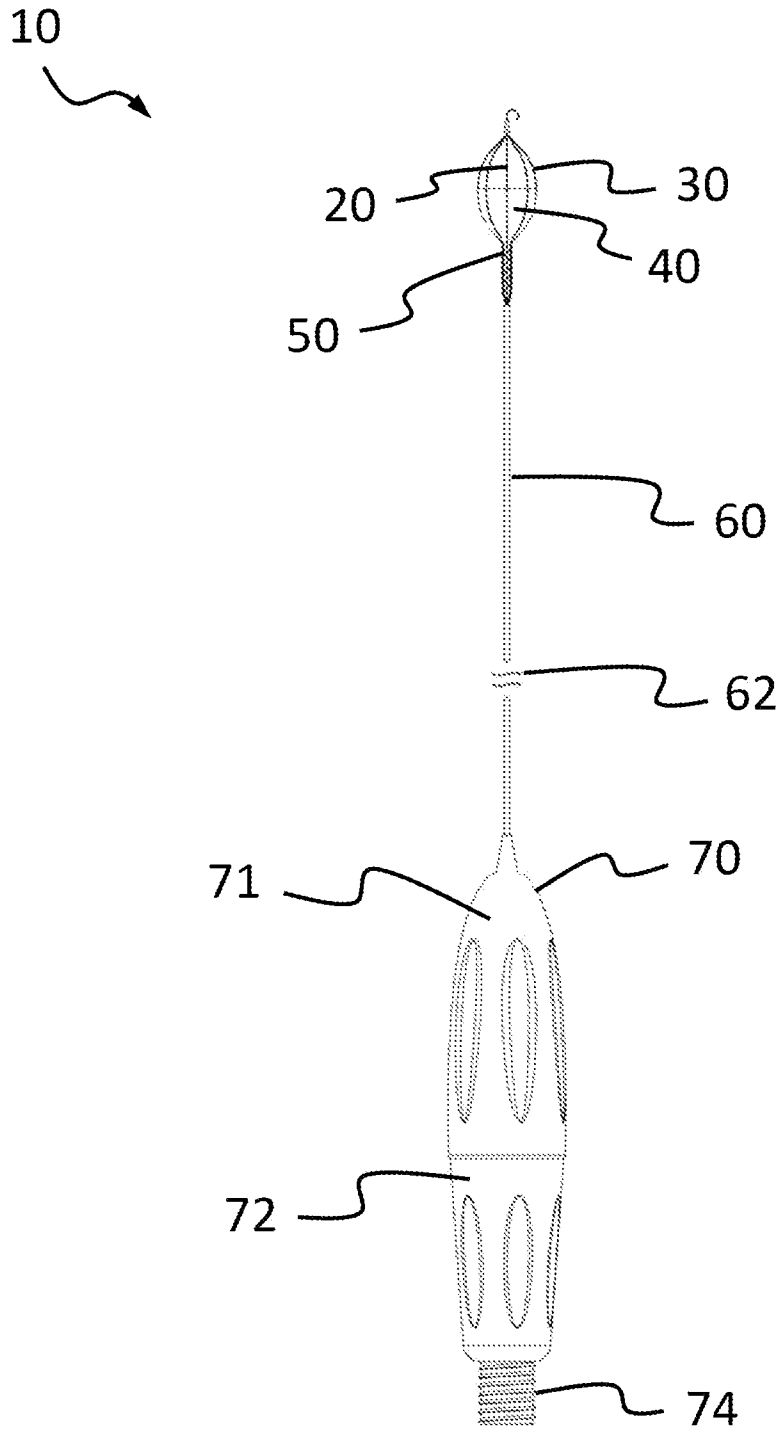


Fig. 1

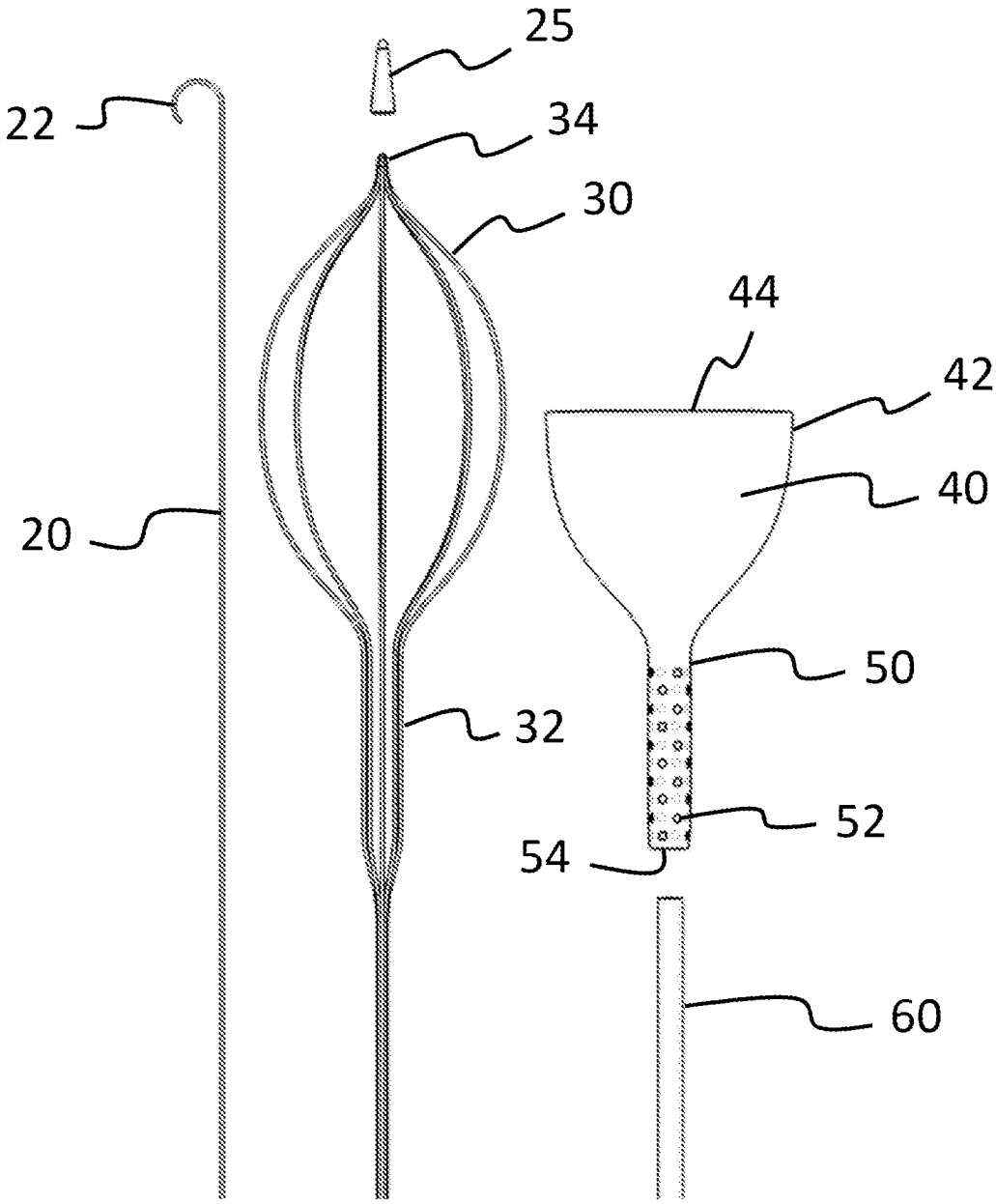


Fig. 2

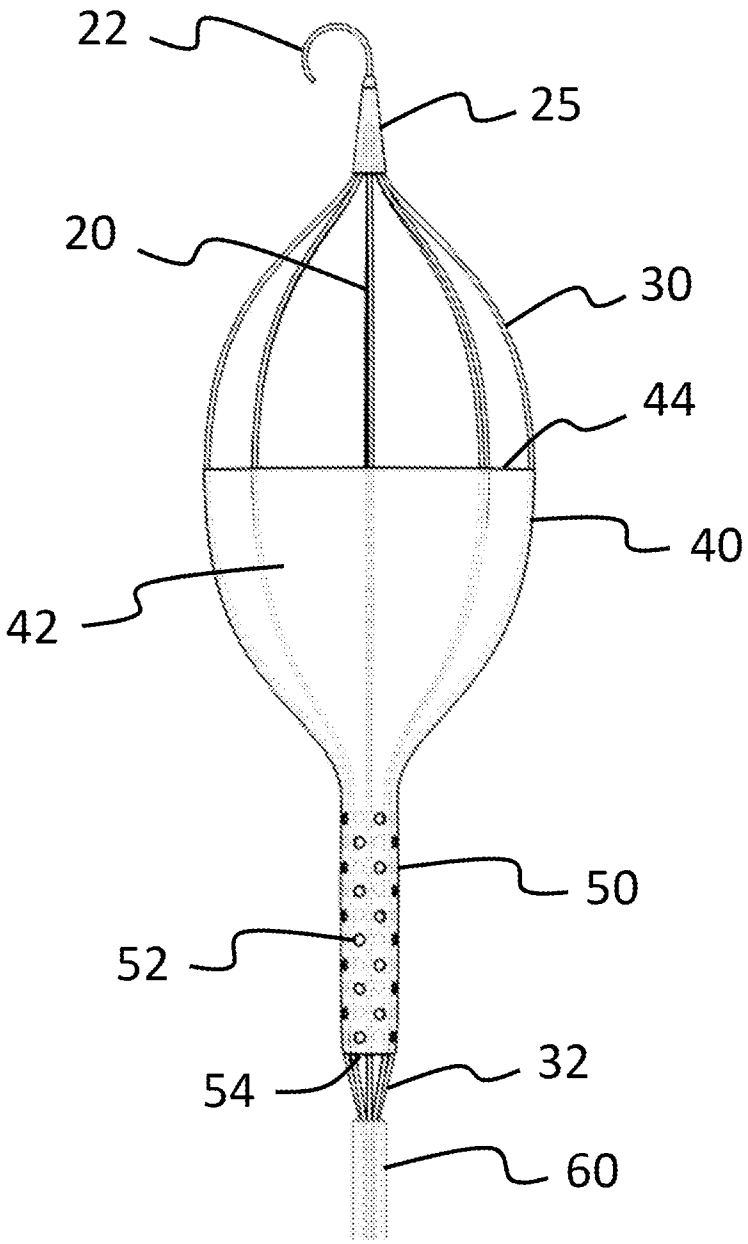


Fig. 3

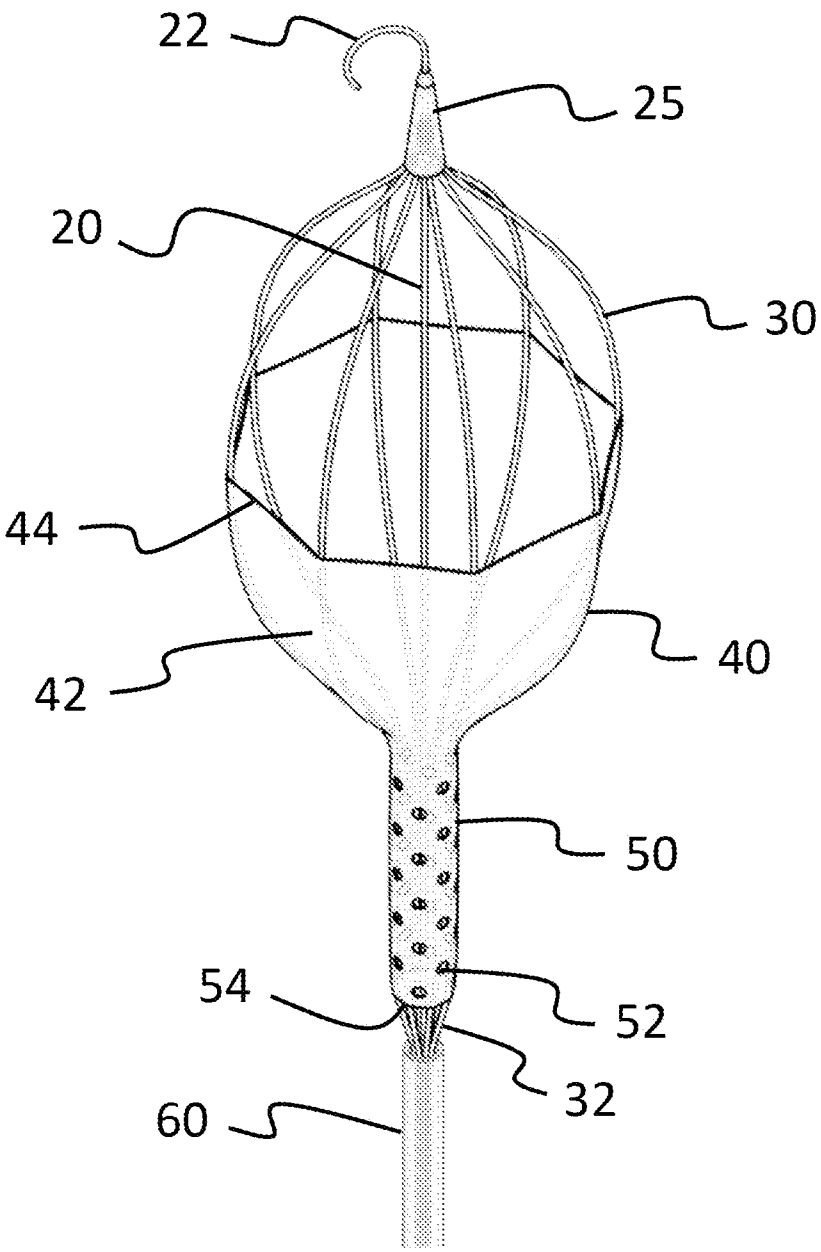


Fig. 4

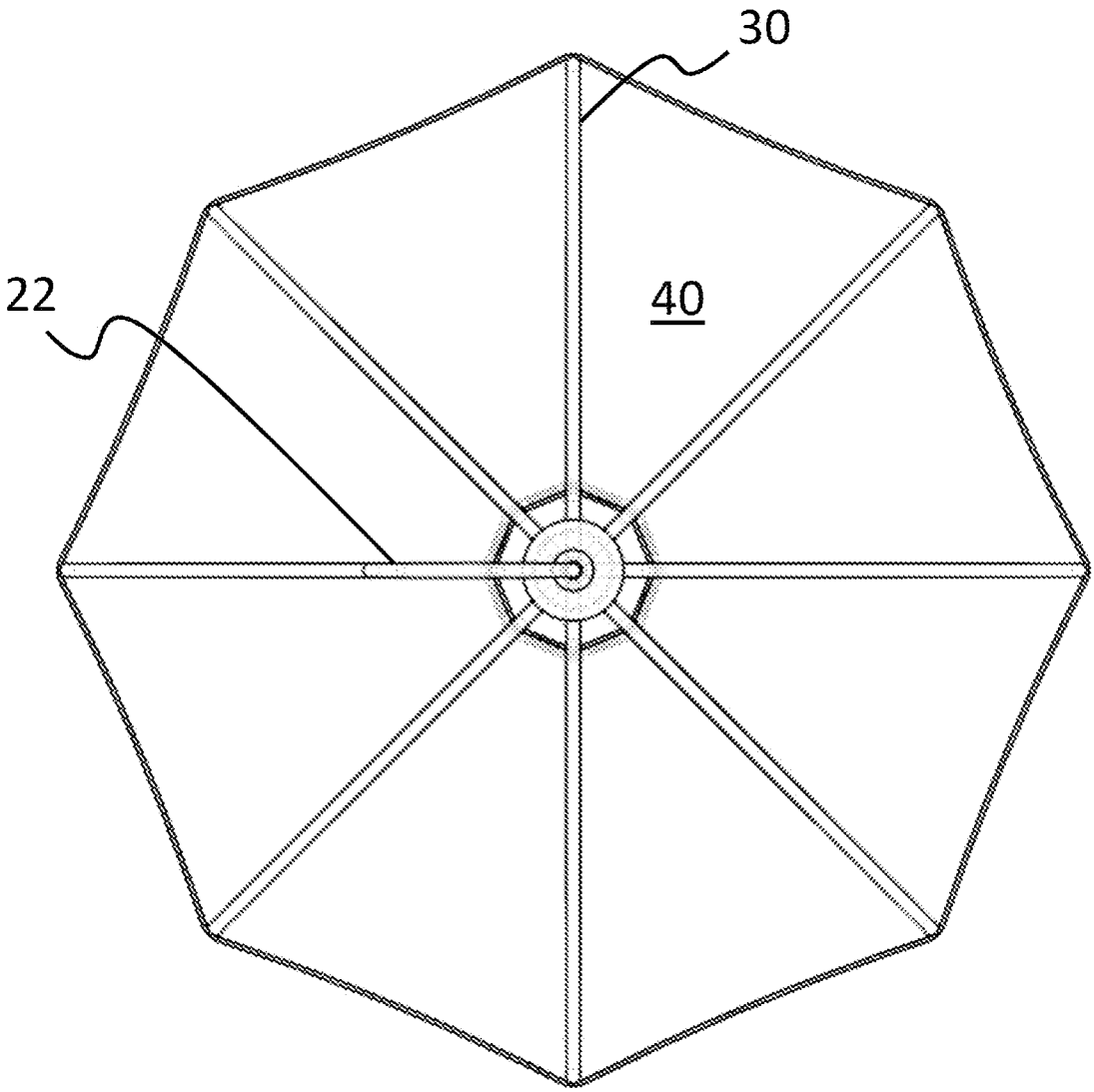


Fig. 5

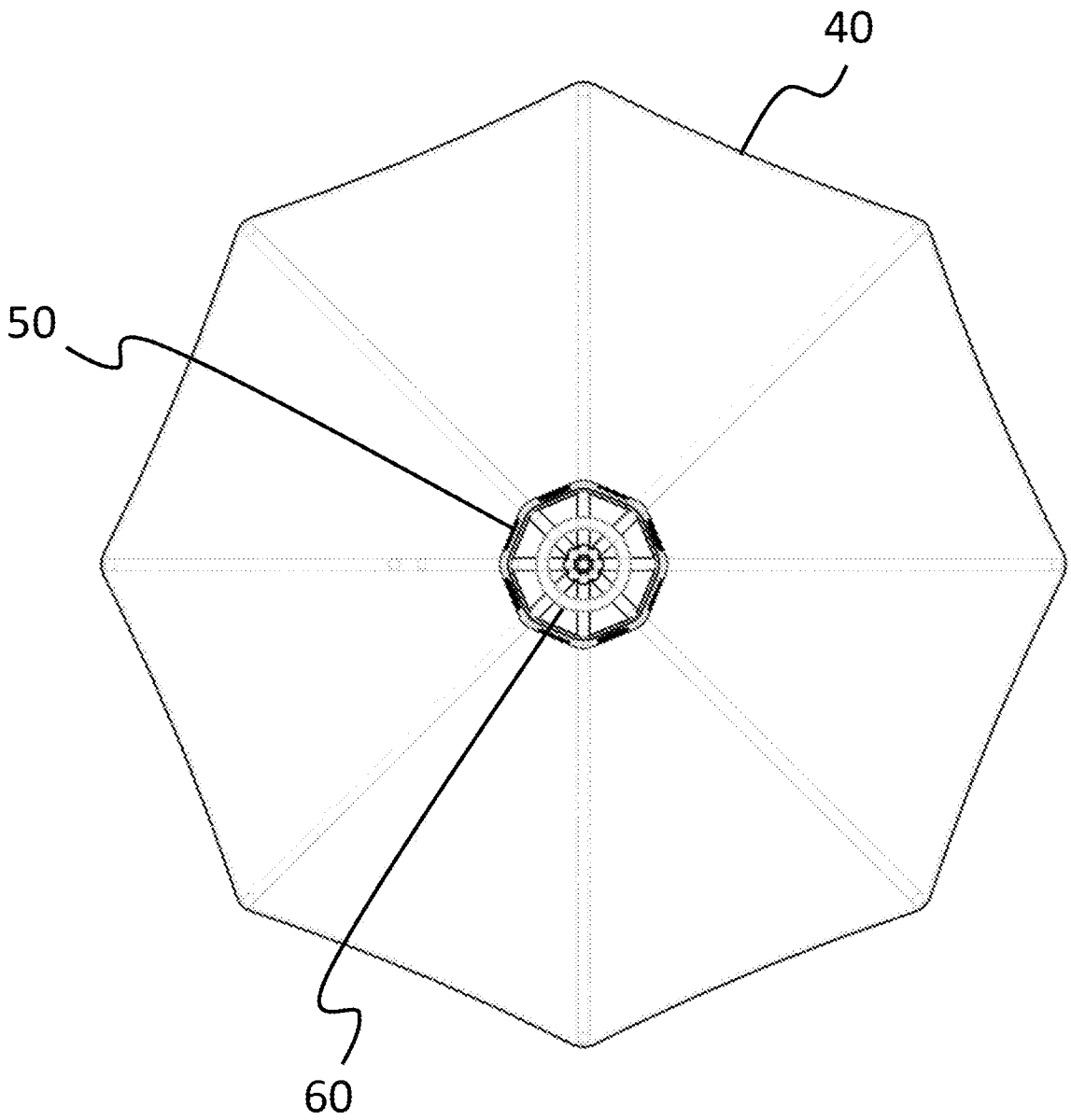


Fig. 6

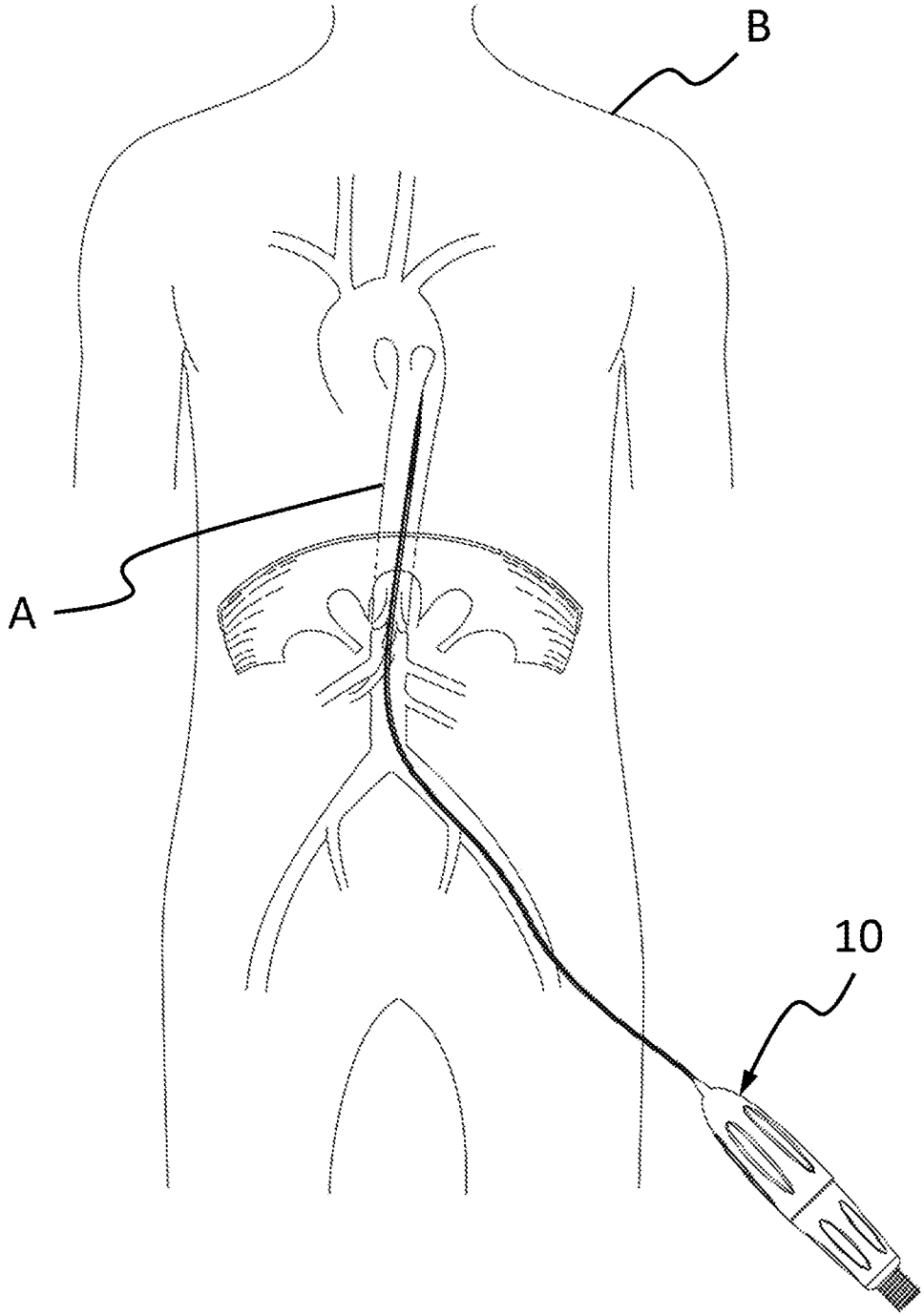


Fig. 7

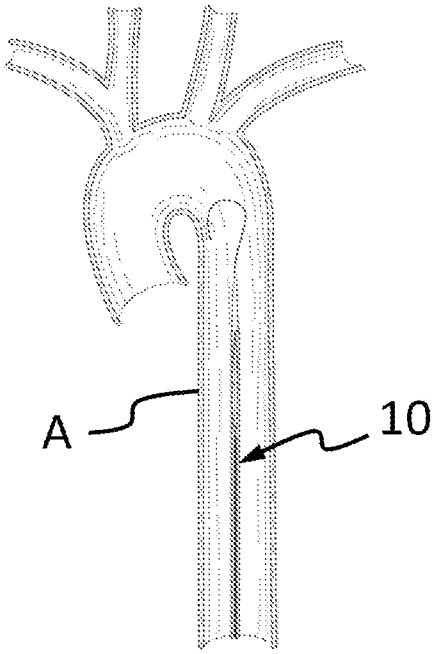


Fig. 8A

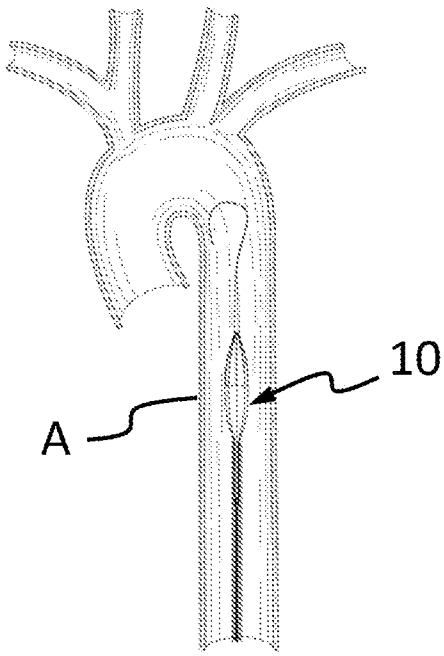


Fig. 8B

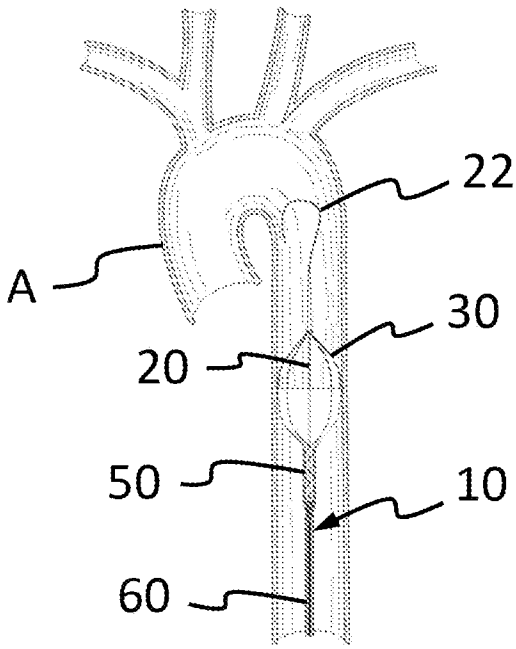


Fig. 8C

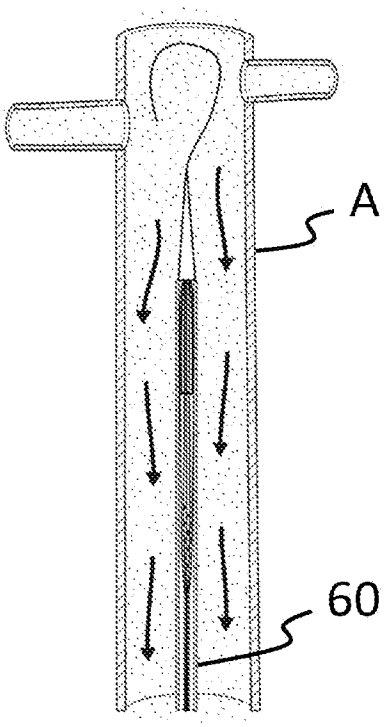


Fig. 9A

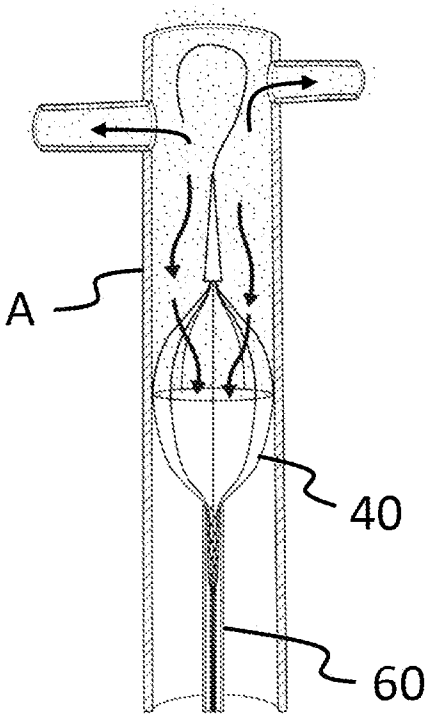


Fig. 9B

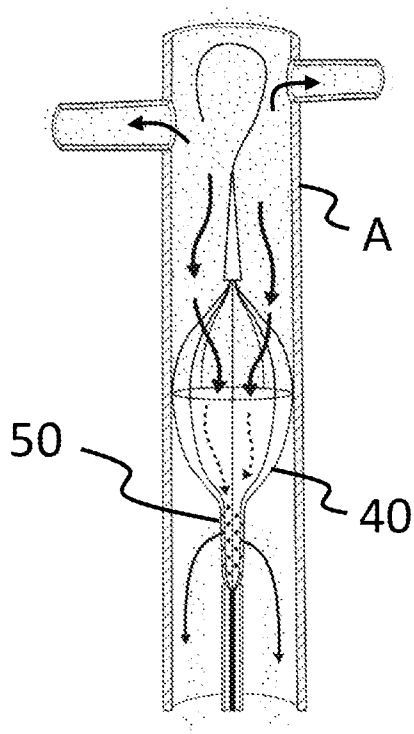


Fig. 9C

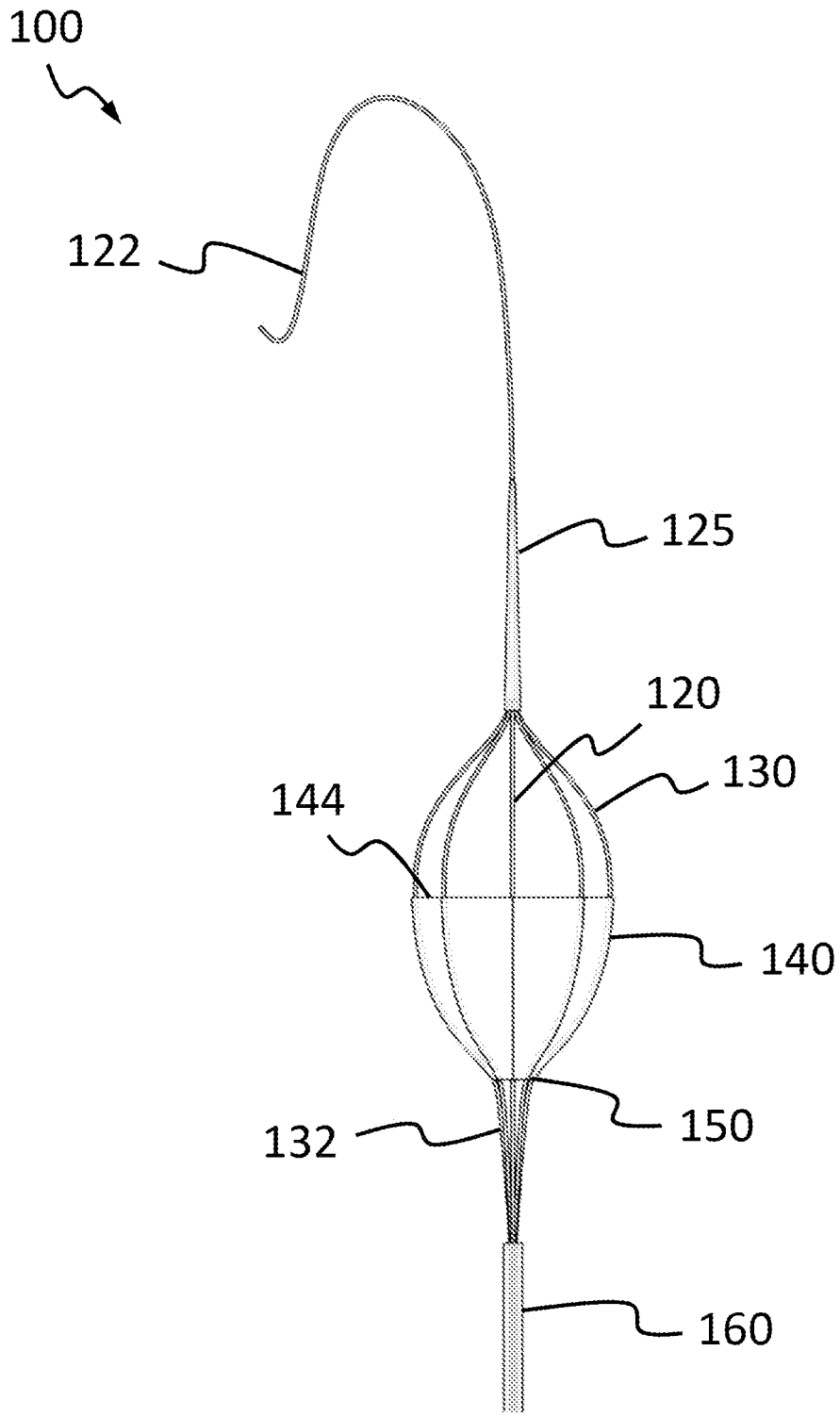


Fig. 10

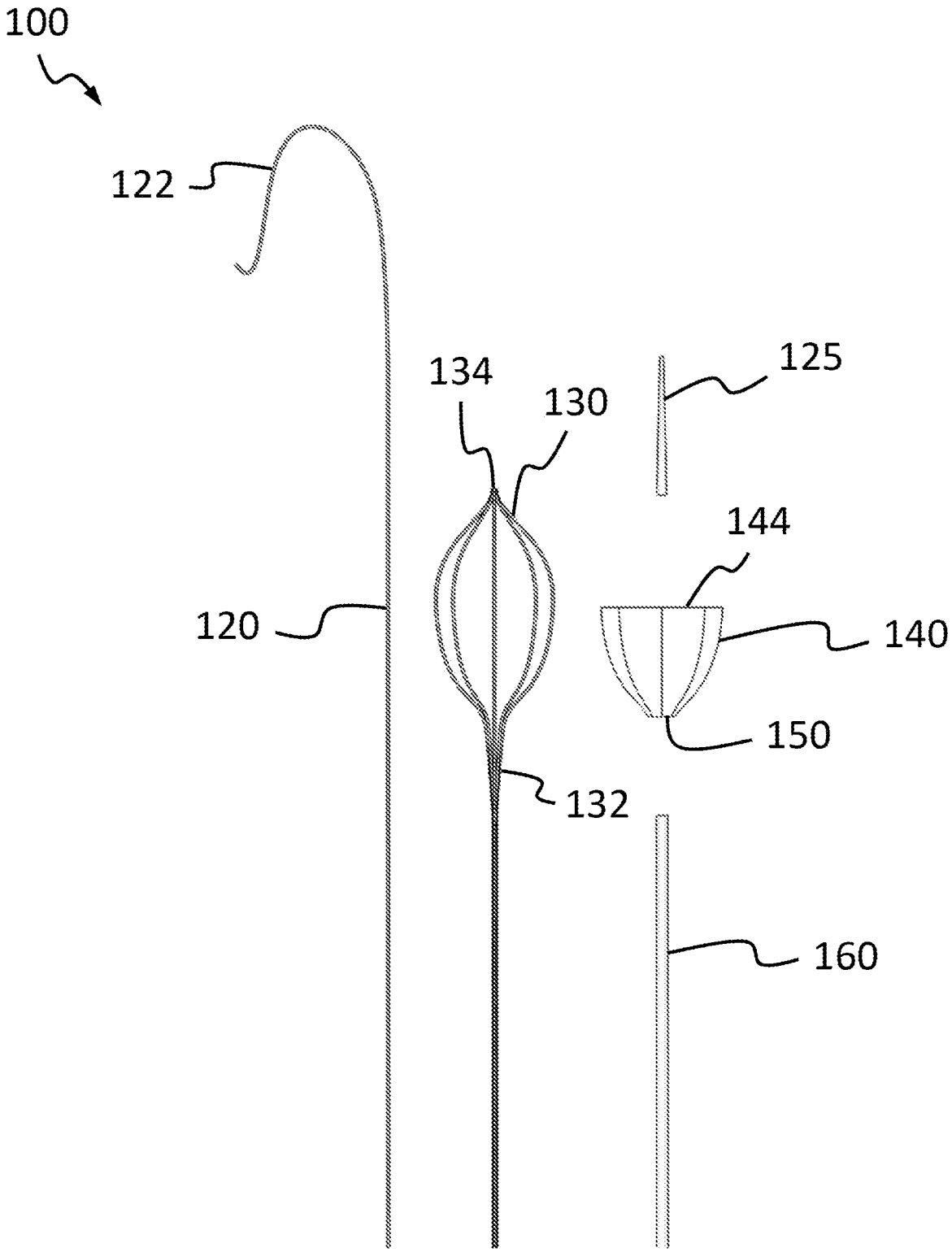


Fig. 11

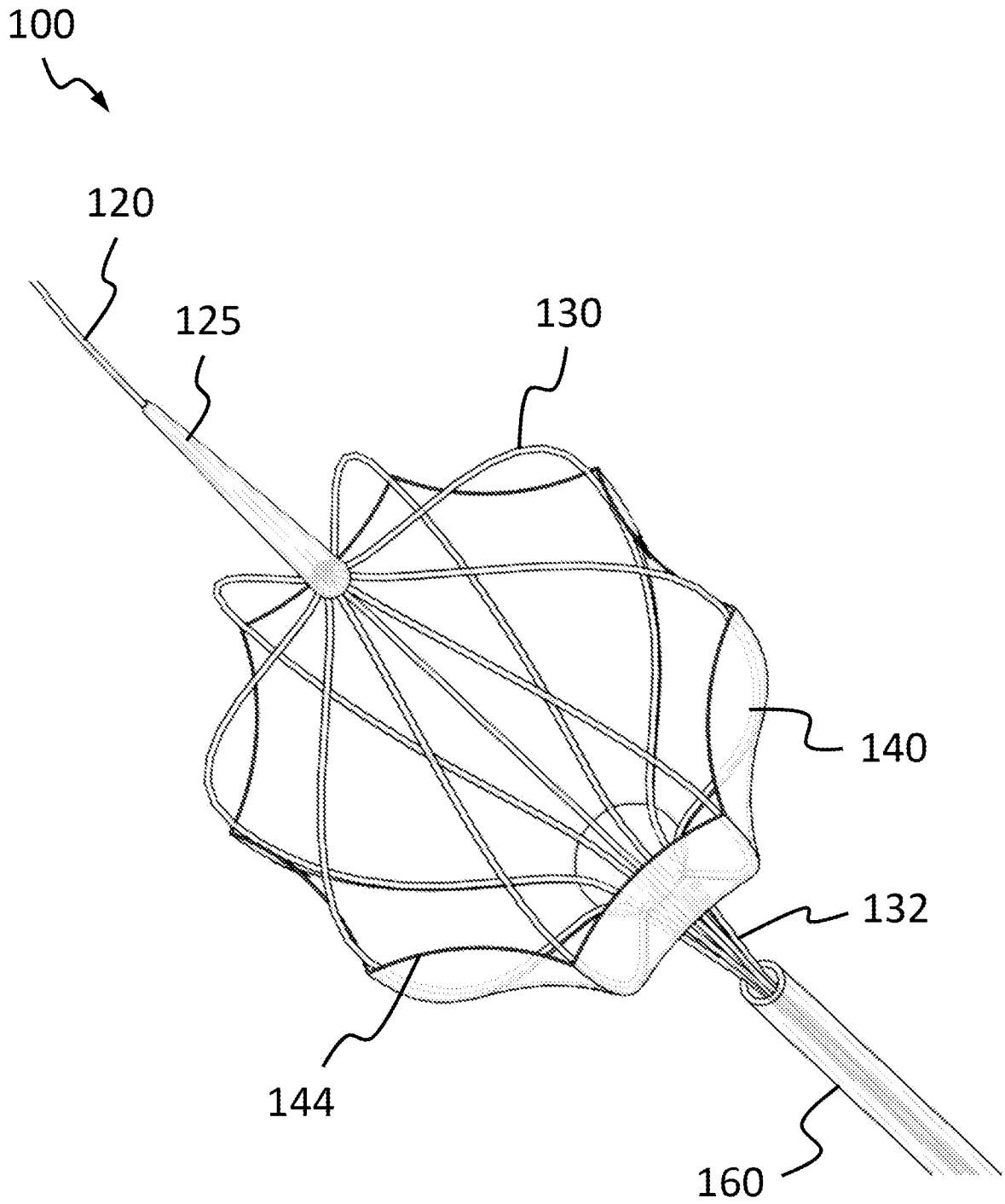


Fig. 12

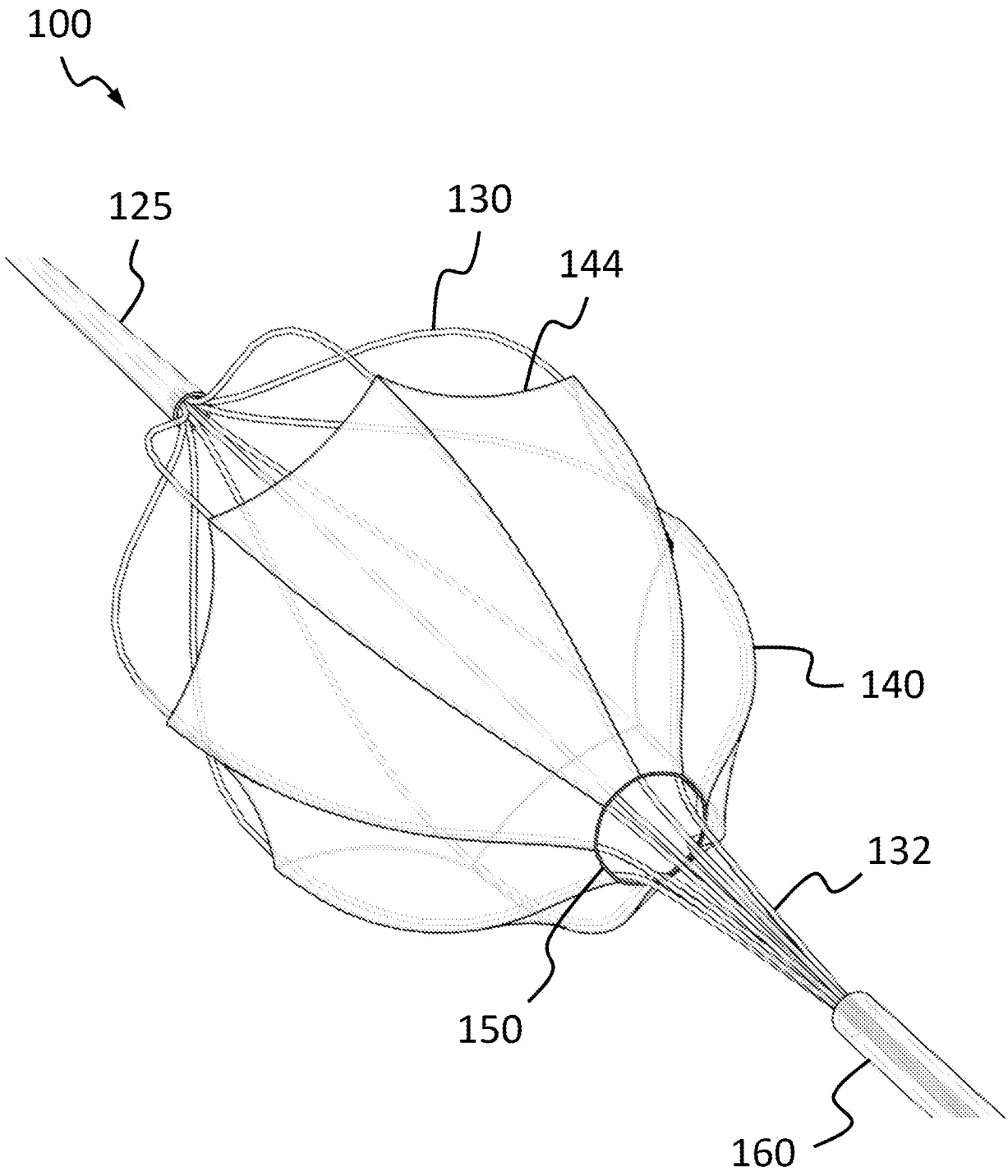


Fig. 13

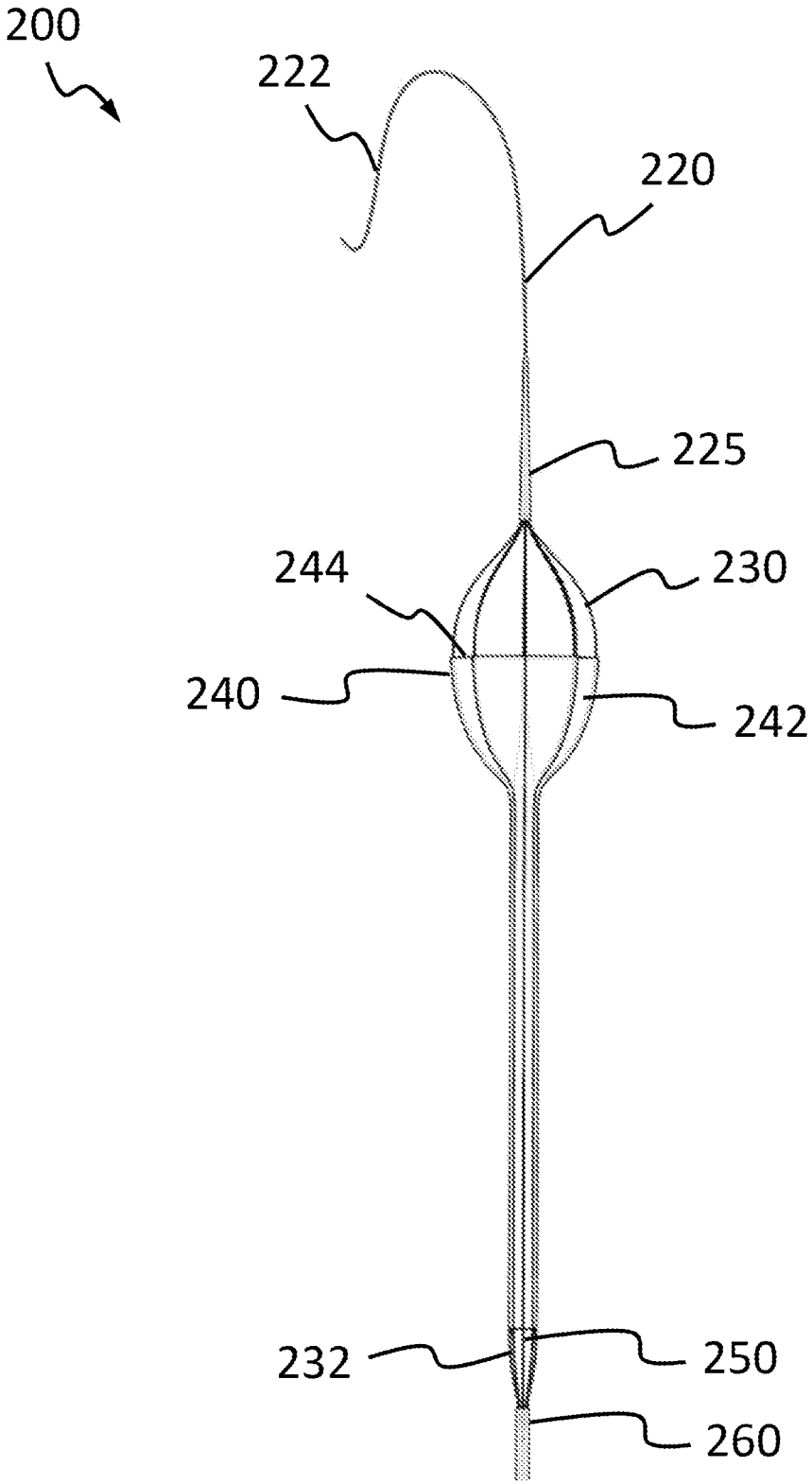


Fig. 14

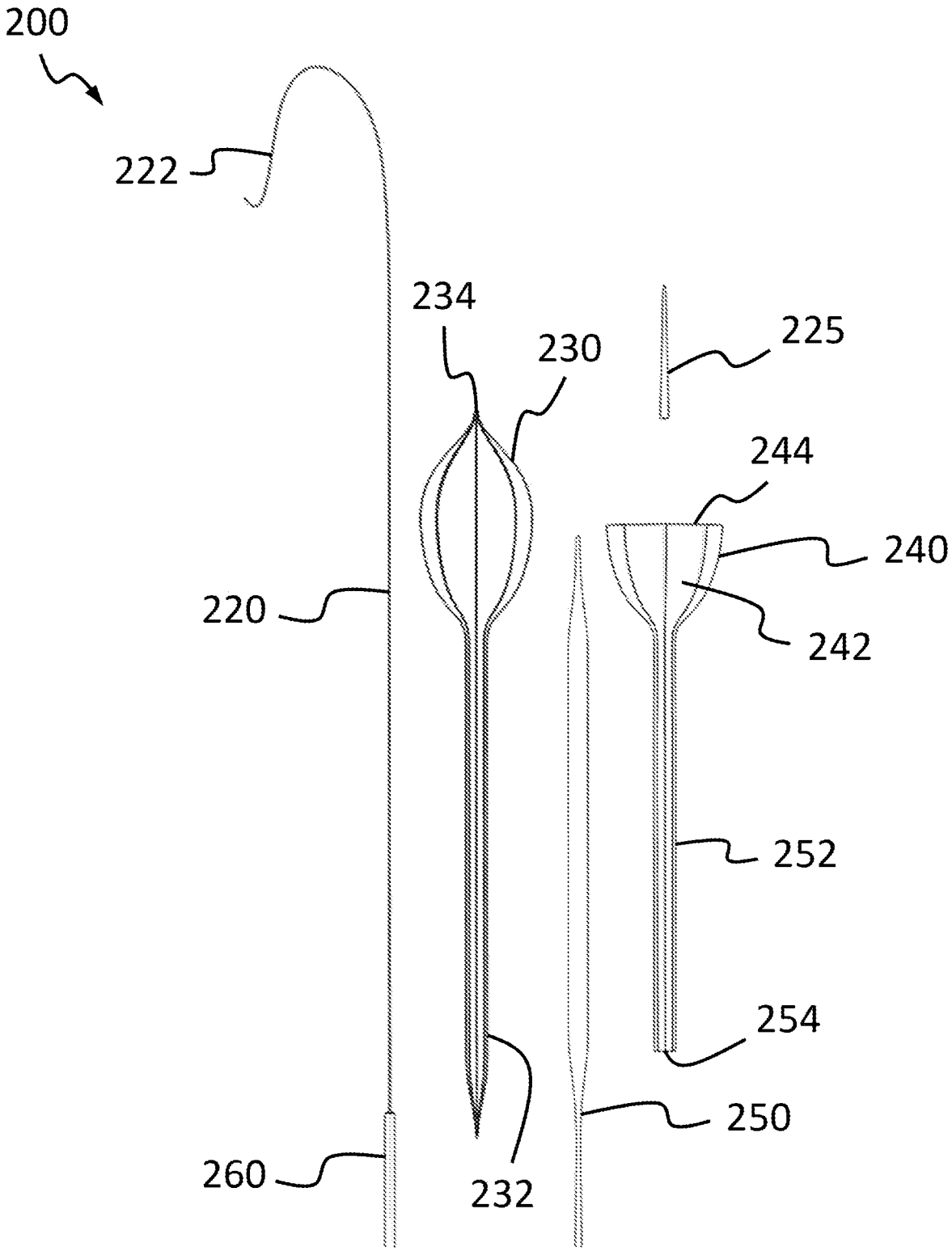


Fig. 15

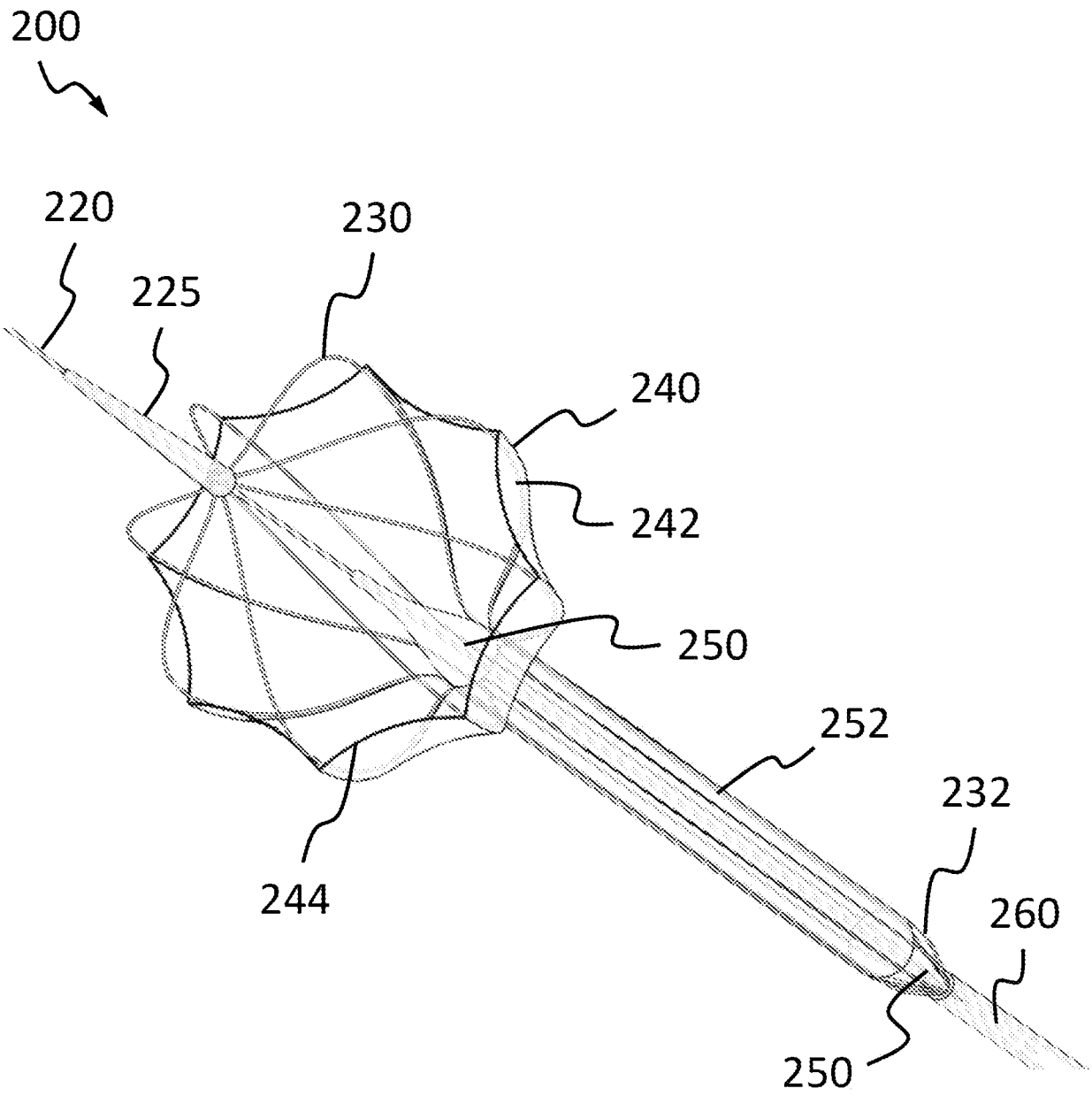


Fig. 16

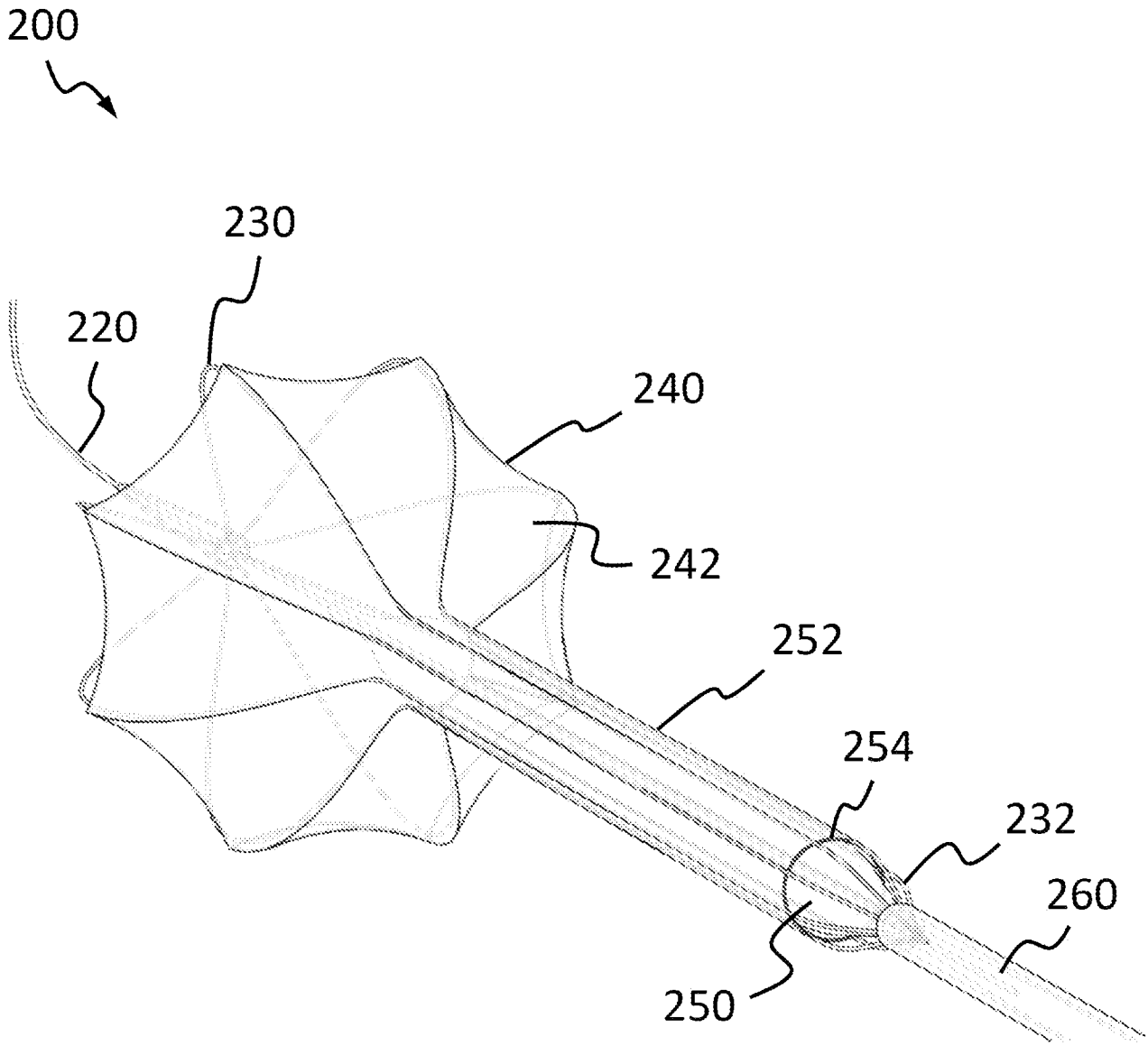


Fig. 17

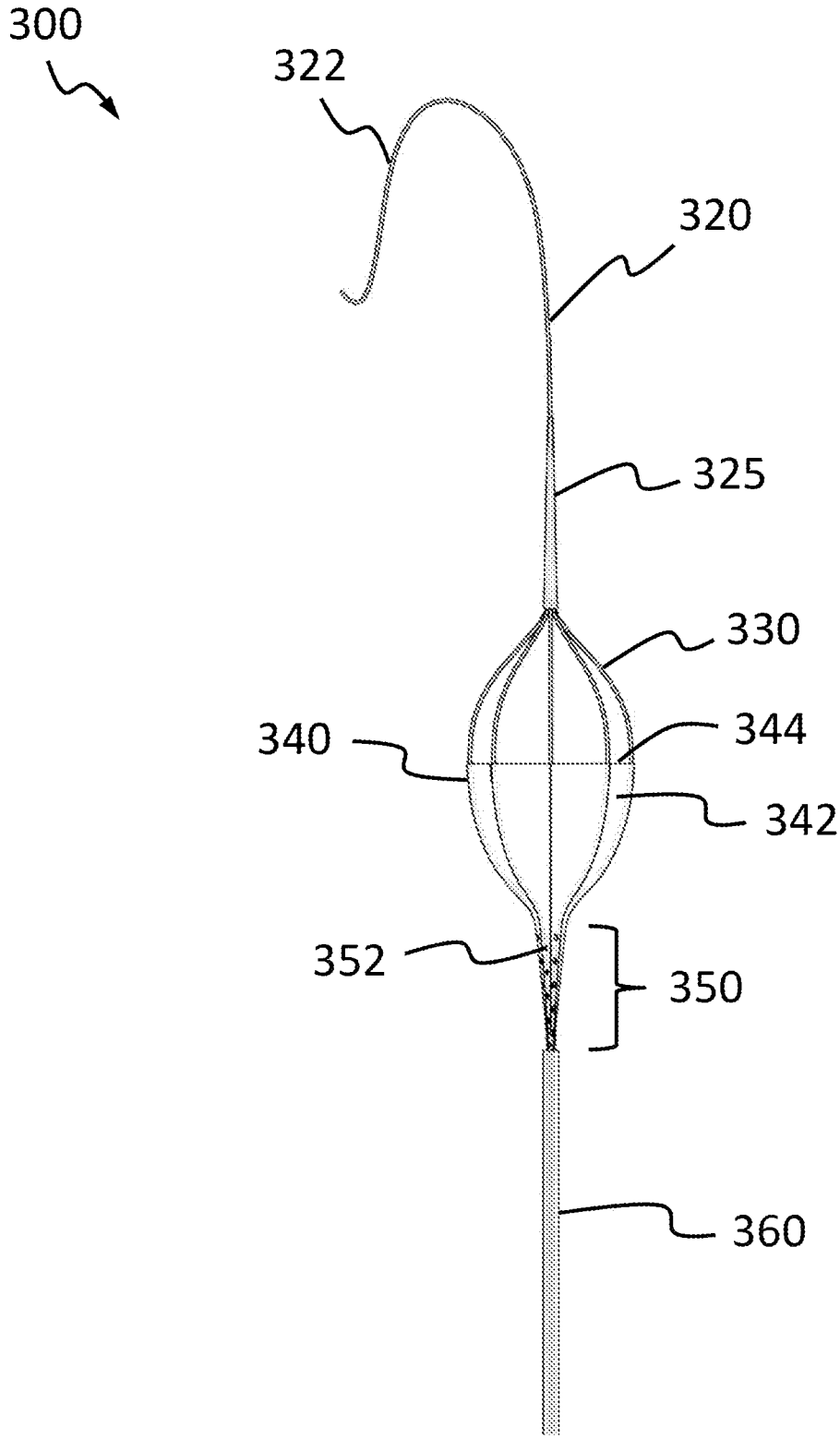


Fig. 18

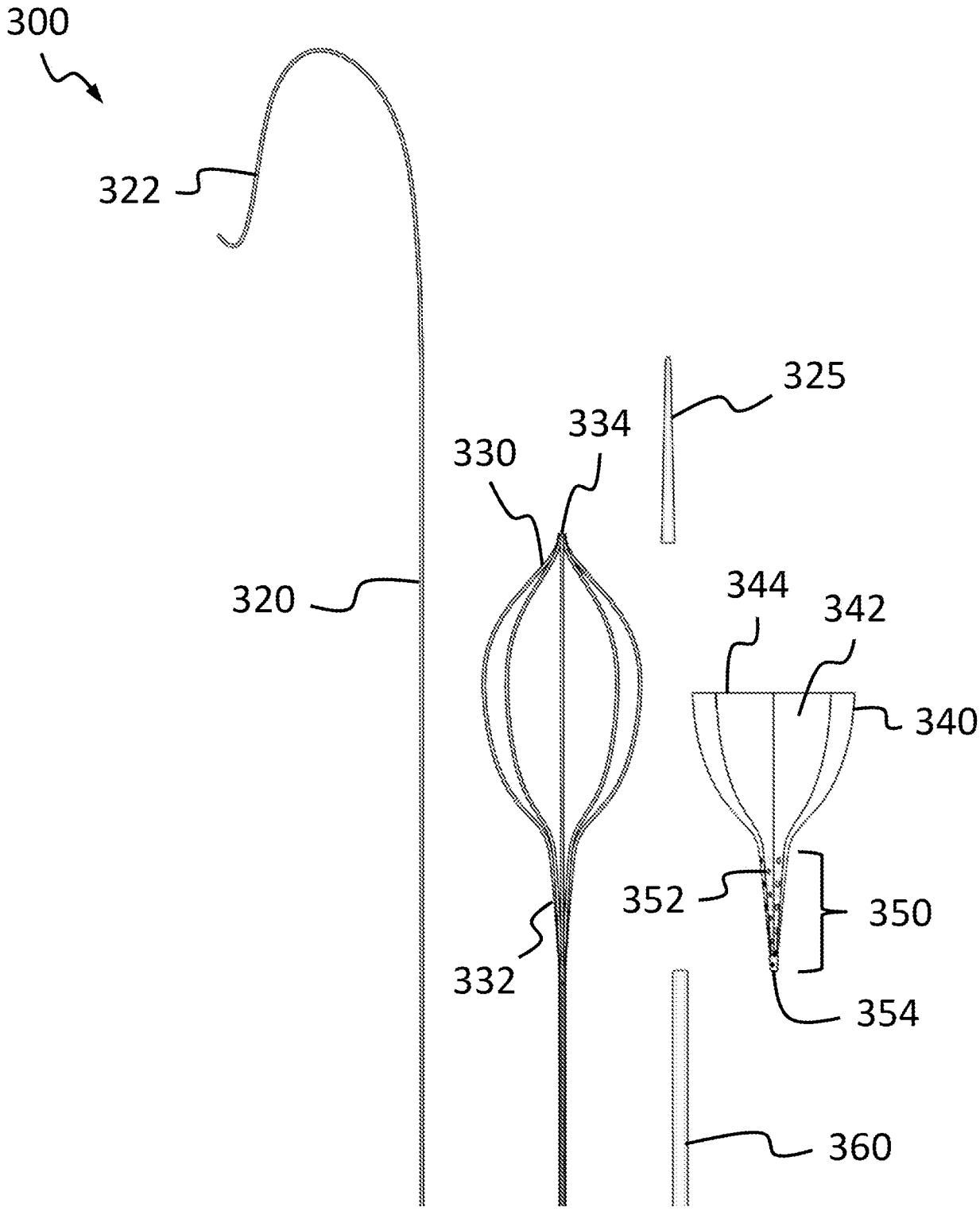


Fig. 19

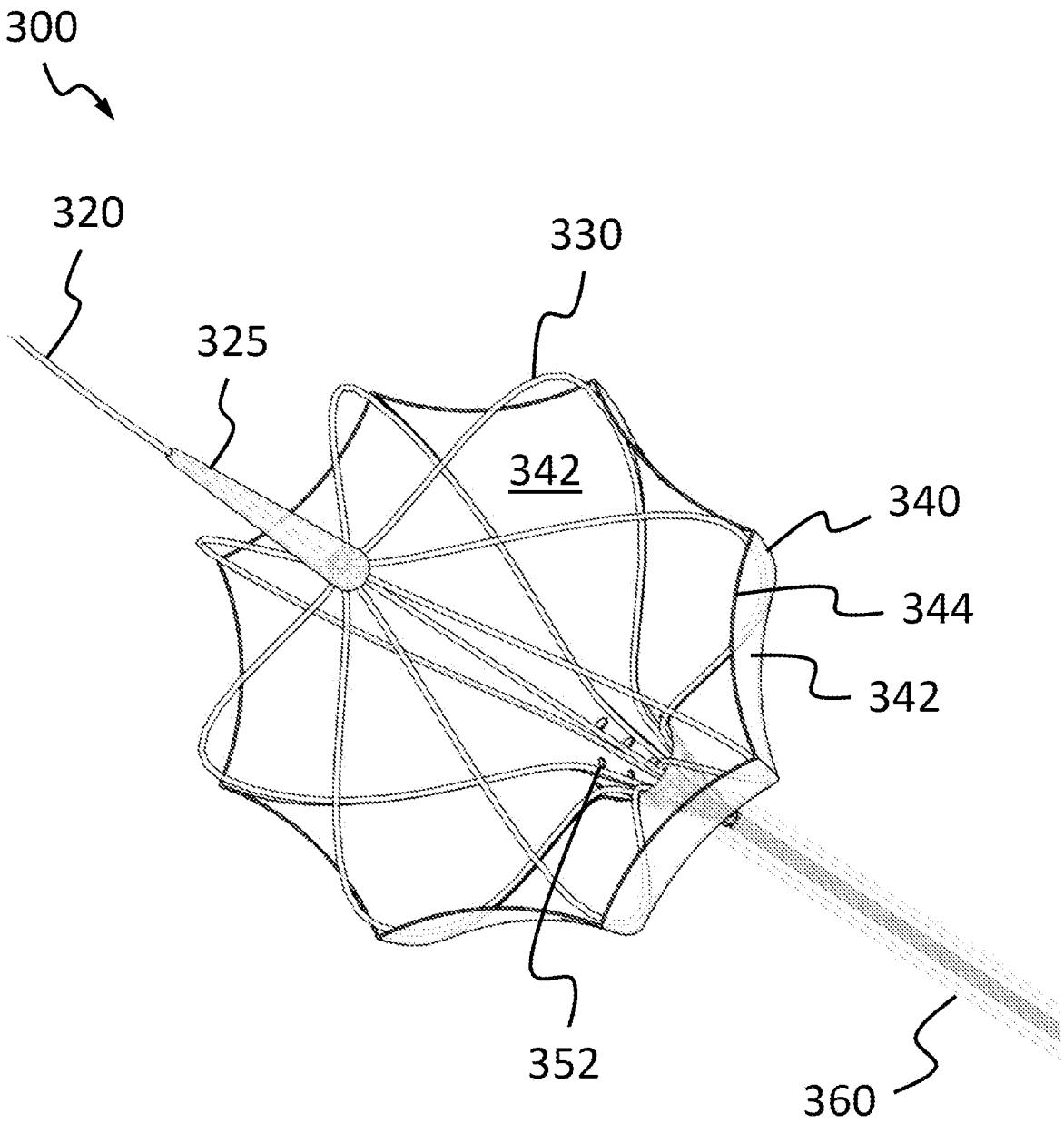


Fig. 20

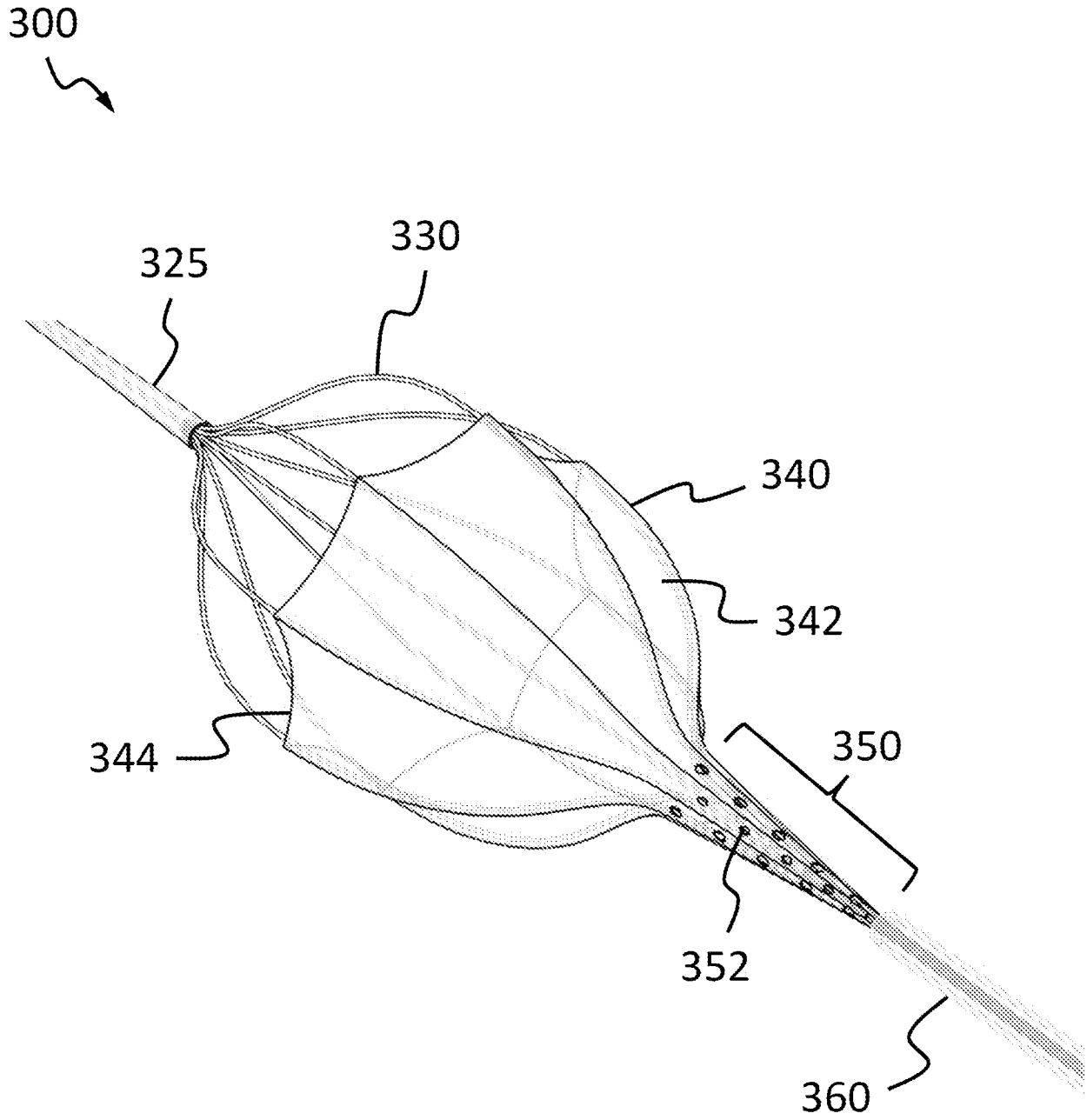


Fig. 21

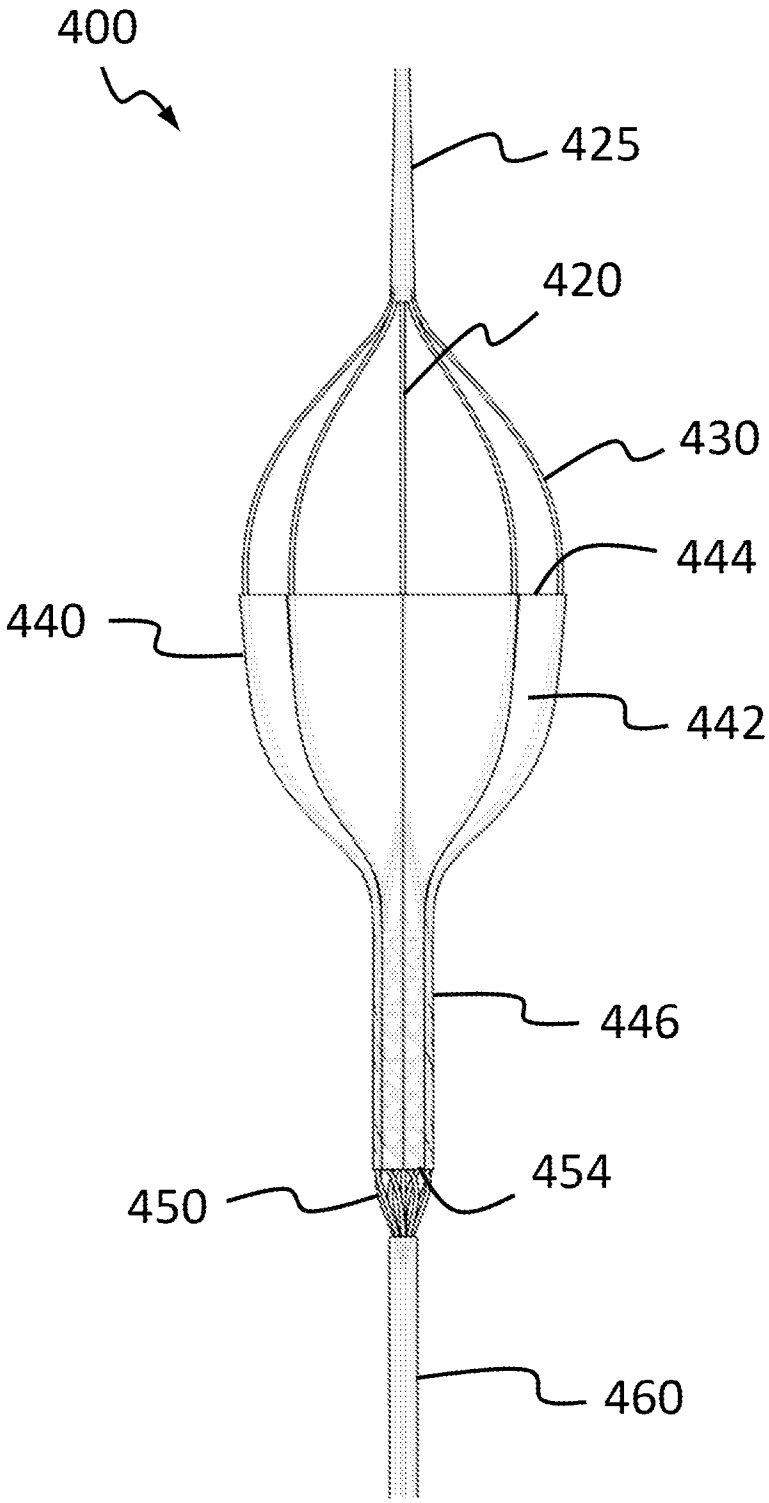


Fig. 22

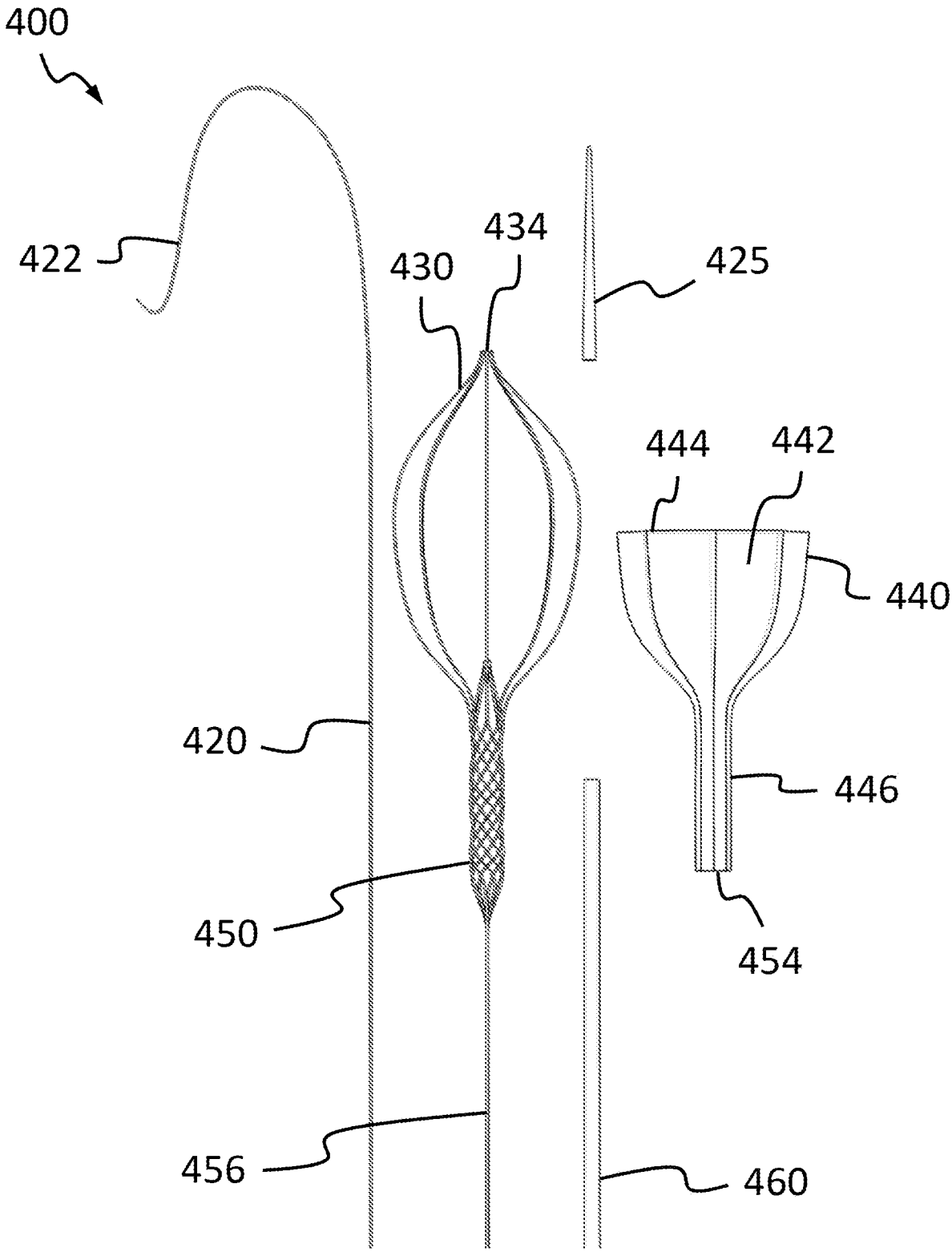


Fig. 23

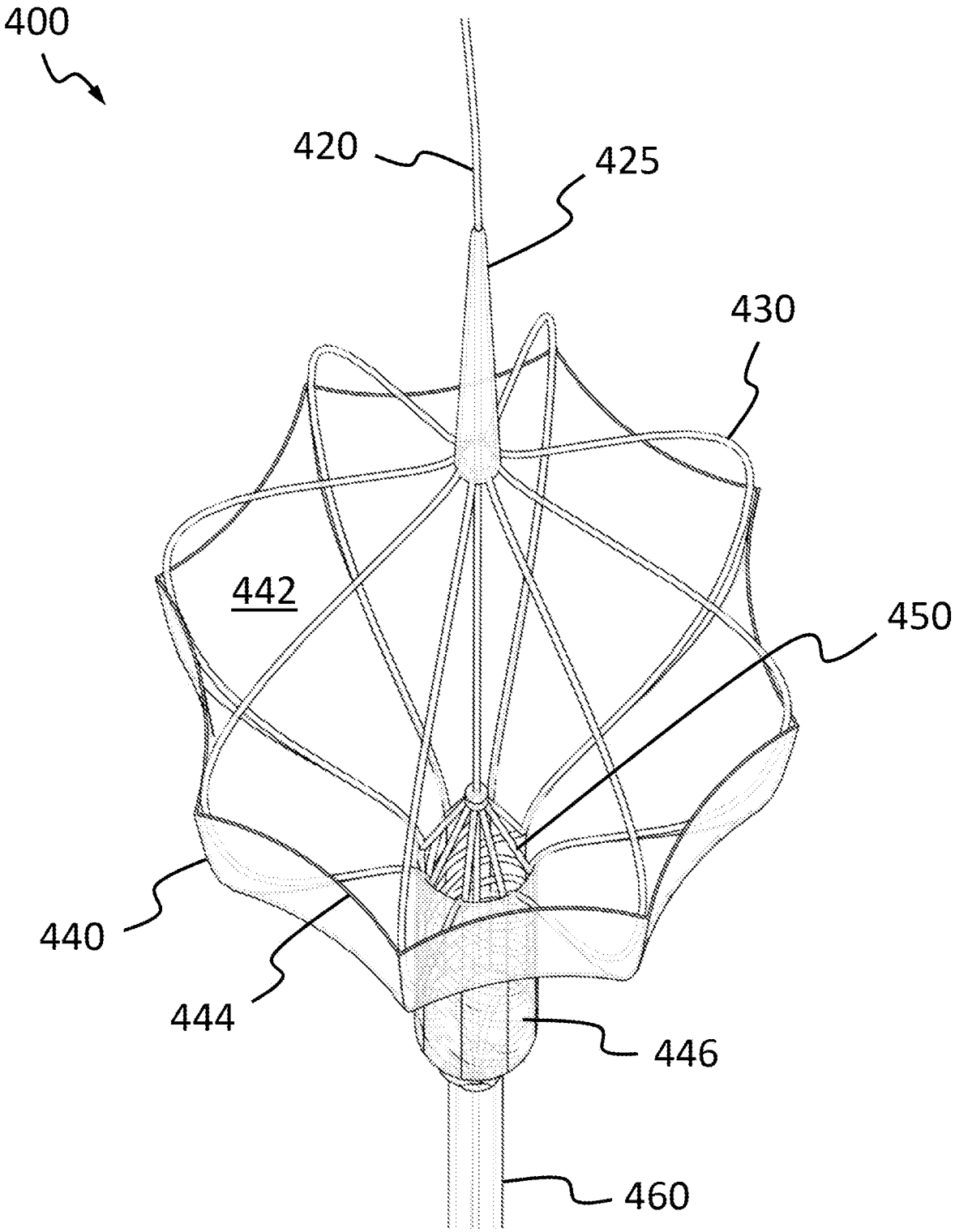


Fig. 24

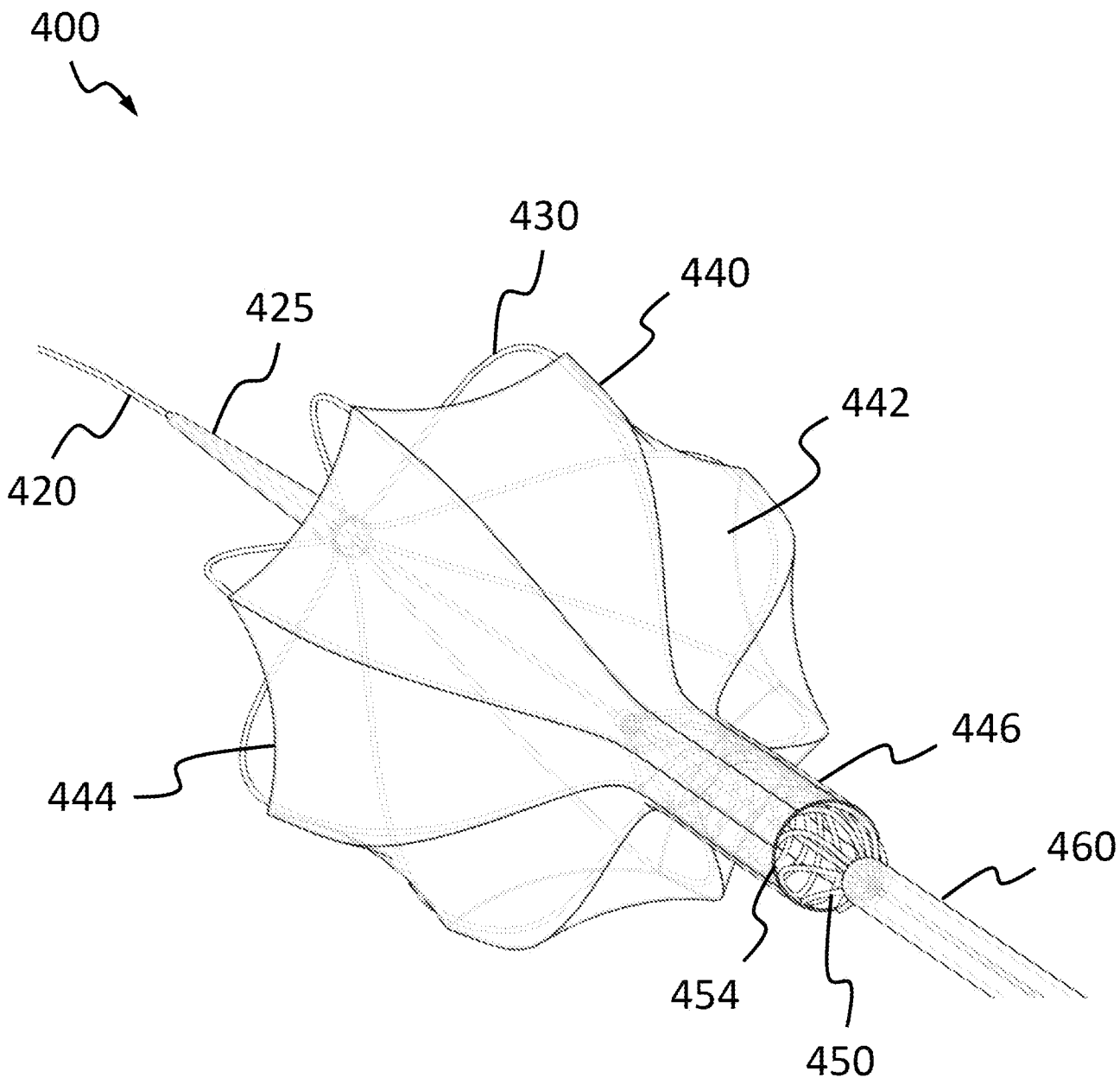


Fig. 25

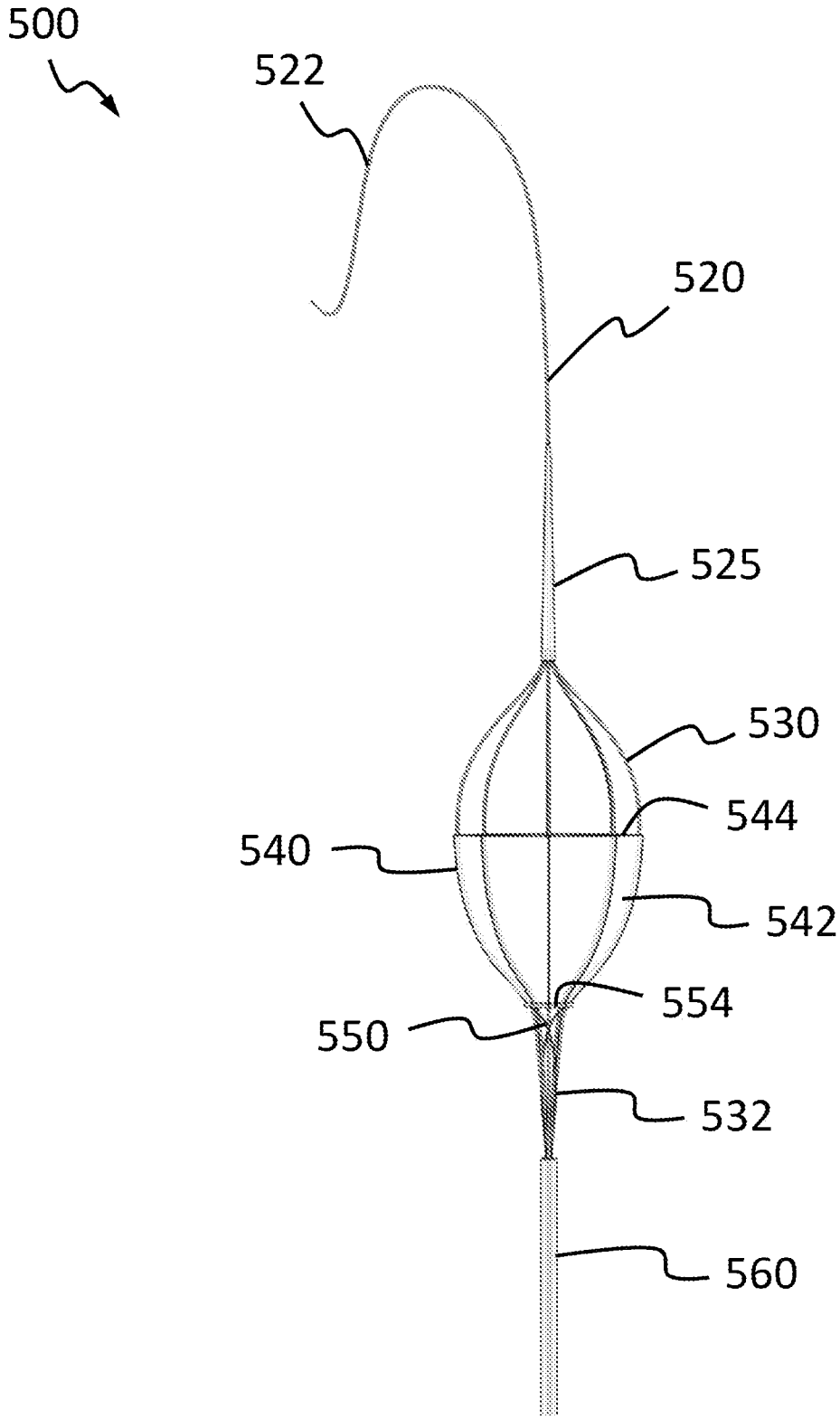


Fig. 26

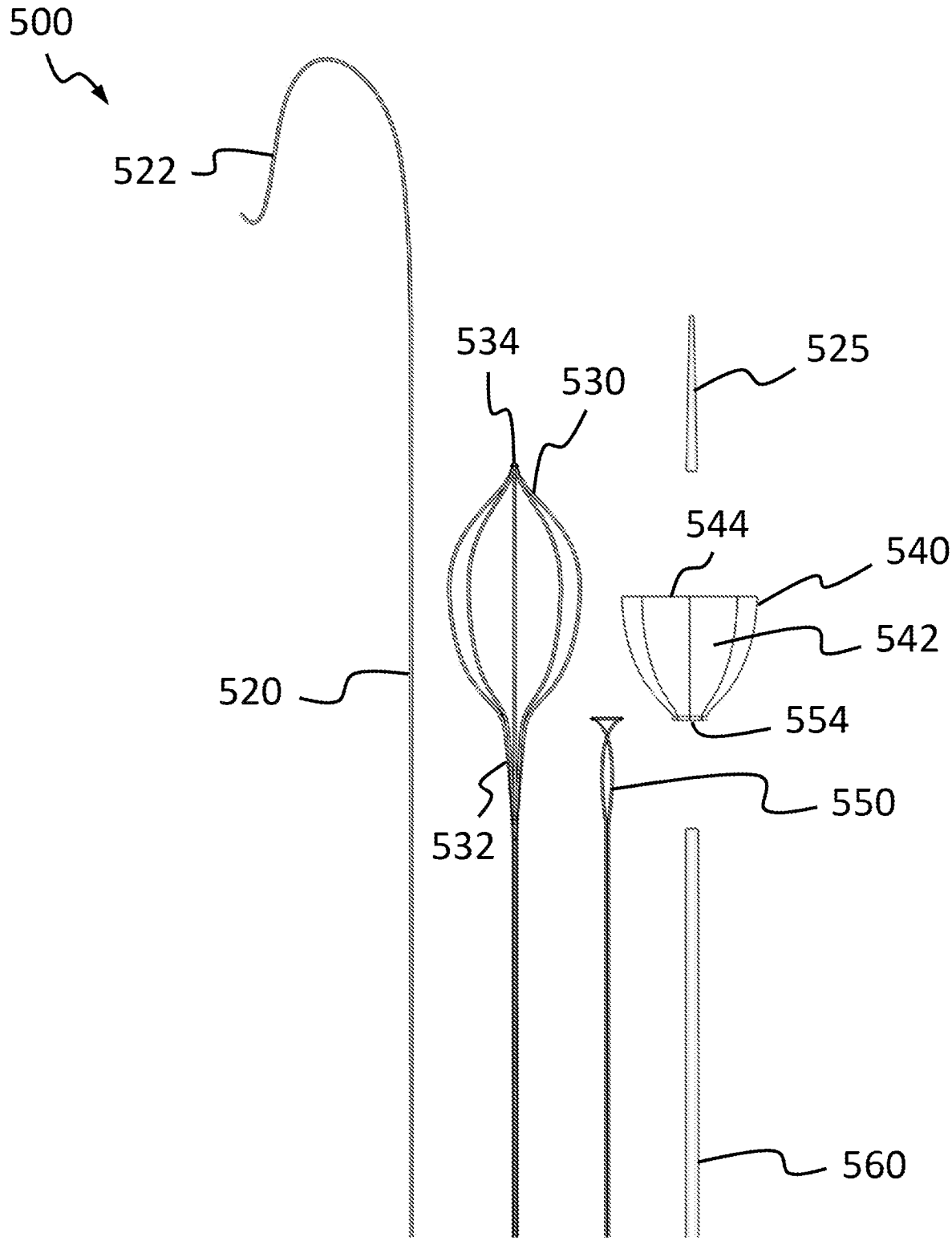


Fig. 27

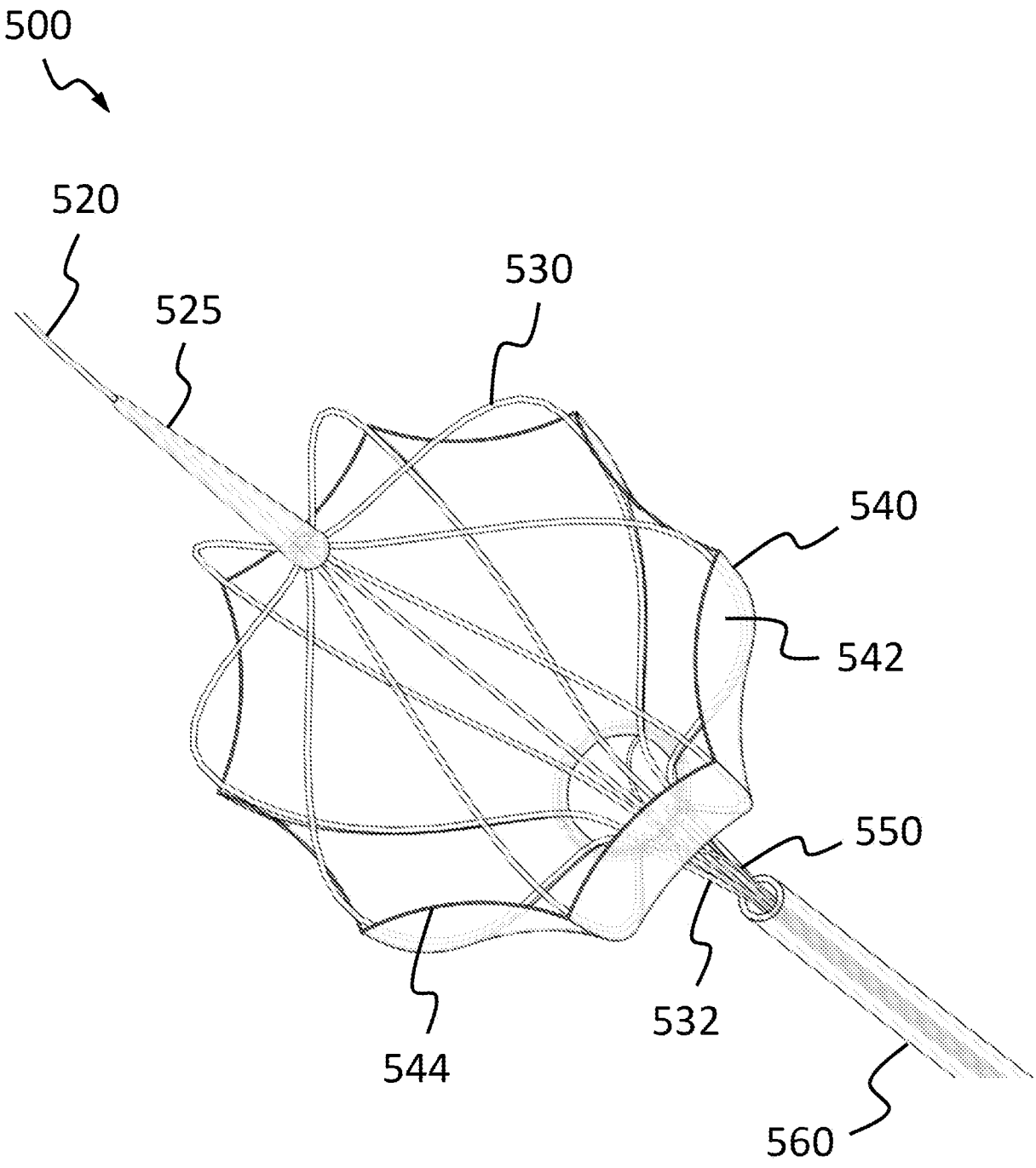


Fig. 28

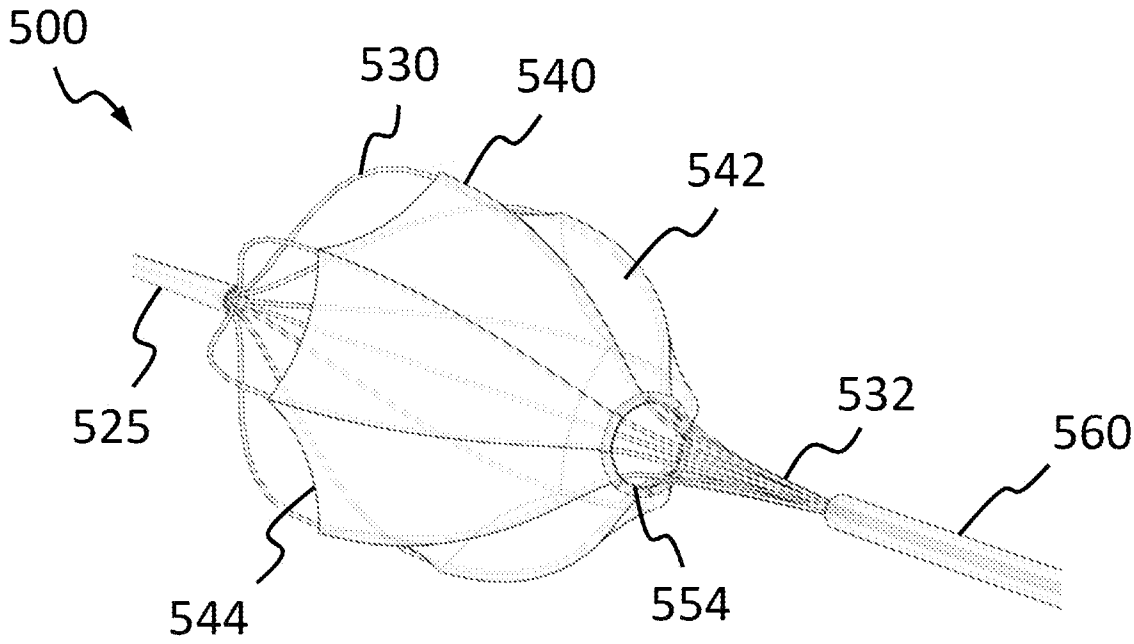


Fig. 29A

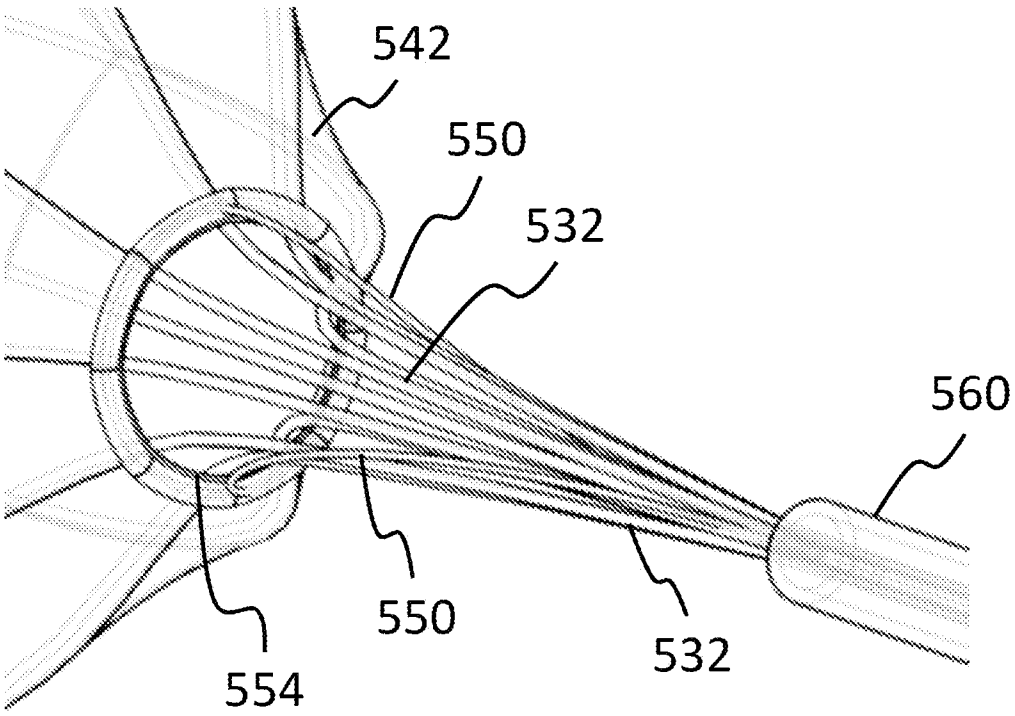


Fig. 29B

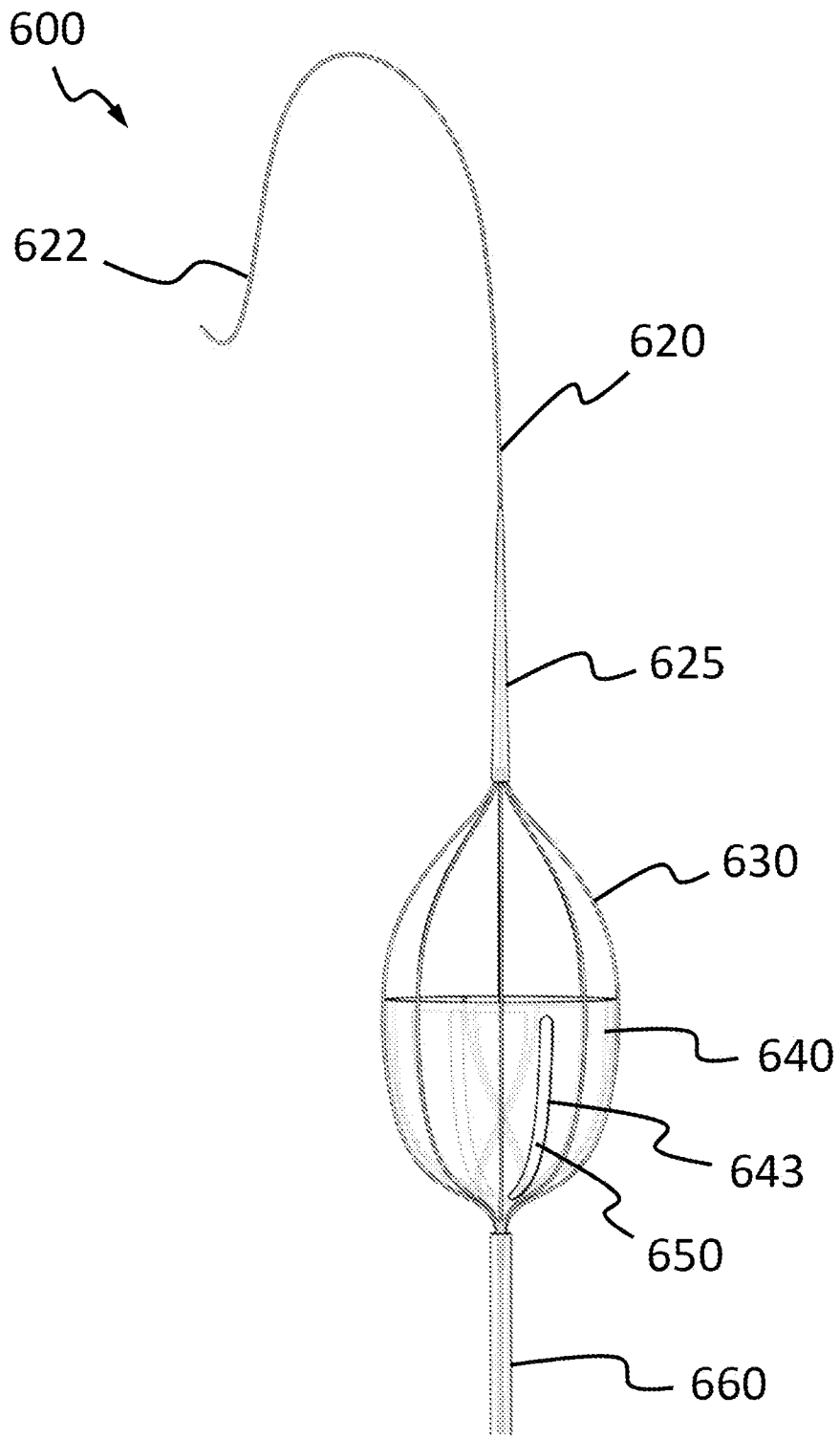


Fig. 30

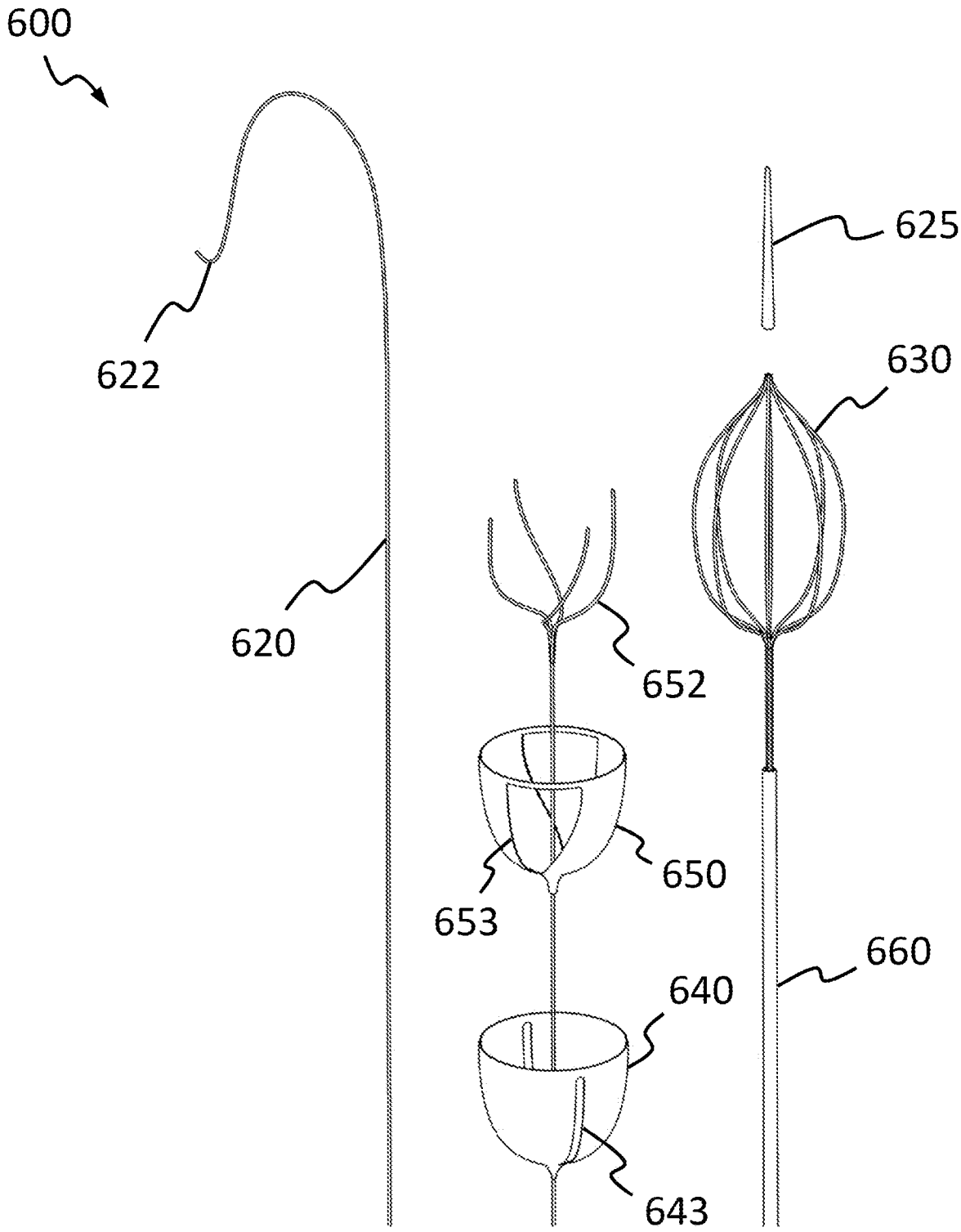


Fig. 31

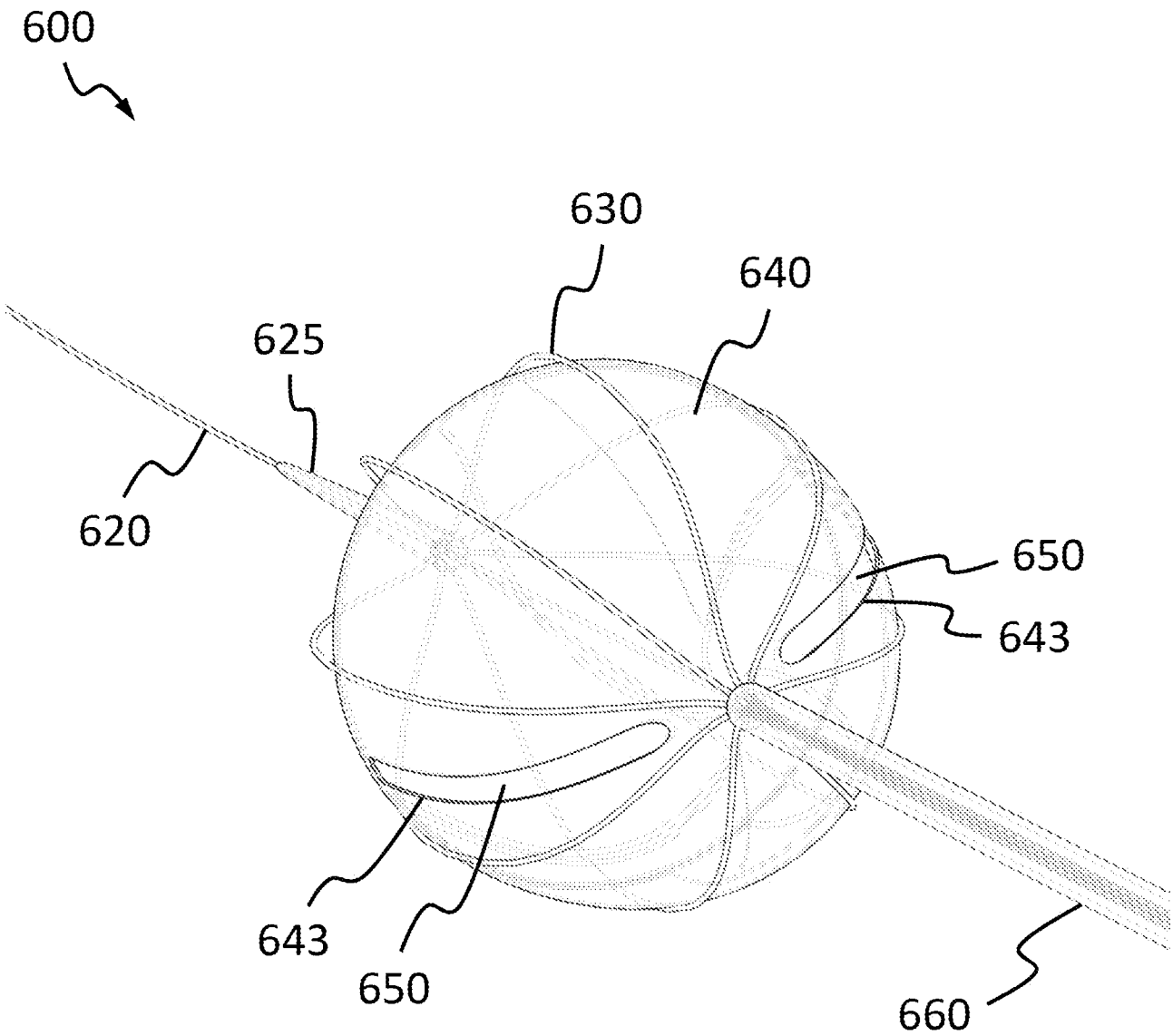


Fig. 32A

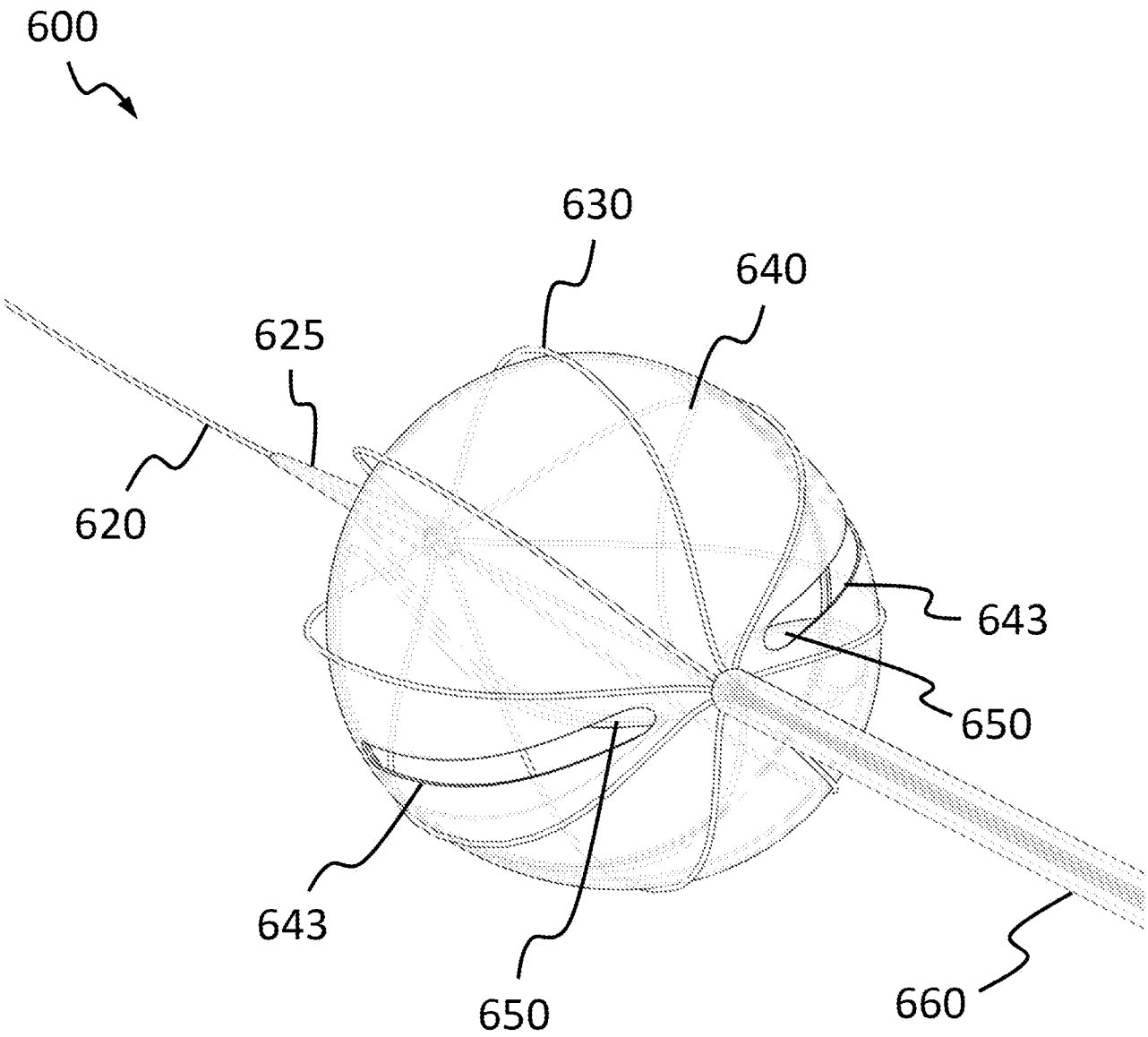


Fig. 32B

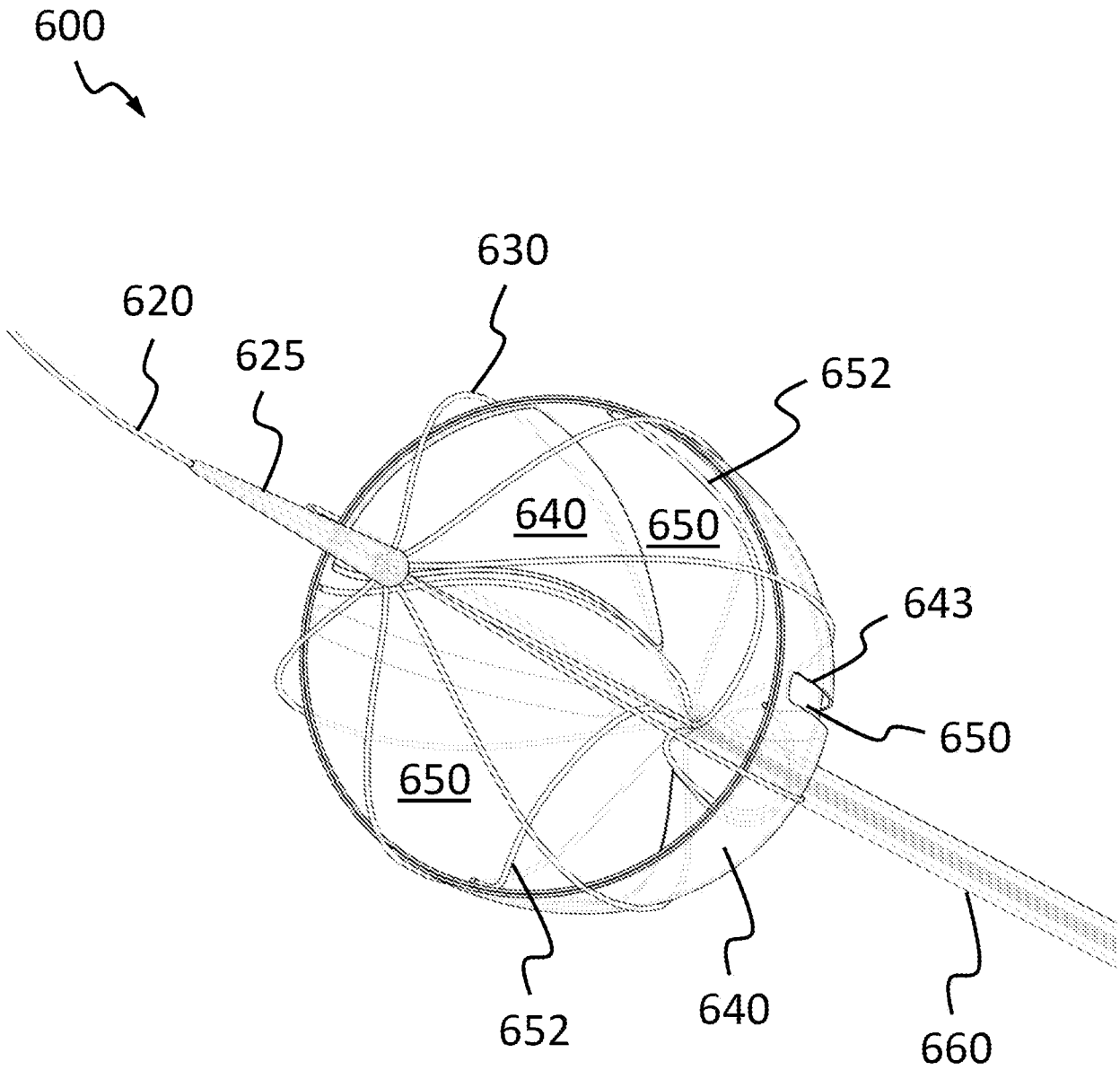


Fig. 33A

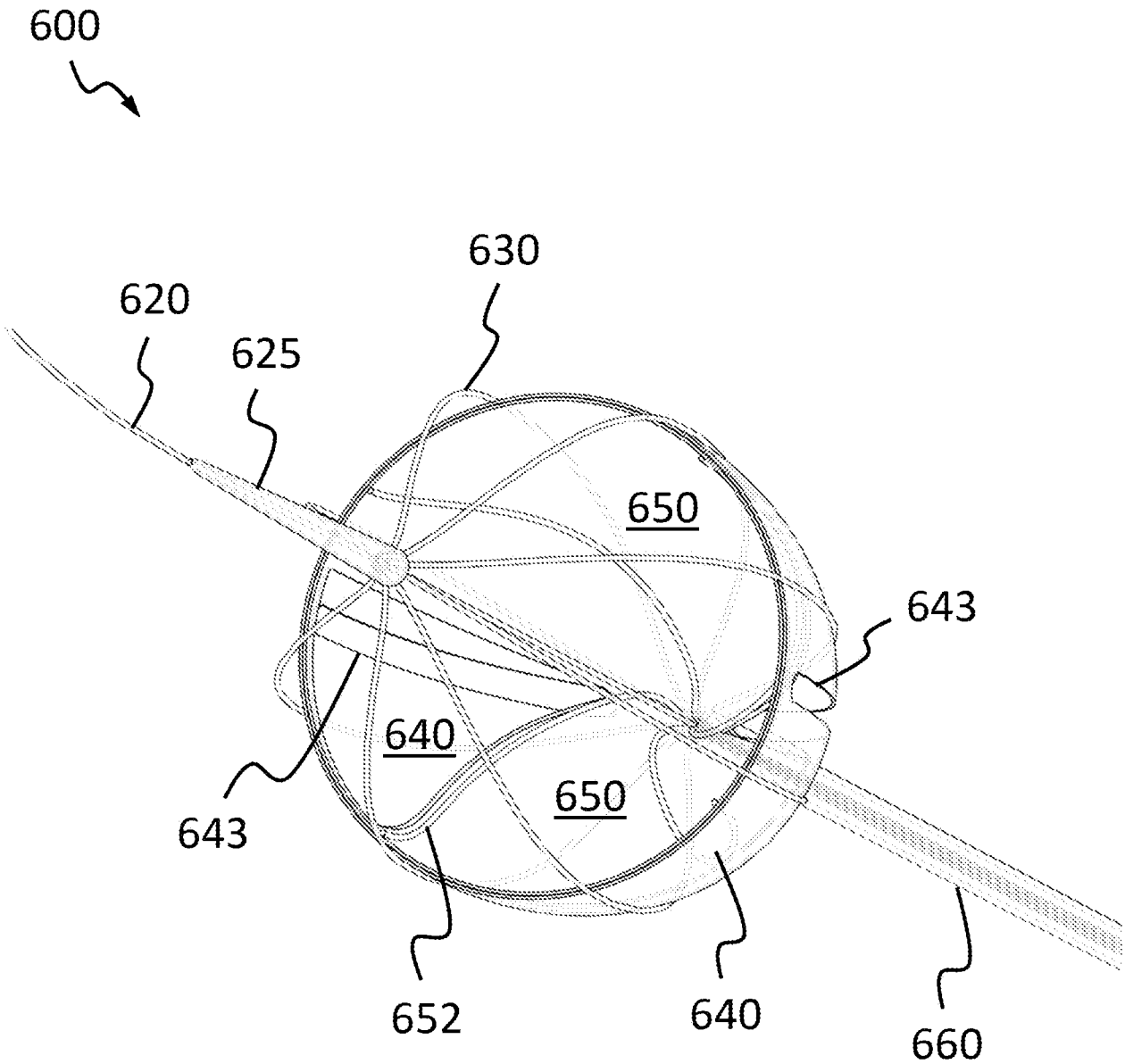


Fig. 33B

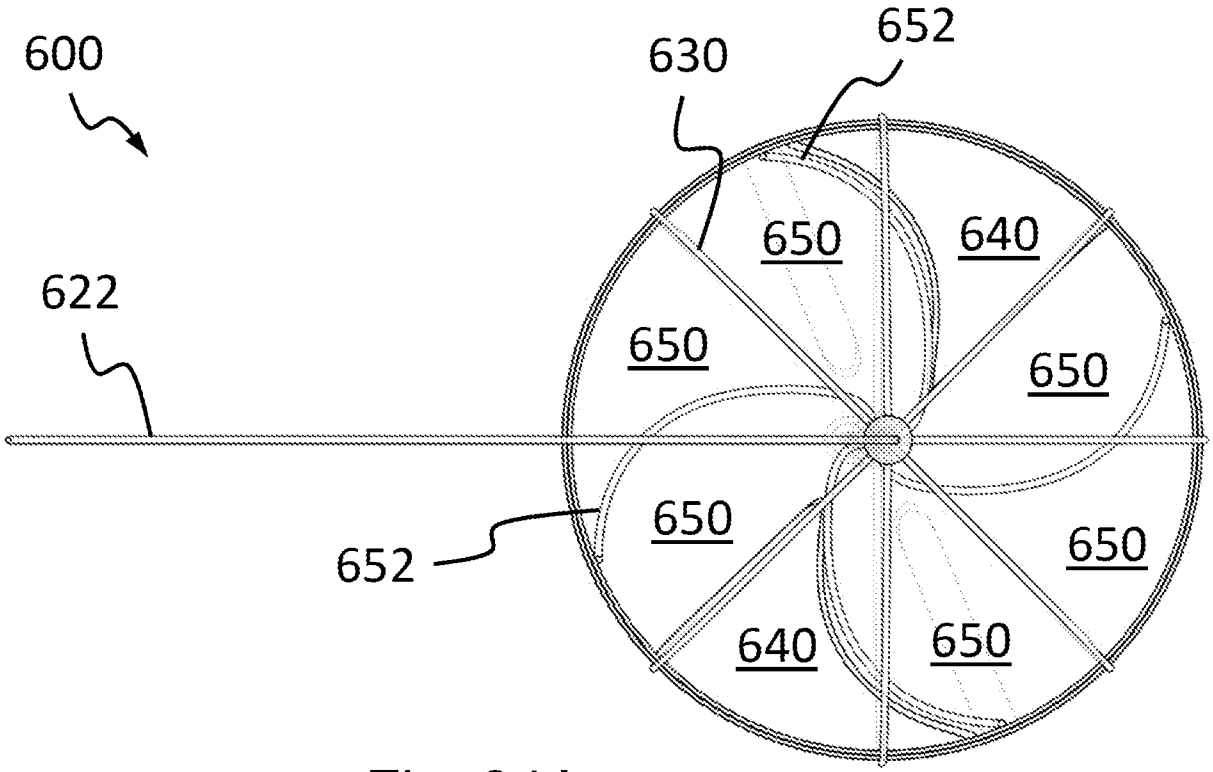


Fig. 34A

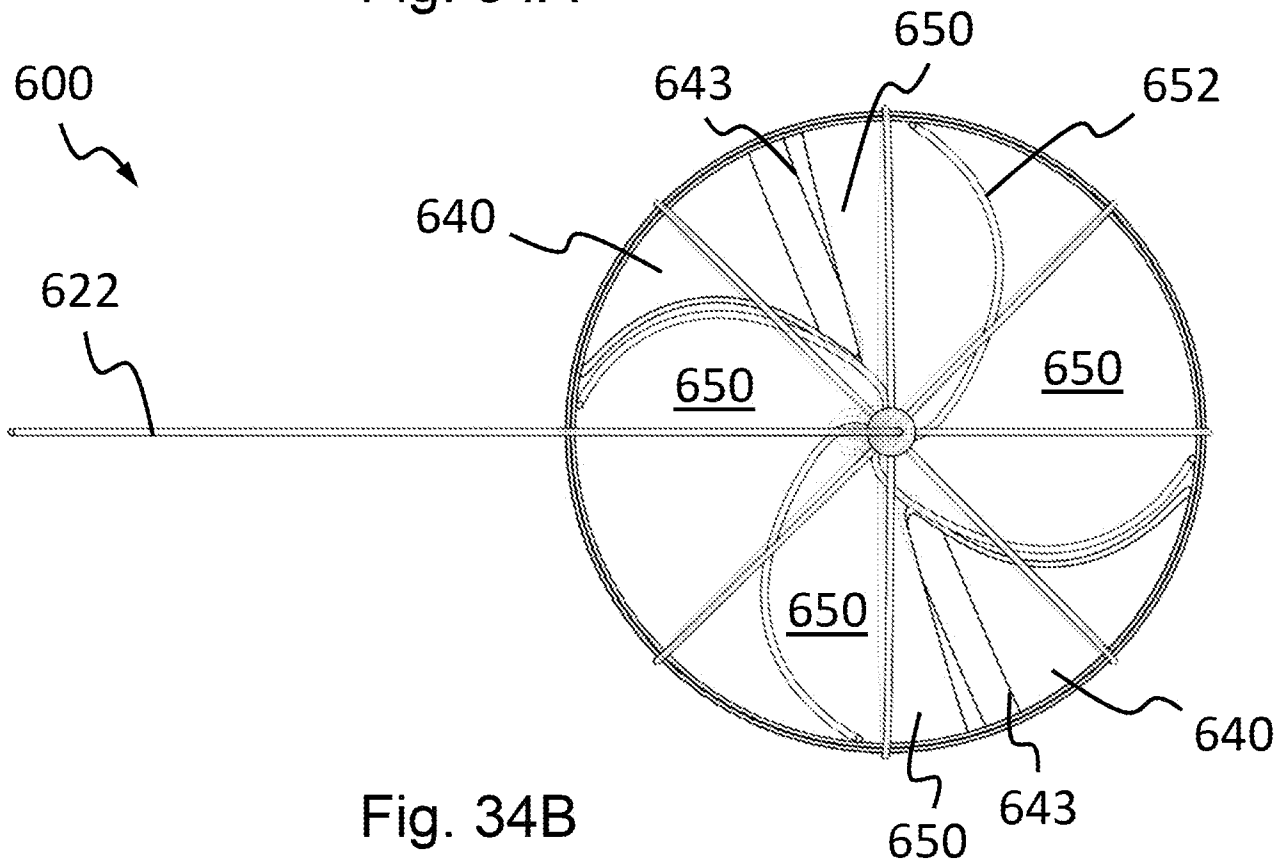


Fig. 34B

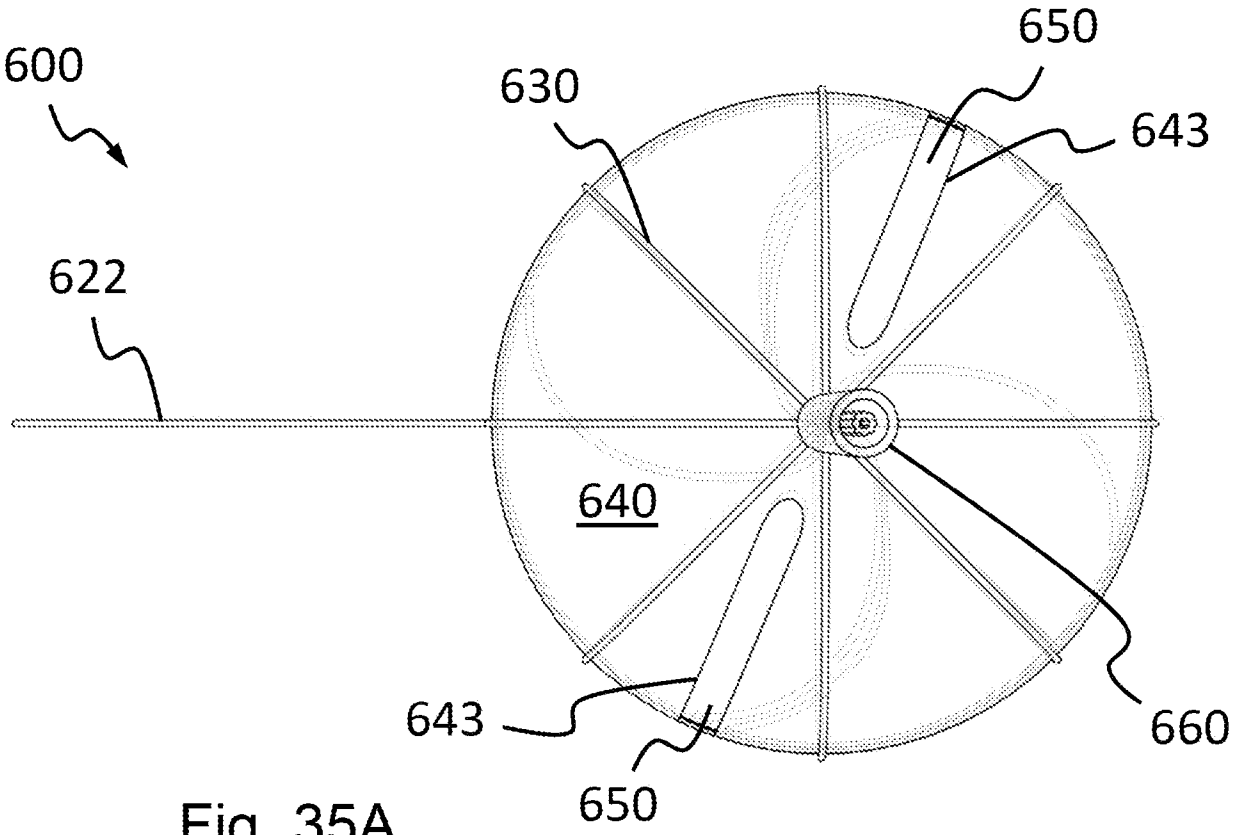


Fig. 35A

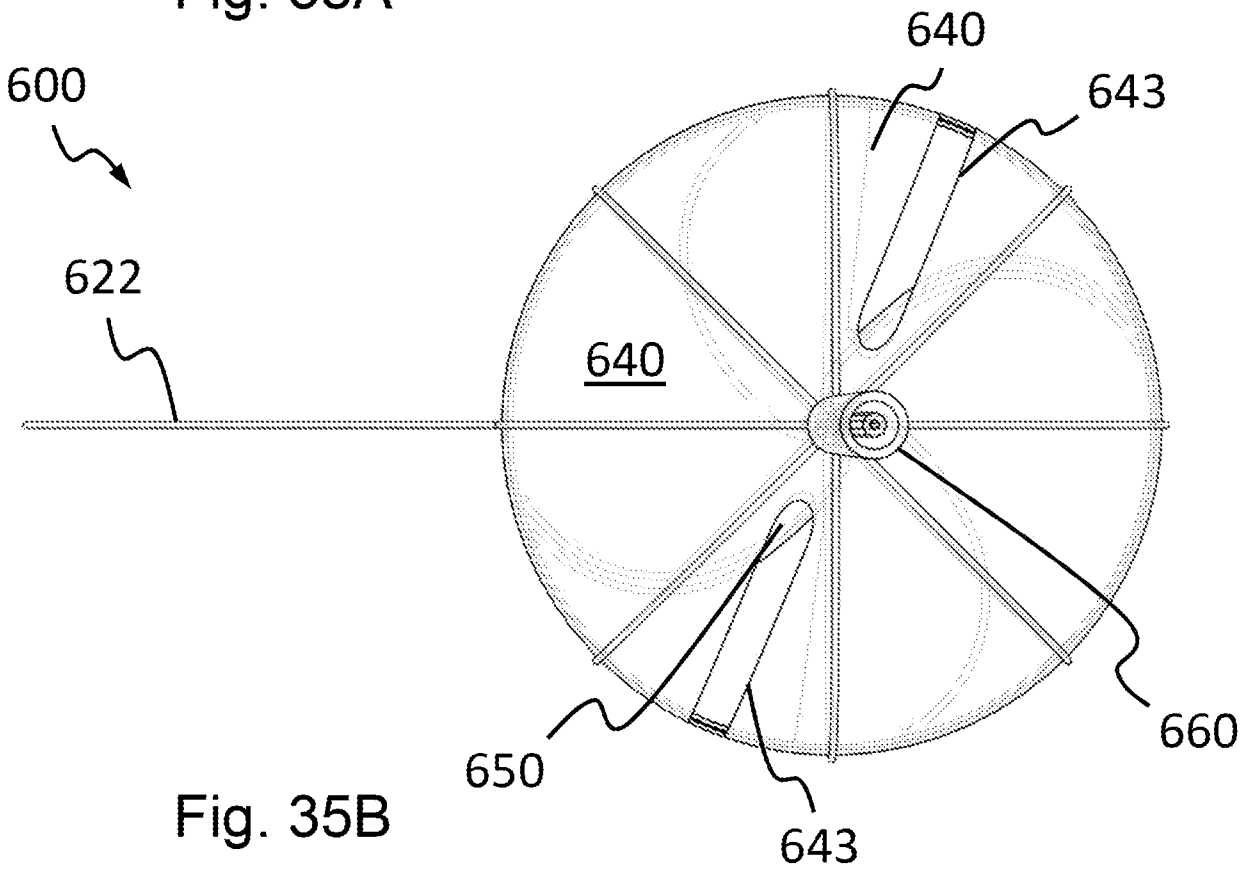


Fig. 35B

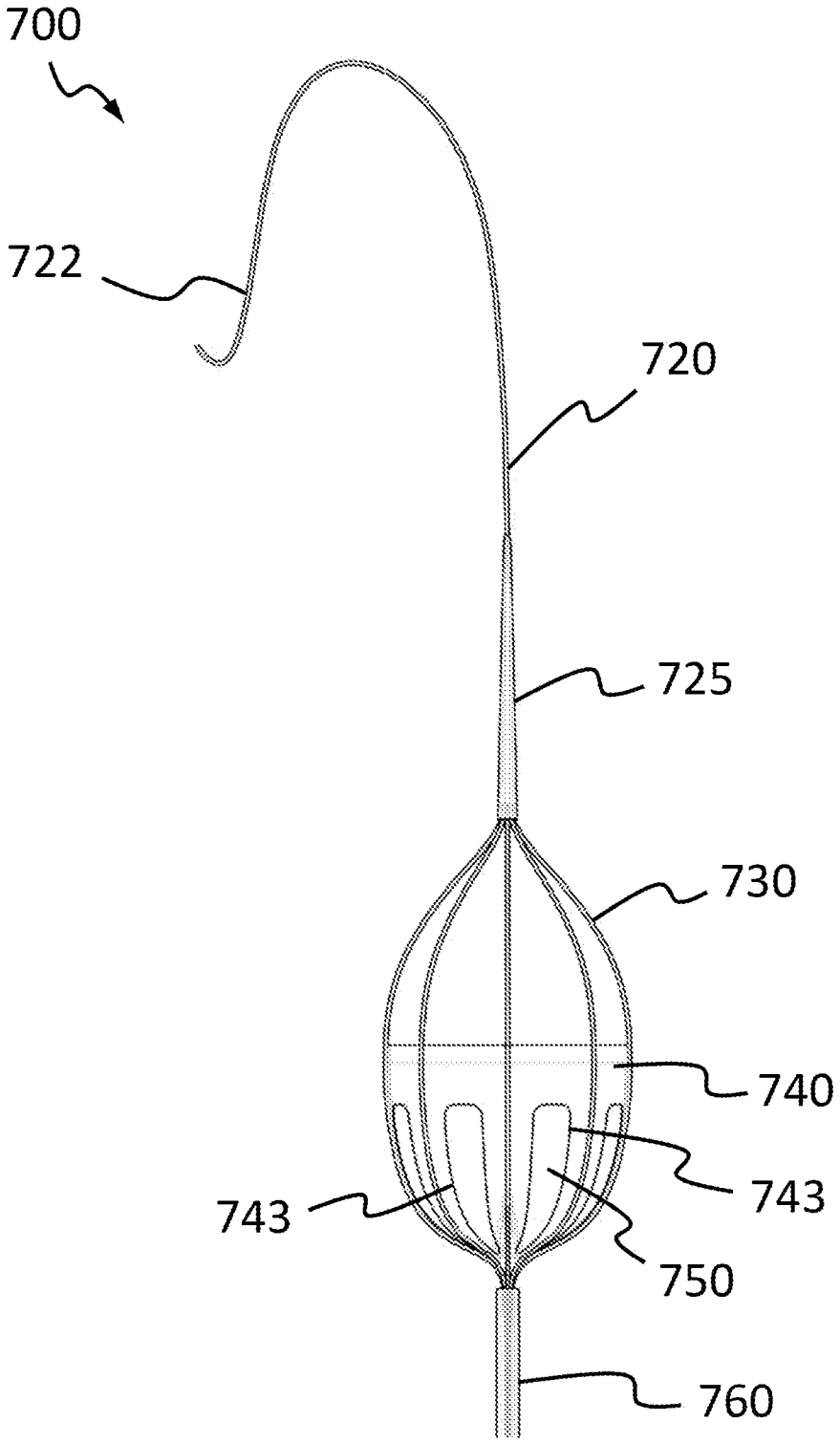


Fig. 36A

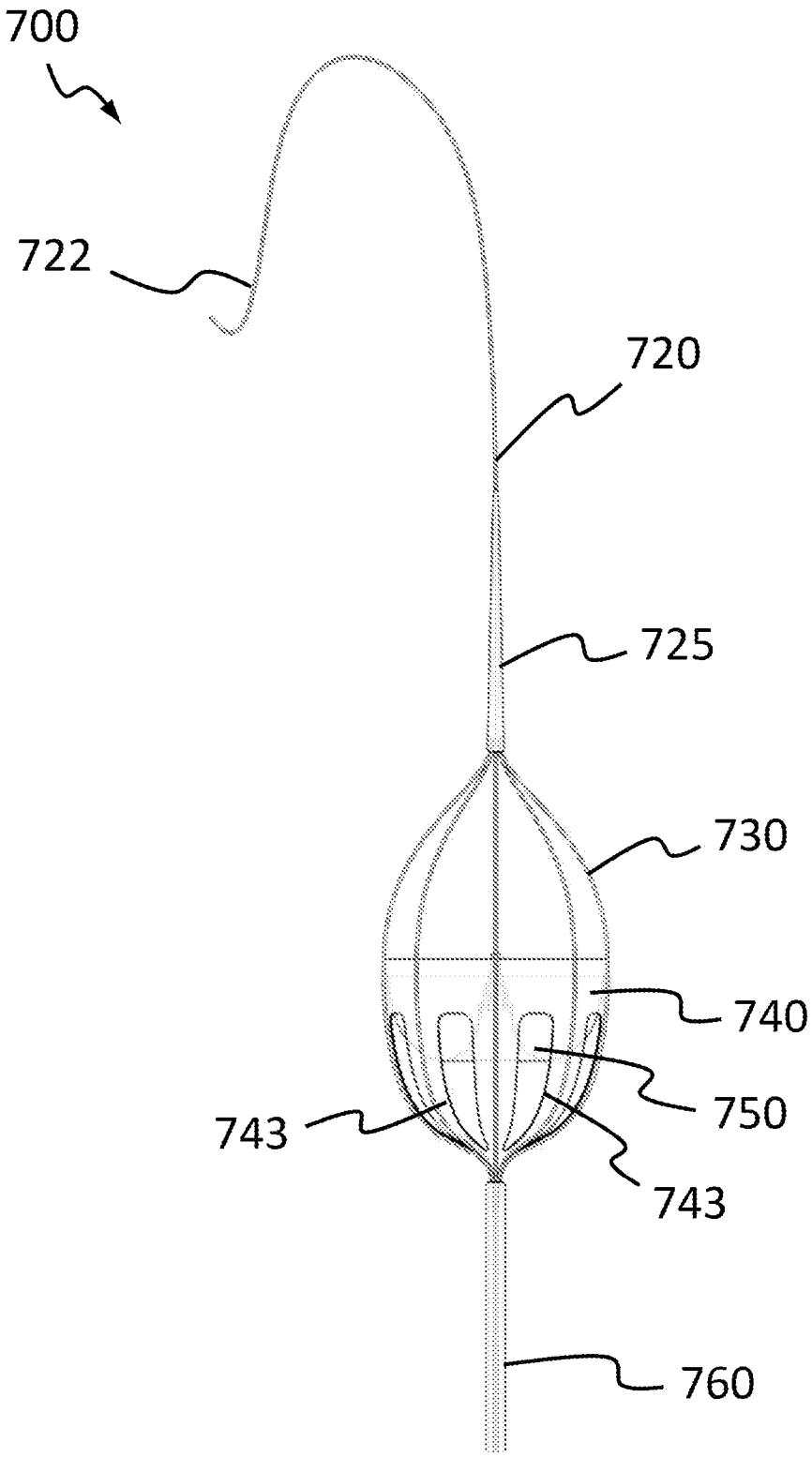


Fig. 36B

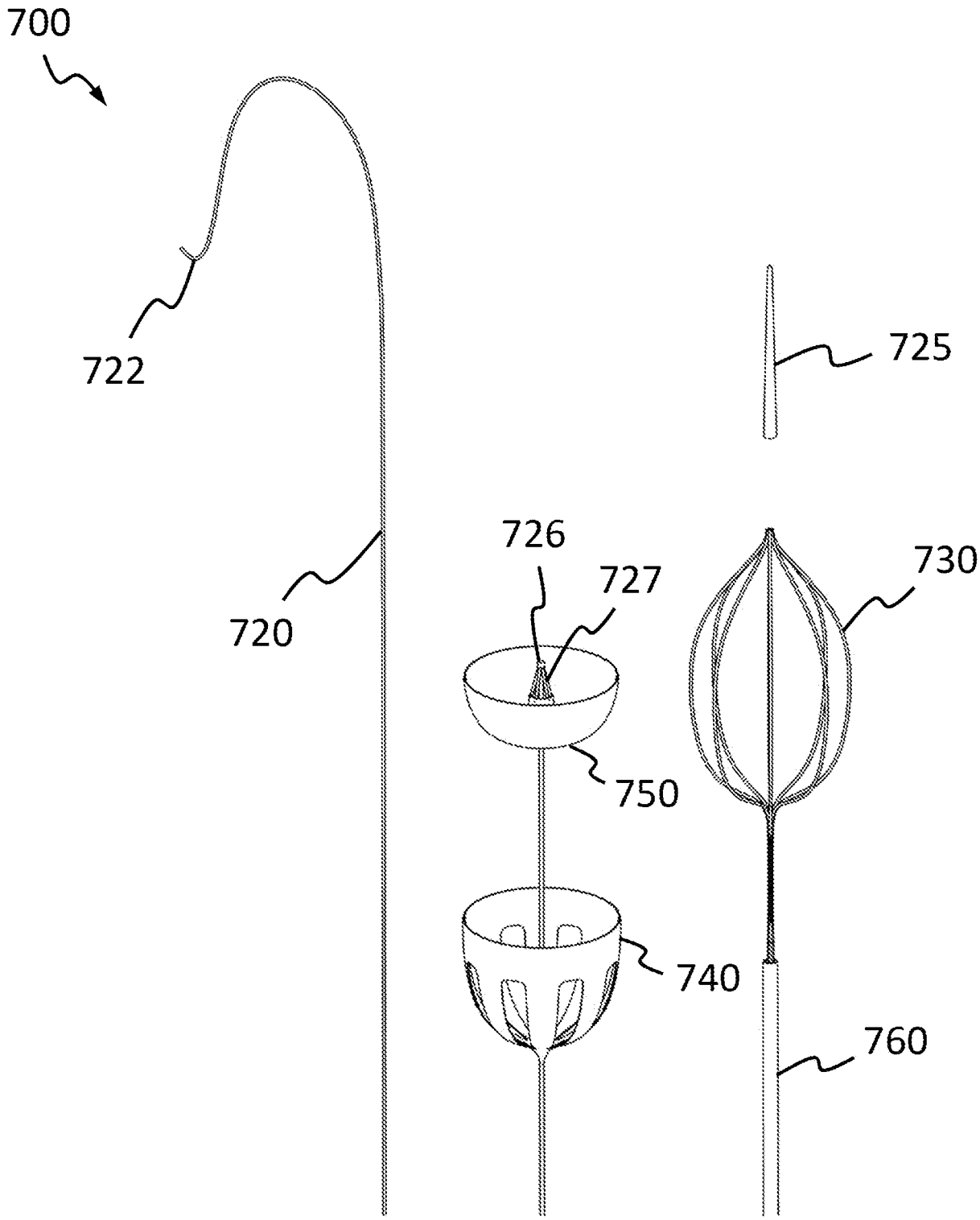


Fig. 37

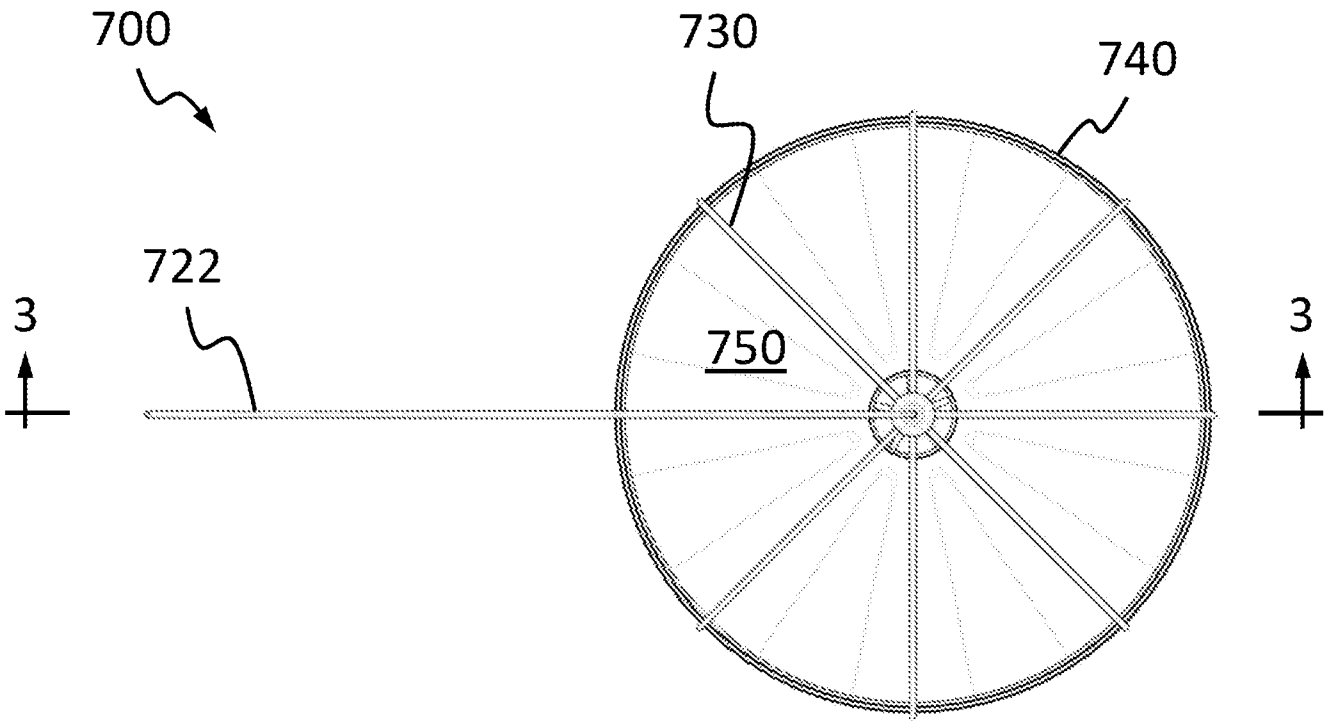


Fig. 38A

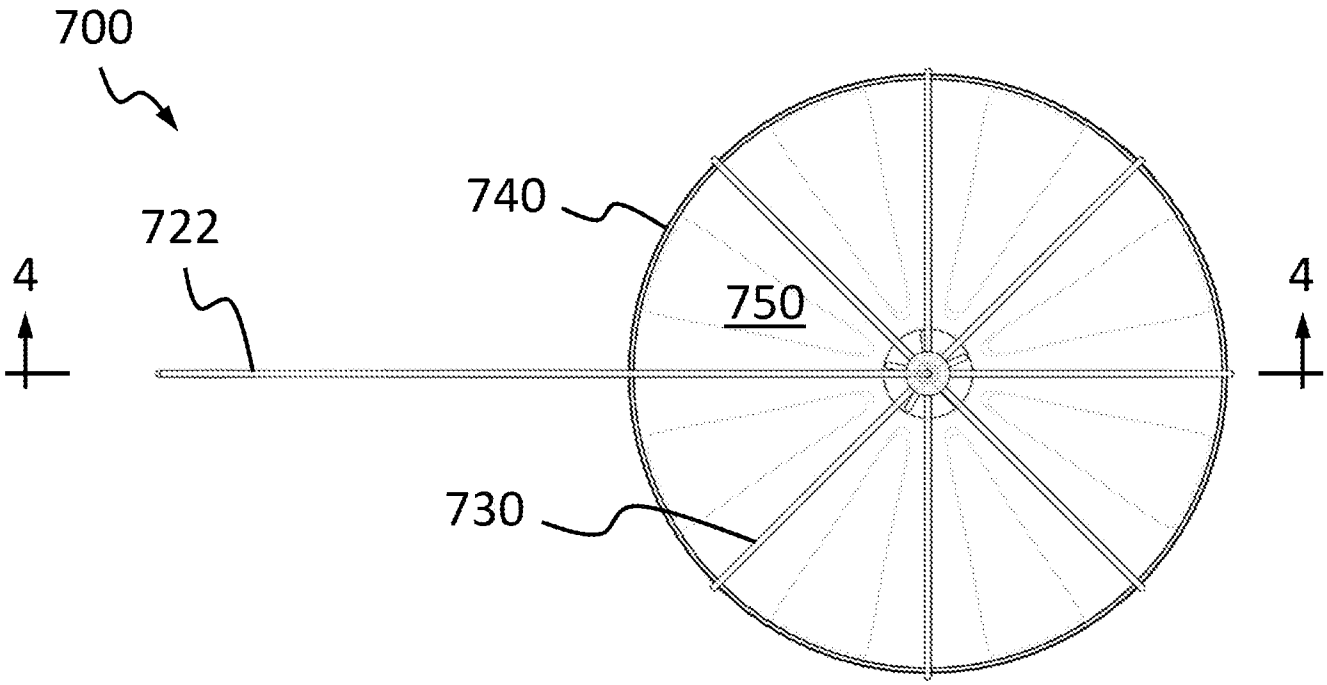


Fig. 38B

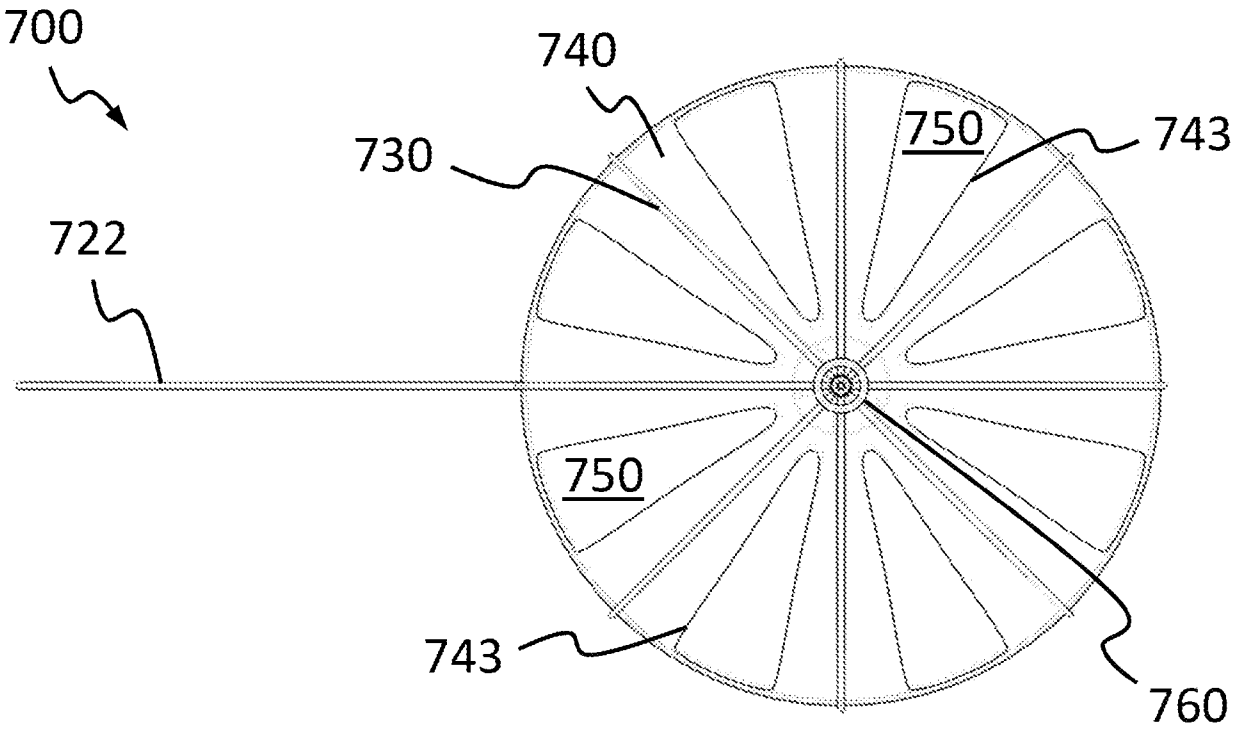


Fig. 39A

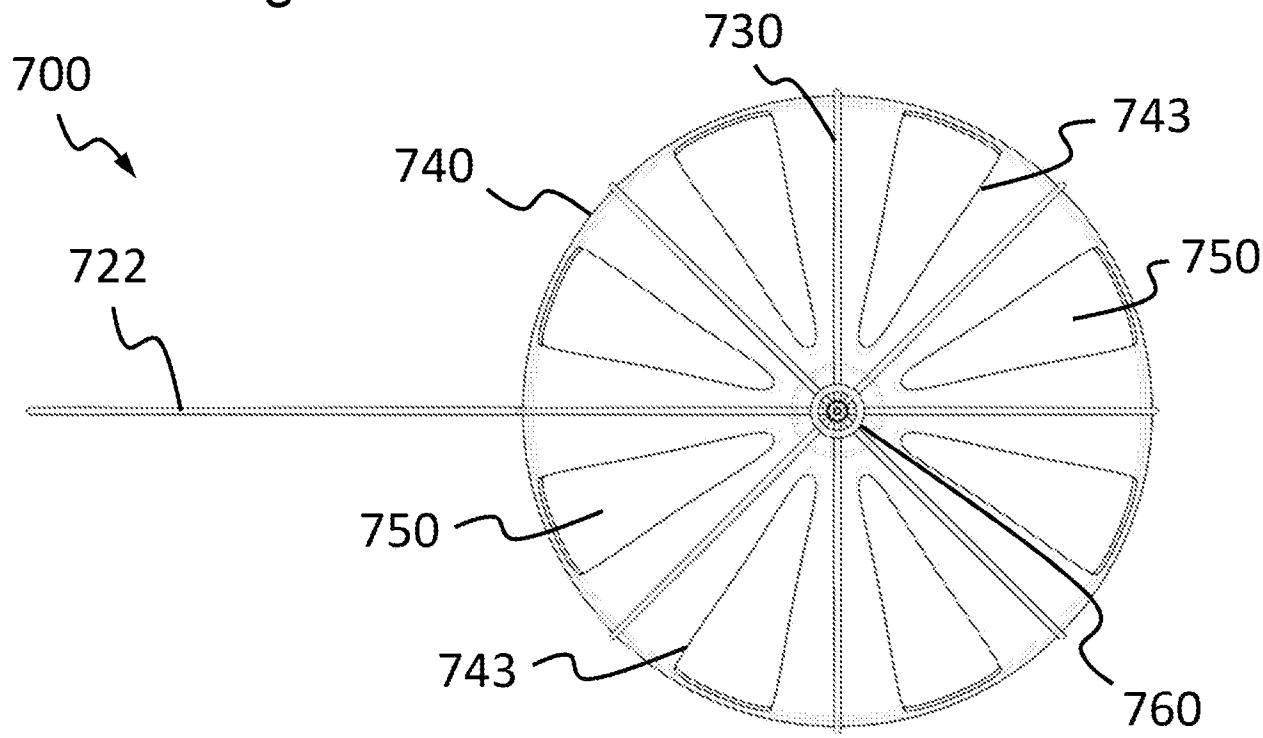


Fig. 39B

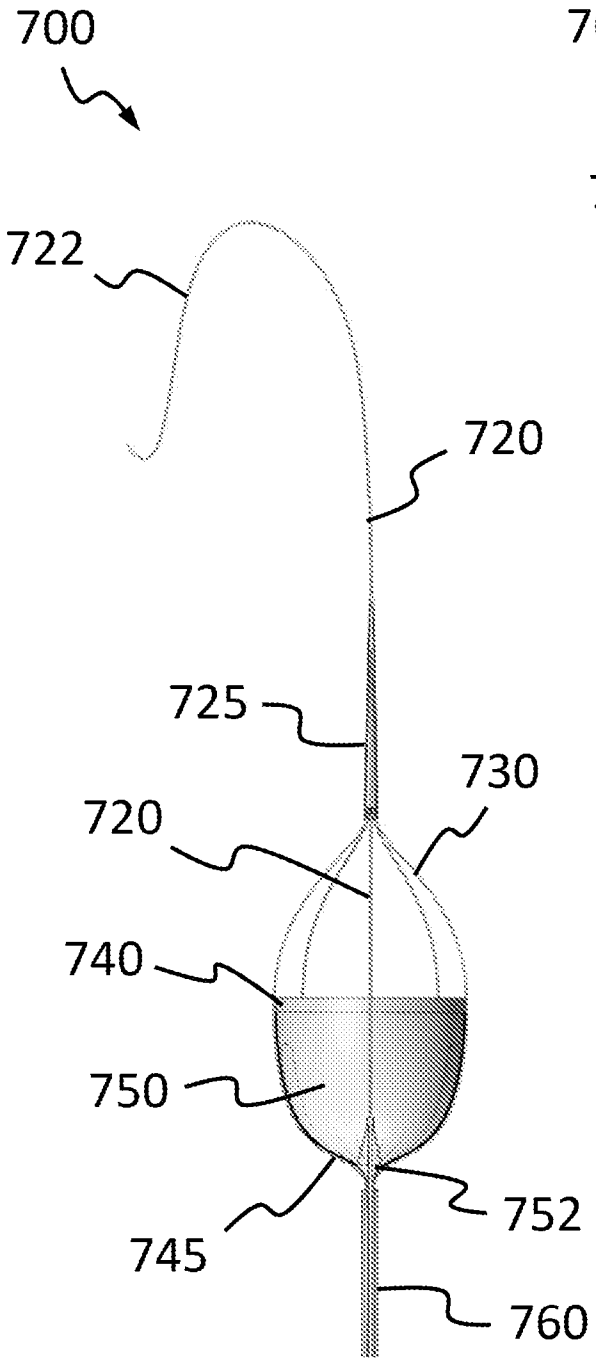


Fig. 40A

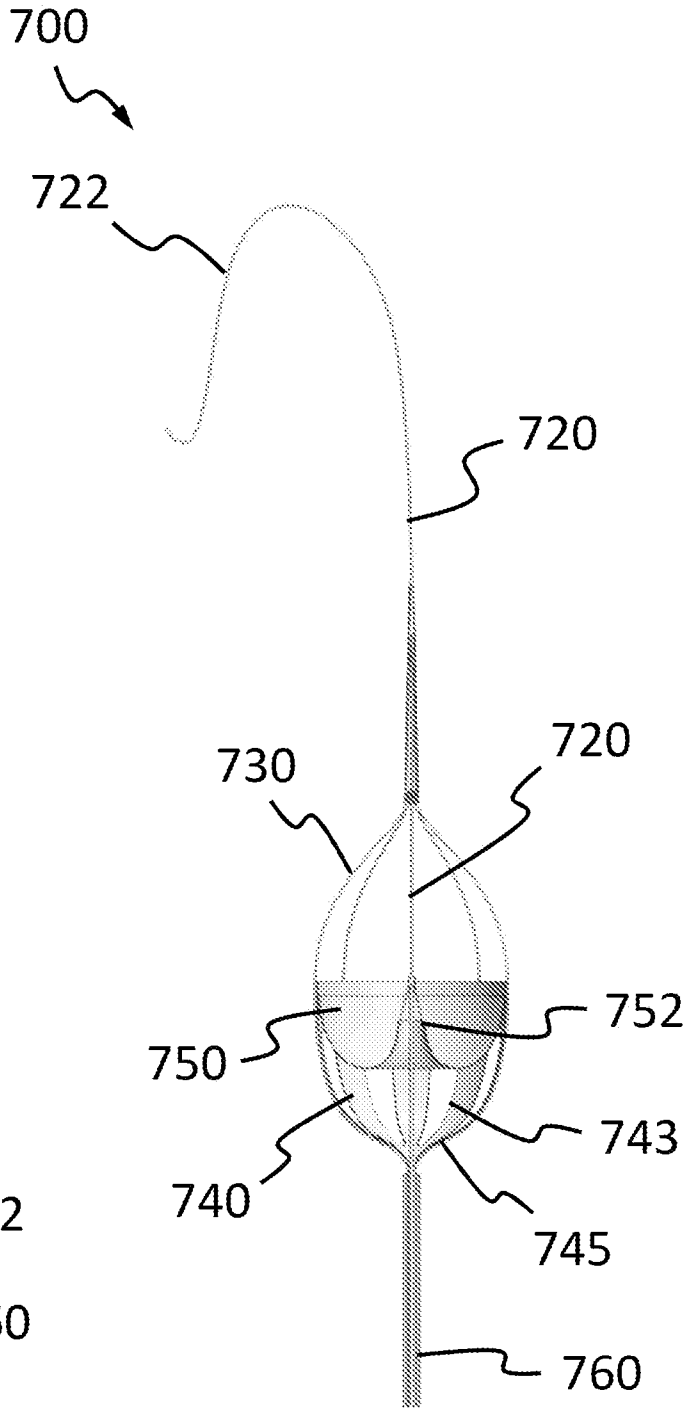


Fig. 40B

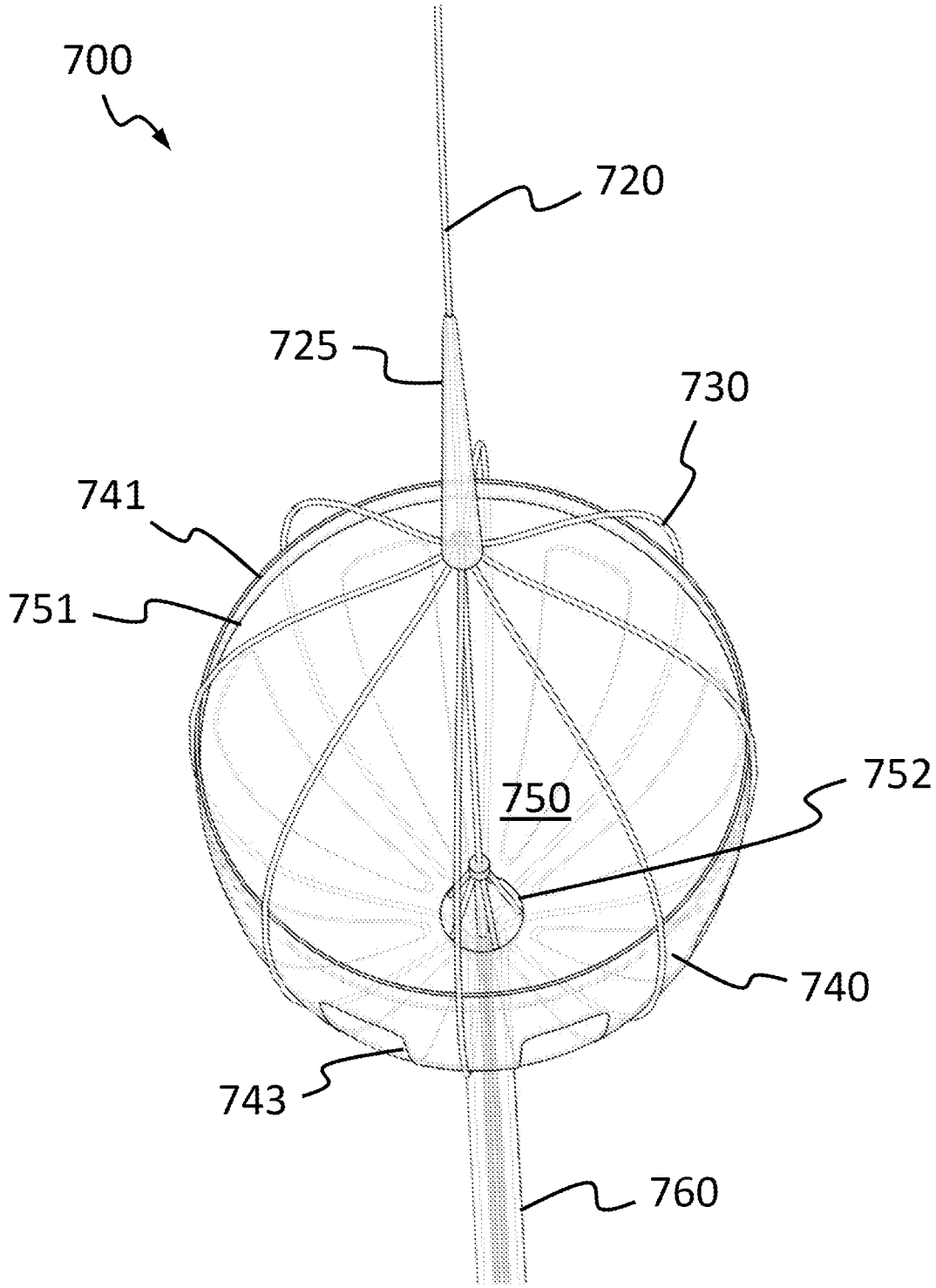


Fig. 41A

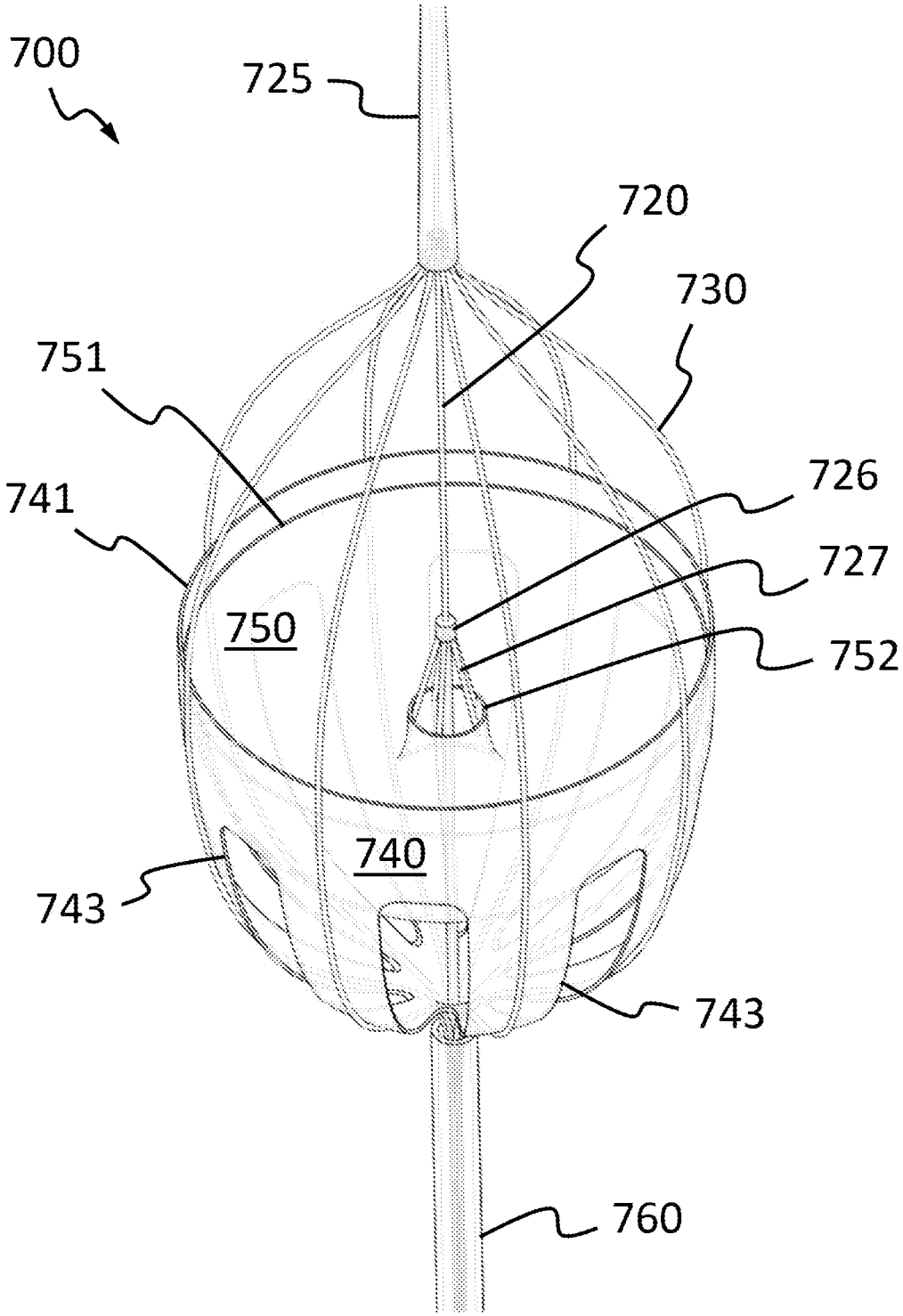


Fig. 41B

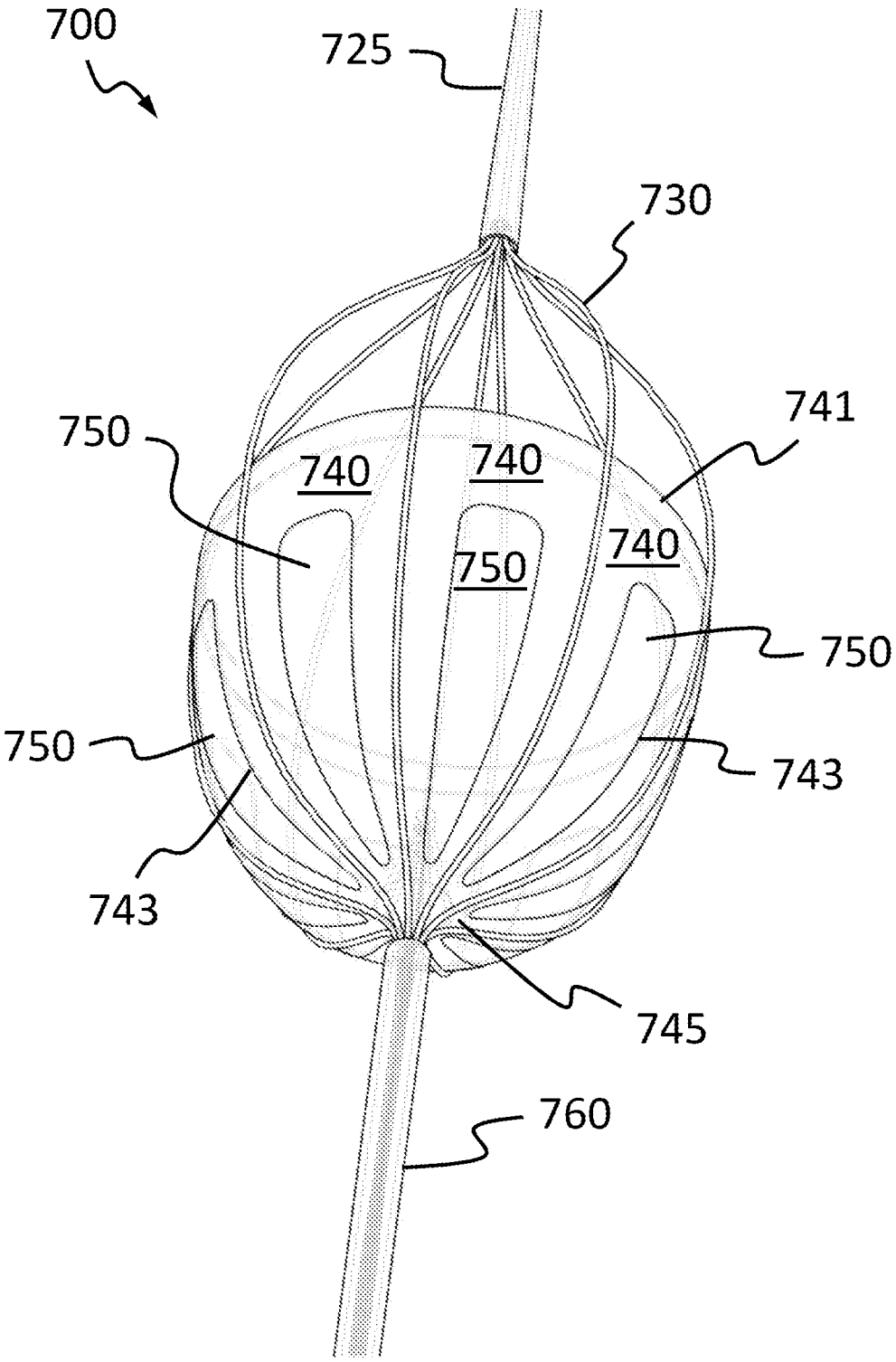


Fig. 42A

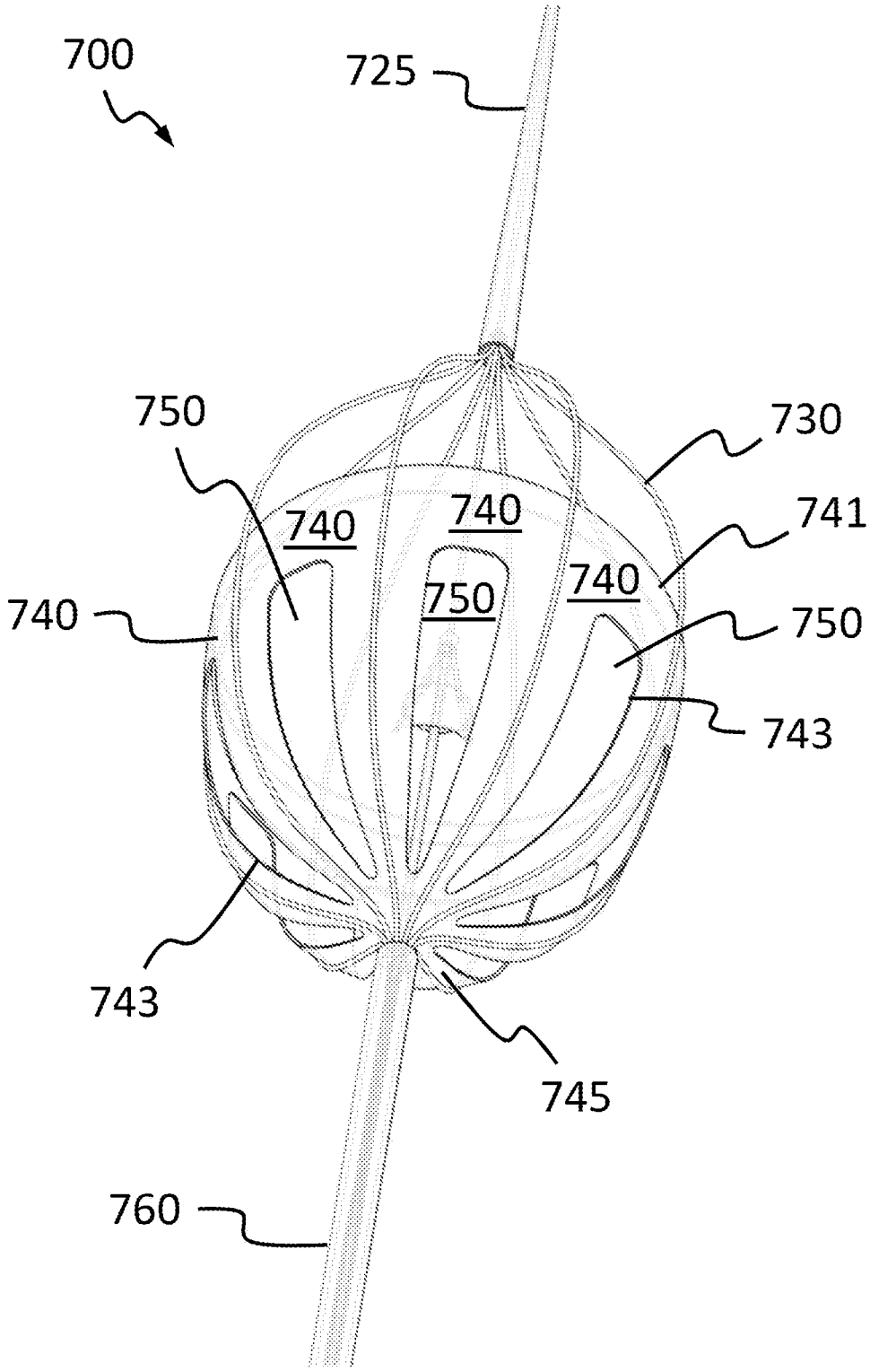


Fig. 42B

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US16/14080

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 25/10, 25/14 (2016.01)
CPC - A61M 25/10, 25/14
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) Classification(s): A61B 5/02, 5/027, 5/1459, 5/1473, 8/12; A61L 29/14; A61M 25/01, 25/10, 25/14, 25/16 (2016.01)
CPC Classification(s): A61B 5/02, 5/027, 5/1459, 5/1473, 8/12, 17/12113, 17/12027; A61L 29/14; A61M 25/01, 25/10, 25/14, 25/16

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google; Google Scholar; EBSCO; IP.com; keywords: blood, occlude, vary, control, adjust, regulate, sheath, membrane, barrier, sheet, hole, passage, slot, orifice, opening, outlet, inlet, artery, aorta, lumen, catheter, enlarge, expand, stop, obstruct, block, wire

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 7,220,269 B1 (ANSEL GM et al.) May 22, 2007; entire document | 1-21 |
| A | US 2004/0010282 A1 (KUSLEIKA RS) January 15, 2004; entire document | 1-21 |
| A | US 2012/0078343 A1 (FISH RD) March 29, 2012; entire document | 1-21 |
| A | US 2009/0082800 A1 (JANARDHAN V) March 26, 2009; entire document | 1-21 |
| A | US 2004/0172055 A1 (HUTER SJ et al.) September 2, 2004; entire document | 1-21 |
| A | US 2003/0212361 A1 (BOYLE WJ et al.) November 13, 2003; entire document | 1-21 |
| A | US 2006/0282115 A1 (ABRAMS RM et al.) December 14, 2006; entire document | 1-21 |

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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 29 February 2016 (29.02.2016) | 11 MAR 2016 |
| Name and mailing address of the ISA/<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Shane Thomas<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

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