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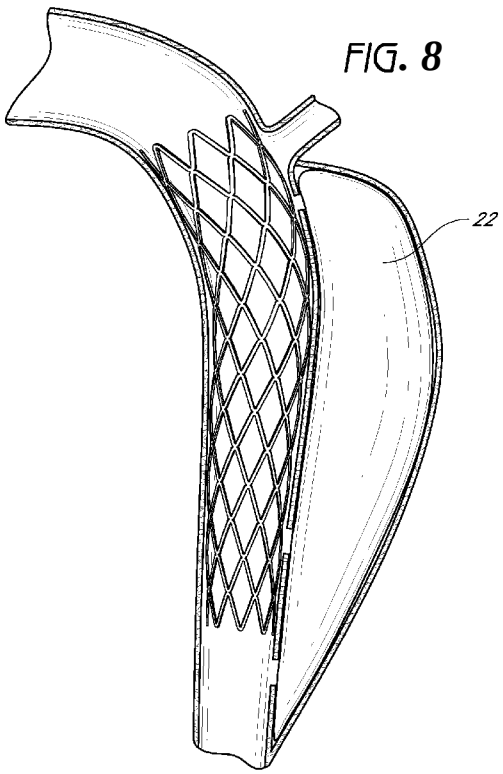

FIG. 8

(57) Abstract: A device system and method for the treatment of aortic dissections comprising placing a stent in the true lumen and displacing the blood in the false lumen with an inflatable bag. An exemplary method of treating an aortic dissection having a true lumen and a false lumen, comprises: deploying a support structure in the true lumen of a blood vessel adjacent to or overlapping a portion of the dissection to maintain the true lumen in an open state; advancing an inflatable structure in a collapsed state into the false lumen; and inflating the inflatable structure to displace the blood in the false lumen.

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DEVICES AND METHODS TO TREAT VASCULAR DISSECTIONS

BACKGROUND OF THE DISCLOSURE

Priority Information and Incorporation By Reference

[0001] This application claims priority benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application 61/414,819 filed November 17, 2010, which application is hereby incorporated by reference as if fully set forth herein.

Field of the Invention

[0002] The present disclosure relates to methods and devices for the treatment of aortic dissections.

Background of the Disclosure

[0003] An aortic dissection is a dangerous condition with a high mortality rates. In an aortic dissection, a tear typically develops in the intima of the aorta that propagates along the vessel wall delaminating the inner layer of the aorta from the outer layer. Blood enters the space between the layers creating a false lumen. Several additional tears or entry points can be created between true lumen of the aorta and the false lumen. In the acute phase, dissections may close off perfusion from the aorta to vital organs. In the chronic phase, the weakened tissue can develop into aneurysm and ultimately rupture. Dissections involving the ascending aorta are referred to as Type A dissections. Dissections only involving the descending aorta are referred to as Type B dissections.

[0004] Current treatments for dissections include medical management to lower the blood pressure of the patient and reduce the hemodynamic stresses on the diseased vessel. If dissections are symptomatic, surgical intervention is necessary. Portions of the diseased aorta are replaced by a surgical graft and the dissection flap is reattached. More recently, stent grafts have been used to close the primary entry point into the false lumen with the goal to thrombose the false lumen and maintain patency of the true lumen.

[0005] Endovascular treatment of aortic dissections in the thoracic aorta using a stent graft may risk inter-operative and post-operative complications. Catheter delivery systems of thoracic stent grafts typically have a profile of 20-24Fr requiring a cut-down or conduit for delivery. Vessel damage by the large delivery catheters used is common. Stent

grafts are difficult to deploy accurately in the thoracic aorta due to high blood flow. Often only the primary entry point of a dissection is covered by the stent graft allowing continuous pressurization of the false lumen through secondary entry points. Long term, a pressurized false lumen tends to expand and become aneurismal. Coverage of all entry points along the dissection by stent grafts contains the risk of local ischemia or paraplegia due to obstruction of vital branch vessels.

[0006] There is a clear need for an improved method to treat aortic dissections. The current application provides novel solutions to the treatment of aortic dissections.

SUMMARY OF SOME EMBODIMENTS

[0007] Some embodiments disclosed herein relate to a device for treating aortic dissections having a false lumen comprising a support structure in a true lumen of the aorta and an inflatable structure in the false lumen. In some embodiments, the support structure can be in a compressed state during the delivery in the aorta. The support structure can be expanded to approximately the diameter of the true lumen when placed in the true lumen. The inflatable structure can be in a collapsed state during the delivery in the false lumen and inflated to displace the blood in the false lumen.

[0008] Some embodiments disclosed herein relate to a device for redirecting flow between at least two blood lumen in the body comprising a support structure in the first lumen and an inflatable structure in a second lumen. In some embodiments, the support structure can be in a compressed first state during the delivery into a first lumen. The support structure can be expandable to a second state to maintain blood flow through the first lumen. The inflatable structure can be in a collapsed state during the delivery into a second lumen and inflated to a second state to block blood flow through the second lumen.

[0009] Some embodiments disclosed herein relate to a method of treating an aortic dissection comprising placing a support structure in the true lumen to maintain the patency of the true lumen, placing an inflatable structure into the false lumen, and inflating the inflatable structure to displace the blood in the false lumen.

[0010] Some embodiments disclosed herein relate to a method of redirecting blood flow between two lumens in the body comprising placement of a implantable support

structure in a first lumen to maintain blood flow through the first lumen and placement of an implantable inflatable structure into a second lumen and inflating the inflatable structure to block blood flow through the second lumen.

[0011] Some embodiments disclosed herein comprise a device and method for the treatment of aortic dissections comprising placing a stent in the true lumen and displacing the blood in the false lumen with an inflatable bag. The device can have a support structure for supporting a true lumen of an aorta and an inflatable structure to be positioned in the false lumen. The support structure can be supported in a compressed state when the device is in a pre-deployment state and during delivery to the true lumen, and can be expanded in the aorta during deployment to approximately the diameter of the true lumen. The inflatable structure can be supported in a compressed state when the device is in a pre-deployment state and during advancement of the inflatable structure into the false lumen, and can be inflated in the false lumen to displace the blood in the false lumen.

[0012] Some embodiments disclosed herein comprise a device for treating aortic dissections having a false lumen, comprising a support structure to be positioned in a true lumen of the aorta to support the true lumen when the support structure is deployed, and an inflatable structure for positioning in the false lumen. The support structure can be supported in a compressed state when the device is in a pre-deployment state and during delivery to the true lumen and expandable in the aorta to the approximate diameter of the true lumen. The inflatable structure can be supported in a compressed state when the device is in a pre-deployment state and during advancement into the false lumen and inflatable in the false lumen to displace the blood in the false lumen.

[0013] Some embodiments disclosed herein comprise a device for altering blood flow in the body, comprising a support structure to be deployed in a first body lumen, and an inflatable structure to be deployed in a second body lumen. In some embodiments, the support structure can be in a compressed first state during delivery into the first lumen and expanded to a second state in the first lumen to maintain blood flow through the first lumen. The inflatable structure can be in a collapsed state during delivery into the second lumen and after being advanced into the second lumen be inflated to a second state in the second lumen

to block blood flow through the second lumen. In some embodiments, the second lumen is adjacent to the first lumen.

[0014] Some arrangements disclosed herein comprise a method of treating an aortic dissection having a true lumen and a false lumen, comprising deploying a support structure in the true lumen of a blood vessel adjacent to or overlapping a portion of the dissection to maintain the true lumen in an open state, advancing an inflatable structure in a collapsed state into the false lumen, and inflating the inflatable structure to displace the blood in the false lumen.

[0015] Some arrangements disclosed herein comprise a method of redirecting blood flow between two lumens in the body, comprising positioning an implantable support structure in a first lumen to maintain blood flow through the first lumen, and positioning an implantable inflatable structure into a second lumen and inflating the inflatable structure to block blood flow through the second lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] These and other features, aspects and advantages of the present disclosure will now be described in connection with non-exclusive embodiments, in reference to the accompanying drawings. The illustrated embodiments, however, are merely examples and are not intended to be limiting. The following are brief descriptions of the drawings, which may not be drawn to scale.

[0017] Figure **1** illustrates one non-limiting example of an aortic dissections.

[0018] Figure 2 illustrates treatment of an aortic dissection with a stent and a stent graft of the prior art.

[0019] Figure 3 illustrates an embodiment of a device system configured to treat dissections

[0020] Figure 4 illustrates the advancement of guidewires into the diseased portion of a blood vessel.

[0021] Figure 5 illustrates the advancement catheters over the guidewires.

[0022] Figure 6 illustrates a support structure deployed in the true lumen.

[0023] Figure 7 illustrates a support structure in a state of being partially deployed in the false lumen.

[0024] Figure 8 illustrates support structure of Fig. 7 fully inflated to act as the support structure in the false lumen.

[0025] Figure 9 illustrates details of an inflatable support structure.

DETAILED DESCRIPTION

[0026] This disclosure relates to a novel devices and methods for treating aortic dissections. Specifically, methods and devices are disclosed herein that are appropriate for the treatment of acute Type B dissections involving the descending aorta. However, some embodiments and/or components of the devices and methods disclosed herein have applications to treat other vascular defects or diseases and all such uses are contemplated as being part of this disclosure.

[0027] Some embodiments of the proposed devices or treatment are configured to obliterate the false lumen while maintaining patency of the true lumen. This can be accomplished by placement of a stent in the true lumen to reestablish the original flow lumen of the aorta. The false lumen can be filled with an inflatable bag that displaces the blood in the false lumen and prevents further pressurization of the aortic wall in the false lumen.

[0028] Figure 1 illustrates a non-limiting example of a type B dissection in the human aorta. A tear 3 in the inner layer of the aorta 1 distal to the subclavian artery 2 typically allows blood to enter into the aortic wall (see arrows) and separate or peel the inner layer 4 of the aorta from the outer layer 5. The space created by the blood between the two layers is referred to as the false lumen 6. The tear 3 is referred as the primary entry point into the false lumen. The separated inner layer 4 is referred to as the flap. The portion of the aorta within the inner layer of the aorta along the dissection is referred to as the true lumen 7. In some cases, multiple entry and exit openings may exist along the flap, as indicated by the openings 8 and 9.

[0029] Figure 2 show devices used in a current method for treating type B dissections. A covered stent 11 is placed at the location of the primary entry point to prevent blood from entering the false lumen through the primary entry point. A bare stent 12 is

placed in the true lumen distal to the covered stent 11 to prevent the flap from obstructing the true lumen.

[0030] Figure 3 shows an embodiment of the proposed device. A support structure 21 such as a balloon expandable stent or a self-expandable stent is placed in the true lumen to maintain patency of the true lumen. An inflatable structure 22is placed in the false lumen such that, in the inflated state, it displaces the blood in the false lumen. By displacing the blood in the false lumen, the effect of blood pressure on the wall of the false lumen can be reduced or eliminated and further dilation of the false lumen can be prevented or inhibited.

[0031] The support structure in the true lumen can comprise a single stent or multiple stents. In the case of multiple stents, the stents can be positioned adjacent to one another, spaced apart or can be positioned relative to one another so as to at least partially overlap. The stents can be flexible so as to conform to the curvature of the aorta. Some embodiments of the stents can have large spaces between the struts to allow for flow into branch vessels of the aorta.

[0032] Figures 4-8 illustrate the steps of a method of treating a dissection with a device system as described herein. The order of the steps described below can be altered or adjusted, and some of the steps can be omitted or combined with other steps. For example, a support structure can be deployed in the false lumen before a support structure is deployed in the true lumen, or vice versa. Figure 4 illustrates the advancement of two guidewires from the femoral artery into the aorta. A first guidewire 31 is located in the true lumen and a second guidewire 32 is placed into the false lumen. Figure 5 illustrates a catheter 33 comprising a support structure 21 having been inserted over the first guidewire 31 into the true lumen, and a catheter 34 comprising an inflatable structure 22 having been inserted into the false lumen. In the next step, the support structure is deployed in the true lumen. Figure 6 illustrates the support structure (a stent) 21 deployed in the true lumen and the first catheter retracted. With reference to Figure 7, the inflatable structure 22 is shown unsheathed (partially deployed). Figure 7 illustrates the unsheathed inflatable (support) structure 22. As illustrated in Figure 8, the inflatable structure 22 has been inflated to displace the blood in the false lumen.

[0033] Figure 9 shows an embodiment of the inflatable structure 22. The inflatable structure 22 can comprise a bag 41, a catheter 42 with a guidewire lumen 43, and a fill lumen 44. Openings along the catheter 42 can allow inflation medium to pass from the fill lumen 44 into the bag 41. Section A-A illustrates a first cross-section 45 of the catheter 42 comprising the guidewire lumen 43 and the fill lumen 44. Section B-B illustrates a second cross-section 46 of the catheter 42 comprising the guidewire lumen 43 and the fill lumen 44. The second cross-section 46 can be located proximal to the bag 41. The catheter shaft as shown in cross-section 46 can be weakened or otherwise configured to be predictably frangible to allow for breaking and detachment of the catheter 42 at approximately the location of the second cross-section 46 on the catheter and removal of the distal portion of the catheter 42 from the body of the patient.

[0034] There are many suitable methods of or embodiments filling the inflatable structure. Several potential embodiments are discussed here for illustration purposes. In some embodiments, the bag can be porous to allow blood to enter the interior of the bag. Hydrogel can be inserted into the bag through the fill lumen. The hydrogel can be delivered in form of spheres, tubes, or pellets. In some embodiments, when the hydrogel enters the bag, the hydrophilic properties of the bag can draw blood through the porous wall into the bag. The hydrogel can absorb the blood and swell. The swelling hydrogel can cause the bag to inflate. Hydrogel can be inserted into the bag until the inflated bag fills the false lumen. The swell pressure in the bag can be equal or higher than the blood pressure. The stagnant blood in the hydrogel can coagulate, causing the false lumen to thrombose. Contrast medium can be added to the hydrogel during filling to visualize the expanding bag under fluoroscopy.

[0035] In some embodiments, the bag can be impermeable. Blood can be extracted from the patient and a thrombolytic agent can be added to the blood. The mixture can be injected into the bag to inflate the bag. Additionally, a polymeric solution comprising a polymer and a cross-linking agent can be injected through the fill lumen into the bag. The polymer cross-links after injection. Alternatively, the hydrogel can be a thermosensitive sol-gel reversible hydrogel. The hydrogel can be configured such that, below body temperature, the hydrogel is in a liquid state. This can facilitate injection of the hydrogel into the

inflatable structure. When the hydrogel warms up to body temperature, it can undergo a phase transition and become more rigid or become a solid.

[0036] It will obvious to the reader skilled in the art that many materials can be used to fill the bag. Preferably, the fill medium is biocompatible. As mentioned, in some embodiments, the fill medium can be configured to be liquid during the injection phase and to solidify after injection.

[0037] The bag can be made from various thin-wall materials including but not limited to ePTFE, polyurethane, and woven and knitted polyester or silk. The wall can have a thickness between 0.0001 in (or approximately 0.0001 in) and 0.01 in (or approximately 0.01 in) or between 0.001 in (or approximately 0.001 in) and 0.004 in (or approximately 0.004 in). The bag can be made from a material that is strong enough to avoid rupture of the bag during inflation. In some embodiments, the bag can be inflated to a pressure in excess of the systolic blood pressure to completely displace the blood from the false lumen. The bag can be configured such that the burst pressure of the bag is higher than the difference between the systolic and diastolic blood pressure. If the wall of the bag is porous to allow for blood to enter the bag, the pore size can be larger than the size of a blood cell. The pores can be larger than 6 micrometers (or approximately 6 micrometers) and smaller than the size of the hydrogel pellets. The pore size can be between 10 micrometers (or approximately 10 micrometers) and 1 millimeter (or approximately 1 millimeter). In arrangements in which liquid medium is injected through the fill lumen into the bag, the wall of the bag can be configured to be impermeable to the fill medium during injection and during solidification of the medium. The entry pressure needed to pass the fill medium through the wall of the bag can be larger than 50 mmHg (or approximately 50 mmHg). In some embodiments, the entry pressure can be larger than 200 mmHg (or approximately 200 mmHg).

[0038] In some embodiments, the delivery system and the fill lumen to the bag can be detached from the bag and retracted from the patient once the bag is filled. In some embodiments, the bag can have a one-way valve that prevents fill medium from escaping from the bag once the fill tube is detached.

[0039] The filling of the bag can be monitored under fluoroscopy. Additionally, radiopaque markers can be attached to the bag to visualize the size of the bag during

inflation. In some embodiments, contrast medium can be injected into the bag to visualize the size of the bag. The contrast medium can be injection into the false lumen to visualize the blood being displaced by the bag. In some embodiments, the inflation of the bag can be monitored by measuring the pressure in the bag. A pressure sensor can be placed in the bag. Alternatively or additionally, the pressure in the fill lumen can be monitored. In some arrangements, a second lumen can be connected to the bag and the pressure in the second lumen can be monitored. Further, in some arrangements, the pressure in the aorta and the bag can be measured and the differential pressure between the aortic pressure and the bag pressure can be displayed.

[0040] As mentioned earlier, the stent in the true lumen can be partially covered with a graft. The graft can cover the primary entry point into the false lumen to reduce the blood pressure in the false lumen. This can reduce the force that the flap exerts on the stent in the true lumen. Alternatively, an aortic balloon can be placed at or proximal to the primary entry point during filling of the bag to block blood from entering the false lumen. To prevent the stent from collapsing during filling of the bag, a balloon can be placed inside the stent and inflated to support the stent.

[0041] The support structure and the inflatable structure can be delivered to the treatment site through the leg arteries of the patient or other branch vessels of the aorta including but not limited to the head arteries and the arm arteries. Alternatively, the devices can be delivered through surgical incisions into the aorta. For example, access to the thoracic aorta can be obtained by an incision into the ascending aorta or the aortic arch. In an alternative approach, access to the aorta may be gained through the apex of the heart or from the right heart. This approach may be preferred in case of Type A dissections that originate in the ascending aorta. It will obvious to those skilled in the art that any combinations of the above approaches can be used to deliver and deploy the support structure into the true lumen and the inflatable structure in the false lumen.

[0042] In some dissections, vital organs can be perfused by the false lumen and not the true lumen. In this case, it may be preferred to place the support structure in the false lumen and the inflatable structure in the true lumen. It will obvious to those skilled in the art

that the combination of a support structure and an inflatable structure can be used to redirect flow between any of two parallel blood or air lumens in the body.

[0043] As will be recognized, certain embodiments described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others. Unless otherwise defined herein, the term approximate or approximately means values within 10% of the stated value.

[0044] Although this disclosure has been described in the context of exemplifying embodiments and examples, it will be understood by those skilled in the art that the embodiments disclosed herein extend beyond the specifically disclosed embodiments to other alternative embodiments and obvious modifications and equivalents thereof. In addition, while a number of variations have been shown and described in detail, other modifications, which are within the scope of this disclosure, will be readily apparent to those of skill in the art based upon this disclosure. It can be also contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments can be made and still fall within the scope of the invention. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combine with or substituted for one another in order to form varying modes of treatment as described herein. Thus, it is intended that the scope of that herein disclosed should not be limited by the particular disclosed embodiments described above.

WHAT IS CLAIMED IS:

1. A method of treating an aortic dissection having a true lumen and a false lumen, comprising:

deploying a support structure in the true lumen of a blood vessel adjacent to or overlapping a portion of the dissection to maintain the true lumen in an open state;

advancing an inflatable structure in a collapsed state into the false lumen; and

inflating the inflatable structure to displace the blood in the false lumen.

2. The method of Claim 1, wherein the support structure is a balloon expandable stent or a self-expandable stent.

3. The method of any one of the previous claims, wherein the support structure is partially covered with a graft to seal the primary entry point of the dissection.

4. The method of any one of the previous claims, wherein the inflatable structure in inflated to a pressure equal or higher than the aortic pressure.

5. The method of any one of the previous claims, comprising inflating the inflatable structure with an inflation medium through a detachable fill tube.

6. The method of any one of the previous claims, comprising inflating the inflatable structure with an inflation medium comprising blood.

7. The method of any one of the previous claims, comprising inflating the inflatable structure with an inflation medium comprising a polymer or monomer that crosslinks after injection.

8. The method of Claim 7, wherein the polymer comprises polyethylene glycol.

9. The method of any one of the previous claims, comprising inflating the inflatable structure with an inflation medium comprising a contrast agent.

10. The method of any one of the previous claims, comprising inflating the inflatable structure with an inflation medium comprising a hydrogel.

11. The method of any one of the previous claims, wherein the inflatable structure is made from ePTFE, polyurethane, Dacron, woven or knitted biocompatible fibers, or other thin-wall biocompatible material.

12. The method of any one of the previous claims, wherein a wall of the inflatable structure is impermeable to an inflation medium during a filling phase.

13. The method of any one of the previous claims, wherein a wall of the inflatable structure is permeable to blood.

14. The method of any one of the previous claims, wherein the inflatable structure comprises an embolization agent.

15. The method of any one of the previous claims, comprising sandwiching a flap of the dissection between the support structure and the inflatable structure with the support structure and the inflatable structure.

16. The method of any one of the previous claims, wherein the stent is sized to extend along the entire length of the dissection.

17. The method of any one of the previous claims, further comprising monitoring a pressure in the inflatable structure during inflation.

18. The method of any one of the previous claims, wherein an inflation medium for inflating the inflatable structure is liquid during injection and changes phase to a solid after injection.

19. The method of any one of the previous claims, comprising inflating the inflatable structure to displace the blood in the false lumen after deploying the support structure in the true lumen of the blood vessel adjacent to or overlapping a portion of the dissection.

20. A method of redirecting blood flow between two lumens in the body, comprising:

positioning an implantable support structure in a first lumen to maintain blood flow through the first lumen; and

positioning an implantable inflatable structure into a second lumen and inflating the inflatable structure to block blood flow through the second lumen.

21. The method of any one of the previous claims, wherein the support structure is a balloon expandable stent or a self-expandable stent.

22. The method of any one of the previous claims, wherein the support structure is partially covered with a graft to seal the primary entry point of the dissection.

23. The method of any one of the previous claims, wherein the inflatable structure in inflated to a pressure equal or higher than the aortic pressure.

24. The method of any one of the previous claims, comprising inflating the inflatable structure with an inflation medium through a detachable fill tube.

25. The method of any one of the previous claims, comprising inflating the inflatable structure with an inflation medium comprising blood.

26. The method of any one of the previous claims, comprising inflating the inflatable structure with an inflation medium comprising a polymer or monomer that crosslinks after injection.

27. The method of Claim 26, wherein the polymer comprises polyethylene glycol.

28. The method of any one of the previous claims, comprising inflating the inflatable structure with an inflation medium comprising a contrast agent.

29. The method of any one of the previous claims, comprising inflating the inflatable structure with an inflation medium comprising a hydrogel.

30. The method of any one of the previous claims, wherein the inflatable structure is made from ePTFE, polyurethane, Dacron, woven or knitted biocompatible fibers, or other thin-wall biocompatible material.

31. The method of any one of the previous claims, wherein a wall of the inflatable structure is impermeable to an inflation medium during a filling phase.

32. The method of any one of the previous claims, wherein a wall of the inflatable structure is permeable to blood.

33. The method of any one of the previous claims, wherein the inflatable structure comprises an embolization agent.

34. The method of any one of the previous claims, comprising sandwiching a flap of the dissection between the support structure and the inflatable structure with the support structure and the inflatable structure.

35. The method of any one of the previous claims, wherein the stent is sized to extend along the entire length of the dissection.

36. The method of any one of the previous claims, further comprising monitoring a pressure in the inflatable structure during inflation.

37. The method of any one of the previous claims, wherein an inflation medium for inflating the inflatable structure is liquid during injection and changes phase to a solid after injection.

38. The method of any one of the previous claims, comprising inflating the inflatable structure to displace the blood in the false lumen after deploying the support structure in the true lumen of the blood vessel adjacent to or overlapping a portion of the dissection.

39. A device system for treating aortic dissections having a false lumen, comprising:

a support structure for deployment in a true lumen of an aorta; and

an inflatable structure for deployment in the false lumen of the aorta;

wherein:

the support structure is supported in a compressed state when the device is in a pre-deployment state and during delivery to the true lumen;

the support structure is expanded in the aorta when deployed to approximately the diameter of a true lumen of the aorta;

the inflatable structure is supported in a compressed state when the device is in a pre-deployment state and during advancement of the inflatable structure into the false lumen; and

the inflatable structure is inflated in the false lumen to displace the blood in the false lumen when deployed.

40. A device system of Claim 39, wherein the support structure is a balloon expandable stent or a self-expanding stent.

41. The device system of any one of Claims 39-40, wherein the support structure is partially covered with a graft to at least substantially seal an entry point of the dissection.

42. The device system of any one of Claims 39-41, wherein a flap of the dissection is sandwiched between the support structure and the inflatable structure after the support structure and the inflatable structure have been deployed.

43. The device system of any one of Claims 39-42, wherein the stent is sized to extend along the entire length of the dissection.

44. The device system of any one of Claims 39-43, wherein the pressure in the inflatable structure is equal to or higher than the aortic blood pressure after the inflatable structure has been inflated in the false lumen to displace the blood in the false lumen.

45. The device system of any one of Claims 39-44, further comprising an inflation medium for inflating the inflatable structure comprising blood.

46. The device system of any one of Claims 39-45, further comprising an inflation medium for inflating the inflatable structure comprising a polymer or monomer that crosslinks after injection.

47. The device system of Claim 46, wherein the polymer comprises polyethylene glycol.

48. The device system of any one of Claims 39-47, further comprising an inflation medium for inflating the inflatable structure comprising a contrast agent.

49. The device system of any one of Claims 39-48, further comprising an inflation medium for inflating the inflatable structure comprising a hydrogel.

50. The device system of any one of Claims 39-49, wherein the inflatable structure comprises an embolization agent.

51. The device system of any one of Claims 39-50, wherein a wall of the inflatable structure is permeable to blood.

52. The device system of any one of Claims 39-51, wherein a wall of the inflatable structure is impermeable to an inflation medium during a filling phase.

53. The device system of any one of Claims 39-52, wherein the inflatable structure is made from ePTFE, polyurethane, Dacron, woven or knitted biocompatible fibers, or other thin-wall biocompatible material.

54. The device system of any one of Claims 39-53, wherein an inflation medium is injected into the inflatable structure through a detachable fill tube.

55. The device system of any one of Claims 39-54, further comprising a delivery catheter supporting the support structure and the inflatable structure in the pre-deployment state.

56. A device system for treating aortic dissections having a false lumen, comprising:

a support structure for positioning in a true lumen of the aorta to support the true lumen when the support structure is deployed; and

an inflatable structure for positioning in the false lumen;

wherein:

the support structure is supported in a compressed state when the device is in a pre-deployment state and during delivery to the true lumen and expandable in the aorta to the approximate diameter of the true lumen; and

the inflatable structure is supported in a compressed state when the device is in a pre-deployment state and during advancement into the false lumen and inflatable in the false lumen to displace the blood in the false lumen.

57. A device system of Claim 56, wherein the support structure is a balloon expandable stent or a self-expanding stent.

58. The device system of any one of Claims 56-57, wherein the support structure is partially covered with a graft to at least substantially seal an entry point of the dissection.

59. The device system of any one of Claims 56-58, wherein a flap of the dissection is sandwiched between the support structure and the inflatable structure after the support structure and the inflatable structure have been deployed.

60. The device system of any one of Claims 56-59, wherein the stent is sized to extend along the entire length of the dissection.

61. The device system of any one of Claims 56-60, wherein the pressure in the inflatable structure is equal to or higher than the aortic blood pressure after the inflatable structure has been inflated in the false lumen to displace the blood in the false lumen.

62. The device system of any one of Claims 56-61, further comprising an inflation medium for inflating the inflatable structure comprising blood.

63. The device system of any one of Claims 56-62, further comprising an inflation medium for inflating the inflatable structure comprising a polymer or monomer that crosslinks after injection.

64. The device system of Claim 63, wherein the polymer comprises polyethylene glycol.

65. The device system of any one of Claims 56-64, further comprising an inflation medium for inflating the inflatable structure comprising a contrast agent.

66. The device system of any one of Claims 56-65, further comprising an inflation medium for inflating the inflatable structure comprising a hydrogel.

67. The device system of any one of Claims 56-66, wherein the inflatable structure comprises an embolization agent.

68. The device system of any one of Claims 56-67, wherein a wall of the inflatable structure is permeable to blood.

69. The device system of any one of Claims 56-68, wherein a wall of the inflatable structure is impermeable to an inflation medium during a filling phase.

70. The device system of any one of Claims 56-69, wherein the inflatable structure is made from ePTFE, polyurethane, Dacron, woven or knitted biocompatible fibers, or other thin-wall biocompatible material.

71. The device system of any one of Claims 56-70, wherein an inflation medium is injected into the inflatable structure through a detachable fill tube.

72. The device system of any one of Claims 56-71, further comprising a delivery catheter supporting the support structure and the inflatable structure in the pre-deployment state.

73. A device system for altering blood flow in the body, comprising:

a support structure to be deployed in a first body lumen; and

an inflatable structure to be deployed in a second body lumen;

wherein:

the support structure is in a compressed first state during delivery into the first lumen and is to be expanded to a second state in the first lumen to maintain blood flow through the first lumen;

the inflatable structure is in a collapsed state during delivery into the second lumen and is to be inflated to a second state in the second lumen to block blood flow through the second lumen after being advanced into the second lumen; and

the second lumen is adjacent to the first lumen.

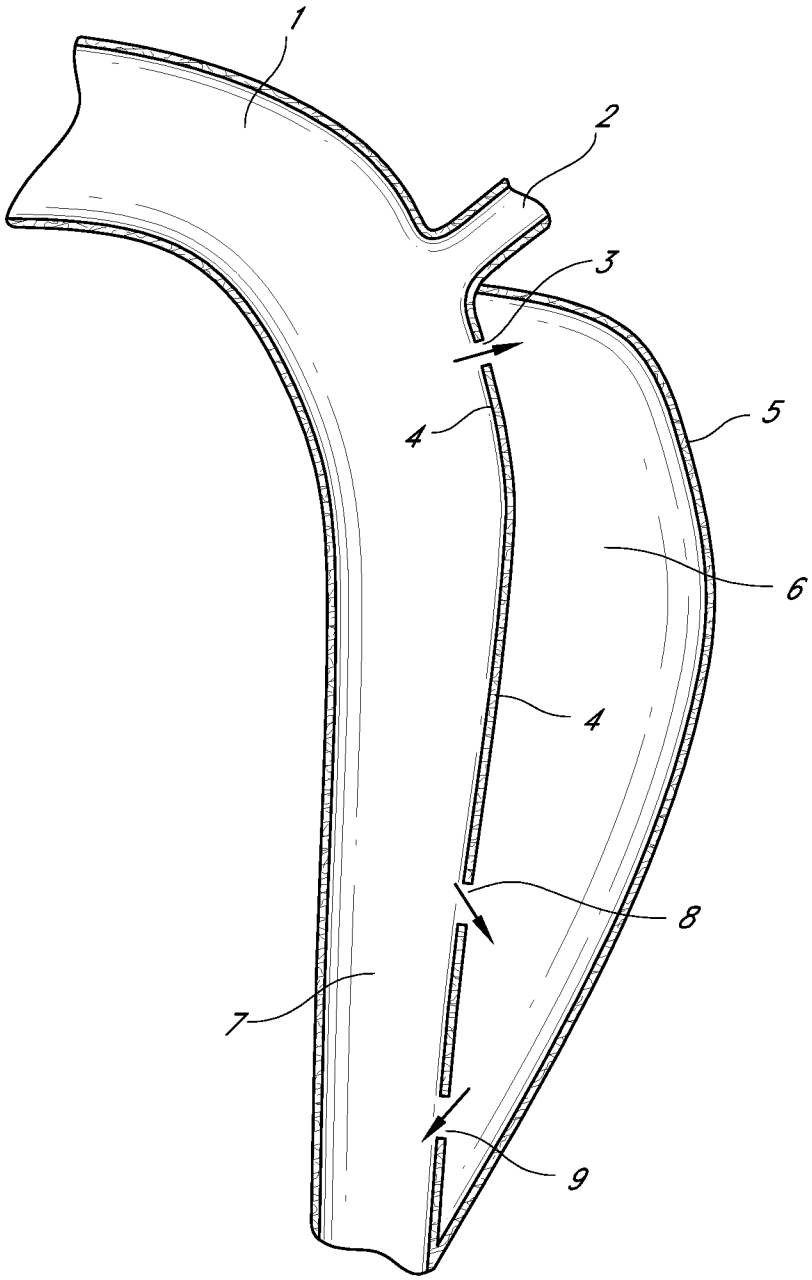

FIG. 1

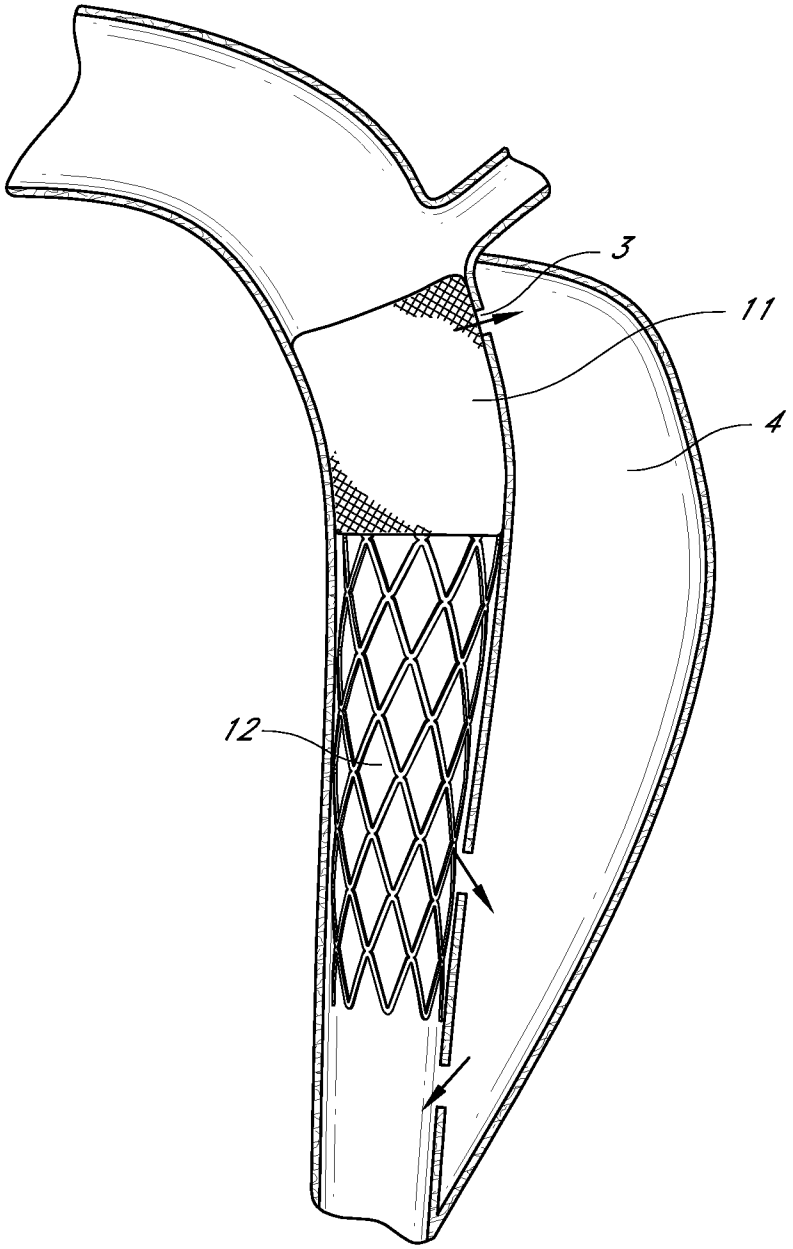

FIG. 2

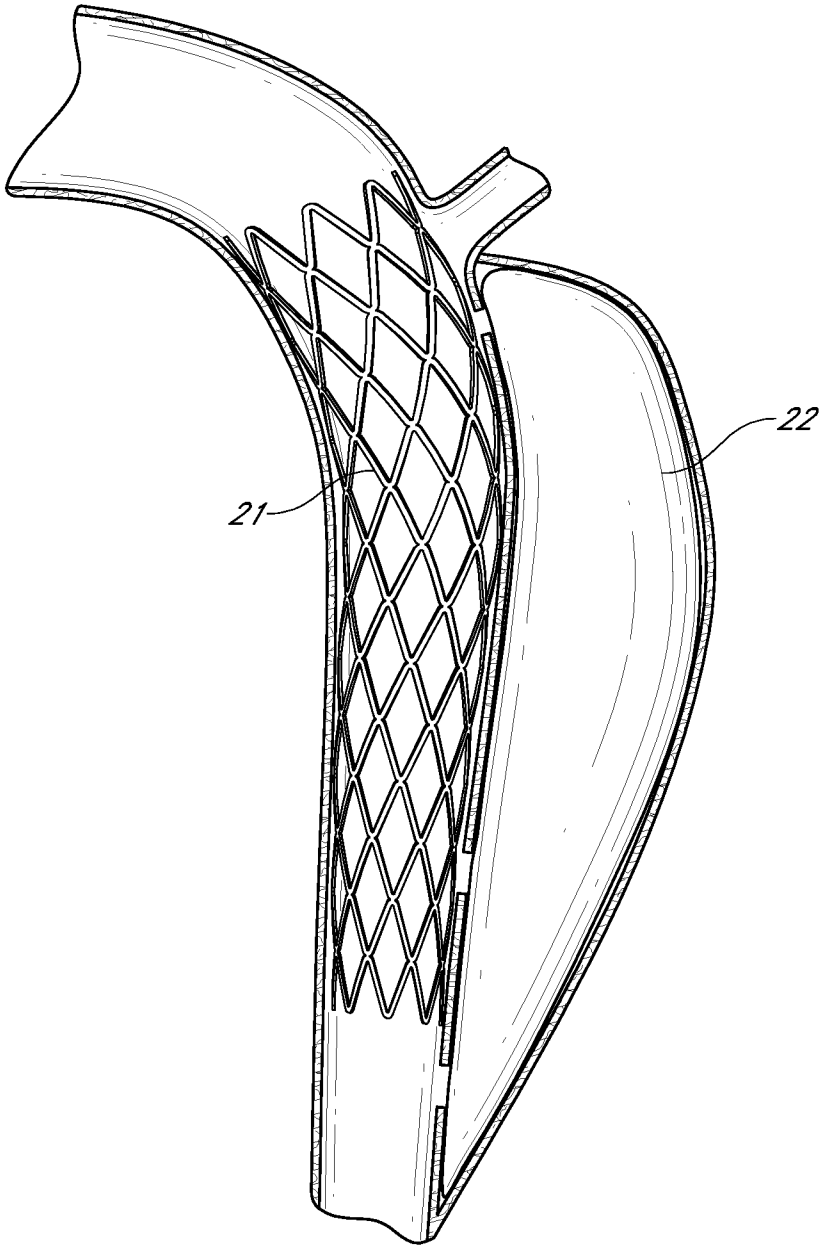

FIG. 3

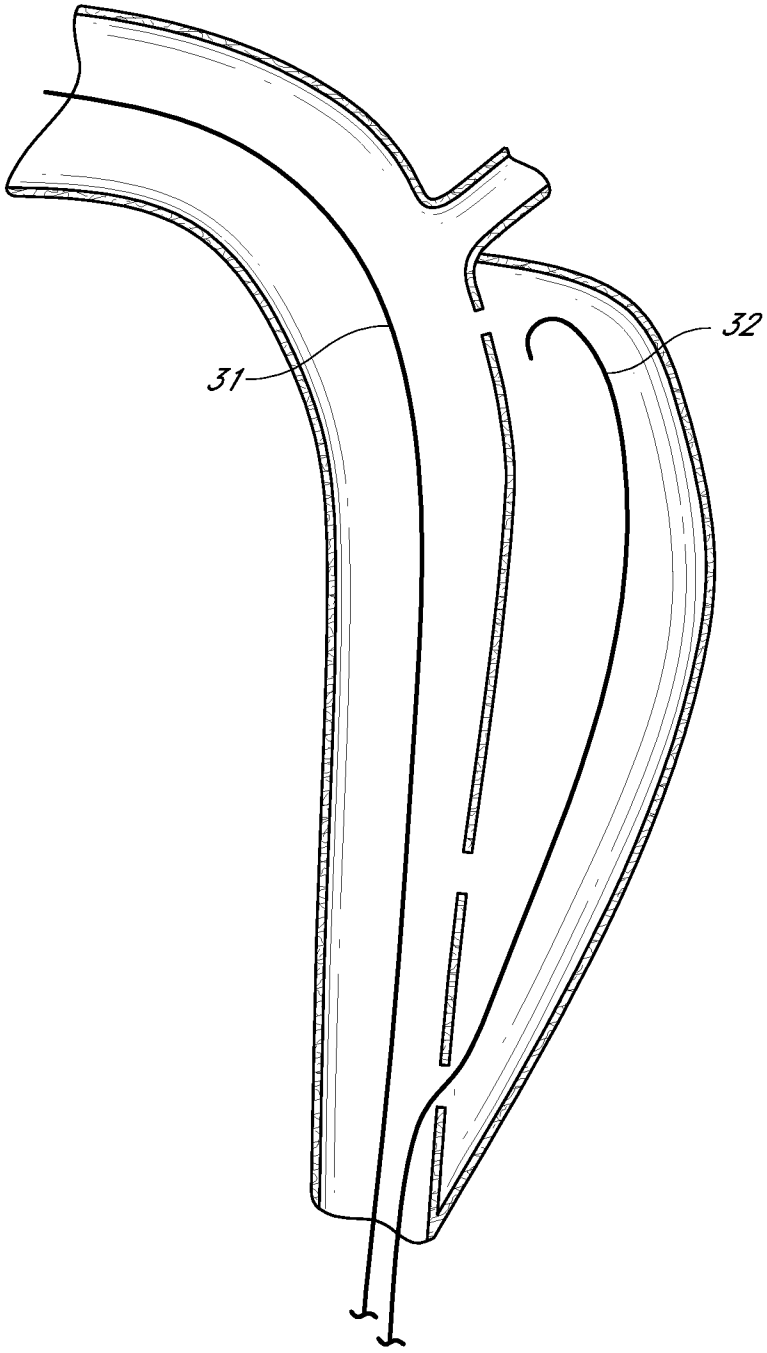

FIG. 4

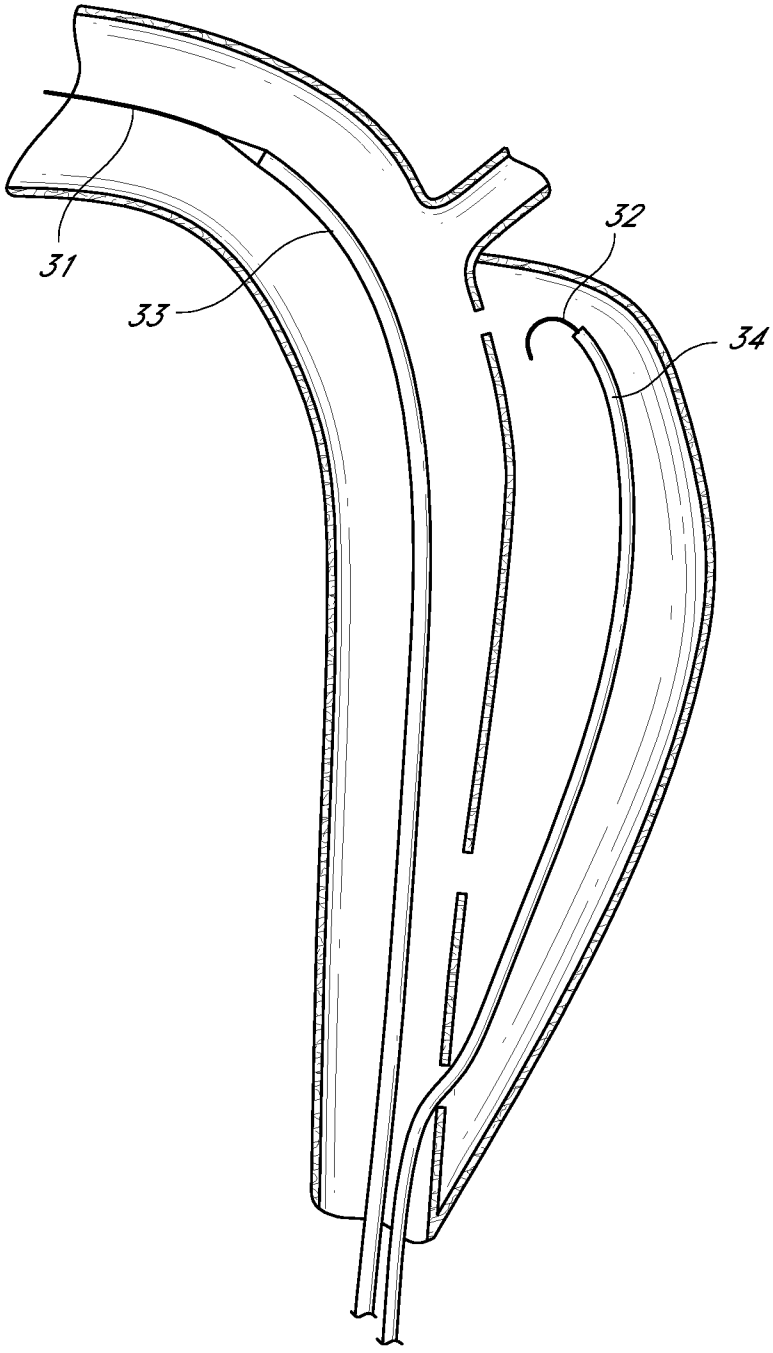

FIG. 5

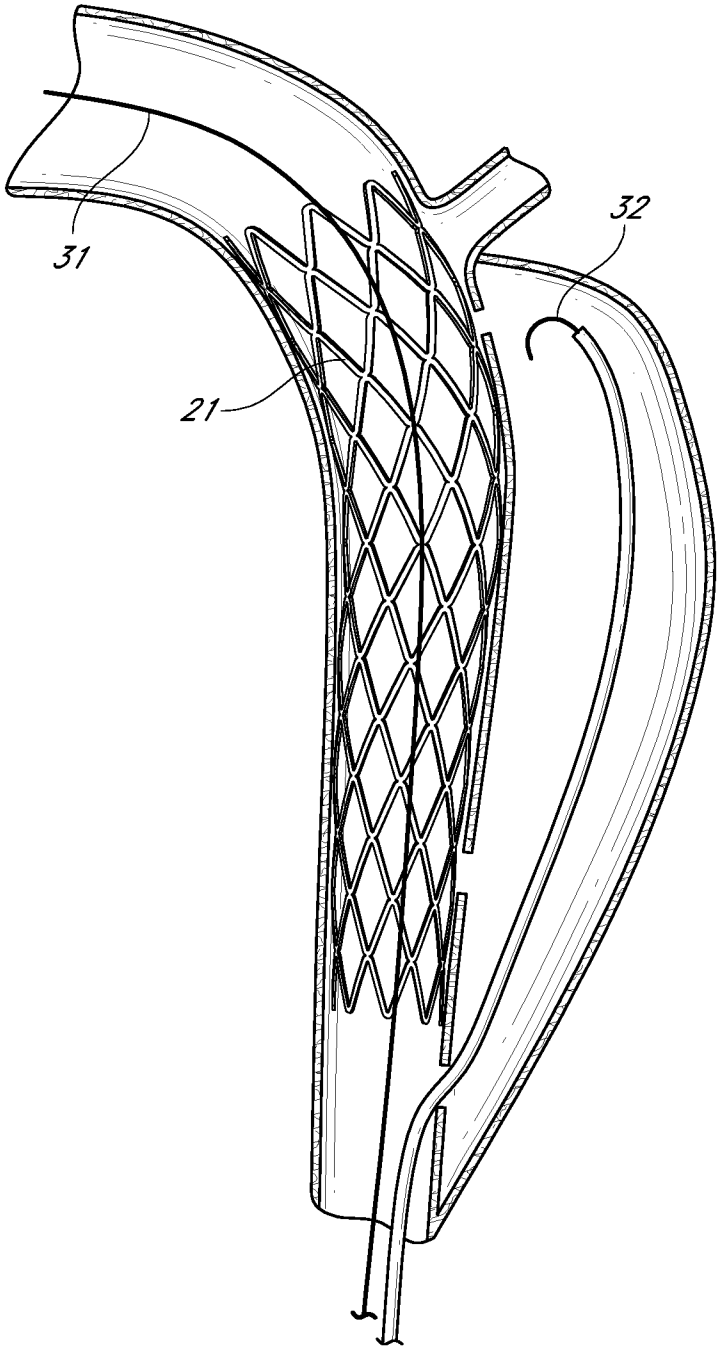

FIG. 6

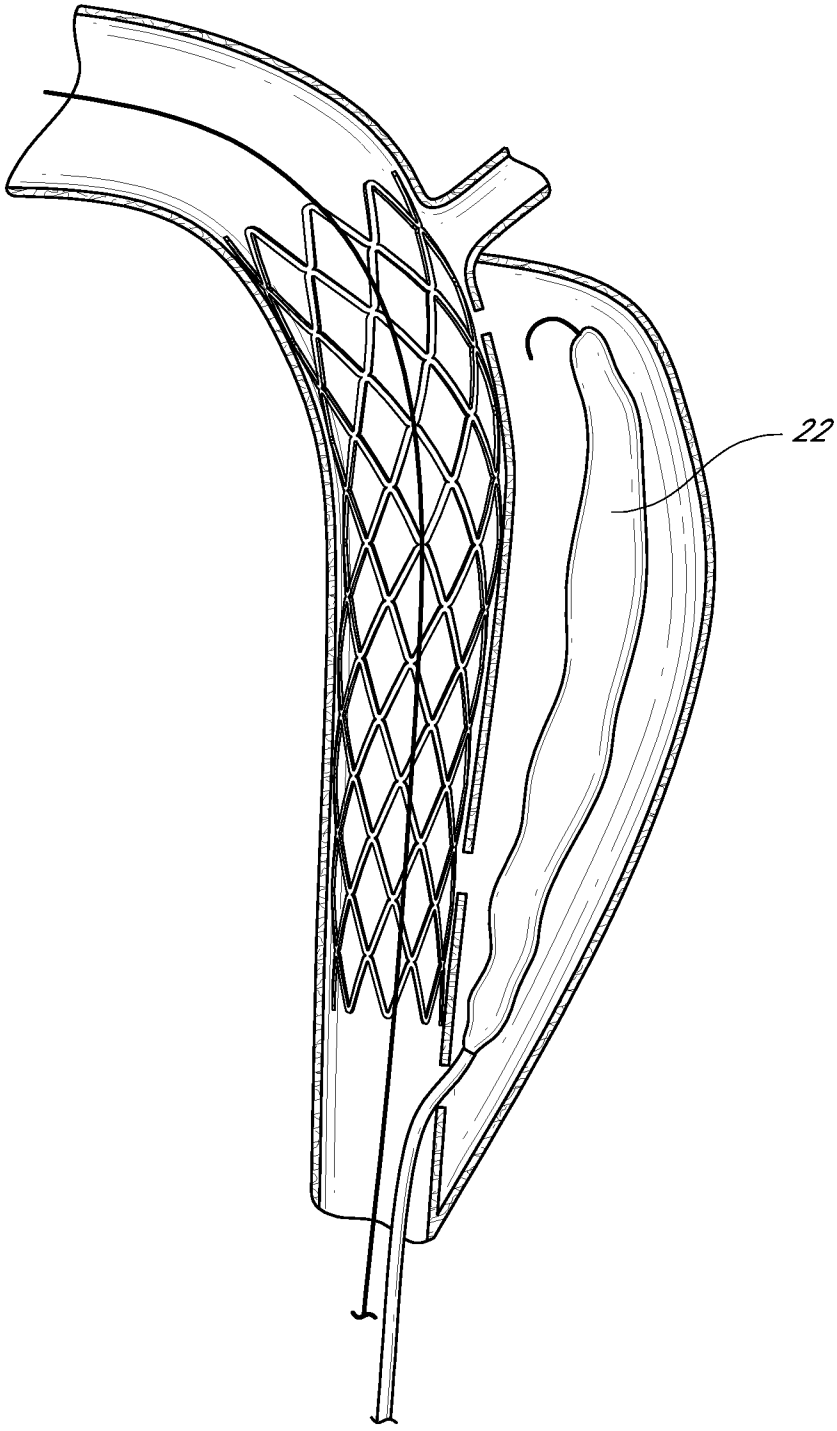

FIG. 7

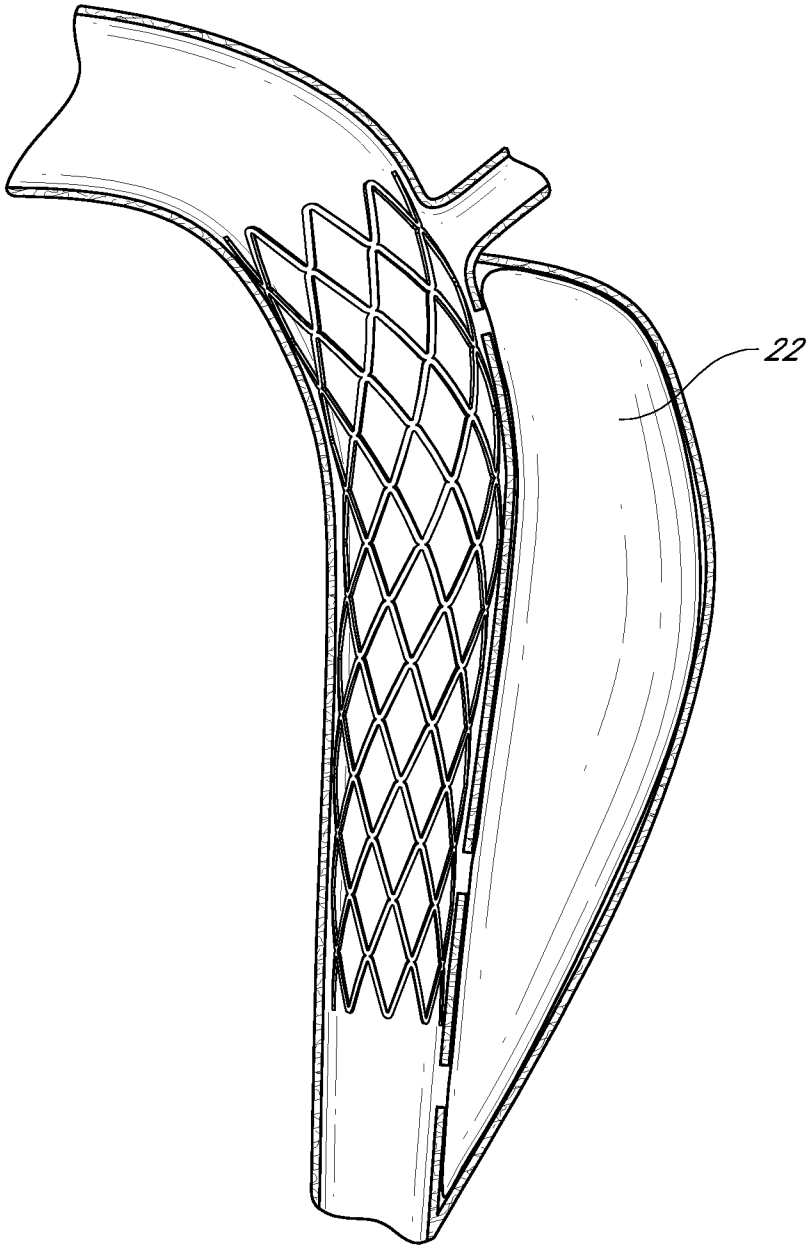

FIG. 8

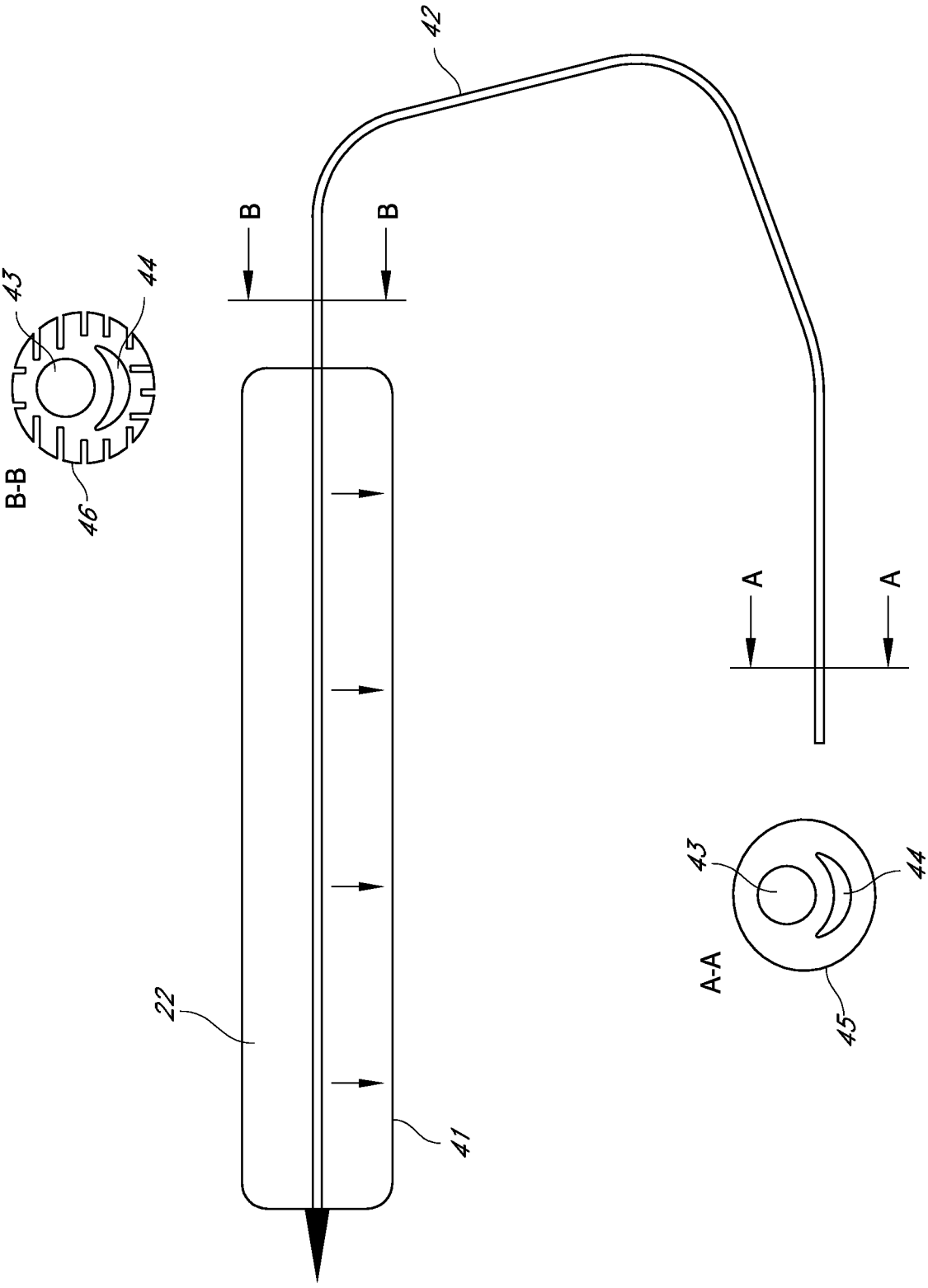

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/061061

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/06 (2012.01)
USPC - 623/1.11
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) - A61F 2/04, 2/06 (2012.01)
USPC - 604/96.01; 606/194, 195; 623/1.11, 1.*

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)
Patbase, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/0163192 A1 (WALLACE et al) 28 August 2003 (28.08.2003) entire document	1-3, 20, 39-41, 56-58, 73
Y	US 6,096,021 A (HELM et al) 01 August 2000 (01.08.2000) entire document	1-3, 20, 39-41, 56-58, 73
Y	US 2006/0142836 A1 (HARTLEY et al) 29 June 2006 (29.06.2006) entire document	3, 41, 58
A	US 2007/0150041 A1 (EVANS et al) 28 June 2007 (28.06.2007) entire document	1-3, 20, 39-41, 56-58, 73

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 February 2012	**23 FEB 2012**

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US201 1/061061

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-19, 21-38, 42-55, 59-72
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. Ill Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.