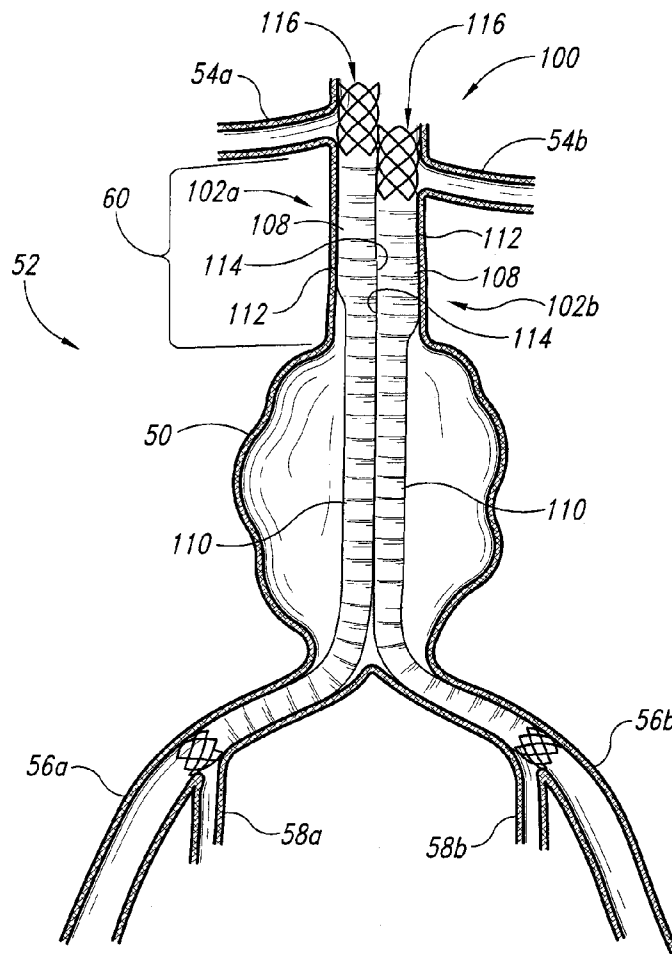


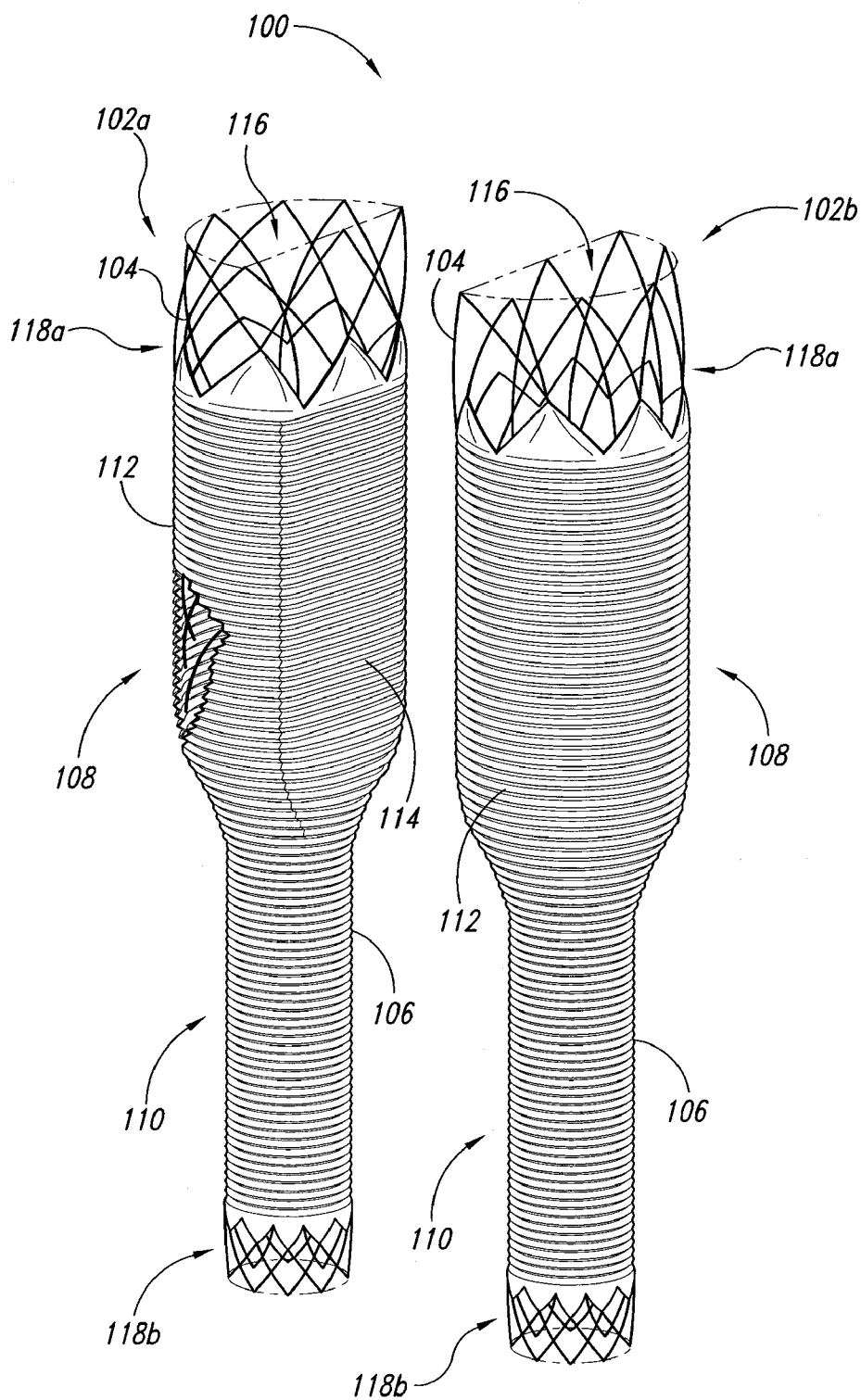


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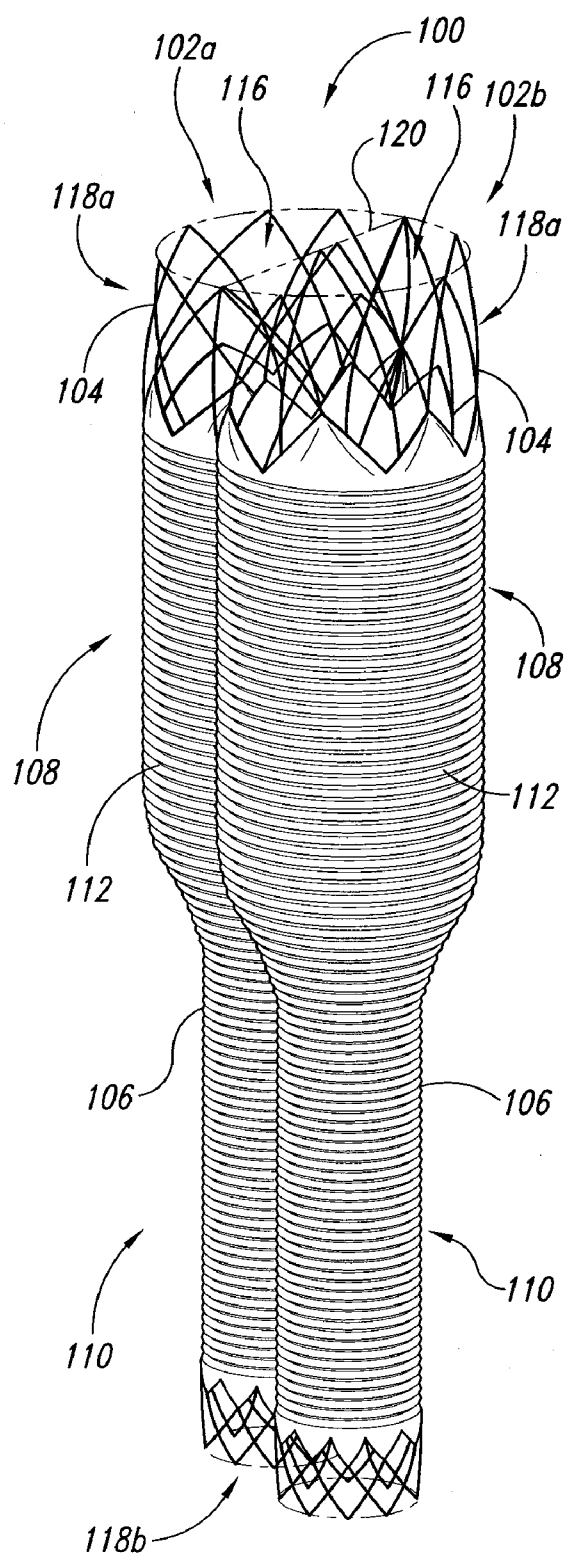
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ASSOCIATED SYSTEMS AND METHODS****Publication Classification**(51) **Int. Cl.**  
**A61F 2/82** (2006.01)  
(52) **U.S. Cl.** ..... **623/1.2**  
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Clemente, CA (US)(21) **Appl. No.:** **12/958,374**(22) **Filed:** **Dec. 1, 2010****Related U.S. Application Data**(60) Provisional application No. 61/265,713, filed on Dec.  
1, 2009, provisional application No. 61/293,581, filed  
on Jan. 8, 2010.

Modular endograft devices and associated systems and methods are disclosed herein. In several embodiments, an endograft system can include a first endograft device and a second endograft device that each include an integrated frame, a cover and a lumen within the cover. Each endograft device further includes a superior portion and an inferior portion. The superior portion can have a convexly curved outer wall and a septal wall. The first and second endograft devices can be configured to extend into a low-profile configuration with a first cross-sectional dimension and a first length and self-expand into an expanded configuration with a second cross-sectional dimension greater than the first cross-sectional dimension and a second length less than the first length. In the expanded configuration, the septal walls can press against each other and form a septum between the lumens of the first and second endograft devices.

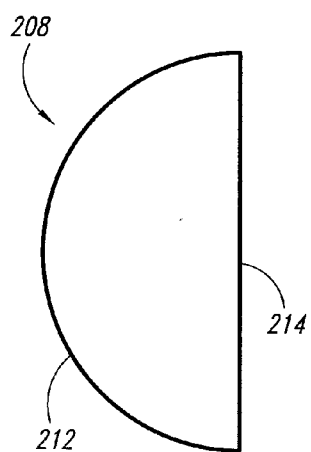




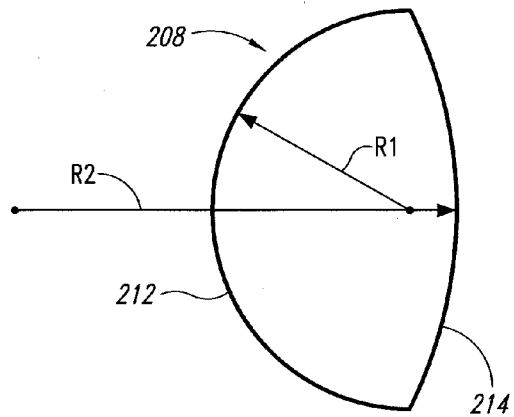
*Fig. 1A*



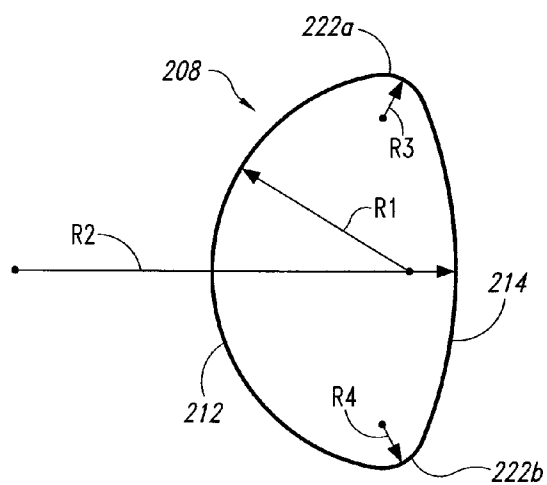
*Fig. 1B*



*Fig. 2A*



*Fig. 2B*



*Fig. 2C*

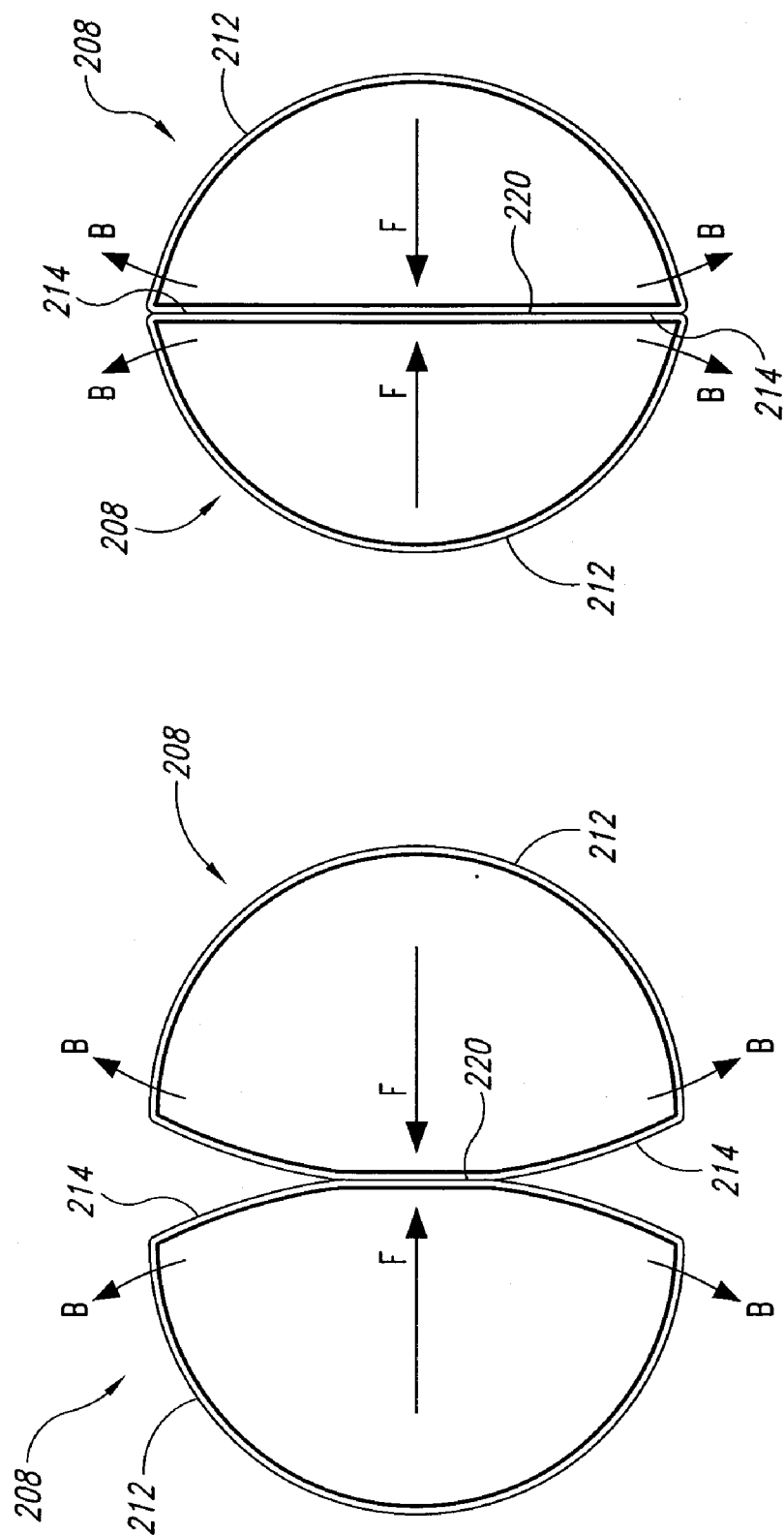
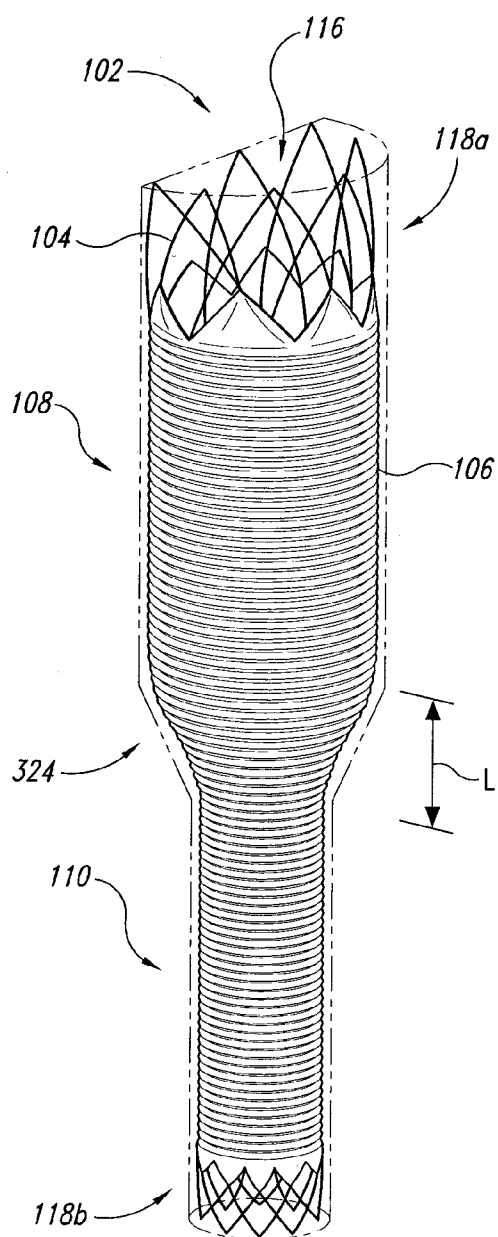
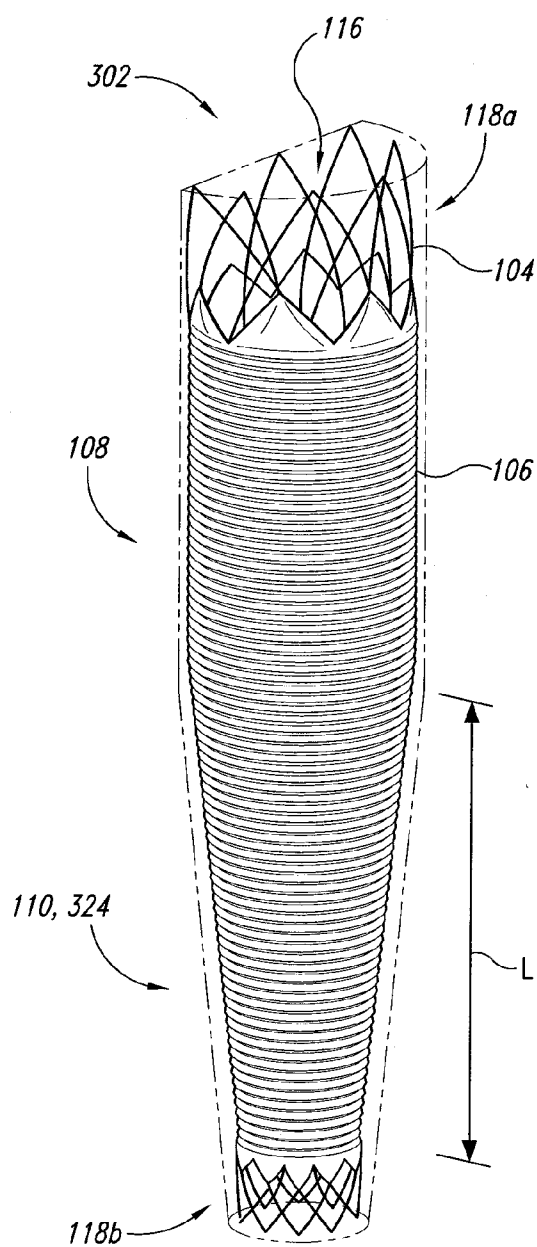


Fig. 2E

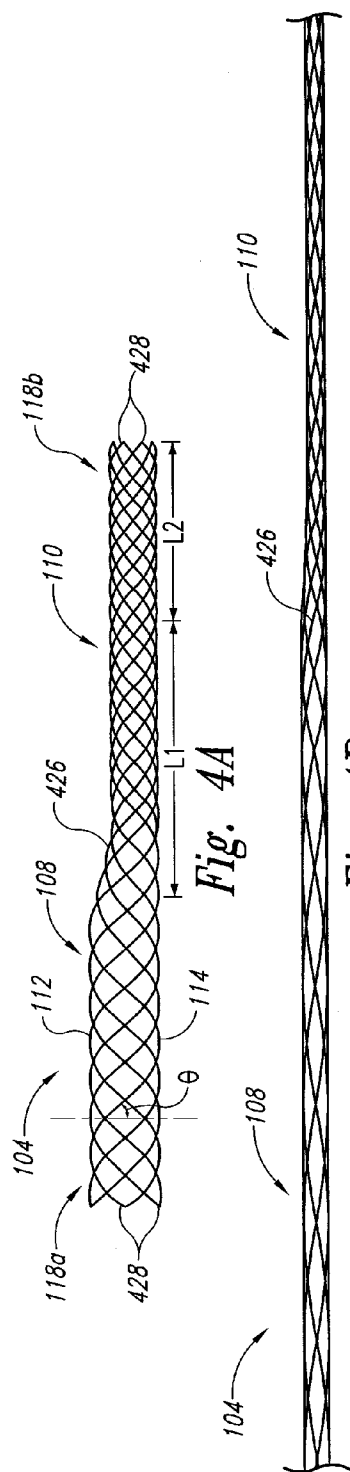
Fig. 2D



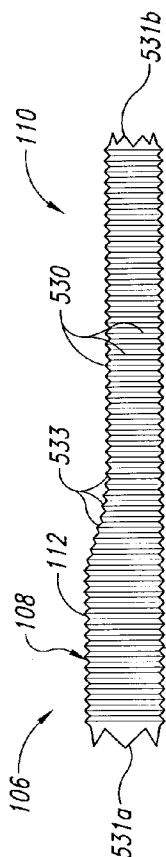
*Fig. 3A*



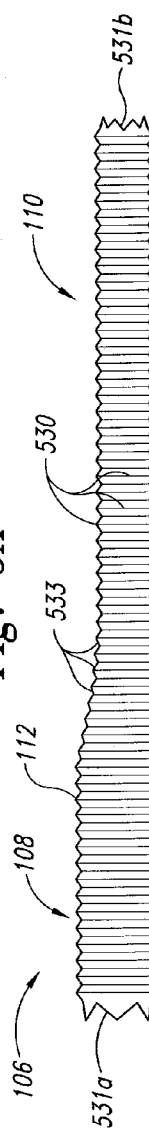
*Fig. 3B*



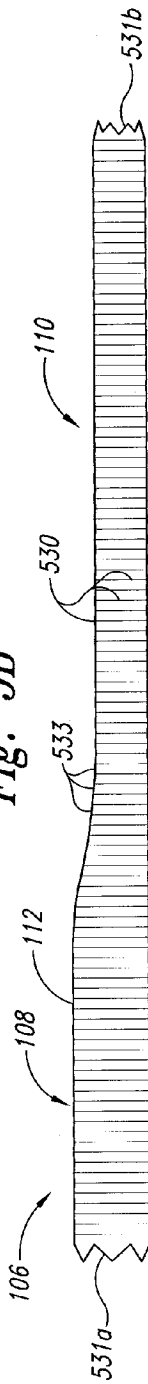
**Fig. 4B**



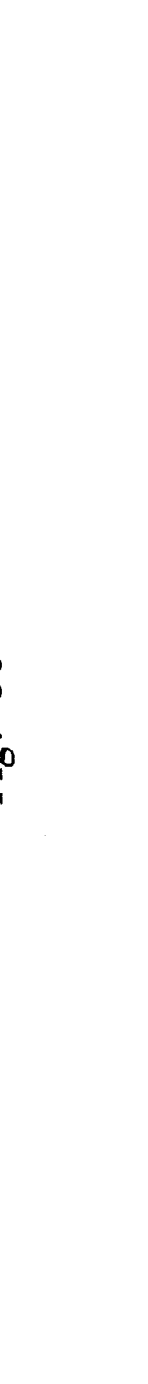
**Fig. 5A**



**Fig. 5B**



**Fig. 5C**



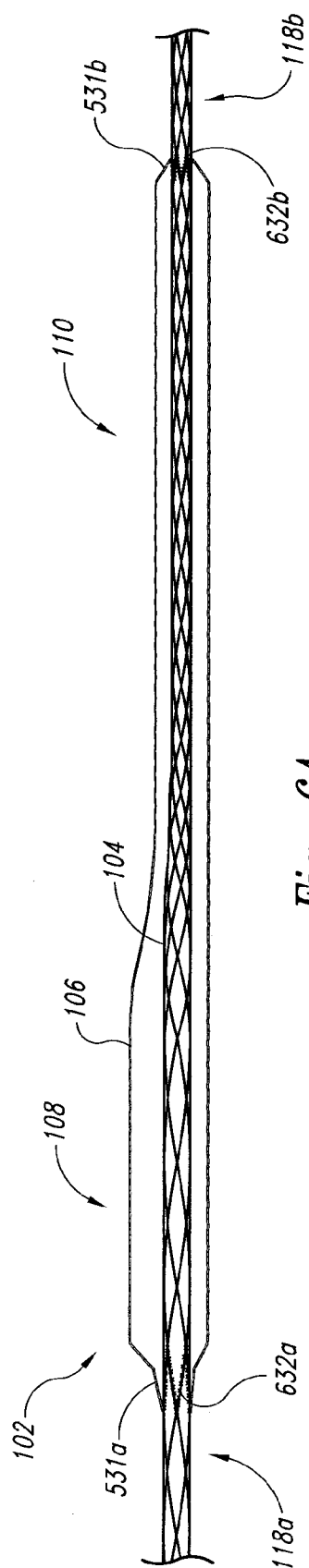


Fig. 6A

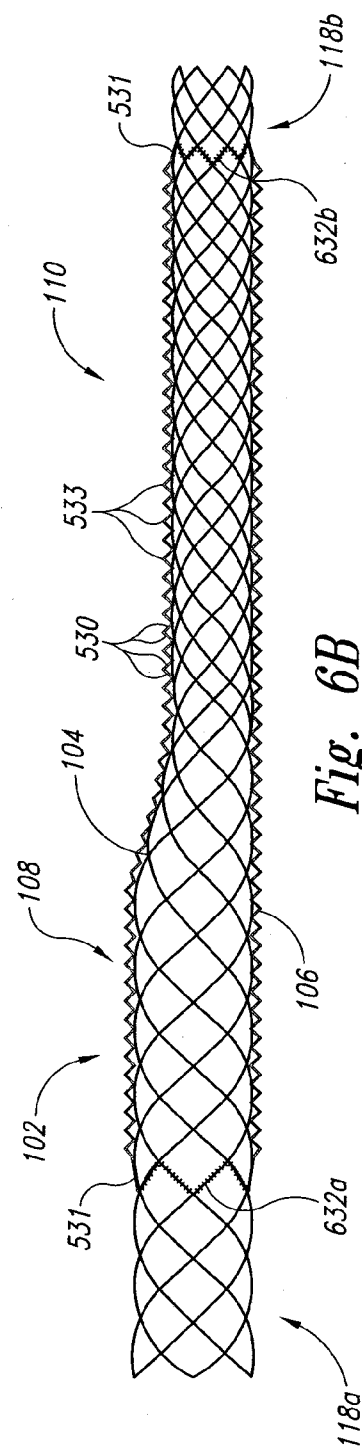
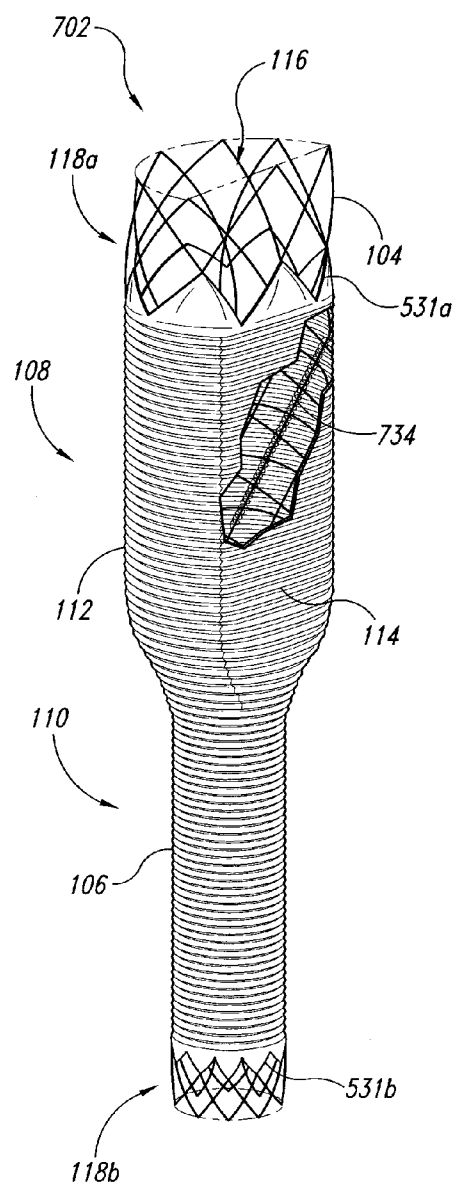
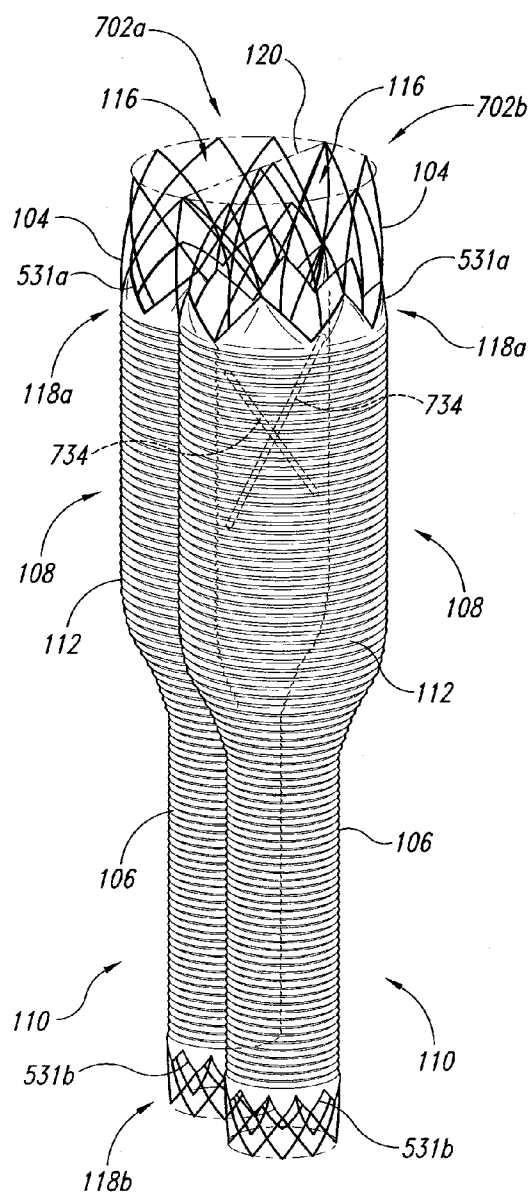


Fig. 6B

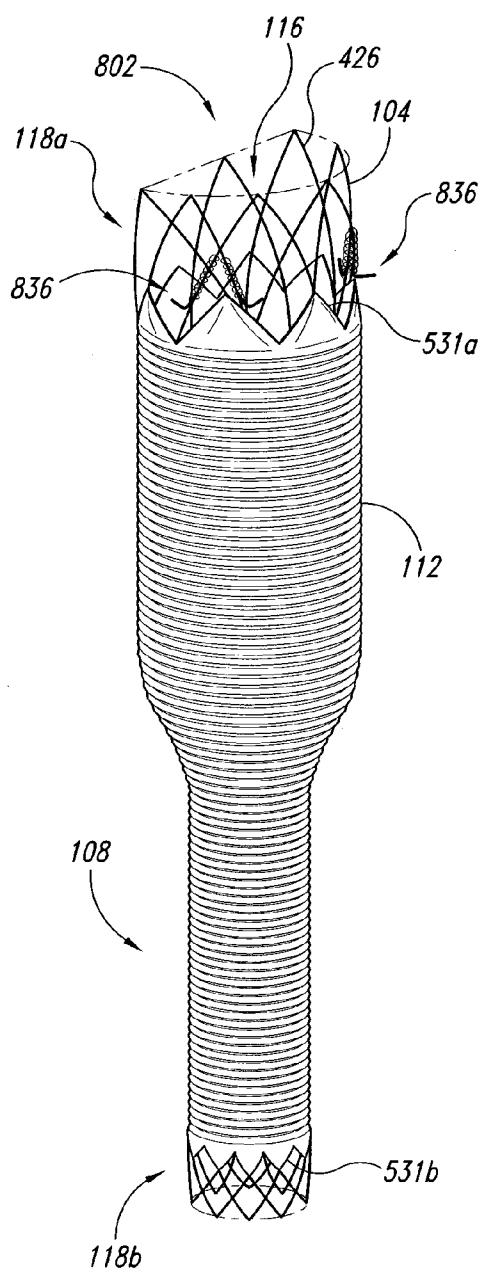




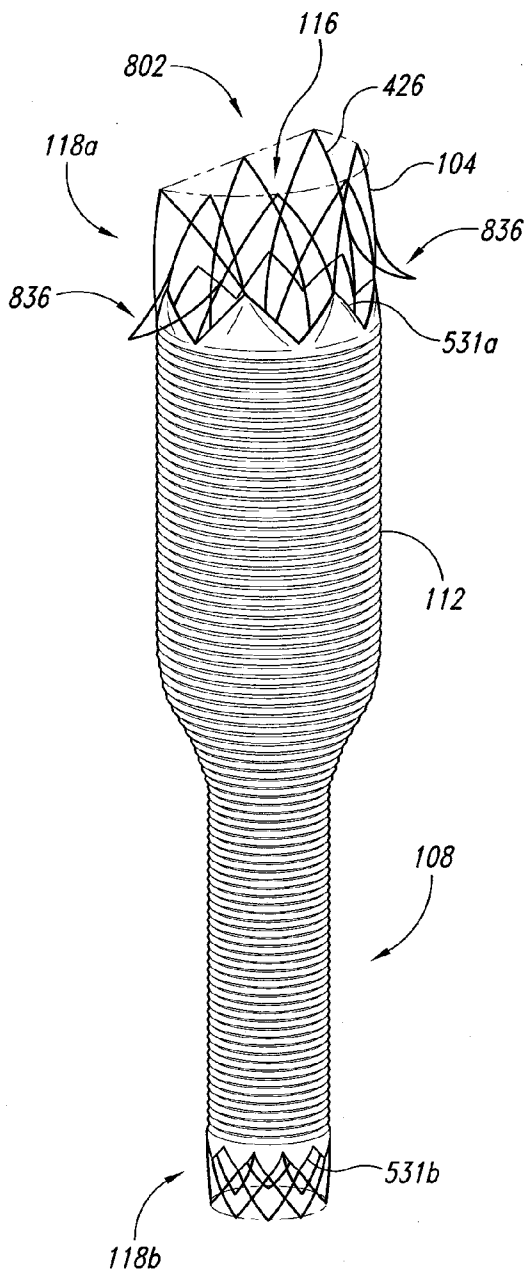
*Fig. 7A*



*Fig. 7B*



*Fig. 8A*



*Fig. 8B*

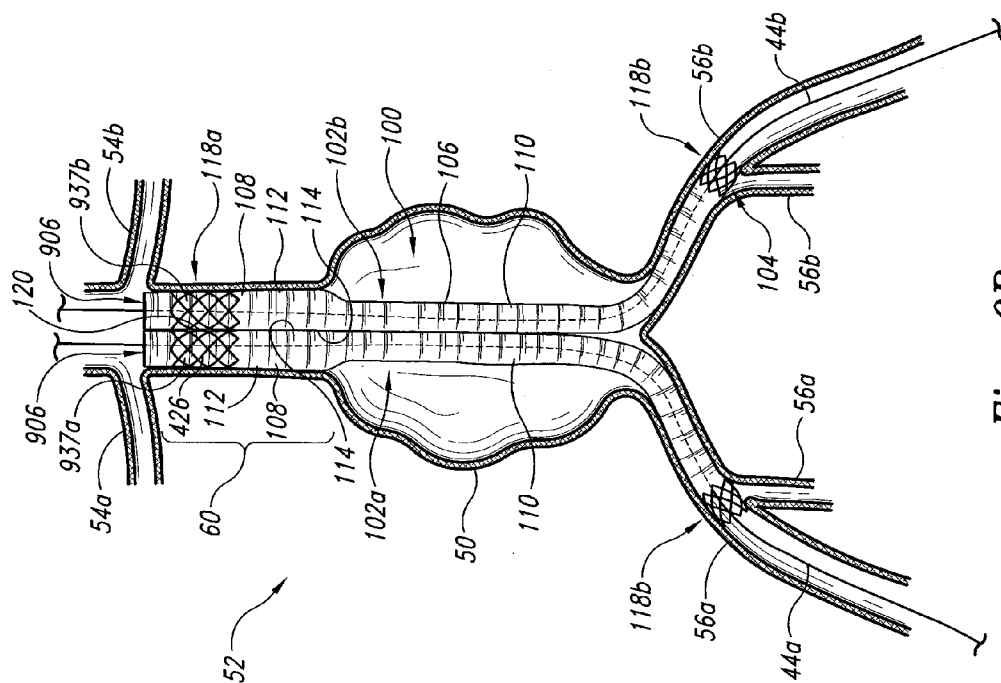


Fig. 9B

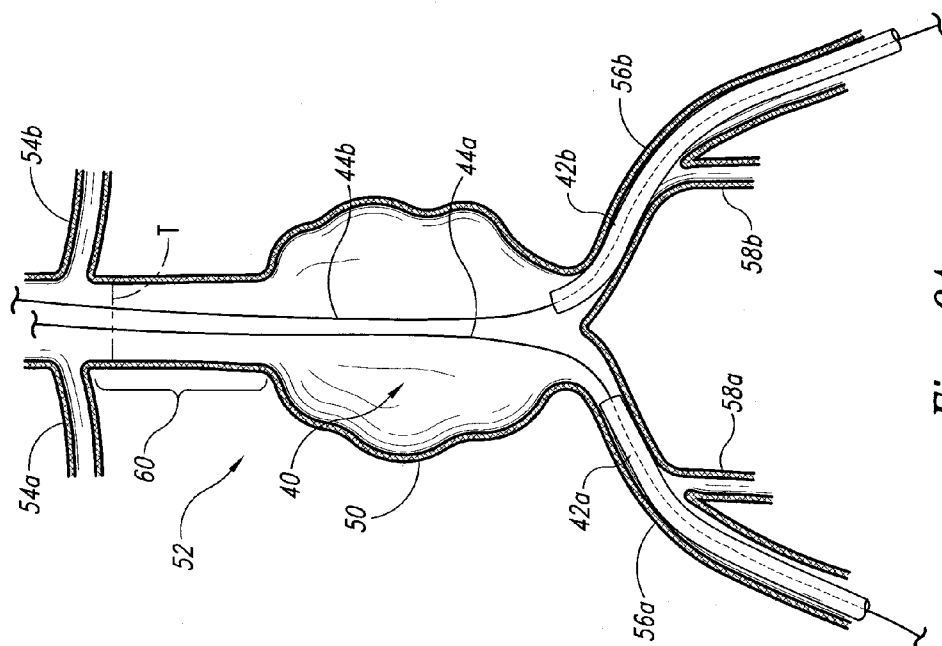
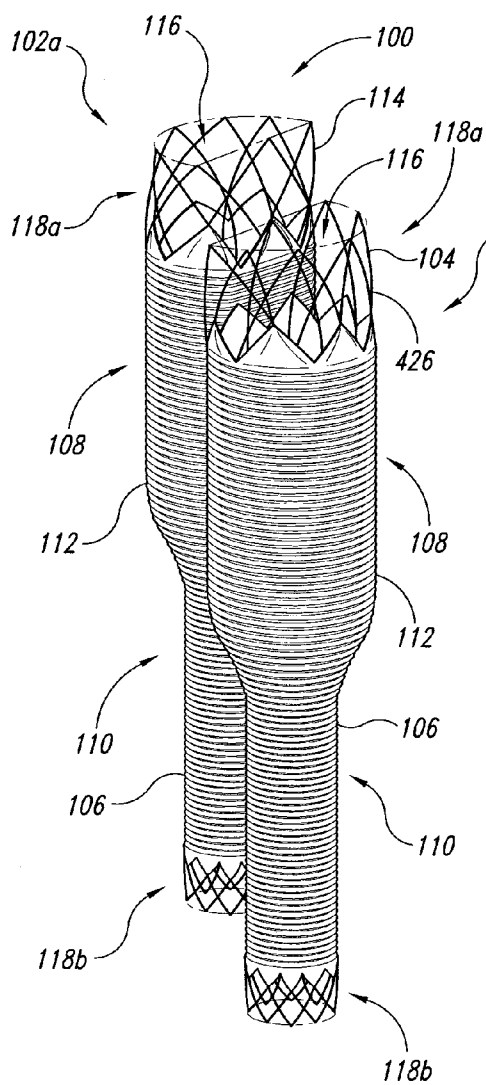
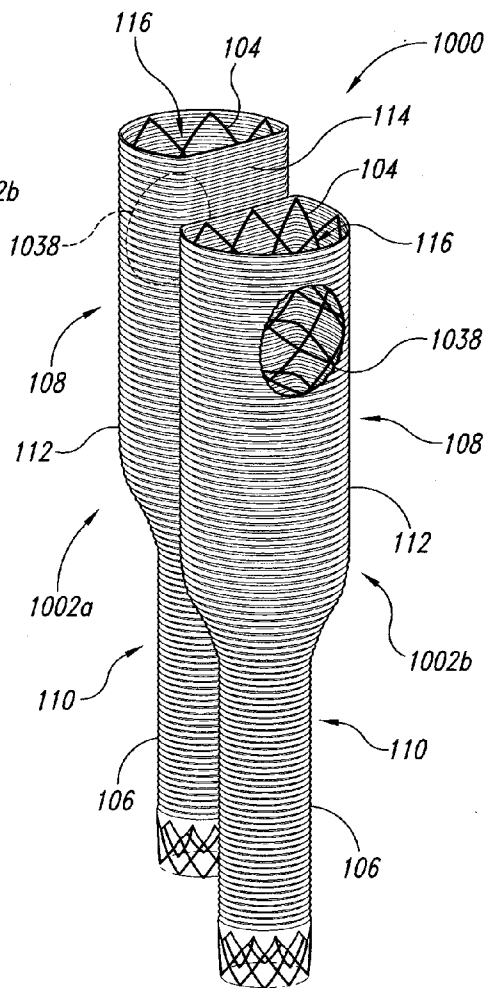


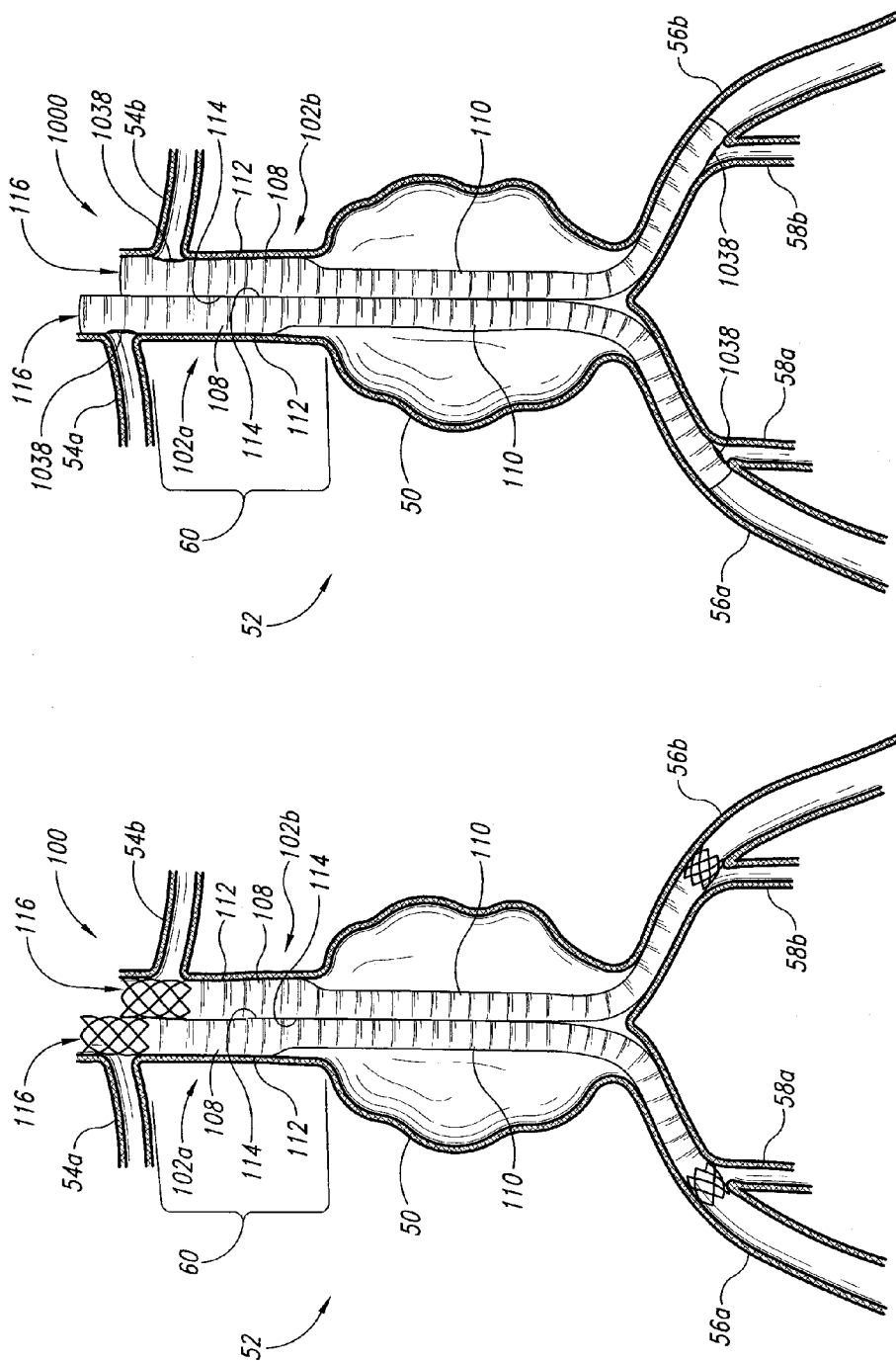
Fig. 9A



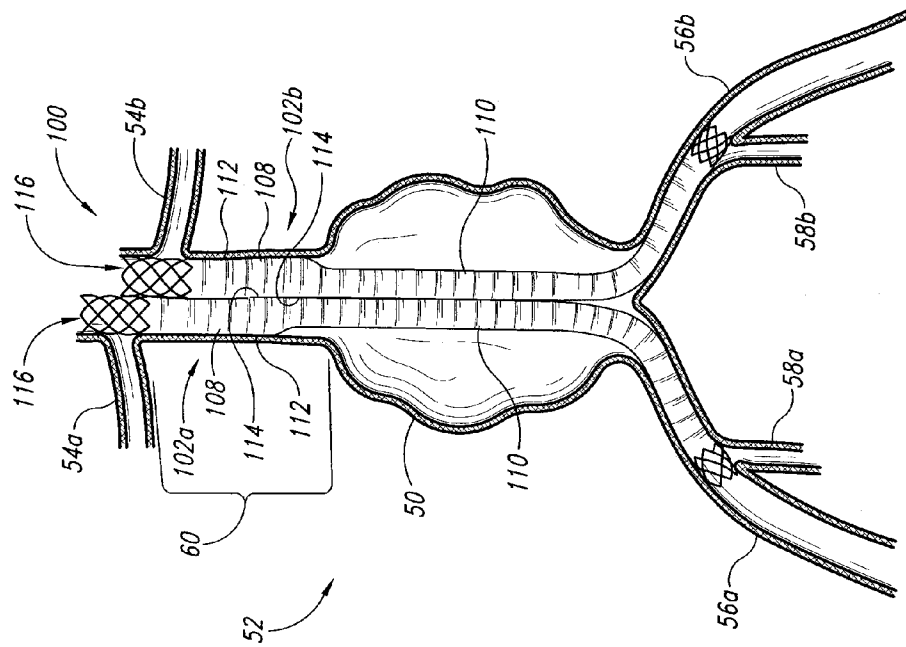
*Fig. 10A*



*Fig. 10B*



**Fig. 11B**



**Fig. 11A**

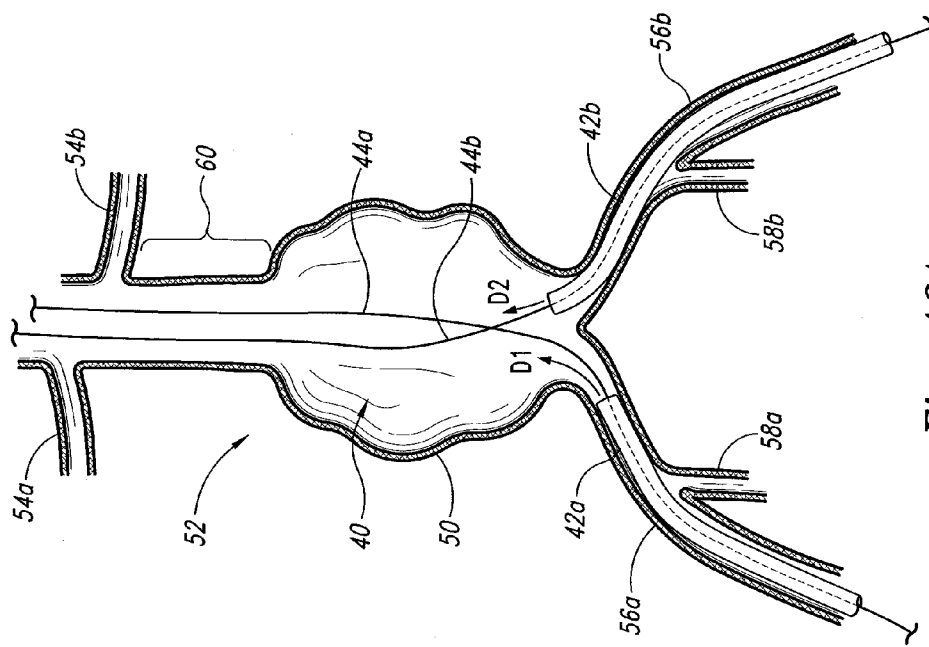


Fig. 13A

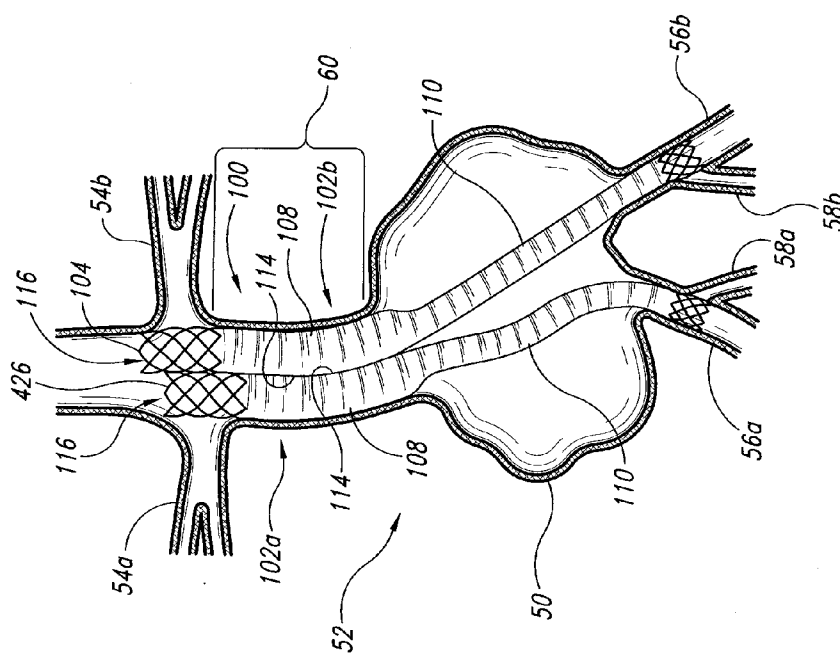


Fig. 12

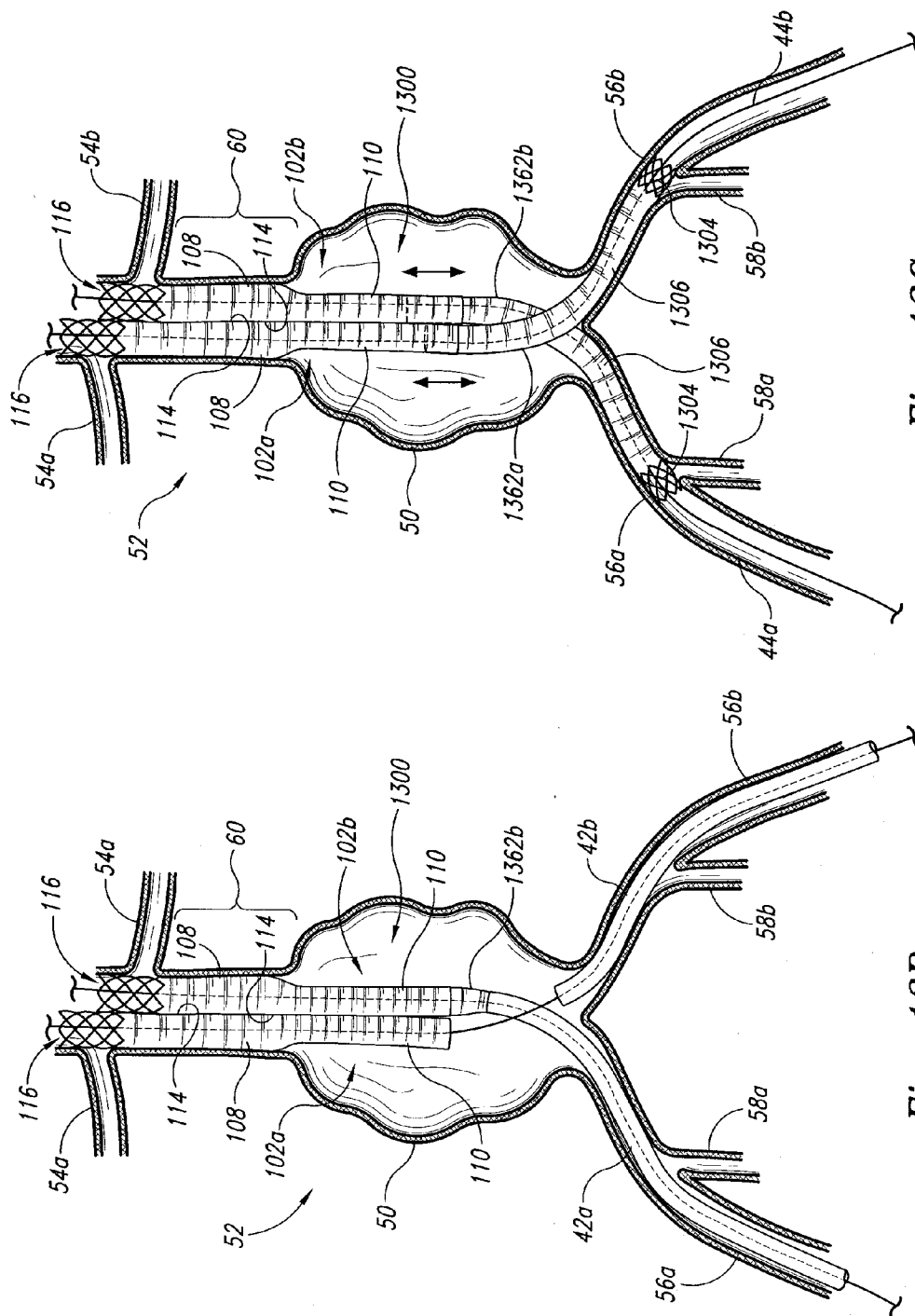


Fig. 13C

Fig. 13B

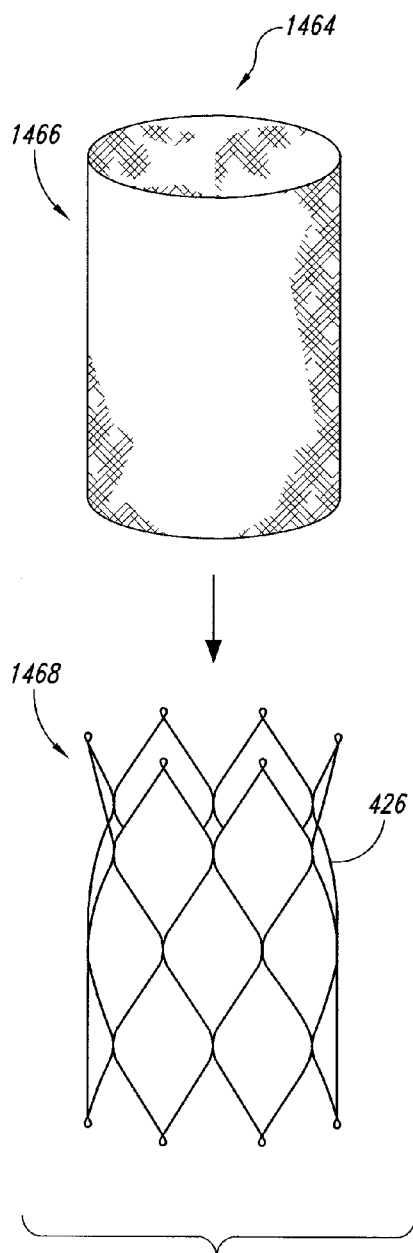


Fig. 14A

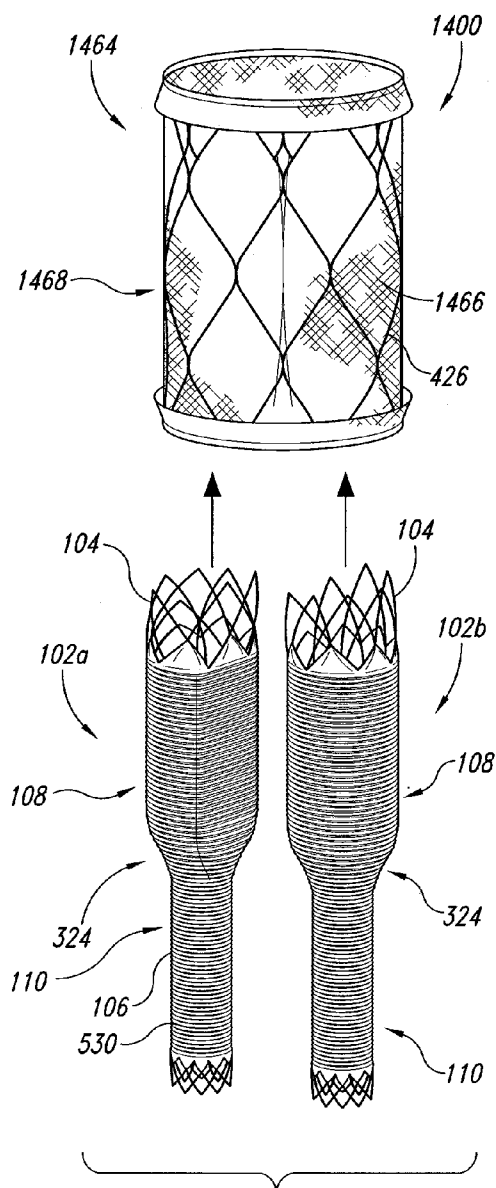


Fig. 14B



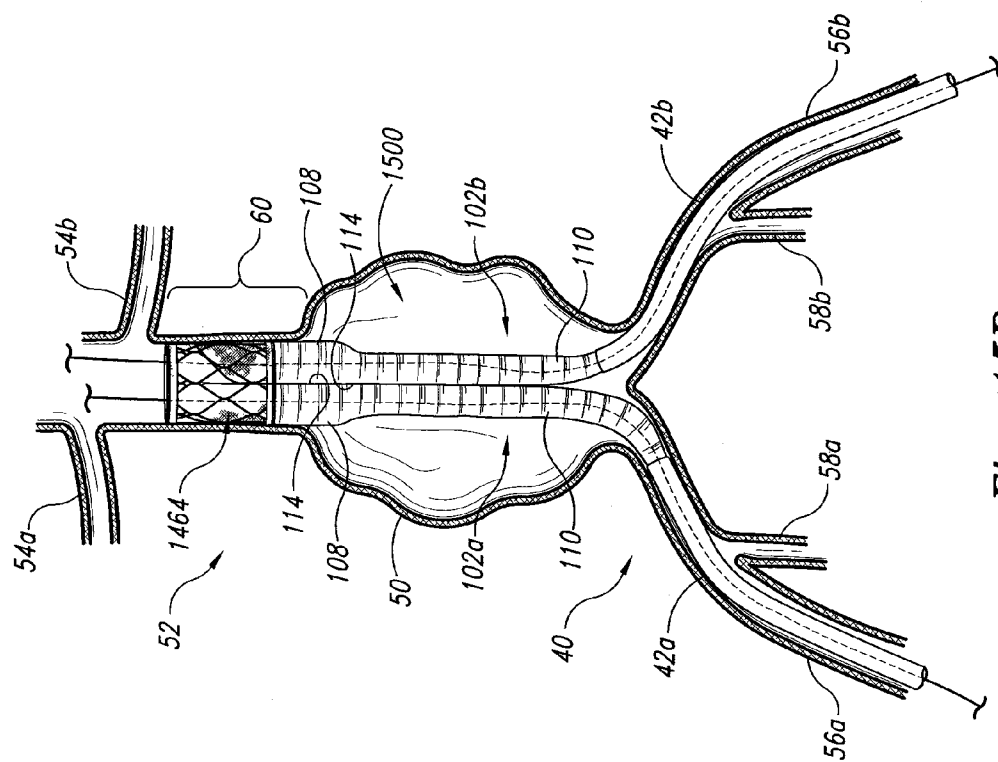


Fig. 15B

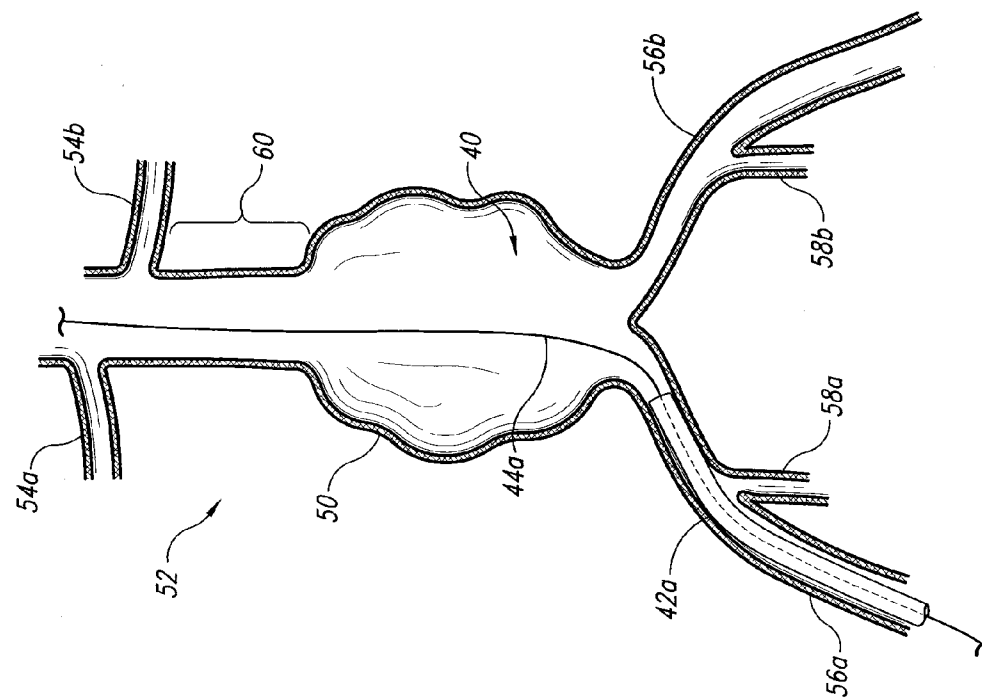
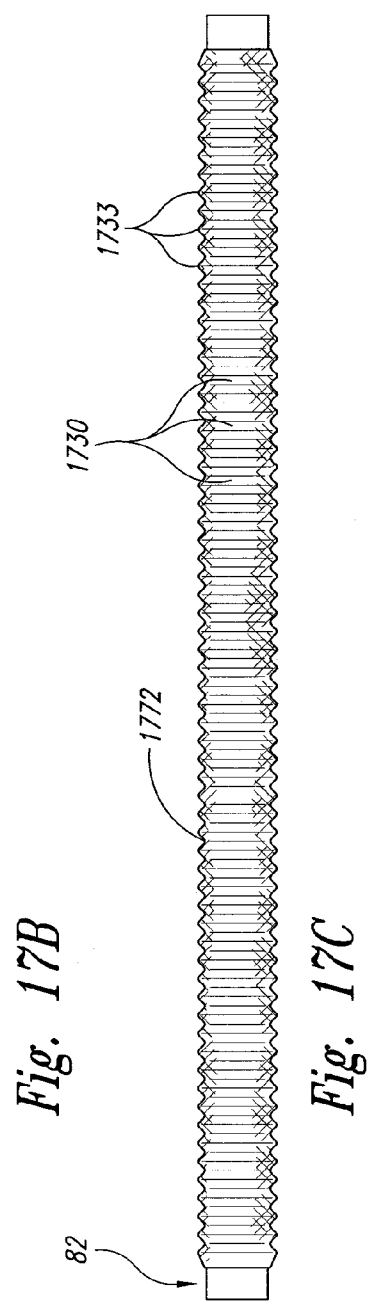
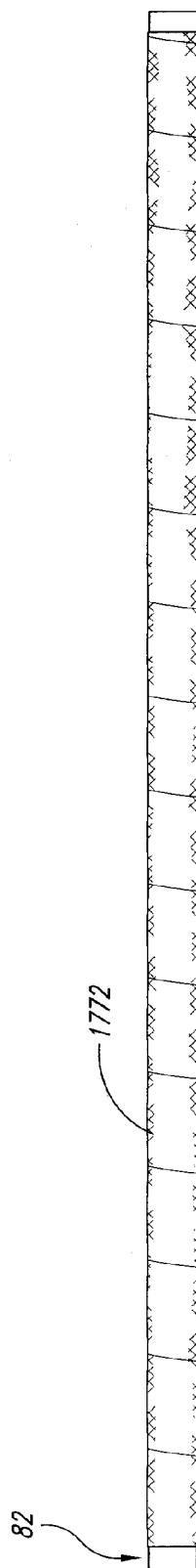
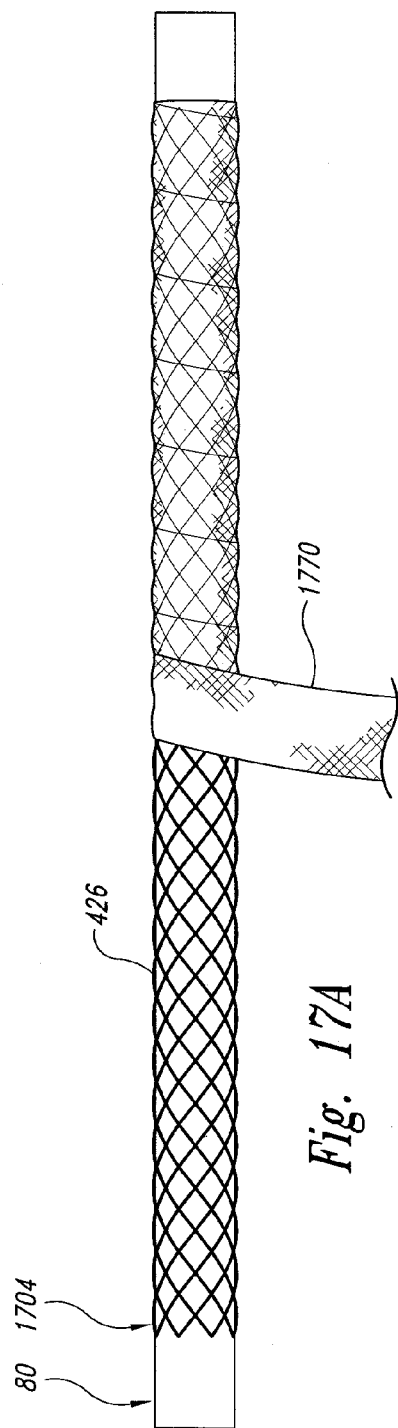


Fig. 15A

*Fig. 16*



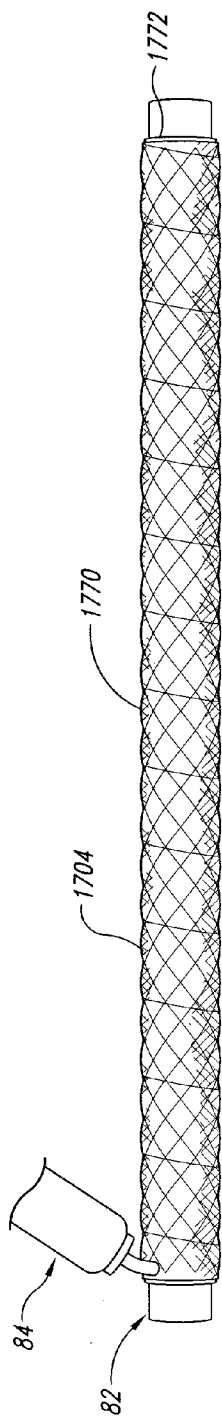


Fig. 17D

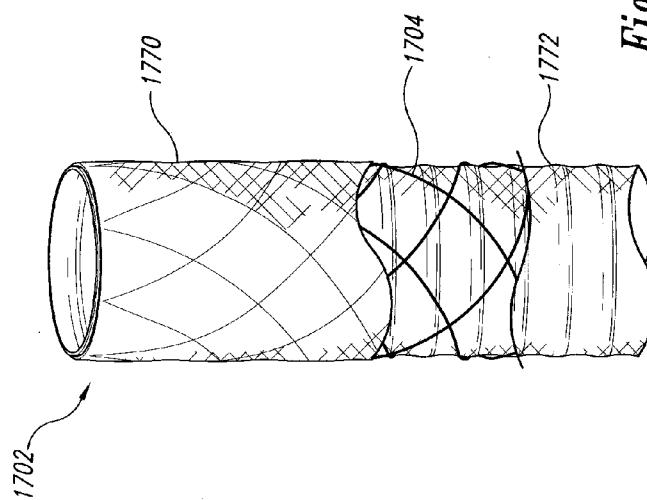


Fig. 17E

## MODULAR ENDOGRAFT DEVICES AND ASSOCIATED SYSTEMS AND METHODS

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** The present application claims priority to each of the following U.S. Provisional Applications:

**[0002]** (A) U.S. Provisional Application No. 61/265,713, filed on Dec. 1, 2009, entitled “IMPROVED SYSTEMS AND METHODS FOR MODULAR ABDOMINAL AORTIC ANEURYSM GRAFT;” and

**[0003]** (B) U.S. Provisional Application No. 61/293,581, filed Jan. 11, 2010, entitled “IMPROVED SYSTEMS AND METHODS FOR MODULAR ABDOMINAL AORTIC ANEURYSM GRAFT.”

**[0004]** All of the foregoing applications are incorporated herein by reference in their entireties.

### TECHNICAL FIELD

**[0005]** The present technology generally relates to endograft devices and methods for percutaneous endovascular delivery of the endograft devices across aneurysms. In particular, several embodiments are directed toward a modular bi-luminal endograft device with independently positioned components for endovascular aneurysm repair.

### BACKGROUND

**[0006]** An aneurysm is a dilation of a blood vessel at least 1.5 times above its normal diameter. The dilated vessel can form a bulge known as an aneurysmal sac that can weaken vessel walls and eventually rupture. Aneurysms are most common in the arteries at the base of the brain (i.e., the Circle of Willis) and in the largest artery in the human body, the aorta. The abdominal aorta, spanning from the diaphragm to the aortoiliac bifurcation, is the most common site for aortic aneurysms. The frequency of abdominal aortic aneurysms (“AAAs”) results at least in part from decreased levels of elastins in the arterial walls of the abdominal aorta and increased pressure due to limited transverse blood flow.

**[0007]** Aneurysms are often repaired using open surgical procedures. Surgical methods for repairing AAAs, for example, require opening the abdominal region from the breast bone to the pelvic bone, clamping the aorta to control bleeding, dissecting the aorta to remove the aneurysmal section, and attaching a prosthetic graft to replace the diseased artery. The risks related to general anesthesia, bleeding, and infection in these types of open surgical repairs result in a high possibility of operative mortality. Thus, surgical repair is not a viable option for many patients. Moreover, the recovery process is extensive for the patients fit for surgical repair. An open surgical repair of an AAA generally requires seven days of post-operational hospitalization and, for uncomplicated operations, at least six to eight weeks of recovery time. Thus, it is a highly invasive and expensive procedure.

**[0008]** Minimally invasive surgical techniques that implant prosthetic grafts across aneurysmal regions of the aorta have been developed as an alternative or improvement to open surgery. Endovascular aortic repairs (“EVAR”), for example, generally require accessing an artery (e.g., the femoral artery) percutaneously or through surgical cut down, introducing guidewires into the artery, loading an endograft device into a catheter, and inserting the loaded catheter in the artery. With the aid of imaging systems (e.g., X-rays), the endograft

device can be guided through the arteries and deployed from a distal opening of the catheter at a position superior to the aneurysm. From there, the endograft device can be deployed across the aneurysm such that blood flows through the endograft device and bypasses the aneurysm.

**[0009]** EVAR devices should be implanted at a precise location across the aneurysmal region and securely fixed to the vessel wall because improper placement, migration, and/or projection of the endograft device into branching vessels may interfere with the blood flow to nearby physiological structures. For example, to avoid impairing renal functions, the endograft device should not inhibit blood flow to the renal arteries. In addition to the variations in the vasculature between patients, the characteristics of the aneurysms themselves can also pose challenges because of the anatomical variations and the different structural features of individual aneurysms. For example, the vascular bifurcation at the iliac arteries and the angulation of aneurysmal sacs are both known to pose challenges to methods and devices for treating AAAs. Conventional systems address these challenges by having many different EVAR devices with different sizes and shapes.

### BRIEF DESCRIPTION OF THE DRAWINGS

**[0010]** FIG. 1A is a partial cut-away, isometric view of a modular endograft system configured in accordance with an embodiment of the technology.

**[0011]** FIG. 1B is an isometric view of the modular endograft system of FIG. 1A configured in accordance with an embodiment of the technology.

**[0012]** FIGS. 2A-C are cross-sectional top views of superior portions for endograft devices shaped in accordance with embodiments of the technology.

**[0013]** FIGS. 2D and 2E are cross-sectional top views of the superior portion of FIG. 2B being mated with a complementary superior portion in accordance with an embodiment of the technology.

**[0014]** FIGS. 3A and 3B are isometric views of endograft devices configured in accordance with embodiments of the technology.

**[0015]** FIGS. 4A and 4B are side views of an integrated frame in an expanded configuration and in a low-profile configuration, respectively, in accordance with an embodiment of the technology.

**[0016]** FIGS. 5A-C are side views of a cover being extended from an expanded configuration to a low-profile configuration in accordance with an embodiment of the technology.

**[0017]** FIGS. 6A and 6B are cross-sectional views of an endograft device in a low-profile configuration and in an expanded configuration, respectively, in accordance with embodiments of the technology.

**[0018]** FIGS. 7A and 7B are isometric views of endograft devices configured in accordance with other embodiments of the technology.

**[0019]** FIGS. 8A and 8B are isometric views of endograft devices configured in accordance with further embodiments of the technology.

**[0020]** FIGS. 9A and 9B are schematic views of a two-part modular endograft system being deployed across an aneurysm in accordance with an embodiment of the technology.

**[0021]** FIGS. 10A and 10B are isometric views of modular endograft systems configured in accordance with additional embodiments of the technology.

[0022] FIGS. 11A and 11B are schematic views of the modular endograft system of FIG. 10A and the modular endograft system of FIG. 10B, respectively, deployed across aneurysms in accordance with other embodiments of the technology.

[0023] FIG. 12 is a schematic view of the modular endograft system of FIG. 9B deployed across an aneurysm in accordance with a further embodiment of the technology.

[0024] FIGS. 13A-C are schematic views of a four-part modular endograft system being deployed across an aneurysm in accordance with an embodiment of the technology.

[0025] FIGS. 14A and 14B are isometric views of a modular endograft system configured in accordance with an additional embodiment of the technology.

[0026] FIGS. 15A and 15B are schematic views of a three-part modular endograft system being deployed across an aneurysm in accordance with an embodiment of the technology.

[0027] FIG. 16 is a schematic view of a five-part modular endograft system being deployed across an aneurysm in accordance with an embodiment of the technology.

[0028] FIGS. 17A-E are views of coating layers being applied to an integrated frame in accordance with an embodiment of the technology.

#### DETAILED DESCRIPTION

[0029] Specific details of several embodiments of the technology are described below with reference to FIGS. 1A-17E. Although many of the embodiments are described below with respect to devices that at least partially repair abdominal aortic aneurysms (“AAAs”), other applications and other embodiments are within the scope of the technology. For example, the technology can be used to repair aneurysms in other portions of the vasculature. Additionally, several other embodiments of the technology can have different configurations, components, or procedures than those described in this section. A person of ordinary skill in the art, therefore, will accordingly understand that the technology may have other embodiments with additional elements, or the technology may have other embodiments without several of the features shown and described below with reference to FIGS. 1A-17E.

[0030] With regard the use of “superior” and “inferior” within this application, inferior generally refers being situated below or directed downward, and superior generally refers to being situated above or directed upward.

[0031] With regard to the use of “expansion” and “constriction” within this application, expansion refers to a radial increase in a cross-sectional dimension of a device or component, and constriction refers to a radial decrease in the cross-sectional dimension of the device or component. For example, FIG. 4A shows an integrated frame 104 in an expanded configuration, and FIG. 4B shows the integrated frame 104 in a constricted configuration.

[0032] With regard to the use of “contraction” and “extension” within this application, contraction refers to a longitudinal decrease in the length of a device or component, and extension refers to a longitudinal increase in the length of the device or component. For example, FIG. 5A shows a cover 106 in a contracted configuration, and FIG. 5C shows the cover 106 in an extended configuration.

[0033] With regard to the terms “distal” and “proximal” within this application, the terms can reference a relative position of the portions of an implantable device and/or a

delivery device with reference to an operator. Proximal refers to a position closer to the operator of the device, and distal refers to a position that is more distant from the operator of the device.

[0034] 1. Endograft System Structures

[0035] 1.1 Selected Endograft Devices

[0036] FIGS. 1A and 1B are isometric views of a modular endograft system 100 (“system 100”) in accordance with an embodiment of the technology. The system 100 can include separate endograft devices 102 (identified individually as a first endograft device 102a and a second endograft device 102b) that can be coupled, mated, or otherwise substantially sealed together in situ. Each endograft device 102, for example, can include an integrated frame 104 (“frame 104”) and a substantially impermeable cover 106 (“cover 106”) extending over at least a portion of the frame 104. The frame 104 and the cover 106 of an individual endograft device 102 can form a discrete lumen 116 through which blood can flow to bypass an aneurysm. In operation, the endograft devices 102 are generally delivered separately and positioned independently across the aneurysm.

[0037] As shown in FIGS. 1A and 1B, each endograft device 102 includes a superior portion 108 and an inferior portion 110. The superior portion 108 can include a convexly curved outer wall 112 and a septal wall 114. As shown in FIG. 1A, the septal wall 114 can be substantially flat such that the superior portion 108 forms a “D” shape at a superior portion of the lumen 116. In other embodiments, the septal wall 114 can be convexly curved with a larger radius of curvature than the outer wall 112 such that the superior portion 108 forms a complex ellipsoid having another D-shaped cross-section at the superior portion of the lumen 116. In further embodiments, the superior portion 108 can have asymmetrical shapes or other suitable cross-sectional configurations that can mate with each other in the septal region and mate with an arterial wall around the periphery of the outer wall 112. The inferior portion 110 can have a circular cross-sectional shape as illustrated in FIG. 1A, or the inferior portion 110 can have an elliptical shape, a rectangular shape, an asymmetrical shape, and/or another suitable cross-sectional shape for an inferior portion of the lumen 116.

[0038] The superior portions 108 of the endograft devices 102 are mated together and at least substantially sealed along the septal walls 114 within the aorta above the aneurysm. In some embodiments, the superior portion 108 can be approximately 2-4 cm in length to adequately fix the outer walls 112 to the arterial walls such that they are at least substantially sealed together. In other embodiments, the superior portion 108 can be longer or shorter. In one embodiment in accordance with the technology, the inferior portions 110 can extend through an inferior portion of the aneurysm and into corresponding iliac arteries to bypass the aneurysm. In another embodiment, one or both inferior portions 110 can terminate within the aneurysm to form what is known to those skilled in the art as a “gate.” As described in further detail below, limbs (not shown) can be attached to the proximal ends of the inferior portions 110 and extended into the iliac arteries to bypass the aneurysm.

[0039] In the embodiment shown in FIGS. 1A and 1B, the frames 104 have bare end portions 118 (identified individually as first end portions 118a and second end portions 118b) that extend beyond the covers 106. As shown in FIGS. 1A and 1B, the first end portion 118a can extend distally from the superior terminus of the cover 106, and the second end portion

tion **118b** can extend proximally from the inferior terminus of the cover **106**. In some embodiments, the end portions **118** can be trumpeted or flared to interface with the arterial walls of the aorta and/or the iliac arteries. This can promote cell ingrowth that strengthens the seal between the endograft devices **102** and the adjacent arteries.

[0040] The end portions **118** can also increase the available structure for securing the endograft device **102** to the artery and increase the surface area of the covers **106** for sealably fixing the endograft devices **102** to arterial walls. This decreases the precision necessary to position the endograft devices **102** and increases the reliability of the implanted system **100**. For example, a short infrarenal aortic neck (e.g., less than 2 cm) generally requires precise placement of the endograft devices **102** to preserve blood flow to the renal arteries while still providing enough surface area for the endograft devices **102** to be properly affixed with the aorta. In the embodiment shown in FIGS. 1A and 1B, however, the first end portions **118a** can be placed at the entrance of the renal arteries to allow lateral blood flow into the renal arteries and provide a larger structure for fixing the endograft devices **102** to the arterial wall and a larger sealing area with the arterial wall. The end portions **118** can also provide accessible sites for recapture (e.g., by guidewires, bead and collet, etc.) that enhance the accuracy of positioning the endograft devices **102** across the aneurysm.

[0041] During deployment of the system **100**, each endograft device **102** can be delivered independently to an aneurysmal region in a low-profile configuration. The low-profile configuration has a first cross-sectional dimension and a first length that can facilitate percutaneous endovascular delivery of the system **100**. Because each device **102** extends around only a portion of the vessel periphery, the individual endograft devices **102** can be constricted (i.e., radially collapsed) to a smaller diameter than conventional AAA devices with a single superior portion that extends around the complete periphery of the vessel wall. In some embodiments, for example, each of the endograft devices **102** can have a diameter of 25 mm in the expanded configuration, and can be constricted to a diameter of 4 mm in the low-profile configuration to be percutaneously deployed across the aneurysm through a 12 F catheter. Additionally, as described in more detail below, because each endograft device **102** is delivered independently, the end portions **118** and fenestrations can facilitate staggering the endograft devices **102** to accommodate asymmetrical anatomies.

[0042] At a target site in the aneurysmal region, the endograft devices **102** can self-expand to an expanded configuration (e.g., shown in FIGS. 1A and 1B). The expanded configuration can have a second cross-sectional dimension greater than the first cross-sectional dimension and a second length less than the first length. In the expanded configuration shown in FIG. 1B, the septal wall **114** (FIG. 1A) of the first endograft device **102a** can be forced against the opposing septal wall **114** of the second endograft device **102b**. When in situ within the aorta, the forces between the opposing septal walls **114** form a septum **120** in which the first and second septal walls **114** are at least substantially sealed together to prevent blood from flowing between the endograft devices **102** and into the aneurysm. Additionally, as shown in FIG. 1B, the texture (e.g., ribbing) on the covers **106** can mate at the septum **120** to further strengthen the seal between the septal walls **114**. Similarly, the texture of the cover **106** on the

outer walls **112** can interface with the adjacent vessel walls to strengthen the seal around the periphery of the endograft devices **102**.

[0043] In operation, the system **100** can prevent blood from collecting in a diseased aneurysmal portion of a blood vessel (e.g., the aorta, the iliac arteries, etc.). Rather, the system **100** can direct blood into the lumens **116**, funnel the blood through the superior and inferior portions **108** and **110**, and discharge the blood into healthy portions of the iliac arteries, thereby at least substantially bypassing the aneurysm. The bifurcated system **100** facilitates independent positioning of the first and second endograft devices **102** to accommodate disparate structures and morphologies of the abdominal aorta and/or iliac arteries. For example, the first endograft device **102a** can be positioned independently in a desired location without being constrained by a desired placement of the second endograft device **102b**. Accordingly, the system **100** can easily adapt to a variety of different anatomies and thereby provide a modular alternative to customized endograft systems.

#### [0044] 1.2 Select Embodiments of Superior Portions

[0045] FIGS. 2A-C are cross-sectional top views of superior portions **208** of endograft devices (e.g., endograft devices **102** shown in FIGS. 1A and 1B) shaped in accordance with embodiments of the technology. The superior portions **208** can have generally similar features as the superior portions **108** shown in FIGS. 1A and 1B. For example, each superior portion **208** includes an outer wall **212** and a septal wall **214**. The outer wall **212** is generally semi-circular, but can otherwise be configured according to the shape, geometry, and/or morphology of an arterial wall. The septal wall **214** can be shaped to mate with a complementary septal wall **214** of another endograft device. More specifically, in the embodiment illustrated in FIG. 2A, the superior portion **208** includes a convexly curved, substantially semi-circular outer wall **212** and a substantially flat septal wall **214**. Thus, the superior portion **208** forms a “D” shape and can be part of a system (e.g., the system **100** shown in FIGS. 1A and 1B) including a corresponding D-shaped superior portion of a mating endograft device.

[0046] In other embodiments, both the outer wall **212** and the septal wall **214** can be convexly curved such that the superior portion **208** forms a complex ellipsoid with at least two distinct radii. FIG. 2B, for example, shows the superior portion **208** can include a convexly curved outer wall **212** that has a first radius **R1** and a convexly curved septal wall **214** that has a second radius **R2** greater than the first radius **R1**. In the embodiment illustrated in FIG. 2B, the second radius **R2** is substantially greater than the first radius **R1** such that the superior portion **208** has a substantially D-like shape.

[0047] Similarly, the superior portion **208** shown in FIG. 2C includes the convexly curved outer wall **212** that has the first radius of curvature **R1** and the convexly curved septal wall **214** that has the second radius of curvature **R2** greater than the first radius **R1**. As shown in FIG. 2C, the superior portion **208** can further include convexly curved corner sections **222** (identified individually as a first corner section **222a** and a second corner section **222b**). The first corner section **222a** can have a third radius **R3**, and the second corner section **222b** can have a fourth radius **R4** distinct from or equivalent to the third radius **R3**. In the embodiment shown in FIG. 2C, the third and fourth radii **R3** and **R4** are substantially smaller than the first and second radii **R1** and **R2** such that the superior portion **208** forms another substantially D-like shape. In other

embodiments, the superior portion **208** can include greater or smaller radii, more or less curved portions, and/or can have another shape suitable for mating and at least substantially sealing two endograft devices together within a blood vessel.

[0048] FIGS. 2D and 2E are cross-sectional top views of the superior portion **208** of FIG. 2B being mated with a complementary superior portion **208** to form a sealed septum **220** in accordance with an embodiment of the technology. More specifically, FIG. 2D shows the superior portions **208** being pressed toward one another by a force **F**. The force **F** can derive from the self-expansion of the superior portions **208** within the confined space of an aorta. As shown in FIG. 2D, the force **F** can cause the superior portions **208** to contact one another near the center of their respective convexly curved septal walls **214** and flatten the septal walls **214**. The apposition of the septal walls **214** can generate an outward force generally tangential to the septal walls **214** that can cause a slight outward bowing **B** near the interface of the outer and septal walls **212** and **214**.

[0049] As shown in FIG. 2E, the force **F** can continue to press the superior portions **208** against one another until the convexly curved septal walls **214** straighten to form the septum **220**. The initial convexities of the septal walls **214** can induce more pressure between the septal walls **214** than straight septal walls (e.g., FIG. 2A) and promote an even distribution of the force along the septum **220** to enhance the seal. Additionally, the outward bowing **B** can enhance the seal at the edges of the septal walls **214**. The superior portions **208** shown in FIGS. 2A and 2C can be similarly joined to form the substantially straight septum **220**. For example, the superior portion **208** shown in FIG. 2C can be pressed against a corresponding superior portion such that the relative forces between the superior portions **208** substantially straighten the septal walls **214** and corner sections **222** (e.g., approximately 60° to 90° between the outer and septal walls **112** and **114**) to form the septum **220**. In operation, the septum **220** can be at least substantially sealed to prevent fluids (e.g., blood) from flowing between the superior portions **208**.

### [0050] 1.3 Select Embodiments of Transition Portions

[0051] FIGS. 3A and 3B are isometric views of transition portions **324** of endograft devices configured in accordance with embodiments of the technology. The transition portions **324** can promote laminar blood flow by gradually changing the size of the lumen **116** from the wider, superior portion **108** to the narrower, inferior portion **110**. Additionally, the transition portions **324** can be configured to reduce the downforce exerted on the endograft devices **102** as blood flows through the lumen **116**.

[0052] More specifically, FIG. 3A is an isometric view of the endograft device **102** described above with reference to FIGS. 1A and 1B. The endograft device **102** includes the transition portion **324** positioned between the superior portion **108** and the inferior portion **110**. As shown in FIG. 3A, the transition portion **324** can be tapered to gradually narrow the cross-section of the lumen **116** and thereby reduce disruptions to the blood flow. The transition portion **324** can have a length **L** related to the distance necessary to continue substantially laminar blood flow through the lumen **116**. For example, in some embodiments, the length **L** can be 4 cm. In other embodiments, the length **L** can differ due to the geometry of the endograft device **102**, the rheologic characteristics of the blood flow, and/or other relevant factors in decreasing turbulent blood flow. In other embodiments, the transition portion **324** can be sloped, stepped, and/or have another suit-

able shape that can decrease the cross-section of the lumen **116** from the superior portion **108** to the inferior portion **110** without inducing turbulent blood flow.

[0053] FIG. 3B is an isometric view of an endograft device **302** in accordance with another embodiment of the technology. The endograft device **302** can include generally similar features as the endograft **102** shown in FIG. 3A. However, the tapered transition portion **324** shown in FIG. 3B has a more gradual taper and a much greater length **L** than the transition portion **324** shown in FIG. 3A. As shown in FIG. 3B, the tapered transition portion **324** extends from the superior portion **108** to the second end portion **118b** such that the transition portion **324** defines the inferior portion **110** (not visible). Accordingly, the tapered transition portion **324** can steadily decrease the cross-section of the lumen **116** to facilitate laminar blood flow through the lumen **116**. The gradual taper of the transition portion **324** may, however, cause the endograft device **302** to migrate in the direction of blood flow more than the more aggressive taper of the transition portion **324** shown in FIG. 3A. Accordingly, the length **L** and angle of the tapered transition portion **324** can be optimized to mitigate migration of the endograft device **302** without inducing undo turbulent blood flow. In other embodiments, the transition portion **324** can optimize the geometry of a different shape (e.g., stepped) to maintain laminar blood flow and mitigate migration of the endograft device **302**.

### [0054] 2. Endograft System Components

#### [0055] 2.1 Integrated Frames

[0056] FIGS. 4A and 4B are side views of the integrated frame **104** described with reference to FIGS. 1A and 1B in an expanded configuration (FIG. 4A) and a low-profile configuration (FIG. 4B) in accordance with an embodiment of the technology. As discussed above, the frame **104** includes the superior portion **108**, the inferior portion **110**, and the exposed end portions **118**. In some embodiments, the smallest radius of the outer wall **112** of each superior portion **108** in the expanded configuration may not be less than 10 mm (i.e., the smallest diameter of the superior portions **108** of mated endograft devices **102** is more than 20 mm).

[0057] As shown FIGS. 4A and 4B, the frame **104** can be a braided structure made from one or more continuous, interwoven wires **426** that provide a continuous, integrated support longitudinally along the length of the frame **104**. For example, as shown in FIG. 4A, the wire **426** is braided such that a first longitudinal segment **L1** of the frame **104** supports an adjacent second longitudinal segment **L2** of the frame **104**. Accordingly, each area of the frame **104** influences the radial expansion or contraction of an adjacent area of the frame. In some embodiments, the frame **104** is woven with one wire **426** that continuously crosses itself along the length of the frame **104**. The intersections of the wire **426** may not be welded or otherwise fixed together such that they remain unbound to increase the flexibility of the frame **104**. In other embodiments, the frame **104** includes a plurality of wires **426** that can be interwoven and/or concentrically layered to form the frame **104**. The frame **104**, for example, can include eight wires **426** in which several of the wires **426** can end at intermediate points along the length of the frame **104**. Such a staggered, multi-wire construction prevents the wire ends from weakening the frame **104** and/or from wearing on a subsequently attached cover (e.g., the cover **106** shown in FIGS. 1A and 1B). The number of wires **426** can also vary at different sections along the length of the frame **104**. For example, in one embodiment, the inferior portion **110**



includes fewer wires **426** than the superior portion **108** such that the density or pitch of the wires **426** does not increase at inferior portion **110** and the frame **104**. This enables the inferior portion **110** to have a small diameter in the constricted, low-profile configuration (FIG. 4B).

[0058] As shown in FIG. 4A, the wires **426** can form a loop **428** at one end portion **118** to reverse direction and continue weaving along the length of the frame **104** toward the opposite end portion **118**. The optimal number of loops **428** at each end portion **118** can be associated with the diameter of the wires **426**. Too few loops **428** can decrease the strength at the end portions **118** of the contracted frame **104** shown in FIG. 4A. Too many loops **428** can increase the profile of the extended frame **424** shown in FIG. 4B, and can also cause difficulty attaching the cover. A wire **426** with a diameter of 0.008 inch, for example, may have an optimal number of ten to twelve loops **428** (five to six at each end portion **118**), whereas a wire **426** with a diameter of 0.009 inch may have an optimal number of twelve to fourteen loops **428**. In other embodiments, the wires **426** can include more or less loops **428** to optimize characteristics of the frame **104**. Additionally, the degree of curvature of each of the loops **428** can impact the durability of the wires **426**. For example, tightly wound loops **428** with high degrees of curvature are subject to fatigue and failure at the end portions **118** because of the stress induced upon constriction. Therefore, in some embodiments, the degree of curvature of the loops **428** can be the least degree of curvature permissible for the optimal number of loops **428**.

[0059] In the expanded configuration shown in FIG. 4A, the wires **426** can cross at a braid angle  $\theta$  selected to mitigate kinking and provide adequate extension/constriction. Lower braid angles  $\theta$  can reduce or eliminate kinking of the wires **426** when the frame **104** is flexed or bent. For example, a braid angle  $\theta$  of less than  $45^\circ$  allows the frame **104** to bend with smaller radii of curvature without substantial reduction of its cross-sectional area along the length of the frame **104**. Therefore, a frame **104** with a braid angle  $\theta$  of less than  $45^\circ$  can be flexed and bent within the anatomy (e.g., the aorta) without restricting blood flow through the frame **104**. Additionally, lower braid angles  $\theta$  can increase the outward spring force (i.e., the inherent force within the frame **104** that self-expands the frame **104** to the expanded configuration) and hoop strength (i.e., the radial strength of the frame **104** that restricts kinking and maintains the expanded configuration) of the frame **104**. Therefore, braid angles  $\theta$  of not more than  $45^\circ$  can also provide an advantageous increase in the strength and corresponding durability of the frame **104**.

[0060] Lower braid angles  $\theta$ , however, can also adversely affect the extension and constriction of the frame **104** in the low-profile configuration shown in FIG. 4B. For example, extension and constriction can be negatively impacted at braid angles  $\theta$  of less than  $30^\circ$ . Therefore, in some embodiments, the frame **104** can include a braid angle  $\theta$  between  $30^\circ$  and  $45^\circ$  that promotes kink resistance and frame strength, while also maintaining extension and constriction abilities necessary for the low-profile configuration. In other embodiments, the optimal braid angle  $\theta$  can be higher or lower.

[0061] In some embodiments in accordance with the technology, the braid angle  $\theta$  can vary along the length of the frame **104** to vary kink resistance, outward spring force, hoop strength, and extension properties at different portions of the frame **104**. For example, the braid angle  $\theta$  can be higher at the superior portion **108** (e.g.,  $40^\circ$ ) such that the superior portion

**108** can extend and constrict into the low-profile configuration, and the braid angle  $\theta$  can be lower at the inferior portion **110** (e.g.,  $30^\circ$ ) to provide kink resistance where the frame **104** is most likely to bend (e.g., within the aneurysmal sac and toward the iliac arteries). The smaller braid angle  $\theta$  at the inferior portion **110** may not adversely affect the profile of the frame **104** because the inferior portion **110** need not constrict as much as the superior portion **108** to reach the desired low-profile configuration. In other embodiments, the braid angle  $\theta$  of the frame **104** may vary in another way.

[0062] The wires **426** can have a diameter sufficient to support the frame **104** while still providing substantial flexibility for the frame **104**. The diameter of the wires **426** can be selected to attain a desired cross-sectional dimension in the low-profile configuration, a desired outward spring force to self-expand to the expanded configuration, and a desired hoop strength to support the frame **104** in the expanded configuration. For example, in some embodiments, the wires **426** can have a diameter from approximately 0.007 inch to approximately 0.014 inch. In specific embodiments, the wires have a diameter from approximately 0.011 inch to 0.013 inch. In other embodiments, the wires **426** can have a smaller diameter, a greater diameter, and/or the diameter of the wires **426** can vary along the length of the frame **104**. For example, in one embodiment, the wires **426** can have a greater diameter at the superior portion **108** than at the inferior portion **110** such that the wires **426** of the superior portion **108** have a outward spring force and greater hoop strength where the first and second endograft devices mate (e.g., at the septal walls **114**) and the increased density of wires **426** at the inferior portion **110** does not negatively impact the flexibility of the frame **104**.

[0063] The frame **104** may be constructed from a variety of resilient metallic materials, polymeric materials (e.g., polyethylenes, polypropylenes, Nylons, PTFEs, and the like), and composites of materials. For example, the wires **426** can be made from biocompatible stainless steels, highly elastic metallic alloys, and biocompatible shape setting materials that exhibit shape memory properties. In some embodiments, for example, the wire **426** can be made from a shape setting alloy, such as Nitinol, that has a preferred or native configuration. For example, a Nitinol structure can be deformed or constrained into a secondary configuration, but upon release from the constraint, the structure returns toward its native configuration with high fidelity. Accordingly, a frame **104** made from Nitinol wires **426** can reliably self-expand from the low-profile configuration the expanded configuration (i.e., its native configuration).

[0064] For endovascular delivery of a device (e.g., the endograft devices **102** shown in FIGS. 1A and 1B), the frame **104** is extended to constrict the frame **104** into a low-profile configuration in which the frame **104** can be loaded into a delivery device. The braid angle  $\theta$  of the wires **426** can facilitate significant extension of the frame **104** to produce a slender profile during delivery as described above, and yet the interwoven characteristic of the braid restricts over extension. This extension-constriction functionality of the frame **104** allows the frame **104** to have variable diameters (e.g., the diameter of the superior portion **108** compared to the diameter of the inferior portion **110**) using the same number of wires **426** on each portion of the frame **104** such that the frame **104** has a low introduction profile (e.g., diameter) along the length of the frame **104**. The frame **104** can also include an optimal

number of loops **428** at each end portion **118** such that the loops **428** do not increase the profile of the frame **104** upon full extension.

**[0065]** At a target site (e.g., above an aneurysm), the frame **104** self-expands to the expanded configuration shown in FIG. 4A as it is removed from the delivery device. The braid angle  $\theta$  can be adjusted to change the outward spring force and hoop strength of the expanded frame **104** as explained above. In some circumstances, the endograft device may need to be repositioned after being partially deployed. The frame **104** is well suited for such repositioning because the loops **428** and the continuous, interwoven wires **426** can simplify recapture of the frame **104** and allow for constriction after expansion to correctly reposition the endograft device. Additionally, portions of the frame **104** can remain exposed (e.g., the end portions **118**) to encourage cell ingrowth for securely anchoring the frame **104** to the arterial walls. Moreover, as described in more detail below, the interwoven wires **426** of the braided frame **104** can provide a continuous longitudinal support along the length of the frame **104** such that the frame **104** can be staggered and free end portions can support themselves. The frame **104** can also facilitate attachment to other endograft devices. For example, the frame **104** can interlace with another interwoven wire **426** of a supra-renal endograft.

**[0066]** Once deployed across the aneurysm, the frame **104** can also accommodate disparate anatomies and morphologies. In several patients, the aneurysmal sac extends at an angle with respect to the neck of the aneurysm. Because the frame **104** can have a braid angle  $\theta$  that prevents kinking, the frame **104** can bend and flex without kinking to accommodate angulated aneurysmal sacs without restricting blood flow. Additionally, the unbound, woven wires **426** give the frame **104** a radial elasticity such that the frame **104** mimics the changes in the shape and morphology of the aorta without hindering the interface or seal between the endograft device and the vessel wall. For example, the frame **404** can constrict and expand to maintain the seal when pressure and other conditions alter the vasculature of the aorta. Moreover, the woven wires **426** inherently generate a spring force that biases the frame **104** toward a substantially straight trajectory within an aneurysmal sac and thereby limits migration of the endograft device.

**[0067]** In addition, the constant outward spring force and hoop strength of the braided frame **104** can be adjusted by changing the braid angle  $\theta$  and/or the diameter of the wires **426**. This allows the formation of large diameter frames **104** without a significant change in the low-profile cross-sectional dimensions. Additionally, this feature allows the frames **104** to contract to a much smaller introduction profiles (e.g., diameters) compared to standard Z-frames or M-frames because the standard Z-frames and M-frames tend to require more wire and therefore larger introduction profiles to maintain a constant outward spring force and hoop strength.

#### **[0068]** 2.2 Covers

**[0069]** FIGS. 5A-C are views of a cover being extended from an expanded configuration (FIG. 5A) to a low-profile configuration (FIG. 5C) in accordance with embodiments of the technology. More specifically, FIG. 5A is a side view of the cover **106** described above with reference to FIGS. 1A and 1B in the expanded configuration. The cover **106** can include a plurality of circumferential ribs **530** such that the cover **106** has an undulating profile. As shown in FIG. 5A, the individual ribs **530** can have a substantially triangular shape with an apex **533**. In other embodiments, the individual ribs **530** have

rounded edges, rectangular edges, and/or other suitable textures that can extend and contract.

**[0070]** The ribs **530** of one cover can mate with opposing ribs **530** of an opposing cover and interface with vessel walls to enhance the seal and fixation between endograft devices in an endograft system (e.g., the endograft devices **102** of the endograft system **100** shown in FIGS. 1A and 1B) and between the endograft devices and the arterial walls. For example, the apices **533** of the ribs **530** at the septal wall **114** of the superior portion **108** of one endograft device can interface or mate with the troughs of the corresponding ribs **530** on a cover of an opposing endograft device. Additionally, the ribs **530** at the outer wall **112** can contact the arterial walls in a manner that at least substantially seals them together. The ribs **530** can also allow the cover **106** to flex and bend without wrinkling in situ. In some embodiments, the ribs **530** can be at only selected portions of the cover **106** (e.g., the septal wall **114**). In other embodiments, the ribs **530** can have different shapes and/or geometries on different portions of the cover **106**. For example, the apices **533** of the ribs **530** can have a first height on the superior portion **108** to enhance sealing forces between the endograft devices and a second height less than the first height at the inferior portion **110** to allow the cover **106** to freely flex and bend to accommodate the anatomy.

**[0071]** The ribs **530** change with the expansion and contraction of the cover **106**. As shown in FIG. 5A, the apices **533** of the ribs **530** protrude to the maximal extent in the expanded configuration. Referring to FIG. 5B, as the cover **106** extends, the ribs **530** also extend and constrict. When the cover **106** is fully extended in the low-profile configuration shown FIG. 5C, the ribs **530** are completely elongated and constricted. In some embodiments, the size of each rib **530** can be predetermined to ensure the ribs **530** are completely flattened in the low-profile configuration and project radially outwardly to interface with adjacent surfaces in the expanded configuration. Accordingly, the ribs **530** do not limit the mobility of the endograft device as it is delivered to the aorta in the low-profile configuration.

**[0072]** Additionally, as shown in FIGS. 5A-C, the cover **106** can include zigzagged edges at a superior terminus **531a** and an inferior terminus **531b** of the cover **106**. The zigzagged termini **531** can facilitate substantially seamless attachment between the cover **106** and an integrated frame (e.g., the frame **104** shown in FIGS. 4A and 4B). For example, in some embodiments, the zigzagged termini **531** can correspond to the braid angle  $\theta$  of interwoven wires. The zigzagged termini **531** generally prevent the cover **106** from wrinkling or bunching at first and second end portions (e.g., the first and second end portions **118a** and **118b** shown in FIGS. 4A and 4B) when the cover **106** and the frame are constricted. In other embodiments, the superior and inferior termini **531a** and **531b** can be scalloped, straight, and/or have another suitable shape that facilitates attachment and/or limits wrinkling.

**[0073]** The cover **106** can be made from a substantially impermeable, biocompatible, and flexible material. For example, the cover **106** can be made from synthetic polymers, polyurethanes, silicone materials, polyurethane/silicone combinations, rubber materials, woven and non-woven fabrics such as Dacron®, fluoropolymer compositions such as a polytetrafluoroethylene (PTFE) materials, expanded PTFE materials (ePTFE) such as TEFLON®, GORE-TEX®, SOFTFORM®, IMPRA®, and/or other suitable materials. Additionally, in some embodiments, the cover **106** can be

made from a material that is sufficiently porous to permit ingrowth of endothelial cells. Such a porous material can provide more secure anchorages of endograft devices and potentially reduce flow resistance, shear forces, and leakage of blood around the endograft devices.

[0074] In some embodiments in accordance with the technology, the cover 106 may also include drug-eluting coatings or implants. For example, the cover 106 can be coated and/or imbedded with a slow-releasing drug that can block cell proliferation, promote reendothelialization of the aneurysm, and/or otherwise medicate the aneurysmal region. Suitable drugs can include calcium, proteins, mast cell inhibitors, and/or other suitable medicines that encourage beneficial changes at the aneurysmal region.

[0075] In accordance with other embodiments of the technology, the cover 106 can be eliminated in favor of one or more layers of a coating material (shown and described in more detail with reference to FIGS. 17A-E). The coating layer can be made from a biocompatible synthetic polymer, such as PTFE. The coating layer can be placed on the interior of an integrated frame (e.g., the frame 104 shown in FIGS. 4A and 4B), the exterior of the frame, and/or interwoven throughout the frame. Like the cover 106, the coating layers can encase the frame to form a lumen (e.g., the lumen 116 shown in FIGS. 1A and 1B). Additionally, the coating can have a selected porosity that encourages tissue ingrowth.

#### [0076] 2.3 Integrated Frame and Cover

[0077] FIGS. 6A and 6B are cross-sectional views of the endograft device 102 of FIGS. 1A and 1B in a low-profile configuration and an expanded configuration, respectively, in accordance with embodiments of the technology. As shown in FIGS. 6A and 6B, the cover 106 can be attached to the exterior of the frame 104 at one or more attachment areas 632 (identified individually as a first attachment area 632a and a second attachment area 632b). The attachment areas 632 can have sutures, adhesives, welds, and/or other suitable fasteners that discretely hold the cover 106 to the frame 104 at the attachment areas 632.

[0078] In the embodiment shown in FIGS. 6A and 6B, the endograft device 102 has attachment areas 632 at only the superior and inferior termini 531a and 531b of the cover 106 such that the remainder of the cover 106 between the attachment areas 632 is not attached directly to the frame 104. As a result, the frame 104 and the cover 106 can fully extend and constrict as shown in FIG. 6A without interfering with one another. For example, in the low-profile configuration shown in FIG. 6A, the frame 104 does not directly pull the central portion of the cover 106 downward and longitudinally with the frame 104 such that the ribs 530 can stretch uniformly along the length of the cover 106 to accommodate full extension of the frame 104. Similarly, the intermediate portions of the cover 106 do not hinder the extension or constriction of the frame 104. Fewer attachment areas 632 can also limit the potential for fatigue and undesirable porosity that may arise at the attachment areas 632, such as from needle pricks and other fastening mechanisms that puncture the cover 106.

[0079] As shown in FIG. 6B, the cover 106 can substantially conform to the shape of the frame 104 when they are in the expanded configuration. Proper alignment between the cover 106 and the frame 104 prevents the cover 106 from adversely affecting constriction and expansion. For example, alignment between the cover 106 and the frame 104 at the superior and transition portions 108 and 324, respectively, ensures the frame 104 can expand properly and generate the

force necessary to mate with a superior portion of an opposing endograft device. Additionally, in some embodiments, the cover 106 is sized to restrict the expansion and corresponding contraction of the frame 104.

[0080] Attaching the cover 106 to the exterior of the frame 104 as shown in FIGS. 6A and 6B can provide a plurality of benefits for the endograft device 102. For example, unlike endograft devices with internal covers that must fold within a frame during delivery, the exterior cover 106 does not inhibit constriction of the frame 104 (e.g., FIG. 6A). In the expanded configuration, the exterior cover 106 does not bunch or wrinkle within the frame 104, and thus does not cause thrombotic problems within the lumen 116. Additionally, unlike more rigid Z-stents, the flexibility of the frame 104 can prevent abrasive rubbing and deterioration of the cover 106 in the expanded configuration (e.g., FIG. 6B). The exterior attachment of the cover 106 can also prevent over expansion of the frame 104.

#### [0081] 2.4 Alignment Aids

[0082] FIGS. 7A and 7B are isometric views of endograft devices 702 in accordance with additional embodiments of the technology. The endograft devices 702 can have generally similar features as the endograft devices 102 shown in FIGS. 1A and 1B. Additionally, the endograft devices 702 can include alignment aids 734 that are visible under imaging systems (e.g., X-rays) to facilitate accurate positioning and subsequent monitoring of the endograft devices 702 in the vasculature.

[0083] FIG. 7A is a partial cut-away isometric view of the endograft device 7-2 showing an alignment aid 734 in accordance with an embodiment of the technology. As shown in FIG. 7A, the alignment aid 734 can extend diagonally along the septal wall 114 of the frame 104 to indicate the position of the septal wall 114 relative to the endograft device 702. The alignment aid 734 can thus provide an indication of the rotational orientation and axial location of the endograft device 702 such that during deployment opposing septal walls 114 can be properly aligned and mated with one another. Additionally, as shown in the embodiment in FIG. 7A, the alignment aid 734 can terminate at the superior terminus 531a of the cover 106 to indicate where the first end portion 118a begins. Thus, the alignment aid 734 provides a definitive indicator to ensure that the cover 106 does not block transverse flow (e.g., from the aorta to the renal arteries). In other embodiments, the alignment aids 734 may be positioned elsewhere along the endograft device 702 to provide spatial location and orientation that can aid delivery and deployment of the endograft device 702.

[0084] The alignment aid 734 can be made from radiopaque and/or fluoroscopic materials, such as tantalum, platinum, gold, and/or other materials that are visible under an imaging system (e.g., X-rays). For example, as shown in FIG. 7A, the alignment aid 734 is made from a radiopaque wire (e.g., tantalum) wound around a segment of the frame 104. In another embodiment, a radiopaque composition is applied to the frame 104 and/or incorporated in the septal walls 114 of the cover 106.

[0085] FIG. 7B shows the first and second endograft devices 702 mated together using the alignment aids 734 in accordance with an embodiment of the technology. As shown in FIG. 7B, the alignment aids 734 on the first and second endograft devices 702a and 702b are symmetrical such that when the endograft devices 702 are correctly oriented and the septal walls 114 oppose one another, the alignment aids 734

can intersect to form an “X” indicator. In other embodiments, the intersection of the alignment aids **734** forms other characters, numbers, and/or symbols that indicate the rotational orientation and longitudinal location of the endograft devices **702**. In further embodiments, the alignment aids **734** can be applied to different portions of the septal wall (e.g., the cover **102**) and/or the outer wall **112**. In still further embodiments, the endograft devices **702** include a plurality of alignment aids **734** to distinguish different portions of the endograft devices **702** and further aid rotational and/or other orientation. For example, in some embodiments, the inferior portions **110** include alignment aids **734** that differentiate the inferior portions **110** of the first and second endograft devices **702**.

#### [0086] 2.5 Anchors

[0087] FIGS. **8A** and **8B** are isometric views of endograft devices **802** configured in accordance with additional embodiments of the technology. The endograft devices **802** can include generally similar features as the endograft devices **102** shown in FIGS. **1A** and **1B**. Additionally, the endograft devices **802** can include one or more anchors **836** that project outwardly from the frame **104** and/or cover **106** to engage the interior surfaces of arterial walls. The anchors **836** can be barbs, hooks, and/or other shapes that can penetrate into the arterial walls. For example, as shown in FIG. **8A**, the anchors **836** can be “V” shaped projections. In some embodiments, the anchors **836** eventually become embedded in cell growth on the interior surface of the arterial wall. In operation, the anchors **836** resist migration of the endograft devices **802** within the artery and reduce the likelihood of endoleaks between the outer wall **112** and the arterial wall.

[0088] In an embodiment shown in FIGS. **8A** and **8B**, the anchors **836** project from the outer walls **112** to secure the superior portions **108** to the aorta. In other embodiments, additional anchors **836** can project from the second end portions **118b** to secure the inferior portions **110** to the iliac arteries. The anchors **836** can also protrude from the septal walls **114**, extend through the lumen **116**, and project outward beyond the outer wall **112** to enhance the strength of the engagement. The anchors generally project inferiorly such that downward forces applied to the endograft devices **802** (e.g., blood flow) drive the anchors **836** further into the arterial walls.

[0089] In one embodiment in accordance with the technology, the anchors **836** are separate elements that are attached to the frame **104**. For example, in the embodiment shown in FIG. **8A**, the anchors **836** are small barbs or wires that are fastened to the frame **104** by winding another wire (e.g., a Nitinol wire) around the anchors **836** and the adjacent wire **426** of the braid. In other embodiments, the anchors **326** are integrally formed with the wire **426** used in the braid of the frame **104**. For example, as shown in FIG. **8B**, the anchors **836** are woven into the outer wall **112** of the frame **104**. The interwoven anchors **836** can be deployed (i.e., project outwardly) when the frame **104** expands and can retract when the frame **104** constricts. Accordingly, the interwoven anchors **836** do not inhibit movement of the endograft device **802** during delivery in the low-profile configuration. In other embodiments, the anchors **836** can be attached to a different portion of the endograft device **802** (e.g., the cover **106**).

[0090] The anchors **836** can be made from resilient metallic materials, polymeric materials (e.g., polyethylenes, polypropylenes, Nylons, PTFEs), and/or other suitable materials that can anchor the endograft devices **802** to arterial walls. For

example, the interwoven anchors **836** shown in FIG. **8B** can be made from Nitinol wire **426** that comprises the frame **104**.

#### [0091] 3. Methods of Implementation and Assembled Endograft Systems

[0092] Described below are methods of deploying and assembling modular endograft systems across an aneurysm in accordance with embodiments of the technology. The associated Figures (i.e., FIGS. **9A**, **9B**, **11-13C** and **15A-16**) include schematic representations of an abdominal portion of an aorta. More specifically, FIG. **9A** shows an aneurysm **50** located along an infrarenal portion of the aorta **52**, which is the most common site of an AAA. A right or first renal artery **54a** and a left or second renal artery **54b** stem from the aorta **52**. The region of the aorta **52** superior to the aneurysm **50** and inferior to the renal arteries **54** is the aortic neck **60**. The distal end portion of the aorta **52** bifurcates into common iliac arteries **56** (identified individually as a first iliac artery **56a** and a second iliac artery **56b**), and the internal iliac arteries **58** (identified individually as a first internal iliac artery **58a** and a second internal iliac artery **58b**) branch from the common iliac arteries **56**. Other arteries and structures proximate to the abdominal portion of the aorta **52** have been removed for clarity.

#### [0093] 3.1 Modular Endograft Systems

[0094] FIGS. **9A** and **9B** are schematic views of the two-part modular endograft system **100** described above being deployed across the aneurysm **50** in accordance with an embodiment of the technology. FIG. **9A** shows a delivery system **40** for implanting the first and second endograft devices **102a** and **102b**. The delivery system can include a first catheter **42a**, a first guidewire **44a** associated with the first catheter **42a**, a second catheter **42b**, and a second guidewire **44b** associated with the second catheter **42b**. Each endograft device **102** (FIG. **9B**) can be extended to the low-profile configuration and loaded into the corresponding catheter **42**. Because the endograft devices **102** are delivered separately, the sizes of the catheters **42** are not constrained by the system **100** as a whole. In some embodiments, for example, the low-profile configurations of each endograft device **102** can fit within a 12 F catheter. In other embodiments, the low-profile configuration of the endograft devices **102** can fit within differently sized catheters **42**.

[0095] During deployment, the first catheter **42a** and the first guidewire **44a** are inserted percutaneously into a blood vessel (e.g., a femoral artery; not shown). With the aid of imaging systems, the first guidewire **44a** is endoluminally navigated through the vasculature, up the first iliac artery **56a**, and to a location superior to a target site T above the aneurysm **50**. The first catheter **42a** is then passed through the vasculature along the first guidewire **44a** to the target site T. Using a generally similar method, the second guidewire **44b** and the second catheter **42b** are delivered through the second iliac artery **56b** to the target site T. The first and second endograft devices **102a** and **102b** can be delivered simultaneously or in succession.

[0096] The endograft devices **102** can be urged out of the distal ends of the catheters **42** at the target site T by withdrawing the catheters **42** proximally while holding the endograft devices **102** in place using pushers or other suitable endovascular instruments. Alternatively, the endograft devices **102** can be pushed distally while holding the catheters **42** in place. Upon release, the endograft devices **102** self-expand to the expanded configuration shown in FIG. **9B**. The guidewires **44**

generally remain in place to facilitate adjusting the endograft devices **102**. This eliminates the need to cannulate either of the endograft devices **102**.

**[0097]** Each endograft device **102** can be positioned at its desired location independently of the other endograft device **102** while the endograft devices **102** are in, or at least partially within, the catheters **42**. For example, in the embodiment illustrated in FIG. 9B, the superior portions **108** contact the aortic neck **60** at the same level, and the inferior portions **110** extend through the aneurysm **50** to their respective iliac arteries **56**. More specifically, the inherent hoop force of the frame **104** caused by the constant outward spring force of the braid at least substantially seals (a) the covers **106** at the outer walls **112** against the aortic neck **60** and (b) the septal walls **114** to each other to form the septum **120**. The inferior portions **110** extend through the aneurysm **50** and can bend to enter the iliac arteries **56**. The proximal portion of the inferior portions **110** contact the iliac arteries **56** and can form a seal therebetween. The flexibility of the frame **104** prevents the endograft devices **102** from kinking at the bend and restricting blood flow. Additionally, as shown in FIG. 9B, the spring force within the frame **104** biases the inferior portions **110** to extend in a substantially straight trajectory through the aneurysm **50**. This inhibits migration of the inferior portions **110** to a side of the aneurysm **50** that could break the contact and/or seal at the aortic neck **60**. As described in more detail below, in other embodiments the endograft devices **102** can be positioned independently at different elevations along the aortic neck **60**.

**[0098]** As further shown in FIG. 9B, the endograft system **100** can include extension units **937** (identified individually as a first extension unit **937a** and a second extension unit **937b**) projecting distally from the superior termini **531** of the covers **106**. The extension units **937** can include an extension frame **904** (not visible) and an extension cover **906** at least generally similar to the frame **104** and the cover **106** of the endograft devices **102** described above. The extension units **937** can have a substantially similar shape as the superior portions **108** of the endograft devices (e.g., a D-like shape) such that the extension units **937** can mate with the interior of at least a part of the superior portions **108**. For example, as shown in FIG. 9B, the extension covers **906** can be positioned inferior to the renal arteries **54** within the frame **104** such that the extension covers **906** can interface with the aortic neck **60** and mate with one another to extend the septum **120** distally. Therefore, the extension units **937** can increase the fixation area and the sealing area of the endograft devices **102** when the superior termini **531** of the covers **106** of the endograft devices **102** are offset from the entrances of the renal arteries **54**. For example, in some embodiments, the extension units **937** add approximately one inch of fixation structure and sealing area to the endograft devices **102**. In other embodiments, the inferior portions **110** can also include extension units **937** that can affix and at least substantially seal to the iliac arteries **56**.

**[0099]** During deployment, the extension units **937** can be added to the system **100** after the first and second endograft devices **102** are positioned within the aortic neck **60**. With the aid of the delivery system **40**, the extension units **937** can advance along the guidewires **44** and be deployed from the catheters **42** at desired positions within the first and second frames **104** just inferior of the renal arteries. Upon deployment, the extension units **937** can self-expand via an inherent spring force in the extension frame **904** to an expanded configuration to contact and at least substantially seal with the

interior of the superior portions **108** of the endograft devices **102**. As shown in FIG. 9B, the extension cover **906** can interface with the first end portions **118a** of the frames **104** to strengthen the seal therebetween. In other embodiments, the extension units **937** can connect and seal to the endograft devices **102** using other suitable attachment methods. The extension units **937** can be positioned independently such that they accommodate anatomical variations (e.g. staggered renal arteries). For example, a superior terminus of the first extension unit **937a** can be longitudinally offset from a superior terminus of the second extension units **937b**. Similarly, the inferior portions **110** can include extension units **937** that increase the sealing area with the iliac arteries **56**.

**[0100]** In some embodiments, alignment aids, such as the alignment aids **734** described with reference to FIGS. 7A and 7B, are used to rotationally orient the endograft devices **102** and align the septal walls **114** during delivery. Additionally, to prevent migration and/or projection of the system while in situ, anchors, such as the anchors **836** described above with reference to FIGS. 8A and 8B, can be deployed from the outer walls **112** to engage the arterial walls of the aortic neck **60** and/or from the second end portions **118b** to engage the arterial walls of the iliac arteries **56**.

**[0101]** FIGS. 10A-11 show additional embodiments of implementing endograft systems (e.g., the system **100**) in which the superior portions **108** are longitudinally offset from each other. For example, in some embodiments, the superior portions **108** are longitudinally offset by at least 5 mm. The features of the systems below allow one or both of the superior portions **108** to be placed over transverse arteries to increase the available fixation structure and sealing area for the endograft devices **102** without inhibiting blood flow.

**[0102]** FIG. 10A is an isometric view of the modular endograft system **100** in which the endograft devices **102** are staggered such that the superior portion **108** of the first endograft device **102a** is above the superior portion **108** of the second endograft device **102b**. The first end portion **118a** of the second endograft device **102b** can prevent the unsupported free first end portion **118a** of the first endograft device **102a** from splaying outward into the blood flow in a manner that induces undo turbulence. Moreover, the interplay between the woven wires **426** of the frame **104** of the first endograft device **102a** restricts the outward movement of the first end portion **118a** of the first endograft device **102a** and provides substantially continuous support along the length of the frame **104** such the free first end portion **118a** retains substantially the same shape as if it were supported. These features maintain the generally straight or convex shape of the unsupported septal region of the first portion **118a** of the first endograft device **102a**. Using shape-setting Nitinol wire **426** in the frame **104** can further facilitate maintaining the shape of the unsupported portion of the frame **104**.

**[0103]** Compared to conventional devices that have a common height across the diameter of a vessel (e.g., the aorta), the staggered configuration shown in FIG. 10A allows one or both of the first end portions **118a** to extend over the entrance of the renal arteries to increase the available structure for fixing the endograft devices **102** to the vessel wall. The staggered configuration also increases the sealing area of the superiorly positioned first endograft device **102a** for anatomies having a short aortic neck (e.g., less than 2 cm). Similarly, the second end portions **118b** can extend over the entrances of the internal iliac arteries to ensure the inferior portions **110** each have an adequate structure for fixing and at

least substantially sealing the inferior portions **110** to the iliac arteries. To the extent migration occurs, the additional sealing area between the endograft devices **102** and the vessel walls will reduce the potential for leakage at the aortic neck.

[0104] FIG. 10B is an isometric view of a modular endograft system **1000** configured in accordance with an additional embodiment of the technology. The system **1000** can have a first endograft device **1002a** and a second endograft device **1002b** that are generally similar to the endograft devices **102** described above. The covers **106** of the endograft devices **1002** in FIG. 10B, however, extend to the distal ends of the superior portions **108**. Additionally, the endograft devices **1002** further include fenestrations **1038** on the outer walls **112** of the superior portions **108**.

[0105] The fenestrations **1038** can be openings through the cover **106** that expose the frame **104** and provide a channel through which blood can flow to and from transverse arteries. For example, the endograft devices **1002** can be positioned independently and staggered such that the fenestration **1038** of each endograft device **1002** is aligned with one of the left or right renal arteries. The fenestrations **1038** accordingly increase the available sealing area between the outer walls **112** and the arterial walls because the superior portions **108** can be positioned independently over the renal arteries such that one endograft device **1002** does not need to be limited to the elevation of the inferior renal artery. This provides optimal placement for each endograft device **1002** within the vasculature without requiring customized devices. In other embodiments in accordance with the technology, the endograft devices **1002** can include additional fenestrations **1038** to increase the available sealing area without restricting blood flow. For example, the inferior portions **110** can include fenestrations **1038** that allow the inferior portions **110** to extend over the entrance of the internal iliac arteries.

[0106] FIG. 11A is a schematic view of the modular endograft system **100** deployed across an aneurysm such that the superior portions **108** of the endograft devices **102** are staggered to accommodate for anatomical variations in the vasculature in a manner that takes advantage of the available structure for fixing the endograft devices **102** to arterial walls and the available sealing area in the aortic neck **60**. In the embodiment shown in FIG. 11A, for example, the left renal artery **54b** is inferior the right renal artery **54a**. The first endograft device **102a** can, therefore, also be positioned higher in the aorta **52** to utilize the available fixation and sealing areas on the ipsilateral side of the aortic neck **60** without having to be concerned about blocking the entrance of the left renal artery **54b**. The first end portion **118a** of the second endograft device **102b** can be positioned over the left renal artery **54b** without inhibiting blood flow to lengthen the structure for fixing the second endograft device **102b** to the arterial wall and mating the septal walls **114** together. The longer fixation and sealing areas along the outer wall **112** of the first endograft device **102a** and the longer mating and sealing areas between the septal walls **114** can strengthen the seals of the system **100** as a whole to reduce the likelihood of endoleaks. Additionally, as shown in FIG. 11A, the system **100** can be staggered to accommodate an anatomy with less fixation and sealing area in one of the iliac arteries **56**.

[0107] FIG. 11B is a schematic view of the modular endograft system **1000** of FIG. 10B deployed across the aneurysm **60**. Similar to the configuration of the system **100** shown in FIG. 11A, the endograft devices **1002** are staggered to accommodate for anatomical variations in the vasculature in

a manner that takes advantage of the available anatomical structure for fixing and sealing the outer walls **112** of the endograft devices **102** to the arterial walls in the aortic neck **60**. As shown in FIG. 11B, for example, the first endograft device **1002a** can be positioned superior to the second endograft device **1002b** in the aortic neck **60** to utilize the available fixation and sealing area on the ipsilateral side of the aortic neck **60**. The fenestrations **1038** can be placed independently at the entrance of each renal artery **54** to increase the available fixation and sealing area in the aortic neck **60** and accommodate asymmetrical anatomies. Additionally, as further shown in FIG. 11B, the endograft devices can include fenestrations **1038** at the inferior portions **110** that can be placed independently at the entrance of each internal iliac artery **58** to accommodate an anatomy with less sealing area in the iliac arteries **56**. In other embodiments, the endograft devices **102** can include fenestrations **1038** to accommodate other anatomical variations.

[0108] FIG. 12 is a schematic view of the modular endograft system of FIGS. 9A and 9B deployed across an angulated aneurysm in accordance with an additional embodiment of the technology. The system **100** can accommodate this anatomical abnormality because the endograft devices **102** are flexible. More specifically, the interwoven wires **426** of the frame **104** are sufficiently flexibility to bend without kinking. Thus, the bent endograft devices **102** can maintain unrestricted flow through the lumens **116**. Accordingly, the system **100** can accommodate other anatomical variations that may require the endograft devices **102** to flex or bend without disturbing blood flow.

[0109] FIGS. 13A-C are schematic views of a four-part modular endograft **1300** system ("system **1300**") being deployed across the aneurysm **50** in accordance with an embodiment of the technology. The system **1300** can include generally similar features as the system **100** described with reference to FIGS. 9A and 9B. However, as shown in FIG. 13B, the inferior portions **110** of the endograft devices **102** terminate within the aneurysm **50**. Therefore, as shown in FIG. 13C, the system **1300** further includes separate limbs **1362** (identified individually as a first limb **1362a** and a second limb **1362b**) that contact and substantially seal with corresponding inferior portions **110** and extend into corresponding iliac arteries **56**. The limbs **1362** can be generally similar to the inferior portions **110**. For example, the limbs **1362** can include an integrated frame **1304** and a cover **1306** generally similar to the frame **104** and the cover **106** described above with reference to FIGS. 1A-6B. As shown in FIG. 13C, the limbs **1362** self-expand within the inferior portions **110** to the expanded configuration and thereby the superior portions of the limbs **1362** at least substantially seals to the proximal section of the inferior portions **110**. The length of the limbs **1362** within the inferior portions **110** can be adjusted to increase the available structure for fixing and sealing the limbs **1362** to the endograft devices **102**. Additionally, in some embodiments, the covers **1306** of the limbs **1362** can include ribs, such as the ribs **530** described above with reference to FIGS. 5A-C, that interface with the interior of the frames **104** and the covers **106** at the inferior portions **110** to connect and at least substantially seal the limbs **1362** to the inferior portions **110**. In other embodiments, the limbs **1362** can connect and at least substantially seal to the exteriors of the inferior portions **110** using anchors (e.g., the anchors **836** described with reference to FIGS. 8A and 8B), self-constricting forces, and/or other suitable attachment and

sealing methods. The limbs 1362 extend the lumens 116 of the endograft devices 102 to the iliac arteries 56 such that blood can flow through the system 1300 to bypass the aneurysm 50.

[0110] Referring to FIG. 13A, the delivery system 40 is shown within the abdominal portion of the aorta 52 before deploying the endograft system 1300. The insertion of the delivery system 40 can be generally similar as described above with reference to FIG. 9A. However, as shown in FIG. 13A, the first and second guidewires 44a and 44b can cross after they enter the aneurysm 50 such that each catheter 42 extends from its respective iliac artery 54 to the contralateral side of the aorta 52. For example, the first catheter 42a can be delivered from the first iliac artery 56a to the left side of the aorta 52 proximate to the left renal artery 54b (Arrow D<sub>1</sub>), and the second catheter 42b can be delivered from the second iliac artery 56b to the right renal artery 54a (Arrow D<sub>2</sub>). In other embodiments, such as in the deployment method described above with reference to FIGS. 9A and 9B, the guidewires 44 do not cross within the aneurysm 50.

[0111] Referring to FIG. 13B, after the first and second catheters 42a and 42b are positioned in the aortic neck 60, they are pulled proximally to deploy the endograft devices 102 through the distal ends of the catheters 42. The crossing catheters 42 and guidewires 44 deploy the endograft devices 102 on opposite sides of the aortic neck 60.

[0112] As shown in FIG. 13B, the inferior portions 110 of the endograft devices 102 terminate within the aneurysm 50 and form a “gate.” In general, gates are considered undesirable because in conventional systems they must be cannulated to deliver and deploy limbs that extend the endograft devices into the iliac arteries 56. However, as shown in FIG. 13B, the guidewires 44 remain within the endograft devices 102 after they are deployed; this eliminates the need for time-consuming cannulation of the gates because the inferior portions 110 of the endograft devices 102 are in effect pre-cannulated. Such pre-cannulated gates allow the limbs 1362 to be delivered through the distal ends of the catheters 42 and connected to the inferior portions 110 much faster and more accurately than conventional systems.

[0113] FIG. 13C shows the system 1300 after both limbs 1362 are connected to the endograft devices 102. As shown in FIG. 13C, the delivery system 40 can also be used to adjust the length of the limbs 1362 and the length of the fixation area between the limbs 1362 and the inferior portions 110 in the direction of the arrows. In the embodiment shown in FIG. 13C, for example, the second limb 1362b extends further into the inferior portion 110 of the second endograft device 102b such that the second limb 1362b is effectively shorter than the first limb 1362a. The length of the limbs 1362 can be adjusted to accommodate disparate anatomies of the iliac arteries 56, maximize the fixation and sealing areas of the limbs 1362, and/or otherwise optimize the position of the limbs 1362. This is possible because, at least in part, the inferior portions 110 of the endograft devices 102 can be relatively long to allow significant longitudinal leeway in positioning the limbs 1362 while still providing adequate surface area to at least substantially seal the limbs 1362 to the inferior portions 110.

[0114] The four-part, two-wire system 1300 can easily accommodate anatomical variations without requiring customized components. For example, the superior portions 108 can be staggered to maximize the mating and sealing area of each outer wall 112 with the aortic walls. Additionally, each limb 1362 can be selected from a relatively small number of

different lengths to extend a desired length within the iliac arteries 56 that both adequately connects and substantially seals the limbs 1362 to the arterial walls and does not block transverse arterial flow. The limbs 1362 can also be adjusted independently relative to the inferior portions 110 to increase the available structure for fixing and sealing the limbs 1362 and the inferior portions 110 together, and to shorten or lengthen the limbs 1362 within the iliac arteries 56. Additionally, the braided structure of the frames 104 can decrease infolding of the covers 106 such that the lengths of the frame 104 can be selected from standardized cross-sectional dimensions. Thus, the four-part system 1300 can be highly customizable, but yet comprise standardized components.

### [0115] 3.2 Modular Endograft System with Aortic Cuff

[0116] FIGS. 14A and 14B are isometric views of a modular endograft system 1400 (“system 1400” shown in FIG. 14B) configured in accordance with embodiments of the technology. More specifically, FIG. 14A is an isometric view of an aortic cuff 1464 for use with the endograft devices 102 (FIG. 14B). The aortic cuff 1464 can include a sleeve 1466 and a cuff frame 1468. As shown in FIG. 14A, the sleeve 1466 and the cuff frame 1468 can be separate components. In other embodiments, the sleeve 1466 and the cuff frame 1468 can be formed integrally. The aortic cuff 1464 can expand from a low-profile configuration having a first cross-section to an expanded configuration (e.g., FIG. 14B) having a second cross-section larger than the first cross-section. The low-profile configuration can be used during delivery of the aortic cuff 1464 from which the cuff-device 1464 can self-expand to the expanded configuration in situ. The aortic cuff 1464 can be configured to interface and substantially seal with an infrarenal portion of the aorta superior to an aneurysm.

[0117] The sleeve 1466 can be attached to the interior and/or exterior of the cuff frame 1468 using suitable fastening methods. For example, as shown in FIG. 14B, the sleeve 1466 is positioned within the interior of the cuff frame 1468, and the ends of the sleeve 1466 extend over and are fixed to proximal and distal ends of the cuff frame 1468 using suitable fastening methods (e.g., stitching, gluing, welding, etc.). In some embodiments, the proximal and distal ends of the cuff frame 1468 can be flared, and the sleeve 1466 can wrap around the flared ends to the exterior of the cuff frame 1468 such that the attachment can be sealed by the arterial walls when the aortic cuff 1464 is expanded to the expanded configuration in situ. The sleeve 1466 can have generally similar characteristics as the cover 106 described above. For example, the sleeve 1466 can be made from one or more substantially impermeable materials, such as Dacron® and PTFE, and can include ribs that can interface with arterial walls and/or endograft devices 102 (FIG. 14B). The cuff frame 1468 can have generally similar characteristics as the integrated frame 104 described above. In other embodiments, the cuff frame 1468 can be made from individual zigzagged wire hoops like a Z-stent.

[0118] The sleeve 1466 and the cuff frame 1468 can have a substantially cylindrical shape. In some embodiments, the aortic cuff 1464 can include two channels to support superior portions 108 of endograft devices 102 (FIG. 14B). For example, the channels can be formed by stitching the fabric of the sleeve 1466 together to divide the interior of the aortic cuff 1464. Additionally, the sleeve 1466 and/or the cuff frame 1468 can have flared proximal and distal ends to form a stronger seal with adjacent arterial walls.



[0119] Referring to FIG. 14B, the endograft devices 102 are deployed within the aortic cuff 1464 after the cuff 1464 has been at least substantially sealed against the aortic neck 60. The superior portions 108 can mate with and substantially seal to the interior of the aortic cuff 1464. The ribs 530 of the cover 106 can interface with the interior surface of the sleeve 1466 to further strengthen the seal. Additionally, the integrated frame 104 can further improve the seal between the endograft devices 102 and the aortic cuff 1464. For example, the cross-section of the frame 104 in the expanded configuration can be slightly larger than an interior cross-section of the aortic cuff 1464. As the endograft devices 102 are deployed within the aortic cuff 1464, the radial forces from the expansion of the endograft devices 102 can strengthen the seal therebetween. Additionally, in some embodiments, the transition portion 324 of the endograft devices can mate with a complementary taper within the aortic cuff 1464.

[0120] In some embodiments in accordance with the technology, the aortic cuff 1464 can include alignment aids, such as the alignment aids 734 described above with reference to FIGS. 7A and 7B, to facilitate positioning the endograft devices 102 within the aortic cuff 1464. For example, the aortic cuff 1464 and the outer walls 112 of the endograft devices 102 can include orthogonal alignment aids that intersect to indicate the endograft devices 102 are properly aligned within the aortic cuff 1464.

[0121] In additional embodiments, the aortic cuff 1464 can include anchors, such as the anchors 836 described above with reference to FIGS. 8A and 8B, to secure the system 1400 in situ. For example, the cuff frame 1468 can include anchors that project radially outwardly and engage adjacent arterial walls.

[0122] FIGS. 15A and 15B are schematic views of a three-part modular endograft system 1500 ("system 1500") being deployed across the aneurysm 50 in accordance with an embodiment of the technology. The system 1500 can include the endograft devices 102 described with respect to the system 100 and the aortic cuff 1464 described above with reference to FIGS. 14A and 14B.

[0123] Referring to FIG. 15A, the delivery system 40 can be inserted using a generally similar method as described above with reference to FIG. 9A. In the embodiment shown in FIG. 15A, however, the first catheter 42a and the first guidewire 44a can be inserted first to deliver the aortic cuff 1464 (FIG. 15B) to the target site T. The aortic cuff 1464 can be deployed using a generally similar method as deploying the endograft devices 102 described above with reference to FIGS. 9A and 9B. The first guidewire 44a can be used to adjust the aortic cuff 1464 to a desired position in the aortic neck 60.

[0124] As shown in FIG. 15B, the endograft devices 102 can be deployed within the aortic cuff 1464. The endograft devices 102 can be deployed using a substantially similar method as described with reference to FIG. 9B. For example, the endograft devices 102 can be delivered through the first and second catheters 42 and positioned independently within the aortic cuff 1464 using the guidewires 44. Similar to the method of deploying the superior portions 108 directly against the arterial walls described with reference to FIGS. 9B and 13B, here the outer walls of the superior portions 108 can at least partially interface with the interior surface of the aortic cuff 1464 such that the septal walls are aligned with each other to form the septum 120 (not visible). In some embodiments in accordance with the technology, the aortic

cuff 1464 can include sections shaped to receive the endograft devices 102 and thereby ease alignment. In further embodiments, the first endograft device 102a can be anchored or otherwise secured to the aortic cuff 1464 before deployment such that only the second endograft device 102b must be positioned within the aortic cuff 1464.

[0125] FIG. 16 is a schematic view of a modular endograft system 1600 ("system 1600") being deployed across the aneurysm 50 in accordance with another embodiment of the technology. The system 1600 can be deployed using generally similar methods as the system 1500 described above with reference to FIGS. 15A and 15B. As shown in FIG. 16, however, the superior portions 108 project above the aortic cuff 1464 such that the first end portions 118a provide additional structure for securing the endograft devices to the arterial walls of the aorta 52. Additionally, the inferior portions 110 of the endograft devices 102 terminate within the aneurysm 50. Therefore, the system 1600 further includes limbs (not shown), such as the limbs 1362 described above with reference to FIGS. 13A-C, that connect to the inferior portions 110 and extend into the iliac arteries 56. The catheters 42 can be used to adjust the length of the limbs to accommodate differing anatomies of the iliac arteries 56 and to maximize the fixation and sealing areas between the limbs and the arterial walls. Additionally, in some embodiments, the limbs can intersect (e.g., the limbs 1362 shown in FIG. 13C) to strengthen the seal at the aortic neck 60 and decrease the likelihood of endoleaks. Similar to the four-part system 1300 described above, the five-part system 1600 can accommodate anatomical variations without requiring customized components.

[0126] In the embodiments illustrated in FIGS. 9A, 9B, 11-13C, 15A, 15B and 16, the aneurysm 50 is shown in the infrarenal portion of the aorta 52 because this is the most common site of an AAA. In other embodiments in accordance with the technology, the modular endograft systems 100, 1000, 1300, 1500 and 1600 can be deployed across aneurysms 50 at different portions of the aorta 52 or in other vessels altogether. For example, in some embodiments, the aneurysm 50 can extend from the infrarenal portion of the aorta 52 into one or both of the common iliac arteries 56. The inferior portions 110 or the limbs 1362 of the systems 100, 1000, 1300, 1500 and 1600 can extend past the diseased, aneurysmal portion of the iliac arteries 56 without blocking blood flow to the internal iliac arteries 58. In other embodiments, the systems 100, 1000, 1300, 1500 and 1600 can be deployed across aneurysms 50 located in the supra renal portion of the aorta 52 with the fenestrations 1038 and/or the first end portions 118a positioned at the entrance of the renal arteries 54. In further embodiments, the systems described above can be deployed across aneurysms in other portions of the vasculature that benefit from the use of a bifurcated, bi-luminal modular endograft system that can be independently positioned.

[0127] 4. Methods of Manufacturing

[0128] 4.1 Integrated Frame

[0129] Referring back to FIGS. 4A and 4B, the integrated frame 104 can be made by weaving or braiding one continuous wire 426 in a pattern along a cylindrical mandrel. In some embodiments, the wire 426 is woven with a one over and one under pattern. In other embodiments, the wire 426 is woven with a two over and one under pattern, another integrated pattern, and/or a pattern that varies over the length of the frame 104. The intersections of the wire 426 can remain



unbound to increase flexibility of the frame 104. The wire 426 can form the loops 428 to change direction and continue the pattern of intersecting wires 426. As described above, the number of loops 428 at each end portion 118 and the braid angle  $\theta$  can be selected based on the diameter of the wire 426 and the desired properties of the frame 104.

[0130] The wire 426 can be removed from the mandrel after it is braided into the frame 104 and formed into a desired shape (e.g., the endograft devices 102 shown above). The frame 104 can then be heated to a shape-setting temperature specified for the wire material (e.g., Nitinol), and subsequently quenched. Optionally, the frame 104 can be annealed to increase the strength of the frame 104. The mandrel can be cylindrical or have the shape of the frame 104 such that the wire 426 remains on the mandrel during heat treatment. In further embodiments, the frame 104 can be manufactured using other suitable methods for shaping resilient biocompatible materials.

#### [0131] 4.2 Covers and Coatings

[0132] Referring to FIGS. 5A-C, the cover 106 can be made by shaping a substantially non-permeable cover material, such as Dacron®, PTFE, and/or other suitable biocompatible materials. The cover 106 can be formed by first placing the cover material over a mandrel. The mandrel can include thin grooves that can correspond to the desired geometry of the ribs 530 on the cover 106. A wire or thread can be wrapped over the cover material and into the grooves to corrugate the cover material. The cover material can then be heated on the mandrel until the ribs 530 are formed and the cover 106 is substantially non-permeable. In some embodiments, the superior and inferior termini 531a and 531b of the cover 106 can be shaped to facilitate attaching the cover 106 to a frame (e.g., the frame 104 shown in FIGS. 4A and 4B) and prevent the cover 106 from wrinkling at end portions (e.g., the end portions 118 shown in FIGS. 1A and 1B) during constriction. For example, the superior and inferior termini 531a and 531b can be zigzagged as shown in FIGS. 5A and 5B, scalloped, or otherwise shaped to limit wrinkling of the cover on the frame.

[0133] In other embodiments in accordance with the technology, coating layers can be used in place of or in conjunction with the cover 106. FIGS. 17A-E are views of coating layers being applied to an integrated frame 1704 ("frame 1704") in accordance with embodiments of the technology. The frame 1704 has generally similar features as the frame 104 described above. For example, the frame 1704 can be made from the braided wire 426.

[0134] Referring to FIG. 17A, the frame 1704 is positioned over a mandrel 80 in the expanded configuration. As shown in FIG. 17A, a first coating layer 1770 can be wrapped onto the frame 1704. The first coating layer 1770 can be a single or double layer of unsintered tape that can be approximately 0.0005" thick and made from PTFE. In other embodiments, the first coating layer 1770 can have a different thickness and/or the first coating layer 1770 can be made from another suitable coating material.

[0135] Once the first coating layer 1770 is applied over the frame 1704, the first coating layer 1770 and the frame 1704 can be heated on the mandrel 80 in an oven. For example, the first coating layer 1770 and the frame 1704 can be heated for less than thirty minutes in a 370° C. oven. After heating, the coated frame 1704 is removed from the mandrel 80 and extended and contracted from the low-profile configuration to

the expanded configuration to ensure the first coating layer 1770 properly adhered to the frame 1704 during heat treatment.

[0136] As shown in FIG. 17B, a second coating material 1772 is placed over a narrower, second mandrel 82. The second coating material 1772 can be extended a distance equivalent to the length of the frame 1704 in the low-profile configuration. Referring to FIG. 17C, the second coating material 1772 is contracted to the length of the frame 1704 in the expanded configuration. This contraction can form small ribs 1730 in the second coating material 1772. The ribs 1730 can be generally similar to the ribs 530 described above with reference to FIGS. 5A-C, but they are on the interior of the frame 1704. The ribs 1730 prevent the second coating material 1772 from wrinkling or bunching when the subsequently attached frame 1704 flexes or bends and thereby reduce the likelihood of thrombotic problems within the lumen.

[0137] As shown in FIG. 17D, the coated frame 1704 is then extended to the low-profile configuration and placed over the extended second coating material 1772 on the second mandrel 82. Each diamond opening along the frame 1704 can be spot welded using a welding device 84. Then, the frame 1704 is removed from the second mandrel 82 and extended and contracted from the low-profile configuration to the expanded configuration to ensure that the first and second coating layers 1770 and 1772 have adequately adhered to the frame 1704. Additionally, the proximal and distal ends of the frame 1704 are verified to ensure that the first and second coating layers 1770 and 1772 have properly adhered to the frame 1704. If necessary, tacking can be performed and the edges can be trimmed to form a dual coated endograft device 1702 shown in FIG. 17E.

[0138] From the foregoing, it will be appreciated that specific embodiments of the invention have been described herein for purposes of illustration, but that various modifications may be made without deviating from the spirit and scope of the technology. For example, the embodiments illustrated in FIGS. 1A-16 include covers 106 that extend over the exterior of the integrated frames 104. However, other embodiments of the technology can include covers 106 that are attached to the interior of the integrated frame 104 and/or are formed integrally with the frame 104. Certain aspects of the new technology described in the context of particular embodiments may be combined or eliminated in other embodiments. For example, in the embodiments illustrated above, each endograft device (e.g., 102, 1002) includes a singular lumen 116. However, the endograft devices can include additional lumens that transverse, bisect, and/or otherwise communicate with the lumen 116 to accommodate the vasculature. For example, the endograft devices can include lumens that extend into the renal arteries, the internal iliac arteries, and/or other arteries. Further, while advantages associated with certain embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

I/We claim:

1. A modular endograft system, comprising:
  - a first endograft device having a first superior portion, a first inferior portion having a smaller cross-sectional dimension than the first superior portion, and a first

- lumen through the first superior and first inferior portions, the first superior portion having a convexly curved first outer wall and a first septal wall that define a substantially D-shaped cross-section;
- a second endograft device having a second superior portion, a second inferior portion having a smaller cross-sectional dimension than the second superior portion, and a second lumen through the second superior and second inferior portions, the second superior portion having a convexly curved second outer wall and a second septal wall that define a substantially D-shaped cross-section; and
- wherein the first and second endograft devices are configured to self-expand into an expanded configuration via inherent hoop force of the first and second endograft devices such that the first and second septal walls press against each other and form a septum between the first and second lumens.
2. The modular endograft system of claim 1 wherein the first and second septal walls are convexly curved, and wherein:
- the first outer wall and the first septal wall define a first complex ellipsoid in which the first outer wall has a first radius and the first septal wall has a second radius greater than the first radius;
  - the second outer wall and the second septal wall define a second complex ellipsoid in which the second outer wall has the first radius and the second septal wall has the second radius; and
  - the self-expansion of the first and second endograft devices produces opposing forces between first and second septal walls in the expanded configuration.
3. The modular endograft system of claim 2 wherein the opposing forces between the first and second septal walls are substantially uniform along the septum.
4. The modular endograft system of claim 1 wherein the first and second septal walls are at least substantially straight.
5. The modular endograft system of claim 1 wherein the inferior portions have a substantially circular cross-section.
6. The modular endograft system of claim 1 wherein:
- the first endograft device has a first frame and a first cover attached to the first frame, the first cover having a plurality of first circumferential ribs; and
  - the second endograft device has a second frame and a second cover attached to the second frame, the second cover having a plurality of second circumferential ribs mated with the first circumferential ribs along at least a portion of the first and second septal walls.
7. The modular endograft system of claim 1 wherein:
- the first septal wall is convexly curved in an opposite direction relative to the first outer wall, and the first septal wall and the first outer wall are joined at curved corners; and
  - the second septal wall is convexly curved in an opposite direction relative to the second outer wall, and the second septal wall and the second outer wall are joined at curved corners.
8. The modular endograft system of claim 7 wherein:
- the first outer wall and the second outer wall each have a first radius of curvature;
  - the first septal wall and the second septal wall each have a second radius of curvature greater than the first radius of curvature; and
  - the curved corners have a radius of curvature less than the first radius of curvature.
9. The modular endograft system of claim 1 wherein the first endograft device has a first alignment marker and the second endograft device has a second alignment marker, wherein the first and second alignment markers are configured to indicate at least one of a rotational orientation and longitudinal position of the first and second endograft devices relative to each other.
10. The modular endograft device of claim 1 wherein:
- the first endograft device has a first braided frame and a first cover attached to the first braided frame, the first cover having a first inferior terminus and a first superior terminus, and the first braided frame having a first end extending distally beyond the first superior terminus of the first cover and second end extending proximally beyond the first inferior terminus of the first cover; and
  - the second endograft device has a second braided frame and a second cover attached to the second braided frame, the second cover having a second inferior terminus and a second superior terminus, and the second braided frame having a first end extending distally beyond the second superior terminus of the second cover and a second end extending proximally beyond the second inferior terminus of the second cover.
11. The modular endograft system of claim 1 wherein:
- the first endograft device has a first frame and a first cover attached to the first frame, the first frame comprising an open braided wire, and the first cover having a first opening at the first outer wall;
  - the second endograft device has a second frame and a second cover attached to the second frame, the second frame comprising an open braided wire, and the second cover having a second opening at the second outer wall; and
- wherein the first and second openings allow blood to flow laterally relative to a longitudinal axis of the first and second lumens.
12. A modular endograft system, comprising:
- a first endograft device having a first superior portion with a first distal section, a first inferior portion, and a first lumen through the first superior and first inferior portions, the first superior portion having a convexly curved first outer wall and a first septal wall that define a substantially D-shaped cross-section;
  - a second endograft device having a second superior portion with a second distal section, a second inferior portion, and a second lumen through the second superior and second inferior portions, the second superior portion having a convexly curved second outer wall and a second septal wall that define a substantially D-shaped cross-section; and
- wherein the first and second endograft devices are longitudinally staggered with respect to each other such that the first distal section of the first endograft device is positioned superiorly relative to the second distal section of the second endograft device.
13. The modular endograft system of claim 12 wherein:
- the first endograft device has a first frame and a first cover attached to the first frame, the first cover having a first inferior terminus and a first superior terminus, and the first frame having a first end extending distally beyond the first superior terminus of the first cover, wherein the first end of the first frame defines the first distal section of the first endograft device; and

the second endograft device has a second frame and a second cover attached to the second frame, the second cover having a second inferior terminus and a second superior terminus, and the second frame having a first end extending distally beyond the second superior terminus of the second cover, wherein the first end of the second frame defines the second distal section of the second endograft device.

**14.** The modular endograft system of claim **13** wherein the first ends of the first and second frames have openings through which blood can flow laterally relative to a longitudinal axis of the first lumen and second lumens.

**15.** The modular endograft device of claim **12** wherein the first and second septal walls are convexly curved, and wherein:

the first outer wall and the first septal wall define a first complex ellipsoid in which the first outer wall has a first radius and the first septal wall has a second radius greater than the first radius;

the second outer wall and the second septal wall define a second complex ellipsoid in which the second outer wall has the first radius and the second septal wall has the second radius; and

the self-expansion of the first and second endograft devices produces opposing forces between first and second septal walls in an expanded configuration.

**16.** The modular endograft system of claim **15** wherein the pressure between the first and second septal walls is substantially uniform along the septum.

**17.** The modular endograft system of claim **12** wherein the first and second septal walls are at least substantially straight.

**18.** The modular endograft system of claim **12** wherein: the first septal wall is convexly curved in an opposite direction relative to the first outer wall, and the first septal wall and the first outer wall are joined at curved corners; and the second septal wall is convexly curved in an opposite direction relative to the second outer wall, and the second septal wall and the second outer wall are joined at curved corners.

**19.** The modular endograft system of claim **18** wherein: the first outer wall and the second outer wall each have a first radius of curvature;

the first septal wall and the second septal wall each have a second radius of curvature greater than the first radius of curvature; and

the curved corners have a radius of curvature less than the first radius of curvature.

**20.** The modular endograft system of claim **12** wherein: the first superior portion has a cross-sectional dimension of at least 20 mm in an expanded configuration and a cross-sectional dimension of at most 5 mm in a low-profile configuration; and

the second superior portion has a cross-sectional dimension of at least 20 mm in an expanded configuration and a cross-sectional dimension of at most 5 mm in a low-profile configuration.

**21.** A modular endograft system comprising:

a first endograft device having a first superior portion, a first inferior portion having a smaller cross-sectional dimension than the first superior portion, a first braided frame, and a first lumen through the first superior and first inferior portions, the first superior portion having a substantially D-shaped cross-section;

a second endograft device having a second superior portion, a second inferior portion having a smaller cross-sectional dimension than the second superior portion, a second braided frame, and a second lumen through the second superior and second inferior portions, the second superior portion having a substantially D-shaped cross-section;

wherein the first and second braided frames are configured to have substantially continuous longitudinal support along the superior and inferior portions of the first and second endograft devices, respectively; and

wherein the first and second superior portions press against each other and form a septum between the first and second lumens.

**22.** The modular endograft system of claim **21** wherein the first and second braided frames are woven from a wire such that each longitudinal segment of each frame supports adjacent longitudinal segments along the length of each frame.

**23.** The modular endograft system of claim **22** wherein each longitudinal segment of the frame influences the radial expansion or contraction of the adjacent longitudinal segment of the frame.

**24.** The modular endograft system of claim **21** wherein the first and second septal walls are convexly curved, and wherein:

the first superior portion includes a convexly curved first outer wall and a convexly curved first septal wall, wherein the first outer wall has a first radius and the first septal wall has a second radius greater than the first radius;

the second superior portion includes a convexly curved second outer wall and a convexly curved second septal wall, wherein the second outer wall has the first radius and the second septal wall has the second radius; and

the first and second endograft devices are configured to self-expand via an inherent spring force such that the first and second septal walls exert opposing forces against each other.

**25.** The modular endograft system of claim **21** wherein the first endograft device has a first alignment aid and the second endograft device has a second alignment aid, and wherein the first and second alignment aids are configured to indicate a rotational orientation and a longitudinal position of the first and second endograft devices relative to each other.

**26.** The modular endograft system of claim **21** wherein:

the first endograft device further includes a first tapered transition portion between the first superior portion and the first inferior portion, wherein the transition portion is configured to maintain substantially laminar blood flow through the first lumen in an expanded configuration; and

the second endograft device further includes a second tapered transition portion between the second superior portion and the second inferior portion, wherein the second transition portion is configured to maintain substantially laminar blood flow through the second lumen in an expanded configuration.

**27.** The modular endograft system of claim **21** wherein the first endograft device has a first cover attached to a portion of the first frame, and the first cover having a first opening, and wherein the first opening allows blood to flow laterally relative to the first lumen.

- 28.** The modular endograft system of claim **21** wherein:  
the first superior portion has a cross-sectional dimension of at least 20 mm in an expanded configuration and a cross-sectional dimension of at most 5 mm in a low-profile configuration; and  
the second superior portion has a cross-sectional dimension of at least 20 mm in an expanded configuration and a cross-sectional dimension of at most 5 mm in a low-profile configuration.
- 29.** A method of treating an aneurysm located in a primary vessel before a bifurcation into a first vessel and a second vessel, comprising:  
positioning a first endograft device relative to the aneurysm such that at least a segment of a first superior portion of the first endograft device is positioned superior to the aneurysm and a first inferior portion of the first endograft device extends at least partially through the aneurysm, the first superior portion having a convexly curved first outer wall and a first septal wall that define a substantially D-shaped cross-section;  
positioning a second endograft device relative to an aneurysm such that at least a segment of a second superior portion of the second endograft device is positioned superior to the aneurysm and a second inferior portion of the second endograft device extends at least partially through the aneurysm, the second superior portion having a convexly curved second outer wall and a second septal wall that define a substantially D-shaped cross-section, and wherein the second endograft device is positioned independently of positioning the first endograft device;  
deploying the first endograft device from a first catheter and deploying the second endograft device from a second catheter such that the first and second superior portions self-expand to an expanded configuration in which the first and second septal walls press against each other via an inherent spring force to form a septum between the first and second lumens.
- 30.** The method of claim **29** wherein the first septal wall is convexly curved in a direction opposite the first outer wall and the second septal wall is convexly curved in a direction opposite the second outer wall, and wherein deploying the first and second endograft devices comprises urging the convexly curved first and second septal walls together.
- 31.** The method of claim **30** wherein urging convexly the curved first and second septal walls together results in a more uniform distribution of pressure between the first and second septal walls compared to straight first and second septal walls.
- 32.** The method of claim **29** wherein positioning the first and second endograft devices independently of each other comprises staggering the first superior portion of the first

endograft device relative to the second superior portion of the second endograft device such that a portion of the first septal wall is positioned superior relative to a distal terminus of the second septal wall.

**33.** The method of claim **29** wherein:

the first catheter has a maximum cross-sectional dimension of 5 mm and the first outer wall of the first superior portion of the first endograft device has a radius of curvature not less than 10 mm after being deployed from the first catheter; and

the second catheter has a maximum cross-sectional dimension of 5 mm and the second outer wall of the second superior portion of the second endograft device has a radius of curvature not less than 10 mm after being deployed from the second catheter.

**34.** The method of claim **29** wherein:

the first catheter has a maximum cross-sectional dimension of 5 mm and the first outer wall of the first superior portion of the first endograft device has a radius of curvature not less than 10 mm after being deployed from the first catheter; and

the second catheter has a maximum cross-sectional dimension of 5 mm and the second outer wall of the second superior portion of the second endograft device has a radius of curvature not less than 10 mm after being deployed from the second catheter.

**35.** The method of claim **29** wherein the primary blood vessel includes a third blood vessel and a fourth blood vessel branching from the primary blood vessel before the aneurysm, the third and fourth blood vessels being longitudinally offset along the primary blood vessel, and wherein:

the first endograft device has a first frame and a first cover attached to a portion of the first frame, the first frame comprising an open braided wire, and the first cover having a first opening at the first outer wall;

the second endograft device has a second frame and a second cover attached to the second frame, the second frame comprising an open braided wire, and the second cover having a second opening at the second outer wall, wherein the first and second openings allow blood to flow laterally relative to a longitudinal axis of the first lumen and second lumen; and

deploying the first and second endograft devices comprises positioning the first end portion of the first frame at the entrance of the third blood vessel and positioning the first end portion of the second frame at the entrance of the fourth blood vessel such that the first and second endograft devices are staggered with respect to a longitudinal axis of the primary vessel.

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