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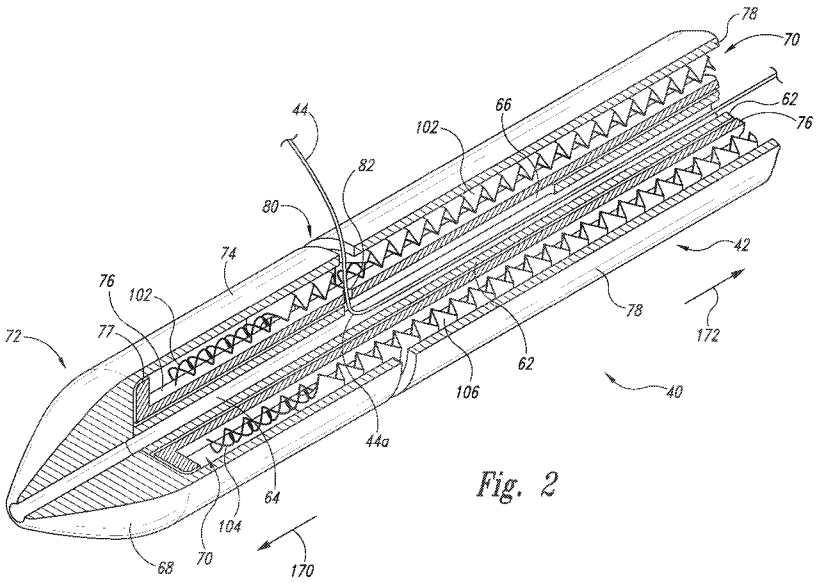


Fig. 2

(57) Abstract: Modular endograft devices and associated systems and methods are disclosed herein. In several embodiments, an endograft system can include constrained first and second endograft devices that extend across a vascular defect and expanded to press mating septal walls against each other. At least one of the endograft devices can include a fenestration that is aligned with a renal artery to provide bloodflow to the artery. A delivery device configured in accordance with the present technology can include a guidewire that passes through the fenestration to guide the endograft to an implant site and self align the fenestration with the renal artery to faciliate connection of the endograft to to the renal artery. An additional stent can be connected to the fenestation to secure the renal artery to the endograft device.

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ENDOGRAFT DEVICE DELIVERY SYSTEMS AND ASSOCIATED METHODS

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims the benefit of currently pending U.S. Provisional Patent Application No. 61/786,364, filed March 15, 2013, the disclosure of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to endograft devices and methods for percutaneous endovascular delivery of such endograft devices across aneurysms. In particular, several embodiments of the present technology are directed toward delivery devices for a modular bi-luminal endograft device with independently positioned components for endovascular aneurysm repair, and an associated delivery system and method for delivering the endograft device in desired alignment with a renal artery.

BACKGROUND

[0003] An aneurysm is a dilation of a blood vessel at least 1.5 times above its normal diameter. A 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.

[0004] 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.

[0005] 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.

[0006] 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. Many conventional systems address these challenges by requiring that hospitals/clinics maintain significant inventories of different EVAR devices with different sizes and shapes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Figure 1A is a partial cut-away, isometric view of a modular endograft system configured in accordance with an embodiment of the technology.

[0008] Figure 1B is an isometric view of the modular endograft system of Figure 1A configured in accordance with an embodiment of the technology.

[0009] Figure 2 is a partial cross-sectional view of an endograft delivery system configured in accordance with embodiments of the technology.

[0010] Figures 3A-3F are schematic views of a two-part modular endograft system being deployed across an aneurysm in accordance with an embodiment of the technology.

DETAILED DESCRIPTION

[0011] The present technology is directed toward endograft devices and methods for percutaneous endovascular delivery of endograft devices across aneurysms. In particular, several embodiments of the present technology are directed toward delivery devices for a modular bi-luminal endograft device with independently positioned components for endovascular aneurysm repair, and associated delivery systems and methods for delivering the endograft device in desired alignment with renal arteries of the patient. As compared with conventional endograft devices, various embodiments of the present technology are expected to provide improved sealing between the endograft device and healthy vascular tissue on each side of the AAA or vascular defect. Endograft devices configured in accordance with the present technology are also expected to provide enhanced control of the rotational and axial position of the device when placing the device within the vasculature, thereby enabling such devices to achieve sufficient sealing and bridging of the AAA or vascular defect.

[0012] Certain specific details are set forth in the following description and in Figures 1A-3F to provide a thorough understanding of various embodiments of the technology. For example, many embodiments are described below with respect to the delivery of stent grafts that at least partially repair AAAs. In other applications and other embodiments, however, the technology can be used to repair aneurysms in other portions of the vasculature. Other details describing well-known structures and systems often associated with endografts and associated delivery devices and procedures have not been set forth in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. 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 Figures 1A-3F.

[0013] In this application, the terms "distal" and "proximal" 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.

[0014] The terms "inferior" within this application generally refers to being situated below or directed downward, and the term "superior" generally refers to being situated above or directed upward.

[0015] In this application, the term "expansion" refers to a radial increase in a cross-sectional dimension of a device or component, and the term "constriction" refers to a radial decrease in the cross-sectional dimension of the device or component. For example, Figures 1A and 1B show an integrated frame 104 in an expanded configuration, and Figure 2 shows the integrated frame 104 in a constricted configuration.

[0016] The term "extension" also refers to a longitudinal increase in the length of the device or component, while the term "contraction" refers to a longitudinal decrease in the length of a device or component.

1. Endograft System Structures

[0017] Figures 1A and 1B are isometric views of a modular endograft system 100 ("system 100") configured in accordance with an embodiment of the technology. The system 100 can include separate endograft devices or endografts 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*. The first and second endograft devices 102a and 102b can be identical or essentially identical to each other (as shown in Figures 1A and 1B) or, as described further below, have some different structural features that provide a system 100 having one endograft device 102 embodying the present technology and another endograft device that differs from the present technology (generically referred to as a "vascular device" for clarity). 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 (revealed in the cut-away view presented in Figure 1A in the middle of endograft 102a). 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 (or the endograft device 102 and a vascular device) are generally delivered to a implant target site separately and positioned independently across the aneurysm.

[0018] As shown in Figures 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 Figure 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 Figure 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.

[0019] Referring to Figure 1B, 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 commonly owned U.S. Application No. 12/958,367, incorporated herein by reference in its entirety, 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.

[0020] In the embodiment shown in Figures 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 Figures 1A and 1B, the first end portion 118a can extend distally (in distal direction 170) from the superior terminus of the cover 106, and the second end portion 118b can extend proximally (in proximal direction 172) 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.

[0021] Referring to Figures 1A and 1B, each endograft device 102 can also include a fenestration 138 configured in accordance with embodiments of the technology. The

fenestration(s) 138, for example, can be openings that provide communication to the interior lumen 116 through the frame 104 and cover 106 and provide a channel through which blood flow can be shared with transverse arteries. In other embodiments, the fenestration 138 may comprise a slot that extends from a single opening of the frame 104 (intended for alignment with a renal artery) to the termini of the cover 106, which is a configuration that leaves several opening through the frame exposed (i.e., without a cover 106) but disposed to engage the vascular wall to prevent leakage to or from the lumen 116. The fenestration(s) 138 can be formed, for example, by cutting the cover 106 in a desired location to form a passage through the cover 106 and the underlying frame 104. The edges of the cover 106 defining the fenestration 138 can be secured to the frame 104 by, for example, sutures or glue. In still other embodiments, however, other suitable techniques may be used to form each fenestration 138. The cutting and/or the securing can be done (a) immediately prior to the implantation of the corresponding endograft 102; (b) while the corresponding endograft 102 is in the low-profile position within a delivery chamber of a delivery catheter (as described in greater detail below with reference to Figure 2); or (c) while the corresponding endograft 102 is partially expanded and accessible through a portion of the delivery catheter before being returned to a low-profile configuration for implantation (as also described in greater detail below with reference to Figure 2).

[0022] The fenestration(s) 138 may be positioned at an angle relative to the septal wall 114 of the endograft 102 or relative to the septum 120 provided by the mating of two endografts 102 (as best seen in Figure 1B). The angle of the fenestration(s) 138, for example, may be based on an anatomical angulation/arrangement of a transverse vessel such that, when the endograft 102 is implanted, the fenestration 138 is generally centered relative to an opening of the transverse vessel. The particular anatomy at the implant target site may be determined, for example, using suitable imaging techniques.

[0023] In some embodiments, two mating endografts 102 including fenestrations 138 may define a fenestration axis passing through a middle of each fenestration. The two fenestrations 138, for example, can be opposed to each other so that the two fenestration axes are the same axis. In other embodiments, however, the two fenestration axes may offset from each other with one disposed more in the distal direction 170 than the other such that the two fenestration axes define an angle between them that is not 180 degrees, or such that the two fenestrations axes have any combination of the aforementioned configurations. In this configuration, the clinical operator can choose an endograft device or pair of endograft devices

having the appropriate circumferential offset to match the renal artery orientation of a given patient. In another configuration, the endograft device can include multiple circumferentially offset (e.g., radially disposed) fenestrations to better enable the clinical operator to align one of the fenestrations with the branch renal vessel. In this configuration, for example, the endograft device might have two, three, four, or more fenestrations circumferentially offset by a suitable angle (e.g., 15 degrees, 30 degrees, 45 degrees 60 degrees).

[0024] In another configuration, the endograft device can have a fenestration covered by a fabric flap, wherein the flap can be opened (with or without stenting) or removed to create the fenestration. If unused, the flap can be replaced and/or remain closed to maintain a sealed surface. Additionally or alternatively, the endograft device can include one or more slits horizontally or vertically disposed relative to the longitudinal axis of the endograft. Such a slit can be opened (e.g., via stenting) to create a fenestration and enable perfusion via a branch vessel. If oriented horizontally, the slit could extend substantially around the perimeter of the convexly curved outer wall to allow for incremental change in orientation due to variations in renal artery anatomy. If oriented vertically, the slit could extend axially to optimize axial orientation.

[0025] As described in greater detail below with reference to Figures 3A-3F, the location of the fenestration(s) 138 may be customized for patients to correspond to the positions of renal arteries of the patient (e.g., as observed by an imaging system before the implant procedure). For example, each fenestration 138 can be positioned on the cover 106 proximal to the first end portion 118a to increase the portions of the endograft 102 extending distal to the renal artery to provide improved contact between the endograft 102 and the arterial wall. The arrangement of the fenestration(s) 138 through the cover 106 also maximizes the portion of the endograft 102 having both a frame 104 and a cover 106 located between the renal artery and the aneurysm, which is believed to provide an improved seal and provide greater flexibility in adapting the endograft device 102 to unique anatomies.

[0026] In another embodiment, the endograft design may allow for one or more preformed or preshaped fenestrations. For example, due to the density of the braid design, the endograft and fenestration positioned therein would be able to retain its original shape and fenestration position following delivery and deployment, thereby making for more reliable positioning. The braid density may also enable more complex fenestration shapes to accommodate anatomical variability and challenges. For example, the endograft devices described herein can be configured with one or more preformed troughs at the apex of the convexly curved outer

wall of the superior portion to allow the positioning of a "chimney" stent graft for perfusion to the renal artery or other branch vessels.

2. Endograft System Deployment

[0027] During deployment of the system 100, each endograft device 102 can be delivered independently to an aneurysmal region in a low-profile configuration (e.g., as described in further detail with reference to Figure 2 below). 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 approximately 25 mm in the expanded configuration, and can be constricted to a diameter of approximately 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 can facilitate staggering of the endograft devices 102 to accommodate asymmetrical anatomies, with one endograft device 102 disposed more in the distal direction than the mating endograft device 102 or vascular device.

[0028] At an implant target site in the aneurysmal region, the endograft devices 102 can self-expand from the low-profile configuration to an expanded configuration (e.g., as shown in Figures 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 Figure 1B, for example, the septal wall 114 (Figure 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 Figure 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.

[0029] As described above, each endograft device 102 can include the fenestration 138 as shown in Figures 1A and 1B, providing communication through the frame 104 and cover 106 proximally to the end portions 118 so as to provide greater flexibility in adapting the endograft device 102 to unique anatomies. During deployment, for example, the fenestrations 138 in combination with the end portion 118 can increase the available structure for securing the endograft devices 102 to the artery and increase the available surface area for sealably fixing the endograft device 102 to arterial walls. This increase in available endograft structure at the ends of the endograft device 102 is expected to decrease the precision necessary to position the endograft device 102, while increasing the reliability of the implanted system 100.

[0030] In operation, the system 100 is configured to 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 directs blood into the lumens 116, funnels the blood through the superior and inferior portions 108 and 110, and discharges the blood into healthy portions of the iliac arteries, thereby at least substantially bypassing the aneurysm. As noted previously, 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. Furthermore, in another example, the selection and placement of the fenestrations 138 on either or both of the endograft devices 102 can be made to conform with patient anatomy thereby allowing greater control in how each of the endograft devices 102 are positioned relative to unique patient anatomy. Accordingly, the system 100 can easily adapt to a variety of different anatomies and thereby provide a modular alternative to customized endograft systems.

3. Endograft Delivery System

[0031] Figure 2 is a partial cross-sectional view of a delivery system 40 configured in accordance with an embodiment of the technology. For clarity, the delivery system 40 in Figure 2 has been illustrated to have an overly-short axial length and an overly-large diameter so as to better show the axial and radial arrangement of components in a single figure; it will be appreciated, however, that a delivery device 40 sized for use with, for example, the endografts 102 of Figures 1A and 1B, would have a significantly longer and thinner appearance). The delivery system 40 can include a catheter 42 configured for delivery via a

guidewire 44, and can be used to deliver and deploy the endograft 102 at the implant target site. The catheter 42 can have a distal end configured to deliver the endograft 102 as shown in Figure 2 and a proximal end (not shown) configured to be manipulated by an operator (not shown) to control delivery of the endograft 102. The distal end of the catheter 42 can have an inner tube 62 with a distal end of the inner tube 62 connected to a nose cone 72 having a distal end with a tapering tip 68 and a proximal end with a cup-like shape and a peripheral cylindrical wall 74 that extends in the proximal direction 172 to define a first internal volume within the cylindrical wall that encloses part of the distal end of the inner tube 62. The distal end of the catheter 42 can also have a pusher tube 76 enclosing the inner tube 62 within an internal lumen of the pusher tube 76, with a distal end of the pusher tube 76 having an abutment 77 disposed within the cylindrical wall 74. The distal end of the catheter 42 can also include a sheath 78 enclosing the pusher tube 76. A distance between the distal end of the sheath 78 and the pusher tube 76 defines a second internal volume. The first and second internal volumes can together provide a delivery chamber 70 for holding the endograft 102 in a low-profile configuration with a distal end of the endograft 102 releasably held by the cylindrical wall 74 and a proximal end of the endograft 102 releasably held by the sheath 78. The delivery chamber 70 is defined, at least in part, by the pusher tube 76, the abutment 77 of the pusher tube 76, the cylindrical wall 74, and the sheath 78.

[0032] As shown in Figure 2, the guidewire 44 includes a distal portion extending from the distal end of the catheter 42 and a proximal portion extending though the inner lumen 64 in the proximal direction 172. As shown, the guidewire 44 can pass through the catheter 42 and the endograft 102 carried within the delivery chamber 70 along a guidewire path defined by the catheter 42 and the endograft 102. The guidewire path can have one end where the distal end of the guidewire 44 enters the catheter 42 between the cylindrical wall 74 and the sheath 78. The cylindrical wall 74 can provide an edge on the proximal surface of the cylindrical wall 74 that is positioned to face, abut, or overlap a distal edge of the sheath 78 to define a separation 80 between the sheath 78 and the cylindrical wall 74 of the nose cone 72. The guidewire path can continue into the distal end of the catheter 42 and can pass through a fenestration 138 of the endograft 102 (see Figures 1A and 1B) and then lead into a transverse opening 82 passing through the side of the pusher tube 76 to enter the lumen of the pusher tube. The guidewire path can continue on to pass through the transverse slot 66 of the inner tube 62 and enter the inner lumen 64. As shown in Figure 2, the guidewire 44 can have a bend 44a where the orientation of the guidewire 44 changes from an coaxial direction along the length of the

catheter 42 within the inner lumen 64 to a transverse direction passing out of a side of the catheter 42 through a fenestration 138 of the endograft 102.

[0033] The delivery system 40 can be operated to position the endograft 102 at the implant target site and operated to uncover and expand the constricted endograft 102 from the low-profile configuration to the expanded configuration. The delivery system 40, for example, can also be operated (outside the patient) to partially expose and partially expand the covered endograft 102 within the catheter 42 to provide access to the fenestration 138 to facilitate the introduction of the guidewire 44 into the guidewire path, and operated to constrict and re-cover the exposed portion of the endograft 102 in preparation for the insertion into a patient vasculature. To facilitate these operations, the delivery system 40 provides sliding arrangements between components. For example, the guidewire 42 can be in a sliding arrangement with the components of the delivery system 40 that define the guidewire path. During an implantation procedure, a distal end of the guidewire 44 can be positioned in a patient at a desired location near the target site, and a proximal end of the guidewire 44 may be held by the operator. While the guidewire 44 remains in a static position, the catheter 42 supporting the endograft 102 can be slid over the guidewire 44 in the distal direction 170 with the catheter 42 and endograft 102 passing over the guidewire 44 along the guidewire path. As will be appreciated by those of skill in the art, when the catheter 42 and endograft 102 are slid over the guidewire 44, the bend 44a can appear to move along the guidewire 44 in the distal direction 170 because of the bending and unbending of the guidewire 44 caused by the distal movement of the catheter 42 where the guidewire 44 changes (at the bend 44a) from the transverse direction to the coaxial direction.

[0034] To expose at least a portion of the covered endograft 102 (or to re-cover a partially-uncovered endograft 102), the inner tube 62 can be slidably arranged within the pusher tube 76, the nose cone 72 (at the cylindrical wall 74) can be slidably arranged over the distal end of the endograft 102, and the sheath 78 can be slidably arranged over the pusher tube 76 and the proximal end of the endograft 102. For example, with the pusher tube 76 held in a static position, the inner tube 62 can be slid in the distal direction 170 within the lumen of the pusher tube 76 to carry the nose cone 72 forward in the distal direction 170. As the nose cone 72 is moved in the distal direction 170 (based, at least in part, on the movement of the pusher tube 76 supporting the nose cone 72), the cylindrical wall 74 can slide over the distal end of the endograft 102 contained within the delivery chamber 70 to expose the constricted endograft 102. In some embodiments, the endograft 102 can also be exposed by the sliding movement of

the sheath 78 in the proximal direction 172 over the proximal end of the endograft 102 and the outer surface of the pusher tube 76.

[0035] As will be appreciated by those of skill in the art, the movement of the sheath 78 in the proximal direction 172 and/or the movement of the cylindrical wall 74 in the distal direction 170 can increase the separation 80. Further, the separation 80 may be reduced by the movement of sheath 78 and cylindrical wall 74 towards each other. In some instances, the endograft 102 can slide over the pusher tube 76 in the distal direction 170 due to friction between the self-expanding endograft 102 and the cylindrical wall 74 as the cylindrical wall 74 is moved in the distal direction 170 during the uncovering of the endograft 102. Such movement may be undesirable and interfere with a desired arrangement of the guidewire path and fenestration 138 relative to the implant target site. To inhibit or counter such movement of the endograft 102, in some embodiments the pusher tube 76 may include an abutment 77 that can be held in place or moved in the proximal direction 172 (e.g., by sliding the pusher tube 76 over the inner tube 62) to cause the abutment 77 to contact and maintain the position of the endograft 102 or to nudge the endograft 102 back into a desired position in the proximal direction 172.

[0036] Referring again to Figure 2, in order to maintain the position of the guidewire 44 at a desired location while uncovering the endograft 102, the transverse slot 66 is configured to move past the stationary guidewire 44 within the separation 80, so as to not disturb the position of the guidewire 44. For example, as the inner tube 62 is moved in the distal direction 170, the transverse slot 66 also moves in the distal direction 170 so that the guidewire 44 stays in place (relative to the fenestration 138 and the renal artery (not shown)), resulting in the stationary guidewire 44 starting at one end of the transverse slot 66 and then ending at the opposing end of the transverse slot 66 due to the movement of the inner tube 62. In some embodiments, the transverse opening 82 of the pusher tube 76 may also comprise a slot (not shown) configured to allow the pusher tube 76 to move in the proximal direction 172 to adjust the position of the endograft 102 relative to the abutment 77. The transverse opening 82 can also be a slot to facilitate the insertion of the guidewire 44 into the guidewire path by providing a larger opening that is sufficiently long and wide to provide access to the underlying transverse slot 66 of the inner tube 62.

[0037] When the endograft 102 is carried by the delivery system 40, one end of the endograft 102 can be secured to inner tube 62 and the opposing end of the endograft 102 can be secured to the pusher tube 76. By securing each end of the endograft 102 to the sliding

tubes 62 and 76, the ends of the endograft 102 can be moved away from each other to further stretch out the endograft 102 and to reduce the outer diameter of the endograft 102. Likewise, the ends of the endograft 102 can be moved towards each other to reduce the length of the endograft 102 and increase the outer diameter of the endograft 102. Such manipulation of the sliding tubes 62 and 76 can cause selective expansion or constriction of the endograft 102 diameter or cross-sectional dimensions, and can cause selective extension or contraction of the length of the endograft 102. As will be appreciated, manipulation of the sliding tubes 62 and 76 can provide a controlled minimal expansion of the endograft during the insertion of the guidewire 44 through the fenestration 138 and can facilitate positioning of the guidewire 44 in the guidewire path. Further, after satisfactory placement of the guidewire 44 in the guidewire path, the sliding tubes 62 and 76 can be used to stretch the endograft 102 to return the endograft 102 into a covered position suitable for delivery to the implant target site.

4. Methods of Delivering and Deploying Endograft Systems

4.1 Delivery and Deployment

[0038] Described below are methods of delivering and deploying endografts 102 with the endograft delivery system 40 to bypass an aneurysm in accordance with embodiments of the technology are described below. The associated Figures (i.e., Figures 3A-3F) include schematic representations of an abdominal portion of an aorta. More specifically, Figure 3A 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.

[0039] Figures 3A and 3B are schematic views of two delivery systems configured in accordance with an embodiment of the technology. More specifically, the delivery system on the right side of the figures is the endograft delivery system 40 described above, and the system on the right of the figures comprises a vascular device delivery system 340 delivering a vascular device 302 (such as the endograft device described in U.S. Application No.

12/958,367, which as noted above is incorporated herein by reference in its entirety) that can be disposed to mate with the endograft 102. The delivery and mating of a vascular device 302 with the endograft 102 embodying one form of the technology is shown in Figures 3A and 3B to illustrate a use of the present technology with another device and delivery system. As can be appreciated, any difference between the left and right-side systems does not mean that such difference exists in other embodiments of the present technology. As can be also appreciated, the left-side delivery system 340 shown in Figures 3A and 3B can be substituted with the endograft delivery system 40 described above so as to provide for the delivery and mating of two endografts 102 using two endograft delivery systems 40. Furthermore, although Figures 3A and 3B show a system on a right side and a system on a left side of the illustrated anatomy, the delivery systems can be disposed to cross each other so that a system introduced from the right-side of the figure can cross over the other system to deliver a device to the left-side of the figure and vice versa. Likewise, the deployed endografts 102 (or endograft 102 and vascular device 302) can be deployed to cross over each other with the use of crossing delivery systems.

[0040] Referring to Figure 3A, endograft delivery system 40 (shown on the right side of Figure 3A) is configured for delivering and deploying the endograft 102 (not shown because it is enclosed within system 40 in Figure 3A),and the vascular device delivery system 340 (shown on the left side of Figure 3A) is configured for delivering and deploying a vascular device 302 (not shown because it is enclosed within system 340 in Figure 3A). In this embodiment, the endograft delivery system 40 can include a catheter 42 holding an enclosed endograft 102 in the low-profile configuration (not viewable in Figure 3A) and a guidewire 44 passing through the catheter 42 and the enclosed endograft 102. The vascular device delivery system 340 includes a catheter 342 holding an enclosed vascular device 302 in a constricted configuration (not viewable in Figure 3A) and a guidewire 344 passing through the catheter 342. Because the endograft 102 is delivered separately from its mating device (i.e., the vascular device 302 or another endograft 102) and is thus one half of a two-part modular endograft system 100, the size of the catheter 42 can be less than a catheter configured to carry a unitary endograft system. In some embodiments, the low-profile configuration of the endograft device 102 can fit within a 12 F or 14 F catheter. In other embodiments, the low-profile configuration of the endograft device 102 can fit within a catheter 42 that has a different size than the catheter associated with the mating device (e.g., the catheter 342 associated with vascular device 302).

[0041] In one of the initial steps of the delivery and deployment procedure, the guidewires 44 and 344 can be inserted percutaneously into a blood vessel (e.g., via a femoral artery). With the aid of a suitable imaging system, the distal end of the guidewire 344 can be endoluminally navigated in the distal direction 170 through the vasculature, up the first iliac artery 56a, through the aneurysm 50 and the aortic neck 60, past the first renal artery 54a, and to a location superior to a target site T. Also with the aid of a suitable imaging system, the distal end of the guidewire 44 can be endoluminally navigated in the distal direction 170 through the vasculature, up the second iliac artery 56b, through the aneurysm 50 and the aortic neck 60, into the second renal artery 54b, and to a location beyond the target site T. As shown in Figure 3A, the guidewire 344 can remain generally straight as it passes through the aortic neck 60 and the target site T. As also shown in Figure 3A, the guidewire 44 can turn within the aortic neck 60 and/or the target site T as it changes directions to enter the second renal artery 54b, thereby forming an elastic bend 44a in the guidewire 44. It will be appreciated that the bend 44a can be an elastic deformation of the guidewire 44 that remains within the aortic neck 60 and/or the target site T as the guidewire 44 is advanced in the distal direction.

[0042] After satisfactory placement of the guidewires 44 and 344, the catheter 42 can then be passed through the vasculature over the guidewire 44 in the distal direction 170 to the target site T (as shown in Figures 3A and 3B). As described above with regard to Figure 2, the guidewire 44 can enter the catheter 42 from the side through the separation 80 where it passes through the fenestration 138 of the enclosed endograft 102 within the catheter 42 and continues on along the guidewire path to the inner lumen 64 of the inner tube 62 to continue in the proximal direction 172. When the catheter 42 is advanced sufficiently to reach the target site T (as shown in Figure 3B) the distal end of the catheter 42 can slide over the bend 44a in the guidewire 44 and abruptly alter its course from a path following the aortic neck 60 to a path following the second renal artery 54b, which causes the distal end of the catheter 42 to move laterally towards the renal artery 54b. In some instances, this lateral movement of the distal end of the catheter 42 can cause the side of the catheter 42 to engage the arterial wall because the side of the catheter 42 is too large to enter the renal artery 54b in a sideways orientation. The lateral movement of the distal end of the catheter 42 can also press the catheter 42 against the arterial wall and align the fenestration 138 with the end of the renal artery 54b. The catheter 342 can also be advanced over the guidewire 344 until reaching a desired position at the target site. As the catheter 342 slides over the guidewire 344 in a straight path through the aorta 52 that extends beyond the target site T, the catheter 342 is free to advance beyond the

target site T unless brought to a proper position while being viewed with an imaging system. In one embodiment, one of the catheters 42 or 342 can be brought into position at the target site T before the other in succession. In other embodiments, however, both catheters 42 or 342 can be brought into position simultaneously or approximately simultaneously.

[0043] More specifically, the increase of the separation 80 (Figure 3A) can be achieved by withdrawing the sheath 42 in the proximal direction 172 while holding the endograft device 102 in place due to the transverse passage of the guidewire 44 through the fenestration 138 and/or by using the inner tube 62, pusher tube 76, nose cone 72, or other suitable endovascular instruments to provide an opposing force to the proximal movement of the sheath 78. The increase of the separation 80 may also be achieved by advancing the nose cone 72 away from the sheath 78 and/or fenestration 138, with the position of the endograft 102 being maintained due to the transverse passage of the guidewire 44 through the fenestration 138 and/or with the sheath 78 or the abutment 77 of the pusher tube 76 providing an opposing force to the movement of the nose cone 72. In some embodiments, the increase of the separation 80 may also be achieved by simultaneous movement of the nose cone 72 and sheath 78 away from each other with the position of the endograft 102 maintained by the transverse passage of the guidewire 44 through the fenestration 138 and/or with controlled movements of the nose cone 72 and sheath 78 that keep one component from dominating the uncovering of the endograft 102. As shown in Figure 3C, the vascular device 302 can be uncovered using suitable means appropriate for the design of the catheter 342, and the catheter 342 may be ultimately removed from the vasculature (for clarity the catheter 342 has been removed from the vascular device shown in Figure 3C but, as will be appreciated, the catheter 342 could remain over a portion of the vascular device 302 in a partial deployment of vascular device 302). In an embodiment where two endografts 102 are implanted, the deployment process can be essentially the same for both endografts 102. In still other embodiments, other suitable deployment arrangements may be used.

[0044] In some embodiments, during uncovering of the endograft 102, the first portion of the endograft 102 to be uncovered can be near the separation 80. This partial uncovering of the endograft 102 can allow a partial expansion of the endograft 102 as shown in Figure 3C, which is a point in the deployment when the endograft 102 can be moved slightly into a better position or rotated. This positioning or rotating can be done to improve the position of the endograft 102 relative to local anatomical features, to better position the endograft 102 relative to the mating device (the vascular implant 302 or second endograft 102), to achieve better

mating between the septal wall 114 of the endograft 102 and the opposing wall of the mating device (the vascular implant 302 or second endograft 102), to improve seating of anchors extending from the endograft 102, and/or to improve alignment of the fenestration 138 of the endograft 102 with the second renal artery 54b. The endograft 102, the sheath 78, and the nose cone 72 can also be configured to allow the re-covering of the partially expanded endograft 102 by decreasing the separation 80 to cause the endograft 102 to return fully to the low-profile configuration or to return to a more constricted configuration suitable for repositioning of the endograft 102 or for removal of the endograft 102 from the vasculature if removal is warranted.

[0045] Referring to Figure 3D, a fully-deployed vascular device 302 is seated next to the endograft 102 to provide an implanted modular endograft system 100. In the illustrated embodiment, proximal movement of the sheath 78 (in the proximal direction 172) and distal movement of the nose cone 72 (in the distal direction 170) bring the endograft 102 from the partially uncovered and partially expanded configuration shown in Figure 3C to the fully uncovered and fully expanded configuration shown in Figure 3D. Referring to Figure 3D, the nose cone 72 (mounted on the distal end of the inner tube 62 and in part within the pusher tube 76) has advanced sufficiently in the distal direction 170 to allow the distal end of the endograft 102 to expand to a diameter greater than the cylindrical wall 74 of the nose cone 72. Further, the sheath 78 has withdrawn sufficiently in the proximal direction 172 to allow the proximal end of the endograft 102 to expand. As shown in Figure 3D, the sheath 78 can be withdrawn (in the proximal direction 172) from the target site T and the endograft 102 to leave the inner tube 62 and the pusher tube 76 in place within the lumen 116 of the endograft 102 to support the nose cone 72 as it extends distal to the endograft 102. The guidewire 44 can continue to pass through the fenestration 138 of the expanded endograft 102, and continue through the transverse opening 82 and the transverse slot 66 and into the inner lumen 64 in the proximal direction 172.

[0046] Figure 3E illustrates withdrawal of the pusher tube 76, inner tube 62, and nose cone 72 in the proximal direction 172 from the endograft 102. The nose cone 72, which has an outer diameter that is less than the inner dimensions of the lumen 116 of the endograft 102, can be withdrawn in the proximal direction 172 as it slides over the guidewire 44. The pusher tube 76, inner tube 62, and nose cone 72 along with the sheath 78 (unless removed already) can then be removed from the patient entirely and dismounted from the guidewire 44 at the proximal end of the guidewire 44. After the removal of the pusher tube 76, inner tube 62, nose

cone 72, and sheath 78, the remaining components in the patient can be the two guidewires 44 and 344 (unless guidewire 344 has already been removed), the endograft 102, and the vascular device 302.

[0047] Figure 3F illustrates introduction of a stent catheter 442 over the guidewire 44 carrying a stent (not shown) in a constricted configuration within the stent catheter 422. The stent and the stent catheter 442 can be sized and configured to advance through the lumen 116 of the endograft 102, navigate the bend 44a, and pass through the fenestration 138 and enter the second renal artery 54b. The stent can also be sized and configured to approach the endograft 102 and engage the fenestration 138 from the distal end of the guidewire 44. In one embodiment, the stent can be a self-expanding stent that expands when a covering sheath is retracted, and can have surface features that facilitate the engagement of the stent to the endograft 102 at the fenestration 138. The stent can also have end portions that flare outward within the lumen 116 to engage the endograft 102 with the remainder of the stent extending away from the endograft within the second renal artery 54b. The stent can also include surfaces, surface features, a covering graft, or other coatings or coverings that enhance the sealing of the stent with the walls of the second renal artery 54b and to inhibit blood flow around the outside of the stent. In other embodiments, the stent may have a different arrangement and/or different features.

[0048] After the stent has been expanded within the second renal artery 54b, the stent catheter 442 can be removed from the patient, and the guidewires 44 and 344 can also be removed. As can be appreciated, the sequence of the steps in the above-described methods and the introduction, use, and withdrawal of components can be modified to achieve the delivery and deployment of the endograft 102 and/or the stent engaging the fenestration 138 of the endograft 102.

4.2 Endograft System Sealing and Alignment

[0049] Referring back to Figures 1A and 1B, the endograft device 102 (with or without a fenestration 138) can be positioned at its desired location independently of the mating device while the endograft device 102 is in, or at least partially within, the catheter 42 (Figure 2). The independent positioning feature can allow for an offset of one device relative to the other such that an end of one device can extend farther than the other in the proximal or distal direction. Further, even with this offset, the inherent hoop force of the mating frames 104 caused by the constant outward spring force of the wire 126 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.

[0050] When additional sealing is desired, extension units (not shown) can be added to the system 100 after the first and second endografts 102 are positioned within the aortic neck 60. Example extension units are shown and described in U.S. Application No. 12/958,367, which as provided above is incorporated herein by reference in its entirety. The endograft system 100 can include extension units projecting distally from the superior termini 131 of the covers 106. The extension units can include an extension frame and an extension cover at least generally similar to the frame 104 and the cover 106 of the endograft devices 102 described above. The extension units 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 can mate with the interior of at least a part of the superior portions 108. For example, the extension covers can be positioned inferior to the renal arteries 54 within the frame 104 such that the extension covers can interface with the aortic neck 60 and mate with one another to extend the septum 120 distally. Therefore, the extension units can increase the fixation area and the sealing area of the endograft devices 102 when the superior termini 131 of the covers 106 of the endograft devices 102 are offset from the entrances of the renal arteries 54 or where additional length or support is needed. For example, in some embodiments, the extension units 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 that can affix and at least substantially seal to the iliac arteries 56.

[0051] The extension units can be deployed from catheters at desired positions within the first and second frames 104. Upon deployment, the extension units can self-expand via an inherent spring force in the extension frame to an expanded configuration to contact and at least substantially seal with the interior of the superior portions 108 of the endograft devices 102. The extension cover can interface with the first end portions 118a of the frames 104 to strengthen the seal therebetween. In other embodiments, the extension units can connect and seal to the endograft devices 102 using other suitable attachment methods. Similarly, the inferior portions 110 can include extension units that increase the sealing area with the iliac arteries 56.

[0052] The embodiments of the present technology, such as shown in Figure 1B, can have superior portions 108 that are longitudinally offset from each other. For example, in some embodiments, the superior portions 108 are longitudinally offset by at least 5 mm. One or both

of the superior portions 108 can be placed superior to the transverse arteries to increase the available fixation structure and sealing area for the endograft devices 102 without inhibiting blood flow through the fenestrations 138. In such offsetting, the interplay between the woven wires 126 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. When the endografts 102 are offset, 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 in the frame 104 can further facilitate maintaining the shape of the unsupported portion of the frame 104.

[0053] Independent positioning or staggering of the endograft devices 102 can also include positioning the devices independently such that the fenestration 138 of the each endograft device 102 is aligned with a corresponding left or right renal artery. By providing an opening through the cover 106 that can communicate with the renal artery, the frame 104 extending past the termini 131 of the cover 106 can be dedicated to providing a sealing area between the outer walls 112 and the arterial walls. Also, by providing an opening through the cover 106 that can communicate with a renal artery, the frame 104 extending past the termini 131 of the cover 106 can facilitate the independent positioning of the superior portions 108 over the renal arteries such that one endograft device 102 (of a mating pair) does not need to be limited to the elevation of the inferior renal artery. This increase in the available sealing area and the ability to provide a sealing area unconstrained by the location of the renal artery facilitates optimal placement for each endograft device 102 within the vasculature without requiring devices with customized superior portions 108. This feature is expected to allow offsetting or staggering without degradation of such sealing or support. Endograft devices 102 that are staggered can take advantage of such additional endograft end structure for fixing the endograft devices 102 to arterial walls and increasing the available sealing area in the aortic neck 60. The longer fixation and sealing areas along the outer wall 112 of the endograft devices 102 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, the system 100 can be offset or staggered to accommodate an anatomy with less fixation and sealing area in one of the iliac arteries 56. In other embodiments, the endograft devices 102 may include one or more additional fenestrations 138 to increase the available sealing area without restricting blood

flow. For example, the inferior portions 110 can include one or more fenestrations 138 that allow the inferior portions 110 to extend over the entrance of the internal iliac arteries.

[0054] In some embodiments, alignment aids, such as the alignment aids described above, 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 described above, 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. Example alignment aids and anchors are shown and described in U.S. Application No. 12/958,367, incorporated herein by reference.

[0055] In the embodiment illustrated in Figures 3A-3F, the aneurysm 50 is shown in the infrarenal portion of the aorta 52, a common site of an AAA. In other embodiments, however, the modular endograft system 100 may be deployed across aneurysms 50 at different portions of the aorta 52 or in other vessels altogether. In some embodiments, for example, 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 of the systems 100 can extend past the diseased, aneurysmal portion of the iliac arteries 56 without blocking blood flow to the internal iliac arteries 58. In still other embodiments, the system 100 can be deployed across aneurysms 50 located in the supra renal portion of the aorta 52 with the fenestrations 138 and/or a stent positioned at the entrance of the renal arteries 54. In still further embodiments, the systems described herein may 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.

Examples

[0056] The following examples are illustrative of several embodiments of the present technology:

1. An endograft delivery system, comprising:

a catheter defining a catheter axis and opposing proximal and distal ends, the proximal and distal ends of the catheter defining a proximal direction and a distal direction along the catheter axis, wherein the distal end of the catheter comprises—

an inner tube having a distal end and an inner lumen extending within the inner tube, the distal end of the inner tube having a transverse slot communicating with the inner lumen, the transverse slot extending in the proximal direction;

a nose cone engaging the distal end of the inner tube, the nose cone having a cylindrical wall extending in the proximal direction to a cylindrical wall edge to cover at least a portion of the distal end of the inner tube and define a first internal volume within the cylindrical wall of the nose cone;

a pusher tube slidably disposed over the inner tube, the pusher tube having a distal end at least in part disposed within the first internal volume of the nose cone, the distal end of the pusher tube having a transverse opening communicating with the inner tube; and

a sheath slidably disposed over the pusher tube and having a distal end terminating at a sheath edge disposed to face the cylindrical wall edge of the nose cone to define a separation therebetween, the distal end of the sheath and the pusher tube defining a second internal volume therebetween that communicates with the first internal volume to define a delivery chamber; and

an endograft device disposed within the delivery chamber of the catheter, the endograft device comprising an expandable frame in a low-profile configuration within the delivery chamber and configured to expand to an expanded configuration when the separation between the sheath edge and the cylindrical wall edge is sufficiently increased to uncover the endograft device,

wherein the catheter and the endograft together define a guidewire path configured to direct a guidewire through the endograft delivery system, wherein the guidewire path comprises a proximal end extending in the proximal direction within the inner lumen of the inner tube and a distal end extending past the separation between the sheath edge and the cylindrical wall edge of the nose cone, the guidewire path further passing though the transverse slot of the inner tube and the transverse opening of the pusher tube proximate to the separation.

2. The endograft delivery system of example 1 wherein:

the endograft device further comprises a cover attached to the frame, the cover having a superior terminus and an inferior terminus, the frame having a first end extending distally beyond the superior terminus of the cover and a second end extending proximally beyond the inferior terminus of the cover,

wherein the superior terminus of the cover and the first end of the frame define a superior portion of the endograft and a lumen of the endograft, the superior portion having a fenestration passing through the cover and the frame to communicate with the lumen.

3. The endograft delivery system of example 2 wherein at least a portion of the fenestration is disposed at a distance up to approximately 5 mm from the superior terminus of the cover.

4. The endograft delivery system of example 2 or example 3 wherein the fenestration passing through the cover comprises a slot extending towards the superior terminus of the cover.

5. The endograft delivery system of any one of examples 2 to 4 wherein the fenestration is configured to engage a stent.

6. The endograft delivery system of any one of examples 1 to 5 wherein the transverse slot of the inner tube has an axial length of approximately 30 mm and a circumferential width of approximately 1 mm.

7. The endograft delivery system of any one of examples 1 to 6 wherein the transverse opening of the pusher tube is a slot extending in the proximal direction.

8. The endograft delivery system of any one of examples 1 to 7 wherein the distal end of the pusher tube has an abutment configured to limit movement of the endograft when the inner tube and the nose cone are moved together in the distal direction.

9. The endograft delivery system of any one of examples 1 to 8 wherein the guidewire path is configured to remain in place adjacent an implant target site when the sheath is moved in the proximal direction and the inner tube and the nose cone are moved together in the distal direction.

10. The endograft delivery system of any one of examples 1 to 9 wherein the frame of the endograft has a superior portion and an inferior portion, and wherein the superior portion has an outer wall configured to engage a wall of a blood vessel and a septal wall configured to press against a vascular device.

11. The endograft delivery system of example 10 wherein the outer wall and the septal wall, respectively, define first and second complex ellipsoids in the expanded configuration with the outer wall having a first radius and the septal wall having a second radius greater than the first radius, and wherein, in the expanded configuration, the first and second complex ellipsoids comprising a substantially D-shaped cross-section.

12. The endograft delivery system of example 11 wherein the endograft outer wall and septal wall define a lumen of the endograft, the outer wall having a fenestration passing through the outer wall and communicating with the lumen, the fenestration defininig an angle relative to the septal wall corresponding to an angulation of a renal blood vessel observed at an implant target site.

13. The endograft delivery system of any one of examples 1 to 12 wherein the endograft further comprises a cover, the cover having a superior terminus and an inferior terminus, the cover attached over the frame at the superior terminus and the inferior terminus of the cover, the cover and the frame configured such that the cover substantially conforms to the frame in the expanded configuration.

14. A catheter for delivering an endograft over a guidewire, the catheter comprising:

an inner tube having a distal end and an inner lumen extending within the inner tube, the inner tube defining a catheter axis and opposing proximal and distal ends of the catheter, the proximal and distal ends of the catheter defining a proximal

direction and a distal direction along the catheter axis, the distal end of the inner tube having a transverse slot communicating with the inner lumen, the transverse slot extending in the proximal direction;

a cylindrical wall engaging the distal end of the inner tube, the cylindrical wall covering at least a portion of the distal end of the inner tube and defining a first internal volume between the cylindrical wall and the covered inner tube, the cylindrical wall extending in the proximal direction to a cylindrical wall edge;

a pusher tube slidably disposed over the inner tube, the pusher tube having a distal end at least in part disposed within the first internal volume, the distal end of the pusher tube having a transverse opening communicating with the inner tube; and

a sheath slidably disposed over the pusher tube and having a distal end terminating at a sheath edge disposed to face the cylindrical wall edge of the cylindrical wall to define a separation therebetween, the distal end of the sheath and the pusher tube defining a second internal volume therebetween that communicates with the first internal volume to define a delivery chamber,

wherein the catheter and the endograft together define a guidewire path through the catheter and though the transverse slot of the inner tube and the transverse opening of the pusher tube proximate to the separation.

15. The catheter of example 14 wherein the transverse slot of the inner tube has an axial length of approximately 30 mm and a circumferential width of approximately 1 mm.

16. The catheter of example 14 or example 15 wherein the transverse opening of the pusher tube comprises a slot extending in the proximal direction.

17. The catheter of any one of examples 14 to 16 wherein the distal end of the pusher tube comprises an abutment at least in part defining the delivery chamber.

18. The catheter of any one of examples 14 to 17 wherein the guidewire path is configured to remain in place adjacent an implant target site when the sheath is moved in the proximal direction and the inner tube and the cylindrical wall are moved together in the distal direction.

19. A method for treating an abdominal aortic aneurysm, the method comprising:

exposing a portion of an expandable endograft carried within a catheter of an endograft delivery system, wherein the endograft comprises a frame and a cover defining an endograft lumen, the frame having a plurality of frame openings with the cover extending over at least one frame opening;

cutting the cover extending over the at least one frame opening to form a fenestration through the cover and frame of the endograft, the fenestration communicating with the endograft lumen, the endograft lumen enclosing a pusher tube slidably disposed over an inner tube having an inner tube lumen; and

advancing a guidewire though the fenestration and into the inner tube lumen.

20. The method of example 19 wherein exposing a portion of an expandable endograft comprises increasing a separation between a sheath and a nose cone covering the enclosed endograft.

21. The method of example 19 or example 20 wherein exposing a portion of an expandable endograft comprises partially expanding at least a portion of the exposed endograft.

22. The method of any one of examples 19 to 21 wherein the endograft has an outer wall and an opposing septal wall defining a lumen of the endograft, and wherein cutting the cover to form the fenestration comprises disposing the fenestration at an angle corresponding to an angulation of a renal blood vessel observed at an implant target site.

23. The method of any one of examples 19 to 22 wherein the cover extends over the frame to a superior terminus of the cover with the frame extending beyond the superior terminus, and wherein cutting the cover comprises foring the fenestration up to approximately 5 mm from the superior terminus.

24. The method of example 23 wherein the cover is cut to define a slot extending towards the superior terminus.

25. The method of any one of examples 19 to 24 wherein advancing the guidewire through the fenestration comprises advancing the guidewire through a transverse slot of the inner tube.

26. The method of example 25 wherein advancing the guidewire through the fenestration comprises advancing the guidewire through a transverse opening of the pusher tube.

27. The method of example 26 wherein advancing the guidewire through the fenestration comprises advancing the guidewire through a separation between a sheath and a nose cone covering the enclosed endograft.

28. A method of implanting an expandable endograft at an implant target site having a primary blood vessel directing a primary blood flow and communicating with an intersecting secondary blood vessel directing a transverse blood flow relative to the primary blood flow, the method comprising:

advancing a guidewire through the primary blood vessel to the implant target site and into the secondary blood vessel so that the guidewire bends where the secondary blood vessel intersects the primary blood vessel;

advancing an endograft delivery system along the guidewire towards the target site, the endograft delivery system including a catheter with a distal end enclosing the endograft in an unexpanded low-profile configuration, the advancing including passing the guidewire through a fenestration of the endograft and into an internal lumen of the catheter; and

positioning the fenestration of the endograft at the bend of the guidewire at the implant target site.

29. The method of example 28, further comprising:

expanding the endograft to provide an endograft lumen directing at least a portion of the primary blood flow, the expanding disposing the fenestration at an opening of the secondary blood vessel so that the primary blood flow communicates with the transverse blood flow.

30. The method of example 29 wherein expanding the endograft comprises separating a nose cone from a sheath in different axial directions of the catheter to uncover the endograft.

31. The method of example 29 wherein expanding the endograft comprises expanding a septal wall of the endograft so that the septal wall presses against a vascular device disposed in the primary blood vessel.

32. The method of example 31, further comprising:
withdrawing the endograft delivery system over the guidewire; and
advancing a stent delivery system along the guidewire to dispose a stent within the secondary blood vessel in engagement with the fenestration.

33. The method of any one of examples 28 to 32 wherein the bend of the guidewire inhibits further advancement of the catheter after the fenestration reaches the bend of the guidewire.

34. A method of implanting first and second expandable endografts at an implant target site having a main artery communicating with first and second renal arteries, the method comprising:
disposing a first guidewire within the main artery and the first renal artery;
disposing a second guidewire within the main artery and the second renal artery;
advancing the first endograft over the first guidewire;
advancing the second endograft over the second guidewire;
aligning a first fenestration of the first endograft with the first renal artery; and
aligning a second fenestration of the second endograft with the second renal artery,
wherein alignment of the first and second fenestrations of the first and second endografts, respectively, are independent of each other.

Conclusion

[0057] From the foregoing, it will be appreciated that specific embodiments of the technology 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 Figures 1A-3F 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. Further, in some embodiments a removable guidewire insertion aid (e.g., a liner, a shoehorn) can be provided to facilitate the introduction of the guidewire 44 through the separation 80, through the fenestration 138, and into the guidewire path, with the guidewire insertion aid oriented to direct the guidewire into the transverse opening 82 of the pusher tube 76 and into the transverse slot 66 of the inner tube 62 so that the guidewire 44 can enter the inner lumen 64.

[0058] 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 102 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.

CLAIMS

I/We claim:

1. An endograft delivery system, comprising:

a catheter defining a catheter axis and opposing proximal and distal ends, the proximal and distal ends of the catheter defining a proximal direction and a distal direction along the catheter axis, wherein the distal end of the catheter comprises—

an inner tube having a distal end and an inner lumen extending within the inner tube, the distal end of the inner tube having a transverse slot communicating with the inner lumen, the transverse slot extending in the proximal direction;

a nose cone engaging the distal end of the inner tube, the nose cone having a cylindrical wall extending in the proximal direction to a cylindrical wall edge to cover at least a portion of the distal end of the inner tube and define a first internal volume within the cylindrical wall of the nose cone;

a pusher tube slidably disposed over the inner tube, the pusher tube having a distal end at least in part disposed within the first internal volume of the nose cone, the distal end of the pusher tube having a transverse opening communicating with the inner tube; and

a sheath slidably disposed over the pusher tube and having a distal end terminating at a sheath edge disposed to face the cylindrical wall edge of the nose cone to define a separation therebetween, the distal end of the sheath and the pusher tube defining a second internal volume therebetween that communicates with the first internal volume to define a delivery chamber; and

an endograft device disposed within the delivery chamber of the catheter, the endograft device comprising an expandable frame in a low-profile configuration within the delivery chamber and configured to expand to an expanded configuration when the separation between the sheath edge and the cylindrical wall edge is sufficiently increased to uncover the endograft device,

wherein the catheter and the endograft together define a guidewire path configured to direct a guidewire through the endograft delivery system, wherein the guidewire path comprises a proximal end extending in the proximal direction within the inner lumen of the inner tube and a distal end extending past the separation between the sheath edge and the cylindrical wall edge of the nose cone, the guidewire path further passing though the transverse slot of the inner tube and the transverse opening of the pusher tube proximate to the separation.

2. The endograft delivery system of claim 1 wherein:

the endograft device further comprises a cover attached to the frame, the cover having a superior terminus and an inferior terminus, the frame having a first end extending distally beyond the superior terminus of the cover and a second end extending proximally beyond the inferior terminus of the cover,

wherein the superior terminus of the cover and the first end of the frame define a superior portion of the endograft and a lumen of the endograft, the superior portion having a fenestration passing through the cover and the frame to communicate with the lumen.

3. The endograft delivery system of claim 2 wherein at least a portion of the fenestration is disposed at a distance up to approximately 5 mm from the superior terminus of the cover.

4. The endograft delivery system of claim 2 wherein the fenestration passing through the cover comprises a slot extending towards the superior terminus of the cover.

5. The endograft delivery system of claim 2 wherein the fenestration is configured to engage a stent.

6. The endograft delivery system of claim 1 wherein the transverse slot of the inner tube has an axial length of approximately 30 mm and a circumferential width of approximately 1 mm.

7. The endograft delivery system of claim 1 wherein the transverse opening of the pusher tube is a slot extending in the proximal direction.

8. The endograft delivery system of claim 1 wherein the distal end of the pusher tube has an abutment configured to limit movement of the endograft when the inner tube and the nose cone are moved together in the distal direction.

9. The endograft delivery system of claim 1 wherein the guidewire path is configured to remain in place adjacent an implant target site when the sheath is moved in the proximal direction and the inner tube and the nose cone are moved together in the distal direction.

10. The endograft delivery system of claim 1 wherein the frame of the endograft has a superior portion and an inferior portion, and wherein the superior portion has an outer wall configured to engage a wall of a blood vessel and a septal wall configured to press against a vascular device.

11. The endograft delivery system of claim 10 wherein the outer wall and the septal wall, respectively, define first and second complex ellipsoids in the expanded configuration with the outer wall having a first radius and the septal wall having a second radius greater than the first radius, and wherein, in the expanded configuration, the first and second complex ellipsoids comprising a substantially D-shaped cross-section.

12. The endograft delivery system of claim 11 wherein the endograft outer wall and septal wall define a lumen of the endograft, the outer wall having a fenestration passing through the outer wall and communicating with the lumen, the fenestration defininig an angle relative to the septal wall corresponding to an angulation of a renal blood vessel observed at an implant target site.

13. The endograft delivery system of claim 1 wherein the endograft further comprises a cover, the cover having a superior terminus and an inferior terminus, the cover attached over the frame at the superior terminus and the inferior terminus of the cover, the

cover and the frame configured such that the cover substantially conforms to the frame in the expanded configuration.

14. A catheter for delivering an endograft over a guidewire, the catheter comprising:

an inner tube having a distal end and an inner lumen extending within the inner tube, the inner tube defining a catheter axis and opposing proximal and distal ends of the catheter, the proximal and distal ends of the catheter defining a proximal direction and a distal direction along the catheter axis, the distal end of the inner tube having a transverse slot communicating with the inner lumen, the transverse slot extending in the proximal direction;

a cylindrical wall engaging the distal end of the inner tube, the cylindrical wall covering at least a portion of the distal end of the inner tube and defining a first internal volume between the cylindrical wall and the covered inner tube, the cylindrical wall extending in the proximal direction to a cylindrical wall edge;

a pusher tube slidably disposed over the inner tube, the pusher tube having a distal end at least in part disposed within the first internal volume, the distal end of the pusher tube having a transverse opening communicating with the inner tube; and

a sheath slidably disposed over the pusher tube and having a distal end terminating at a sheath edge disposed to face the cylindrical wall edge of the cylindrical wall to define a separation therebetween, the distal end of the sheath and the pusher tube defining a second internal volume therebetween that communicates with the first internal volume to define a delivery chamber,

wherein the catheter and the endograft together define a guidewire path through the catheter and though the transverse slot of the inner tube and the transverse opening of the pusher tube proximate to the separation.

15. The catheter of claim 14 wherein the transverse slot of the inner tube has an axial length of approximately 30 mm and a circumferential width of approximately 1 mm.

16. The catheter of claim 14 wherein the transverse opening of the pusher tube comprises a slot extending in the proximal direction.

17. The catheter of claim 14 wherein the distal end of the pusher tube comprises an abutment at least in part defining the delivery chamber.

18. The catheter of claim 14 wherein the guidewire path is configured to remain in place adjacent an implant target site when the sheath is moved in the proximal direction and the inner tube and the cylindrical wall are moved together in the distal direction.

19. A method for treating an abdominal aortic aneurysm, the method comprising:

exposing a portion of an expandable endograft carried within a catheter of an endograft delivery system, wherein the endograft comprises a frame and a cover defining an endograft lumen, the frame having a plurality of frame openings with the cover extending over at least one frame opening;

cutting the cover extending over the at least one frame opening to form a fenestration through the cover and frame of the endograft, the fenestration communicating with the endograft lumen, the endograft lumen enclosing a pusher tube slidably disposed over an inner tube having an inner tube lumen; and

advancing a guidewire though the fenestration and into the inner tube lumen.

20. The method of claim 19 wherein exposing a portion of an expandable endograft comprises increasing a separation between a sheath and a nose cone covering the enclosed endograft.

21. The method of claim 19 wherein exposing a portion of an expandable endograft comprises partially expanding at least a portion of the exposed endograft.

22. The method of claim 19 wherein the endograft has an outer wall and an opposing septal wall defining a lumen of the endograft, and wherein cutting the cover to form the fenestration comprises disposing the fenestration at an angle corresponding to an angulation of a renal blood vessel observed at an implant target site.

23. The method of claim 19 wherein the cover extends over the frame to a superior terminus of the cover with the frame extending beyond the superior terminus, and wherein

cutting the cover comprises foring the fenestration up to approximately 5 mm from the superior terminus.

24. The method of claim 23 wherein the cover is cut to define a slot extending towards the superior terminus.

25. The method of claim 19 wherein advancing the guidewire through the fenestration comprises advancing the guidewire through a transverse slot of the inner tube.

26. The method of claim 25 wherein advancing the guidewire through the fenestration comprises advancing the guidewire through a transverse opening of the pusher tube.

27. The method of claim 26 wherein advancing the guidewire through the fenestration comprises advancing the guidewire through a separation between a sheath and a nose cone covering the enclosed endograft.

28. A method of implanting an expandable endograft at an implant target site having a primary blood vessel directing a primary blood flow and communicating with an intersecting secondary blood vessel directing a transverse blood flow relative to the primary blood flow, the method comprising:

advancing a guidewire through the primary blood vessel to the implant target site and into the secondary blood vessel so that the guidewire bends where the secondary blood vessel intersects the primary blood vessel;

advancing an endograft delivery system along the guidewire towards the target site, the endograft delivery system including a catheter with a distal end enclosing the endograft in an unexpanded low-profile configuration, the advancing including passing the guidewire through a fenestration of the endograft and into an internal lumen of the catheter; and

positioning the fenestration of the endograft at the bend of the guidewire at the implant target site.

29. The method of claim 28, further comprising:

expanding the endograft to provide an endograft lumen directing at least a portion of the primary blood flow, the expanding disposing the fenestration at an opening of the secondary blood vessel so that the primary blood flow communicates with the transverse blood flow.

30. The method of claim 29 wherein expanding the endograft comprises separating a nose cone from a sheath in different axial directions of the catheter to uncover the endograft.

31. The method of claim 29 wherein expanding the endograft comprises expanding a septal wall of the endograft so that the septal wall presses against a vascular device disposed in the primary blood vessel.

32. The method of claim 31, further comprising:

withdrawing the endograft delivery system over the guidewire; and

advancing a stent delivery system along the guidewire to dispose a stent within the secondary blood vessel in engagement with the fenestration.

33. The method of claim 28 wherein the bend of the guidewire inhibits further advancement of the catheter after the fenestration reaches the bend of the guidewire.

34. A method of implanting first and second expandable endografts at an implant target site having a main artery communicating with first and second renal arteries, the method comprising:

disposing a first guidewire within the main artery and the first renal artery;

disposing a second guidewire within the main artery and the second renal artery;

advancing the first endograft over the first guidewire;

advancing the second endograft over the second guidewire;

aligning a first fenestration of the first endograft with the first renal artery; and

aligning a second fenestration of the second endograft with the second renal artery,

wherein alignment of the first and second fenestrations of the first and second endografts, respectively, are independent of each other.

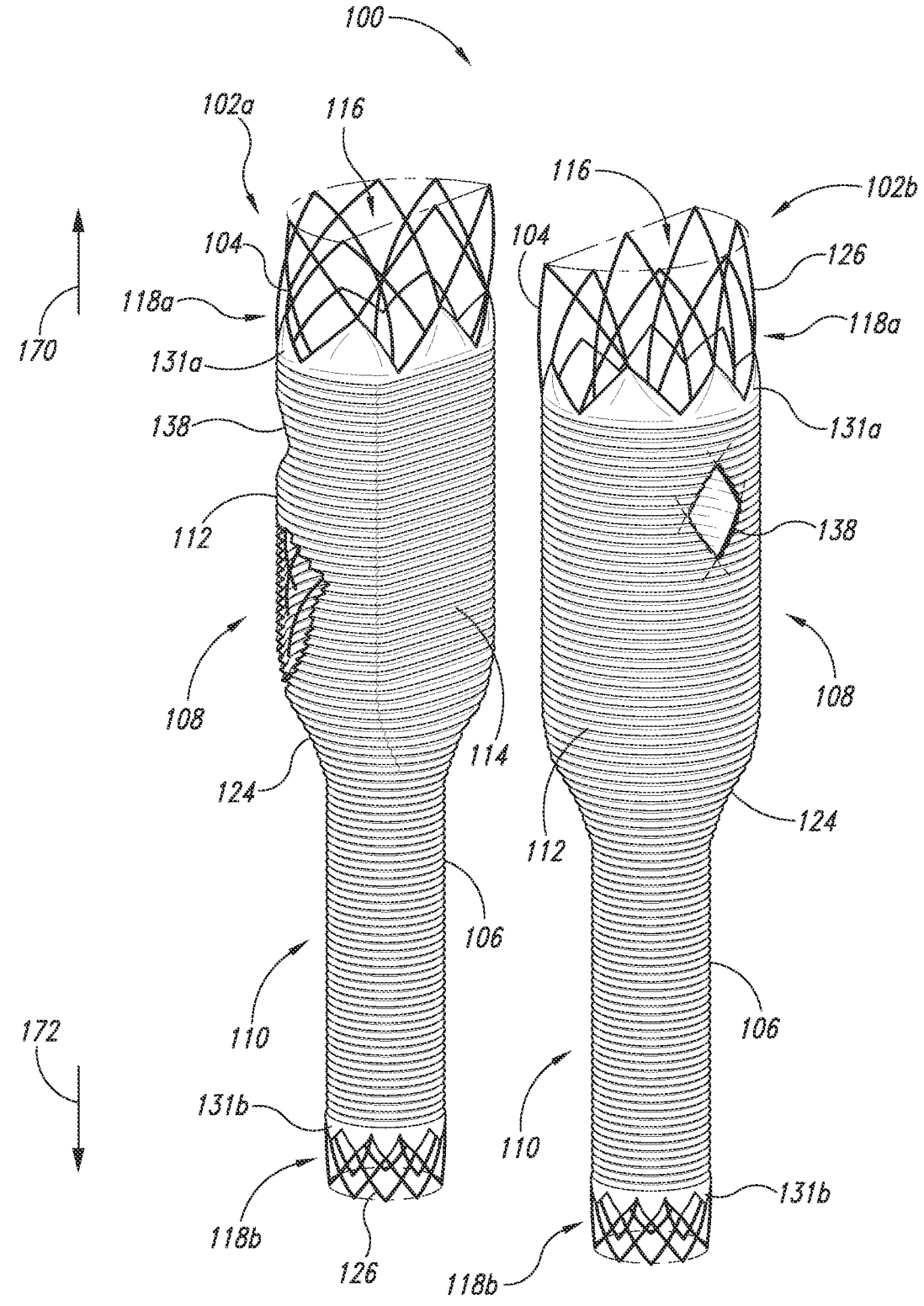

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Fig. 1A

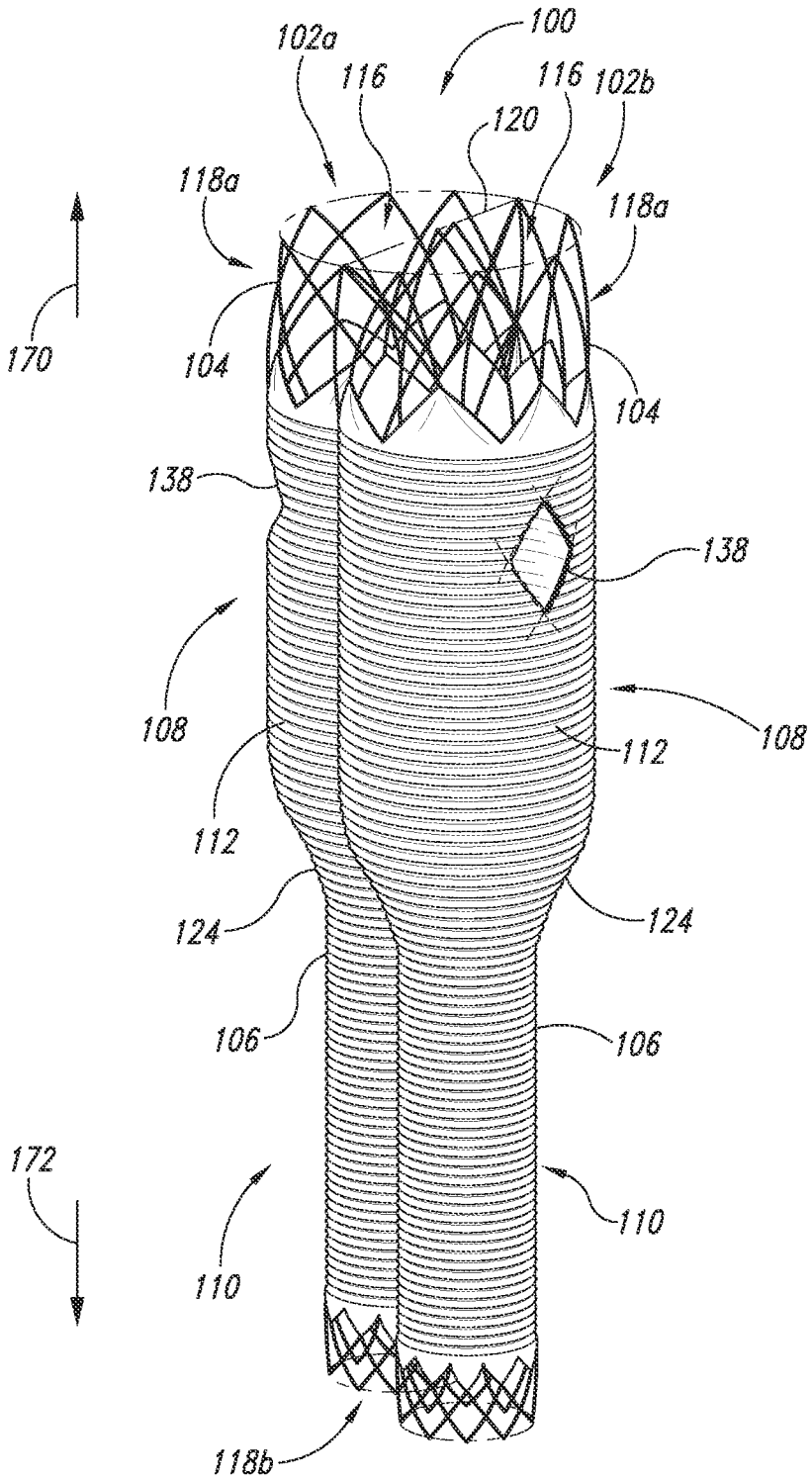

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Fig. 1B

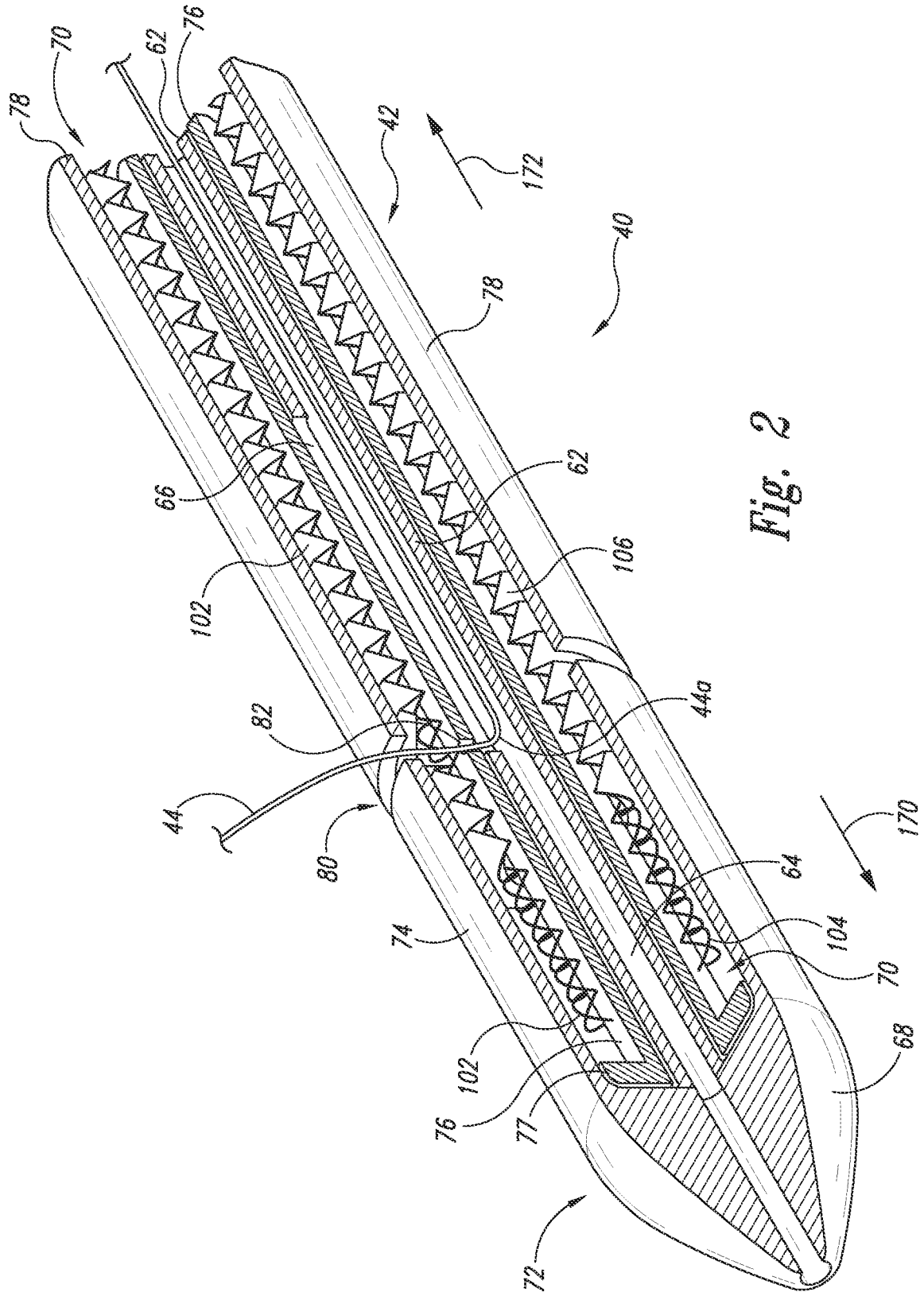

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Fig. 2

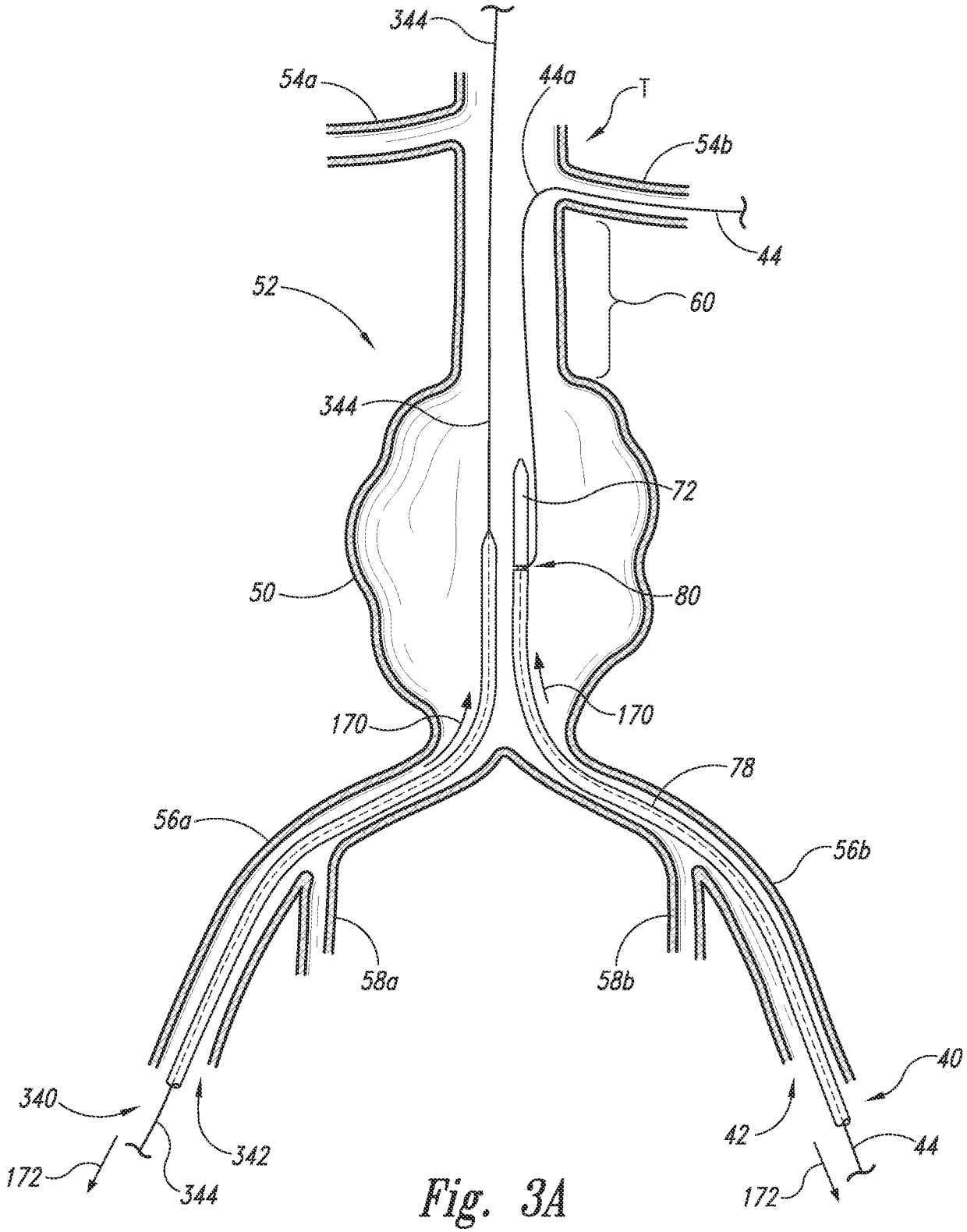

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Fig. 3A

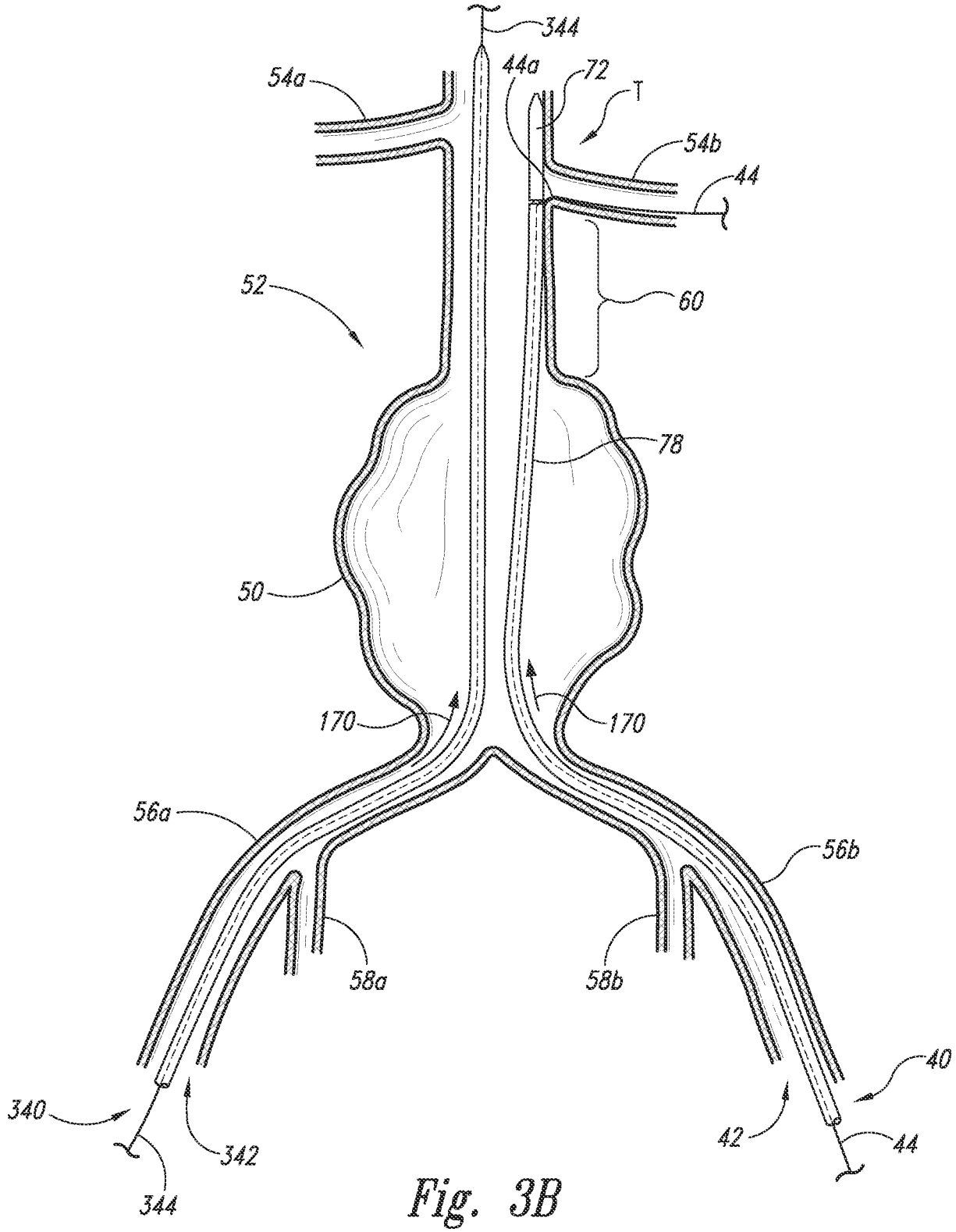

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Fig. 3B

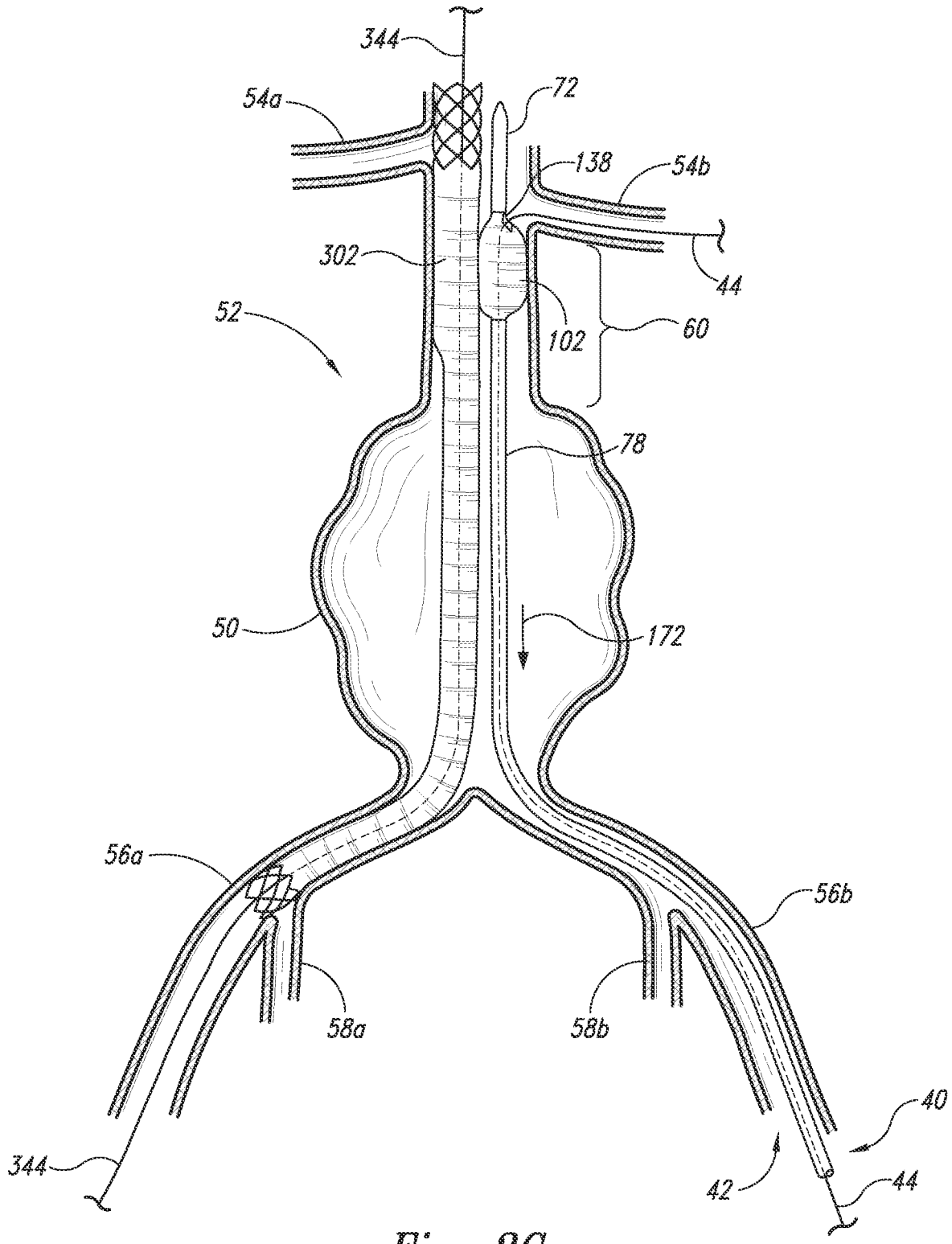

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Fig. 3C

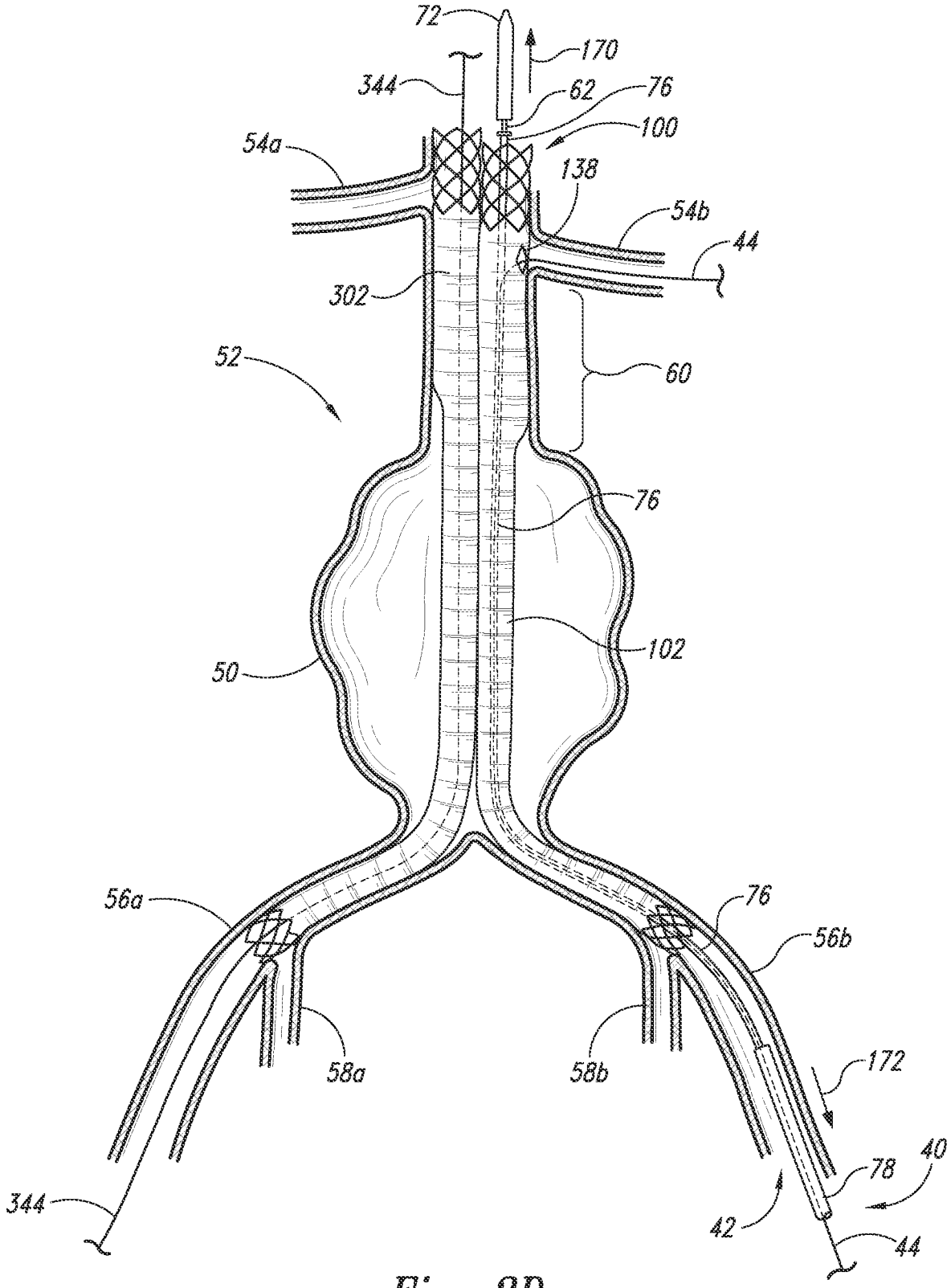

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Fig. 3D

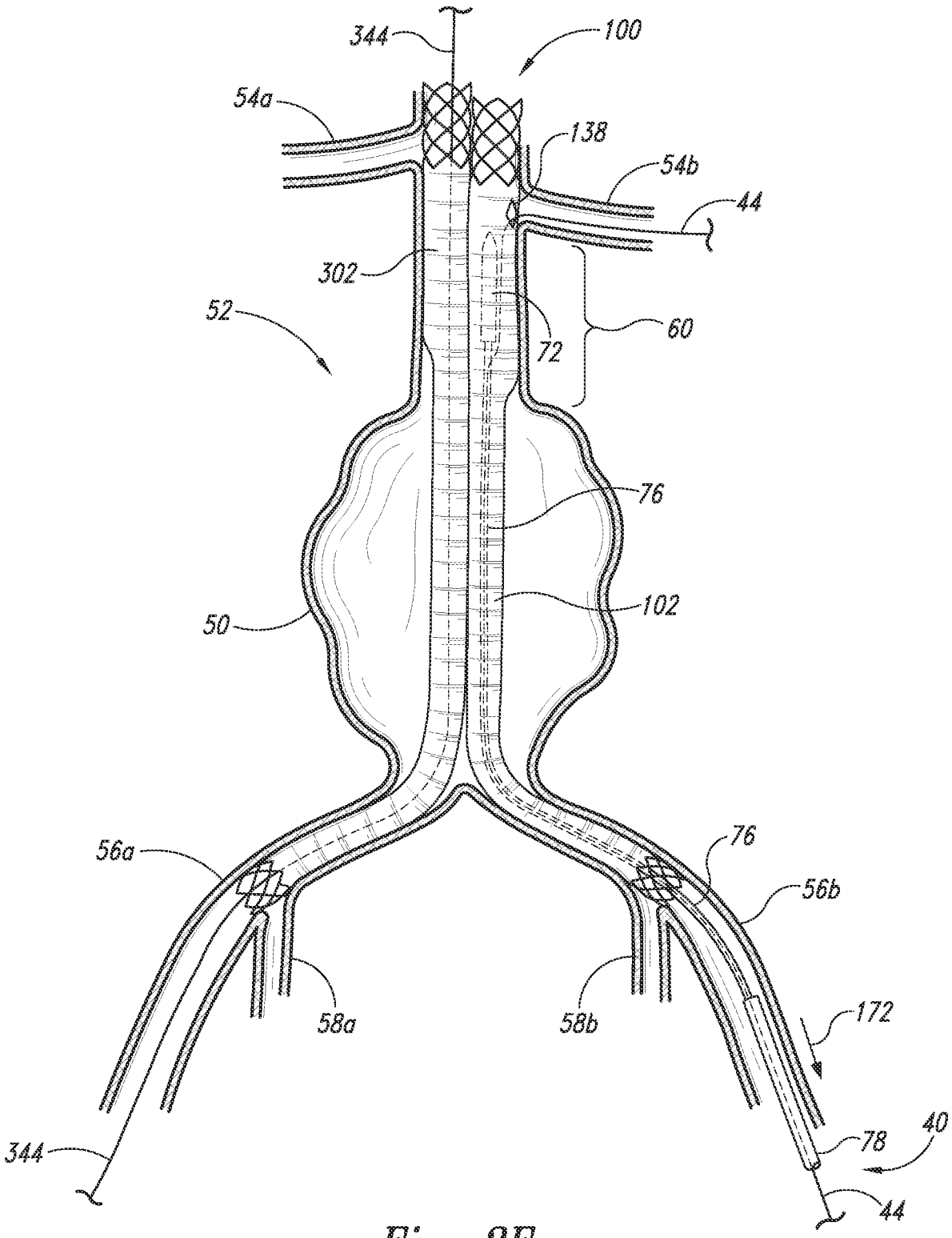

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Fig. 3E

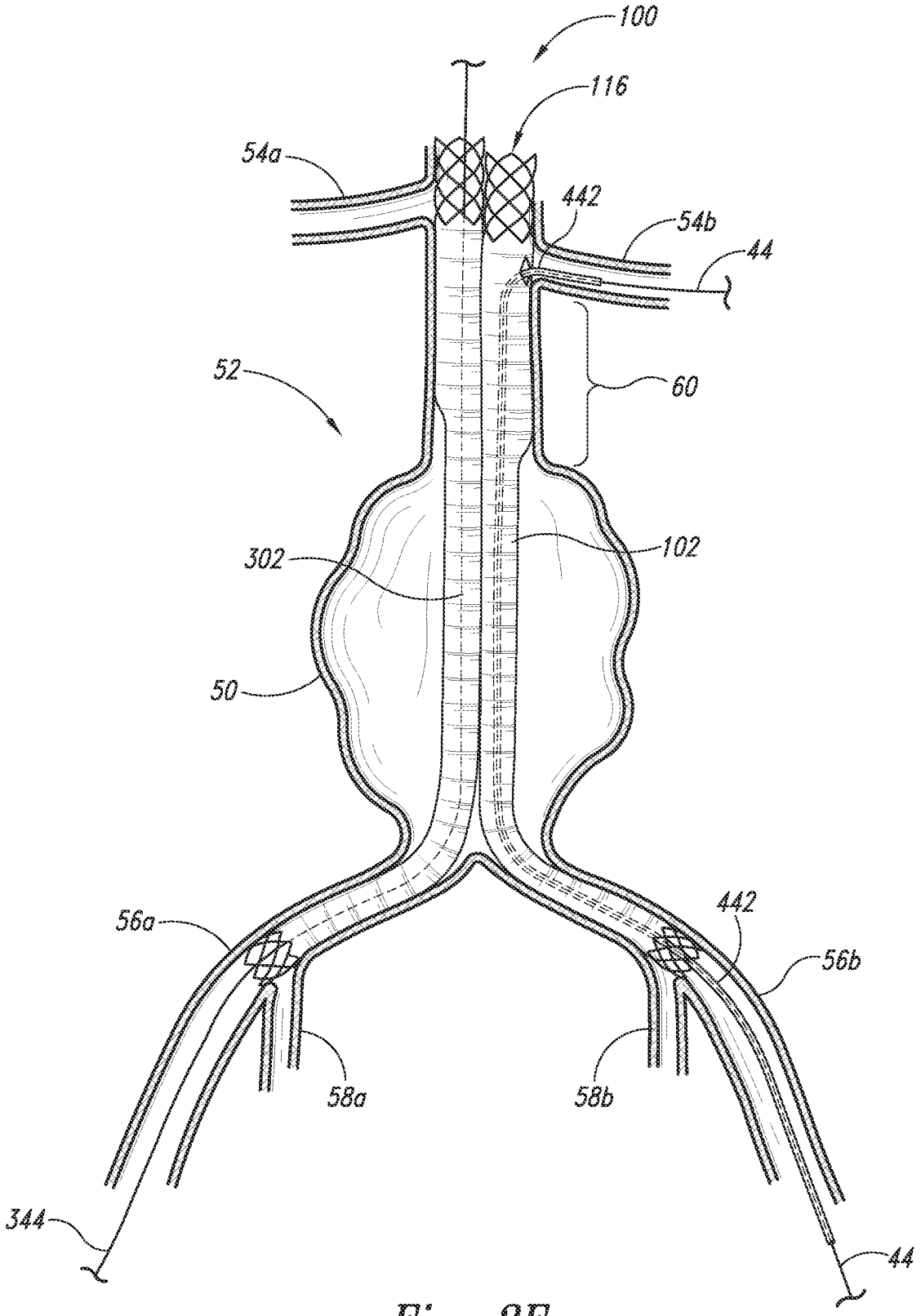


Fig. 3F

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/029373

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/966 A61F2/07
ADD. A61F2/954 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/03762 A1 (ENDOLOGIX INC [US]) 18 January 2001 (2001-01-18) page 11, line 9 - page 13, line 17; figures 13-16	1-18
X	WO 2010/127040 A1 (ENDOLOGIX INC [US]; MAYBERRY KEVIN [US]; CLAIR DANIEL [US]; WELK CRAIG) 4 November 2010 (2010-11-04) paragraphs [0237] - [0260]; figures 43A-49B	1-18
A	WO 2012/088888 A1 (MICROPORT MEDICAL SHANGHAI CO [CN]; XIE ZHIYONG [CN]; LIU YAJIE [CN];) 5 July 2012 (2012-07-05) page 4, line 10 - page 5, line 17; figure 1	1-18

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 August 2014	12/08/2014

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Chevalot, Nicolas

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/029373

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

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

1. [X] Claims Nos.: 19-34
because they relate to subject matter not required to be searched by this Authority, namely:

The subject-matter of claims 19-34 has not been searched (Rule 39.1(iv) PCT) and no examination of said subject-matter will be carried out (Rule 67.1(iv) PCT): said-subject-matter is related to a method for treatment of the human body by surgery.

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

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

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

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

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

Remark on Protest

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

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

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/029373

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010/268327 A1 (BRUSZEWSKI WALTER [US] ET AL) 21 October 2010 (2010-10-21) paragraphs [0040] - [0046]; figures 11-15	1-18

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/029373

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