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(54) Title: STENT GRAFT SYSTEM AND METHOD OF USE

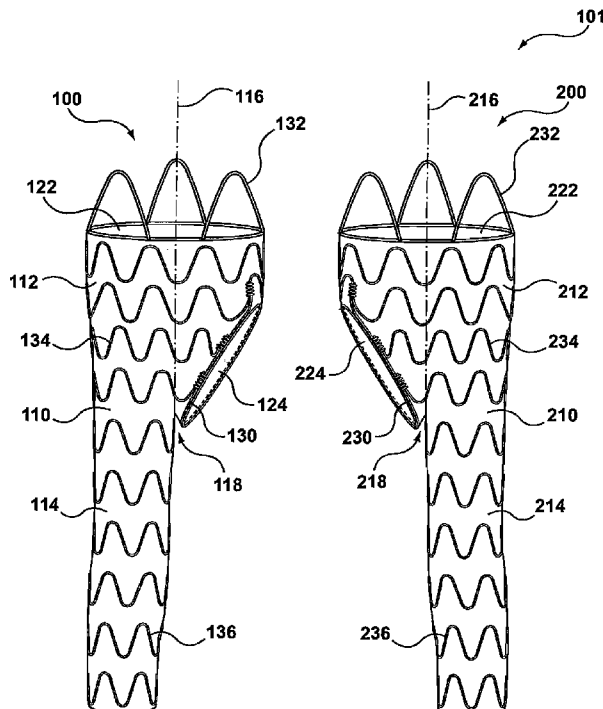


FIG. 2

(57) Abstract: A stent graft system and method of use including a stent graft system with a first stent graft component and a second stent graft component. A first tubular graft of the first stent graft component has an integral first body and first leg, with the first body defining a first crown opening and a first substantially elliptical opening. The second body of the second stent graft component is disposed in the first body of the first stent graft component with the second leg of the second stent graft component disposed through the first substantially elliptical opening of the first stent graft component with the perimeter of the first elliptical opening of the first stent graft component in contact with the second body of the second stent graft component.



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STENT GRAFT SYSTEM AND METHOD OF USE

TECHNICAL FIELD

[0001] The technical field of this disclosure is medical implantation devices, particularly, a stent graft system and method of use.

BACKGROUND

[0002] Stent grafts have been developed for the treatment of abdominal aortic aneurysms. An abdominal aortic aneurysm is a bulge that forms in the wall of the abdominal aorta, which is the main vessel of the arterial system of the body that extends through the abdomen.

Abdominal aortic aneurysms can have various causes, such as high blood pressure, accident, or atherosclerosis, and can lose elasticity over time and rupture under normal blood pressure.

A stent graft is typically a woven tube (graft) supported by one or more tubular metal or plastic stents. The stent graft is placed inside and spanning an aneurysm to exclude the abdominal aortic aneurysm from normal blood flow and reduces pressure on the aneurysmal vessel.

[0003] Presently, stent grafts include a number of pieces that are assembled within the patient to provide the finished stent graft assembly. The main larger piece includes a trunk with two descending limbs: an iliac limb and a contralateral limb. The contralateral limb can be shorter than or equal in length to the iliac limb, but both have a length extending from the trunk. A limb segment is deployed in the contralateral limb to extend between the contralateral limb and the iliac artery. Iliac extension stent grafts can be used to extend the iliac limb and/or the limb segment as required. Unfortunately, the number of parts required for the stent graft increases manufacturing and inventory costs. The stent graft pieces must be manufactured and stocked in a number of lengths and diameters at the supplier and at the hospital, so each separate part greatly increases the complexity of the therapy delivery.

[0004] The present stent grafts also present challenges during deployment. The typical contralateral limb has a small opening, making it difficult to locate and feed in a guidewire for guiding deployment of the limb segment in the contralateral limb. In addition, the thickness of the graft material when compressed creates bulk (volume) which limits the amount of graft material and thereby the diameter of the stent graft delivery configuration that can be compressed into a given size catheter, limiting flexibility and deployment location access.

[0005] It would be desirable to have a stent graft system and method of use that would overcome the above disadvantages.

SUMMARY

[0006] One aspect according to the present invention provides a stent graft system including a first stent graft component and a second stent graft component. The first stent graft component includes a first tubular graft having an integral first body and first leg, the first body having a first longitudinal axis, the first body defining a first crown opening and a first substantially elliptical opening, the first substantially elliptical opening being oriented at a first acute angle to the first longitudinal axis. The second stent graft component includes a second tubular graft having an integral second body and second leg, the second body having a second longitudinal axis, the second body defining a second crown opening and a second substantially elliptical opening, the second substantially elliptical opening being oriented at a second acute angle to the second longitudinal axis. The second body is disposed in the first body, and the second leg is disposed through the first substantially elliptical opening with the perimeter of the first elliptical opening in contact with the second body.

[0007] Another aspect according to the present invention provides a stent graft including a tubular graft having an integral body and leg, the body having a longitudinal axis, the body defining a crown opening and a substantially elliptical opening, the substantially elliptical opening being oriented at an acute angle to the longitudinal axis; an elliptical opening stent operably connected to the substantially elliptical opening; and a crown stent operably connected around the crown opening.

[0008] Another aspect according to the present invention provides a method of use of a stent graft system including positioning a first stent graft component in a first compressed configuration at a deployment site. The first stent graft component includes a first tubular graft having an integral first body and first leg, the first body having a first longitudinal axis, the first body defining a first crown opening and a first substantially elliptical opening, the first substantially elliptical opening being oriented at a first acute angle to the first longitudinal axis; and a first elliptical opening stent operably connected to the first substantially elliptical opening. The method further includes releasing the first stent graft component from the first compressed configuration to expand at the deployment site; and advancing a second stent graft component in a second compressed configuration through the first substantially elliptical opening to the deployment site. The second stent graft component includes a second tubular graft having an integral second body and second leg, the second

body having a second longitudinal axis, the second body defining a second crown opening and a second substantially elliptical opening, the second substantially elliptical opening being oriented at a second acute angle to the second longitudinal axis; and a second elliptical opening stent operably connected to the substantially elliptical opening. The method further includes releasing the second stent graft component from the second compressed configuration to expand with the second body within the first body and the second leg disposed through the first substantially elliptical opening with the perimeter of the first substantially elliptical opening in contact with the second body.

[0009] The foregoing and other features and advantages will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings

BRIEF DESCRIPTION OF THE DRAWINGS

- [0010] FIG. 1 is a side view of a stent graft component;
- [0011] FIG. 2 is a side view of a stent graft system;
- [0012] FIG. 3 is a side view of an assembled stent graft system;
- [0013] FIG. 4 is a flow chart of a method of creating a stent graft system;
- [0014] FIGS. 5A-5F are cut-away side views of a method of creating a stent graft system;
- [0015] FIG. 6 is a close-up view of an elliptical opening stent for a stent graft system;
- [0016] FIGS. 7-9 are additional embodiments of a stent graft component; and
- [0017] FIGS. 10A-10D are various views of an exemplary stent graft system;
- [0018] FIGS. 11A & 11B are side views of another exemplary stent graft system; and
- [0019] FIG. 12 is a side view of another exemplary assembled stent graft system.

DETAILED DESCRIPTION

[0020] FIG. 1 is a side view of a stent graft component. The first stent graft component 100 includes a tubular graft 110, an elliptical opening stent 130, a crown stent 132, body stents 134, and leg stents 136. The tubular graft 110 has an integral body 112 and leg 114. In this example, the body 112 has a longitudinal axis 116 and a leg intersection point 118 near the longitudinal axis 116 where the leg 114 meets the body 112. The body 112 defines a crown opening 122 and a substantially elliptical opening 124. The substantially elliptical opening 124 is oriented at an acute angle α to the longitudinal axis 116. The elliptical opening stent 130 is operably connected to the substantially elliptical opening 124, the crown stent 132 is operably connected around the crown opening 122, the body stents 134 are operably

connected around the body 112, and the leg stents 136 are operably connected around the leg 114. In this example, the elliptical opening stent 130 is attached to several of the body stents 134. In one embodiment, the acute angle α is between 20 degrees and 70 degrees. In another embodiment, the acute angle α is about 30 degrees. The longitudinal axis 116 is generally parallel to the sides of the body 112 and need not be located in the center of the body 112. The body 112 can be symmetrical in cross section, or can have the larger portion aligned with the leg 114 or the substantially elliptical opening 124.

[0021] Those skilled in the art will appreciate that the stent graft component can be adapted as desired for a particular application. Substantially elliptical as used herein in conjunction with the substantially elliptical opening is defined as having a generally elliptical shape, such as a regular or irregular ellipse, circle, oval, egg shape, eggplant shape, tear drop shape, or the like. The perimeter of the generally elliptical shape can include minor deviations from the generally elliptical shape as desired for a particular application, e.g., the perimeter can be peanut shaped. In one embodiment, the elliptical opening stent extends around the whole perimeter of the substantially elliptical opening. In another embodiment, the elliptical opening stent extends partially around the perimeter of the substantially elliptical opening. In yet another embodiment, the elliptical opening stent includes a number of separate stent segments extending partially or fully around the perimeter of the substantially elliptical opening. In yet another embodiment, the elliptical opening stent is one of the other stents, such as the body stent, with a portion of the body stent urging open the substantially elliptical opening without necessarily following the perimeter of the substantially elliptical opening. The elliptical opening stent as used herein is defined as any stent or portion of a stent that urges open the substantially elliptical opening when the stent graft component is in an expanded configuration. In yet another embodiment, no elliptical opening stent is provided around the substantially elliptical opening.

[0022] The stent graft component can be made of any suitable biocompatible materials. Exemplary materials for the elliptical opening stent 130, crown stent 132, body stent 134, and leg stent 136 include stainless steels, such as 316L stainless steel; shape memory alloys, such as nitinol; and nickel-cobalt-chromium-molybdenum alloy, such as MP35N[®] alloy available from SPS Technologies, Inc., of Jenkintown, Pennsylvania; titanium; tantalum; or the like. Those skilled in the art will appreciate that various stent configurations are possible. In one alternative, the stent is woven into the graft material. In another alternative, the stent is added

when the stent graft component is at the deployment site, by injecting a hardenable material into recesses within the stent graft component.

[0023] Exemplary materials for the tubular graft **110** include biocompatible, blood-impermeable graft membranes, such as polyester, polyethylene, expanded polytetrafluoroethylene (ePTFE), polyurethane, propylene, nylon, and the like. In one embodiment, the material for the tubular graft **110** can be thinner than conventional graft material because the two bodies of the stent graft components overlap in the assembled stent graft system.

[0024] **FIG. 2**, in which like elements share like reference numbers with **FIG. 1**, is a side view of a stent graft system. The stent graft system **101** includes first stent graft component **100** and second stent graft component **200**. In this example, the first stent graft component **100** is identical to the second stent graft component **200**, although in other embodiments the stent graft components can be different in size and/or shape.

[0025] The second stent graft component **200** includes a tubular graft **210**, an elliptical opening stent **230**, a crown stent **232**, body stents **234**, and leg stents **236**. The tubular graft **210** has an integral body **212** and leg **214**. The body **212** has a longitudinal axis **216** and a leg intersection point **218** on the longitudinal axis **216** where the leg **214** meets the body **212**. The body **212** defines a crown opening **222** and a substantially elliptical opening **224**. The elliptical opening stent **230** is operably connected to the substantially elliptical opening **224**, the crown stent **232** is operably connected around the crown opening **222**, the body stents **234** are operably connected around the body **212**, and the leg stents **236** are operably connected around the leg **214**. In this example, the elliptical opening stent **230** is attached to several of the body stents **234**. Also in this example, the crown stent **132** and the crown stent **232** each includes an odd number of peaks beyond the graft material of the body **112** and body **212**, respectively, so that when the components are combined the peaks are complementary and follow the whole perimeter of the crown opening to form a continuous row of peaks when the stent graft system is assembled. Those skilled in the art will appreciate that the number and configuration of the crown stent peaks can be selected as desired for a particular application. In another embodiment, the number of peaks can be even. In one embodiment, the peaks are aligned so the peaks of one stent graft component overlap the peaks of the other stent graft component, providing an overlapping double row of peaks when the stent graft system is assembled.

[0026] FIG. 3, in which like elements share like reference numbers with FIG. 2, is a side view of an assembled stent graft system. The assembled stent graft system 300 has body 212 of the second stent graft component 200 disposed in the body 112 of the first stent graft component 100. In this example, the crown opening 222 of the second stent graft component 200 substantially aligned with the crown opening 122 of the first stent graft component 100. In one embodiment, the body 212 is held in place relative to the body 112 by friction of the interference fit between the body 212 and the body 112. In one embodiment, the body 212 is held in place relative to the body 112 by operably connecting the body 212 to the body 112 with fasteners, such as sutures, staples, hooks, anchors, adhesives, rivets, screws, or the like. The second leg 214 of the second stent graft component 200 is disposed through the substantially elliptical opening 124 of the first stent graft component 100 with the perimeter of the first elliptical opening 124 in contact with the body 212 of the second stent graft component 200. The longitudinal axis 116 of the first stent graft component 100 is substantially aligned with the longitudinal axis 216 of the second stent graft component 200. In this example, the peaks of the crown stent 132 and the crown stent 232 alternate around the perimeter of the crown opening. Substantially aligned as used herein in conjunction with the crown opening 222 and crown opening 122 is defined as being generally coplanar, with allowance for minor angular and/or axial (dimensional) offsets that do not affect function. In another embodiment, the body of one of the stent graft components is longer than the body of the other stent graft component, so that the crown openings are not aligned. This allows the crown stent of one stent graft component to contact the aorta at a position longitudinally offset from the position where the crown stent of the other stent graft component contacts the aorta. In yet another embodiment, the crown openings are not aligned due to the particular placement of the individual stent graft components even though the body of the two stent graft components are the same length.

[0027] Those skilled in the art will appreciate that additional stent graft components can be added to the stent graft system as desired for a particular application. In one example, a seal graft, such as a tubular graft with or without supporting stents, can be placed within the body of the second stent graft component and the leg of the first stent graft component to seal the joint where the second stent graft component meets the first stent graft component. The seal graft extends across the substantially elliptical opening of the second stent graft component to provide the seal for blood flow from the body of the second stent graft component into the leg of the first stent graft component and out to the vessel.

[0028] FIG. 4 is a flow chart of the steps of a method of creating a stent graft system. The method 400 includes positioning a first stent graft component in a first compressed configuration at a deployment site 402; releasing the first stent graft component from the first compressed configuration to expand at the deployment site 404; advancing a second stent graft component in a second compressed configuration through the first substantially elliptical opening to the deployment site 406; and releasing the second stent graft component from the second compressed configuration to expand with the second body within the first body 408 and the second leg disposed through the first substantially elliptical opening with the perimeter of the first elliptical opening in contact with the second body.

[0029] The first stent graft component includes a first tubular graft having an integral first body and first leg, the first body having a first longitudinal axis, the first body defining a first crown opening and a first substantially elliptical opening, the first substantially elliptical opening being oriented at a first acute angle to the first longitudinal axis; and a first elliptical opening stent operably connected to the first substantially elliptical opening.

[0030] The second stent graft component includes a second tubular graft having an integral second body and second leg, the second body having a second longitudinal axis, the second body defining a second crown opening and a second substantially elliptical opening, the second substantially elliptical opening being oriented at a second acute angle to the second longitudinal axis; and a second elliptical opening stent operably connected to the second substantially elliptical opening.

[0031] In one embodiment, the method 400 can optionally include attaching the first stent graft component to the second stent graft component with a fastener, such as sutures, staples, hooks, anchors, adhesives, rivets, screws, or the like. In one embodiment, positioning a first stent graft component 402 includes positioning the first stent graft component through the vasculature, such as positioning the first stent graft component in a first compressed configuration at a deployment site through a first common iliac artery, and advancing a second stent graft component 408 includes advancing the second stent graft component from a second common iliac artery through the first substantially elliptical opening.

[0032] FIGS. 5A-5F, in which like elements share like reference numbers, are cut-away side views of the steps of a method of creating a stent graft system. In this example, the stent graft system is being deployed in an aortic aneurysm.

[0033] Referring to FIG. 5A, a guidewire 510 is advanced through the common iliac artery 502 and into the aortic aneurysm 500. A stent graft delivery system 512 holding a first stent

graft component in a compressed configuration is advanced over the guidewire **510** to position the first stent graft component at the deployment site in the aortic aneurysm **500**.

[0034] Referring to **FIG. 5B**, the stent graft delivery system releases the first stent graft component **520** from the compressed configuration to expand at the deployment site. In one embodiment, the stent graft delivery system releases the first stent graft component **520** by retracting a sheath holding the first stent graft component **520** in the compressed configuration. The guidewire can be retracted from the aortic aneurysm **500** after the first stent graft component **520** expands. The body **522** of the first stent graft component **520** is located at the neck **506** of the aortic aneurysm **500** and the leg **524** of the first stent graft component **520** is located in the common iliac artery **502**. The first stent graft component **520** includes a substantially elliptical opening **526** and a crown opening **528**.

[0035] Referring to **FIG. 5C**, a guidewire **540** is advanced through the common iliac artery **504**, the substantially elliptical opening **526**, and the crown opening **528**.

[0036] Referring to **FIG. 5D**, a stent graft delivery system **542** holding a second stent graft component in a compressed configuration is advanced over the guidewire **540** to position the second stent graft component at the deployment site in the aortic aneurysm **500**.

[0037] Referring to **FIG. 5E**, the stent graft delivery system releases the second stent graft component **550** from the compressed configuration to expand at the deployment site. In one embodiment, the stent graft delivery system releases the second stent graft component **550** by retracting a sheath holding the second stent graft component **550** in the compressed configuration. The guidewire can be retracted from the aortic aneurysm **500** after the second stent graft component **550** expands. The body (not shown) of the second stent graft component **550** is located at the neck **506** of the aortic aneurysm **500** and the leg **554** of the second stent graft component **550** is located in the common iliac artery **504**. The second stent graft component **550** includes a substantially elliptical opening **556** (illustrated by dashed lines within the body **522** of the first stent graft component **520**) and a crown opening **558**.

[0038] The first stent graft component **520** and second stent graft component **550** fit together to provide a flow path past the aortic aneurysm **500** to the common iliac arteries **502**, **504**. The body (not shown) of the second stent graft component **550** is located within the body **522** of the first stent graft component **520**. In this example, the crown opening **558** of the second stent graft component **550** is substantially aligned with and inside of the crown opening **528** of the first stent graft component **520**. The leg **554** of the second stent graft component **550** is disposed through the first substantially elliptical opening **526** of the first stent graft

component **520** with the perimeter of the first substantially elliptical opening in contact with the body (not shown) of the second stent graft component **550**. The substantially elliptical opening **556** of the second stent graft component **550** is positioned to align with the lumen of the leg **524** of the first stent graft component **520**. In one embodiment, the first stent graft component **520** can be fastened to the second stent graft component **550** as desired to preclude leakage, with fasteners, such as sutures, staples, hooks, anchors, adhesives, rivets, screws, or the like. In another embodiment, a stent graft sleeve can be installed within the first stent graft component **520** and/or the second stent graft component **550** to provide an added seal.

[0039] Referring to **FIG. 5F**, the deployed stent graft system **560** includes the first stent graft component **520** and the second stent graft component **550**. In one embodiment, the material of the tubular graft can be thinner than the material of conventional stent grafts because the bodies of the stent graft components **520**, **550** overlap at the neck **506** of the aortic aneurysm **500** as illustrated by the hashed portion **562**. Those skilled in the art will appreciate that different deployment approaches are possible as desired for a particular application. For example, in another embodiment, the stent graft system can be deployed without the use of guidewires. In yet another embodiment, the stent graft system can be deployed through the common iliac artery or arteries.

[0040] **FIG. 6** is a close-up view of an elliptical opening stent for a stent graft system. The elliptical opening stent holds the substantially elliptical opening in the stent graft component open to receive the guidewire and stent graft delivery system during deployment and to seal with the other stent graft component after deployment. The elliptical opening stent has a small crossing profile when the stent graft component is in the compressed configuration. In this embodiment, the elliptical opening stent **600** includes a body portion **602** and a spring portion **604**. The body portion **602** has an even profile that allows the body stents to be crimped or wired to the body portion **602**. The spring portion **604** urges the substantially elliptical opening to an open configuration. The elliptical opening stent **600** can be attached to the tubular graft by suture, adhesive, lamination, or the like. The elliptical opening stent **600** need not be affixed directly to the graft material of the tubular graft.

[0041] **FIGS. 7-9** are additional embodiments of a stent graft component. **FIG. 7** is a side view of a stent graft component with a graft flap. The graft flap **700** is a flap of graft material integrally joined to the tubular graft **702**. The graft flap **700** extends outward near the leg intersection point **704** and beyond and around the support stent and springs of substantially

elliptical opening 706. The graft flap 700 can assist in sealing around the substantially elliptical opening between the two stent graft components of the deployed stent graft system. In one embodiment, the graft flap of one stent graft component is operably connected to the other stent graft component with fasteners, such as staples, sutures, adhesives, rivets, screws, or the like. In one embodiment, the graft flap extends partially around the substantially elliptical opening.

[0042] FIG. 8 is a side view of a stent graft component with an elliptical opening stent having longitudinally oriented peaks and a body elliptical stent. The elliptical opening stent 800 of the stent graft component 802 includes a number of peaks 804. The axes 806 of the peaks 804 are longitudinally oriented, which is defined as used herein as substantially oriented parallel to the longitudinal axis 808 of the stent graft component 802. In this embodiment, the stent graft component 802 also includes a body elliptical stent 810 operably connected around the body 812 opposite the substantially elliptical opening 814 and intersecting the leg intersection point 816. The body elliptical stent 810 in this example also has longitudinally oriented peaks and is symmetrical to the elliptical opening stent 800 across the axial mid-plane of the stent graft component 802. The body elliptical stent 810 in one stent graft component assists sealing about the other stent graft component in the deployed stent graft system.

[0043] FIG. 9 is a side view of a stent graft component with an elliptical opening stent having peaks oriented orthogonally to the substantially elliptical opening. The elliptical opening stent 900 of the stent graft component 902 includes a number of peaks 904. The axes 906 of the peaks 904 are oriented orthogonally to the substantially elliptical opening 908.

[0044] FIGS. 10A-10D, in which like elements share like reference numbers, are various views of an exemplary stent graft system. The figures illustrate an exemplary model of a stent graft system.

[0045] FIG. 10A is a side view of a stent graft component. The first stent graft component 1000 includes a tubular graft 1010, a crown stent 1032, body stents 1034, and leg stents 1036. The tubular graft 1010 has an integral body 1012 and leg 1014. The body 1012 has a longitudinal axis 1016 and a leg intersection point 1018 on or near the longitudinal axis 1016 where the leg 1014 meets the body 1012. The body 1012 defines a crown opening 1022 and a substantially elliptical opening 1024. The crown stent 1032 is operably connected around the crown opening 1022, the body stent 1034 is operably connected around the body 1012, and the leg stent 1036 is operably connected around the leg 1014. In this example, some of the

body stents **1034** are attached to the perimeter **1030** of the substantially elliptical opening **1024**, so the body stents acts as the elliptical opening stent.

[0046] FIG. 10B is a top view of a stent graft component. In this example, the crown stent **1032** includes an odd number of peaks around the perimeter **1021** of the crown opening **1022** and outside the body **1012**. The peaks of one stent graft component are complementary with the peaks of the other stent graft component in the stent graft system, so the peaks follow the whole perimeter of the crown opening to form a continuous row of peaks when the stent graft system is assembled.

[0047] FIG. 10C is a side view of a stent graft system. The stent graft system **1001** includes first stent graft component **1000** and second stent graft component **2000**. In this example, the first stent graft component **1000** is identical to the second stent graft component **2000**. The second stent graft component **2000** includes a tubular graft **2010**, an elliptical opening stent **2030**, a crown stent **2032**, a body stent **2034**, and a leg stent **2036**. The tubular graft **2010** has an integral body **2012** and leg **2014**. The body **2012** has a longitudinal axis **2016** and a leg intersection point **2018** on the longitudinal axis **2016** where the leg **2014** meets the body **2012**. The body **2012** defines a crown opening **2022** and a substantially elliptical opening **2024**. The crown stent **2032** is operably connected around the crown opening **2022**, the body stent **2034** is operably connected around the body **2012**, and the leg stent **2036** is operably connected around the leg **2014**. In this example, some of the body stents **2034** are attached to the perimeter **2030** of the substantially elliptical opening **2024**, so the body stents acts as the elliptical opening stent.

[0048] FIG. 10D is a side view of an assembled stent graft system. The assembled stent graft system **2001** has body **2012** of the second stent graft component **2000** disposed in the body **1012** of the first stent graft component **1000** with the crown opening **2022** of the second stent graft component **2000** substantially aligned with the crown opening **1022** of the first stent graft component **1000**. The second leg **2014** of the second stent graft component **2000** is disposed through the substantially elliptical opening **1024** of the first stent graft component **1000** with the perimeter of the first elliptical opening **1024** in contact with the body **2012** of the second stent graft component **2000**. The longitudinal axis **1016** of the first stent graft component **1000** is substantially aligned with the longitudinal axis **2016** of the second stent graft component **2000**. In this example, the peaks of the crown stent **1032** and the crown stent **2032** alternate around the perimeter of the crown opening.

[0049] FIGS. 11A & 11B, in which like elements share like reference numbers, are side views of another exemplary stent graft system. In this example, the body of the stent graft component blends into the leg. The stent graft component in this example does not include a graft flap. Because of the blending, the longitudinal axis is defined as lying along the circumference of the leg and passing through the body. The acute angle between the substantially elliptical opening and the longitudinal axis is defined by the angle between the longitudinal axis and a line in the plane of and bisecting the substantially elliptical opening, although the substantially elliptical opening and the longitudinal axis may not intersect. In this example, no elliptical opening stent is placed around the substantially elliptical opening.

[0050] FIG. 11A is a side view of a stent graft system. The stent graft system **3001** includes first stent graft component **3000** and second stent graft component **4000**. In this example, the first stent graft component **3000** is identical to the second stent graft component **4000**.

[0051] The first stent graft component **3000** includes a tubular graft **3010**, a crown stent **3032**, body stents **3034**, and leg stents **3036**. The tubular graft **3010** has an integral body **3012** and leg **3014**. The body **3012** has a longitudinal axis **3016** lying along the circumference of the leg **3014** and passing through the body **3012**. The body **3012** defines a crown opening **3022** and a substantially elliptical opening **3024**, the perimeter of which is illustrated by dashed lines. The crown stent **3032** is operably connected around the crown opening **3022**, the body stent **3034** is operably connected around the body **3012**, and the leg stent **3036** is operably connected around the leg **3014**.

[0052] The second stent graft component **4000** includes a tubular graft **4010**, an elliptical opening stent **4030**, a crown stent **4032**, a body stent **4034**, and a leg stent **4036**. The tubular graft **4010** has an integral body **4012** and leg **4014**. The body **4012** has a longitudinal axis **4016** lying along the circumference of the leg **4014** and passing through the body **4012**. The body **4012** defines a crown opening **4022** and a substantially elliptical opening **4024**, the perimeter of which is illustrated by dashed lines. The longitudinal axis **4016** and the substantially elliptical opening **4024** are divided by an acute angle α . The crown stent **4032** is operably connected around the crown opening **4022**, the body stent **4034** is operably connected around the body **4012**, and the leg stent **4036** is operably connected around the leg **4014**.

[0053] FIG. 11B is a side view of an assembled stent graft system. The assembled stent graft system **4001** has the body of the second stent graft component **4000** disposed in the body **3012** of the first stent graft component **3000** with the crown opening **4022** of the second stent

graft component **4000** substantially aligned with the crown opening **3022** of the first stent graft component **3000**. The second leg **4014** of the second stent graft component **4000** is disposed through the substantially elliptical opening **3024** of the first stent graft component **3000** with the perimeter of the first elliptical opening **3024** in contact with the body of the second stent graft component **4000**. The longitudinal axis **3016** of the first stent graft component **3000** is substantially aligned with the longitudinal axis **4016** of the second stent graft component **4000**. In this example, the peaks of the crown stent **3032** and the crown stent **4032** alternate around the perimeter of the crown opening.

[0054] FIG. 12 is a side view of another exemplary assembled stent graft system. In this example, the body of one stent graft component is longer than the body of the other stent graft component, so the crown openings of the two stent graft components are not substantially aligned.

[0055] The first stent graft component **5000** includes a tubular graft **5010**, a crown stent **5032**, body stents **5034**, and leg stents **5036**. The tubular graft **5010** has an integral body **5012** and leg **5014**. The body **5012** has a longitudinal axis **5016** lying along the circumference of the leg **5014** and passing through the body **5012**. The body **5012** defines a crown opening **5022** and a substantially elliptical opening **5024**, the perimeter of which is illustrated by dashed lines. The crown stent **5032** is operably connected around the crown opening **5022**, the body stent **5034** is operably connected around the body **5012**, and the leg stent **5036** is operably connected around the leg **5014**.

[0056] The second stent graft component **6000** includes a tubular graft **6010**, a crown stent **6032**, body stents (not shown), and leg stents **6036**. The tubular graft **6010** has an integral body **6012** and leg **6014**. The body **6012** has a longitudinal axis **6016** lying along the circumference of the leg **6014** and passing through the body **6012**. The body **6012** defines a crown opening **6022** and a substantially elliptical opening (not shown). The crown stent **6032** is operably connected around the crown opening **6022**, the body stent (not shown) is operably connected around the body **6012**, and the leg stent **6036** is operably connected around the leg **6014**.

[0057] The assembled stent graft system **6001** has the body **6012** of the second stent graft component **6000** disposed in the body **5012** of the first stent graft component **5000** with the crown opening **6022** of the second stent graft component **6000** aligned longitudinally above the crown opening **5022** of the first stent graft component **5000**. The second leg **6014** of the second stent graft component **6000** is disposed through the substantially elliptical opening

5024 of the first stent graft component **5000** with the perimeter of the first elliptical opening **5024** in contact with the body **6012** of the second stent graft component **6000**. The longitudinal axis **5016** of the first stent graft component **5000** is substantially aligned with the longitudinal axis **6016** of the second stent graft component **6000**.

[0058] While specific embodiments are disclosed herein, various changes and modifications can be made without departing from the spirit and scope of the invention.

CLAIMS

1. A stent graft system comprising:
a first stent graft component comprising a first tubular graft having an integral first body and first leg, the first body having a first longitudinal axis, the first body defining a first crown opening and a first substantially elliptical opening, the first substantially elliptical opening being oriented at a first acute angle to the first longitudinal axis; and
a second stent graft component comprising a second tubular graft having an integral second body and second leg, the second body having a second longitudinal axis, the second body defining a second crown opening and a second substantially elliptical opening, the second substantially elliptical opening being oriented at a second acute angle to the second longitudinal axis;
wherein the second body is disposed in the first body, and the second leg is disposed through the first substantially elliptical opening with the perimeter of the first elliptical opening in contact with the second body.
2. The stent graft system of claim 1 wherein the first stent graft component further comprises a first elliptical opening stent operably connected to the first substantially elliptical opening, and the second stent graft component further comprises a second elliptical opening stent operably connected to the second substantially elliptical opening.
3. The stent graft system of claim 1 wherein the first stent graft component is identical to the second stent graft component.
4. The stent graft system of claim 1 wherein the second crown opening is substantially aligned with the first crown opening.
5. The stent graft system of claim 1 wherein friction between the second body and the first body holds the second body in place relative to the first body.
6. The stent graft system of claim 1 further comprising fasteners operably connecting the second body to the first body.

7. The stent graft system of claim 1 further comprising a graft flap integrally joined to the first tubular graft, the graft flap extending at least partially around the first substantially elliptical opening.
8. The stent graft system of claim 7 further comprising fasteners operably connecting the graft flap to the second stent graft component.
9. The stent graft system of claim 1 further comprising a body elliptical stent operably connected around the second body opposite the second substantially elliptical opening.
10. The stent graft system of claim 1 wherein the first stent graft component further comprises a first crown stent operably connected about the first crown opening and the second stent graft component further comprises a second crown stent operably connected about the second crown opening, the first crown stent includes first peaks outside the first body, the second crown stent includes second peaks outside the second body, and the first peaks are complementary with the second peaks to form a continuous row of peaks.
11. A stent graft comprising:
a tubular graft having an integral body and leg, the body having a longitudinal axis, the body defining a crown opening and a substantially elliptical opening, the substantially elliptical opening being oriented at an acute angle to the longitudinal axis;
an elliptical opening stent operably connected to the substantially elliptical opening; and
a crown stent operably connected about the crown opening.
12. The stent graft of claim 11 further comprising a graft flap integrally joined to the tubular graft, the graft flap extending at least partially around the substantially elliptical opening.
13. The stent graft of claim 11 further comprising a body stent operably connected around the body, wherein the elliptical opening stent is the body stent.

14. The stent graft of claim 11 wherein the elliptical opening stent is disposed around the substantially elliptical opening.

15. The stent graft of claim 14 further comprising a body stent operably connected around the body, wherein the elliptical opening stent is attached to the body stent.

16. The stent graft of claim 14 wherein the elliptical opening stent includes a spring portion.

17. The stent graft of claim 14 wherein the elliptical opening stent includes longitudinally oriented peaks.

18. The stent graft of claim 14 wherein the elliptical opening stent includes peaks oriented orthogonally to the substantially elliptical opening.

19. The stent graft of claim 12 further comprising a body elliptical stent operably connected around the body opposite the substantially elliptical opening.

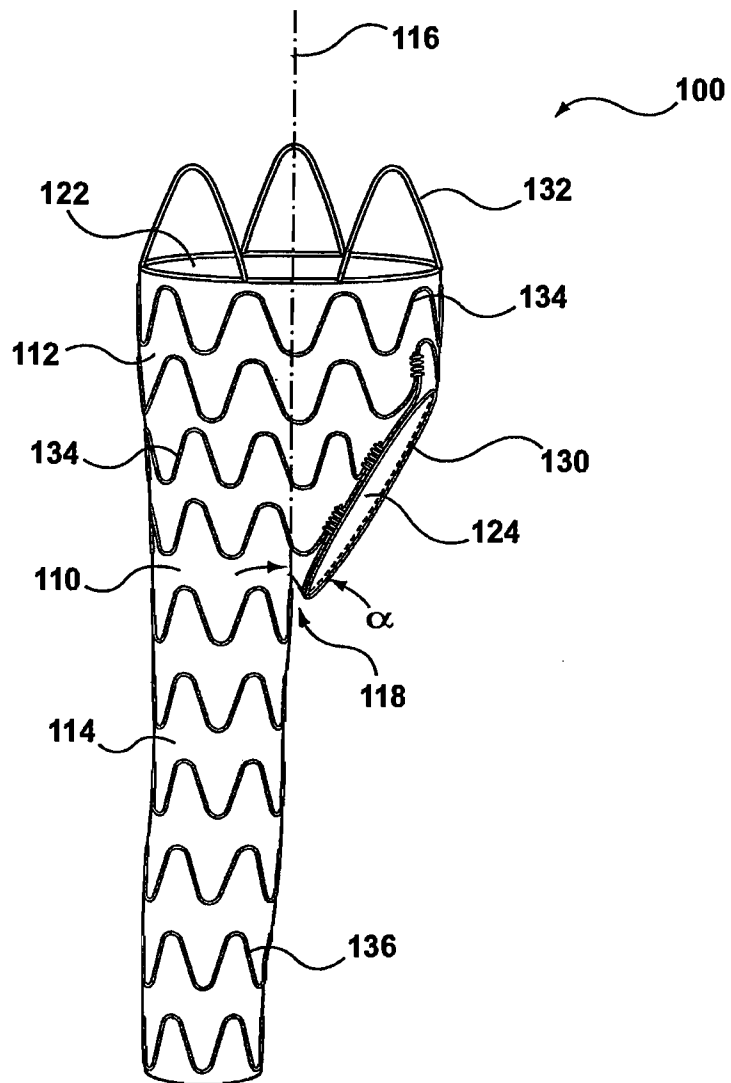
20. The stent graft of claim 12 further comprising a body stent operably connected around the body and a leg stent operably connected around the leg.

21. The stent graft of claim 12 wherein the acute angle is between 20 degrees and 70 degrees.

22. A method of use of a stent graft system comprising:
positioning a first stent graft component in a first compressed configuration at a deployment site, the first stent graft component comprising:
a first tubular graft having an integral first body and first leg, the first body having a first longitudinal axis, the first body defining a first crown opening and a first substantially elliptical opening, the first substantially elliptical opening being oriented at a first acute angle to the first longitudinal axis; and
a first elliptical opening stent operably connected to the first substantially elliptical opening;
releasing the first stent graft component from the first compressed configuration to expand at the deployment site;
advancing a second stent graft component in a second compressed configuration through the first substantially elliptical opening to the deployment site, the second stent graft component comprising:
a second tubular graft having an integral second body and second leg, the second body having a second longitudinal axis, the second body defining a second crown opening and a second substantially elliptical opening, the second substantially elliptical opening being oriented at a second acute angle to the second longitudinal axis; and
a second elliptical opening stent operably connected to the second substantially elliptical opening;
releasing the second stent graft component from the second compressed configuration to expand with the second body within the first body and the second leg disposed through the first substantially elliptical opening with the perimeter of the first substantially elliptical opening in contact with the second body.
23. The method of claim 22 further comprising attaching the first stent graft component to the second stent graft component.
24. The method of claim 22 wherein the positioning comprises positioning the first stent graft component in a first compressed configuration at the deployment site

through a first common iliac artery, and the advancing a second stent graft component comprises advancing the second stent graft component from a second common iliac artery through the first substantially elliptical opening.

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**FIG. 1**

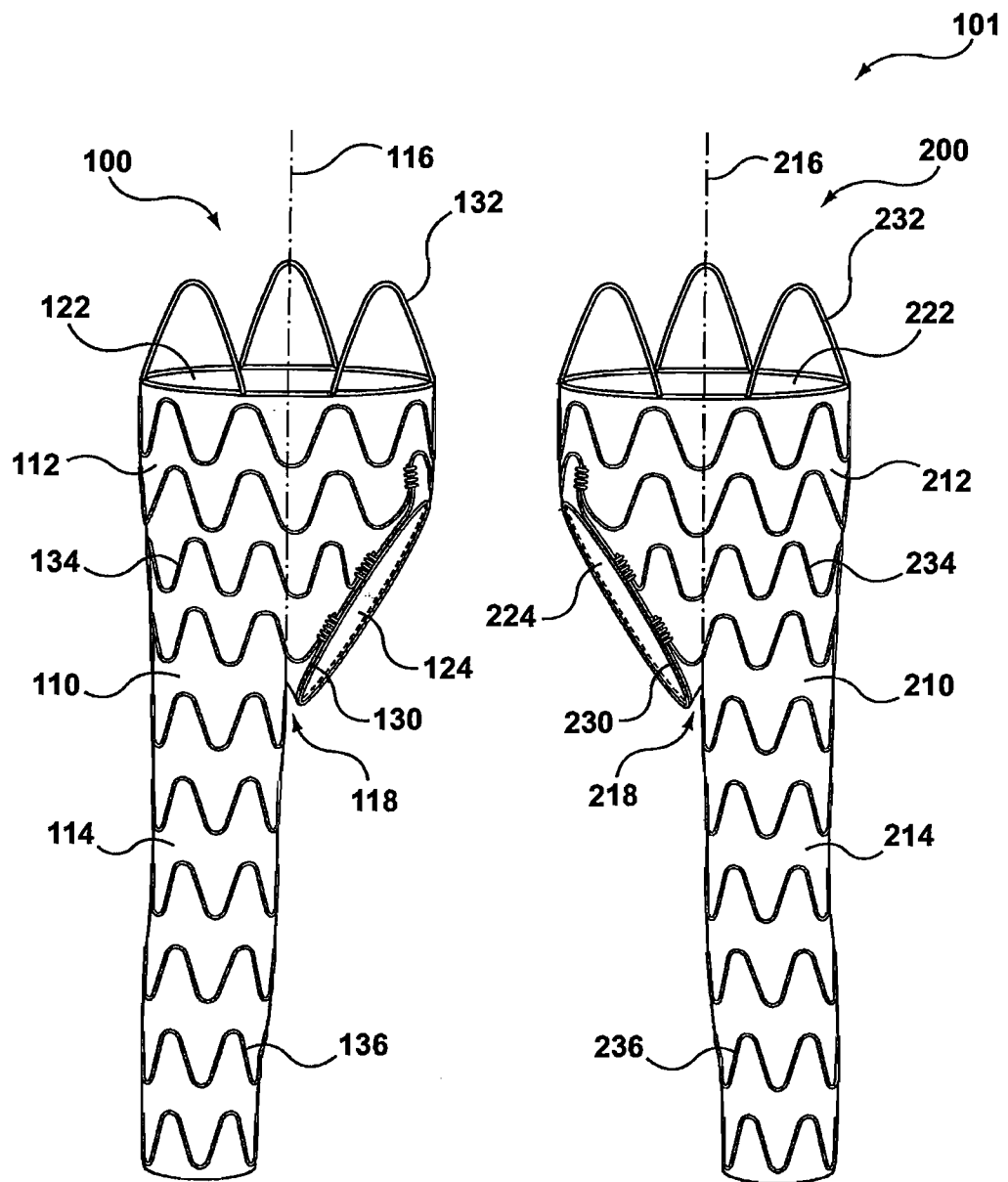


FIG. 2

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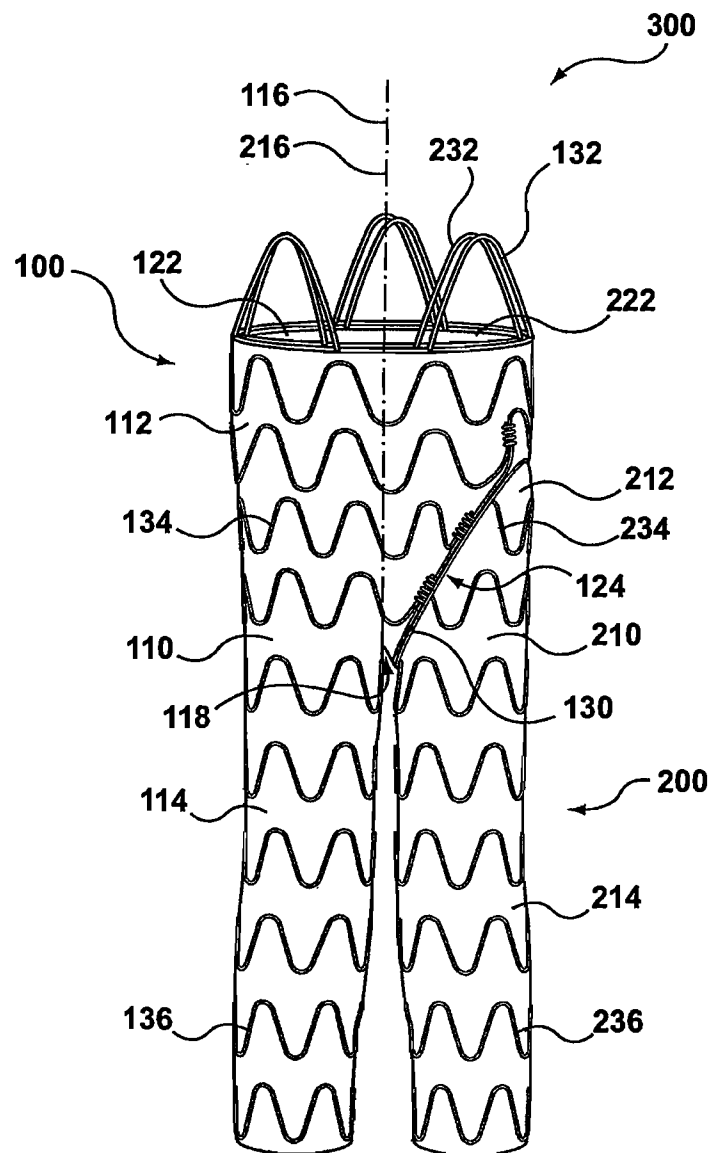
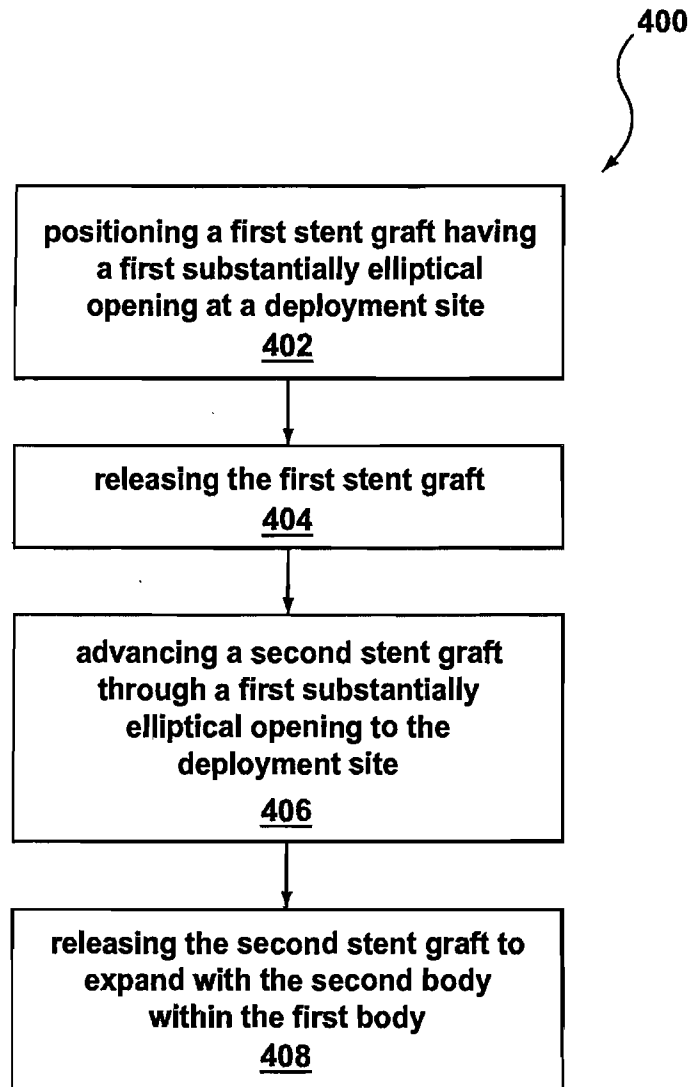


FIG. 3

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**FIG. 4**

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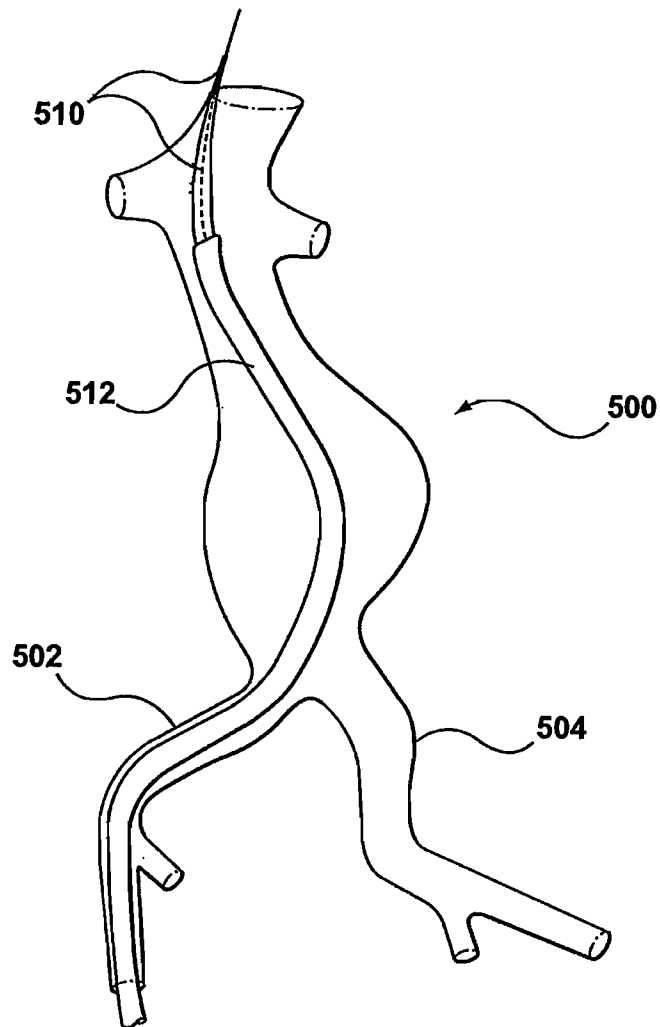


FIG. 5A

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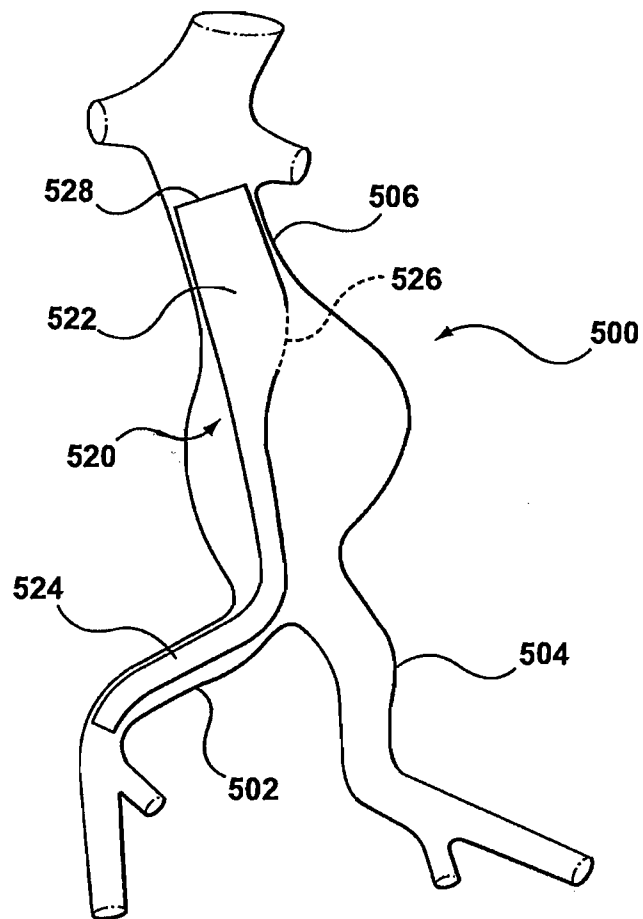


FIG. 5B

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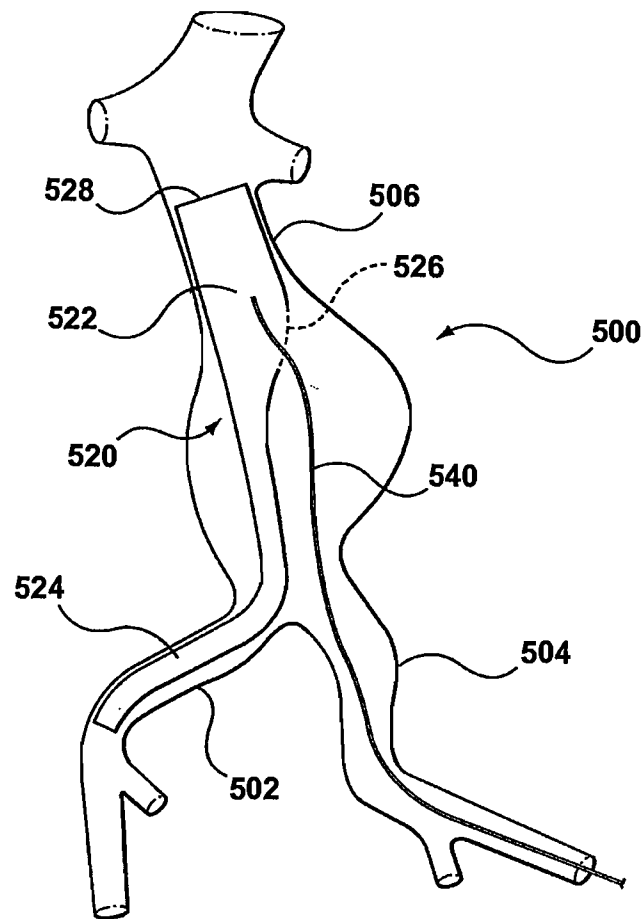


FIG. 5C

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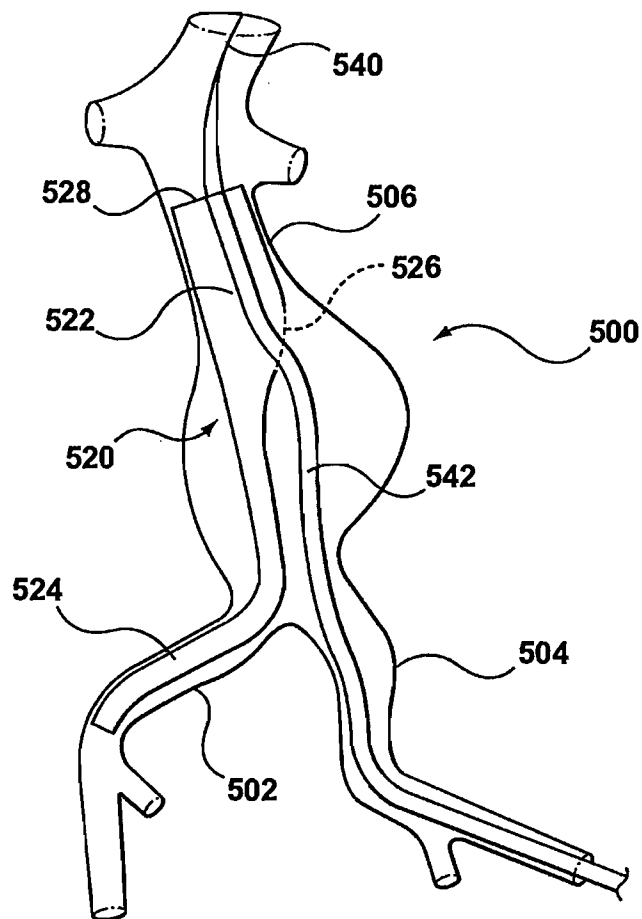


FIG. 5D

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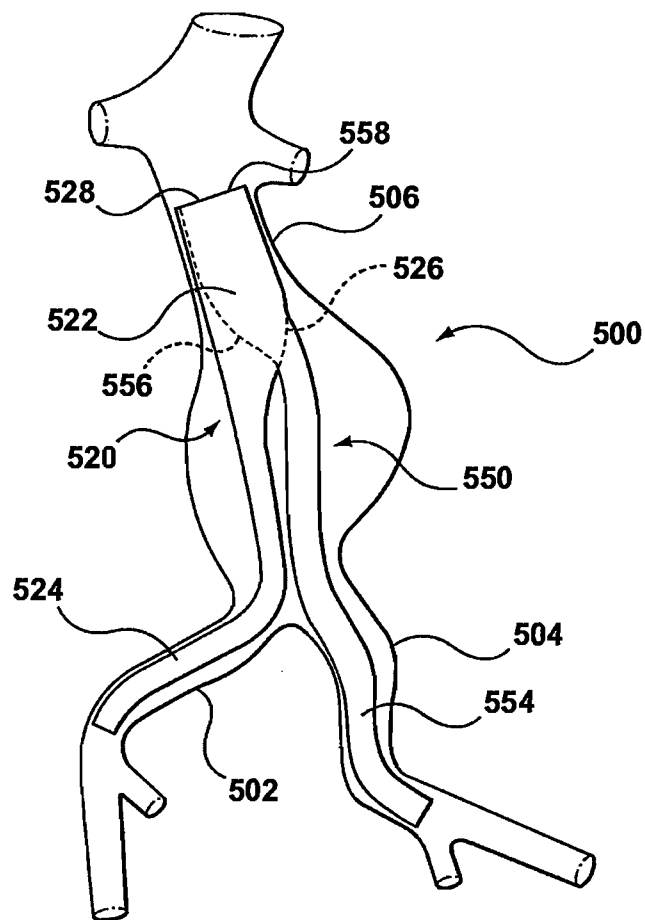


FIG. 5E

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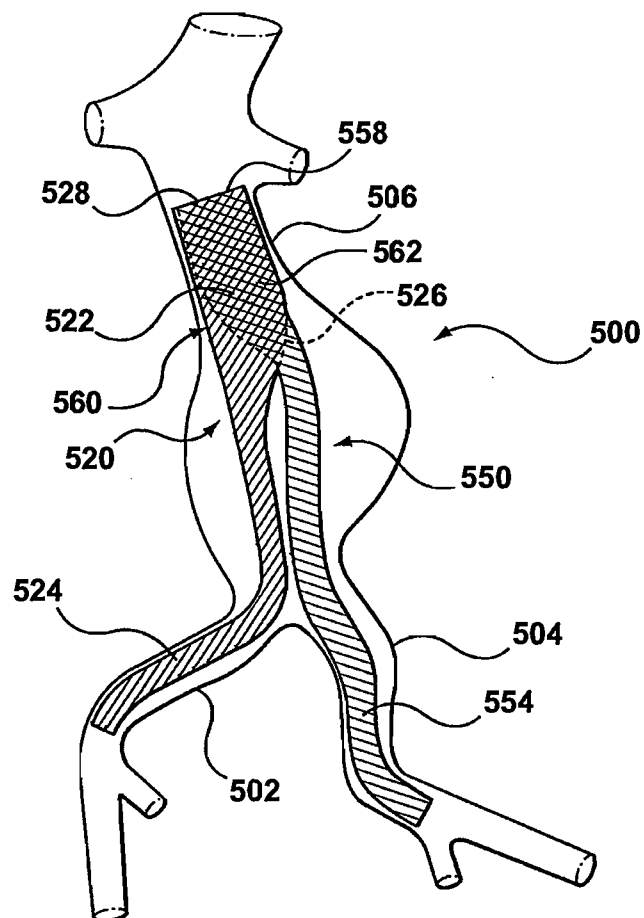


FIG. 5F

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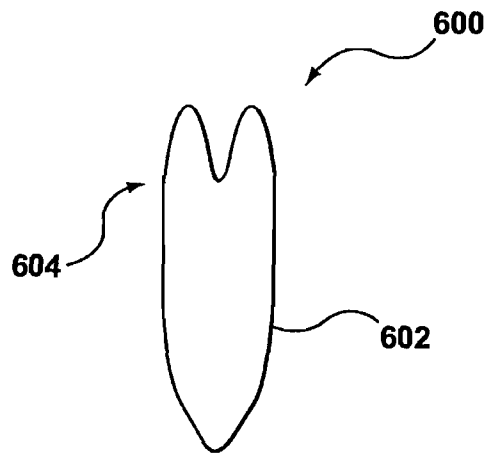


FIG. 6

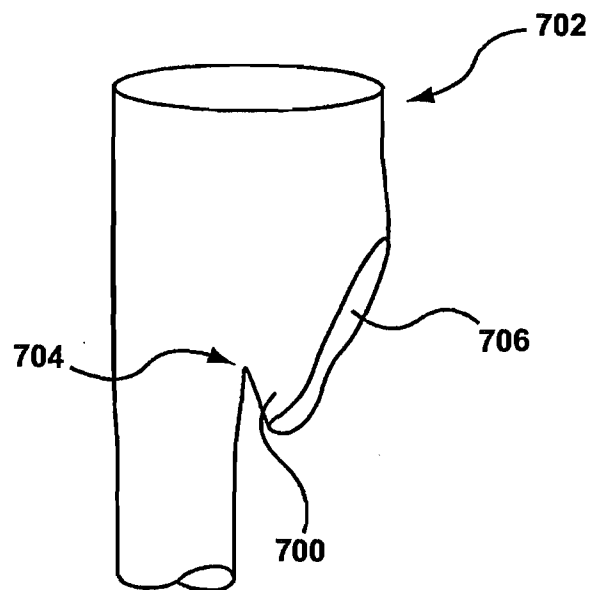


FIG. 7

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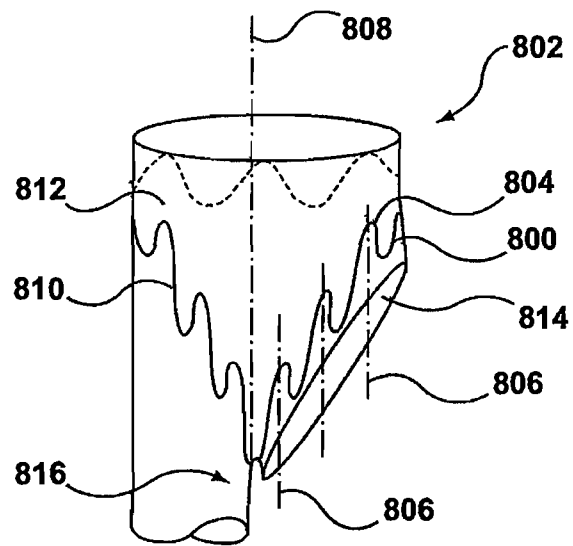


FIG. 8

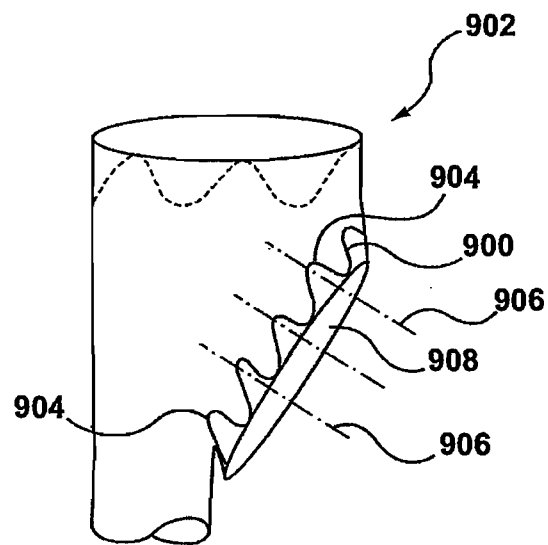


FIG. 9

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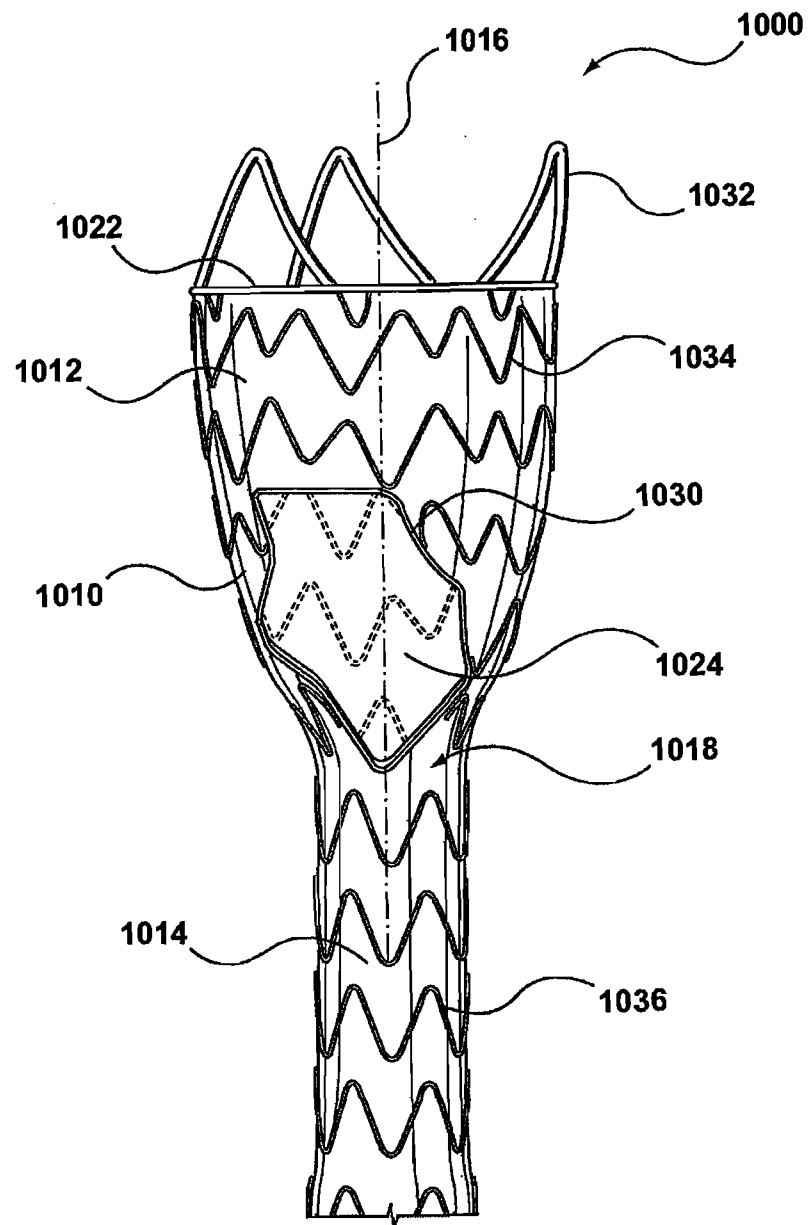


FIG. 10A

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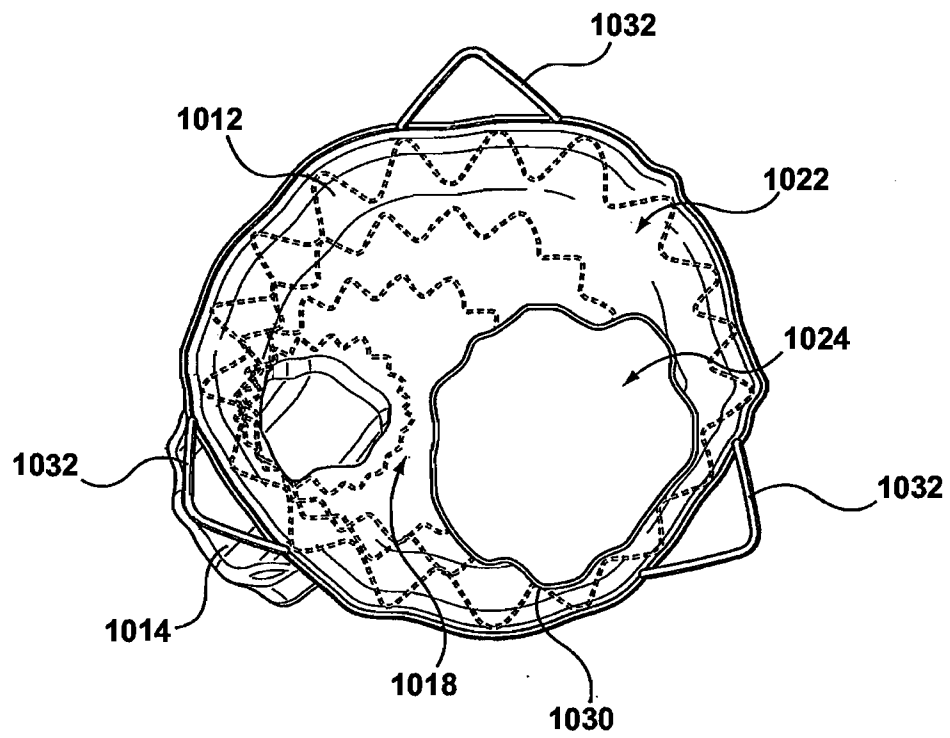


FIG. 10B

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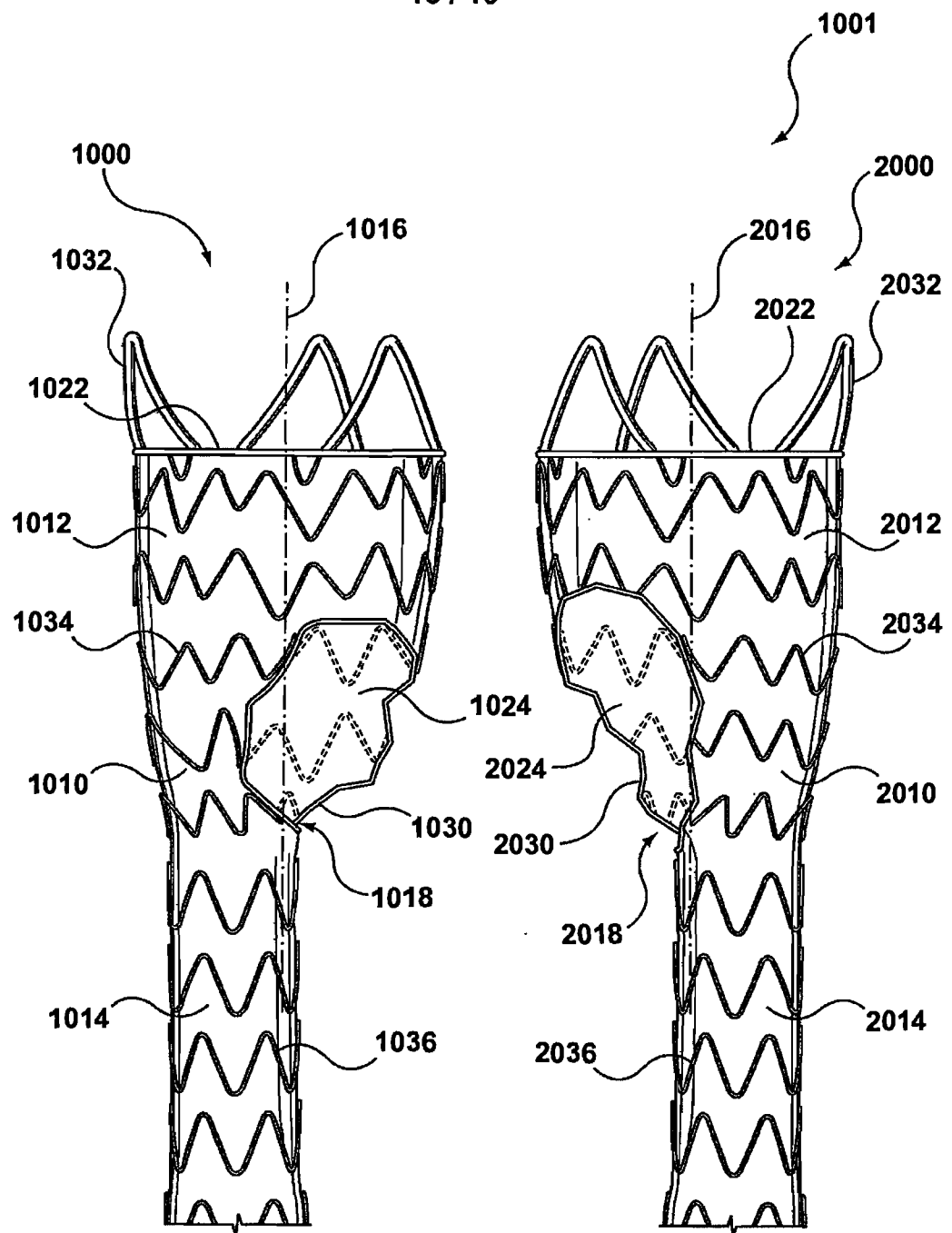


FIG. 10C

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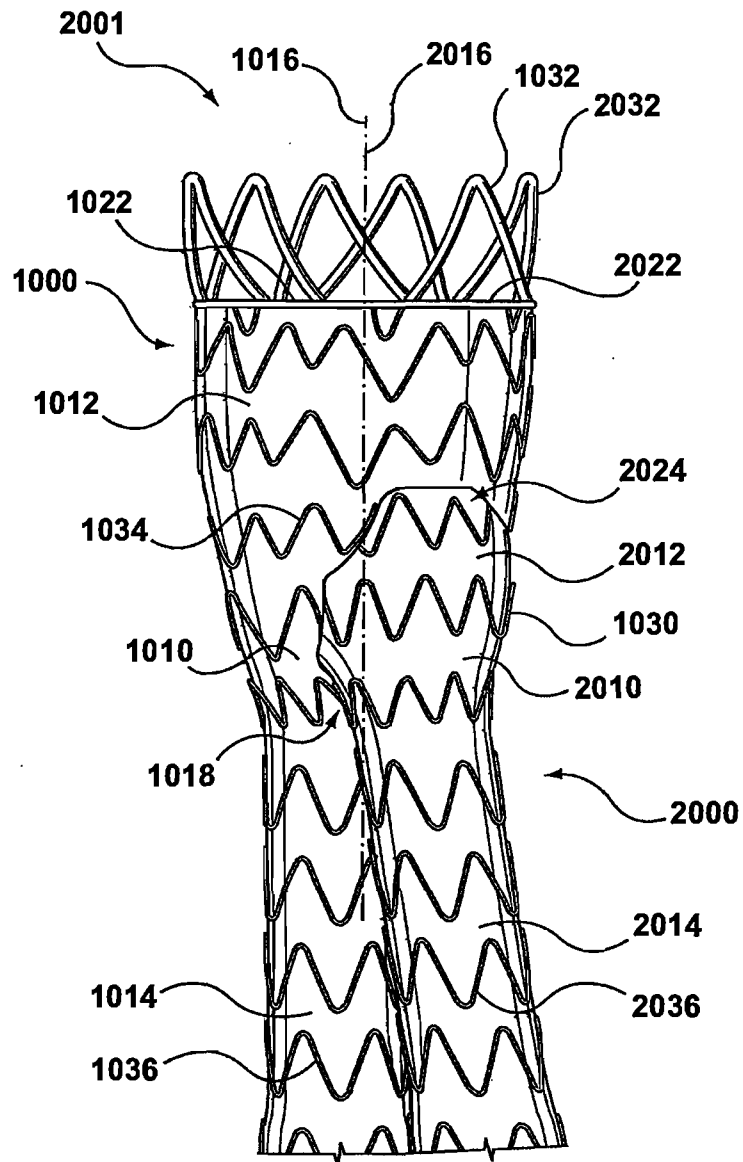


FIG. 10D

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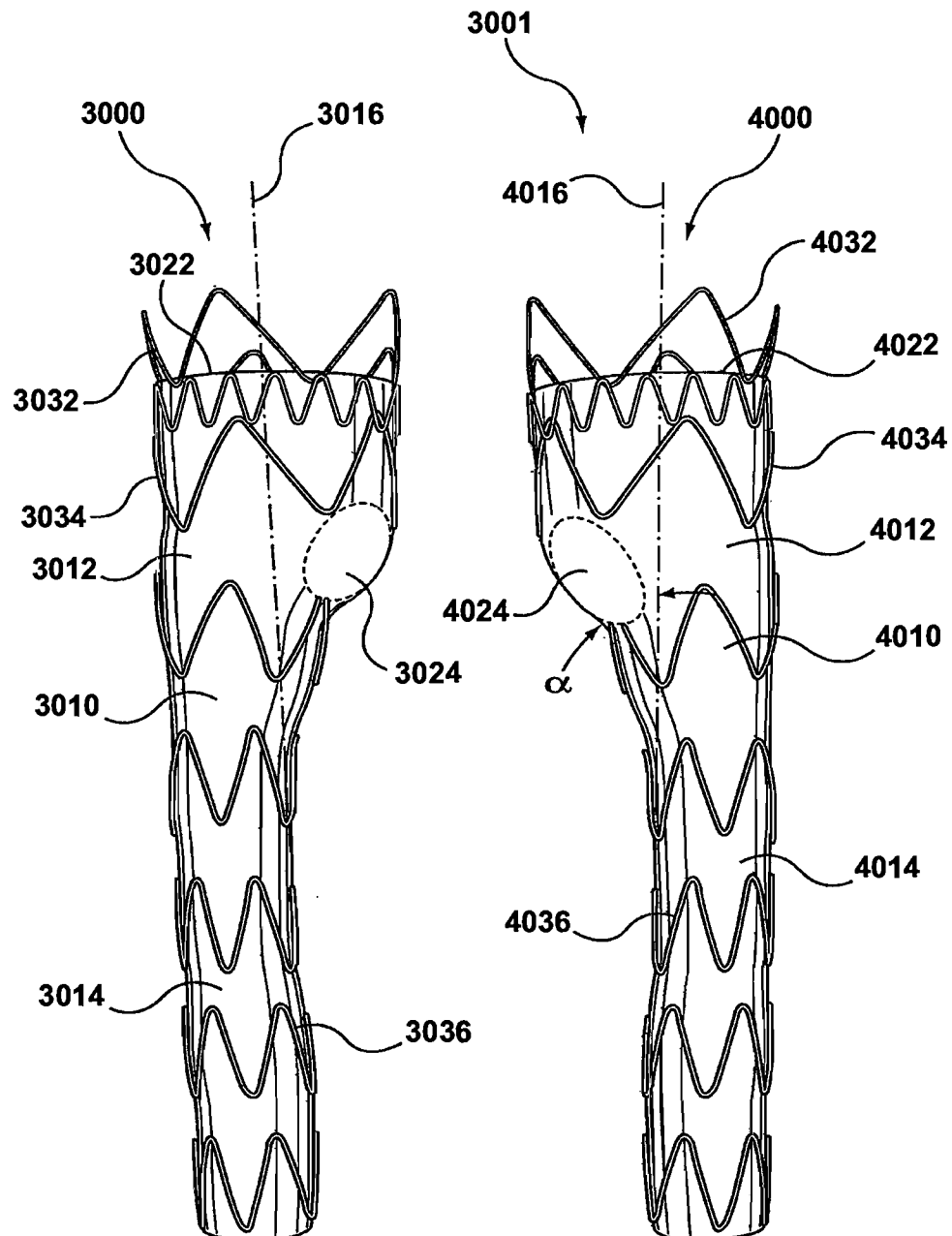


FIG. 11A

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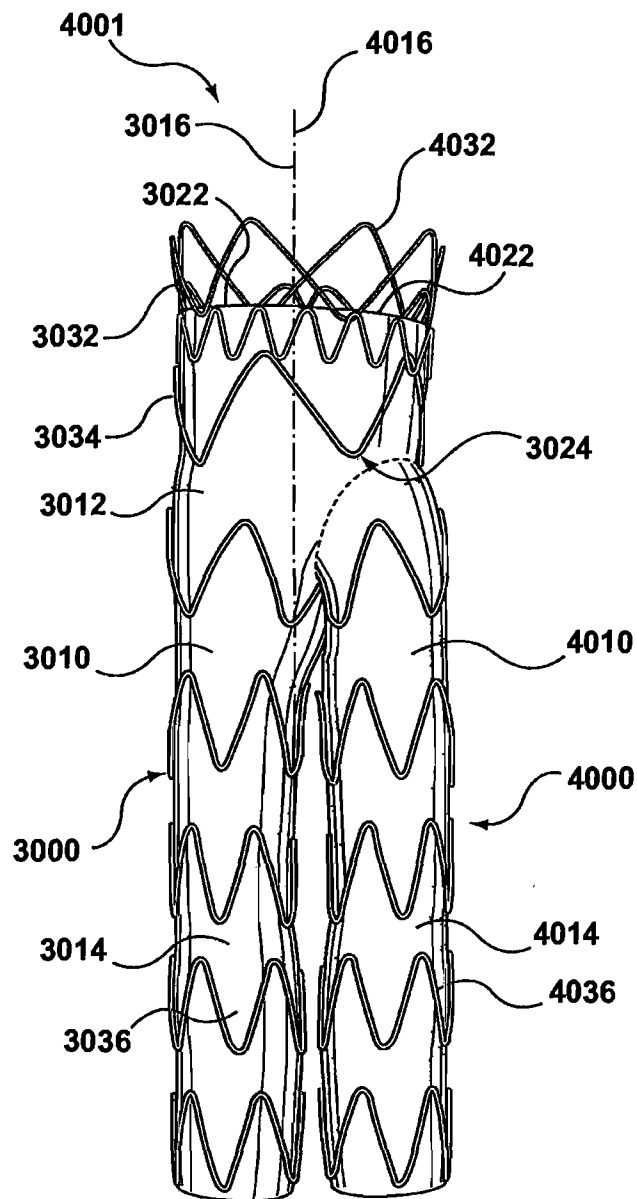


FIG. 11B

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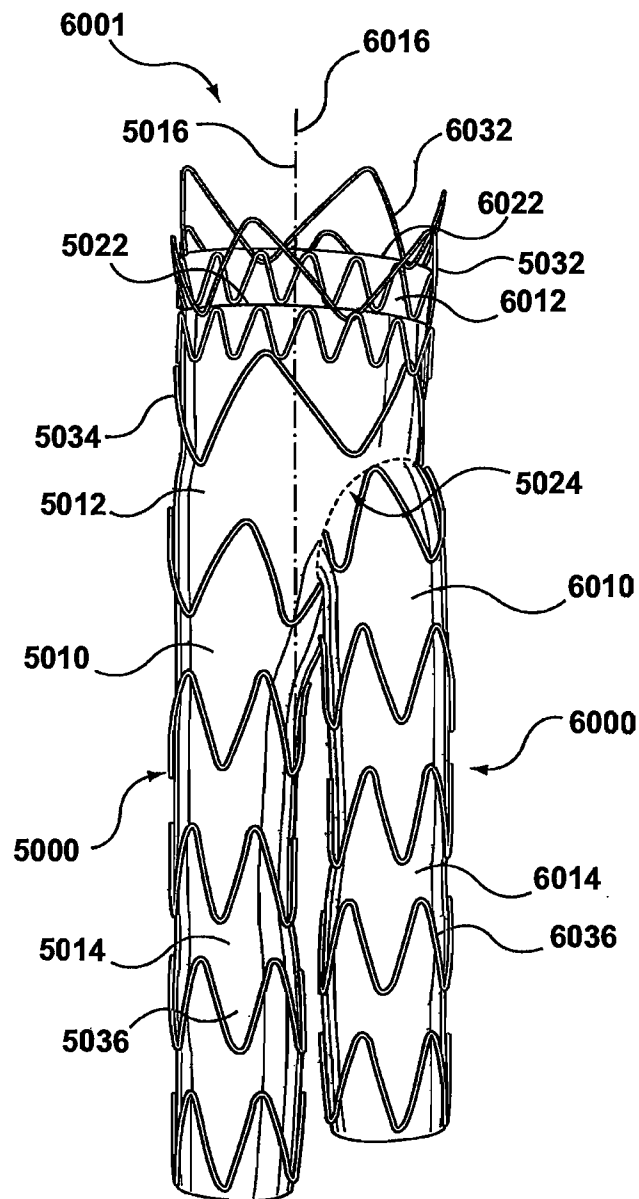


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/044892

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/06
ADD.

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 practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/21102 A1 (EDWARDS LIFESCIENCES CORP [US]; ENDOGAD RES PTY LTD [AU]) 29 March 2001 (2001-03-29)	1,3-6,10
Y	page 14, line 14 - line 27; figures 8-12	2,7-9, 20,21
X	----- WO 2004/089249 A1 (COOK WILLIAM A AUSTRALIA [AU]; COOK WILLIAM EUROP [DK]; COOK INC [US];) 21 October 2004 (2004-10-21)	11-19
Y	page 12, last paragraph - page 14, paragraph 2; figures 6-9	2,7-9, 20,21
X	----- US 2003/088306 A1 (RAKOS RONALD [US] ET AL) 8 May 2003 (2003-05-08)	1,5
A	paragraphs [0017], [0019], [0022], [0025]; figures 1,2,5	11
	----- -/--	

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

☒ 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

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"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

28 September 2011

Date of mailing of the international search report

07/10/2011

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Neumann, Elisabeth

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/044892

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2009/085186 A1 (MED INST INC [US]; DIERKING WILLIAM K [US]; ROEDER BLAYNE A [US]; LEEW) 9 July 2009 (2009-07-09) page 7, line 19 - line 26; figures page 14, line 15 - line 21 -----	1,3,11
A	WO 03/082153 A2 (COOK INC [US]; COOK WILLIAM A AUSTRALIA [AU]; COOK WILLIAM EUROP [DK]) 9 October 2003 (2003-10-09) page 3, paragraph 5 - paragraph 7; figure 3 -----	11,13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/044892

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

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

1. ☒ Claims Nos.: 22-24
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal 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

Information on patent family members

International application No

PCT/US2011/044892

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