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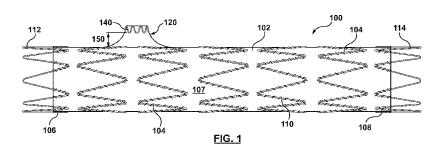
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(57) Abstract: An endovascular prosthesis includes a tubular body and a mobile external coupling. The tubular body includes a graft material and stents coupled thereto, and forms a lumen therethrough. The mobile external coupling includes a graft material, extends outwardly from the tubular body, and is generally frustoconically shaped. The mobile external coupling includes a base coupled to the tubular body, a top spaced from the tubular body, and a coupling lumen disposed between the base and the top that is in flow communication with the body lumen. An annular support wireform is coupled to the mobile external coupling, and is formed into a sinusoidal configuration having a plurality of opposing first crowns and second crowns, the first crowns of the support wireform extending around of the top of the mobile external coupling. The coupling graft material extending between the second crowns of the support wireform and the tubular body is unsupported.





### MOBILE EXTERNAL COUPLING FOR BRANCH VESSEL CONNECTION

### FIELD OF ART

**[0001]** This invention relates generally to endoluminal medical devices and procedures, and more particularly to an endoluminal prosthesis or graft having a mobile external coupling for connecting a main graft to a branch vessel graft.

### **BACKGROUND**

[0002] Aneurysms and/or dissections may occur in blood vessels, and most typically occur in the aorta and peripheral arteries. Depending on the region of the aorta involved, the aneurysm may extend into areas having vessel bifurcations or segments of the aorta from which smaller "branch" arteries extend. Various types of aortic aneurysms may be classified on the basis of the region of aneurysmal involvement. For example, thoracic aortic aneurysms include aneurysms present in the ascending thoracic aorta, the aortic arch, and branch arteries that emanate therefrom, such as subclavian arteries, and also include aneurysms present in the descending thoracic aorta and branch arteries that emanate therefrom, such as thoracic intercostal arteries and/or the suprarenal abdominal aorta and branch arteries that emanate therefrom, such as superior mesenteric, celiac and/or intercostal arteries. Lastly, abdominal aortic aneurysms include aneurysms present in the aorta below the diaphragm, e.g., pararenal aorta and the branch arteries that emanate therefrom, such as the renal arteries.

[0003] The thoracic aorta has numerous arterial branches. The arch of the aorta has three major branches extending therefrom, all of which usually arise from the convex upper surface of the arch and ascend through the superior thoracic aperture. The brachiocephalic artery originates anterior to the trachea. The brachiocephalic artery divides into two branches, the right subclavian artery (which supplies blood to the right arm) and the right common carotid artery (which supplies blood to the right side of the head and neck). The left common carotid artery arises from the arch of the aorta just to the left of the origin of the brachiocephalic artery. The left common carotid artery supplies blood to the left side of the head and neck. The third branch arising from the aortic arch, the left subclavian artery, originates behind and just to the left of the origin of the left common carotid artery and supplies blood to the left arm.

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**[0004]** For patients with thoracic aneurysms of the aortic arch, surgery to replace the aorta may be performed where the aorta is replaced with a fabric substitute in an operation that uses a heart-lung machine. In such a case, the aneurysmal portion of the aorta is removed or opened and a substitute lumen is sewn across the aneurysmal portion to span it. Such surgery is highly invasive, requires an extended recovery period and, therefore, cannot be performed on individuals in fragile health or with other contraindicative factors.

Alternatively, the aneurysmal region of the aorta can be bypassed by use of [0005] am endoluminally delivered tubular exclusion device, e.g., by a stent-graft placed inside the vessel spanning the aneurysmal portion of the vessel, to seal off the aneurysmal portion from further exposure to blood flowing through the aorta. A stentgraft can be implanted without a chest incision, using specialized catheters that are introduced through arteries, usually through incisions in the groin region of the patient. The use of stent-grafts to internally bypass, within the aorta or flow lumen, the aneurysmal site, is also not without challenges. In particular, where a stent-graft is used at a thoracic location, care must be taken so that critical branch arteries are not covered or occluded by the stent-graft yet the stent-graft must seal against the aorta wall and provide a flow conduit for blood to flow past the aneurysmal site. Where the aneurysm is located immediately adjacent to the branch arteries, there is a need to deploy the stent-graft in a location which partially or fully extends across the location of the origin of the branch arteries from the aorta to ensure sealing of the stent-graft to the artery wall.

[0006] To accommodate side branches, main vessel stent-grafts having a fenestration or opening in a side wall thereof may be used. The main vessel stent graft is positioned to align its fenestration with the ostium of the branch vessel. In use, a proximal end of the stent-graft, having one or more side openings, is prepositioned and securely anchored in place so that its fenestrations or openings are oriented when deployed to avoid blocking or restricting blood flow into the side branches. Fenestrations by themselves do not form a tight seal or include discrete conduit(s) through which blood can be channeled into the adjacent side branch artery. As a result, blood leakage is prone to occur into the space between the outer surface of the main aortic stent graft and the surrounding aortic wall between the edge of the graft material surrounding the fenestrations and the adjacent vessel wall. Similar blood leakage can result from post-implantation migration or movement of the stent-graft

causing misalignment between the fenestration(s) and the branch artery(ies), which may also result in impaired flow into the branch artery(ies).

**[0007]** In some cases, the main vessel stent graft is supplemented by another stent-graft, often referred to as a branch stent-graft. The branch graft is deployed through the fenestration into the branch vessel to provide a conduit for blood flow into the branch vessel. The branch stent-graft is preferably sealingly connected to the main graft *in situ* to prevent undesired leakage between it and the main stent-graft. This connection between the branch graft and main graft may be difficult to create effectively *in situ* and is a site for potential leakage.

**[0008]** In some instances, branch graft extensions (stent-grafts) are incorporated into the main stent-graft. Such branch graft extensions are folded or collapsed against the main stent-graft for delivery and require complicated procedures, requiring multiple sleeves and guide wires, to direct the branch extension into the branch vessel and subsequently expand. Further, in some instances, such branch stent-grafts tend to return to their folded or collapsed configuration, and thus do not provide an unobstructed flow path to the branch vessel.

**[0009]** Thus, there remains a need in the art for improvements in stent graft structures for directing flow from a main vessel, such as the aorta, into branch vessels emanating therefrom, such as branch vessels of the aortic arch.

### SUMMARY

**[0010]** Embodiments hereof relate to an endovascular prosthesis including a tubular body and a mobile external coupling. The tubular body includes a graft material and stents coupled thereto, and forms a lumen therethrough. The mobile external coupling extends outwardly from the tubular body. The mobile external coupling includes graft material and is generally frustoconically shaped. The mobile external coupling includes a base coupled to the tubular body, a top spaced from the tubular body in its extended configuration, and a coupling lumen disposed between the base and the top, wherein the coupling lumen is in flow communication with the body lumen. An annular support wireform is attached to, and extends around the mobile external coupling. The annular support wireform is formed into a generally sinusoidal configuration having a plurality of opposing crowns connecting generally straight segments together. The support wireform is oriented such that a longitudinal axis of

the support wireform is generally co-linear with the longitudinal axis of the mobile external coupling. The support wireform is also oriented such that first crowns of the support wireform extend around of the top of the mobile external coupling and second crowns of the wireform are spaced from the top of the mobile external coupling. The coupling graft material extending between second crowns of the support wireform and the tubular body is unsupported.

### **BRIEF DESCRIPTION OF DRAWINGS**

[0011] FIG. 1 is a schematic side view of an endoluminal stent-graft illustrating an embodiment hereof.

**[0012]** FIG. 2 is a schematic close up illustration of a portion of the stent-graft of FIG. 1, the stent-graft having a mobile external coupling with a support wireform coupled thereto.

**[0013]** FIG. 3 is a schematic perspective view of the support wireform removed from the mobile external coupling.

[0014] FIG. 4 is a schematic perspective view of a support wireform according to another embodiment hereof.

[0015] FIG. 5A is a schematic close up illustration of a portion of the stent-graft of FIG. 1, the stent-graft having the mobile external coupling with the support wireform coupled thereto via continuous stitching.

**[0016]** FIG. 5B is a schematic close up illustration of a portion of the stent-graft of FIG. 1, the stent-graft having the mobile external coupling with the support wireform coupled thereto via intermittent stitching.

**[0017]** FIG. 6 is a schematic illustration of a ring that may be used with the mobile external coupling of the stent-graft of FIG. 1.

**[0018]** FIG. 7 is a schematic illustration of the mobile external coupling of the stent-graft of FIG. 1, showing rings disposed at the top and bottom of the mobile external coupling.

**[0019]** FIG. 8 is a schematic close up illustration of a portion of the stent-graft of FIG. 1, the stent-graft having a mobile external coupling with the support wireform coupled thereto, the mobile external coupling having excess material according to another embodiment hereof.

**[0020]** FIG. 9 is a schematic illustration of the mobile external coupling of FIG. 1 having a branch vessel conduit deployed therein.

[0021] FIG. 10 is a schematic close up illustration of a portion of the stent-graft of FIG. 1, the stent-graft having the mobile external coupling with a support wireform according to another embodiment hereof coupled to the mobile external coupling.

[0022] FIG. 11 is a schematic illustration of a stent-graft delivery device.

[0023] FIG. 12 is a schematic illustration of a proximal portion of the stent-graft delivery device of FIG. 11.

[0024] FIG. 13 is a schematic illustration of a distal portion of the stent-graft delivery device of FIG. 11 with a stent-graft disposed therein.

**[0025]** FIG. 14 is a schematic illustration of a stent graft with a side tube for the second guide wire extending through a lumen of the tubular body of the stent-graft and through a lumen of the mobile external coupling.

[0026] FIG. 15 is a schematic illustration of a stent stop including grooves for the side tube.

[0027] FIG. 16 is a schematic illustration of a stent capture assembly of the delivery system of FIG. 11.

[0028] FIG. 17 is a schematic illustration of the tip of the delivery system of FIG. 11.

**[0029]** FIGS. 18-21 are schematic illustrations of progressive steps of deploying the stent-graft from the delivery system of FIG. 11.

[0030] FIGS. 22-27 are schematic illustrations of progressive steps a method for delivering and deploying the stent-graft of FIG. 1 and a branch stent-graft to a target location

### **DETAILED DESCRIPTION**

[0031] Specific embodiments are now described with reference to the figures, wherein like reference numbers indicate identical or functionally similar elements. Unless otherwise indicated, for the delivery system the terms "distal" and "proximal" are used in the following description with respect to a position or direction relative to the treating clinician. "Distal" and "distally" are positions distant from or in a direction away from the clinician, and "proximal" and "proximally" are positions near or in a direction toward the clinician. For the stent graft device "proximal" is the portion nearer the heart by way of blood flow path while "distal" is the portion of the stent graft further from the heart by way of blood flow path.

[0032] With reference to FIGS. 1-2, a stent-graft 100 is configured for placement in a vessel such as the aorta. Stent-graft 100 includes graft material 102 coupled to circumferential stents 104. Graft material 102 may be coupled to circumferential stents 104 using stitching 110 or other means known to those of skill in the art. In the embodiment shown in FIGS. 1-2 circumferential stents 104 are coupled to an outside surface of graft material 102. However, circumferential stents 104 may alternatively be coupled to an inside surface of graft material 102. Graft material 102 may be any suitable graft material, for example and not limited to, woven polyester, DACRON® material, expanded polytetrafluoroethylene, polyurethane, silicone, or other suitable materials. Circumferential stents 104 may be any conventional stent material or configuration. As shown, circumferential stents 104 are preferably made from a shape memory material, such as thermally treated stainless steel or nickel-titanium alloy (nitinol), and are formed into a zig-zag configuration. Stent-graft 100 includes a proximal end 106, a distal end 108, and a body 107 therebetween. Proximal stent 112 and distal stent 114 may extend outside of the graft material 102, as shown, and may also be generally described as anchor stents or crown stents in the art. Body 107 has a lumen 116 therethrough. Stent-graft 100 further includes a mobile external coupling 120, described in detail below. Except for the mobile external coupling 120, stent graft-100 may be similar to the Medtronic, Inc.'s VALIANT® thoracic stent-graft, or other known stent-grafts.

[0033] Mobile external coupling 120 is disposed on an outside surface of stent-graft 100 corresponding to an opening in graft material 102. Mobile external coupling 120 is generally frustoconically shaped. Mobile external coupling 120 includes graft material 128 having a base 124 and a top 126. Graft material 128 is preferably the same type of graft material as graft material 102 of the body 107 and is preferably a continuation of graft material 102, although graft material 128 can be a separate piece of graft material attached to graft material 102. In one embodiment, graft material 128 is a calendared cloth based on a small yarn, resulting in a thin and pliable mobile external coupling 120. Although mobile external coupling 120 is described as generally frustoconical in shape, base 124 is preferably generally elliptical rather than circular. Base 124 may have, for example and not by way of limitation, a long axis of approximately 20-30 mm and a short axis of approximately 15-20 mm. Further, the height of mobile external coupling 120 may be approximately 10-15 mm. Further, the diameter of the top 126 of mobile external coupling may be approximately 6-9 mm if it

is to be used at the junction of the aorta and left common carotid artery or the junction of the aorta and left subclavian artery. If the mobile external coupling 120 is to be used at the junction of the aorta and the brachiocephalic artery, the diameter of the top 126 may be approximately 8-12 mm.

A circumferential stent or annular support wireform 140 may be coupled to [0034] graft material 128 around the top 126 of mobile external coupling 120. For description purposes, FIG. 3 illustrates support wireform 140 removed from mobile external coupling 120. Support wireform 140 may be formed from a tubular structure or wire 142 of a biocompatible resilient material such as nickel-titanium alloy (nitinol), thermally treated stainless steel, MP35N spring wire, an acetal copolymer, or a polymeric material having shape memory characteristics. In another embodiment, support wireform 140 may be formed from a plastically deformable material. Support wireform 140 may be made from the same material as main body circumferential stents 104 or may be made from different material. For example, circumferential stents 104 may be balloon expandable and support wireform 140 may be selfexpanding. Preferably, circumferential stents 104 and support wireform 140 are made from shape memory materials such as nitinol and are self-expanding. In various embodiments, wire 142 may be solid or hollow and have a circular cross-section. In an embodiment, wire 142 has a diameter between 0.008 inch and 0.012 inch, whereas circumferential stents 104 are generally about .018 inch to .021 inch in diameter. In one embodiment, the cross-section of wire 142 may be oval, square, rectangular, or any other suitable shape. As shown, wire 142 is shaped into a zig-zag or generally sinusoidal configuration having a plurality of opposing bends or crowns 144, 146 connecting generally straight segments or struts 147 together, and a crimp 148 connecting or coupling the two ends of wire 142 to form circumferential support wireform 140. Crowns 144 are disposed adjacent top 126 of mobile external coupling 120 and crowns 146 are disposed spaced from top 126. Support wireform 140 is oriented such that a longitudinal axis of support wireform 140 is generally co-linear with the longitudinal axis of the mobile external coupling 140. In one embodiment, support wireform 140 includes eight crowns 144 and eight crowns 146 but it will be understood by those of ordinary skill in the art that the number of crowns is not limited. [0035] In the embodiment of FIG. 3, support wireform 140 is generally frustoconically shaped. Crowns 144 of frustoconical support wireform 140 are symmetrically arranged in a circle having a first diameter D1 and crowns 146 of

frustoconical support wireform 140 are arranged to be equally spaced around a circle having a second diameter D2 which is greater than diameter D1. Although support wireform 140 is described as generally frustoconical in shape, the base thereof may alternatively be elliptical rather than circular to more closely imitate the profile of mobile external coupling 120. If the base of support wireform 140 is elliptical, crowns 146 of frustoconical support wireform 140 are arranged to be equally spaced around an oviod. The height H of support wireform 140, referring to the vertical or longitudinal distance between crowns 144 and crowns 146, may vary between 25% and 33% of the height of mobile external coupling 120. For example, for a mobile external coupling having a height between 12 mm and 15 mm, the height of support wireform 140 may be in the range of 3 mm and 5 mm.

**[0036]** In another embodiment shown in FIG. 4, the support wireform may be generally cylindrical in shape rather than frustoconical. More specifically, a support wireform 440 includes crowns 444 that are symmetrically arranged in a circle having a diameter D and crowns 446 of cylindrical support wireform 440 are arranged to be equally spaced around a circle also having diameter D.

[0037] Support wireform 140 is coupled to mobile external coupling 120 using stitching or other means known to those of skill in the art. In the embodiment shown in FIGS. 5A, support wireform 140 is coupled to an outside surface of the graft material 128 of mobile external coupling 120 via stitching 549A. Coupling support wireform 140 to an outside surface of the graft material 128 avoids the potential of metal-to-metal contact between support wireform 140 and circumferential stents 104 of stent-graft 100. However, support wireform 140 may alternatively be coupled to an inside surface of the graft material 128 of mobile external coupling 120. Stitching 549A extends for the entire length of support wireform 140 in a continuous manner. In another embodiment shown in FIG. 5B, stitching 549B extends for only a portion of support wireform 140 in an intermittent manner. For example, the stitching may extend only on crowns 144, 146 as shown as stitching 549B in FIG. 5B, may extend only on crowns 144, only on crowns 146, or only on the straight segments 147 between crowns 144 and crowns 146.

[0038] In another embodiment shown in FIGS. 6 and 7, a top ring 622 may be disposed at top 126 of mobile external coupling 120. In one embodiment, the crowns 144 of support wireform 140 may be coupled directly to top ring 622. For example, if mobile external coupling 120 includes top ring 622 disposed at the top thereof, crowns

144 may be placed abutting top ring 622 and crowns 144 may be coupled to graft material 128 by creating a blanket stitch which captures the edge of the graft material 128, the top ring 622, and crowns 144 of support wireform 140 with suture material. The suture material may describe a helical path as it progresses around top ring 622. In one embodiment, the density of the stitch may be such that it essentially covers the circular ring with suture material.

[0039] In another embodiment, a bottom ring 702 may be disposed at bottom 124 of mobile external coupling 120. For example, the bottom ring 702 may be coupled to graft material 128 and the body 107 by using a stitch which captures the edge of the graft material 128 and body 107 and secures it to the bottom ring 702 with suture material.

[0040] Top ring 622 and bottom ring 702 may be continuous rings or may be non-continuous rings. The top and bottom rings 622 and 702 may be formed from a solid or hollow tubular ring or wire having a circular or non-circular cross-section. The rings 622 and 702 may be made from a biocompatible resilient material, such as nickel-titanium alloy (nitinol), thermally treated stainless steel, MP35N spring wire. The material may be a braided, wound or the equivalently formed material. In another embodiment, top and bottom rings 622 and 702 may be formed from a plastically deformable material.

[0041] Due to shape and material, mobile external coupling 120 allows for significant flexibility in aligning stent-graft 100 with a branch vessel because the top of the mobile external coupling 120 when deployed can move longitudinally relative to the longitudinal axis of the body 107. In particular, referring back to FIG. 1, mobile external coupling 120 includes an unsupported portion 150 of graft material 128 extending below support wireform 140 to base 124. Stated another way, mobile external coupling 120 is unsupported between crowns 146 and main stent-graft 100. Unsupported portion 150 of graft material 128 does not have any inherent ability to urge top 126 of mobile external coupling 120 into the ostium of a target branch vessel. However, support wireform 140 imparts structural integrity to the top 126 of mobile external coupling 120 to properly orient the distal end of mobile external coupling 120 towards the ostium and to further prevent mobile external coupling 120 from collapsing or everting into body 107 of the main stent-graft 100 when released from a sleeve of the delivery system during delivery and deployment at the target site. Accordingly, if stent-graft 100 is not perfectly aligned with a branch vessel, mobile external coupling

120 can move or shift to cause top 126 to align with and/or extend into the branch vessel. The mobility of mobile external coupling 120 thus reduces the requirement of precise targeting of the ostium while still allowing for perfusion of the branch vessel.

[0042] The mobility of the mobile external coupling with respect to the main stent-graft can be further enhanced by using some excess graft material when forming mobile external coupling 120. More particularly, as shown in FIG. 8, an unsupported portion 850 of a frustoconical mobile external coupling 820, which may be used with a frustoconical support wireform 840, includes redundant or excess material that may result in blousing or wrinkling 852 of the graft material. Wrinkling 852 is present on the graft material even when the top of the mobile external coupling 820 is deployed as far as it can be into the ostium of a target branch vessel. The redundant or excess material is accomplished by increasing the height of the mobile external coupling 820 to between 15 mm to 20 mm.

As will be explained in more detail herein, a branch vessel prosthesis or [0043] conduit is delivered and deployed through mobile external coupling 120. After implantation, pulsatile expansion and/or other movement of the branch vessel may occur during the cardiac cycle. Such movement of the branch vessel may eventually degrade the seal between mobile external coupling 120 and a branch vessel prosthesis due to plastic deformation of the material of the branch vessel prosthesis. The support wireform of the mobile external coupling assists in sealing between the branch vessel prosthesis and the mobile external coupling. More particularly, referring now to FIG. 9, a schematic illustration of a mobile external coupling 920 including a support wireform 940 with a branch vessel prosthesis 943 deployed therein is shown. Support wireform 940 of mobile external coupling 920 is similar to support wireform 140 described above and produces an interference seal between branch vessel prosthesis 943 and mobile external coupling 920. Support wireform 940 enhances sealing between branch vessel prosthesis 943 and mobile external coupling 920 because the branch vessel prosthesis expands or deploys within the mobile external coupling to abut against the support wireform, the result being that the support wireform securely fits around the proximal portion of the branch vessel prosthesis.

**[0044]** In one embodiment, the deployed diameter of support wireform 940 may be undersized or smaller than the deployed diameter of branch vessel prosthesis 943 to provide a more effective seal between the mobile external coupling 920 and branch vessel prosthesis 943. More particularly, the deployed diameter of support wireform

940 may be up to approximately 30% smaller than the deployed diameter of branch vessel prosthesis 943. For example, if mobile external coupling 920 is to be used at the junction of the aorta and left common carotid artery or the junction of the aorta and left subclavian artery in which a prosthesis used in the branch vessel has a deployed diameter between 6-9 mm, the diameter of support wireform 940 may be approximately 4-6 mm. If the mobile external coupling 920 is to be used at the junction of the aorta and the brachiocephalic artery in which a prosthesis used in the branch vessel has a deployed diameter between 8-12 mm, the diameter of support wireform 940 may be approximately 5.5-8.5 mm. Deployment of branch vessel prosthesis 943 into mobile external coupling 920 results in expansion of branch prosthesis 943 to the limiting diameter of support wireform 940. Thus, even if movement of branch vessel prosthesis 943 occurs after implantation, the shape memory of undersized support wireform 940 urges mobile external coupling 920 to the shape memory diameter of support wireform 940 to thereby compensate for the movement and retain the seal between mobile external coupling 920 and branch vessel prosthesis 943. Undersized support wireform 940 and branch vessel prosthesis 943 are two elastic pieces exerting opposing forces onto each other. In other words, because branch prosthesis 943 wants to expand to a larger diameter than the limiting diameter of support wireform 940, branch prosthesis 943 provides an outward force and support wireform 940 provides a counteracting inward force to maintain the seal between mobile external coupling 920 and branch prosthesis 943. When a balloon expandable stent (BES) is used as branch vessel prosthesis 943, the elastic interference interaction described may also exist, but only to the extent that elastic rebound of the balloon expandable stent is minimal.

[0045] FIG. 10 illustrates a mobile external coupling 1020 having a support wireform 1040 coupled thereto according to another embodiment hereof. Mobile external coupling 1020 is similar to mobile external coupling 120 described above, except that the height H of support wireform 1040 may varies between 34% and 99% of the height of mobile external coupling 1020. Height H of support wireform 1040 refers to the vertical or longitudinal distance between crowns 1044 and crowns 1046 of support wireform 1040. For example, for a mobile external coupling having a height between 12 mm, the height of support wireform 1040 may be in the range of 4 mm and 12 mm and for a mobile external coupling having a height between 15 mm, the height of support wireform 1040 may be in the range of 5 mm and 15 mm. The

unsupported portion of mobile external coupling 1020 is reduced accordingly, resulting in a more supported but also more rigid mobile external coupling that has the structural integrity to extend at least partially into the ostium of the target branch vessel when deployed. Support wireform 1040 is preferably frustoconically shaped as described above with respect to support wireform 140, but may also be cylindrical in shape.

**[0046]** FIGS. 11-21 show an example of a delivery system that can be used to deliver stent-graft 100 to the target location within a vessel. FIG. 11 is a schematic partial cross-sectional view of a stent-graft delivery system 200 with stent-graft 100 disposed therein. Stent-graft delivery system 200 includes a distal portion 201 and a proximal portion 250. Distal portion 201 is preferably used to load and deliver stent-graft section 100. Proximal portion 250 includes components such as those found conventionally in catheter delivery systems.

[0047] The components of the proximal portion 250 of the delivery system 100 may preferably include those shown in FIGS. 11 and 12, although additional and/or alternative components are also contemplated. In particular, proximal portion 250 of delivery system 200 includes a Touhy Borst adaptor 266, a stent capture slider 268, a side port extension 262, a side lumen access 264, a rear grip 260, a screw gear 258, an external slider 254 including a button 256, a front grip 252, and a strain relief 269. One or more hemostatic valves may be provided in front grip 106, for example, as described in U.S. Published Patent Application Publication No. 2006/0229561, commonly assigned with the present application, which is incorporated herein by reference in its entirety. The delivery system 200 as described is generally similar to the Xcelerant Delivery System, sold by Medtronic, Inc., but may be any conventional therapy delivery system, with modifications noted in detail below. Delivery system 200 is generally a single use, disposable device with the stent-graft 100 mounted on within distal end 201 of the delivery system 200.

**[0048]** FIG. 13 is a schematic view of the distal portion 201 of delivery system 200. Distal portion 201 includes a tapered tip 202 that is flexible and able to provide trackability in tight and tortuous vessels. Other tip shapes such as bullet-shaped tips could also be used. The tip 202 includes a lumen 204 disposed therethrough for accommodating a first guide wire 220.

[0049] The tapered tip 202 includes a tapered outer surface 216 that gradually decreases in diameter in a distal direction. More particularly, tapered outer surface

216 has a first diameter at a proximal end and gradually decreases in diameter distally, i.e., in the direction away from the operator. Tapered outer surface 216 further includes a groove 218, as best seen in FIG. 17, for accommodating a second guide wire 222 within a lumen of a side tube 224. A shoulder 212 reduces the diameter of a proximal portion of tip 202 to provide a sleeve landing surface 226. Shoulder 212 is generally annular and perpendicular to a longitudinal axis of stent-graft delivery system 200.

[0050] An outer sleeve 210 of stent-graft delivery system 200 extends over the outer cylindrical surface of sleeve landing surface 226 and abuts against shoulder 212 when the stent-graft delivery system 200 is in a pre-deployment configuration, as shown in FIG. 13. Stent-graft delivery system 200 further includes a stent capture system 290 that captures and holds an end of stent-graft 100, as explained in more detail below.

[0051] Stent-graft delivery system 200 also includes an inner tube 205 that is coupled to a tip lumen 204 such that first guide wire 220 may extend the length of delivery system 200. A stent capture tube 284 of stent capture system 290 surrounds inner tube 205, as explained in more detail below. A stop 208 is located at a distal end of stent-graft 100 when stent-graft 100 is loaded onto the delivery system 200. Stop 208 prevents longitudinal movement of stent-graft 100 as outer sleeve 210 is retracted or otherwise removed to release stent-graft 100. Stop 208 includes a lumen 209 through which stent capture tube 284 and inner tube 205 are disposed. Stop 208 further includes grooves 214 disposed between landings 215. Stop 208 in this embodiment extends proximally along the length of the delivery system 200. Side tube 224 may be disposed in any of the grooves 214 and may extend proximally the length of the delivery system to be controlled at proximal portion 250 through side lumen access 264. Stent-graft 100 is disposed within outer sleeve 210 in a compressed or delivery configuration wherein the diameter of stent-graft 100 is reduced such that it can be inserted through the vasculature.

[0052] Second guide wire 222 extends through stent-graft delivery system 200 through a lumen of side tube 224, which extends through lumen 116 of stent-graft 100, through lumen 130 of mobile external coupling 120, between outer sleeve 210 and body 107, and out a distal end of outer sleeve 210 through groove 218 of tip 202. In the delivery or compressed configuration, mobile external coupling 120 may be folded as shown schematically in FIGS. 13 and 14.

[0053] Stent capture system 290 is shown in FIGS. 16 through 19. Stent capture system 290 includes a spindle 270 and a stent capture assembly 280. Stent capture system 290 may be similar to or identical to stent capture system described in U.S. Published Application Publication No. 2009/0276027, published November 5, 2009, which is incorporated by reference herein in its entirety.

[0054] Spindle 270 shown in FIG. 16 is fixed to inner shaft 205 adjacent a proximal end of tip 202. Spindle 270 includes a lumen (not shown) through which inner shaft is disposed. Spindle 270 may also be slidable relative to inner shaft 205, for example, as described in U.S. Published Application Publication No. 2009/0276027, previously incorporated by reference. Spindle 270 includes a number of spindle pins 274 disposed around the circumference of the spindle body. A spindle groove 272 is formed between each pair of adjacent spindle pins 274. A single stent crown (not shown) of proximal anchor stent 112 wraps around each spindle pin 274 and is held in place by a stent capture fitting arm 286 of the stent capture assembly 280 during stent-graft delivery. When the stent capture assembly 280 is retracted, the stent crowns are freed from the spindle pins 274 and proximal anchor stent 112 expands into position in the vessel. The spindle 270 can be made of any rigid biocompatible material and can be formed as a single unit and/or assembled from individual parts. Those skilled in the art will appreciate that the spindle 270 can made of any biocompatible material and can be formed as a single unit and/or assembled from individual parts. Other embodiments of spindle 270, as described for example in U.S. Published Application Publication No. 2009/0276027, may also be used.

[0055] Stent capture assembly 280 includes a stent capture fitting 282 and a stent capture shaft 284. The stent capture assembly 280 defines a stent capture assembly lumen (not shown) along its length through which inner shaft 205 can slide. The diameter of the stent capture assembly lumen is large enough that the inner shaft can slide within the stent capture assembly lumen. The stent capture shaft 284 advances the stent capture fitting 282 to hold the stent crowns wrapped around spindle pins 274 in place during delivery and initial deployment of stent-graft 100. Stent capture shaft 284 retracts the stent capture fitting 282 to release the proximal anchor stent 112 of the stent-graft 100 from the delivery diameter. The stent capture shaft 284 is long enough to reach through the vasculature from the stent graft deployment site in the vessel to the clinician. The proximal end of the stent capture shaft 284 is attached to stent capture slider 268 shown in FIGS. 11 and 12 for manipulation by the clinician

during stent-graft delivery. Those skilled in the art will appreciate that the stent capture assembly 280 can made of any biocompatible material and can be formed as a single unit and/or assembled from individual parts. The stent capture shaft 284 may be constructed of a rigid plastic, such as PEEK polyetheretherketone, polyimide, nylon, or the like. The stent capture shaft 284 can alternatively be constructed of a flexible metal tube such as nitinol, stainless steel, or the like.

The stent capture fitting 282 in cooperation with the spindle 270, retains one end of the stent-graft during stent-graft delivery. In the illustrated embodiment, the stent capture fitting 282 includes a stent capture body 285 having a number of stent capture fitting arms 286 disposed around the circumference of the stent capture body 285. The stent capture body 285 defines a number of stent capture grooves 288 between each of the stent capture fitting arms 286 to receive the bare stent crowns. The stent capture fitting arms 286 can be substantially parallel to the central axis of the stent capture fitting 282, i.e., the axis along the stent capture shaft 284. In other embodiments, the stent capture fitting arms 286 can curve toward or away from the axis of the stent capture fitting 282 as desired for a particular purpose. When the stent capture fitting 282 is retracted, the stent capture fitting arms 286 release the bare stent crowns, and the proximal anchor stent 112 expands into position in the vessel. The stent capture fitting 282 can be made of any rigid and/or compliant biocompatible material and can be formed as a single unit and/or assembled from individual parts. The stent capture fitting may be fabricated from a variety of materials. This may include rigid plastic materials such as PEEK polyetheretherketone, polycarbonate, or the like, and may also include metals such as stainless steel. In one embodiment, a hard plastic or highly polished metal is desirable for the stent capture fitting 282 to avoid damage to the stent surface which is in contact with the stent capture fitting 282. The stent capture fitting 282 can be fastened to the stent capture shaft 284 by bonding the two with adhesive or threading the two components together. The stent capture fitting 282 may alternatively be insert molded directly on the stent capture shaft 284.

[0057] Outer sleeve 210 is a hollow tube and defines a lumen therein within which stent-graft 100, stent capture system 290, side shaft 224 and inner tube 205 are disposed in the delivery configuration shown in FIG. 13. In a first step for deploying the stent-graft, outer sleeve 210 is moved proximally, *i.e.* retracted, relative to inner tube 205 to a position adjacent the mobile external coupling 120, as shown in FIG. 18. Outer sleeve 210 may be retracted by retracting external slider 254 by counter-

clockwise rotational movement, as shown in FIG. 18A. This rotational movement provides a slower retraction of outer sleeve 210 for a controlled release of the proximal portion of stent-graft 100, as shown in FIG. 18. Due to stent capture assembly 290 holding proximal anchor stent 112 of the stent-graft 100 in the radially compressed delivery configuration, and the relatively short distance to the mobile external coupling 120, the portion 190 of the stent that is free to expand is relatively short, as shown in FIG. 18. However, as also shown in FIG. 18, mobile external coupling 120 is no longer constrained by outer sleeve 210, and mobile external coupling 120 is oriented adjacent and/or into the ostium of the branch vessel.

**[0058]** The side tube 224 may be removed by withdrawing it proximally from side lumen access 264 at the proximal portion 250 of the delivery system 200. Second guide wire 222 may be manipulated to adjust the location or orientation of mobile external coupling 120. Optionally, side tube 224 may remain in place while mobile external coupling 120 is adjusted.

[0059] After mobile external coupling 120 is properly located in or adjacent to the ostium of the branch vessel, outer sleeve 210 may be further retracted, as shown in FIG. 19, by further retracting external slider 254. FIG. 19 shows outer sleeve 210 further retracted, but not fully retracted, as distal anchor stent 114 of stent-graft 100 remains disposed within outer sleeve 210. When outer sleeve 210 is fully retracted, as shown in FIG. 20, the entire stent-graft body, except for the portion retained by stent capture assembly 290, is in the radially expanded or deployed configuration. This further retraction of external slider 254 may be done more quickly than the initial controlled retraction by pressing trigger 256 and sliding external slider 254, as shown in FIG. 19A, rather than rotating external slider 254. However, those of ordinary skill in the art will recognize that the initial retraction and further retraction of external slider 254 may each be accomplished through rotation of external slider 254 or sliding of external slider 254. Further, other methods and devices for retracting outer sleeve 210 could be utilized, as known to those of ordinary skill in the art.

**[0060]** After outer sleeve 210 is fully retracted, stent capture slider 268 may be retracted proximally such that stent capture assembly 280 moves proximally away from spindle 270. Stent capture fitting arms 288 thereby release proximal anchor stent 112 such that proximal anchor stent expands, as shown in FIG. 21.

[0061] The stent-graft delivery system 200 described herein is only an example of a delivery system that can be used to delivery and deploy stent-graft 100 and many

other delivery systems known to those skilled in the art could be utilized. For example, stent-graft 100 could be mounted onto a balloon to be expanded when at the target site. Other stent-graft-delivery systems, for example and not by way of limitation, the delivery systems described in U.S. Published Patent Application Publication Nos. 2008/0114442 and 2008/0262590 and U.S. Patent No. 7,264,632, and U.S. Patent Application Nos. 12/425616 and 12/8425628, each filed April 17, 2009, each of which is incorporated herein by reference in its entirety, may be utilized to deliver and deploy stent-graft 100.

**[0062]** FIGS. 22-27 schematically show a method of delivering stent-graft 100 to a target site in a main vessel and a method of delivering a branch stent-graft to branch vessel. In the example described herein, the stent-graft 100 is delivered and deployed into the aorta 300. Portions of the aorta 300 include the ascending aorta 302, the aortic arch 304, and the descending aorta 306. Branching from the aortic arch are the brachiocephalic trunk 308, the left common carotid artery 314, and the left subclavian artery 316. The brachiocephalic trunk branches into the right subclavian artery 310 and the right common carotid artery 312. An aneurysm 318 in the area of the aortic arch 304 can be difficult to bypass or exclude with a stent-graft because blood flow to the branch arteries must be maintained.

[0063] In the embodiment shown in FIGS. 22-27, the aneurysm is sufficiently close to brachiocephalic trunk 308 that the stent-graft 100 must extend between the brachiocephalic trunk 308 and the heart. In such a case and with a stent-graft 100 with only a single mobile external coupling 120, the mobile external coupling 120 is designed so as to be deployed into the brachiocephalic trunk 308 to perfuse the brachiocephalic trunk 308. Prior to the procedure for inserting stent-graft 100, surgical by-pass procedures installing bypass grafts or vessels (not shown) are performed to connect the right common carotid artery 312 to the left common carotid artery 314 and the left common carotid artery to the left subclavian artery 316. Such surgical bypass procedures may be performed one to two weeks prior to insertion of the stent-graft, and present significantly less complications and risk than a surgical solution to repair an aneurysm 318 in the aortic arch. In this manner, maintaining perfusion to the brachiocephalic trunk 308, and hence the right common carotid artery 312, maintains perfusion to the left common carotid artery 314 and the left subclavian artery 316 Thus, the openings (or ostia) to these branch vessels directly from the aortic arch may be blocked by stent-graft 100. In the alternative, multiple mobile external couplings

120 may be provided in stent-graft 100. Further, if the aneurysm only affects the left common carotid artery 314 and the left subclavian artery 316, only one by-pass between the left common carotid artery 314 and the left subclavian artery needs to be performed, and then a stent-graft with a single mobile external coupling 120 can be utilized to perfuse the left common carotid artery 314. Alternatively, in such a situation, a stent-graft with two mobile external couplings may be provided, one for each of the branch vessels noted. Accordingly, while the embodiment of stent-graft 100 in the method described below includes a single mobile external coupling 120 and the mobile external coupling is deployed in the brachiocephalic trunk 308, those skilled in the art would recognize that multiple mobile external couplings can be used and the mobile external coupling(s) may be deployed in other branch arteries.

**[0064]** FIG. 22 shows the first guide wire 220 advanced through the descending aorta 306, through the aortic arch 304, and into the ascending aorta 302 and second guide wire 222 advanced through the descending aorta 306, through the aortic arch 304, and into brachiocephalic trunk 308. Guide wires 200, 222 are typically inserted into the femoral artery and routed up through the abdominal aorta, and into the thoracic aorta, as is known in the art. Second guide wire 222 may also be locked at its distal end so as to prevent second guide wire 222 from retracting. Access from the brachiocephalic artery or carotid artery may be used to lock second guide wire 222 at its distal or superaortic end, as is known to those of ordinary skill in the art as a through-and-through wire technique.

[0065] FIG. 23 shows stent-graft delivery system 200, with stent-graft 100 compressed therein, advanced over guide wires 220, 222 to the target location in the aortic arch 304. The location of the stent-graft delivery system 200 and/or the stent-graft 100 may be verified radiographically and delivery system 200 and/or stent-graft 100 may include radiopaque markers as known in the art.

[0066] After stent-graft delivery system 200 is in the location where the mobile external coupling 120 of the stent graft 100 is approximately aligned with the opening into the branch vessel, outer sleeve 210 is retracted proximally to a position adjacent to mobile external coupling 120 to release mobile external coupling 120, as shown in FIG. 24 (also shown in FIG. 18). Mobile external coupling 120, including support wireform 140, provides structural integrity to the top of mobile external coupling 120, orients the distal end of mobile external coupling towards and/or into the ostium of the target branch vessel, and reduces the possibility of the mobile external coupling 120

collapsing against or within body 107 after deployment. Delivery system 200 may then be moved and/or rotated to better align mobile external coupling 120 with the branch artery, in this case, the brachiocephalic trunk 308. Further, due to the configuration of mobile external coupling 120, even if it is not perfectly aligned with brachiocephalic trunk 308, the top of the mobile external coupling 120 may be moved to properly align its lumen opening with the lumen of the brachiocephalic trunk 308 without having to move the entire stent-graft 100. Force to adjust the position of the top of the mobile external coupling 120 can be created by pulling or pushing on the end of second guide wire 222.

Once mobile external coupling 120 is deployed and in position in or adjacent [0067] to the brachiocephalic trunk 308, outer sleeve 210 may be further retracted as explained above with respect to FIGS. 19, 20 and 19A, thereby deploying the main body of the stent graft 100, as shown in FIGS. 19 and 20. The stent capture fitting 282 is then retracted proximally to release proximal anchor stent 112 of stent 100 to fully release stent-graft 100, as shown in FIGS, 21 and 25. Once mobile external coupling 120 and stent-graft 100 are deployed, delivery system 200 may be removed. Second guide wire 222 may remain in place in brachiocephalic trunk 308 or may be replaced by another guide wire. A branch stent-graft delivery system 404 is advanced over second quide wire 222 and into brachiocephalic trunk 308, as shown in FIG. 26. Branch stent-graft delivery system includes a tip 402 and a sleeve (not shown), and contains therein a branch stent-graft 400. Branch stent-graft delivery system 404 and branch stent-graft 400 may be conventional. Branch stent-graft delivery system 404 is advanced into brachiocephalic trunk 308 such that a proximal portion 406 of branch stent-graft 400 remains inside of mobile external coupling 120. The sleeve constraining branch stent-graft 400 is then retracted proximally, thereby releasing branch stent-graft 400 from delivery system 404. The delivery system 404 is then withdrawn, as shown in FIG. 27. Proximal portion 406 of branch stent-graft 400 is disposed within mobile external coupling 120 when branch stent-graft 400 is expanded, and support wireform 140 of mobile external coupling 120 creates a seal between mobile external coupling 120 and branch stent-graft 400 as described herein. While various embodiments according to the present invention have been described above, it should be understood that they have been presented by way of illustration and example only, and not limitation. It will be apparent to persons skilled

in the relevant art that various changes in form and detail can be made therein without

departing from the spirit and scope of the invention. It will also be understood that each feature of each embodiment discussed herein, and of each reference cited herein, can be used in combination with the features of any other embodiment. All patents and publications discussed herein are incorporated by reference herein in their entirety.

### CLAIMS

What is claimed is:

1. An endovascular prosthesis comprising:

a tubular body having a proximal end, a distal end, and a lumen disposed between the proximal and distal ends, the tubular body including a body graft material and a plurality of stents coupled to the body graft material;

a mobile external coupling extending outwardly from the tubular body, which include a base coupled to the tubular body, a top spaced from the tubular body, and a coupling lumen disposed between the base and the top, wherein the coupling lumen is in flow communication with the body lumen and wherein the mobile external coupling includes a coupling graft material; and

an annular support wireform attached to and extending around the mobile external coupling, the annular support wireform formed into a sinusoidal configuration having a plurality of opposing first crowns and second crowns, wherein the first crowns of the support wireform extend around of the top of the mobile external coupling and wherein the coupling graft material extending between the second crowns of the support wireform and the tubular body is unsupported.

- 2. The prosthesis of claim 1, wherein the support wireform is generally frustoconically shaped.
- 3. The prosthesis of claim 1, wherein the support wireform is generally cylindrical.
- 4. The prosthesis of claim 1, wherein the support wireform is formed from a shape memory material.
- The prosthesis of claim 1, wherein a height of the support wireform is between 25% and 33% of a height of the mobile external coupling.
- 6. The prosthesis of claim 1, wherein a height of the support wireform is between 34% and 99% of a height of the mobile external coupling.

7. The prosthesis of claim 1, wherein the support wireform is attached to the mobile external coupling via stitching.

- 8. The prosthesis of claim 7, wherein the stitching extends for an entire length of the support wireform in a continuous manner.
- 9. The prosthesis of claim 7, wherein the stitching extends along only the first and second crowns of the support wireform in an intermittent manner.
- 10. The prosthesis of claim 1, wherein a top ring is disposed at the top of the mobile external coupling and the first crowns of the support wireform are coupled directly to the top ring.
- 11. The prosthesis of claim 1, wherein the mobile external coupling includes excess coupling graft material that results in wrinkling between the base and the top.

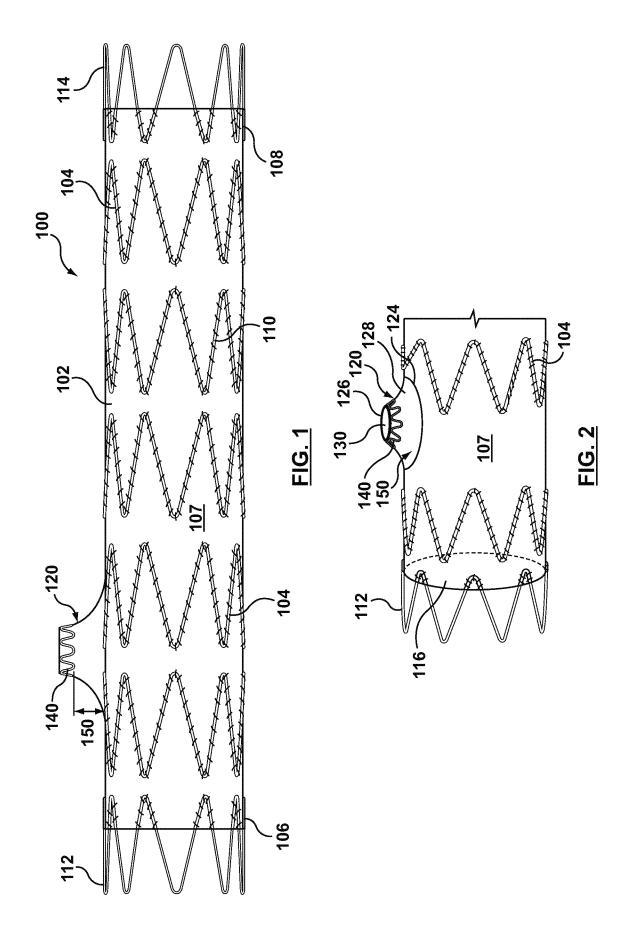
### 12. A prosthesis assembly comprising:

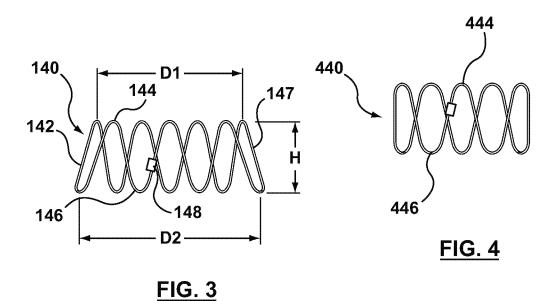
a main prosthesis configured for placement in a main vessel, the main prosthesis including a tubular body and a mobile external coupling, the tubular body having a proximal end, a distal end, a body lumen disposed between the proximal and distal ends, and a body graft material, the mobile external coupling extending outwardly from the tubular body, and the mobile external coupling including a coupling graft material and including a coupling lumen in flow communication with the body lumen,

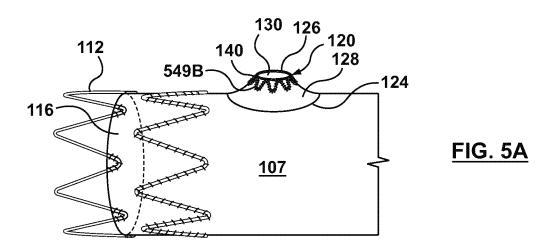
the mobile external coupling including a base coupled to the tubular body, a top spaced from the tubular body, and an annular support wireform attached to and extending around the mobile external coupling, the annular support wireform formed into a sinusoidal configuration having a plurality of opposing first crowns and second crowns, wherein the first crowns of the support wireform extend around of the top of the mobile external coupling and wherein the coupling graft material extending between the second crowns of the support wireform and the tubular body is unsupported;

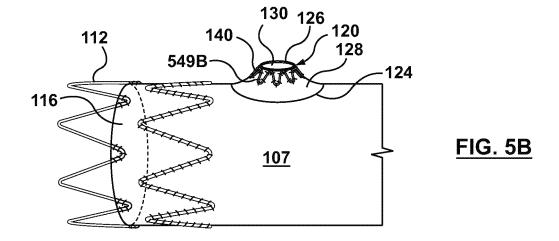
a branch vessel prosthesis configured for placement in a branch vessel that extends from the main vessel, wherein the branch vessel prosthesis is expandable such that an outside surface of a portion of the branch vessel prosthesis is in contact with an inner surface of a portion of the mobile external coupling and the support wireform creates a seal between the branch vessel prosthesis and the mobile external coupling.

- 13. The prosthesis assembly of claim 12, wherein a deployed diameter of the support wireform is smaller than a deployed diameter of the branch vessel prosthesis.
- 14. The prosthesis assembly of claim 13, wherein the deployed diameter of the support wireform is up to 30% smaller than the deployed diameter of the branch vessel prosthesis.
- 15. The prosthesis assembly of claim 12, wherein the support wireform is generally frustoconically shaped.
- 16. The prosthesis assembly of claim 12, wherein a height of the support wireform is between 25% and 33% of a height of the mobile external coupling.
- 17. The prosthesis assembly of claim 12, wherein a height of the support wireform is between 34% and 99% of a height of the mobile external coupling.
- 18. The prosthesis assembly of claim 12, wherein a top ring is disposed at the top of the mobile external coupling and the crowns of the support wireform are coupled directly to the top ring.
- 19. The prosthesis assembly of claim 12, wherein the mobile external coupling includes excess coupling graft material that results in wrinkling between the base and the top.









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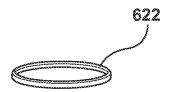


FIG. 6

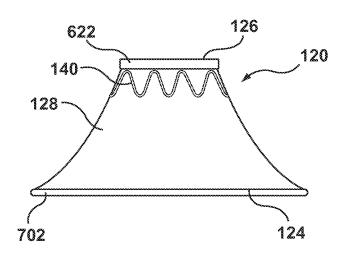
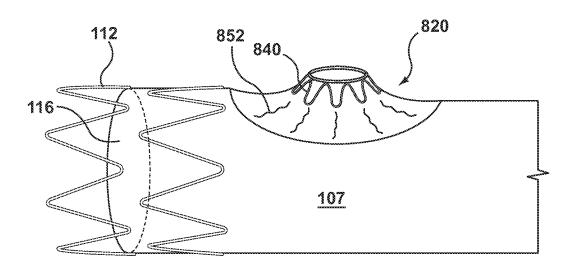
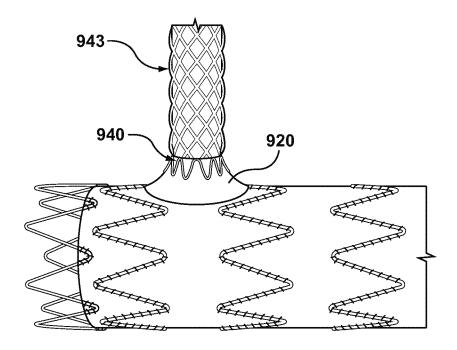


FIG. 7



<u>FIG. 8</u>



<u>FIG. 9</u>

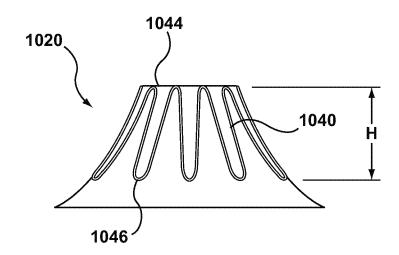
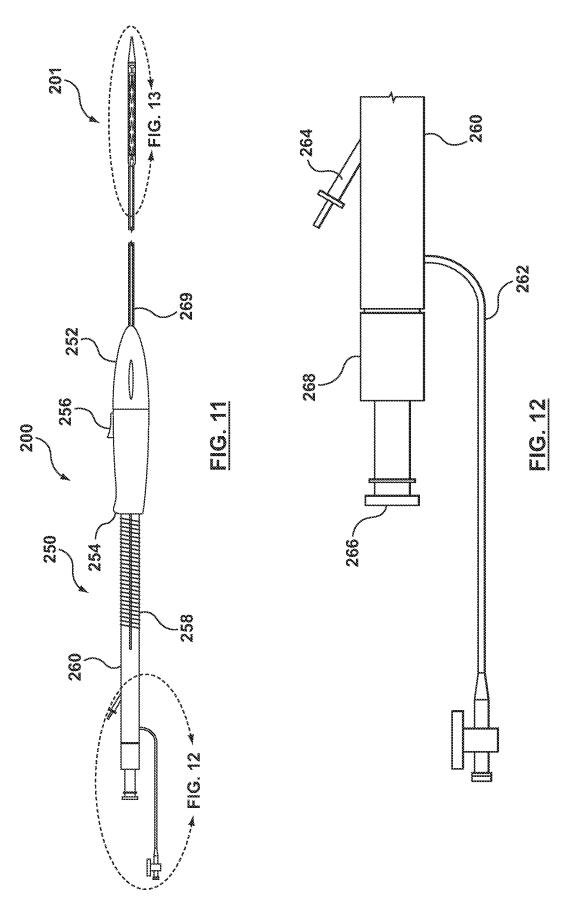
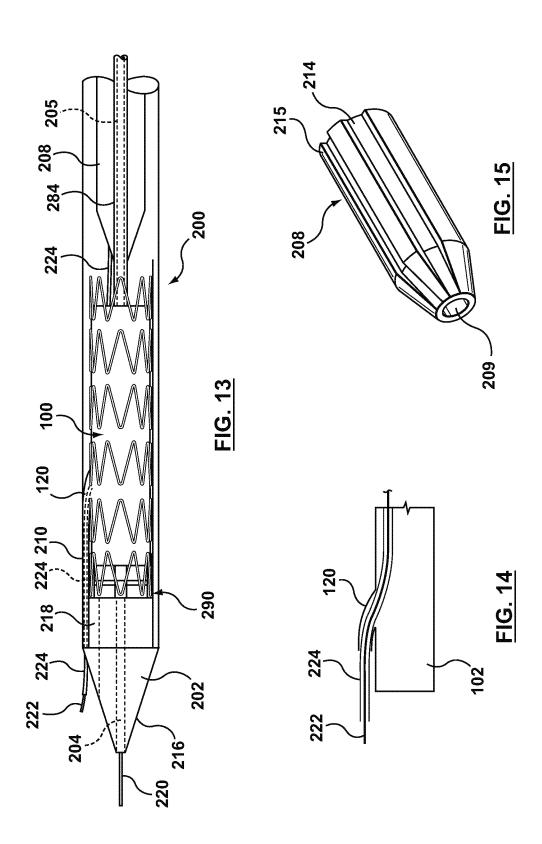


FIG. 10

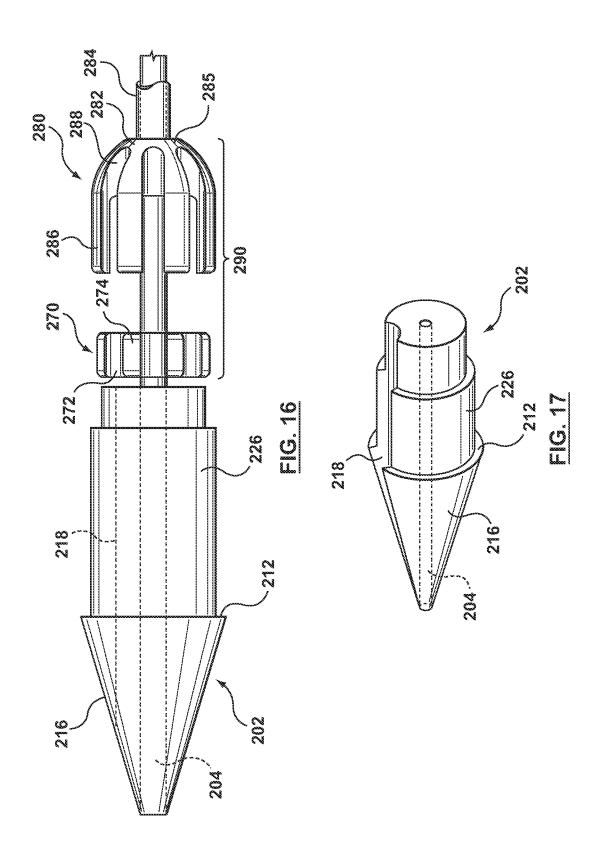




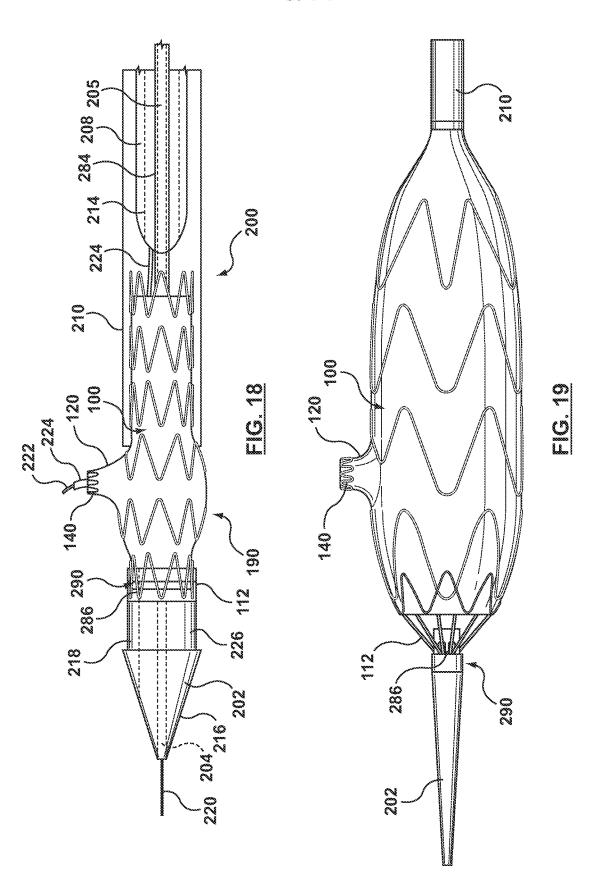
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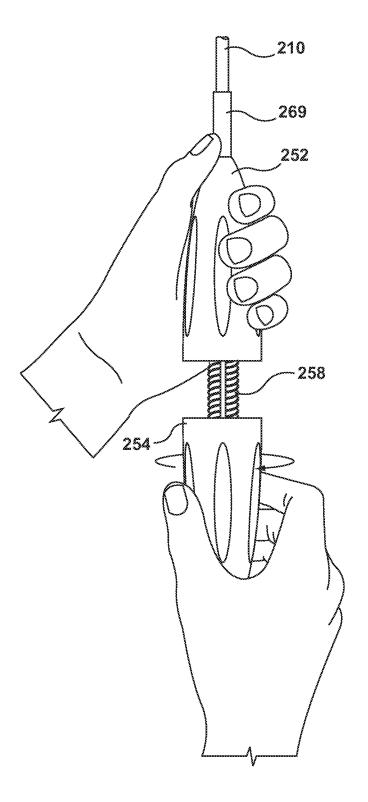


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<u>FIG. 18A</u>

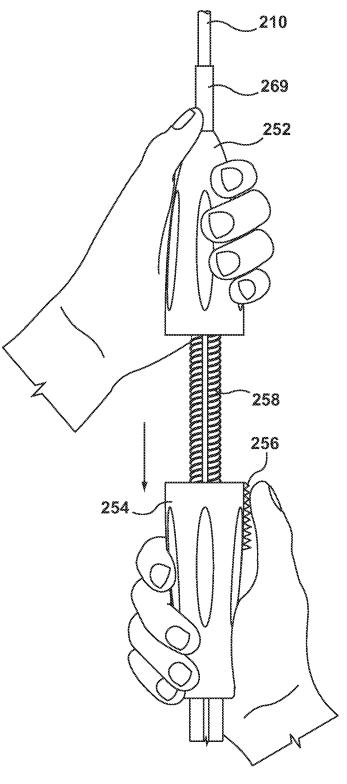
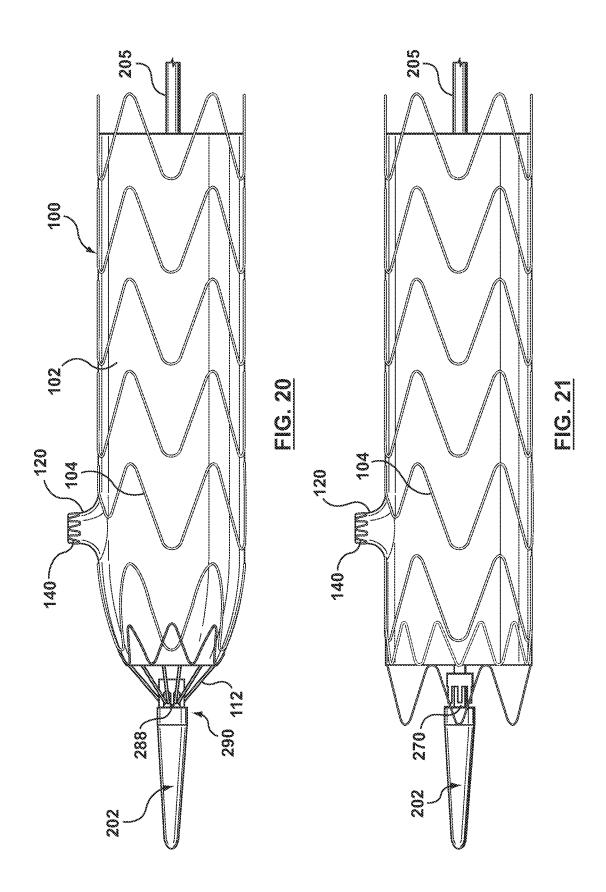
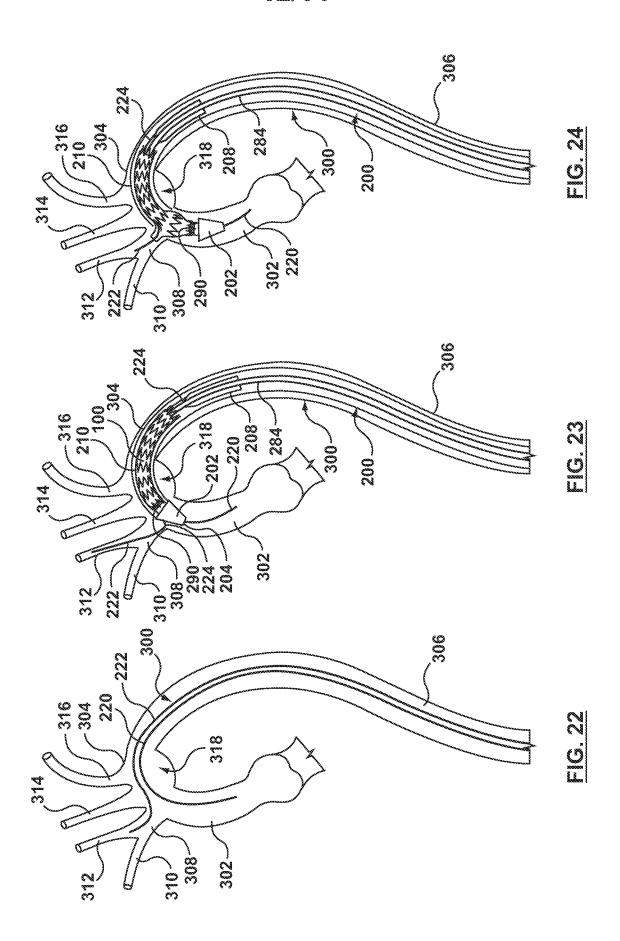
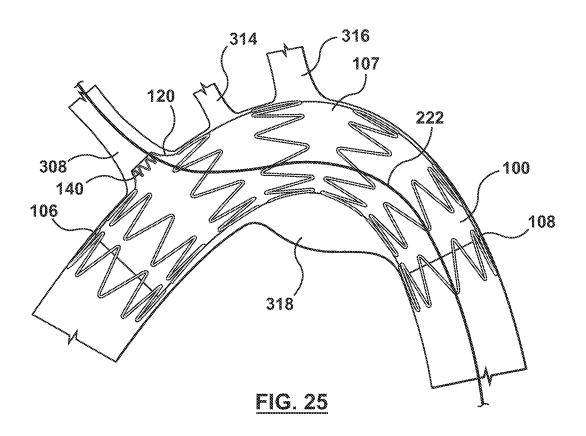
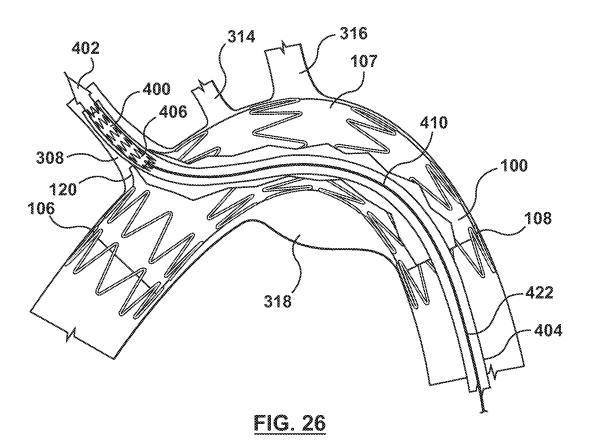


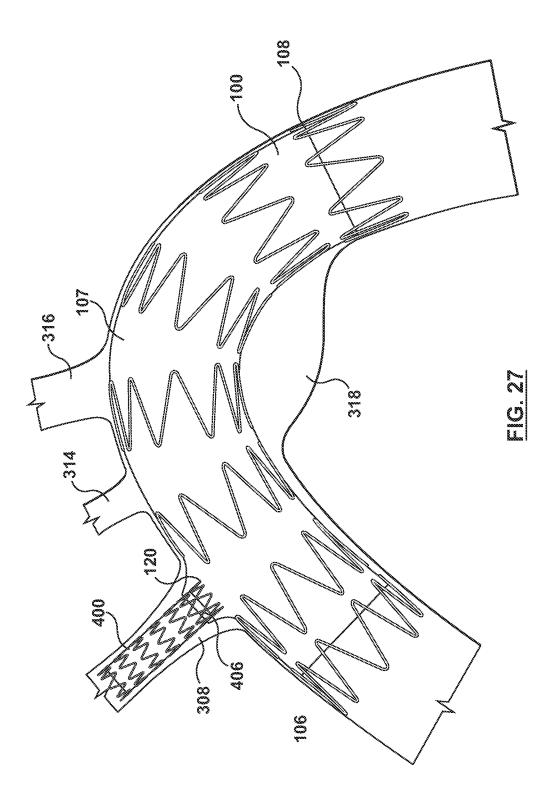
FIG. 19A











#### INTERNATIONAL SEARCH REPORT

International application No PCT/US2012/033523

A. CLASSIFICATION OF SUBJECT MATTER A61F2/95 INV. A61F2/07 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 practicable, search terms used) EPO-Internal, WPI Data C. DOCUMENTS CONSIDERED TO BE RELEVANT Relevant to claim No. Category\* Citation of document, with indication, where appropriate, of the relevant passages WO 2006/036690 A1 (COOK WILLIAM A 1 - 19Χ AUSTRALIA [AU]; COOK WILLIAM EUROP [DK]; COOK INC [US];) 6 April 2006 (2006-04-06) page 16, lines 1-26; figures 16,17 Χ EP 1 847 236 A2 (MEDTRONIC VASCULAR INC 1,2,4-9,[US]) 24 October 2007 (2007-10-24) paragraphs [0052], [0102] - [0112]; figures 13-15 US 2010/268319 A1 (BRUSZEWSKI WALTER [US] ET AL) 21 October 2010 (2010-10-21) Χ 1 - 19paragraph [0040]; figure 15 Х Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents "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 "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 "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive 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 step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be special reason (as specified) considered to involve an inventive step when the document is combined with one or more other such documents, such combination "O" document referring to an oral disclosure, use, exhibition or other being obvious to a person skilled in the art "P" document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 27 June 2012 04/07/2012 Authorized officer Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016 Chevalot, Nicolas

### INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/033523

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2006036690 /	1 06-04-2006	AU 2005289812 A1 CA 2580952 A1 EP 1791498 A1 JP 4703653 B2 JP 2008513157 A US 2011288627 A1 WO 2006036690 A1	06-04-2006 06-04-2006 06-06-2007 15-06-2011 01-05-2008 24-11-2011 06-04-2006
EP 1847236	2 24-10-2007	EP 1847236 A2 US 2007244542 A1 US 2010121429 A1	24-10-2007 18-10-2007 13-05-2010
US 2010268319 /	1 21-10-2010	EP 2429450 A1 US 2010268319 A1 WO 2010120548 A1	21-03-2012 21-10-2010 21-10-2010