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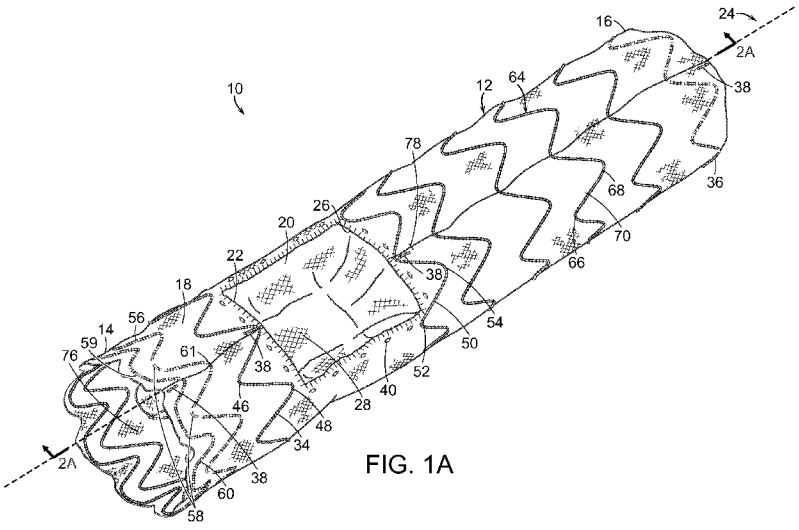


FIG. 1A

(57) Abstract: An aortic graft assembly (10) includes a tubular component (12) that defines a wall aperture (20) having a proximal end (22) that extends perpendicular to a major longitudinal axis (24) of the tubular aortic component, and a tunnel graft (28) connected to the wall (18) of the tubular aortic component and extending from the wall aperture toward a proximal end (14) of the tubular aortic component. The method for delivery of the aortic graft assembly includes delivering the aortic graft assembly through the wall aperture and into interfering relation with the tunnel graft.

WO 2013/074990 A1

DEVICE AND METHOD FOR AORTIC BRANCHED VESSEL REPAIR

RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 61/560,517, filed on November 16, 2011. The entire teachings of the above application are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Aortic aneurysms are life-threatening conditions. Surgical interventions used to treat aortic aneurysms include endovascular repair by transluminal placement of one or more endografts across the longitudinal extent of the lesion. The endograft is placed in the aorta with the intention of bridging the aneurysmal sac to exclude it from the high-pressure of aortic blood flow, which can permit remodeling of the aortic wall in and around the aneurysm site. In certain regions of the aorta accurate placement of the endograft is critical to maintain blood flow to vessels branching from the aorta to minimize compromised blood flow to organs. For example, currently, if aortic devices are placed within the aortic arch in a manner that offsets the aperture for the left carotid artery, the artery can be occluded, which can result in ischemia to the brain. Most surgical methods of treating aneurysms at or near the aortic arch generally involve sternotomy or thoracotomy and may require cardio-pulmonary bypass, often resulting in high morbidity rates. Thus, there is a need to develop new and useful devices and methods of treating aortic aneurysms by endovascular methods.

SUMMARY OF THE INVENTION

The present invention relates to vascular repair systems, delivery systems and methods of using the delivery systems and its components to treat aortic vascular damage, in particular, vascular damage associated with aortic disease, such as, aneurysms, penetrating atherosclerotic ulcers and dissection.

In an embodiment, the invention is an aortic graft assembly that includes a tubular aortic component having a proximal end and a distal end connected by a wall of the tubular aortic component, the wall defining a wall aperture that is between the proximal and distal ends. The aperture has a proximal end that extends perpendicular to a major longitudinal axis of the tubular aortic component when viewed orthogonally to the major longitudinal axis. A tunnel graft is connected to the wall of the tubular aortic component and extends from the wall aperture toward the proximal end of the tubular aortic component. The tunnel graft has a proximal end and a distal end, the distal end being at the wall aperture of the tubular aortic component. A proximal stent abuts the proximal end of the aperture, and a distal stent abuts a distal end of the aperture.

In yet another embodiment, the invention is an aortic graft assembly, comprising a tubular aortic component that includes a proximal end and a distal end connected by a wall of the tubular aortic component, the wall defining a wall aperture that is between the proximal and distal ends, the wall aperture having a proximal end and a distal end, the proximal end of the wall aperture extending perpendicular to a major longitudinal axis of the tubular aortic component when viewed orthogonally to the major longitudinal axis; a tunnel graft connected to the wall of the tubular aortic component and extending from the wall aperture toward the proximal end of the tubular aortic component, the tunnel graft having a proximal end and a distal end, the distal end being at the wall aperture of the tubular aortic component; a proximal stent that supports the proximal end of the tubular aortic component; a distal stent that supports the distal end of the tubular aortic component; a clasping stent at the proximal end of the tubular aortic component, the clasping stent including at least two exposed proximal apices proximate to the proximal end of tubular component and attached to an interior wall of the tubular aortic component; and a crown stent between the clasping stent and the proximal end of the tubular aortic component, the crown stent attached to an interior surface of the tubular aortic component.

In a further embodiment, the invention is an aortic graft assembly, comprising a tubular aortic component that includes a proximal end and a distal end

connected by a wall of the tubular aortic component, the wall defining a wall aperture that is between the proximal and distal ends, the wall aperture having a proximal end and a distal end, the proximal end of the wall aperture extending perpendicular to a major longitudinal axis of the tubular aortic component when viewed orthogonally to the major longitudinal axis; a tunnel graft connected to the wall of the tubular aortic component and extending from the wall aperture toward the proximal end of the tubular aortic component, the tunnel graft having a proximal end and a distal end, the distal end being at the wall aperture of the tubular aortic component; a proximal stent that abuts the proximal end of the tubular aortic component; a distal stent that supports the distal end of the tubular aortic component; an abutting distal stent that includes at least one proximal apex that abut the distal end of the wall aperture; a clasping stent at the proximal end of the tubular aortic component, the clasping stent including at least two exposed proximal apices proximate to the proximal end of tubular component and attached to an interior wall of the tubular aortic component; and a crown stent between the clasping stent and the proximal end of the tubular aortic component, the crown stent attached to an interior surface of the tubular aortic component.

In another embodiment, the invention is a method for implanting a prosthesis, including delivering a tubular aortic component defining a wall aperture through an aorta of a patient to an aneurysm site of the patient, the tubular aortic component being radially and releasably constrained by a distal clasp at a distal end of an outer control tube of a delivery device, and releasably attached by a retention component to a proximal clasp at the outer control tube proximal to the proximal clasp, the tubular aortic component further supported by a control catheter of the delivery device extending within the outer control tube. The wall aperture is aligned over at least one vessel ostium at the aneurysm site of the patient. The outer tube is retracted, thereby releasing the tubular aortic component from the distal and proximal clasps, thereby deploying the tubular aortic component at the aneurysm site.

In an additional embodiment, the invention is a method for implanting a prosthesis, comprising the steps of delivering a tubular aortic component defining a

wall aperture through an aorta to an aneurysm site of a patient, the tubular aortic component being radially and releasably constrained by a distal clasp at a distal end of an outer control tube of a delivery device, and releasably attached by a retention component to a proximal clasp at the outer control tube proximal to the proximal clasp, the tubular aortic component further supported by a control catheter of the delivery device extending within the outer control tube; aligning the wall aperture over at least one vessel ostium at the aneurysm site of the patient; retracting the outer control tube, thereby releasing the tubular aortic component from the distal and proximal clasps, thereby deploying the tubular aortic component at the aneurysm site in the patient, wherein at least one supporting wire extends from the control tube, said supporting wire extending through a suture loop inside the proximal end of the tubular aortic component to thereby prevent collapse of the proximal end of the tubular component during deployment. The method can further includes the step of partially retracting an inner sheath from around the tubular aortic component, whereby the supporting wire at least partially restricts longitudinal movement of the proximal end of the tubular aortic component until the proximal end of the tubular aortic component is secure within the aorta, to thereby prevent collapse of the proximal end of the tubular aortic component at an inferior portion of the aorta, wherein the inner sheath is releasably secured to a distal end within a cavity defined by a proximal end of the nose cone, wherein the steps of the method include partially retracting an inner sheath from around the tubular aortic component to release the distal end of the inner sheath from the nose cone and thereby cause partial deployment of the tubular aortic component; partially retracting the control catheter to thereby release the clasping stent from the distal apex clasp and the retention component from the proximal clasp; further retracting the control catheter to at least partially retract the nose cone to within the tubular aortic component while retaining the suture loops on the supporting wires; advancing the tubular aortic component to a final position in the aorta of the patient spanning the aneurysm; fully retracting the inner sheath from the tubular aortic component; and fully retracting the nose cone and supporting wires to release the suture loops from the supporting

wires, thereby fully deploying the tubular aortic component within the aorta of the patient.

In an embodiment, a stent defining the aperture permits blood flow into the ostium of the target vessel, unlike other systems that rely on a narrowing or dog-bone shape of the body of the tubular aortic component of an aortic graft system to permit blood flow outside and around the tubular graft component if the surgeon is unable to align the aperture with the ostium of the target vessel.

The aortic graft assembly of the invention does not require precise radial or longitudinal alignment in the aorta and permits approximate alignment, which is beneficial in reducing the manipulation of the aortic arch and resulting stroke in the patient. The claimed systems can be fully deployed before the surgeon completes the endovascular procedure by deployment of the first tunnel or second tunnel graft, unlike current aortic components that are in a "dogbone" configuration to guard against unintentional obstruction of the target ostium. The delivery device employed with the graft assembly aids in proper alignment of the assembly in the aorta by, for example, use of a curved guidewire catheter, proximal clasp and distal clasp.

The aortic assembly systems and methods of the invention can be employed to treat aortic aneurysms, such as aortic aneurysms at, near or around the arch of the aorta, or branches from the abdominal aorta (*e.g.*, celiac artery, superior mesenteric artery and renal arteries). The aortic assembly systems of the invention have a relatively large aperture tapered into a tunnel graft that provides the surgeon with a relatively large margin of error in placement of the system, facilitates canulation and permits alignment of a single aperture for at least one blood vessel. Aortic assembly systems of the invention that include a tunnel graft having one aperture extending proximally with two openings permit for easy alignment in the aorta, particularly in regions of the aorta that branch to peripheral and major vessels. The size of the aperture allows blood to flow to target vessels during the procedure. The aortic graft assembly of the invention generally does not restrict blood flow acutely or chronically, in part, because of a relatively large diameter of the tunnel graft and the stent or stents supporting the tunnel graft.

Barbs in the interior of the tunnel grafts of the branched graft assembly have the advantage of securing connection of the tubular component to the tunnel graft. The telescoping ability of the graft assembly systems of the invention, for example, the length and different configurations of the tunnel graft, allow the tubular component to be positioned in-situ to ensure maximum use of a "landing zone" inside the target vessel. A relatively long tunnel length can ensure adequate overlap with the tubular component into the tunnel grafts to ensure a sufficient seal.

The delivery device of the invention also has the advantage of allowing the proximal end of the stent graft to be aligned perpendicular to the center line axis of the "landing zone." This is of key concern when the landing zone is in Zone 0 (FIGs. 15, 16, 17) of the ascending aorta. When landing in this area much care must be taken to avoid accidental coverage of the coronary arteries, typically the left coronary artery.

Thus, the aortic graft assembly, delivery systems, and methods of the invention can be used to treat various aortic pathologies, including aortic aneurysms, penetrating atherosclerotic ulcers, dissections and, therefore, avoid complications and death consequent to life-threatening vascular conditions.

BRIEF DESCRIPTION OF THE FIGURES

FIGs. 1A, 1B and 1C represent an embodiment of an aortic assembly system of the invention.

FIGs. 2A and 3A represent cross sectional views of the aortic assembly system of the invention, shown in FIG. 1A, taken along line 2A.

FIGs. 2B and 3B represent a longitudinal view of FIGs. 2A and 3A of an aortic assembly system of the invention.

FIGs. 4A and 4B represent embodiments of an aortic assembly system of the invention, taken from views 4A and 4B of FIGs. 2A and 2B.

FIG. 5 is a perspective view into the proximal end of one embodiment of the invention.

FIG. 6 represents another embodiment of an aortic assembly system of the invention.

FIGs. 7A and 8A represent additional embodiments of an aortic assembly system of the invention.

FIGs. 7B and 8B represent additional embodiments of an aortic assembly system of the invention taken along lines 7B and 8B of FIGs. 7A and 8A, respectively.

FIGs. 9A and 10A represent additional embodiments of an aortic assembly system of the invention.

FIGs. 9B and 10B represent further embodiments of an aortic assembly system of the invention taken along lines 9B and 10B of FIGs. 10A and 10B, respectively.

FIG. 11 is a perspective view of one embodiment of an aortic assembly system of the invention mounted on one embodiment of a delivery system of the invention.

FIG. 12 represents placement of an embodiment of an aortic graft assembly of the invention in the ascending aorta, aortic arch and a portion of the descending aorta of a subject.

FIG. 13 represents zones (0, 1, 2, 3 and 4) of the aorta and major vessels branching from the aorta (prior art).

FIG. 14 represents zones (0, 1, 2, 3 and 4) of the aorta, an aortic aneurysm, a right carotid artery to left carotid artery bypass, a left carotid artery to left subclavian artery bypass and ligation of the left carotid and left subclavian arteries (prior art).

FIG. 15 represents zones (0, 1, 2, 3 and 4) of the aorta, an aortic aneurysm, a left carotid artery to left subclavian artery bypass and ligation of the left subclavian artery (prior art).

FIGs. 16A-16F are a representation of one embodiment of an aortic assembly system of the invention of one embodiment of a delivery system of the invention.

FIGs. 17A-17C are side, cross-sectional and perspective views of one embodiment of the invention, respectively.

FIG. 18 is a perspective view of a nose cone, and inner sheath tucked into a proximal cavity of the nose cone of one embodiment of the invention.

FIGs. 19A and 19B represent alterative embodiments of an inner sheath of an embodiment of a delivery system of the invention.

FIG. 20 represents an alterative embodiment of an inner sheath of an embodiment of a delivery system of the invention.

FIGs. 21A and 21B represent additional alterative embodiments of an inner sheath of an embodiment of a delivery system of the invention.

FIG. 22 represents an embodiment of a portion of a delivery system employed by the invention.

FIGs. 23A-23D represent additional views of an aortic assembly system and branch graft of the invention.

FIGs. 24A-24E represent method steps of one embodiment of a method of the invention.

FIGs. 25A and 25B represent alterative embodiments of an inner sheath component of one embodiment of the invention.

FIGs. 26A-26C represent method steps of one embodiment of an alternative method of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The features and other details of the invention, either as steps of the invention or as combinations of parts of the invention will now be more particularly described and pointed out in the claims. It will be understood that the particular embodiments of the invention are shown by way of illustration and not as limitations of the invention. The principle features of this invention can be employed in various embodiments without departing from the scope of the invention.

"Proximal" means, when reference is made to a delivery system or a component of a delivery system, such as an apex clasp and a nose cone, closest to the clinician using device. Likewise, "distal" means, when reference is made to a delivery system or a component of a delivery system, such as an apex clasp and a nose cone, away from the clinician using the device.

When reference is made to a prosthesis to be delivered, such as an aortic graft assembly, tubular aortic component, tunnel graft, branch graft and stent, the word "proximal" means that portion of the prosthesis or component of the prosthesis

that is towards the heart of the patient and "distal" means that portion of the prosthesis or component of the prosthesis that is away from the heart of the patient. For clarity, the word "proximate" means close to as opposed to "proximal" or "distal."

Aortic graft assemblies of the invention can be implanted, for example, by transfemoral access. Tubular branch components can be implanted, for example, by supraaortic vessel access (*e.g.*, brachial artery), or by transfemoral or transapical access.

The invention is generally directed to an aortic graft assembly and a method for deploying the aortic graft assembly. The invention is also directed to methods of implanting at least one tubular branch graft into a patient and the aortic graft assembly. In one embodiment of the aortic graft assembly of the invention, represented in FIGs. 1A through FIG. 1C, aortic graft assembly 10 includes tubular aortic component 12 having proximal end 14 and distal end 16 connected by wall 18. Wall 18 defines wall aperture 20 that is between proximal end 14 and distal end 16. Wall aperture 20 has proximal end 22 that extends perpendicular to a major longitudinal axis 24 of tubular aortic component 12 when viewed orthogonally to major longitudinal axis 24. Wall aperture 20 also defines distal end 26 of wall aperture 20.

Tunnel graft 28, shown, for example, in FIGs. 2A, 2B, 3A, 3B, 4A and 4B is connected to wall 18 of tubular aortic component 12 and extends from wall aperture 20 toward proximal end 14 of the tubular aortic component 12. Tunnel graft 28 includes proximal end 30 and distal end 32. Distal end 32 of tunnel graft 28 is at wall aperture 20 of tubular aortic component 12.

Referring back to FIGs. 1A-1C, proximal stent 34 supports proximal end 14 of tubular aortic component 12. Distal stent 36 supports distal end 16 of tubular aortic component 12. Similarly, distal stent 36 can be attached to an interior wall to tubular aortic component 12.

Optionally, radiopaque markers 38 are located along a line parallel to major longitudinal axis 24 of tubular aortic component 12. In one embodiment, radiopaque marker 38 is at a proximal apex of wall aperture distal stent 50 abutting

wall aperture 20. Another radiopaque marker is at a distal apex 48 of proximal stent 34. Further, radiopaque marker 38 is at least one of proximal end 14 and distal end 16 of tubular aortic component 12. Also optionally, radiopaque markers 40 extend about the circumference of wall aperture 20 at tubular aortic component 12. Radiopaque markers 38, 40 can be made of any suitable material such as platinum, iridium, gold, etc. Examples of radiopaque markers are described in the U.S. Patent No.: 8,062,345 and U.S. Published Patent Application No.: US 2010/0030255, the entire teachings of which are incorporated herein by reference.

Proximal stent 34 in one embodiment, shown in FIGs. 1A, 1B and 1C, includes proximal apices 46 and distal apices 48. In one embodiment, at least a portion of distal apices 48 abut proximal end 22 of wall aperture 20. Wall aperture distal stent 50 includes proximal apices 52 and distal apices 54, a portion of proximal apices 52 of wall aperture distal stent 50 abut distal end 26 of wall aperture 20. Clasping stent 56 at proximal end 14 of tubular aortic component 12 includes at least two exposed proximal apices 58 proximate to proximate end 14 of tubular aortic component 12. In one embodiment, clasping stent 56 is attached to an interior wall of tubular aortic component 12.

Crown stent 60 is located between clasping stent 56 and proximal end 14 of tubular aortic component 12. As can be seen in FIG. 5, at least two support wire sutures 62 are located within tubular aortic component 12 at proximal end 14 of tubular aortic component 12, distal to proximal apices 58 of clasping stent 56. Support wires sutures 62 are separated by at least one distal apex 61 of clasping stent 56. In one embodiment, proximal apices 59 of crown stent 60 are blunted, as shown in FIG. 1A. Crown stent 60 and clasping stent 56 can be nested, as shown in FIG. 1A. Crown stent 60 and clasping stent 56 are attached to interior wall 76 of tubular aortic component 12.

At least one stent 64 is located at tubular aortic component 12 between proximal stent 34 and distal stent 36. At least a portion of stents 64 include proximal apices 66 and distal apices 68 connected by struts 70. At least one partial stent 72 is located at tubular aortic component 12 between stents 34, 50 abutting proximal 22 and distal 26 ends of wall aperture 20, respectively, as shown in FIGs.

1B and 1C.

Stents employed in the invention are constructed of a suitable material. In one embodiment, the stents employed by the invention include a suitable shape memory alloy, such as nitinol. Further description of suitable materials for construction of stents for use in the invention can be found in U.S. Patent Nos.: 7,763,063 and 8,062,345, the teachings of which are incorporated herein by reference in their entirety.

In one embodiment, the arc length of proximal end 22 of wall aperture 20 is equal to or less than one-half the circumference of tubular aortic component 12. Examples of suitable arc lengths of proximal end 22 of wall aperture 20 include arc lengths equal to one member selected from the group consisting of about 6 mm, about 8 mm, about 10 mm, about 12 mm or about 14 mm. In one embodiment, a longitudinal length of wall aperture 20 is equal to or less than about 90 mm. In another embodiment, the longitudinal length of wall aperture 20 is equal to or greater than about 14 mm.

Referring to FIGs. 2A, 2B, 3A and 3B, the distance between proximal end 22 of wall aperture 20 and proximal end 14 of tubular aortic component 12 can be in a range of between about 10 mm and about 80 mm. In a typical embodiment, the distance between proximal end 22 of wall aperture 20 and proximal end 14 of tubular aortic component 12 is one member selected from the group consisting of about 20 mm, about 40 mm, about 60 mm, about 80 mm or about 90 mm. In one embodiment, the distance between proximal end 22 of wall aperture 20 and proximal end 12 of tubular aortic component 12 is about 40 mm, as shown in FIGs. 2A and 2B. In another embodiment, the distance between proximal end 22 of wall aperture 20 and proximal end 14 of tubular aortic component 12 is about 60 mm, as shown in FIGs. 3A and 3B.

In one embodiment, shown in FIG. 1A, retention component 78 is located at tubular aortic component 12 distal to wall aperture 20 and within tubular aortic component 12 (only external portion of retention component 78 is shown in FIG. 1A). In one embodiment, retention component is a suture loop. In another embodiment, retention component 78 is at least one of a magnet or a stent apex. In

still another embodiment, retention component 78 is radiopaque. In one embodiment, retention component 78 is at a proximal apex 52 of stent 50 abutting distal end 26 of wall aperture 20.

In another embodiment, shown in FIG. 6, circumferential stent 80 is located at tubular aortic component 12 and surrounds wall aperture 20. In one embodiment, a circumferential stent 80 surrounding wall aperture 20 defines, at least in part, wall aperture 20. In one embodiment, the diameter of proximal end 14 of tubular aortic component 12 is greater than the diameter of distal end 16 of tubular aortic component 12, as shown in FIG. 1B.

In one embodiment, shown in FIGs. 7A, 8A, 9A and 10A, the interface between tubular aortic component 12 and wall aperture 20, when viewed orthogonally to major longitudinal axis 24 of tubular aortic component 12 is a polygon, such as is shown in the referenced figures, a polygon having four sides. In various embodiments, the polygon can be a square, a rectangle, a parallelogram, or a rhombus (not shown).

In a specific embodiment, inferior portion 83 is on one side of tubular aortic component 12 opposite wall aperture 20 and is essentially parallel to major longitudinal axis 24 of tubular aortic component 12, shown in FIG. 1B. Exposed apices 58 of clasping stent 56, when collapsed will cause at least partial collapse of proximal end 14 of tubular aortic component 12 at clasping stent 56, as can be seen in FIG. 11. At least one of support wire sutures 62 are at inferior portion 83 within tubular aortic component 12. In a specific embodiment, support wire sutures 62 are at apices of clasping stent 56. Preferably, support wire sutures 62 are separated by at least one proximal apex of clasping stent.

In one embodiment, distal end 32 of tunnel graft 28 has a diameter greater than that of proximal end 30 of tunnel graft 28, as can be seen in FIGs. 2A and 3A. In another embodiment, proximal end 30 of tunnel graft 28 is between the most proximal edge of proximal end 14 of tubular aortic component 12 and proximal end 22 of wall aperture 20, as shown in FIGs. 2A, 2B, 3A, 3B, 4A and 4B. As shown in FIGs. 4A and 4B, tunnel graft 28 is secured to an interior wall of tubular aortic component 12 by a suitable means, such as by sutures 29.

As can be seen in FIGs. 1B, 1C, 2A, 2B, 3A and 3B, tunnel graft 28 includes open portion 84 at wall aperture 20. Tubular portion 86 extends proximally from open portion 84, as shown in FIGs. 2A, 2B, 3A and 3B. In one embodiment, tubular portion includes stents 88, 90 at each of a proximal 92 and distal end 94 of tubular portion 86, as shown in FIGs. 2B and 3B. Preferably, stents 88, 90 at proximal 92 and distal 94 ends of tubular portion 86 includes proximal and distal apices connected by struts. Preferably, stent 88 at proximal end 92 of tubular portion 86 includes at least one barb 96 (FIG. 2B). In another embodiment shown in FIG. 3B, barbs 96 extend for distal apices of stent 98 of tubular portion 86. Optionally, tubular portion 86 further includes at least one stent 98 between stents 88, 90 at proximal 92 and distal 94 ends, respectively, of tubular portion 86. Preferably, at least one of stents 98 between stents 88, 90 at proximal end 92 and distal end 94 includes at least one barb. Most preferably, stents of tubular portion 86 include nitinol.

As can also be seen in FIGs. 2A and 2B and 3A and 3B, 4A and 4B, distal end 94 of tubular portion 86 is generally conical, whereby distal end 94 of tubular portion 86 essentially matches proximal end 92 of tunnel graft 28 at proximal end 22 of wall aperture 20, as a continuum or, optionally, at a seam, not shown. In one embodiment, a maximum diameter of proximal end of tunnel graft 28 is equal to or less than the diameter of distal end of tubular portion 94. Examples of suitable maximum diameters of proximal end 30 of tunnel graft 28 include, for example, diameters equal to or greater than a diameter selected from the group consisting of about 6 mm, about 8 mm, about 10 mm, about 12 mm or about 14 mm.

Preferably, tubular portion 86 has a major longitudinal axis that is parallel to major longitudinal axis 24 of tubular aortic component 12. Proximal end 92 of tubular portion 86 is distal to the most proximal edge of proximal end 14 of tubular aortic component 12. In one embodiment, not shown, proximal end 92 of tubular portion 86 is coterminous with the most proximal edge of proximal end 14 of tubular aortic component 12 or, alternatively, as shown in FIGs. 2A and 2B and 3A and 3B, 4A and 4B, is distal to proximal end 14 of tubular aortic component 12. In another embodiment, tubular portion 86 has a major axis at an angle A 81 relative to major

longitudinal axis 24 of tubular aortic component 12, as shown in FIG. 9A. In one embodiment, the angle is in the range of at least one of between about 0° and about 90°, such as 10°, 20°, 30°, 45°, 60°, and 90° C.

Further, as shown in FIGs. 9A and 9B, proximal end 92 of tubular portion 86 has geometric center 150 that is distinct from a geometric center 152 of tubular aortic component 12, wherein line 154 defined by geometric center 150 of proximal end 92 of tubular portion 86 and geometric center 152 of tubular aortic component 12 in a plane defined by proximal end 92 of tubular portion 86, taken along line 9 B of FIG. 9A, is at a positive angle B from line 156 defined by geometric center 152 of tubular aortic component 12 and point 158 along centerline 160 bisecting wall aperture 20 and parallel to major longitudinal axis 24 (FIG. 1A) of tubular aortic component 12, point 158 being in the same plane as the geometric centers 150, 152 of proximal end 92 of tubular portion 86 and tubular aortic component 12, respectively. Examples of suitable positive angles B can be at least one member selected for the group consisting of ±10°, ±20°, ±30°, ±45°, ±60°, ±90°, ±120°, ±135°, ±160°, ±170° and 180°.

In one embodiment, at least one radiopaque marker 99 is located at at least one of proximal end 92 of tunnel graft 28 and distal end 94 of tubular portion 86 of tunnel graft 28, as shown in FIGs. 2B, 3B and 4B. Another embodiment includes tubular portion 100 and further includes second tubular portion 102 of tunnel graft 28 extending proximal to open portion 84 of the tunnel graft 28, wherein second tubular portion 102 has distal end 104 and proximal end 106 as shown in FIGs. 7A, 7B, 8A and 8B. In one embodiment, not shown, second tubular portion 102 is of unequal length to that of first tubular portion 100. In another embodiment, shown in FIGS. 7A and 7B, second tubular portion 102 is parallel to first tubular portion 100. First tubular portion 100 and second tubular portion 102 are each a distinct, and integrally complete tubular portion. In another embodiment, shown in FIGs. 8A and 8B, tubular portions share common wall of a first graft material 108 that partition a conduit of the second graft material 110. In this embodiment, first 108 and second 110 graft materials define, at least in part, first tubular portion 100 and second tubular portion 102. As shown in FIGs. 10A and 10B, tubular portions 112 and 114

extend away from each other and proximally from open portion 84.

In still another embodiment, shown in FIGs. 2A, 2B, 3A, 3B, 4A and 4B, proximal end 92 of tunnel graft 28 has a diameter in a range between about 5 mm and about 10 mm, or between about 5 mm and about 15 mm, or between about 8 mm and about 15 mm. Generally, tubular portion 86 has a length in a range of between about 20 mm and about 60 mm, or between about 20 mm and about 100 mm. Most commonly, tubular portion 86 has a length in a range between about 30 and 50 mm. Preferably, proximal end 92 of tunnel graft 28 is within at least about 5 mm, about 10 mm, and about 15 mm or about 20 mm of proximal end 14 of tubular aortic component 12.

FIG. 12 shows one embodiment of aortic graft assembly 10 of the invention fully deployed within aorta 117 of a patient. FIGs. 13-15 show various stages of an aortic bypass operation (prior art).

As shown, in FIGs. 16A-16F, aortic graft assembly 200 (FIG. 16A) includes delivery component 202 (FIG. 16B) to which tubular aortic component 12 (FIG. 16A) is attached (FIGs. 16A and 16C). Delivery component 202 includes control catheter 204 (FIG. 16B), about which tubular aortic component 12 (FIG. 16C) extends, nose cone 206 (FIGs. 16B and 16C) is fixed at a distal end of control catheter 204 (FIGs. 17A and 17B).

In one embodiment, shown in FIGs. 17A, 17B and 17C, delivery component 202 further includes inner sheath 210 extending about control catheter 204. A distal opening at distal end 214 of inner sheath 210, can be tucked into nose cone 206 (FIGs. 17A, 17B and 18). In still another embodiment, shown in FIGs. 19A and 19B, inner sheath 210 includes inferior portion 82, said inferior portion 82 having fluted portion 85 as can be seen in FIG. 20. Optionally, as can be seen in FIGs. 21A and 21B, inner sheath 210 can be tapered to narrow toward distal end 211 or of essentially constant diameter. In one embodiment, inner sheath 210 defines at least one through hole 280 at proximal end 282 of inner sheath 210, as shown in FIGs. 25A and 25B.

As can be seen in FIGs. 17A and 17B, introducer sheath 216 extends about inner sheath 210 and about tubular aortic component 12, wherein introducer sheath

216 is retractable relative to inner sheath 210 to thereby release distal end 214 of inner sheath 210. Nose cone 206 can thereafter be retracted within inner sheath 210.

Delivery component 202, shown in FIGs. 17A, 17B, 17C and 22, further includes at least one supporting wire 230 fixed at proximal end 224 to support base 235, substantially parallel to a major longitudinal axis of outer control tube 232 and free at the distal end 228, wherein free end 228 of at least one of supporting wire 230 and internal sutures 62 (FIG. 17B) at the proximal end 14 of tubular aortic component 12 releasably secures proximal end 14 of tubular aortic component 12 to at least one of supporting wires 230. Outer control tube 232 is slidable along control catheter 204. Supporting wires 230 are fixed at proximal ends 224 to support base 235 at outer control tube 232 distal to proximal apex clasp 240. Free ends 228 of support wires 230 are proximate to proximal end 14 and to nose cone 206. Proximal portion 252 of distal apex clasp 238 and outer control tube 232 are slidable along the control catheter 204 with movement of outer control tube 232 (FIGs. 16B and 22). Distal apex clasp 238 fixes proximal end 14 of tubular aortic component 12 by securing exposed apices 58 (FIG. 16C) of clasping stent 56 at proximal end 14 of tubular aortic component 12. As shown in FIG. 16B, distal portion 248 of distal apex clasp 238 mates with of teeth 252 of proximal portion 250 of distal apex clasp 238 in a closed position that secures exposed apices 58 of clasping stent 56 of tubular aortic component 12.

Proximal apex clasp 240 is at outer control tube 232 (FIG. 17B). Proximal apex clasp 240 includes teeth 246 (FIG. 16B) extending distally from proximal portion 244 of proximal clasp 240. Teeth 246 extend distally through retention component 78 of tubular aortic component 12, as shown in FIG. 17B.

As shown in FIGs. 23A-23D, tubular branch component 254 includes proximal end 256 and distal end 258, wherein proximal end 256 of tubular branch component 254 is configured to engage proximal end 30 of tunnel graft 28. In an embodiment, the engagement is by interfering relation between tubular branch component 254 and tunnel graft 28. When aortic graft assembly 10 is implanted in the aorta of a patient, a seal forms with at least one member of the group consisting of the proximal end of at least one of the tubular aortic component 12, tubular

branch component 254 and second tubular branch component 260, and the distal end of at least one of tubular aortic component 12, tubular branch component 254 and second tubular component 260. A "seal" as defined herein, means that essentially no fluid will seep between the wall of a first conduit and the wall of a second conduit within which the first conduit is located. Such seals typically will be at the most proximal portion of a juncture between nested first and second conduits.

In one embodiment, supporting wire 230 has at least one stop 274 (FIG. 11), wherein stop 274 limits movement of suture loop 62 along supporting wire 230.

In another embodiment, tubular aortic component 12 includes radiopaque sutures 18 and inner sheath 210 includes radiopaque markers 276, all of which are longitudinally aligned along a path of relative movement of inner sheath 210 (FIGs. 16A-16F and 17A-17C) and tubular aortic component 12 during deployment of tubular aortic component 12, and are spaced apart from each other, whereby partial retraction of inner sheath 210 will cause overlap of radiopaque markers 276 with radiopaque markers 38. In one embodiment, radiopaque markers 38 are also, or alternatively, on superior portions of inner sheath 210 and tubular aortic component 12. Preferably, radiopaque markers 38, 276 are asymmetric, wherein a shape of radiopaque markers 38, 276 changes as radiopaque markers 38, 276 are aligned with a surgical site. Preferably, radiopaque markers 38, 276 of tubular aortic component 12 are elongated and are substantially aligned with the major longitudinal axis 24 of inner sheath 210.

In a preferred embodiment, referring back to FIGs. 16A-16F and 17A-17C, tubular aortic component 12 is further constrained at at least one end by a clasp, such as distal apex clasp 238 or proximal apex clasp 240, and the method includes the step of releasing the clasp with retraction of supporting wire 230 from suture loop 62 of tubular aortic component 12. In this embodiment, preferably, tubular aortic component 12 further includes at least one radiopaque marker 38, wherein, preferably, radiopaque marker 38 is located on tubular aortic component 12 facing away from cavity 284 (FIG. 18) of the curve 286 (FIG. 18) defined by control catheter 204. Preferably, inner sheath 210 further includes at least one radiopaque marker 276, wherein radiopaque marker 276 of inner sheath 210 overlaps at least

one radiopaque marker 276 of tubular aortic component 12 when tubular aortic component 12 is partially deployed. In still another embodiment, tubular aortic component 12 is further constrained by proximal clasp 240 and proximal fixed end 234 of supporting wire 230.

A method for implanting a prosthesis of the invention includes the steps of delivering tubular aortic component 12 within introducer sheath 216 along guidewire 320 through an aorta 262 to aneurysm 270 of the patient, shown in FIGs. 24A-24E. Tubular aortic component 12 is radially constrained and supported at least in part by control catheter 204 (FIGs. 16B, 16C, 16D), which is slidable along guidewire 320 (FIGs. 24A-24E). As shown in FIGs. 16A-16F and 17A-17C, tubular aortic component 12 is further longitudinally constrained by at least one supporting wire 230 extending from support base 235 at outer control tube 232 extending about and slidable along control catheter 204. Free end 228 of at least one of supporting wire 230 is arcuate and extends through suture loop 62 (FIG. 17B), within proximal end 14 of tubular aortic component 12.

Referring back to FIGs. 24A-24E, tubular aortic component 12 is guided to aneurysm 270 along guidewire 320. Inner sheath 210 (FIG. 17B), is partially retracted from tubular aortic component 12, whereby supporting wire 230 at least partially restricts longitudinal movement of proximal end 14 of tubular aortic component 12 until proximal end 14 of tubular aortic component 12 is secure within aorta 262 (FIGs. 24A-24E) of the patient to thereby prevent collapse of proximal end 14 of tubular aortic component 12 at an inferior portion 264 of aorta 262.

In one embodiment, inner sheath 210 is releasably secured at distal end 214 within a cavity defined by the proximal end of nose cone 206 (FIG. 18). In this embodiment, as shown in FIGs. 24A-24E, optional inner sheath 210 is partially retracted to release the distal end of the inner sheath 210 from nose cone 206 and thereby cause partial expansion of tubular aortic component 12. Wall aperture 20 is aligned over at least one vessel ostium 290, 292, 294 at aneurysm site 263 of the patient. Optionally, in embodiments of the invention that employ inner sheath 210, inner sheath 210 is then partially retracted to expose the proximal end 14 of tubular aortic component 12, including crown stent 56 and the clasping stent 60 (FIG. 1A).

Control tube 232 is then partially extended to release bare apices 58 (FIG. 1A) of clasping stent 56 from distal clasp 238 and to release retention component 78 from proximal clasp 240 (FIGs. 16B and 17B), while retaining suture loops 62 on ends 228 of support wires 230 (FIGs. 16A-16F and 17A-17C). Nose cone 206 is then partially retracted into proximal end of tubular aortic component 12 and the delivery assembly and tubular aortic component 12 are then advanced to a final position within aorta 262 spanning aneurysm 263 of the patient. Control tube 232 is then further retracted to release suture loops 62 from ends 228 of support wires 230. Inner sheath 210 is then fully retracted (in embodiments of the invention that employ inner sheath 210) and then nose cone 206 and supporting wires 230 are fully retracted to complete deployment of tubular aortic component 12.

In an embodiment, the method of the invention includes the step of implanting at least one tubular branch component 254 in at least one of an innominate artery (also referred to as "brachiocephalic artery") 290, a left subclavian artery 292, a left common carotid artery 294, or right common carotid artery 296 of the patient into wall aperture 20 and tunnel graft 28 within tubular aortic component 12, as shown, with respect to the prior art, in FIGs. 13-15, and in FIGs. 24A-24E. In a preferred embodiment, the method of the invention includes the steps of implanting tubular branch component 254 into innominate artery 290, and another tubular branch component, into the left common carotid artery 294 (FIG. 24E).

Implantation of the aortic graft assemblies of the invention can include implantation in at least one of a portion of the ascending aorta, the aortic arch, the descending aorta and abdominal aorta (see FIGs. 12, 24A-24E and 26A-26C). Implantation near, around or at the arch of the aorta, can include a right common carotid to left common carotid artery bypass with ligation of the left common carotid inferior to the point of the bypass and a left common carotid artery to left subclavian artery bypass with ligation inferior to the bypass. In another embodiment, for example, an aortic graft assembly of the invention that includes two tubular branch components (*e.g.*, one into the right common carotid, another into the left common carotid) can include a left common carotid artery to left subclavian artery bypass, with ligation of the left subclavian artery inferior to the bypass (see FIGs. 16 and

17). Alternatively, as shown in FIGs. 26A-26C, aortic assembly systems can be implanted in the abdominal aorta 300. Opening 84 can be placed in abdominal aorta proximate to celiac artery 302, superior mesenteric artery 304 or renal artery 306, thereby spanning aneurysm 308. Tubular branch component 254 can then be implanted into at least one of celiac artery 302, superior mesenteric artery 304 or at least one renal artery 306.

In another embodiment, shown in FIGs. 25A and 25B, inner sheath 210 about tubular aortic component 12, includes proximal perforated portion 280 that defines through-holes 282. Through-holes 282 can be defined by a mesh or fabric of perforation portion 280, as shown in FIG. 25A, or as distinct openings, such as longitudinal through-hole opening 284 shown in FIG. 25B. The through-holes permit relatively continuous blood flow during implantation of the prosthesis, as further described in U.S. Published Patent Application No.: 2010/0234932, the teachings of which are incorporated herein by reference in their entirety.

Suitable systems, delivery devices and components of systems, stent grafts as described in U.S. Application Nos. 11/449,337, filed on June 8, 2006; 11/699,700, filed on January 30, 2007; 11/700,609, filed on January 31, 2007; 11/701,867, filed on February 1, 2007; 11/828,653, filed on July 26, 2007; 12/137,592, filed on June 12, 2008; 11/701,876, filed on February 1, 2007; 61/164,545, filed on March 30, 2009; 12/459,387, filed on June 30, 2009; and U.S. Patent Nos.: 7,763,063; 8,007,605; 8,062,345; 8,062,349; 8,070,790; 8,292,943 and 8,308,790, the teachings of all of which are hereby incorporated by reference in their entirety, can be employed to deliver the aortic graft assembly of the invention by the method of the invention.

The teachings of all patents, published applications and references cited herein are incorporated by reference in their entirety.

Example 1

A 74 year old male with penetrating atherosclerotic ulcer (PAU) of the aorta located on the interior side of the thoracic arch at the level of the left common carotid was treated. A model of the patient's anatomy was made based on computer tomography (CT) scanning. A right carotid to left carotid bypass was performed initially without ligating the left carotid. A tubular aortic component of an aortic graft assembly (46 mm-42 mm x 80 mm) was deployed at the sinotubular junction. The ascending aorta of this patent had a graft diameter of about 44 mm. A tubular aortic component having a diameter of 46/42 mm x 80 mm was employed to provide a smaller healthy neck. The proximal end of the tubular aortic component of the aortic graft assembly was released to optimize apposition with the wall of the ascending aorta.

A tunnel graft (46 mm-34 mm x 220 mm) was used in the aortic graft assembly. The tunnel graft was 15 mm in diameter. The aperture of the tubular aortic component was 30 mm x 30 mm. A graft of a size of 15 mm – 17 mm x 100 mm or 15 mm – 17 mm x 110 mm) was employed to bridge the graft tunnel with the brachial cephalic trunk and a wire-catheter was positioned prior to implantation as a precautionary bailout. An angiogram was performed to confirm profusion to the and left common carotid arteries. The tunnel graft was advanced to the proximal portion of the aperture of the tubular aortic component with the distal end of at least one tubular branch component. The graft was aligned to allow canulation of the tunnel graft through the innominate or the left common carotid arteries based on movement of the tubular aortic component. The tunnel graft was canulated via the right common carotid. A relatively short tubular branch component was selected in this patient because the tunnel graft was deployed more distally. The distal end of the branch graft was aligned with the brachial cephalic trunk bifurcation and the tubular branch graft deployed without complication. An angiogram showed exclusion of the aneurysm with flow to the innominate artery and left common carotid artery via a carotid-carotid bypass.

Example 2

An 81 year old male with an aneurysm at the arch of the aorta was treated. A CT scan was employed to model the patient's anatomy. The thoracic aneurysm was in a region of the aortic arch and at least a portion of the descending aorta. The tunnel graft had a diameter of about 15 mm.

While this invention has been particularly shown and described with references to example embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

CLAIMS

What is claimed is:

1. An aortic graft assembly, comprising:
   a) a tubular aortic component that includes a proximal end and a distal end connected by a wall of the tubular aortic component, the wall defining a wall aperture that is between the proximal and distal ends, the wall aperture having a proximal end and a distal end, the proximal end of the wall aperture extending perpendicular to a major longitudinal axis of the tubular aortic component when viewed orthogonally to the major longitudinal axis;
   b) a tunnel graft connected to the wall of the tubular aortic component and extending from the wall aperture toward the proximal end of the tubular aortic component, the tunnel graft having a proximal end and a distal end, the distal end being at the wall aperture of the tubular aortic component;
   c) a proximal stent that supports the proximal end of the tubular aortic component; and
   d) a distal stent that supports the distal end of the tubular aortic component.

2. The aortic graft assembly of Claim 1, further including a clasping stent at the proximal end of the tubular aortic component, the clasping stent including at least two exposed proximal apices proximate to the proximal end of tubular component.

3. The aortic graft assembly of Claim 2, wherein the clasping stent is attached to an interior wall of the tubular aortic component.

4. The aortic graft assembly of Claim 3, wherein the tubular aortic component includes a centerline that bisects the wall aperture and two of the exposed proximal apices of the clasping stent are adjacent to the centerline, whereby

collapse of the unattached apices will cause at least partial collapse of the tubular aortic component at the clasping stent.

5. The aortic graft assembly of Claim 2, further including a crown stent between the clasping stent and the proximal end of the tubular aortic component.

6. The aortic graft assembly of Claim 5, wherein the crown stent includes proximal and distal apices connected by struts.

7. The aortic graft assembly of Claim 6, wherein the proximal apices of the crown stent are blunted relative to the distal apices of the crown stent.

8. The aortic graft assembly of Claim 7, wherein the clasping and crown stents are nested with each other.

9. The aortic graft assembly of Claim 8, wherein the crown stent is attached to an interior surface of the tubular aortic component.

10. The aortic graft assembly of Claim 1, further including at least one stent between the proximal and distal stents wherein at least a portion of said stent includes alternating proximal and distal apices connected by struts.

11. The aortic graft assembly of Claim 1, further including at least two support wire sutures within the tubular aortic component at the proximal end of the tubular aortic component.

12. The aortic graft assembly of Claim 11, wherein at least one of the support wire sutures are at an inferior portion within the tubular aortic component.

13. The aortic graft assembly of Claim 12, wherein the support wire sutures are distal to proximal apices of the clasping stent.

14. The aortic graft assembly of Claim 13, wherein the support wire sutures are separated by at least one distal apex of the proximal clasping stent.

15. The aortic graft assembly of Claim 1, wherein the length of the proximal end of the wall aperture transverse to a major longitudinal axis of the tubular aortic component is equal to or less than one-half the circumference of the tubular aortic component.

16. The aortic graft assembly of Claim 15, wherein the length of the proximal end of the wall aperture is about 6 mm, about 8 mm, about 10 mm, about 12 mm or about 14 mm.

17. The aortic graft assembly of Claim 15, wherein a longitudinal length of the wall aperture is equal to or less than about 90 mm.

18. The aortic graft assembly of Claim 15, wherein the longitudinal length of the wall aperture is equal to or greater than about 14 mm.

19. The aortic graft assembly of Claim 1, wherein the proximal stent that includes at one distal apex that abuts the proximal end of the wall aperture.

20. The aortic graft assembly of Claim 19, further including a radiopaque marker at a distal apex of the proximal stent.

21. The aortic graft assembly of Claim 1, wherein the distal stent is attached to an interior wall of the tubular aortic component.

22. The aortic graft assembly of Claim 1, further including an abutting distal stent that includes at least one proximal apex that abut the distal end of the wall aperture.

23. The aortic graft assembly of Claim 22, further including a radiopaque marker at a proximal apex of the abutting distal stent.

24. The aortic graft assembly of Claim 1, further including a retention component distal to the wall aperture.

25. The aortic graft assembly of Claim 24, wherein the retention component is at a proximal apex of the distal stent abutting the distal end of the wall aperture.

26. The aortic graft assembly of Claim 24, wherein the retention component is a suture loop.

27. The aortic graft assembly of Claim 24, wherein the retention component is at least one of a magnet or a stent apex.

28. The aortic graft assembly of Claim 24, wherein the retention component is radiopaque.

29. The aortic graft assembly of Claim 22, wherein the stents abutting the wall aperture abut the wall aperture at apices of the stents.

30. The aortic graft assembly of Claim 29, further including a stent located between the proximal and distal ends of the wall aperture.

31. The aortic graft assembly of Claim 30, wherein the stent between the proximal and distal ends of the wall aperture includes struts that define at least a portion of the wall aperture.

32. The aortic graft assembly of Claim 1, further including a stent that surrounds the wall aperture.

33. The aortic graft assembly of Claim 1, wherein the diameter of the proximal end of the tubular aortic component is greater than the diameter of the distal end of the tubular aortic component.

34. The aortic graft assembly of Claim 1, wherein an interface between the tubular aortic component at the wall aperture and the tunnel graft when viewed orthogonally to the major longitudinal axis of the tubular aortic component is a polygon.

35. The aortic graft assembly of Claim 34, wherein the polygon has four sides.

36. The aortic graft assembly of Claim 34, wherein the polygon is a square.

37. The aortic graft assembly of Claim 34, wherein the polygon is a rectangle.

38. The aortic graft assembly of Claim 34, wherein the polygon is a parallelogram.

39. The aortic graft assembly of Claim 34, wherein the polygon is a rhombus.

40. The aortic graft assembly of Claim 1, wherein an inferior portion is on one side of the tubular aortic component opposite the wall aperture and is parallel to the major longitudinal axis of the tubular aortic component, and a superior portion is on the opposite side of tubular aortic component, and wherein the inferior portion is fluted, whereby the diameter of the tubular aortic component increases from the distal end to the proximal end of the tubular aortic component.

41. The aortic graft assembly of Claim 1, further including radiopaque markers extending about the wall aperture at the tubular aortic component.

42. The aortic graft assembly of Claim 1, wherein the tunnel graft includes an open portion at the wall aperture, the open portion defining a proximal end, and a tubular portion extending proximally from the open portion, the tubular portion defining a proximal end, and a distal end at the proximal end of the open portion.

43. The aortic graft assembly of Claim 42, wherein the tubular portion is secured to the tubular aortic component.

44. The aortic graft assembly of Claim 43, wherein the tubular portion further includes a stent at each of the proximal end and the distal end of the tubular portion.

45. The aortic graft assembly of Claim 44, wherein the stents at the proximal and distal ends of the tubular portion include proximal and distal apices connected by struts.

46. The aortic graft assembly of Claim 45, wherein at least one of the stent includes at least one barb.

47. The aortic graft assembly of Claim 46, wherein the tubular portion further includes at least one stent between the stent at the proximal and distal ends of the tubular portion.

48. The aortic assembly of Claim 47, wherein at least one of the stents between the stents at the proximal and distal ends of the tubular portion includes at least one barb.

49. The aortic graft assembly of Claim 48, wherein the stents of the tubular portion include nitinol.

50. The aortic graft assembly of Claim 42, wherein the distal end of the tubular portion has a diameter greater than that of the proximal end of the tubular portion.

51. The aortic graft assembly of Claim 50, wherein the distal end of the tubular portion is generally conical.

52. The aortic graft assembly of any of Claim 50, wherein the tubular portion has a major longitudinal axis that is parallel to the major longitudinal axis of the tubular aortic component.

53. The aortic graft assembly of Claim 52, wherein the proximal end of the tubular portion is distal to the proximal end of the tubular aortic component.

54. The aortic graft assembly of Claim 52, wherein the proximal end of the tubular portion is coterminous with the proximal end of the tubular aortic component.

55. The aortic graft assembly of Claim 42, wherein the proximal end of the tubular portion has a geometric center that is distinct from a geometric center of the tubular aortic component, wherein a line defined by the geometric centers of the proximal end of the tubular portion and the tubular aortic component in a plane of the proximal end of the tubular portion is at a positive angle from a line defined by the geometric center of the tubular aortic component and a point along a centerline bisecting the wall aperture and parallel to the major longitudinal axis of the tubular aortic component, the point being in the same plane as the geometric centers of the proximal end of the tubular portion and the tubular aortic component.

56. The aortic graft assembly of Claim 55, wherein the angle is selected from the group consisting of $\pm 10^{o}$, $\pm 20^{o}$, $\pm 30^{o}$, $\pm 45^{o}$, $\pm 90^{o}$, $\pm 120^{o}$, $\pm 135^{o}$, $\pm 160^{o}$, $\pm 170^{o}$ and 180^{o}.

57. The aortic graft assembly of Claim 42, further including at least one radiopaque marker at least one of the proximal end of the tunnel graft and the distal end of the tubular portion of the tunnel graft.

58. The aortic graft assembly of Claim 42, wherein the tubular portion is a first tubular portion, and further including a second tubular portion of the tunnel graft extending proximally from the open portion of the tunnel graft, wherein the second tubular portion has a distal end and a proximal end.

59. The aortic graft assembly of Claim 58, wherein the second tubular portion is of about equal length to the first tubular portion.

60. The aortic graft assembly of Claim 59, wherein the second tubular portion is parallel to the first tubular portion.

61. The aortic graft assembly of Claim 60, wherein the first and second tubular portions are each distinct and integrally complete tubular portions.

62. The aortic graft assembly of Claim 61, wherein the tubular portions share a common wall of a first graft material that partition a conduit of a second graft material, the first and second graft materials defining, at least in part, the first tubular portion and the second tubular portion.

63. The aortic graft assembly of Claim 1, wherein the proximal end of the tunnel graft has a diameter in a range of between about 5 mm and about 10 mm, between about 5 mm and about 15 mm or between about 8 mm and about 15 mm.

64. The aortic graft assembly of Claim 1, in which the distance between a proximal end of the wall aperture and the proximal end of the tubular aortic component is in a range of between about 20 mm, about 40 mm, about 60 mm, about 80 mm or about 90 mm.

65. The aortic graft assembly of Claim 1, wherein the tunnel graft has a length in a range of at least one of between about 20 mm and about 60 mm or of between about 20 mm and about 100 mm.

66. The aortic graft assembly of Claim 65, wherein the tunnel graft has a length in a range of between about 30 and about 50 mm.

67. The aortic graft assembly of Claim 66, the proximal end of the tunnel graft is within at least about 5 mm, about 10 mm, about 15 mm or about 20 mm of the proximal end of the tubular aortic component.

68. The aortic graft assembly of Claim 1, wherein the stents include nitinol.

69. The aortic graft assembly of Claim 1, further including a radiopaque marker at each of at least one of the proximal and distal ends of the tubular aortic component.

70. The aortic graft assembly of Claim 1, further including a delivery component to which the tubular aortic component is attached, the delivery component including:

a) a control catheter, about which the tubular aortic component extends; and

b) a nose cone fixed at a distal end of the control catheter.

71. The aortic graft assembly of Claim 70, wherein the delivery component further includes an inner sheath extending about the control catheter that defines a distal opening at a distal end of the inner sheath, wherein the nose cone is retractable within the inner sheath.

72. The aortic graft assembly of Claim 71, further including an introducer sheath about the inner sheath and about the tubular aortic component, wherein the introducer sheath is retractable relative to the inner sheath to thereby release

the distal end of the inner sheath, and whereby the nose cone can thereafter be retracted within the inner sheath.

73. The aortic graft assembly of Claim 72, further including at least one supporting wire fixed at a proximal end, substantially parallel to a major axis of the control catheter and free at a distal end, wherein a free end of at least one of the supporting wires is arcuate and wherein the sutures at the proximal end of the tubular aortic component releasably secures the proximal end of the tubular aortic component to at least one of the supporting wires.

74. The aortic graft assembly of Claim 73, further including an outer control tube slidable along the control catheter, wherein the at least one supporting wire is fixed at the proximal end to the outer control tube.

75. The aortic graft assembly of Claim 74, wherein the supporting wire is fixed at the proximal end to the outer control tube proximal to the nose cone and the free end is distal to the proximal end and is proximate to the nose cone.

76. The aortic graft assembly of Claim 75, further including a distal apex clasp at a distal end of the outer control tube and slidable along the control catheter with movement of the outer control tube.

77. The aortic graft assembly of Claim 76, wherein the distal apex clasp fixes the proximal end of the tubular aortic component by securing the exposed apices of the clasping stent of the tubular aortic component.

78. The aortic graft assembly of Claim 77, wherein the delivery component further includes a proximal apex clasp at a proximal end of the outer control tube that includes a distal portion fixed to the control catheter and a proximal portion, the proximal portion including proximally extending teeth that extend distally through the exposed apices of the clasping stent of the tubular aortic component.

79. The aortic graft assembly of Claim 78, wherein the distal portion of the distal apex clasp includes a clasp sheath that overlays distal ends of the teeth of the distal apex clasp when in a closed position that secures exposed apices of the clasping stent of the tubular aortic component.

80. The aortic graft assembly of Claim 79, wherein the proximally extending teeth of the proximal apex clasp secure the tubular aortic component at the retention component.

81. The aortic graft assembly of Claim 1, further including at least one tubular branch component that includes a proximal end and a distal end, wherein the proximal end of the tubular branch component is configured to engage the proximal end of the tunnel graft.

82. The aortic graft assembly of Claim 81, wherein the wall aperture has a diameter at least twice that of the widest diameter of the combined diameters of the at least one tubular branch component.

83. The aortic graft assembly of Claim 82, wherein the wall aperture has a diameter at least three times that of the widest diameter of the combined diameters of the at least one tubular branch component.

84. A method for implanting a prosthesis, comprising the steps of:

a) delivering a tubular aortic component defining a wall aperture through an aorta to an aneurysm site of a patient, the tubular aortic component being radially and releasably constrained by a distal clasp at a distal end of an outer control tube of a delivery device, and releasably attached by a retention component to a proximal clasp at the outer control tube proximal to the proximal clasp, the tubular aortic component further supported by a control catheter of the delivery device extending within the outer control tube;

b) aligning the wall aperture over at least one vessel ostium at the aneurysm site of the patient; and

c) retracting the outer control tube, thereby releasing the tubular aortic component from the distal and proximal clasps, thereby deploying the tubular aortic component at the aneurysm site in the patient.

85. The method of Claim 84, wherein at least one supporting wire extends from the control tube, said supporting wire extending through a suture loop inside the proximal end of the tubular aortic component to thereby prevent collapse of the proximal end of the tubular component during deployment.

86. The method of Claim 85, further including the step of partially retracting an inner sheath from around the tubular aortic component, whereby the supporting wire at least partially restricts longitudinal movement of the proximal end of the tubular aortic component until the proximal end of the tubular aortic component is secure within the aorta, to thereby prevent collapse of the proximal end of the tubular aortic component at an inferior portion of the aorta.

87. The method of Claim 86, wherein the control catheter is curved.

88. The method of Claim 87, wherein the aperture aligns over two vessel ostiums at the aneurysm site of the patient.

89. The method of Claim 85, wherein the supporting wire has at least one stop, the stop limiting movement of the retention component along the supporting wire.

90. The method of Claim 86, wherein the inner sheath is releasably secured to a distal end within a cavity defined by a proximal end of the nose cone, wherein the steps of the method include:

a) partially retracting an inner sheath from around the tubular aortic component to release the distal end of the inner sheath from the nose cone and thereby cause partial deployment of the tubular aortic component;

b) partially retracting the control catheter to thereby release the clasping stent from the distal apex clasp and the retention component from the proximal clasp;

c) further retracting the control catheter to at least partially retract the nose cone to within the tubular aortic component while retaining the suture loops on the supporting wires;

d) advancing the tubular aortic component to a final position in the aorta of the patient spanning the aneurysm;

e) fully retracting the inner sheath from the tubular aortic component; and

f) fully retracting the nose cone and supporting wires to release the suture loops from the supporting wires, thereby fully deploying the tubular aortic component within the aorta of the patient.

91. The method of Claim 90, wherein the inner sheath defines at least one through hole at a proximal end of the inner sheath.

92. The method of Claim 84, further including the step of partially retracting an inner sheath from around the tubular aortic component, and wherein the tubular aortic component and the inner sheath each include a radiopaque marker longitudinally aligned along a path of relative movement of the inner sheath and tubular aortic component during deployment of the tubular aortic component, and spaced apart from each other, whereby the partial retraction of the inner sheath will cause overlap of the radiopaque markers.

93. The method of Claim 92, wherein the radiopaque markers are on superior portions of the inner sheath and the tubular aortic component.

94. The method of Claim 93, wherein the radiopaque marker of the tubular aortic component is elongate and substantially aligned with the major longitudinal axis of the inner sheath.

95. The method of Claim 84, wherein the tubular aortic component further includes at least one radiopaque marker.

96. The method of Claim 95, wherein the radiopaque marker is located on the tubular aortic component facing away from a concavity of a curve defined by the control catheter.

97. The method of Claim 84, further including the step of implanting a tubular branch component through at least one of a brachial artery or a subclavian artery of the patient into the wall aperture and the tunnel graft within the tubular aortic component.

98. The method of Claim 84, wherein the retention component is a suture loop.

99. The method of Claim 84, wherein the retention component is radiopaque.

100. The method of Claim 84, wherein the retention component is at least one of a magnet or stent apex.

101. An aortic graft assembly, comprising:

a) a tubular aortic component that includes a proximal end and a distal end connected by a wall of the tubular aortic component, the wall defining a wall aperture that is between the proximal and distal ends, the wall aperture having a proximal end and a distal end, the proximal end of the wall aperture extending perpendicular to a major longitudinal axis of the tubular aortic component when viewed orthogonally to the major longitudinal axis;

b) a tunnel graft connected to the wall of the tubular aortic component and extending from the wall aperture toward the proximal end of the tubular aortic component, the tunnel graft having a proximal end and a distal end, the distal end being at the wall aperture of the tubular aortic component;

c) a proximal stent that supports the proximal end of the tubular aortic component;

d) a distal stent that supports the distal end of the tubular aortic component;

e) a clasping stent at the proximal end of the tubular aortic component, the clasping stent including at least two exposed proximal apices proximate to the proximal end of tubular component and attached to an interior wall of the tubular aortic component; and

f) a crown stent between the clasping stent and the proximal end of the tubular aortic component, the crown stent attached to an interior surface of the tubular aortic component.

102. An aortic graft assembly, comprising:

a) a tubular aortic component that includes a proximal end and a distal end connected by a wall of the tubular aortic component, the wall defining a wall aperture that is between the proximal and distal ends, the wall aperture having a proximal end and a distal end, the proximal end of the wall aperture extending perpendicular to a major longitudinal axis of the tubular aortic component when viewed orthogonally to the major longitudinal axis;

b) a tunnel graft connected to the wall of the tubular aortic component and extending from the wall aperture toward the proximal end of the tubular aortic component, the tunnel graft having a proximal end and a distal end, the distal end being at the wall aperture of the tubular aortic component;

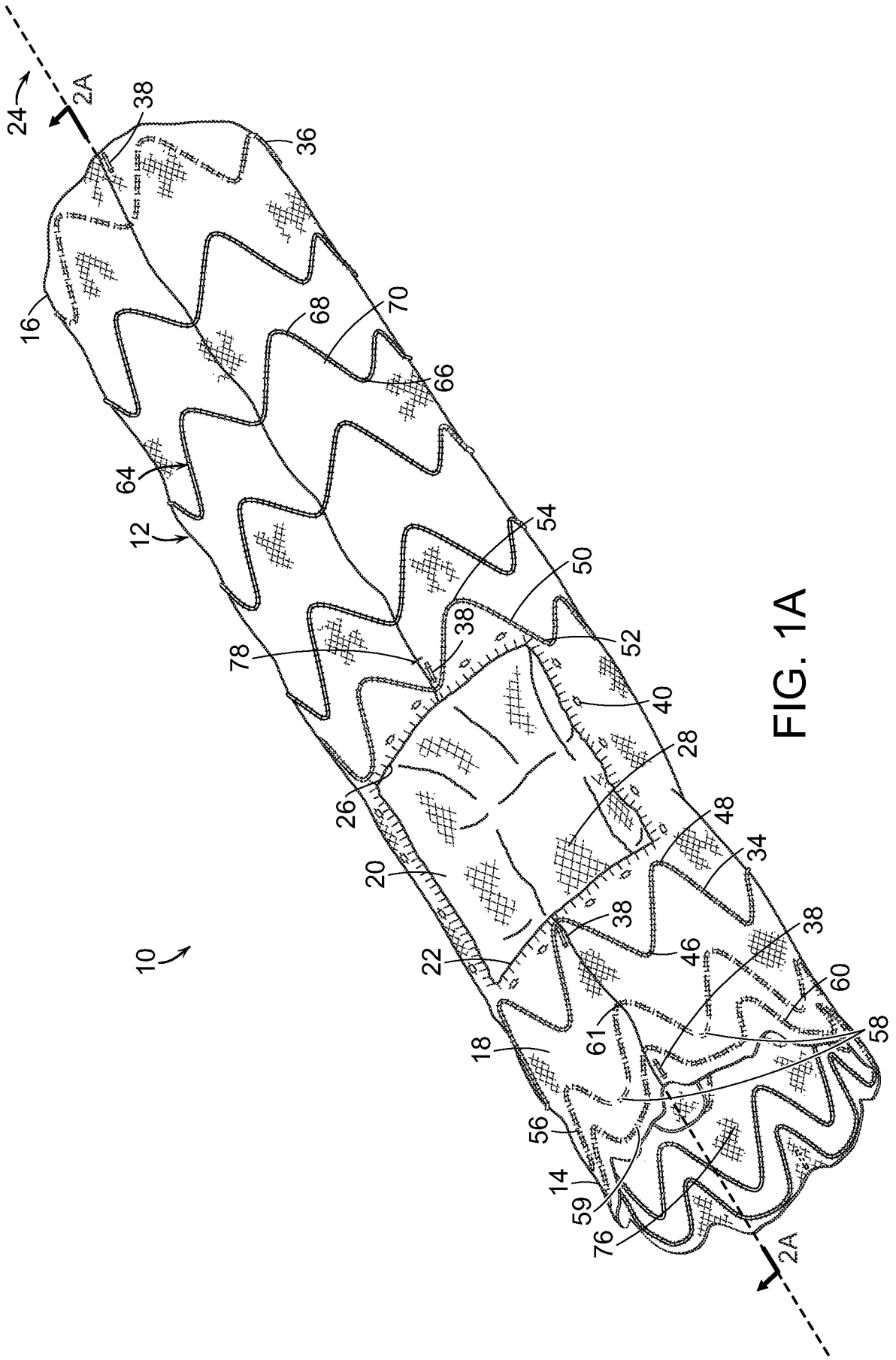
c) a proximal stent that abuts the proximal end of the tubular aortic component;

d) a distal stent that supports the distal end of the tubular aortic component;

e) an abutting distal stent that includes at least one proximal apex that abut the distal end of the wall aperture;

f) a clasping stent at the proximal end of the tubular aortic component, the clasping stent including at least two exposed proximal apices proximate to the proximal end of tubular component and attached to an interior wall of the tubular aortic component; and

g) a crown stent between the clasping stent and the proximal end of the tubular aortic component, the crown stent attached to an interior surface of the tubular aortic component.


24
2A
38
36
16
68
70
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12
54
50
38
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78
40
28
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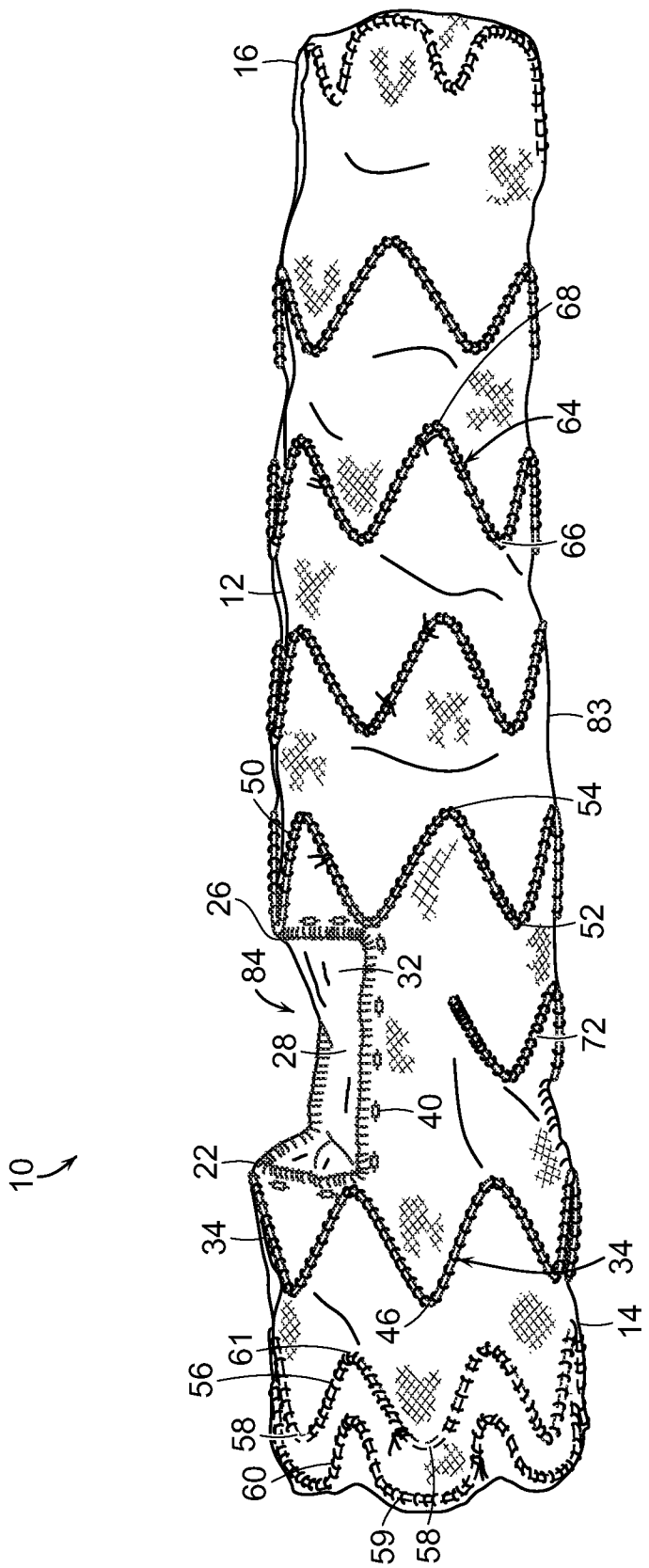
38
22
46
60
61
58
18
56
14
59
76
2A
10

FIG. 1A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61
56
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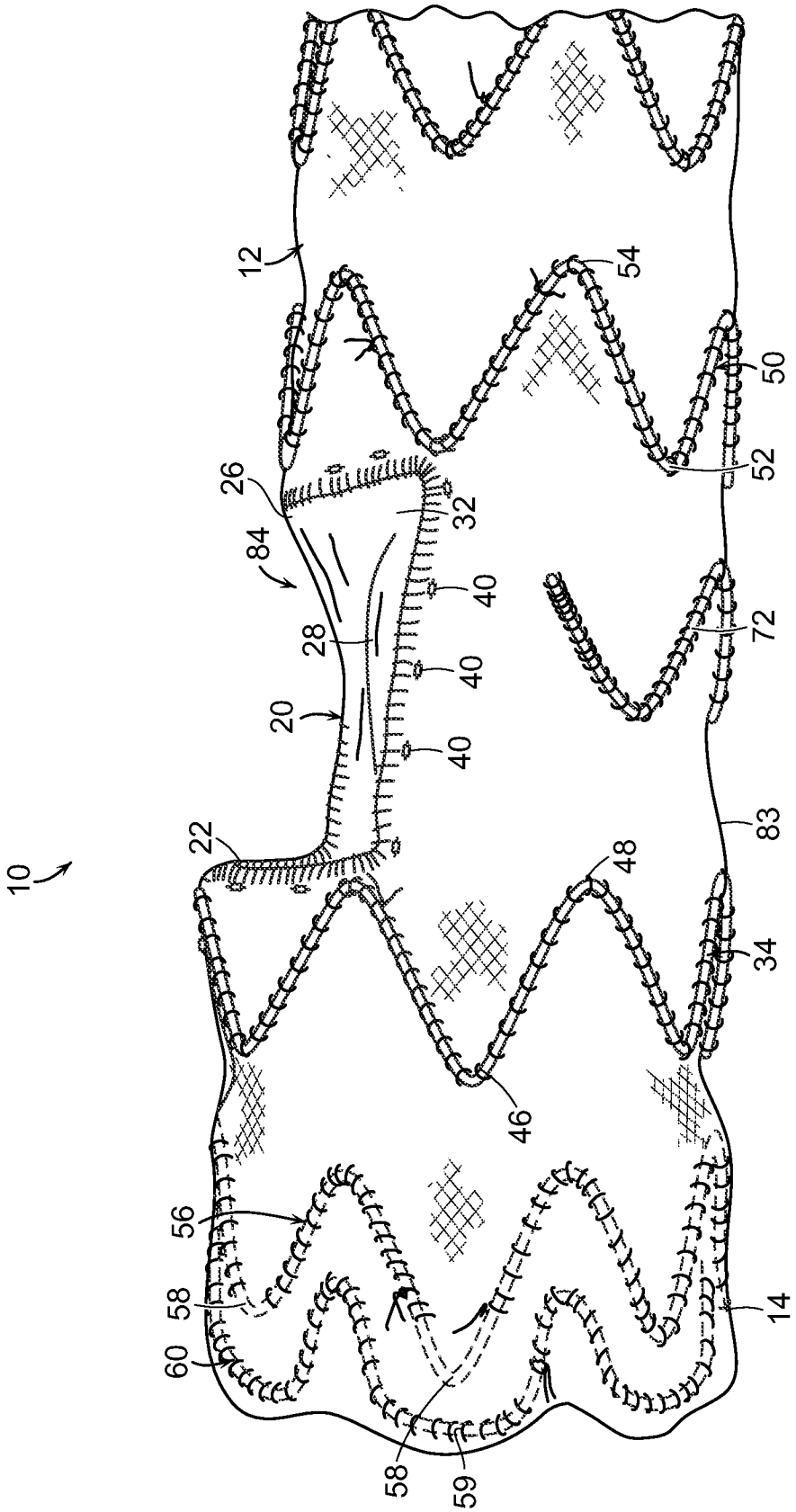
60
59
58

FIG. 1B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14
60
58
59

FIG. 1C

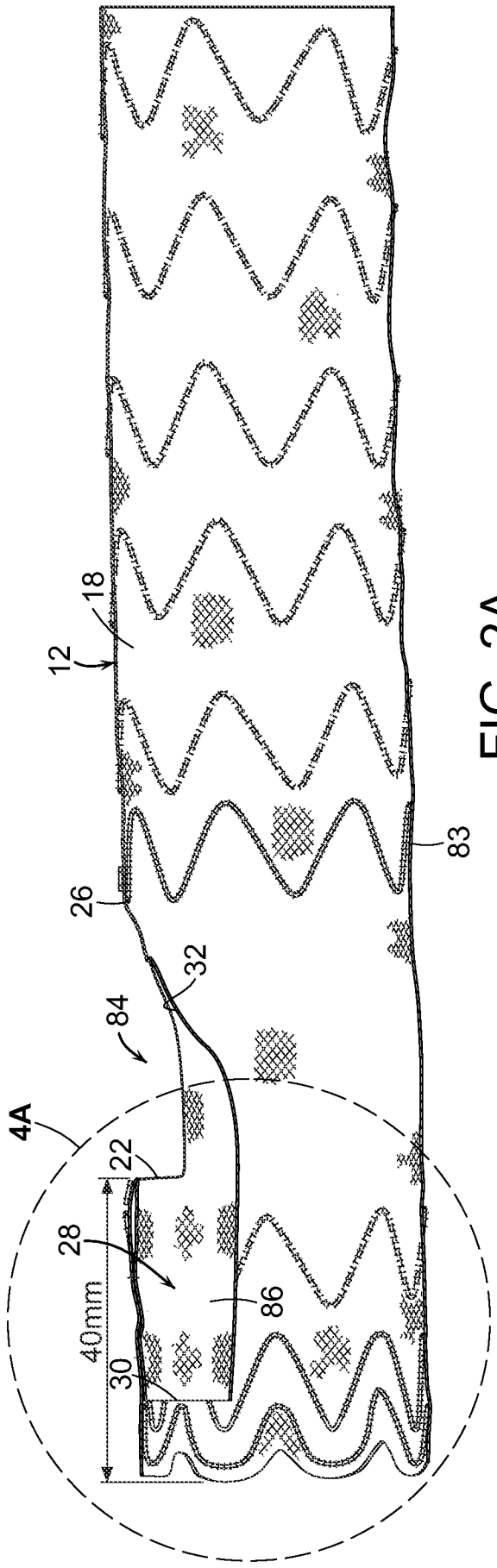

12
18
26
32
84
4A
22
28
40mm
30
86
83

FIG. 2A

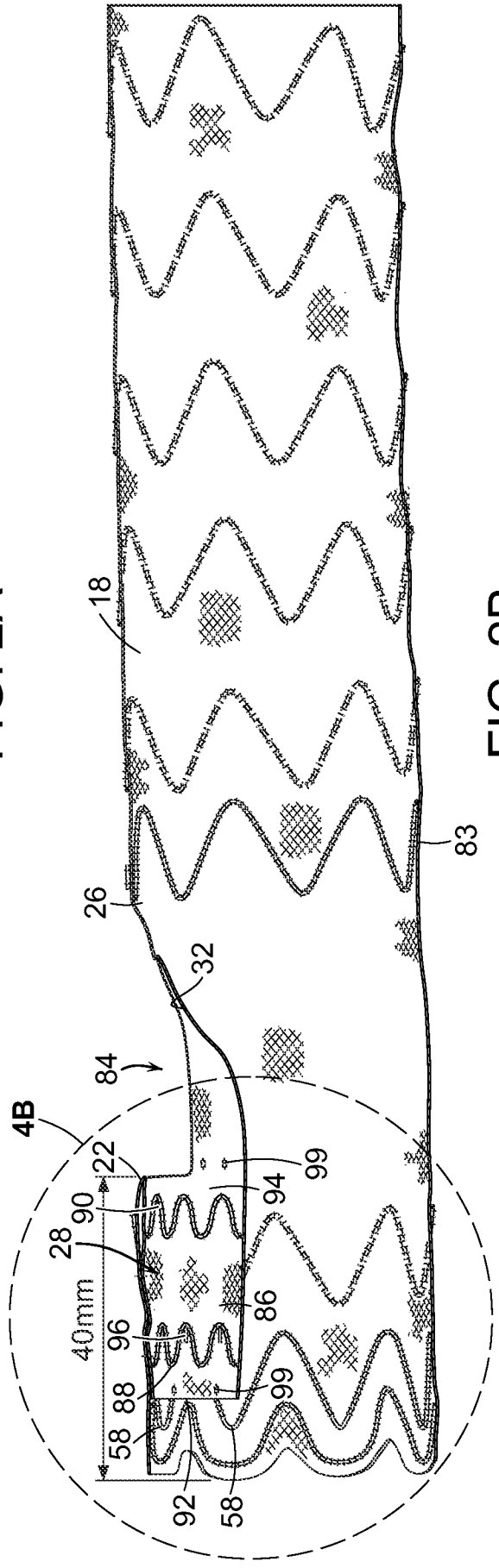

18
26
32
84
4B
22
99
94
90
28
40mm
86
96
88
99
58
92
58
83

FIG. 2B

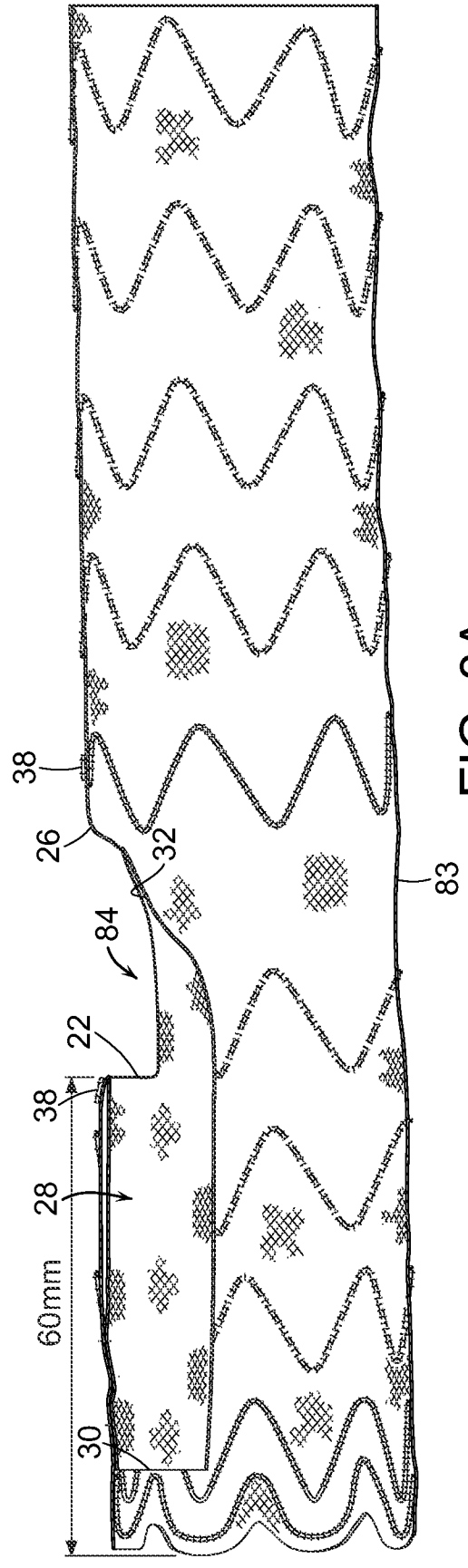
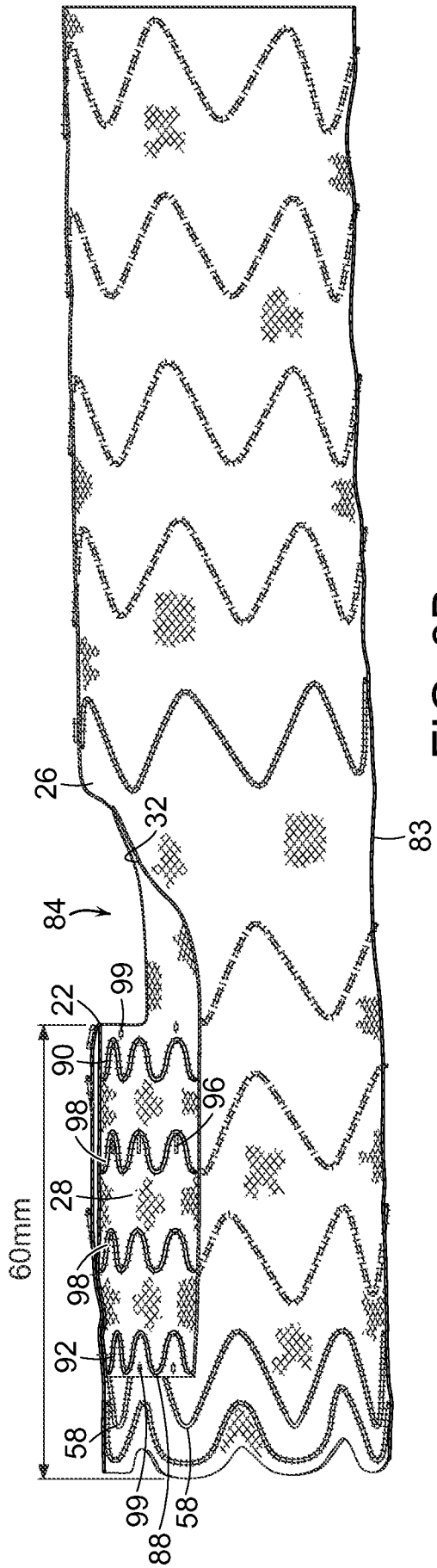

38
26
32
84
22
38
28
60mm
30
83

FIG. 3A


26
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22
99
90
98
96
28
98
92
58
99
88
58
60mm
83

FIG. 3B

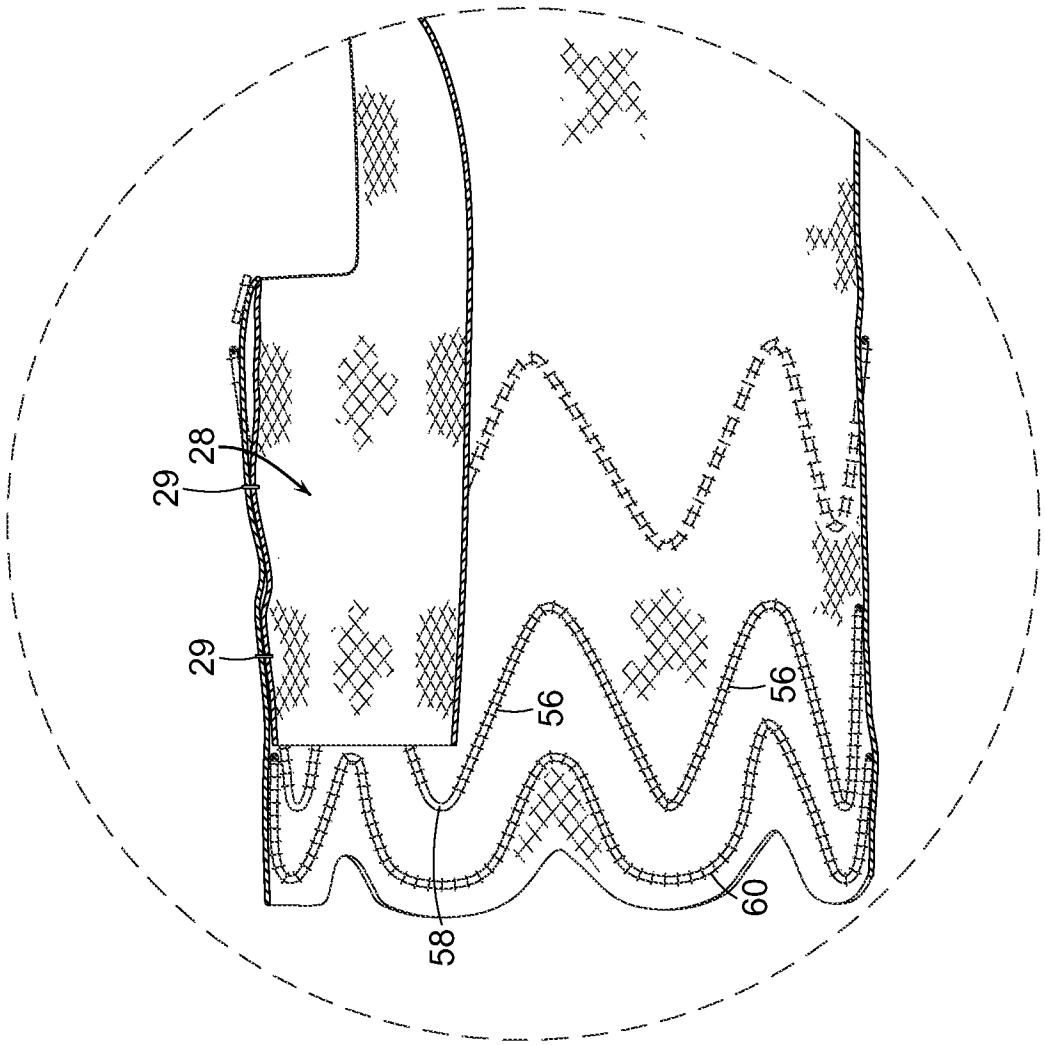


FIG. 4A

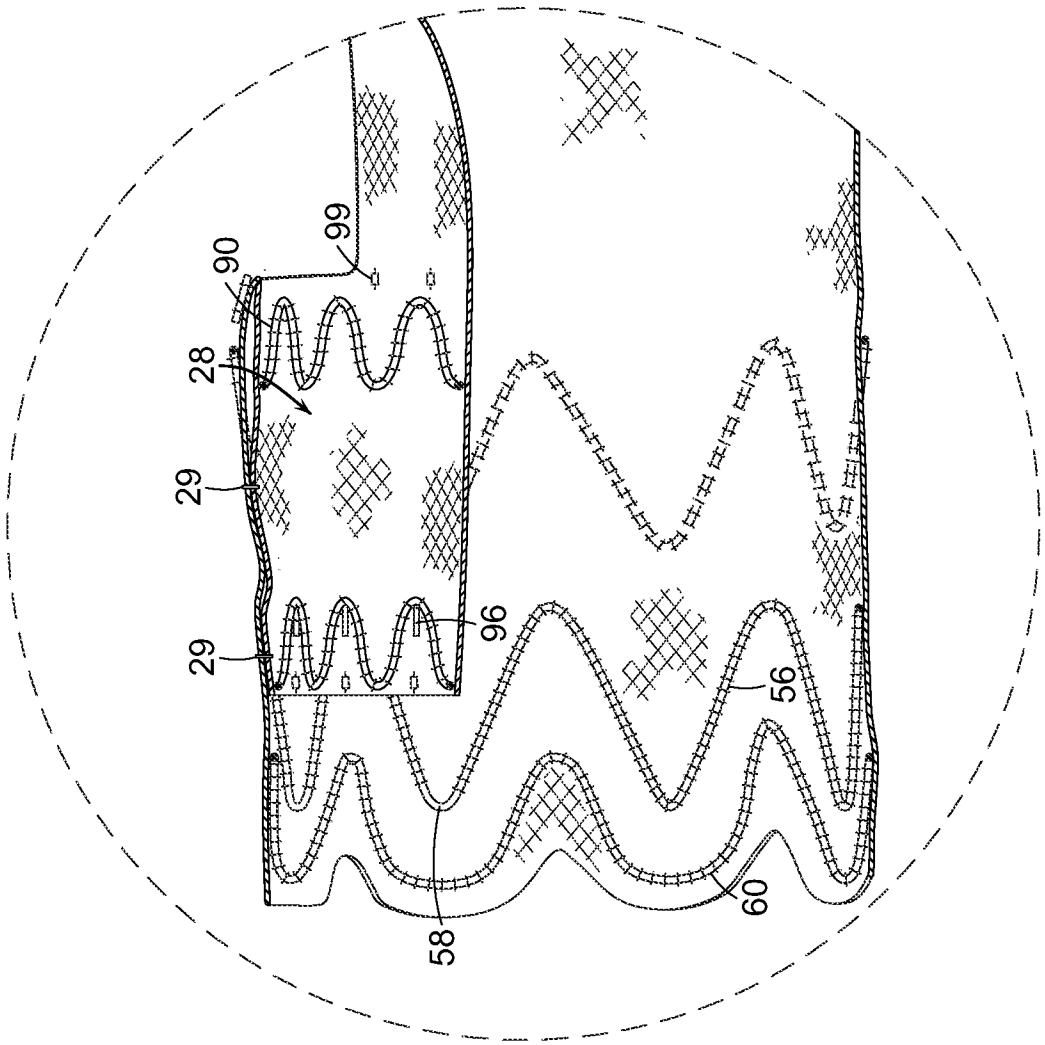


FIG. 4B

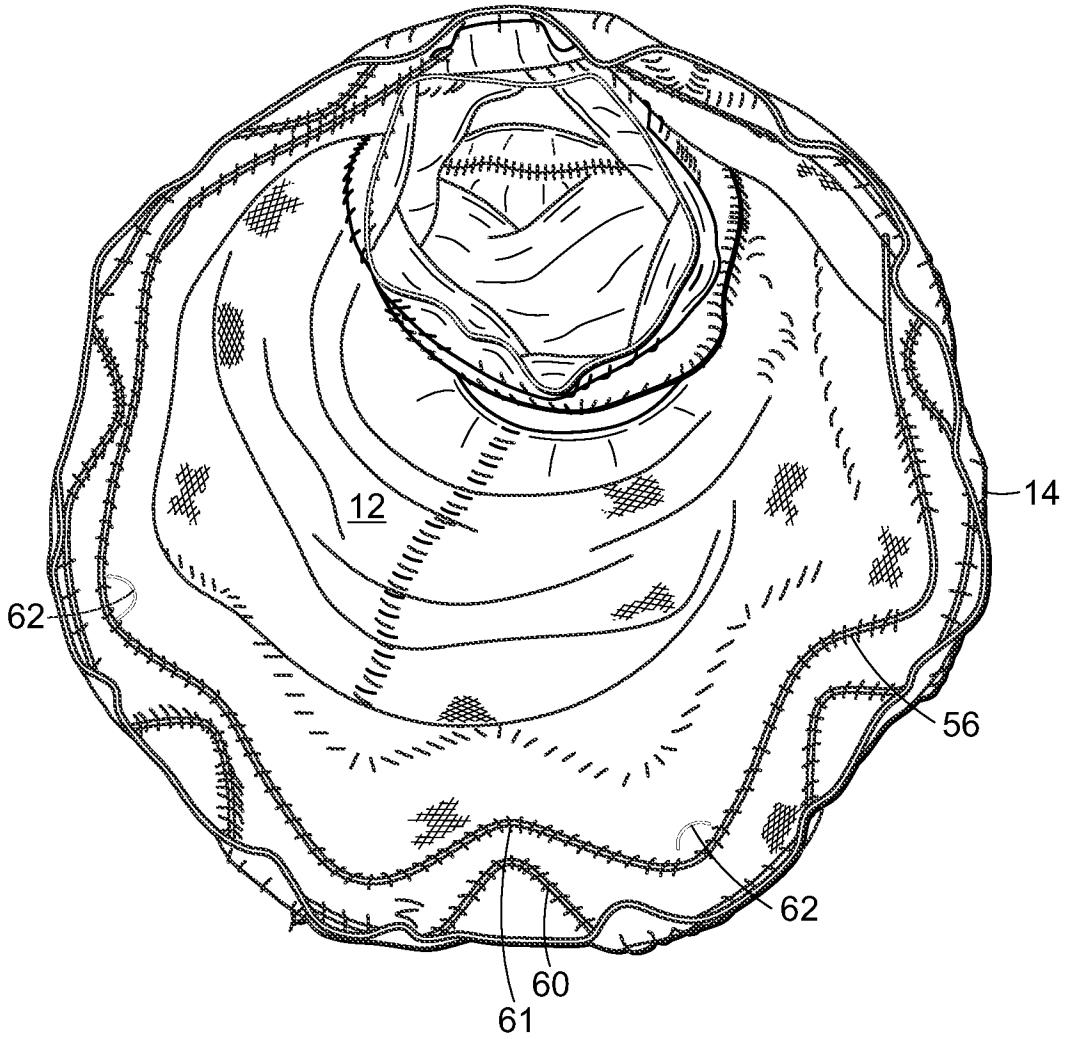


FIG. 5

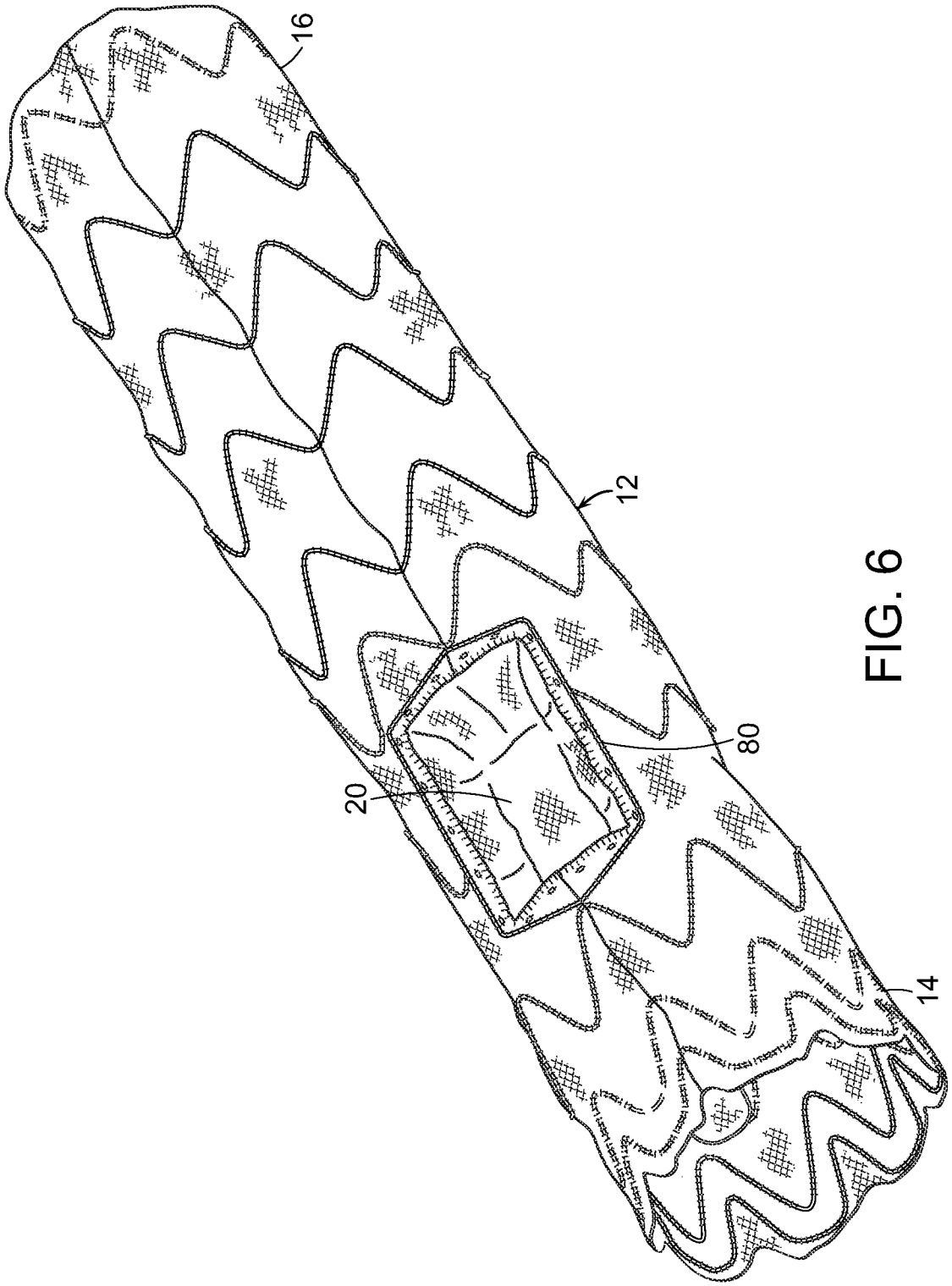


FIG. 6

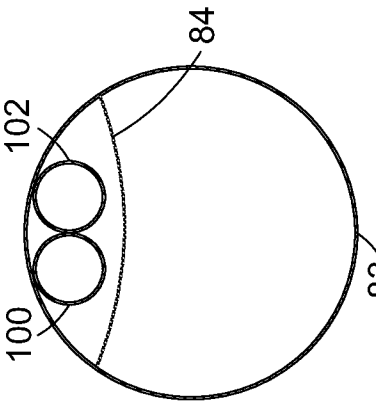


FIG. 7B

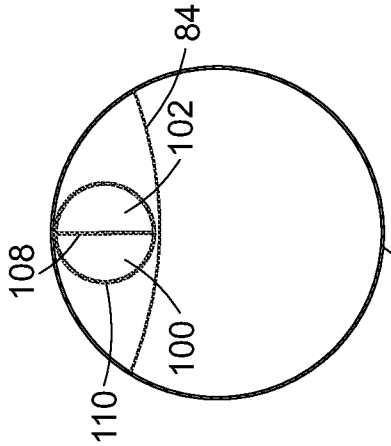


FIG. 8B

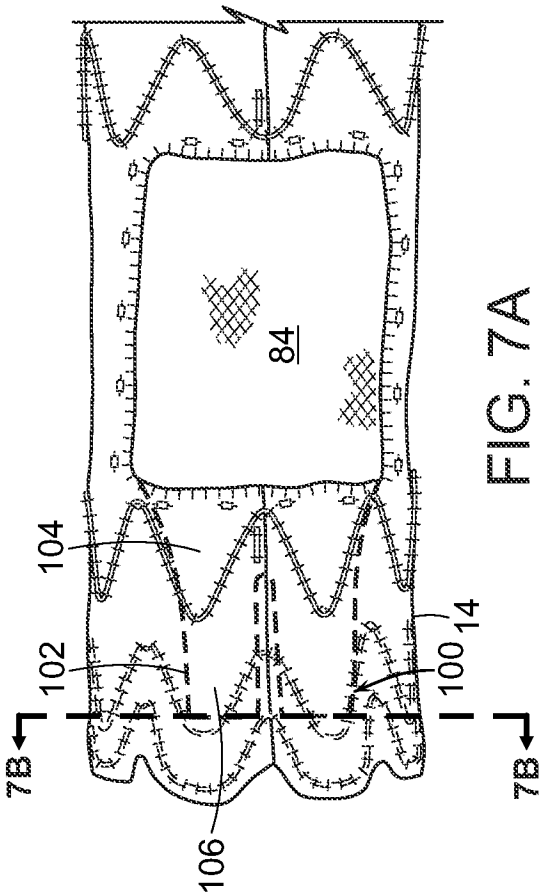


FIG. 7A

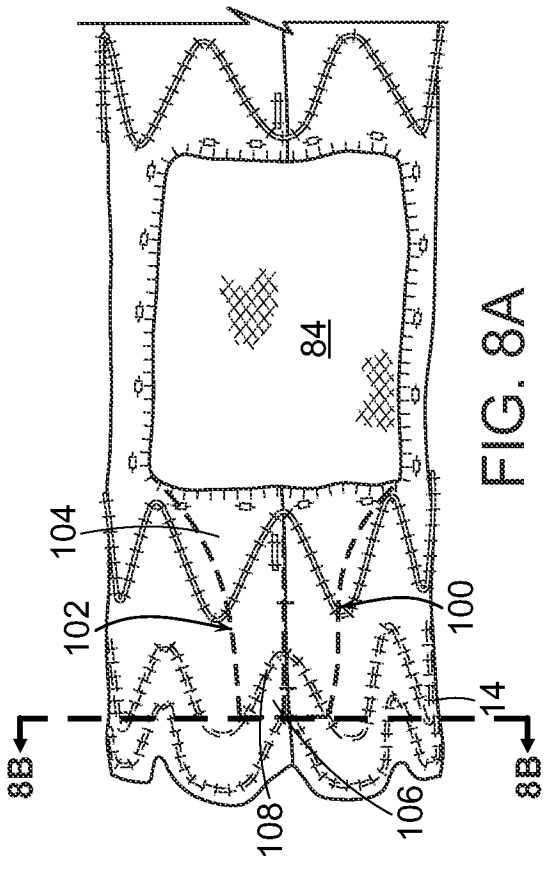


FIG. 8A

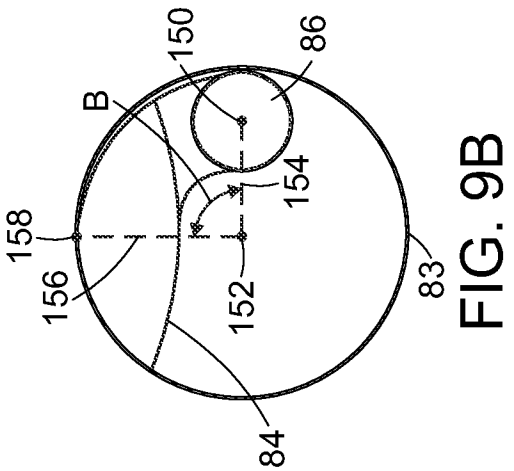


FIG. 9B

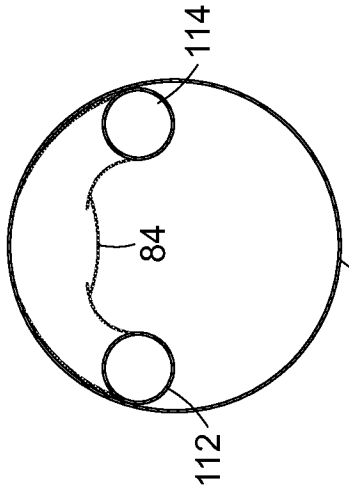


FIG. 10B

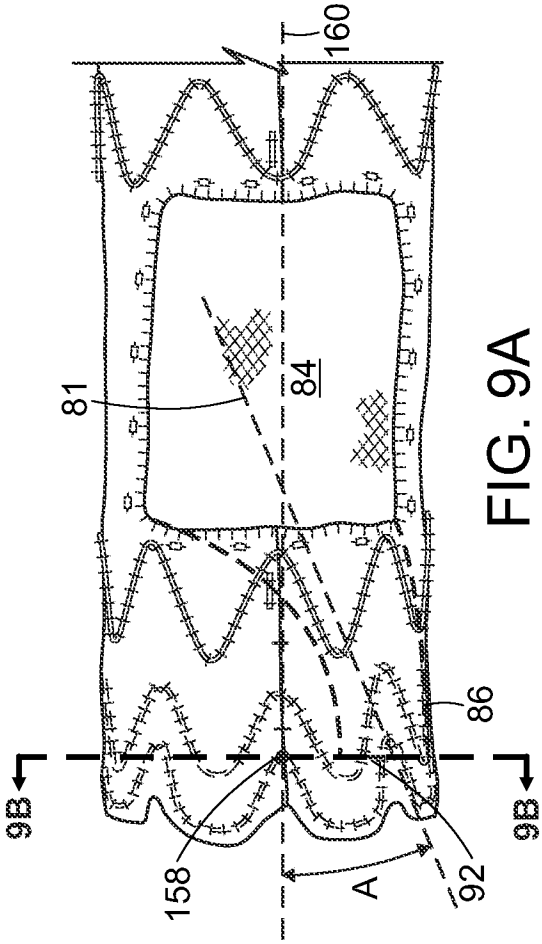


FIG. 9A

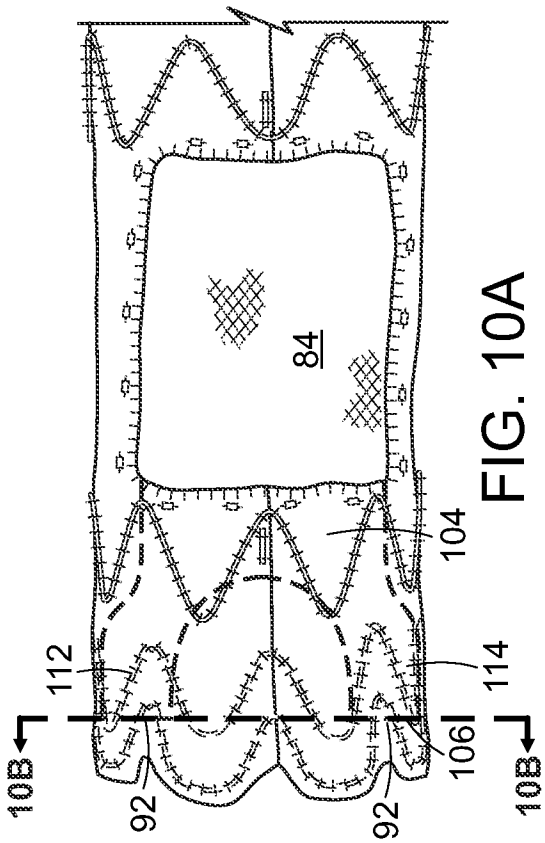


FIG. 10A

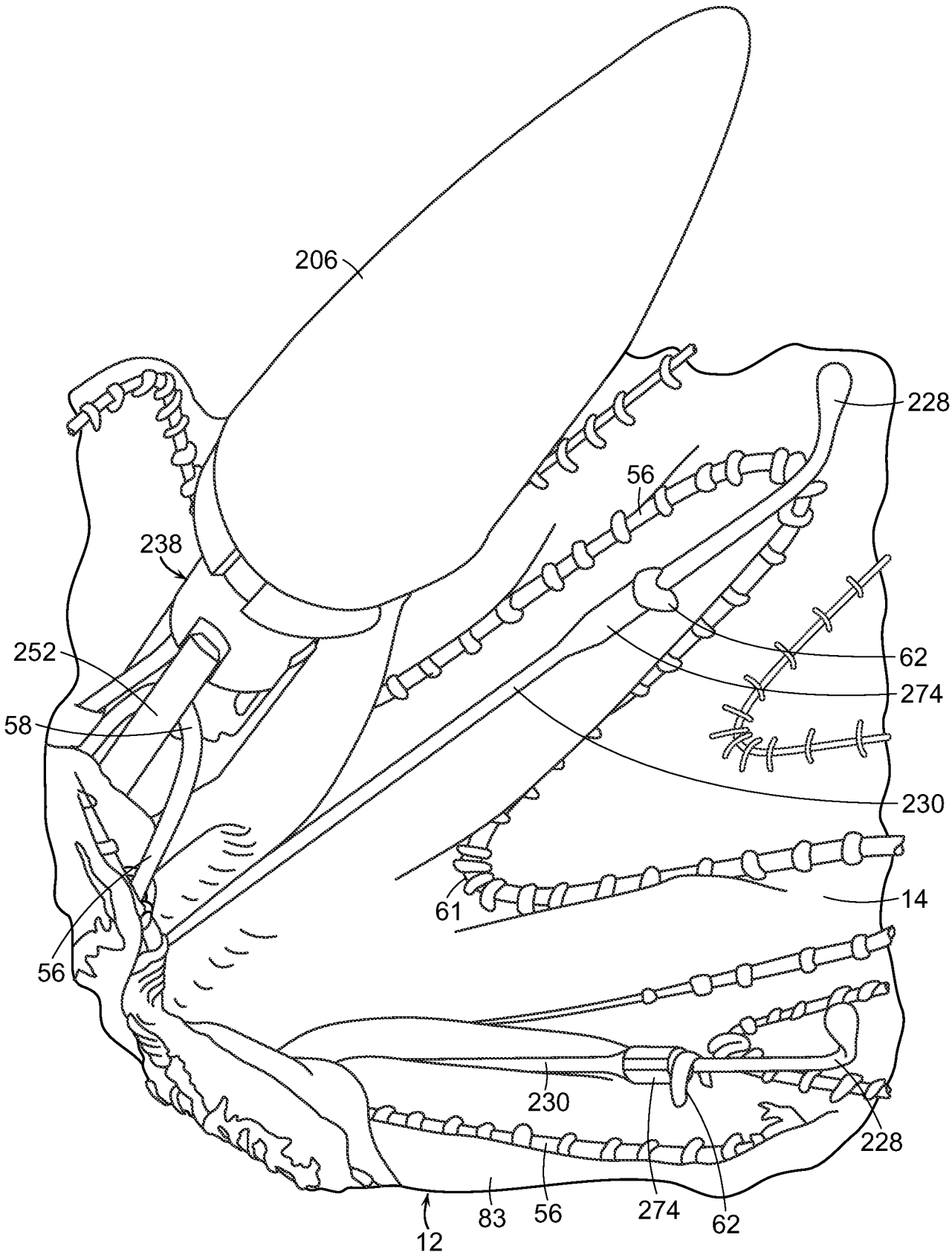


FIG. 11

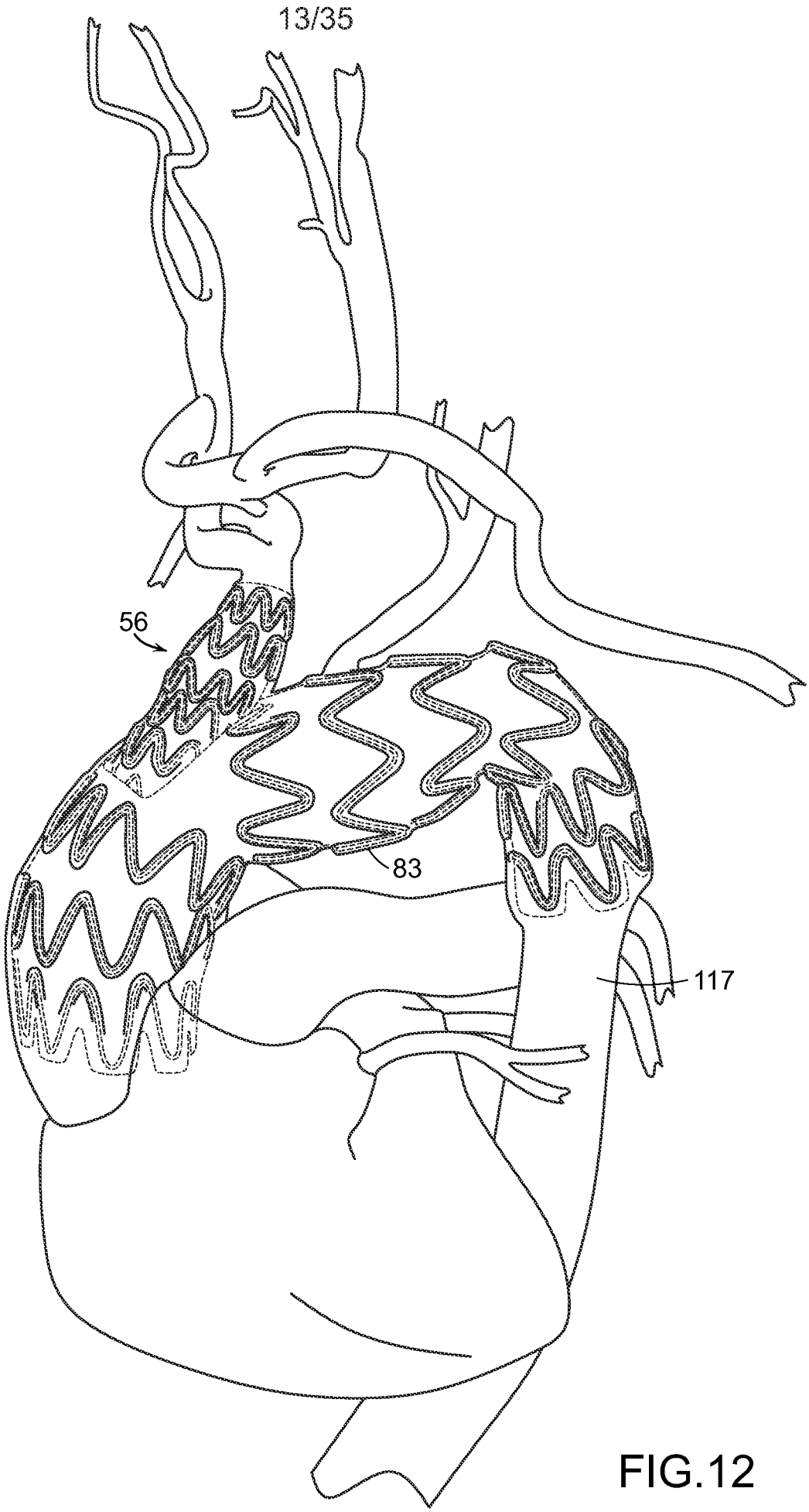


FIG.12

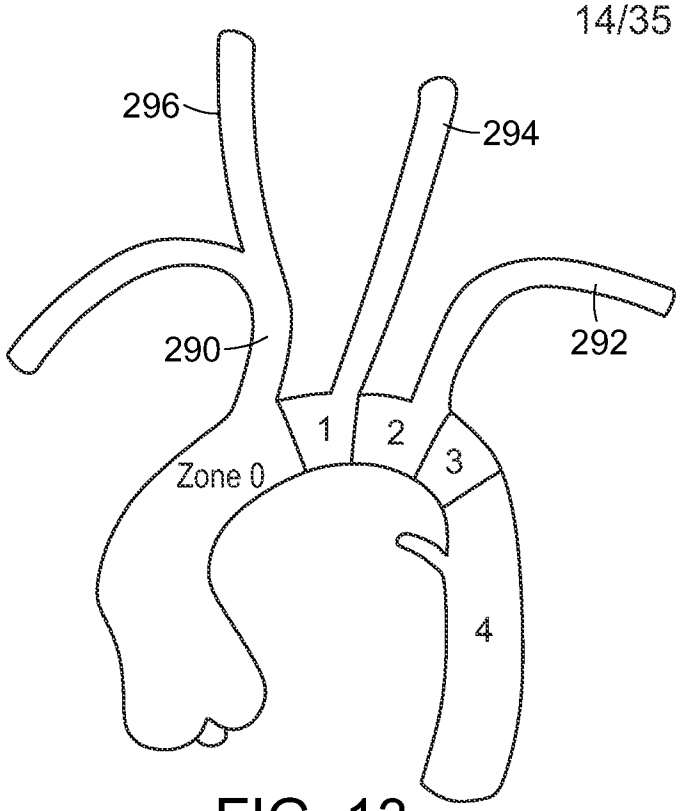


FIG. 13
(PRIOR ART)

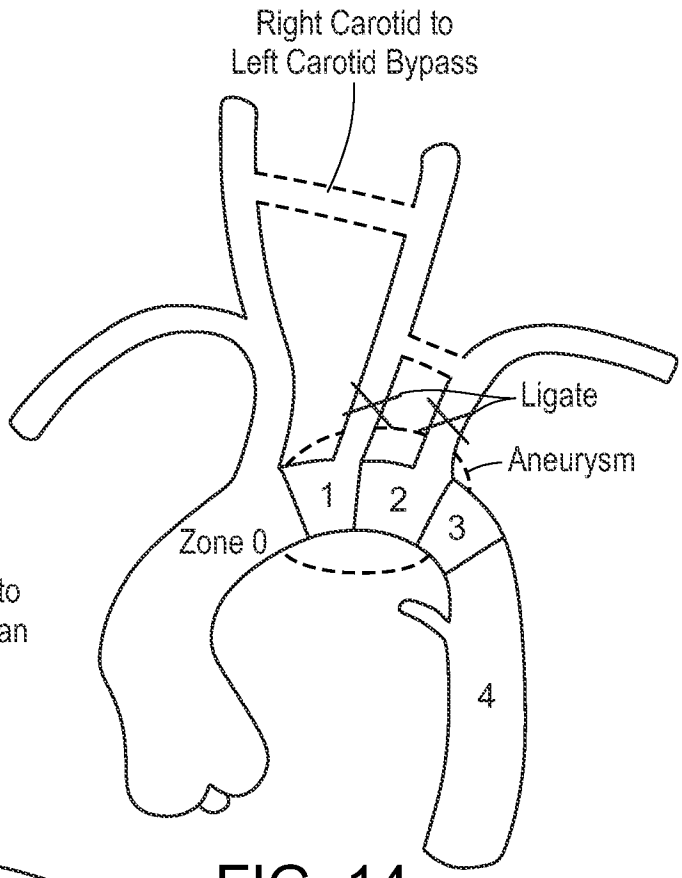


FIG. 14
(PRIOR ART)

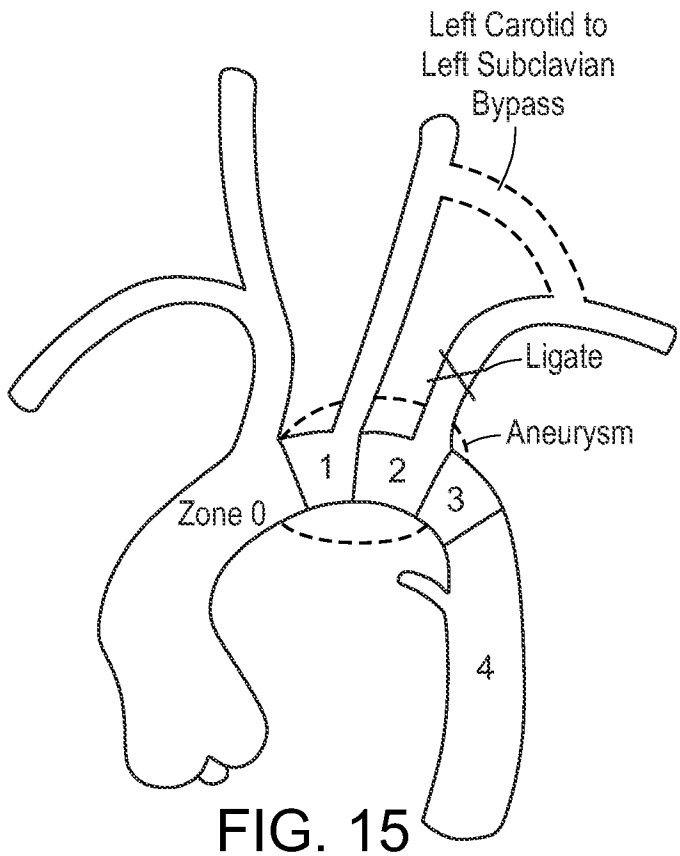


FIG. 15
(PRIOR ART)

FIG. 16A

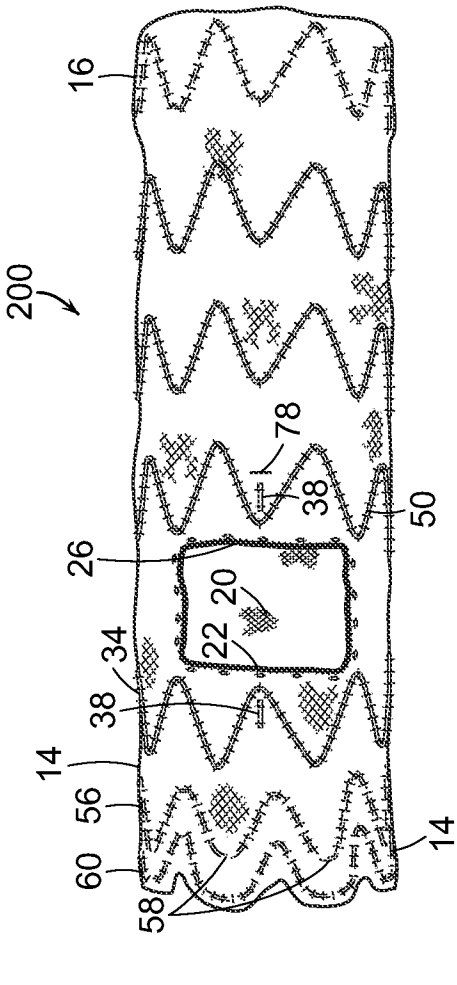


FIG. 16B

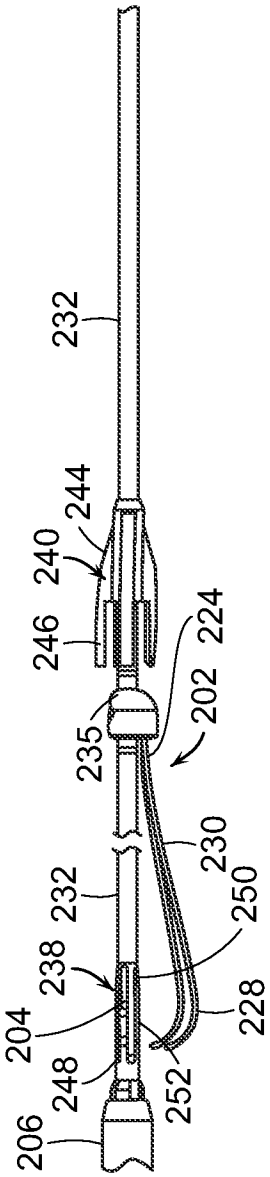


FIG. 16C

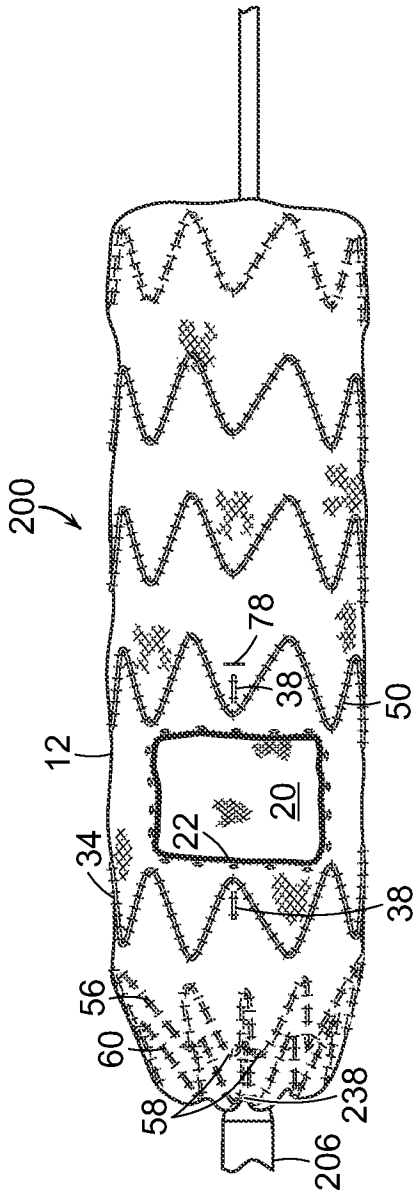


FIG. 16D

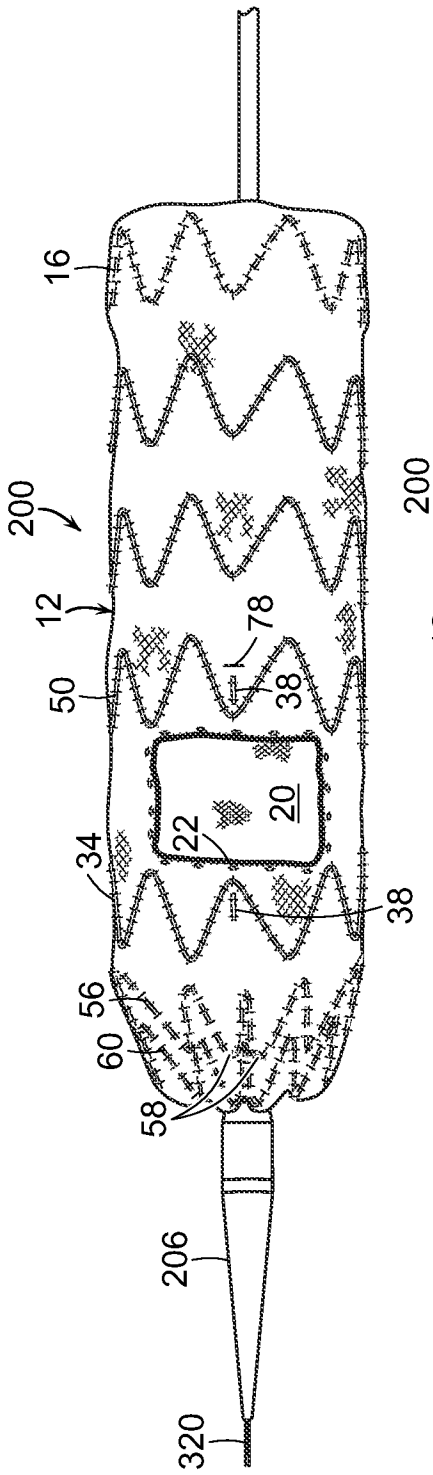


FIG. 16E

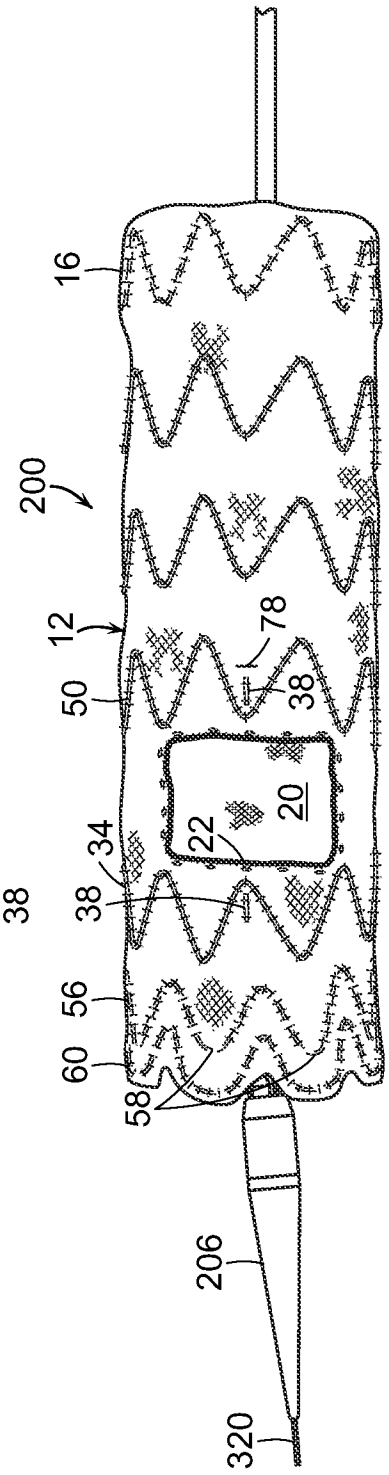
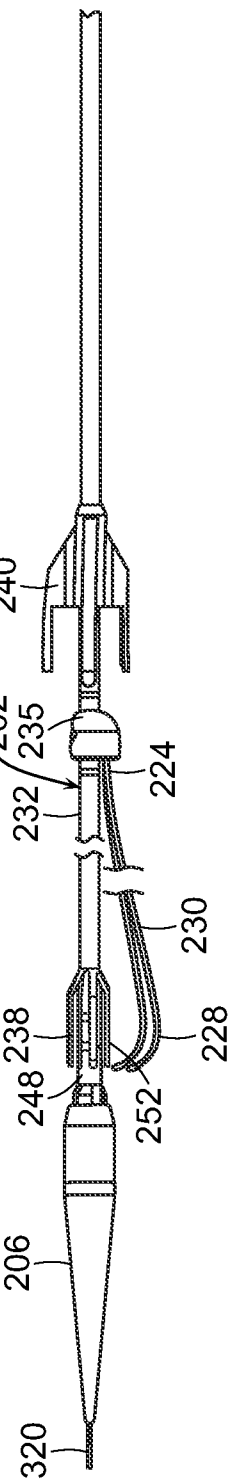


FIG. 16F



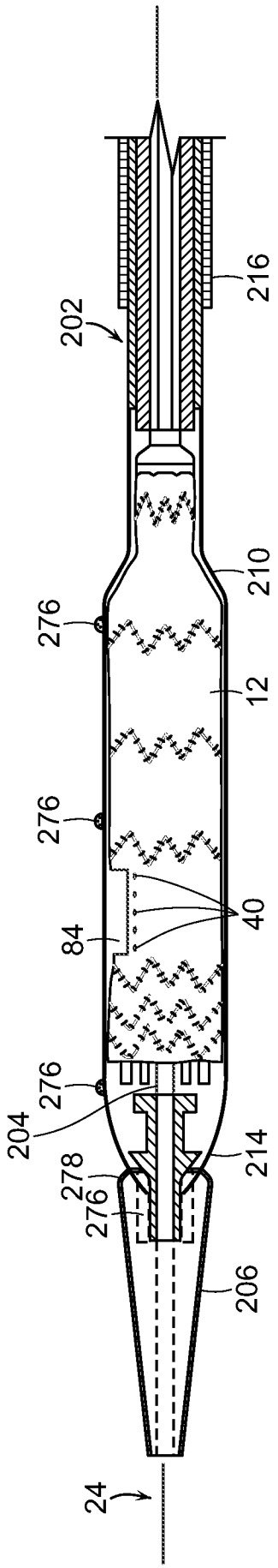


FIG. 17A

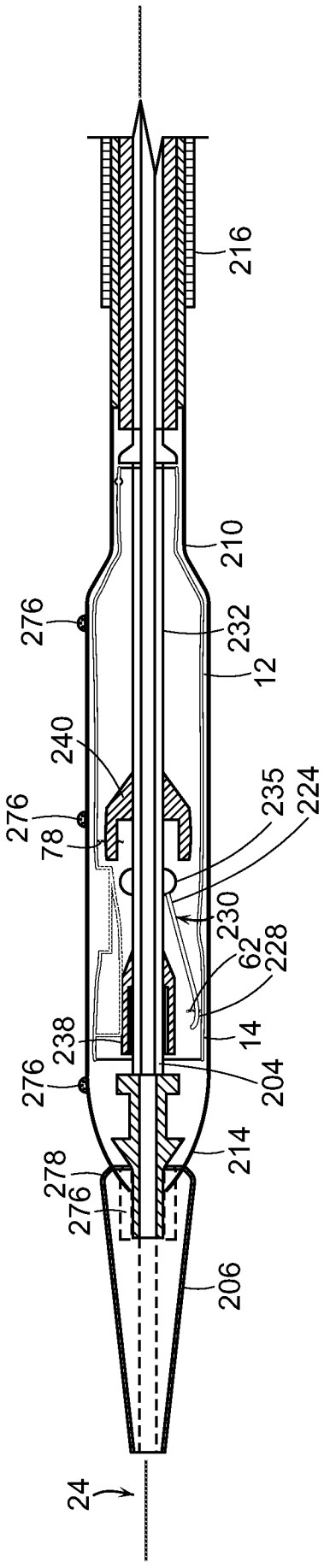

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FIG. 17B

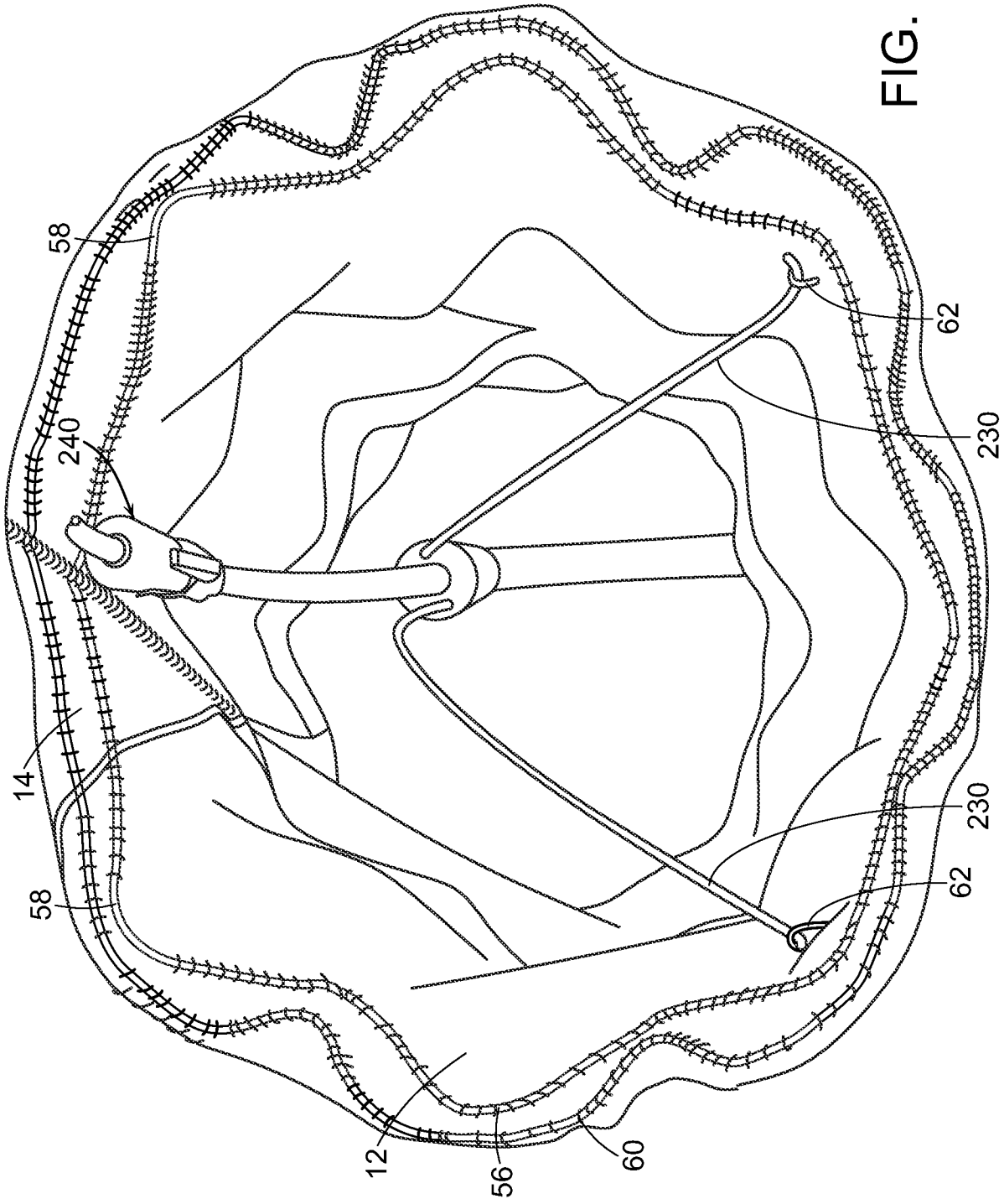

FIG. 17C

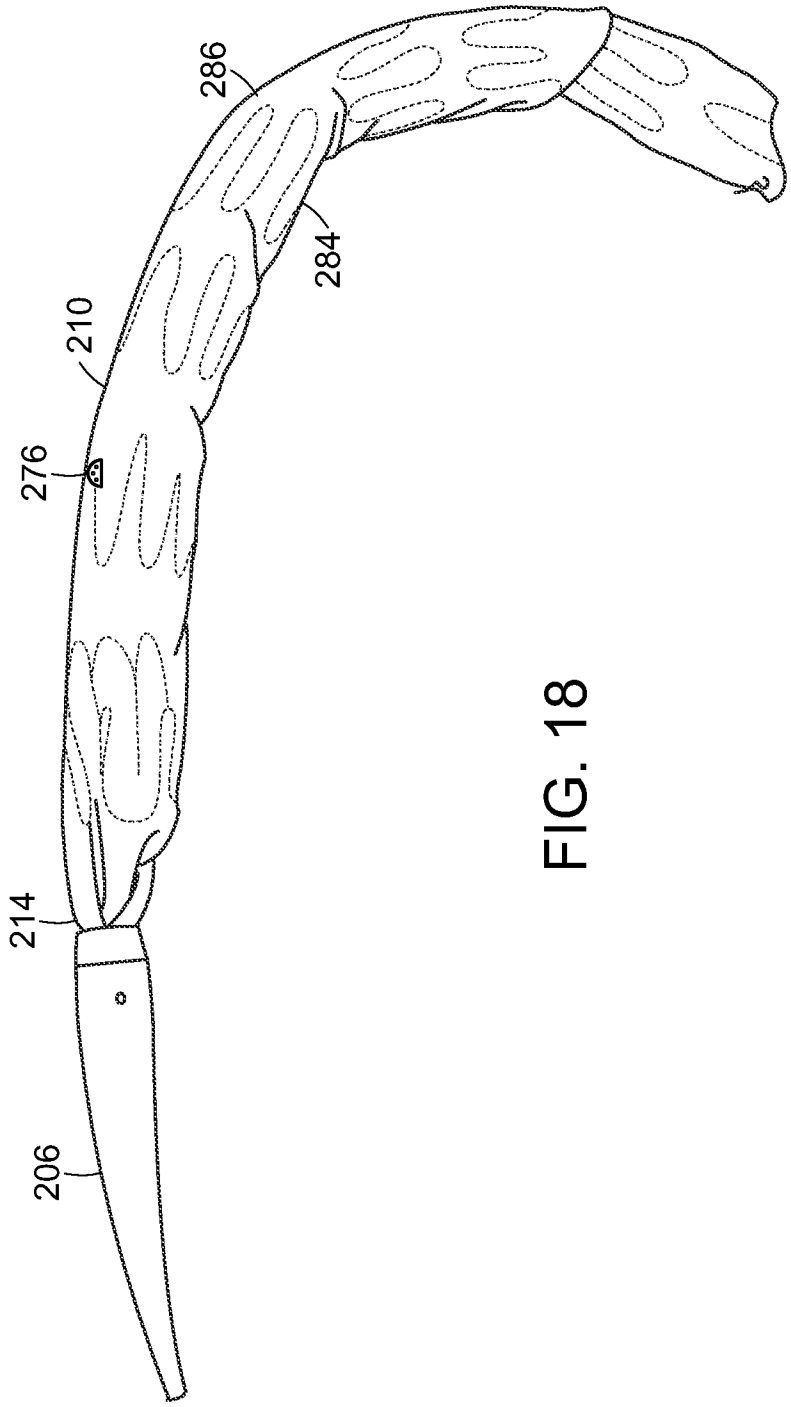

FIG. 18

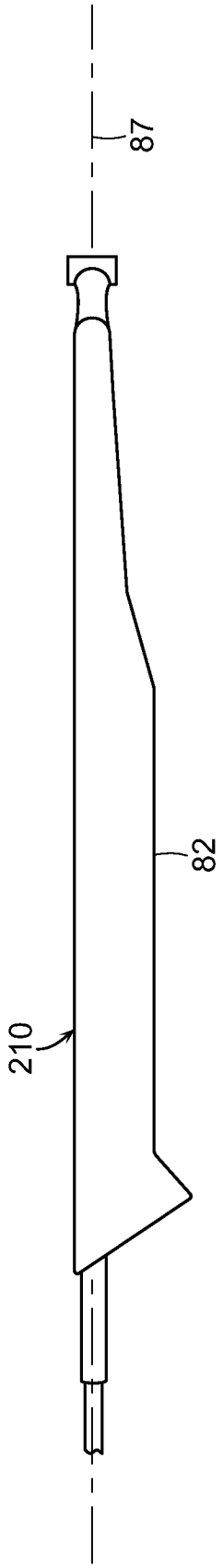

FIG. 19A

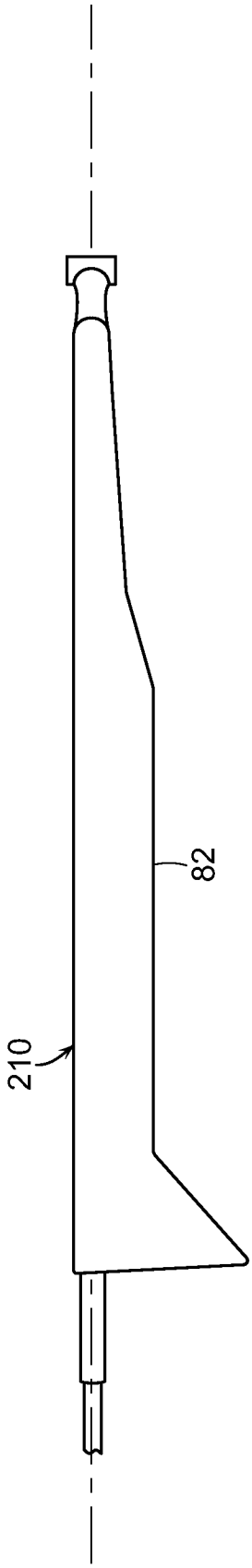

FIG. 19B

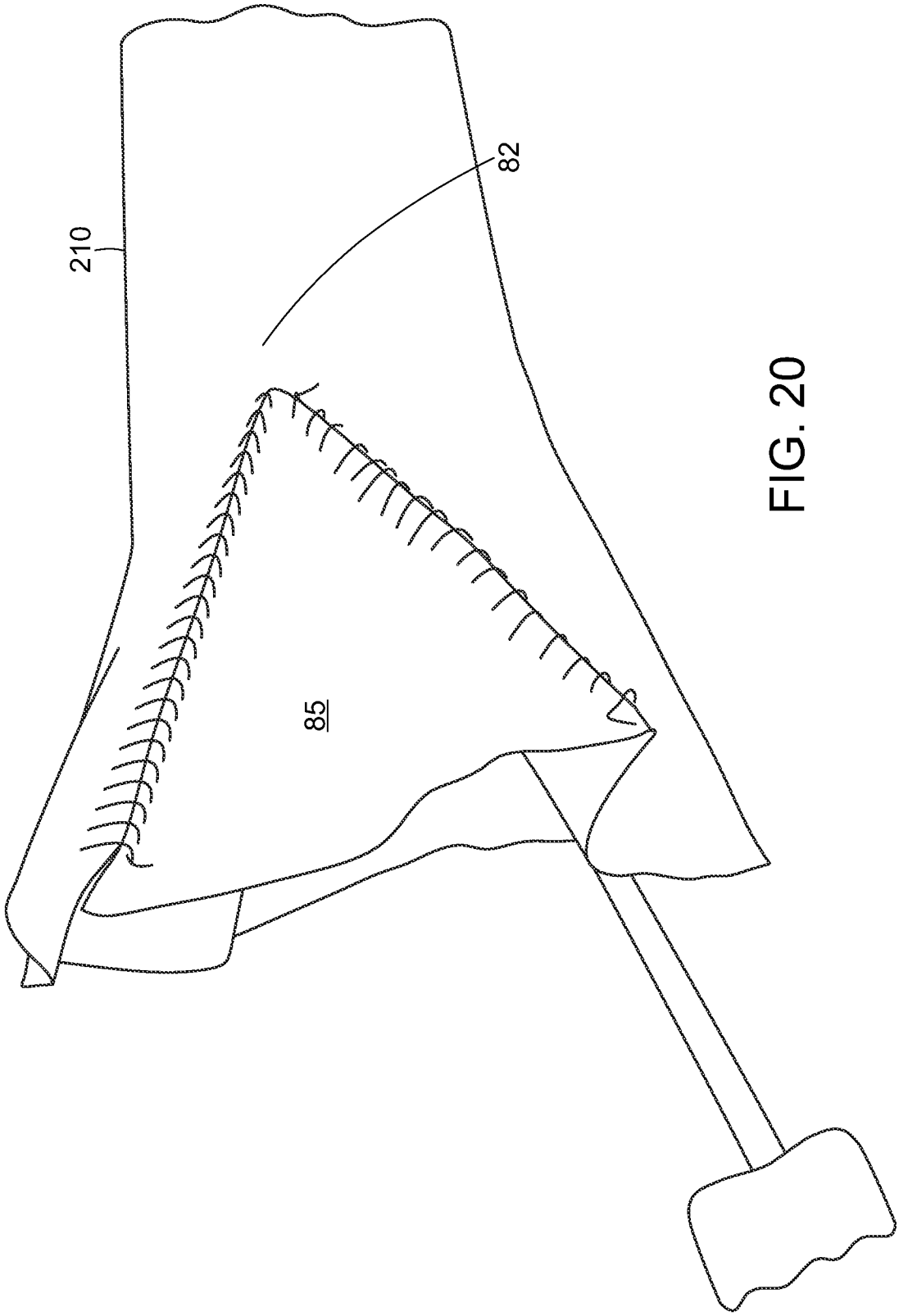

FIG. 20

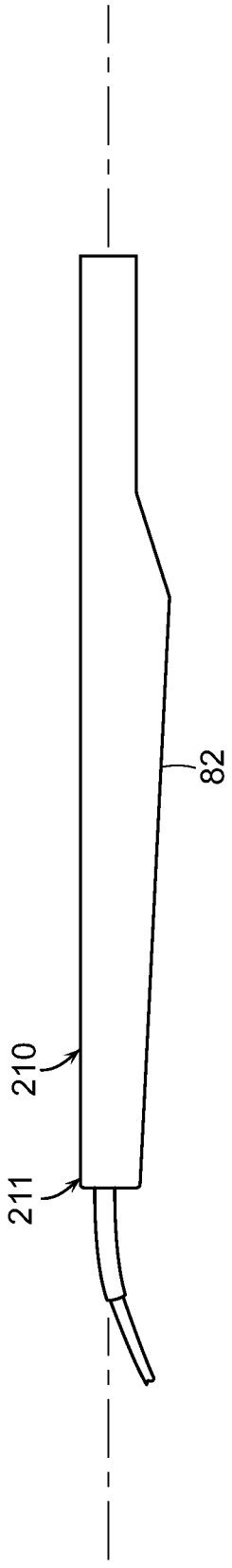

FIG. 21A

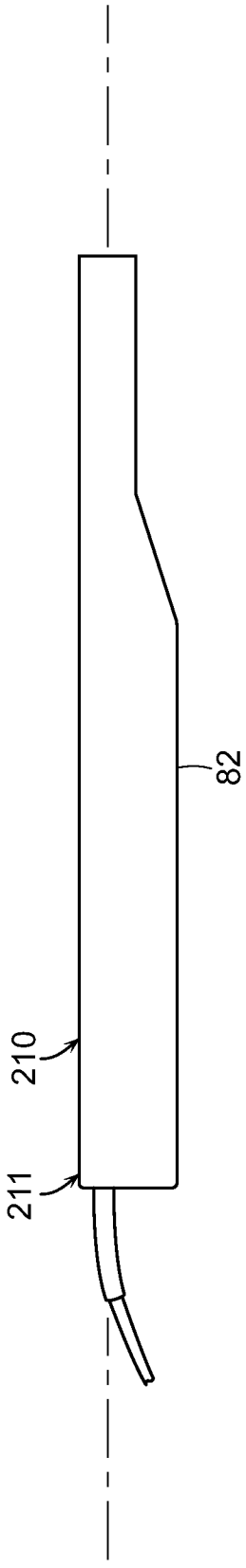

FIG. 21B

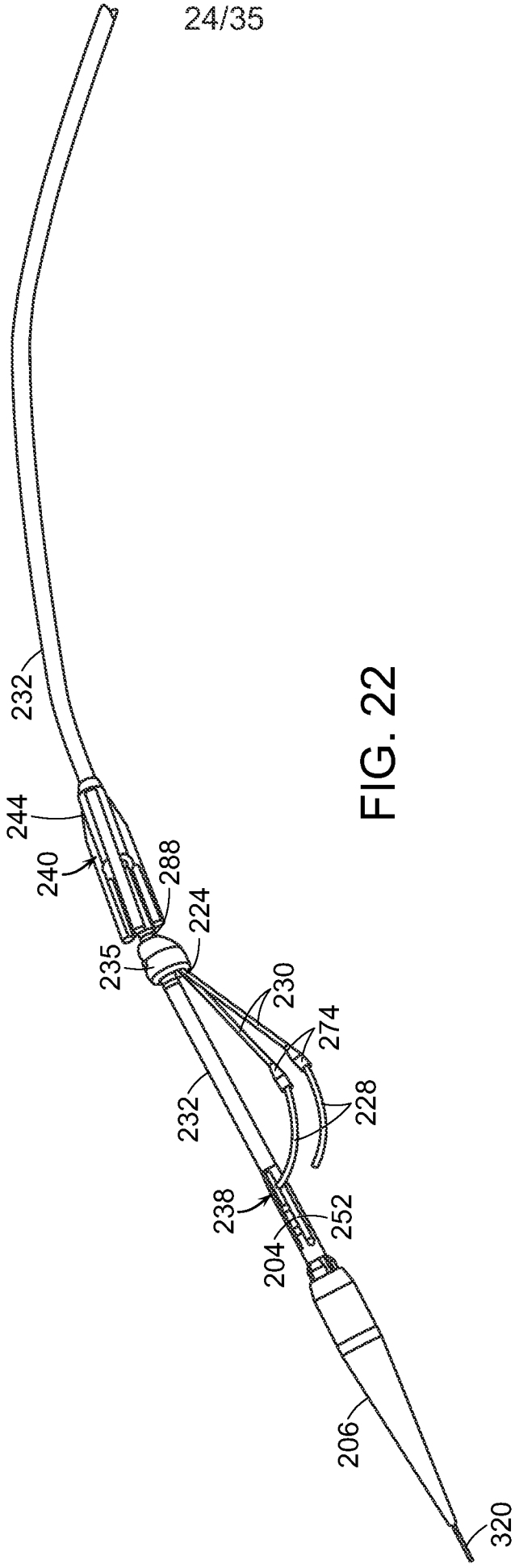

FIG. 22

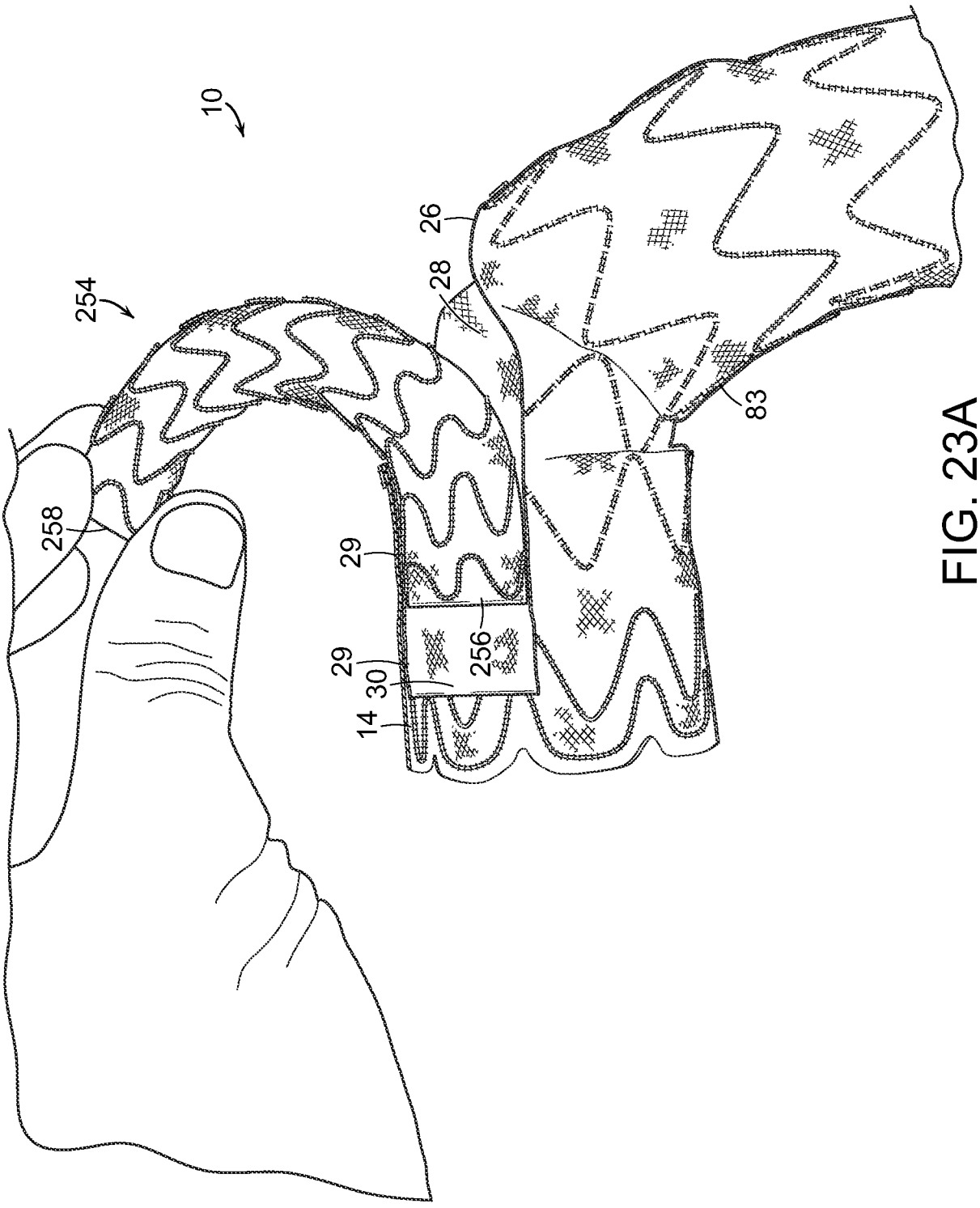

FIG. 23A

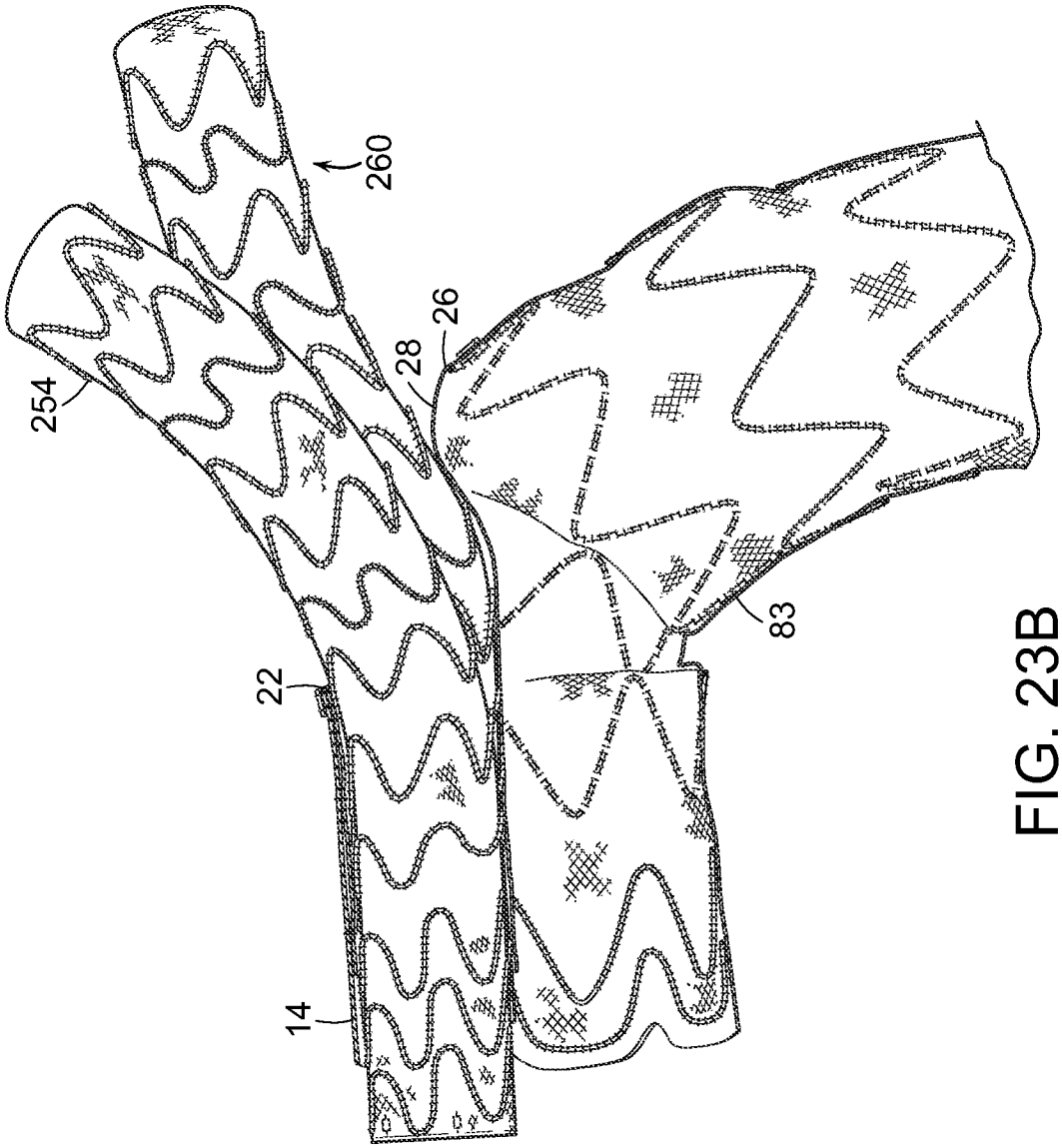

FIG. 23B

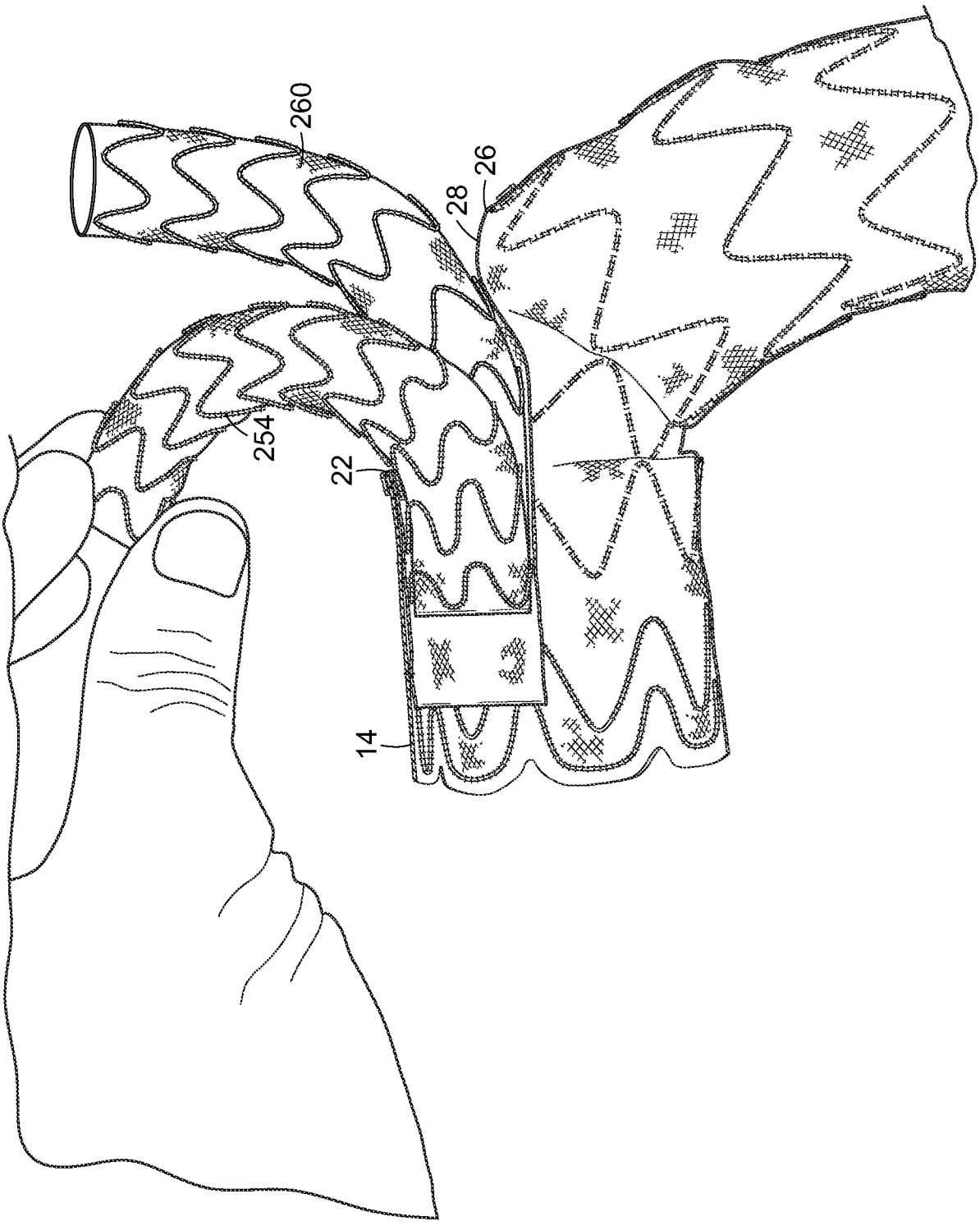

FIG. 23C

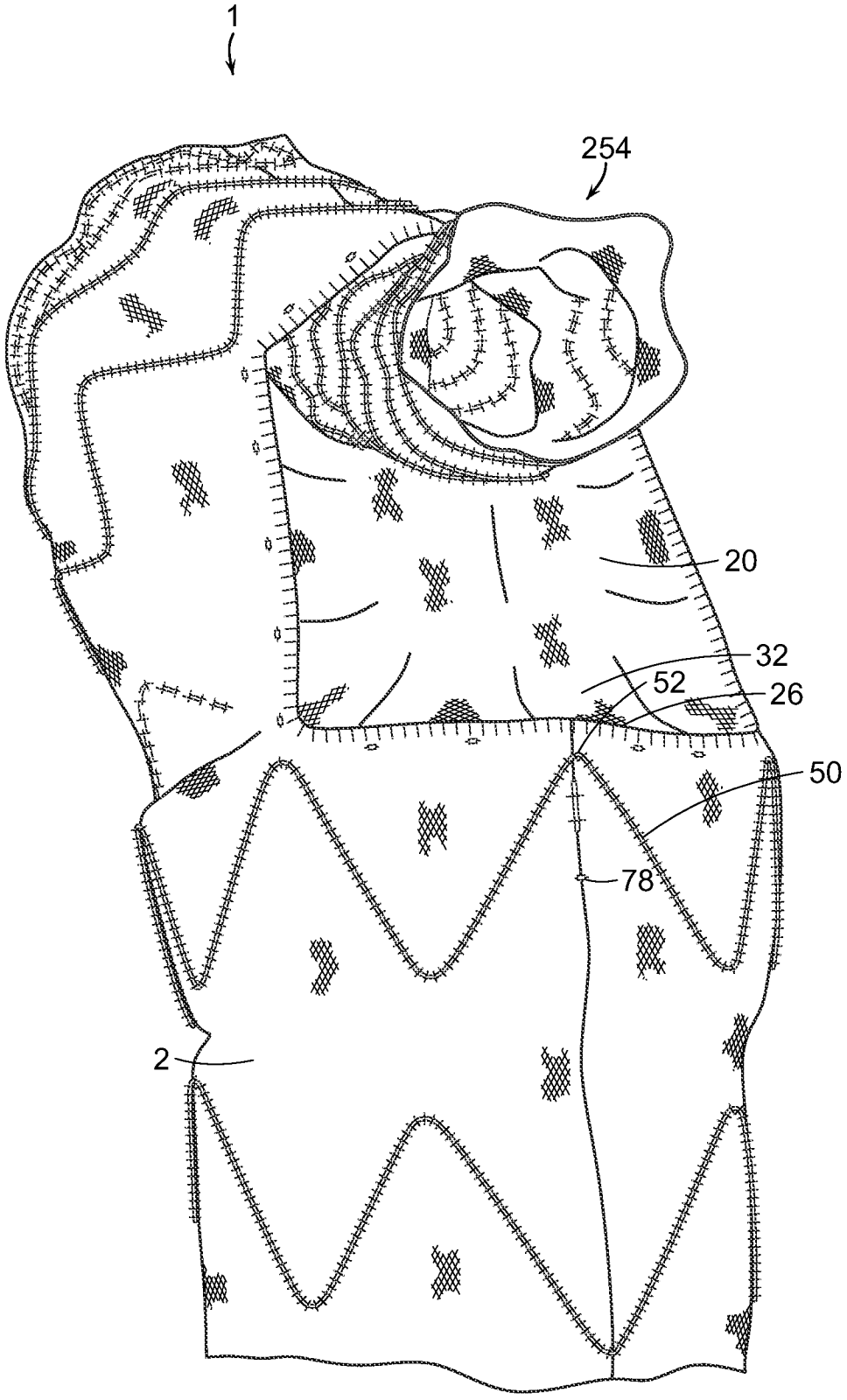

FIG.23D

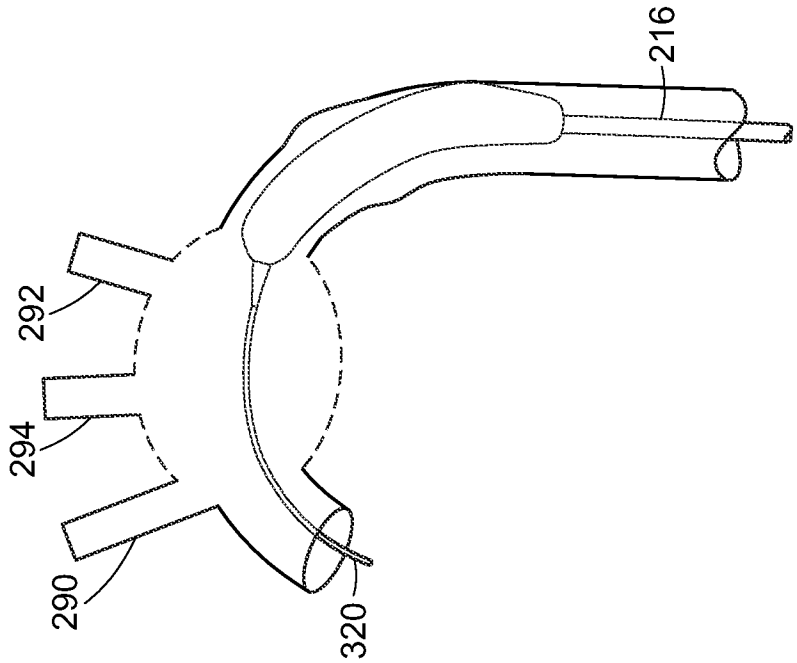

FIG. 24B

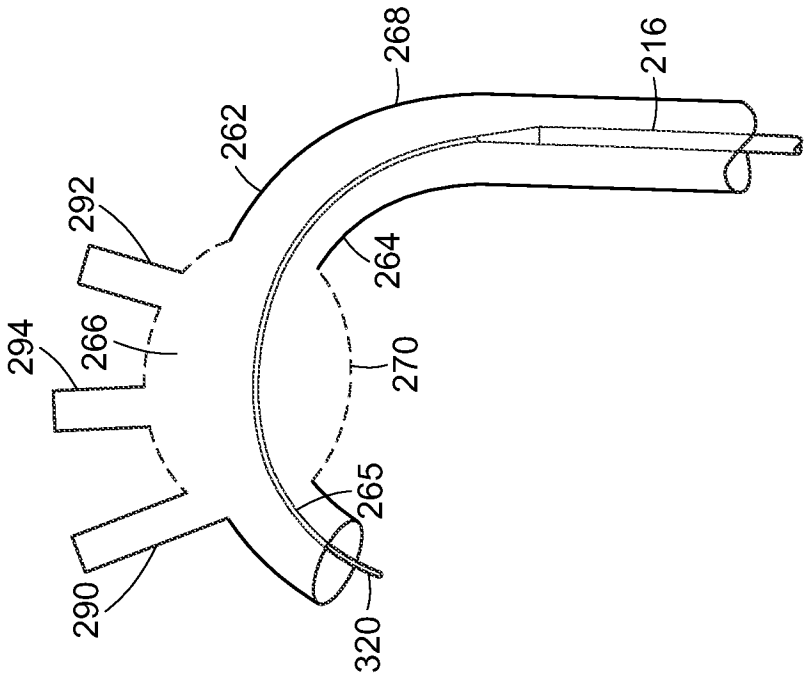

FIG. 24A

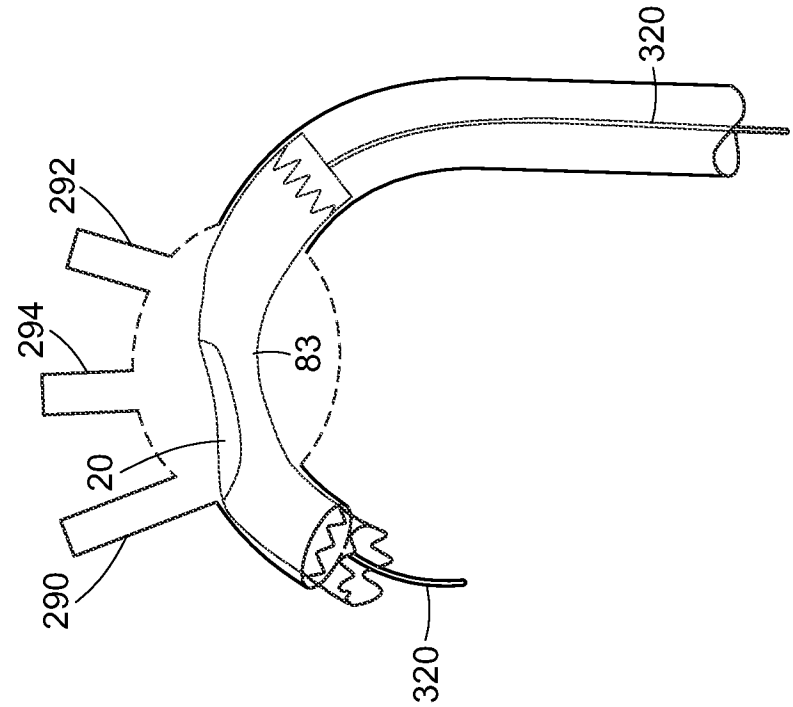

FIG. 24D

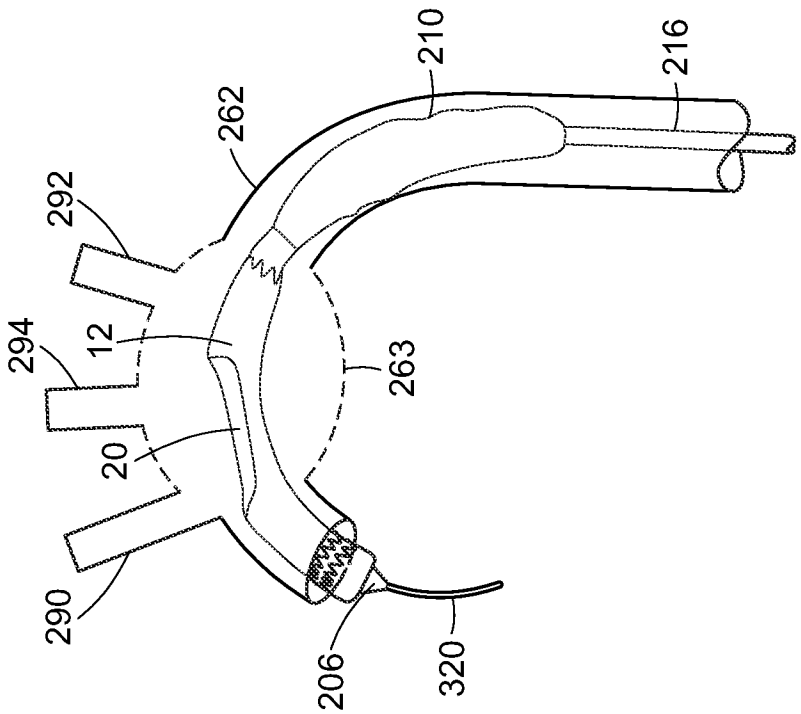

FIG. 24C

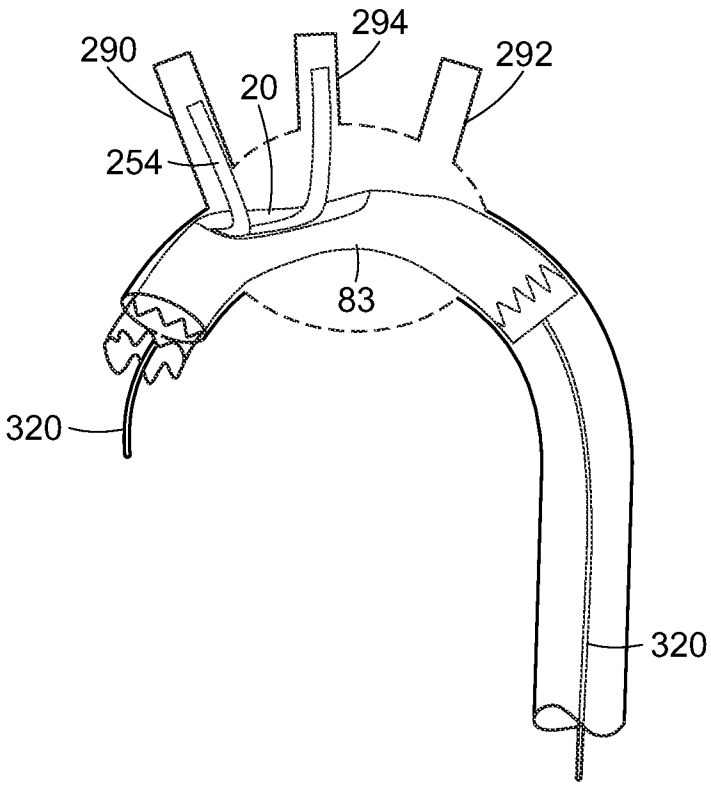

FIG. 24E

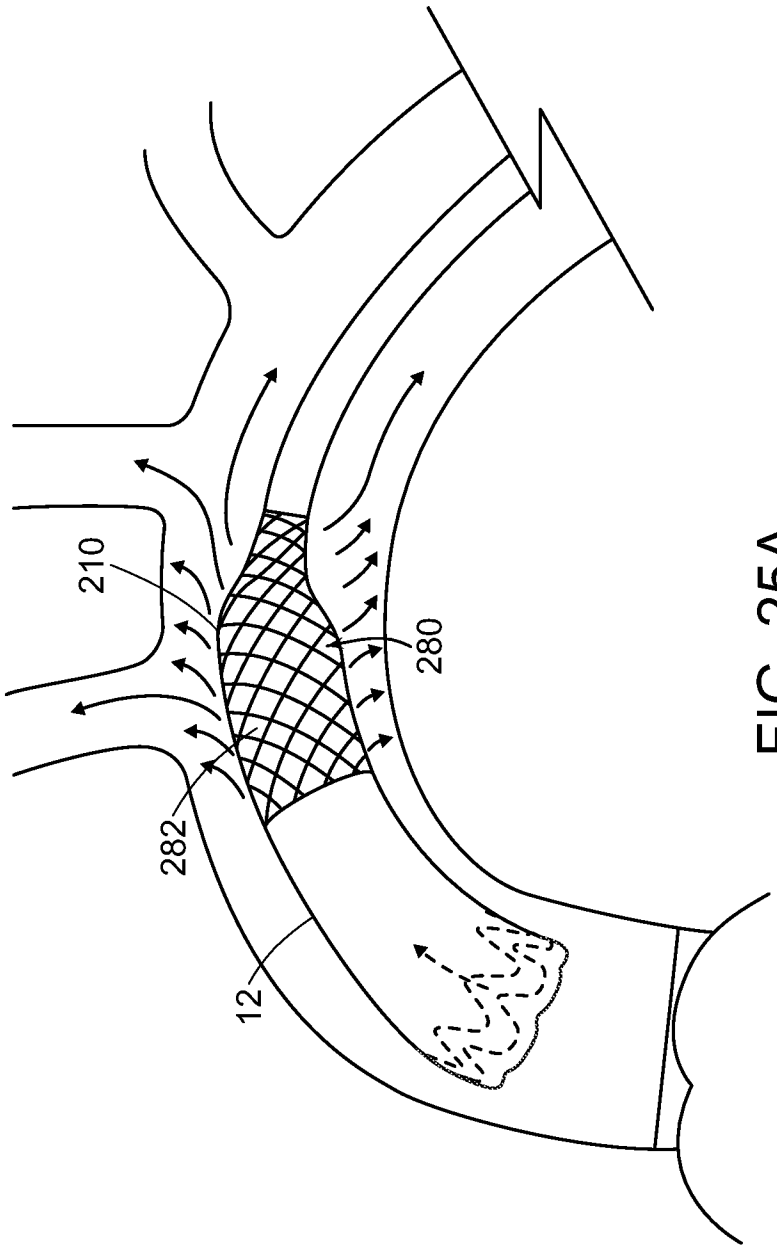

FIG. 25A

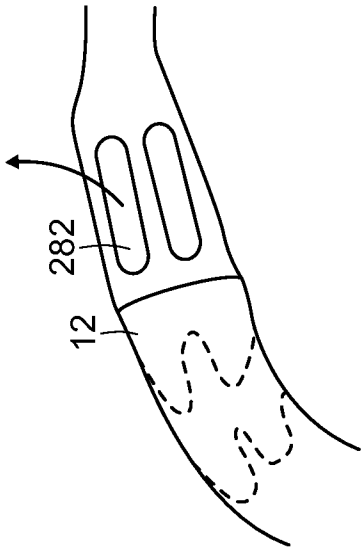

FIG. 25B

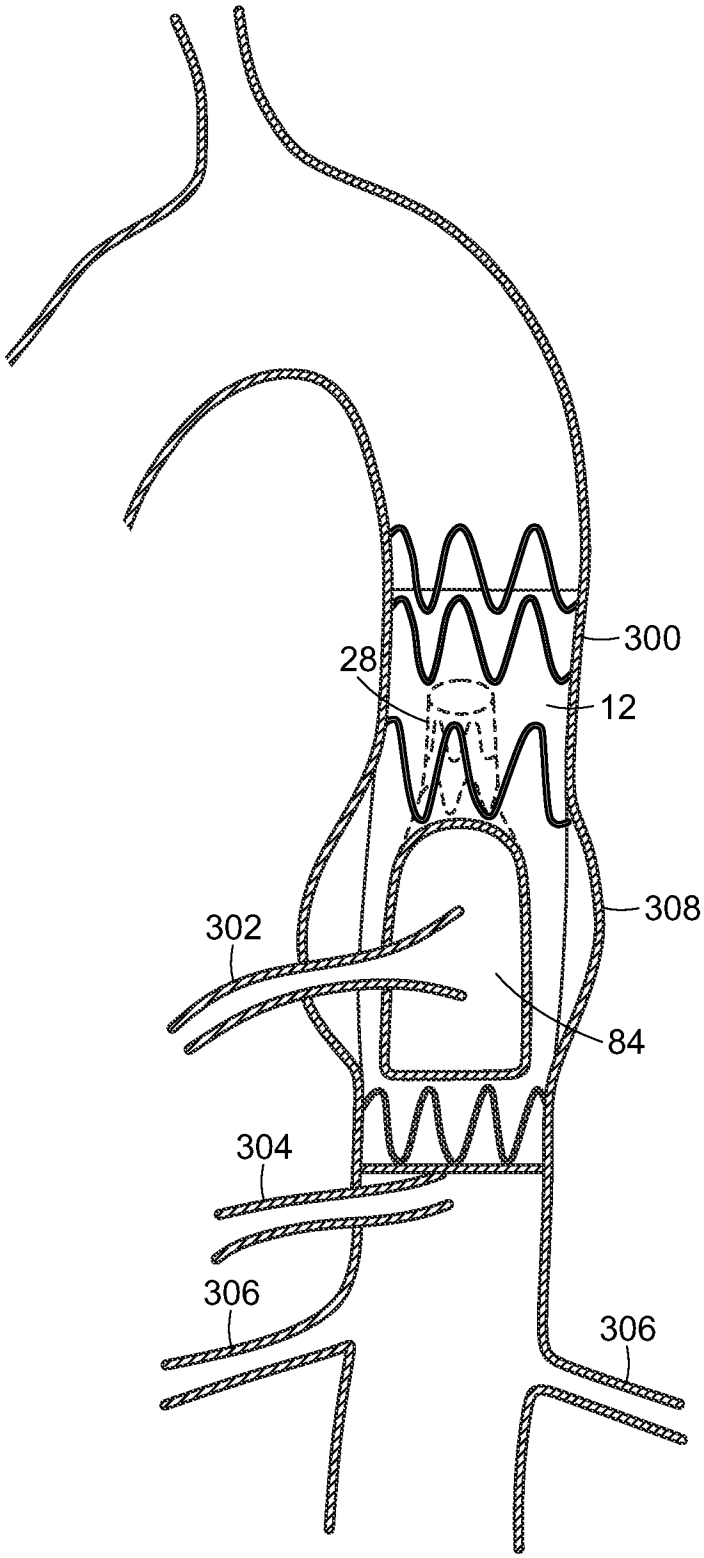

FIG. 26A

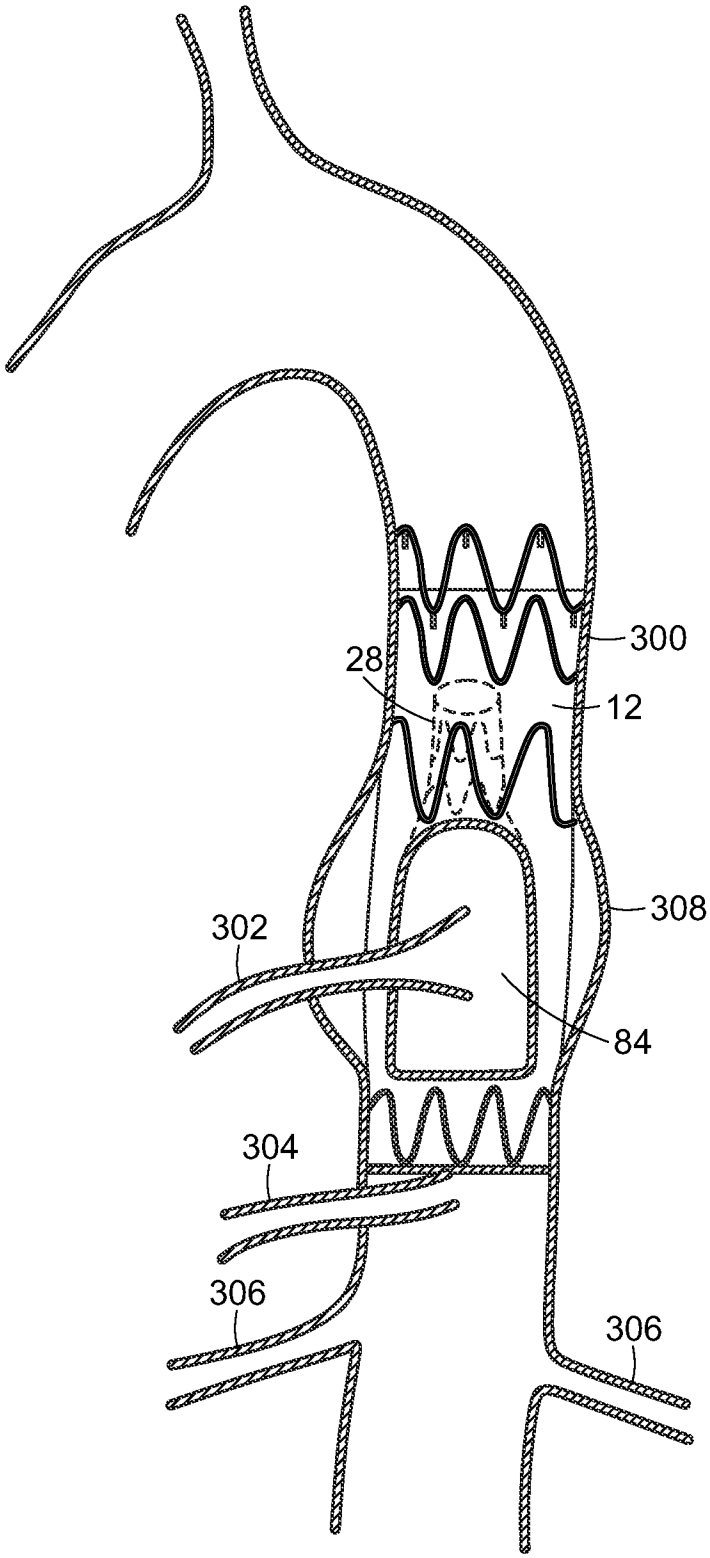

FIG. 26B

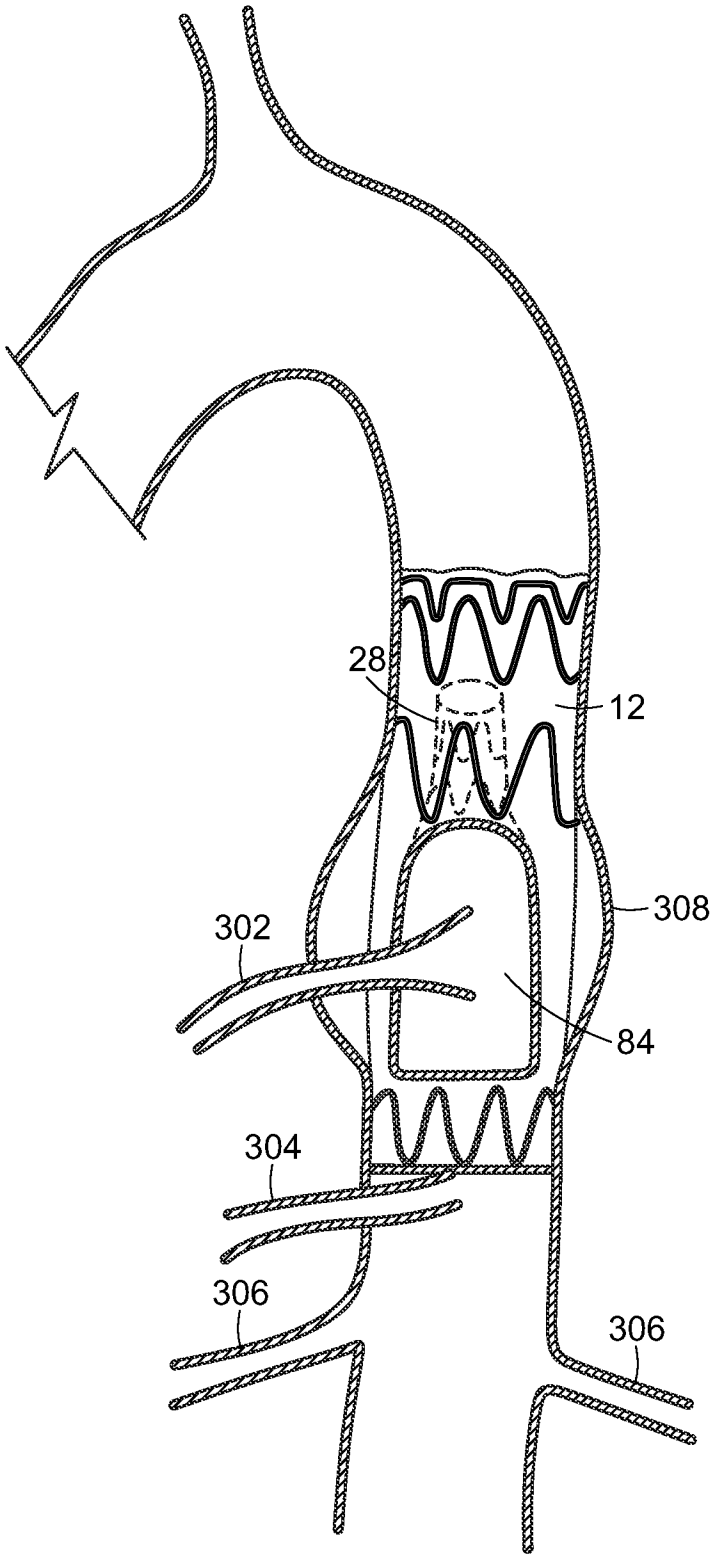

FIG. 26C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/065622

A. CLASSIFICATION OF SUBJECT MATTER
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

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/087318 A1 (DAUGHERTY JOHN R [US] ET AL) 14 April 2011 (2011-04-14)	1,10,15, 16, 18-20, 22,23, 29-83
Y	paragraph [0033] - paragraph [0036]; figure 1	2-9, 11-14, 21, 24-28, 101,102

Y	WO 2010/105195 A2 (BOLTON MEDICAL INC [US]; ARBEFEUILLE SAMUEL [US]; CHRISTIAN FLETCHER [] 16 September 2010 (2010-09-16)	2-9, 11-14, 21, 24-28, 101,102
	page 13, line 32 - page 14, line 5; figures 7D-7F	

	-/--	

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 February 2013	01/03/2013

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

1

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/065622

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 645 242 B1 (QUINN STEPHEN F [US]) 11 November 2003 (2003-11-11) the whole document -----	1-83, 101,102

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/065622

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

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

1. [X] Claims Nos.: 84-100
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/US2012/065622

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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