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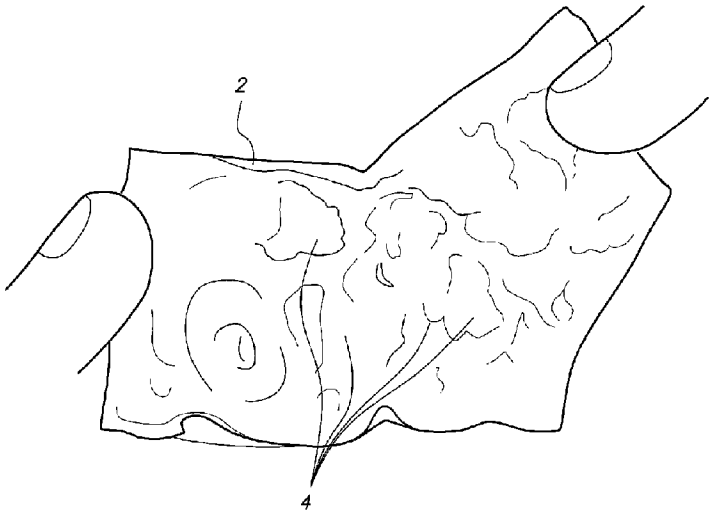
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(54) Titre : SYSTEME PERMETTANT DE METTRE EN PLACE UN DISPOSITIF A UN EMPLACEMENT DISTAL DANS UN VAISSEAU MALADE

(54) Title: SYSTEM FOR DEPLOYING A DEVICE TO A DISTAL LOCATION ACROSS A DISEASED VESSEL



(57) Abrégé/Abstract:
Configurations are described for assisting execution of a percutaneous procedure while protecting the vascular pathway to the operational theater. One embodiment is directed to a system for deploying a device to a distal location across a diseased vessel, comprising a sheath comprising an expandable distal portion comprising a porous wall defining a lumen therethrough, the distal portion having a collapsed configuration, wherein the sheath has a first cross sectional outer diameter and a first lumen inner diameter, and an expanded configuration, wherein the sheath has a second cross sectional outer diameter and a second lumen inner diameter; wherein in the collapsed configuration, the sheath is configured to be advanced across at least a portion of the diseased vessel to a position adjacent the distal location without substantial size interference between the first cross sectional outer diameter of the sheath and an inner diameter profile of a lumen of the vessel.

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(54) Title: SYSTEM FOR DEPLOYING A DEVICE TO A DISTAL LOCATION ACROSS A DISEASED VESSEL

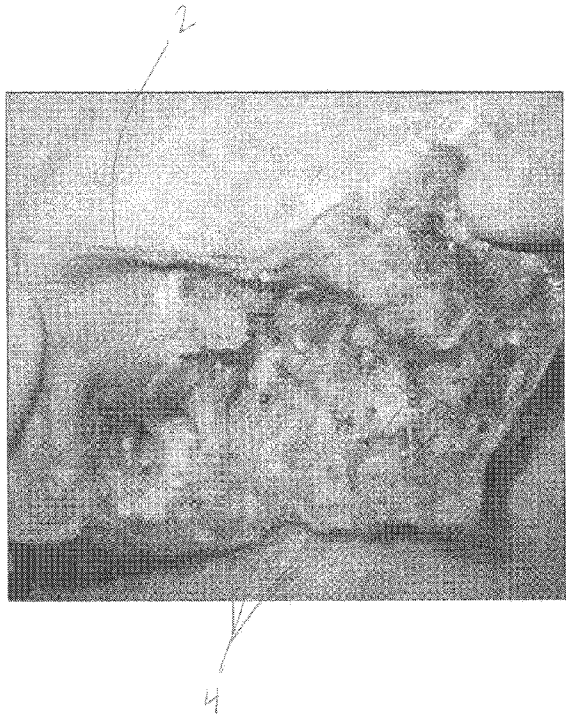


Figure 1A

(57) Abstract: Configurations are described for assisting execution of a percutaneous procedure while protecting the vascular pathway to the operational theater. One embodiment is directed to a system for deploying a device to a distal location across a diseased vessel, comprising a sheath comprising an expandable distal portion comprising a porous wall defining a lumen therethrough, the distal portion having a collapsed configuration, wherein the sheath has a first cross sectional outer diameter and a first lumen inner diameter, and an expanded configuration, wherein the sheath has a second cross sectional outer diameter and a second lumen inner diameter; wherein in the collapsed configuration, the sheath is configured to be advanced across at least a portion of the diseased vessel to a position adjacent the distal location without substantial size interference between the first cross sectional outer diameter of the sheath and an inner diameter profile of a lumen of the vessel.

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System for Deploying a Device to a Distal Location Across a Diseased Vessel

Field of the Invention

The present invention relates generally to medical interventions conducted through vessels such as the major arteries, and more particularly to access and deployment configurations for conducting percutaneous procedures such as percutaneous valve replacement.

Background

Gaining access to the heart is a continued challenge in cardiovascular medicine. Conventional procedures for accomplishing tasks such as valve replacement generally involve a thoracotomy and/or creation of one or more access ports across the wall of the heart itself, which is relatively highly invasive and therefore undesirable. Recent progress has been made in the area of percutaneous intervention, wherein instrumentation, such as catheters, guidewires, and prostheses, are brought to the heart through the vessels connected to the

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heart. One of the challenges with percutaneous approaches to procedures such as valve replacement, is that patients with diseased valves often have diseased major vessels, and the instrumentation required to accomplish a procedure such as a percutaneous valve replacement is often fairly large. For example, the un-expanded delivery size of a CoreValve (RTM) aortic valve prosthesis available from Medtronic, Inc. is approximately 18 French; the un-expanded delivery size of a Sapien (RTM) valve available from Edwards Lifesciences, Inc. is between 18 and 24 French, depending upon which size is utilized. Such outer sizes do not allow for a conventional guide catheter to be inserted as a protective layer between the tools and the tissue, and therefore the standard of care has become direct insertion of the valve instrumentation through the diseased vessels to reach the target location within or adjacent to the heart. Another complicating factor with such interventions is the fact that it is likely that the aorta through which the devices will be advanced will be diseased (one recent study concluded that 61% of patients over 65 years of age severe aortic valve stenosis also have severe aortic atherosclerosis; Osranek et al., American Journal of Cardiology, 2009; 103: 713-717). Figure 1 illustrates a typical diseased aorta (2) with deposits (4) clinging to almost all interior surfaces. This complicated surgical paradigm has lead some clinical researchers to believe that elevated stroke rates associated with such procedures may be related to the physical insertion of large interventional tools through diseased vessels and concomitant scaping or microscraping action of the tools against the diseased vessel walls, which is breaking portions of plaque loose and allowing these to flow with the bloodstream into the brain and other undesirable landing places. There is a need for

a configuration wherein a relatively thin but protective sheath-like member can be put in place to guide the interventional tools and prosthesis while mitigating load concentrations and/or scraping or abrasion of the interior of the subject vessels. The subject invention is directed to address such need.

SUMMARY

One embodiment is directed to a system for deploying a device to a distal location across a diseased vessel, comprising a sheath comprising an expandable distal portion comprising a porous wall defining a lumen therethrough, the distal portion having a collapsed configuration, wherein the sheath has a first cross sectional outer diameter and a first lumen inner diameter, and an expanded configuration, wherein the sheath has a second cross sectional outer diameter and a second lumen inner diameter; wherein in the collapsed configuration, the sheath is configured to be advanced across at least a portion of the diseased vessel to a position adjacent the distal location without substantial size interference between the first cross sectional outer diameter of the sheath and an inner diameter profile of a lumen of the diseased vessel; wherein upon positioning the collapsed configuration to the desired position relative to the distal location, the sheath may be expanded to the expanded configuration to facilitate passage of one or more relatively large diameter structures through the lumen that are larger in diameter than the first cross sectional outer diameter, the expanded configuration diverting at least a portion of the flow of blood through the diseased vessel across the porous wall of the sheath; and wherein upon completion of passage of the one or more relatively large diameter structures, the sheath may be collapsed back to the collapsed configuration. The first lumen inner diameter may be equal to between about 0 mm and about 3 mm. The second lumen inner diameter may be equal to between about 20 mm and about 50 mm. The system further may comprise one or more radioopaque markers coupled to the sheath and configured to assist an operator observing fluoroscopy with

positioning of the sheath relative to the diseased vessel. The porous wall may comprise one or more holes created across a sheetlike member. The holes may have a diameter of about 100 microns. The porous wall may be configured to filter blood flowing through it to prevent passage of emboli that may be present within the lumen. The sheath may comprise one or more radioopaque markers located adjacent the porous wall and being configured to allow an operator to visualize relative positioning of the porous wall relative to one or more anatomical features using fluoroscopy. The system further may comprise a guidewire inserted through at least a portion of the lumen and configured to assist with guidance of the sheath through the diseased vessel. The system further may comprise a filtering device positioned within the diseased vessel in a configuration selected to prevent the passage of emboli to a tributary vessel of the diseased vessel. The system further may comprise a filtering device positioned within the diseased vessel at a location proximal to an access point wherein the sheath is inserted into the diseased vessel, the filtering device configured to prevent the passage of emboli to positions proximal of the location of the sheath. The system further may comprise a balloon dilation probe configured to complete the reconfiguration of the expandable sheath from the collapsed configuration to the expanded configuration. The expandable sheath may be self-expanding from the collapsed configuration to the expanded configuration. The system further may comprise a removable expansion retention member configured to retain the expandable sheath in the collapsed configuration. The expansion retention member may comprise a corset and tensile member assembly wherein the tensile member may be tensioned proximally to release the corset and allow expansion to the expanded

configuration. The system further may comprise a magnetic collapsing probe which may be passed through the lumen of the expanded configuration to assist with affirmative collapsing of the sheath back to the collapsed configuration. The system further may comprise a magnetic collapsing probe which may be positioned through the lumen of the expanded configuration to assist with maintaining the collapsed configuration until a reconfiguration to the expanded configuration is desired, at which point the probe may be withdrawn. The device may comprise an implantable prosthesis selected to be passed through the expandable sheath to the distal location across the diseased vessel. The implantable prosthesis may comprise a cardiac valve prosthesis. The expandable sheath may be configured to be twisted longitudinally to form the collapsed configuration, and untwisted longitudinally to form the expanded configuration. The sheath may comprise a proximal portion having a stiffer structural modulus than the distal portion. The system further may comprise a distal hoop that is controllably closeable by an operator through tensioning of a tensile member operatively coupled to the distal hoop.

In another aspect, the present invention resides in a system for deploying a device to a distal location across a diseased vessel, comprising: a sheath comprising an expandable distal portion comprising a porous wall defining a lumen therethrough, the distal portion having a collapsed configuration, wherein the sheath has a first cross sectional outer diameter and a first lumen inner diameter, and an expanded configuration, wherein the sheath has a second cross sectional outer diameter and a second lumen inner diameter; and an expandable tubular filter removably coupled to an elongate deployment member, the tubular filter

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configured to be deployed before installation of the sheath to provide filtering protection at one or more tributary vessel junctions, wherein the deployment member is removable after deployment of the expandable tubular filter, and wherein the sheath is inserted through the tubular filter after expansion thereof, and wherein the elongate deployment member is configured to recapture the tubular filter for removal thereof; wherein in the collapsed configuration, the sheath is configured to be advanced across at least a portion of the diseased vessel to a position adjacent the distal location without size interference between the first cross sectional outer diameter of the sheath and an inner diameter profile of a lumen of the diseased vessel; and wherein upon positioning the collapsed configuration to the desired position relative to the distal location, the sheath is expandable to the expanded configuration to facilitate passage of one or more relatively large diameter structures through the lumen that are larger in diameter than the first cross sectional outer diameter, the expanded configuration diverting at least a portion of the flow of blood through the diseased vessel across the porous wall of the sheath; and wherein upon completion of passage of the one or more relatively large diameter structures, the sheath is collapsible back to the collapsed configuration.

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Brief Description of the Drawings

Figures 1A - 1B illustrate various portions of a diseased aorta.

Figures 2A - 2F illustrate aspects of a conventional interventional device deployment through a diseased aorta.

Figures 3A - 3Z-4 illustrate various aspects of an inventive expandable railed sheath that may be used in conducting various cardiovascular procedures, such as a percutaneous aortic valve replacement procedure.

Figures 4A - 4H illustrate aspects of a configuration similar to that of Figures 3A - 3Z-4, wherein a branch vessel protection filter is also incorporated.

Figures 5A - 5K illustrate aspects of a configuration similar to that of Figures 3A - 3Z-4, wherein a tubular branch vessel protection filter is also incorporated.

Figure 6 illustrates a configuration wherein a magnetic probe is utilized to collapse a sheath after an intervention has been conducted through an expanded form of the sheath.

Figure 7 illustrates a configuration wherein a magnetic probe is utilized to retain a sheath in a collapsed form until an expansion to an expanded form is desired.

Figures 8A - 8G illustrate aspects of a configuration similar to that of Figures 3A - 3Z-4, wherein a distal protection filter is also incorporated.

Figure 9 illustrate aspects of a configuration similar to that of Figures 3A - 3Z-4, wherein only a proximal portion of the main vessel is protected by an embodiment of the inventive sheath.

Figure 10 illustrates various aspects of a deployment technique in accordance with the present invention.

Figure 11 illustrates various aspects of a deployment technique in accordance with the present invention.

Figure 12 illustrates various aspects of a deployment technique in accordance with the present invention.

Figure 13 illustrates various aspects of a deployment technique in accordance with the present invention.

Figure 14 illustrates various aspects of a deployment technique in accordance with the present invention.

Figure 15 illustrates various aspects of a deployment technique in accordance with the present invention.

Figure 16 illustrates various aspects of a deployment technique in accordance with the present invention.

Figures 17A-17C illustrate aspects of an embodiment of a railed sheath having a frustoconical distal portion configured to interface with a cardiovascular cavity.

Figures 18A-18J illustrate various aspects of an inventive expandable railed sheath that may be used in conducting various cardiovascular procedures, such as a percutaneous aortic valve replacement procedure.

Figure 19 illustrates various aspects of a deployment technique in accordance with the present invention.

Figures 20A-20L illustrate various aspects of an inventive expandable railed sheath configuration that may be used in conducting various cardiovascular procedures, such as a percutaneous aortic valve replacement procedure.

Figure 21 illustrates various aspects of a deployment technique in accordance with the present invention.

DETAILED DESCRIPTION

Referring to Figure 1B, an illustrative representation of a diseased aorta (2) is shown with deposits (4) distributed in several locations, including adjacent or within the left (6) and right (8) iliac arteries, and adjacent the junctions of the aortic arch with the left subclavian (10), left common carotid (12), and innominate artery (14). Navigating a diseased aorta (2) such as that depicted is indeed a challenge with conventional intravascular diagnostic and/or interventional hardware. For example, referring to Figures 2A-2F, a conventional instrument deployment is illustrated to demonstrate the disease-related challenges. Referring to Figure 2A, the elongate instrument (46) is advanced in a retrograde direction through the aorta (2) distal tip (50) first. The instrument (46) may be a valve deployment member or probe, a catheter or conduit for conducting various interventions, etc. Referring to Figure 2B, as the instrument (46) is advanced farther toward the targeted anatomy, the distal end (50) may become a scraping interface (48) as it is urged past and against the tissue comprising the diseased aorta (2), and may accidentally and undesirably cause one or more pieces of the deposit material (4) to become loose and thereby flowing distally - perhaps into the brain or another undesirable deposit flow location. Further, the scraping dynamic between the distal tip (50) of the instrument (46) and the aortic tissue may result in the formation of one or more embolic masses, which also may find themselves undesirably drifting with the flow path toward the brain or other tissue. Figure 2C shows that at the relatively extreme turning portions of the aortic arch, a conventional instrument may find itself located immediately adjacent or

within the takeoff junctions of the joining arteries (10, 12, 14), where plaques and other deposits may be particularly mechanically vulnerable. Figures 2D-2F illustrate further advancement of the instrument (46) until the distal tip (50) is in the desired location for the planned diagnostic or interventional procedure. Subsequently, the instrumentation is typically retracted, causing yet another scraping interface type of interaction as the instrumentation is pulled proximally in a pathway opposite to that described in reference to Figures 2A-2F, and additional risks for undesirable complication related to such interaction.

Referring to Figures 3A - 3Z-4, various aspects of deployment steps and configurations utilizing embodiments of the inventive expandable railed sheath are illustrated. Referring to Figure 3A, a collapsed configuration (16) of a railed sheath is being inserted (80) distal tip (52) first. This collapsed configuration (16) may be inserted over a guidewire using conventional "over-the-wire" technique to assist in guiding the collapsed sheath configuration. As compared with the insertion scenario of, for example, Figure 2A, the collapsed configuration (16) leaves much more room in the diseased aorta (2), thereby decreasing the likelihood of a scraping type mechanical interface relationship as described in reference to Figures 2A-2F above. In one embodiment, the railed sheath may comprise one or more pullwires to facilitate steering by an operator as the collapsed railed sheath (16) is advanced through the diseased aorta (2) using imaging modalities such as transcutaneous ultrasound and/or fluoroscopy to assist with the interactive steering of such configuration through the diseased vessel. Referring to Figure 3B, the distal tip (52) of the collapsed configuration (16) has reached the desired interventional

location (here the aortic outflow tract of the left ventricle cavity of the heart) in a minimally invasive way taking advantage of the relatively small cross sectional size of the collapsed configuration (16). Referring to Figures 3C and 3D, close up views of the collapsed configuration (16) are illustrated to show that the railed sheath indeed comprises a plurality of elongate rail structures (20; in the depicted embodiment 4 independent rail structures) coupled together by a sheet or sheetlike member (22) which, in the depicted collapsed configuration (16) is folded in between the elongate rail structures (20). A lumen (24) is defined through the railed sheath, and remains relatively small in diameter with the collapsed configuration (16).

Referring to Figures 3E-3Q, various configurations of railed sheath embodiments are illustrated in cross sectional views. One key core functionality of each of the illustrative embodiments described herein is the notion of protecting surrounding vascular and other anatomy by providing an intermediate surface between relatively large items to be moved through the vasculature (i.e., such as elongate tools, collapsed prostheses, etc) and the vasculature itself. The intermediate surface, or protective sheath, generally comprises a sheetlike member that is reinforced by a plurality of generally longitudinal rail members that are configured to de-concentrate loads applied from the inside of the sheath toward the nearby vascular anatomy - in a manner somewhat akin to the manner in which point loads from train wheels on a railroad track are de-concentrated by the rails of the railroad track and absorbed over a large surface provided by the substrate underlying the railroad track. This load de-concentration is believed to provide protection of the underlying anatomy from focused loads

that could dislodge plaques or other particles, or create emboli - either from the focused load interface itself, or from any scraping or abrading interfacing that may be related to conventionally pushing a piece of hardware past the unprotected anatomy, as in Figures 2A-2F. Referring to Figure 3E, an expanded form (26) of a railed sheath embodiment is shown having four elongate rail members distributed approximately equidistantly about the circumference of the expanded form (26). The expanded form has an approximately circular outer shape and defines an approximately circular inner lumen. The elongate rail structures themselves have elliptical cross sectional shape profiles (20) configured to atraumatically and easily accommodate sliding of another diagnostic or interventional device through the lumen during a medical procedure such as a percutaneous valve replacement. Figure 3F illustrates one configuration of the same hardware as shown in Figure 3E, but in the compressed or collapsed (16) format, with the sheetlike member (22) folded in both directions (i.e., partially folded onto each of the immediately adjacent rail structures 20). Figure 3G illustrates another configuration wherein the sheetlike member (22) is folded in one direction (i.e., to find mechanical support for slack portions on the next adjacent rail structure 20 in one direction as shown). Either of the collapsed configurations illustrated in Figures 3F and 3G, for example, may be suitable for deployment as in Figures 3A and 3B. Referring to Figures 3H-3M, various expanded configuration (26) embodiments are depicted to illustrate that a great variety of combinations and permutations of hardware subcomponentry is within the scope of the invention. Referring to Figure 3H, four elliptical rail structures (20) are coupled to the outer aspect of a substantially tubular sheetlike member (22), for example,

with polymer welding, adhesive, suturing, or other coupling configuration. The outer aspects of such configuration may be coated with a lubricious polymer to assist in the ease of sliding such a configuration past nearby tissue structures in a collapsed state; similarly, the inner aspects may be coated with a lubricous coating or surface to assist with slidable engagement between the expanded state of the railed sheath and instruments which may be passed through the working lumen during diagnostic and/or interventional procedure steps. Referring to Figure 3I, in one embodiment, elongate rail structures of circular cross section (32) may be utilized for a more uniform bending modulus configuration, and referring to Figure 3J, elongate rail structures of rectangular or square cross section (34) may be utilized to present preferred bending axes to the overall structure of the railed sheath. Referring to Figures 3K-3M, embodiments similar to those illustrated in Figures 3H-3J are depicted, with exception that the embodiments of Figures 3K-3M have the elongate rail structures (20, 32, 34, respectively) more tightly integrated into the outer and inner shape of the overall structure (i.e., the outer aspects of the rail structures don't protrude out as much). This may be accomplished, for example, by co-forming the rails (20, 32, 34, respectively) from the same bulk material as the sheetlike members (22), or at least partially encapsulating the rails (20, 32, 34, respectively) with the sheetlike member (22) material. Referring back to the embodiment of Figure 3E, various embodiments may be created to have a substantially smooth outer shape in the expanded state, and to have the elongate rail structures (20) protrude more into the inner lumen of the overall structure, which may be desired for mechanically guiding various portions of the diagnostic and/or interventional

hardware that may be passed through the working lumen for the medical procedure.

Referring to Figures 3N-3Q, various configurations are shown to illustrate that cross sectional homogeneity is not only not necessary, but may not be preferred in some scenarios. Referring to Figure 3N, one expanded configuration (26) is shown wherein a sheet like member (22) couples two elliptical rail structures (20) and two circular rail structures (32). Referring to Figure 3O, a less cross sectionally homogeneous configuration is shown having two elliptical rail structures (20) coupled to the sheetlike member (22) diametrically across from each other, and a circular rail structure (32) diametrically opposed from a rectangular (34) rail structure at an angle so that the four depicted rail structures are not uniformly distributed about the circumference of the depicted cross section. Referring to Figure 3P, three rectangular rail structures (34) are equidistantly circumferentially distributed about the cross section. Referring to Figure 3Q, a group of triangular (36), elliptical (20), and rectangular (34) rail structures is not equidistantly circumferentially distributed about the cross section. The various cross sectional permutations and combinations may be selected to improve deliverability, to have selected overall shape bending moduli, and to improve utility of the working lumen for passing through diagnostic and/or interventional tools during a medical procedure.

Further, the mechanical performance of the collapsible railed sheath may be customized and modified by changing the shapes, materials, and positions/orientations of various portions longitudinally (i.e., relative to the length of the overall catheter structure). Several such configurations are

illustrated in Figures 3R-3V. Referring to Figure 3R, a longitudinally uniform configuration has the same cross sectional configuration of rail structures (20) and sheetlike member (22) all along its length. Referring to Figure 3S, an embodiment is shown wherein the outer shape of the overall structure does not change longitudinally, but wherein one or more of the rail structures (20) are tapered in shape (38) longitudinally, to provide greater overall bending modulus for the catheter at the end with the more tapered rail structures. Referring to Figure 3T, an embodiment is depicted which has not only one or more tapered (38) rail structures (20), but also a tapered (40) overall outer shape. Such a configuration would have inner lumen size limitations, but would provide greater overall bending modulus for the catheter at the end with the more tapered rail structures and overall shape. Referring to Figures 3U and 3V, the rail structures may be angularly oriented relative to the longitudinal axis of the overall shape. As shown in the expanded configuration (26) of Figure 3U, one or more of the rail structures (20) have a spiral orientation (42). Figure 3V shows that the same embodiment as shown in Figure 3U may be collapsed into a collapsed configuration (16), with the spiral orientation (42) of the one or more rail structures retained, but to a lesser spiraling angle relative to the longitudinal axis of the overall shape.

Referring to Figures 3W and 3X, the transition between collapsed configuration (16) and expanded configuration (26) may be accomplished by advancing a diagnostic and/or interventional instrument (44) through the lumen of the railed sheath. As shown in Figure 3W, the proximal portion of the railed sheath through which the instrument (44) has been advanced are in the expanded configuration (26), while the distal portion which has

not yet been reached by the instrument (44) remains in the collapsed configuration (16). In one embodiment, the rails are specifically configured to assist in maintaining the orientation of the instrument (44) relative to the railed sheath and associated tubular anatomy as the instrument (44) is advanced through the railed sheath, to ensure that a predictable orientation is maintained when the instrument (44) reaches the desired diagnostic and/or interventional tissue theater. For example, in the case of a percutaneous valve replacement procedure, it is highly desirable to make sure that the valve prosthesis gets to the desired location, such as in the aortic outflow tract, in a predictable orientation relative to the structural tissue of the outflow tract, but also that damage is not caused to the patient during the deployment; the subject configurations are designed with such priorities in mind. In another embodiment, as described in further detail below, the railed sheath may be a self-expanding sheath that is affirmatively retained in a collapsed configuration (16) until a desired time upon which it may be controllably converted to the expanded configuration (26). A corset-style collapse-retention member with a releasable (i.e., by proximal tension) tensile member may be utilized to retain the collapsed configuration, as in International PCT Publication No. WO 97/21403.

Referring to Figure 3Y, in one embodiment, an expanded configuration of a railed sheath (26) may comprise one or more porous regions (132) configured to be positioned adjacent tributary vessels to maintain flow through such vessels when the expanded railed sheath is in place. As shown in Figure 3Y, a porous region (132) is configured in this embodiment to ensure that flow coming into the distal tip (52) of the expanded railed

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sheath (26) is at least partially diverted up the associated tributary vessels (10, 12, 14) to supply with brain of the patient with blood during the procedure. The margins of the porous region may be marked with radioopaque markers to facilitate confirmation of placement of the porous region in a desired configuration relative to the anatomy, and transcutaneous and/or intravascular ultrasound and/or fluoroscopy with contrast agent may be utilized to confirm flow out of the aorta and into important tributary vessels during placement of the railed sheath. Preferably the porous region functions not only as a flow bypass, but also as a filter to capture any deposits or emboli that are being routed through the railed sheath; this may be accomplished by sizing the pores of the porous region to be large enough to pass blood plasma and red blood cells, but small enough to not pass typical emboli and deposits. Referring ahead to Figures 17A-17C, an embodiment similar to that of Figure 3Y is depicted, but in this case the distal end of the railed sheath comprises a trumpet or frustoconical shape (140) configured to maximize the likelihood that emboli or deposits that exit the adjacent anatomy (here the aortic outflow tract of the left ventricle cavity of the heart 138) by providing a more contoured fit of the adjacent anatomy. Referring to Figure 17B, during deployment, the flared distal frustoconical portion (140) may be retained in a compressed form by a movable or slideable cuff member (142), which, as shown in Figure 17C, may be retracted (144) proximally to allow the flared distal frustoconical portion (140) to be expandable or expanded (146) into the adjacent anatomy.

In both Figure 17A and 3Y, an elongate insertion device (56) is shown inserting a diagnostic and/or interventional device (54), such as a collapsed aortic valve prosthesis, toward

the desired anatomical location using the subject railed sheath. Referring to Figures 3Z, and 3-Z1 with the device (56) safely deployed into the subject anatomy, the elongate insertion device (56) may be safely retracted (58) back out through the expanded configuration (26) of the railed sheath. Referring to Figure 3-Z2, with the diagnostic and/or interventional procedure substantially completed, the railed sheath may be removed by pulling proximally (60) on the sheath and retracting it out, as shown in Figures 3-Z3 and 3-Z4. In another embodiment, as described in further detail below, the sheath may be forcibly converted from expanded configuration (26) to collapsed configuration (16) for removal, using, for example, an electromagnetic collapsing device. With all of the instrumentation removed, the access wound (for example, to one of the femoral arteries) may be closed and the procedure completed.

Referring to Figures 4A-4H, in one embodiment a separate filtering device, such as that sold under the tradename Embrella (RTM) by Edwards Lifesciences, Inc., may be utilized to assist in preventing unwanted particles or emboli from entering certain tributary vessels. Referring to Figure 4A, a collapsed filtering device (68) may be advanced (62) with an elongate deployment member (66). Referring to Figure 4B, the filtering device may be converted to an expanded configuration (70) wherein one or more wings (72, 74) form filtrating barriers across one or more tributary vessels (12, 14) and are temporarily retained in place by a retainer member (76). Referring to Figure 4C, the deployment member (66) may be retracted (78), and as shown in Figure 4D, a collapsed railed sheath configuration (16) may be advanced (80). Referring to Figure 4E, the collapsed railed sheath configuration (16) may be

utilized as in reference to Figures 3A to 3Z-4 above, but with the temporary filter device in place. After the railed sheath has been utilized for a diagnostic and/or interventional procedure, it may be removed, and an elongate recapture device (56) may be inserted (62) to recapture the filtration device (64), as shown in Figures 4F and 4G, followed by retraction (58) and completion of the case.

Referring to Figures 5A-5K, in another embodiment, a tubular filter may be deployed before installation of a railed sheath to assist with filtering protection at one or more tributary vessel junctions. Referring to Figure 5A, an elongate deployment member (88) removably coupled to a collapsed tubular filter (84) may be advanced (90) toward the anatomic location of interest, using, for example, fluoroscopic and/or ultrasound imaging guidance, which may be assisted by radioopaque markers on the filter (84) and/or deployment member (88), and/or the injection of imaging contrast agent. Referring to Figure 5B, with the collapsed tubular filter (84) in the desired longitudinal position, the tubular filter may be converted to the expanded configuration depicted in Figure 5C, using, for example, a balloon expansion element of the deployment member, or a release of a constraining member that retains a self-expanding configuration of the tubular filter until expansion is desired, after which the restraint is released and expansion ensues to the expanded configuration (86) of the tubular filter, which is configured to screen emboli and/or unwanted particles from entering the associated tributary vessels (10, 12, 14 in the depicted example). The deployment member (88) may be removed (92), as shown in Figure 5D, and a collapsed railed sheath configuration (16) may be inserted (80) through the expanded tubular filter (86), as shown in Figures 5E and 5F, to

conduct a procedure in similar fashion as described above in reference to Figures 3A to 3-Z4 (in one embodiment the porosity of the porous portion (132) may be increased to maximize flow, since an additional filter is already in place; in another embodiment the porous portion (132) may simply comprise an open window section of the railed sheath). Referring to Figure 5G, with the procedure coming to completion, the railed sheath (26) may be removed (60), and as shown in Figure 5H, the filter deployment member (88) may be advanced to recapture the filter and pull it proximally out (92), causing it to slightly collapse and become mobile relative to the anatomy. Referring to Figure 5I, in another embodiment, two or more pullwires (94, 96) may be coupled to the tubular filter (either intraoperatively, or preoperatively and left in place during the procedure with leads to a proximal manual access point) and utilized to forcibly dislodge the tubular filter for withdrawal by causing radial collapse of at least a proximal portion (98) of the tubular filter (86) as it is pulled toward the small aperture of the deployment member (88) through which the pullwires or tether lines (94, 96) exit to couple to the filter. Referring to Figure 5J, in another embodiment, a distal portion of an electromagnetic deployment probe (100) may be configured to controllably attract ferromagnetic portions of the tubular filter to draw the filter back into a collapsed state when a voltage source (104) provides electromagnetic attraction toward one or more electromagnets coupled to the distal portion (102) of the electromagnetic deployment probe (100). Referring to Figure 5K, the tubular filter may be retracted and removed.

Referring to Figure 6, a deployment probe (106) with a longer electromagnetic portion than that of Figure 5K may be utilized to assist in the affirmative re-collapsing of a railed

sheath embodiment that comprises ferromagnetic portions which may be controllably attracted toward the electromagnetic deployment probe (106) using an operatively coupled voltage controller (108). In one embodiment, the voltage controller (108) may be configured to activate all of the electromagnets on the probe (106) simultaneously to re-collapse the associated length of the railed sheath simultaneously. In another embodiment, the controller (108) may be configured to sequentially activate (and retain activation until release is desired) the various electromagnets comprising the probe to provide for a sequential longitudinal collapsing of the associated railed sheath (i.e., from the most proximal portion to the most distal portion, vice versa, etc).

Referring to Figure 7, a deployment probe (106) similar to that depicted in Figure 6 may be utilized to forcibly retain a collapse configuration until sequential or simultaneous expansion of all portions of the railed sheath is desired. In other words, the magnet controller (108) may be configured to retain the collapsed state of the entire exposed length of the railed sheath during insertion. When the desired longitudinal positioning has been accomplished, the magnet controller may be configured to either simultaneously or sequentially release portions of the railed sheath to allow for expansion to the expanded form (26). Completion of expansion to the expanded form (26) may be completed as a result of a self-expanding infrastructure of the railed sheath, with the help of an expandable balloon, etc.

Referring to Figures 8A - 8G, a proximal filter, or "distal protection device", may be placed proximal to the access point for the aforementioned hardware embodiments to prevent particles or emboli from flowing distally. Referring to Figure 8A, a

close up view of an access point (110, such as an arteriotomy) and associated vessels (6, 8) and deposits (4) is shown with a collapsed filtration device (112) being advanced (116) with a deployment member (114) through the access point (110). Referring to Figure 8B, the deployment member (114) may be shaped such that the collapsed filtration device (112) can be tucked immediately proximal of the access point (110). As shown in Figure 8C, the filtration device may be self expanding or expandable (i.e., with a balloon) to be controllably converted into an expanded/deployed configuration (120) wherein blood flow (124) is directed across a filter mesh (112) portion of the expanded filter (120) to prevent passage of emboli, particles, and the like. Preferably the filter (120) has a tether member (126) which may be extended out of the access point (110) and used subsequently for recapture and removal of the filter. Referring to Figures 8D and 8E, with the expanded filter (120) in place, a collapsed railed sheath (16) may be advanced and utilized as in the embodiments described in reference to Figures 3A to 3Z-4, with the further benefit of the distal protection filter in place. With the procedure coming to a close, the railed sheath (26) may be retracted (60) past the still-deployed filter (120), as shown in Figure 8F, after which the tether member (126) may be utilized to assist in retraction (128) of the filter member out of the access point (110) and completion of the procedure.

Referring to Figure 9, a railed sheath may be utilized to only partially protect a route to a targeted anatomical position for a diagnostic and/or interventional instrument. For example, if the main objective is to protect the subject vessel pathway between the lower ascending aorta (130) and the access point, a railed sheath (26) may be deployed only across this length, and

the instrumentation (56, 54) may be advanced across this length through the railed sheath (26), and then across the remainder of the length of the vessel to the targeted anatomy without the protection and/or mechanical guidance of the railed sheath.

Referring to Figure 10, a deployment technique is illustrated wherein subsequent to preoperative analysis (302) and establishment of vascular access (304), a guidewire and/or introducer sheath may be advanced across the access location to provide for guidance and support of additional instrumentation which may be advanced (306). A compressed configuration of a railed sheath may be advanced - for example, over-the-guidewire and through the introducer sheath - in a compressed configuration (308). Once the railed sheath has reached a desired longitudinal position (310) for the interventional and/or diagnostic procedure, the railed sheath may be expanded or allowed to expand to, for example, accommodate passage of an advancing interventional device (such as a percutaneous valve deployment assembly) across the railed sheath to the anatomical location of interest (312). With the expanded configuration of the railed sheath remaining in situ, the procedure may be conducted (314), after which the tools may be retracted (316), the railed sheath returned to a collapsed or partially collapsed configuration (for example, by simple proximal tensioning to partially collapse the railed sheath, by electromagnet-induced forced to fully collapse the railed sheath, etc) (318), and vascular access closed (320) to complete the procedure.

Referring to Figure 11, an embodiment similar to that of Figure 10 is illustrated, with the exception that a folding embolic filter may be advanced (322) and deployed (324) prior to introduction of the railed sheath (308); this filter may be reconfigured into a collapsed transport configuration (326) and

retracted (328) before final closing of the vascular access (320).

Referring to Figure 12, an embodiment similar to that of Figure 10 is illustrated, with the exception that a tubular embolic filter may be advanced (330) and deployed (332) prior to introduction of the railed sheath (308); this filter may be reconfigured into a collapsed transport configuration (334) and retracted (336) before final closing of the vascular access (320).

Referring to Figure 13, an embodiment similar to that of Figure 10 is illustrated, with the exception that after removal of the interventional tools (316), the railed sheath may be returned to a compressed configuration with the help of magnet-induced loads from a magnetic probe or portion of a probe (338) before retraction using the probe (340).

Referring to Figure 14, an embodiment similar to that of Figure 10 is illustrated, with the exception that for railed sheath introduction, the collapsed configuration is actively maintained using magnetic loads (342), and expansion (344) to the expanded configuration after appropriate longitudinal advancement (310) is controllably facilitated by controllably decreasing or removing the magnetic loads, followed by retraction of the magnetic tool (346) and advancement of the interventional or diagnostic tools through the railed sheath (348).

Referring to Figure 15, an embodiment similar to that of Figure 10 is illustrated, with the exception that after vascular access is established (304), a proximal filter, or "distal protection device" is installed (350) proximally; this filter may be removed (352) after ultimate removal of the railed sheath (318).

Referring to Figure 16, an embodiment similar to that of Figure 10 is illustrated, with the exception that the railed sheath may be only partially positioned across the length of the vascular route to the targeted anatomy (i.e., rather than protecting the entire length with a railed sheath, only a portion, such as a proximal portion, may be protected) (354).

The rail structures may comprise various bio-compatible metals, such as titanium, alloys thereof such as Nitinol superalloy, and/or polymers such as polyethylene, ultra-high-molecular weight polyethylene, polyethylene terepthalate, polyoxymethylene, polytetrafluoroethylene, and co-polymers thereof.

The sheetlike member may comprise a material such as polyethylene, polytetrafluoroethylene, or co-polymers thereof.

In one embodiment, a vacuum device such as a syringe may be operatively coupled to the configuration (for example, coupled to or integrated into a proximal handle that forms a manual interface for inserting a railed sheath catheter), and may have an elongate distal portion that may be inserted into a deployed railed sheath catheter to vacuum away emboli that may be present.

Referring to Figures 18A-18J, various aspects of another embodiment of an intervention protection configuration are shown, wherein a distal portion of the delivery configuration is allowed to expand relative to a more proximal portion which may remain substantially more contracted or collapsed. Referring to Figure 18A, a railed sheath in a collapsed configuration (16) has been inserted through a diseased vessel such as aorta (2), starting with transvascular access through a portion of the associated vasculature such as the left iliac artery (6), followed by insertion of the instrument assembly into a position

as shown wherein the distal tip is located in a preferred location, such as adjacent an aortic valve of the patient. A proximal portion of the instrumentation, including a proximal control assembly (150) remains external to the vascular access for manipulation and control of the procedure, along with optional external drainage or exit of fluids or embolic or other materials which may collect within the instrumentation. The depicted embodiment comprises an atraumatic obturator tip (148) selected to reduce the results of impacts that such distal instrumentation may have during insertion and placement. Referring to Figure 18B, without the associated anatomy (i.e., from the illustration of Figure 18A), the assembly may comprise a collapsed railed sheath portion (16) removably coupled to a distal obturator-jacket assembly (168) which has an atraumatic tip (148). The obturator-jacket assembly (168) preferably is coupled, through the lumen of the sheath and proximally out through a valved (154) port (156) defined through the tubular body assembly (164) of the proximal assembly (150), to an elongate obturator coupling member (152) which may be movably positioned through a central working lumen of the sheath (such as that referred to as element 24 above). The depicted proximal assembly (150) also comprises a second valved (158) port (160) which may be occupied by a portion of a sheath tip manipulation assembly, which may comprise a proximal manipulation structure or handle (162) which is coupled to a distal portion of the sheath using a movable tension-applying element such as a pullwire. In one embodiment, as described below, an operator may manually manipulate, or pull, the proximal manipulation structure (162) to tension the movable tension-applying element and cause closure of the distal tip of the sheath using a hoop configuration. The obturator-jacket assembly may be configured

to assist in temporarily maintaining a collapsed configuration of a distal portion of the sheath, and may be configured to extend the full length of a particularly expandable portion of the sheath which may be expanded outward subsequent to removal of the obturator-jacket assembly (168) from its collapse restraint configuration as shown in Figure 18B. For example, referring to Figure 18C, with the sheath in a desired position relative to the associated anatomy, the obturator-jacket assembly (168) may be advanced or urged (166) distally relative to the remainder of the sheath assembly (16, 150), causing the obturator-jacket assembly (168), with its atraumatic distal tip (148), to become released from the remainder of the sheath assembly (16, 150) with such advancement. In one embodiment, such distal advancement causes a thin jacket-like wrapper portion of the obturator-jacket assembly (168) to become torn or fractured along a predetermined pathway (i.e., via preexisting perforations created in the jacket-like wrapper portion) in a manner that substantially releases and decouples the underlying collapsed portions of the railed sheath assembly from the jacket-like wrapper portion (while the jacket-like wrapper portion remains firmly attached to the obturator tip 148), allowing a portion of the sheath to self-expand to an expanded configuration (26) as shown in Figure 18C and the close-up view of Figure 18D. Referring to Figure 18E, with full distal advancement of the obturator assembly (168, 152), the distal portion of the railed sheath may be allowed to become fully expanded (26), and then the obturator assembly (168, 152) may be pulled proximally (170) through the lumen of the sheath (24) and through the proximal assembly (150) where it may be removed.

Referring to Figures 18F-18H, with the obturator assembly removed, this embodiment of the railed sheath is in an expanded

configuration wherein a proximal portion of the railed sheath remains in a relatively collapsed or small diameter configuration (16) as compared with the expanded distal portion (26), which features a plurality of structural rail members (32) configured to self expand and support a tubular or frustoconical porous filter mesh (132) surface configured to capture particles that may enter it, such as clots or plaque particles. In one embodiment wherein the sheath assembly is configured for aortic deployment, the expanded distal portion may be selected to have a length approximately equivalent to the arcuate length of the subject aortic arch. The embodiment depicted in close-up view in Figures 18G-18H features six elongate structural rail members (32) which may comprise a material such as a nickel titanium Nitinol superalloy; other embodiments may feature 4, 5, 7, 8, 9, 10, 11, 12, or more rail members (32), which may be configured to be prominent either to the inner surface or outer surface of the expanded portion (26), and may be configured to have various cross sectional areas and/or positions, as in the embodiments described above in reference to Figures 3E-3Q. Referring to Figure 18G, in one embodiment the most distal portion of the expanded sheath portion (26) may comprise a vessel engagement portion (172) selected to maximize physical accommodation of local endovascular geometry and/or terrain, so that particles moving through the pertinent vessel are biased to be captured by the railed sheath, not diverted around it. The depicted vessel engagement portion comprises a relatively low-modulus sheetlike material, which may comprise a thin biocompatible polymer, coupled in a cylindrical fashion to a relatively low-modulus zig-zag structure (176) intercoupled between two relatively low-modulus hoops (184, 186). These structures (176, 184, 186) may comprise relatively small-

diameter Nitinol superalloy material, for example. A controllably collapsible hoop (174) may be intercoupled into the distal assembly and movably coupled to the proximal manipulation assembly (element 162 of Figure 18B, for example) to allow an operator to pull upon the proximal manipulation assembly and cause increased hoop tension in the controllably collapsible hoop (174), causing such hoop to controllably collapse and close the distal assembly into a closed-distal configuration (178), as shown in Figure 18I, after which the entire sheath assembly may be proximally (180) removed out of the subject anatomy while safely containing the contents of the sheath assembly which may have been captured during deployment, such as clots and/or plaque particles. In one embodiment, the entire expanded portion (26), such as illustrated in Figure 18G, is a self-expanding structure, in that it is biased to expand to the expanded configuration (26) upon release of mechanical constraint such as the aforementioned obturator jacket. In another embodiment, only a tip portion is a self-expanding structure, such as a tip portion including the distal engagement portion (172) and a distal subportion of the frustoconical distal portion (140) of the sheath.

In another embodiment, the removable obturator jacket covering and restraining the underlying compressed distal portion of the sheath, such as in the assembly of Figure 18B, may be removed directly from the outside using a tensile member coupled to the outer surface of the jacket and configured to tear the jacket away from the underlying compressed distal portion of the sheath to allow such compressed distal portion to self-expand. In other words, rather than inserting, then retracting the obturator member to detach and remove the jacket covering from the underlying compressed distal portion of the

sheath by pulling the removed jacket out through the working lumen of the sheath, the jacket covering may be pulled off from the outside using a tensile member, such as a pullwire configured to be manually and controllably tensioned from a proximal location using a handle or other tensioning fixture, coupled between the jacket and a proximal location accessible using the proximal assembly (150) and pulled proximally away from the sheath in a tear-away fashion prescribed by predetermined patterning (i.e., through perforated tear-away lines or patterns). In another embodiment, a combination of release/removal from through the working lumen, and release/removal from the outside aspect of the sheath as described immediately above, may be utilized to fully release the sheath distal end and allow self-expansion.

In summary, as described above, the inventive protective configurations provide a means for conducting an intervention while also protecting the underlying tissue and related anatomy; further, the railed sheath configurations assist with delivery and alignment of tools and/or prostheses which may be related to the vascular intervention.

Referring to the process flow embodiment of Figure 19, for example, after preoperative analysis (302), vascular access may be established (304) and a guidewire and/or introducer may be advanced into the subject vessel lumen (306). A protective or railed sheath may be introduced (360) and advanced (310) in a compressed configuration to place the distal portion in a desired position relative to the subject anatomy (for example, in an aortic valve prosthesis deployment configuration, the sheath may be positioned to allow for deployment of the valve prosthesis adjacent the aortic outflow tract of the patient, as planned preoperatively). The protective or railed sheath may be

converted to its expanded configuration, which may comprise advancement and then retraction of an obturator assembly, as described above in reference to Figures 18A-18J, which may remove a wrapper layer or compression layer coupled to the obturator, thereby allowing the underlying sheath portion to self-expand in a manner akin to that of a self-expanding stent prosthesis (362). With the protective or railed sheath in the expanded/deployed configuration, intervention steps may be conducted which involve insertion and/or retraction of one or more devices, tools, or prostheses through the working lumen defined through the sheath, with protection provided to associated tissues by virtue of such sheath deployment (364). Subsequently the tools may be removed (316), and the expanded distal portion of the sheath controllably returned to a safe removal configuration wherein at least a distal portion of the sheath is controllably collapsed or closed, such as by a hoop closure actuated by proximally pulling a tension or pullwire, as described above in reference to Figures 18A-18J (368). Vascular access may then be closed after removal of the sheath assembly (320).

Referring to Figures 20A-20L, various aspects of embodiments suitable for deploying a percutaneous prosthesis, such as an 18-French aortic valve prosthesis which may be available from suppliers such as Medtronic CoreValve (RTM), are depicted. The depicted assembly may be utilized as an introducer itself in the vascular access procedure, or may be passed through another tubular member functioning as an introducer. Referring to Figure 20A, an assembly similar to that depicted in Figure 18B is shown with an obturator (or "dilator") assembly comprising an elongate coupling member (152) and an atraumatic obturator tip (or "dilator nose cone") (148)

positioned through a working lumen of an introducer (16). A peel-away outer sleeve (168) is depicted covering the distal portion of the collapsed configuration (16). The embodiment of Figure 20A also features tubular body assembly (164) in the form of a hub with integrated hemostasis valve which is operatively coupled to a side port with 3-way stopcock (186) and actuation mechanism (162) configured to allow for manipulation of an operatively coupled actuation wire which is configured to facilitate controlled expansion or collapse of the distal portion of the porous portion (132) of the assembly, as described below. The actuation mechanism (162) may comprise a mechanical slider positioned within a channel, the slider coupled to a pull or push wire that functions as the actuation wire. Approximate dimensions are illustrated for certain lengths of the depicted embodiment. Referring to Figure 20B, a closer orthogonal view of an unrestrained porous portion (132) comprising a polyester mesh having pores approximately 105 microns in size in one embodiment. The distal portion of the porous portion (132) is held in an expanded configuration by the hoop member (174), which may comprise a material such as Nitinol, and which may be configured to self-expand to the depicted expanded hoop configuration when enough slack or tension release is present in the actuation wire which is threaded through the depicted polymer support conduit (188), or which may be configured to be urged into expansion by insertion of the actuation wire through the polymer support conduit (188). Two or more radiopaque markers (190) may be positioned about the distal portion of the assembly to allow for fluoroscopic or radiographic confirmation of expanded diameter dimensions.

Figure 20C depicts a close up side view of the distal portions of the assembly shown in broader view in Figure 20A.

In this embodiment, a clear peel-away sleeve (168) is tucked under the proximal aspect of the atraumatic obturator tip (148) to further facilitate atraumatic insertion. Referring to Figure 20D, with the peel-away sleeve (168) removed (i.e., peeled away via proximal tensioning), the polymer mesh (132) becomes exposed but generally is configured to remain collapsed with the hoop (element 174 in Figure 20B, for example) constrained by the proximal aspect of the atraumatic obturator tip (148). Such an interface is shown in further close-up in Figure 20E.

Referring to Figure 20F, when expansion of the porous mesh (132) is desired, the obturator/dilator assembly (148, 152) may be inserted relative to the porous mesh (132) and hoop (174) to allow for radial expansion of the hoop (174). The obturator/dilator assembly (148, 152) may be withdrawn through the porous mesh (132), leaving the expanding or expanded configuration as the most distal structure, as shown in Figures 20G (expanding) and 20H (expanded). Referring to Figure 20I, at a desired time, the actuation wire may be tensioned to effectively "purse-string-shut" the distal end of the porous mesh (132) using the hoop (174), which becomes tensioned by virtue of its coupling with the actuation wire. The contents of the mesh structure, such as blood clots or plaque pieces, become effectively captured.

Referring to Figure 20J, in one embodiment the introducer shaft (16) body may comprise a co-extrusion defining a main working lumen (196) for passage of structures such as the obturator (148, 152) assembly or various guidewires or other elongate instruments, as well as an actuation wire lumen (192) for passing an actuation wire en route to the porous mesh assembly, wherein as described above, it may be contained by a conduit until it meets or at least partially forms the hoop

(174). The embodiment of Figure 20J has a substantially circular outer cross sectional shape for generally homogeneous loading to the associated tissues under rotation. The embodiment of Figure 20K has an elliptical outer cross-sectional shape. The embodiment of Figure 20L features a cresent shape which may be collapsed to occupy a smaller cross section under loading (194) when the space within the working lumen (196) is not needed during a particular interventional phase.

Referring to Figure 21, a particular interventional embodiment is depicted. After preoperative analysis (302) and establishment of vascular access (304), in the depicted embodiment two 6-French introducers may be placed bilaterally (i.e., one in each of the right and left common femoral arteries) (380). A 6-French pigtail type catheter, such as those available from Medtronic, Inc., may be inserted through one of the 6-French introducers and tracked into the ascending aorta just distal of the aortic valve of the heart (382). The other 6-French introducer may be removed and the associated tissue track and puncture site dilated up to a larger diameter, such as about 14-French (384). A compressed protective sheath may be advanced over a 0.035" guidewire and into the abdominal aorta (386). The radially-constraining peel-away sleeve may be removed (388), and the distal portion of the protective assembly may be advanced (i.e., over the 0.035" guidewire) over the aortic arch and down into the mid-ascending aorta (390). The distal tip (i.e., the obturator assembly) may be intentionally advanced by approximately 1cm relative to the compressed porous assembly to remove the distal constraint from the distal portion of the porous assembly, which may become at least partially opened with such decrease in constraint (392). The obturator assembly may be withdrawn through the porous assembly (394).

With the porous assembly now the most distal structure of the protective assembly, the actuation wire, as operated by the proximal actuation interface manipulable by the surgeon or operator, may be utilized to allow for full hoop expansion of the distal portion of the porous mesh assembly; the pigtail catheter will still extend distal of the hoop in this embodiment, and may be pressed or constrained against one aortic wall portion by the hoop expansion (396). The porous mesh preferably is configured to provide a protective barrier, akin to that of a thin sheath, between the surrounding vascular tissue (i.e., such as that of the aorta) and devices or instruments (i.e., such as guidewires, balloon catheters, valve devices) which may be inserted therethrough. The 0.035" guidewire may be advanced through the aortic valve of the heart (398), and balloon catheter may be advanced through the protective assembly to pre-dilate or size the aortic valve for prosthesis placement (400). The balloon catheter may be retracted and removed (402), and the aortic valve prosthesis assembly may be inserted through the protective assembly (404). The aortic valve prosthesis may be deployed (406), after which the associated deployment hardware may be retracted and removed (408). At least the distal portion of the porous mesh assembly may be controllably collapsed by operating the actuation wire, to contain captured items such as clots or pieces of plaque (410). The at least partially collapsed protective assembly may be withdrawn into the descending aorta (412), which generally is somewhat straight geometrically, and a preferably atraumatic elongate structure, such as the obturator assembly (148, 152) may be inserted into at least a portion of the porous assembly (without insertion past the end of the porous assembly - to prevent release of any captured items) to provide some

structural enhancement during further withdrawal (414). The remaining assembly componentry may be withdrawn and vascular access closed (416).

Various exemplary embodiments of the invention are described herein. Reference is made to these examples in a non-limiting sense. They are provided to illustrate more broadly applicable aspects of the invention. Various changes may be made to the invention described and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process act(s) or step(s) to the objective(s), spirit or scope of the present invention. Further, as will be appreciated by those with skill in the art that each of the individual variations described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present inventions. All such modifications are intended to be within the scope of claims associated with this disclosure.

Any of the devices described for carrying out the subject diagnostic or interventional procedures may be provided in packaged combination for use in executing such interventions. These supply "kits" may further include instructions for use and be packaged in sterile trays or containers as commonly employed for such purposes.

The invention includes methods that may be performed using the subject devices. The methods may comprise the act of providing such a suitable device. Such provision may be performed by the end user. In other words, the "providing" act merely requires the end user obtain, access, approach, position,

set-up, activate, power-up or otherwise act to provide the requisite device in the subject method. Methods recited herein may be carried out in any order of the recited events which is logically possible, as well as in the recited order of events.

Exemplary aspects of the invention, together with details regarding material selection and manufacture have been set forth above. As for other details of the present invention, these may be appreciated in connection with the above-referenced patents and publications as well as generally known or appreciated by those with skill in the art. For example, one with skill in the art will appreciate that one or more lubricious coatings (e.g., hydrophilic polymers such as polyvinylpyrrolidone-based compositions, fluoropolymers such as tetrafluoroethylene, hydrophilic gel or silicones) may be used in connection with various portions of the devices, such as relatively large interfacial surfaces of movably coupled parts, if desired, for example, to facilitate low friction manipulation or advancement of such objects relative to other portions of the instrumentation or nearby tissue structures. The same may hold true with respect to method-based aspects of the invention in terms of additional acts as commonly or logically employed.

In addition, though the invention has been described in reference to several examples optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention. Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. In addition, where a range of values is provided, it is understood that every intervening value, between the upper

and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the invention.

Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in claims associated hereto, the singular forms "a," "an," "said," and "the" include plural referents unless the specifically stated otherwise. In other words, use of the articles allow for "at least one" of the subject item in the description above as well as claims associated with this disclosure. It is further noted that such claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation.

Without the use of such exclusive terminology, the term "comprising" in claims associated with this disclosure shall allow for the inclusion of any additional element--irrespective of whether a given number of elements are enumerated in such claims, or the addition of a feature could be regarded as transforming the nature of an element set forth in such claims. Except as specifically defined herein, all technical and scientific terms used herein are to be given as broad a commonly understood meaning as possible while maintaining claim validity.

The breadth of the present invention is not to be limited to the examples provided and/or the subject specification, but

rather only by the scope of claim language associated with this disclosure.

CLAIMS

1. A system for deploying a device to a distal location across a diseased vessel, comprising:

a sheath comprising an expandable distal portion comprising a porous wall defining a lumen therethrough, the distal portion having a collapsed configuration, wherein the sheath has a first cross sectional outer diameter and a first lumen inner diameter, and an expanded configuration, wherein the sheath has a second cross sectional outer diameter and a second lumen inner diameter; and

an expandable tubular filter removably coupled to an elongate deployment member, the tubular filter configured to be deployed before installation of the sheath to provide filtering protection at one or more tributary vessel junctions, wherein the deployment member is removable after deployment of the expandable tubular filter, and wherein the sheath is inserted through the tubular filter after expansion thereof, and wherein the elongate deployment member is configured to recapture the tubular filter for removal thereof;

wherein in the collapsed configuration, the sheath is configured to be advanced across at least a portion of the diseased vessel to a position adjacent the distal location without size interference between the first cross sectional outer diameter of the sheath and an inner diameter profile of a lumen of the diseased vessel; and

wherein upon positioning the collapsed configuration to the desired position relative to the distal location, the sheath is expandable to the expanded configuration to facilitate passage of

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one or more relatively large diameter structures through the lumen that are larger in diameter than the first cross sectional outer diameter, the expanded configuration diverting at least a portion of the flow of blood through the diseased vessel across the porous wall of the sheath; and wherein upon completion of passage of the one or more relatively large diameter structures, the sheath is collapsible back to the collapsed configuration.

2. The system of claim 1, wherein the first lumen inner diameter is equal to between about 0 mm and about 3 mm.

3. The system of claim 1, wherein the second lumen inner diameter is equal to between about 20 mm and about 50 mm.

4. The system of claim 1, further comprising one or more radioopaque markers coupled to the sheath and configured to assist an operator observing fluoroscopically with positioning of the sheath relative to the diseased vessel.

5. The system of claim 1, wherein the porous wall comprises one or more holes created across a sheetlike member.

6. The system of claim 5, wherein the holes have a diameter of about 100 microns.

7. The system of claim 1, wherein the porous wall is

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configured to filter blood flowing through the porous wall to prevent passage of emboli through the porous wall.

8. The system of claim 1, wherein the sheath comprises one or more radioopaque markers located adjacent the porous wall and being configured to allow an operator to visualize relative positioning of the porous wall relative to one or more anatomical features using fluoroscopy.

9. The system of claim 1, further comprising a guidewire inserted through at least a portion of the lumen and configured to assist with guidance of the sheath through the diseased vessel.

10. The system of claim 1, wherein the tubular filter is positioned within the diseased vessel in a configuration selected to prevent the passage of emboli to a tributary vessel of the diseased vessel.

11. The system of claim 1, wherein the tubular filter is positioned within the diseased vessel at a location proximal to an access point wherein the sheath is inserted into the diseased vessel, the filtering device configured to prevent the passage of emboli to positions proximal of the location of the sheath.

12. The system of claim 1, further comprising a balloon dilation probe configured to complete the reconfiguration of the expandable sheath from the collapsed configuration to the expanded

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configuration.

13. The system of claim 1, wherein the expandable sheath is self-expanding from the collapsed configuration to the expanded configuration.

14. The system of claim 13, further comprising a removable expansion retention member configured to retain the expandable sheath in the collapsed configuration.

15. The system of claim 13, wherein the expansion retention member comprises a corset and tensile member assembly wherein the tensile member is able to be tensioned proximally to release the corset and allow expansion to the expanded configuration.

16. The system of claim 13, further comprising a magnetic collapsing probe which is passable through the lumen of the expanded configuration to assist with affirmative collapsing of the sheath back to the collapsed configuration.

17. The system of claim 13, further comprising a magnetic collapsing probe which is able to be positioned through the lumen of the expanded configuration to assist with maintaining the collapsed configuration until a reconfiguration to the expanded configuration is desired, at which point the probe is able to be withdrawn.

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18. The system of claim 1, further comprising the device, the device comprising an implantable prosthesis selected to be passed through the expandable sheath to the distal location across the diseased vessel.

19. The system of claim 18, wherein the implantable prosthesis comprises a cardiac valve prosthesis.

20. The system of claim 1, wherein the expandable sheath is configured to be twisted longitudinally to form the collapsed configuration, and untwisted longitudinally to form the expanded configuration.

21. The system of claim 1, wherein the sheath comprises a proximal portion having a stiffer structural modulus than the distal portion.

22. The system of claim 1, further comprising a distal hoop that is controllably closeable by an operator through tensioning of a tensile member operatively coupled to the distal hoop.

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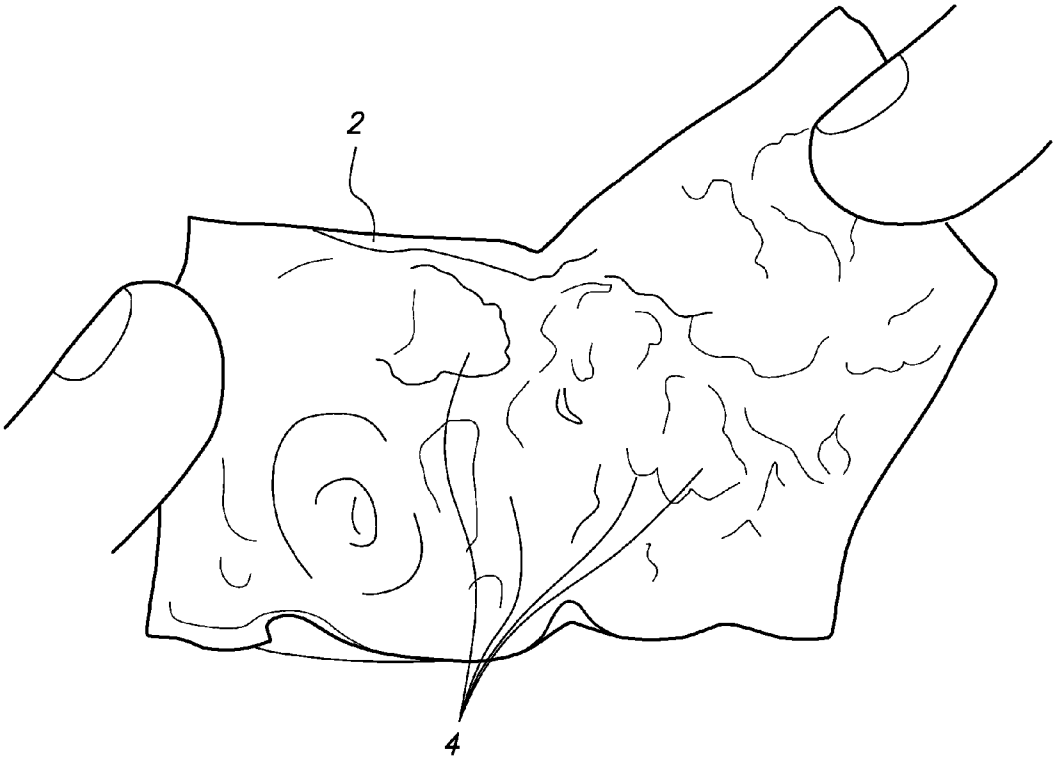


FIG. 1A

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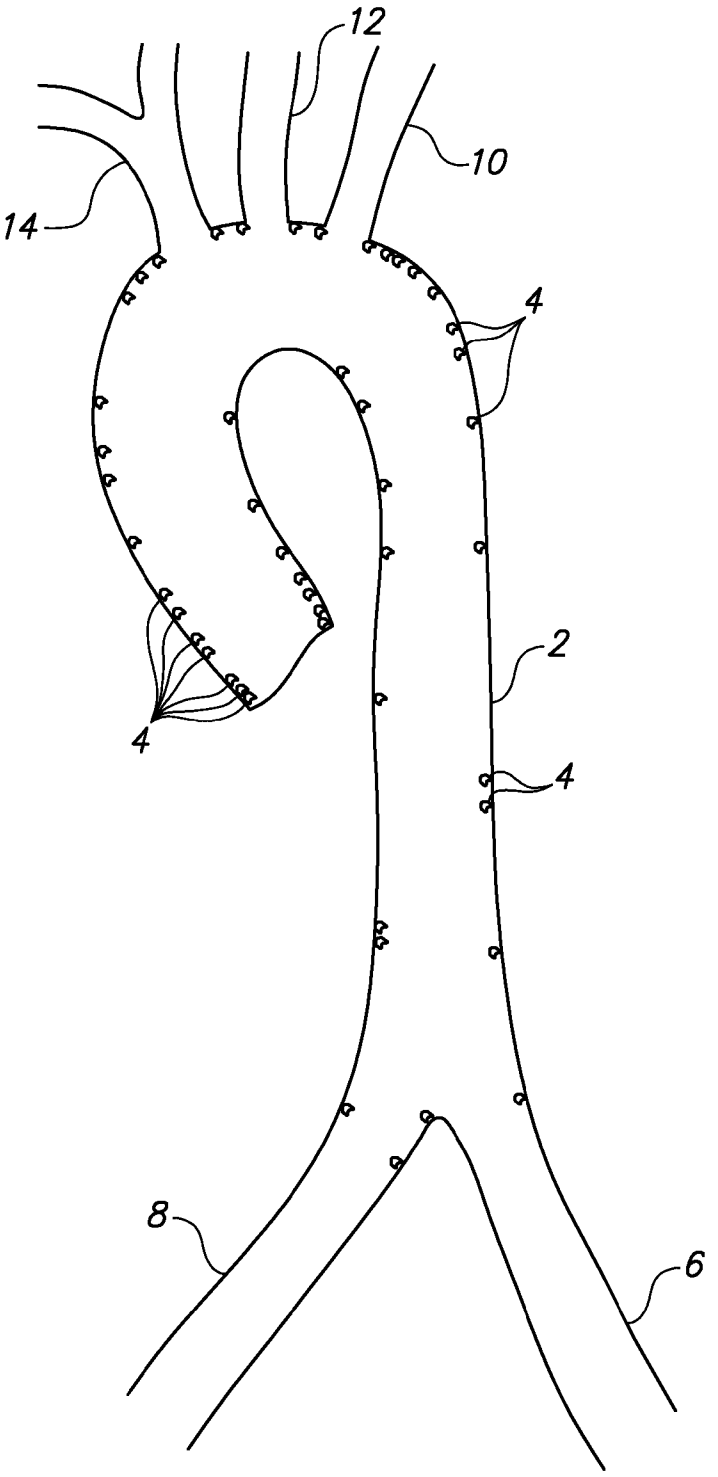


FIG. 1B

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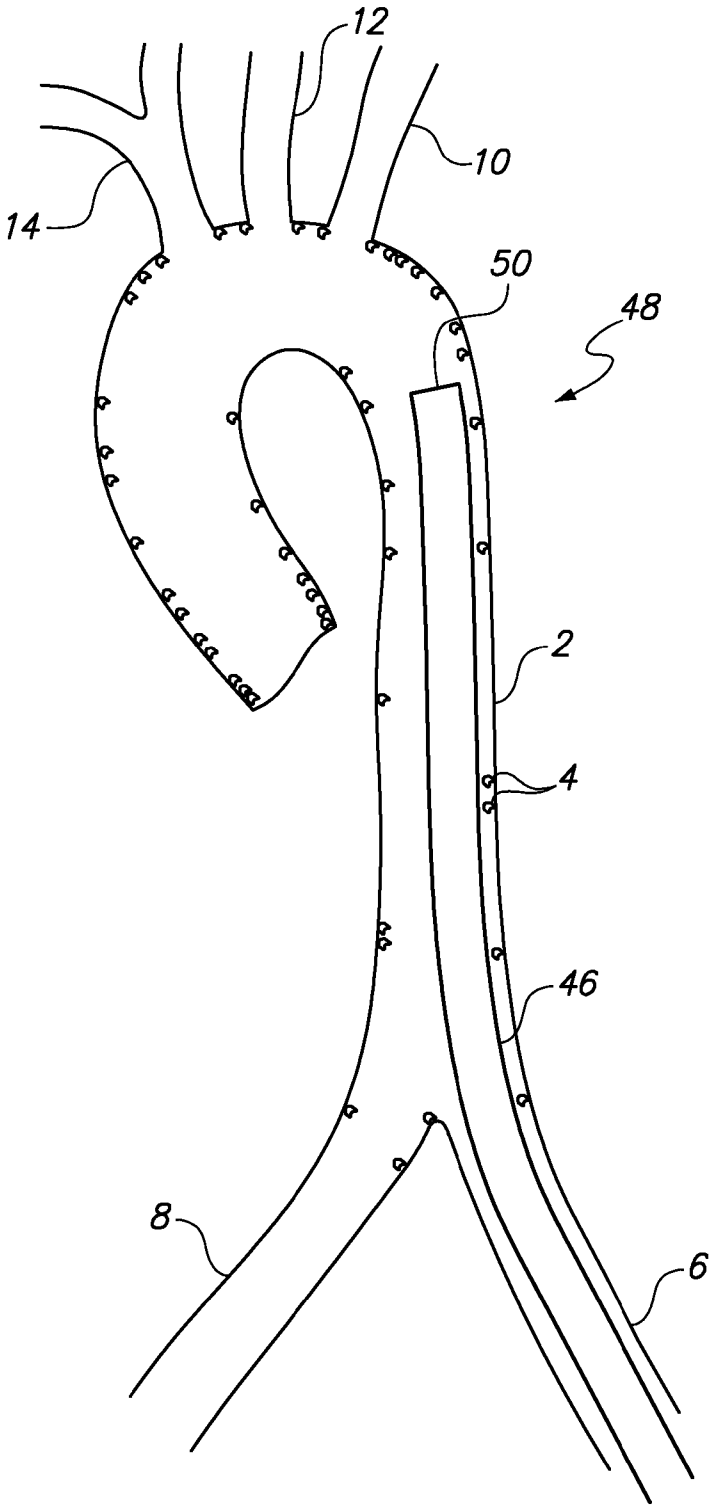


FIG. 2A

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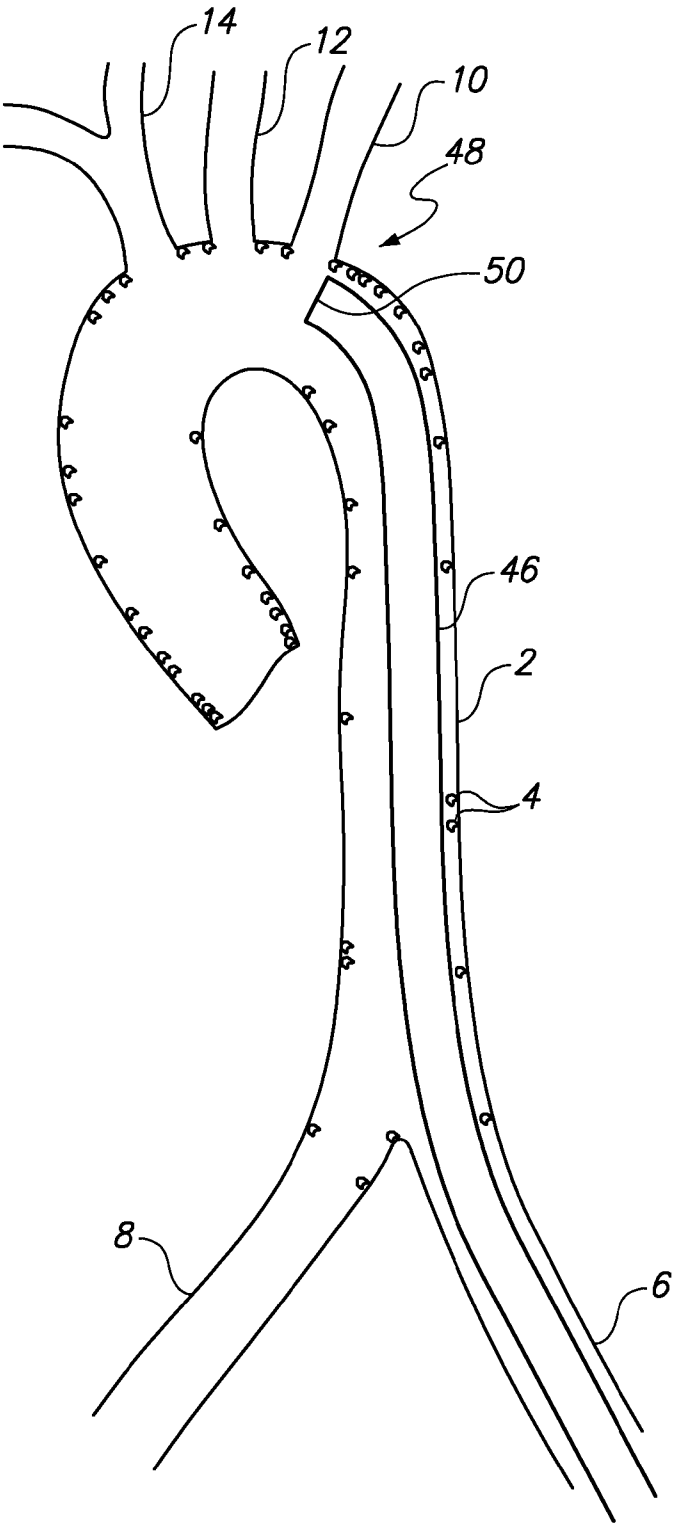


FIG. 2B

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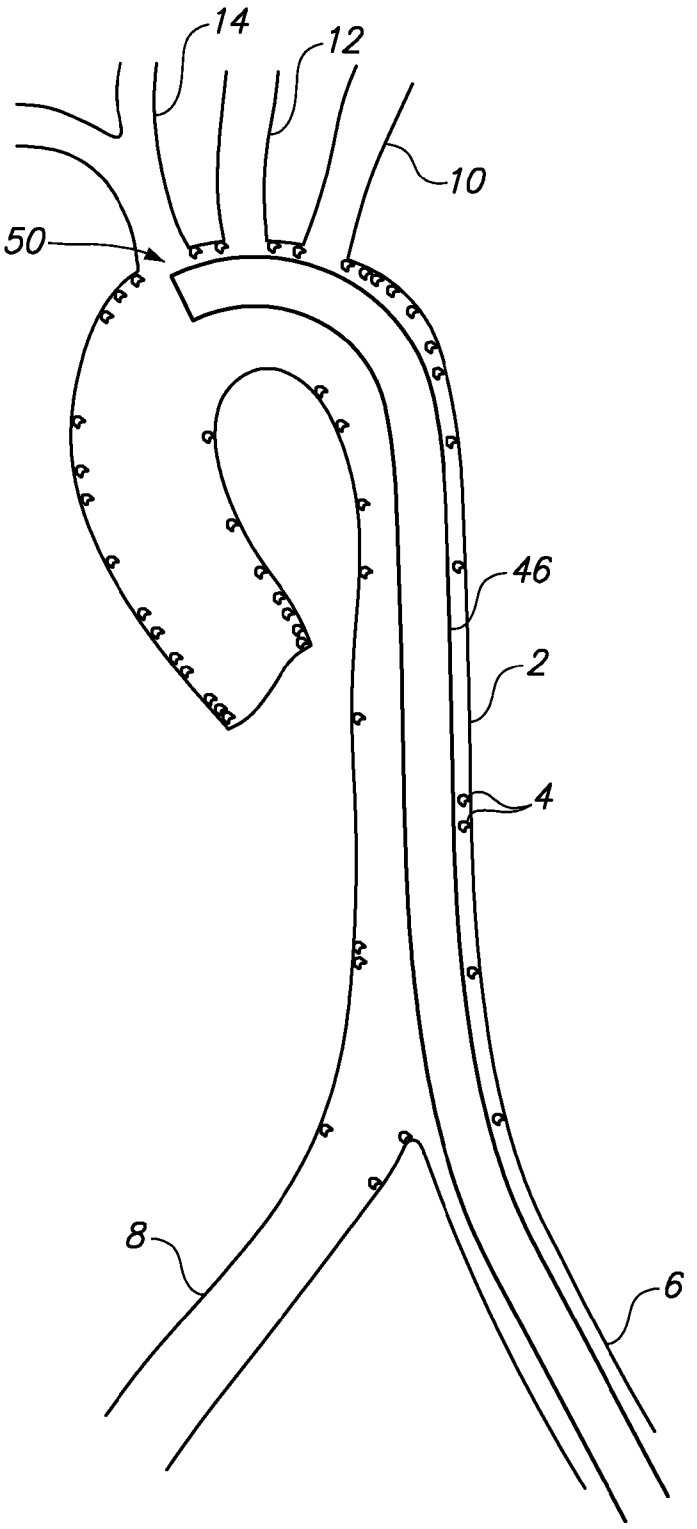


FIG. 2C

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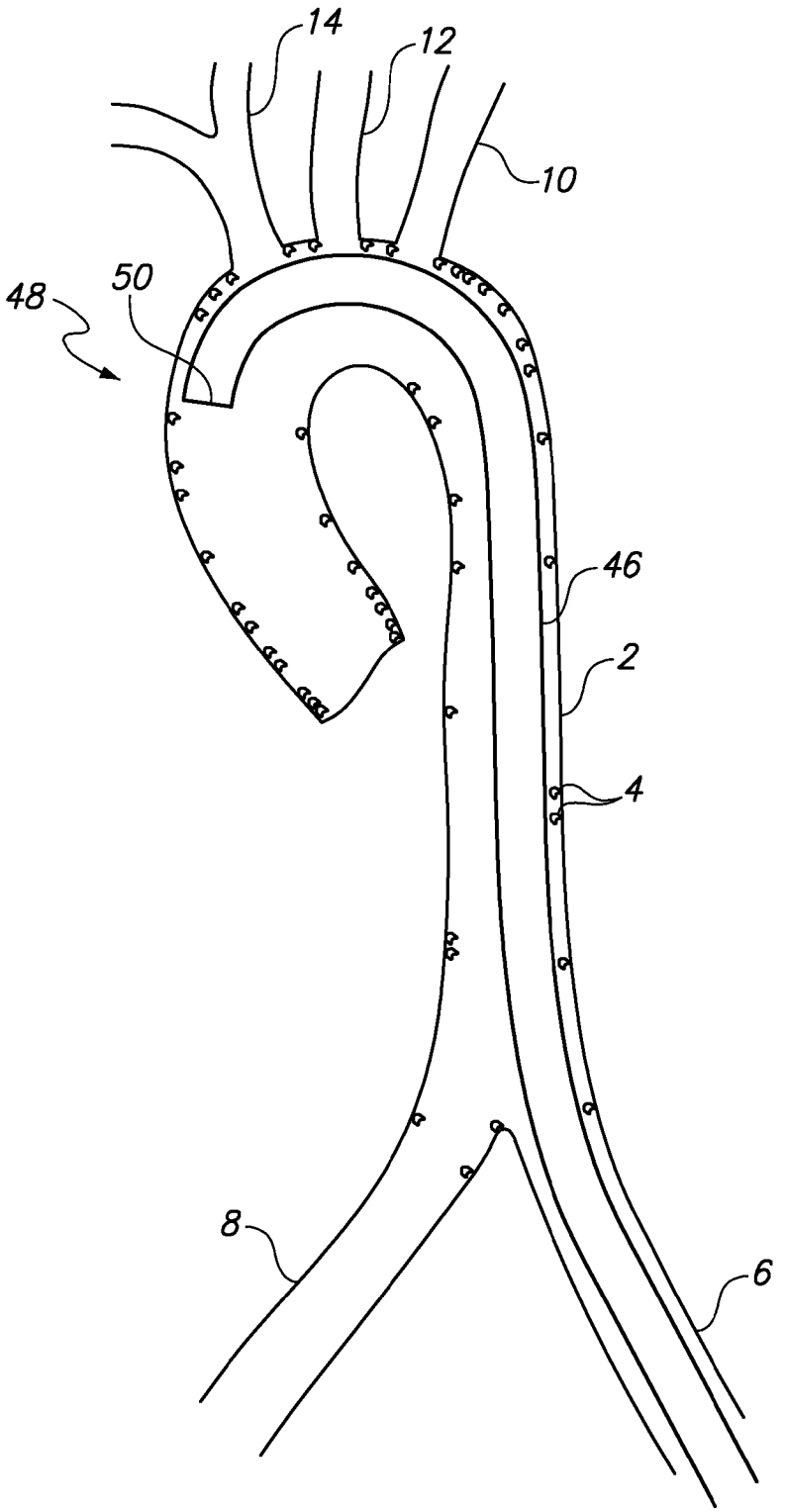


FIG. 2D

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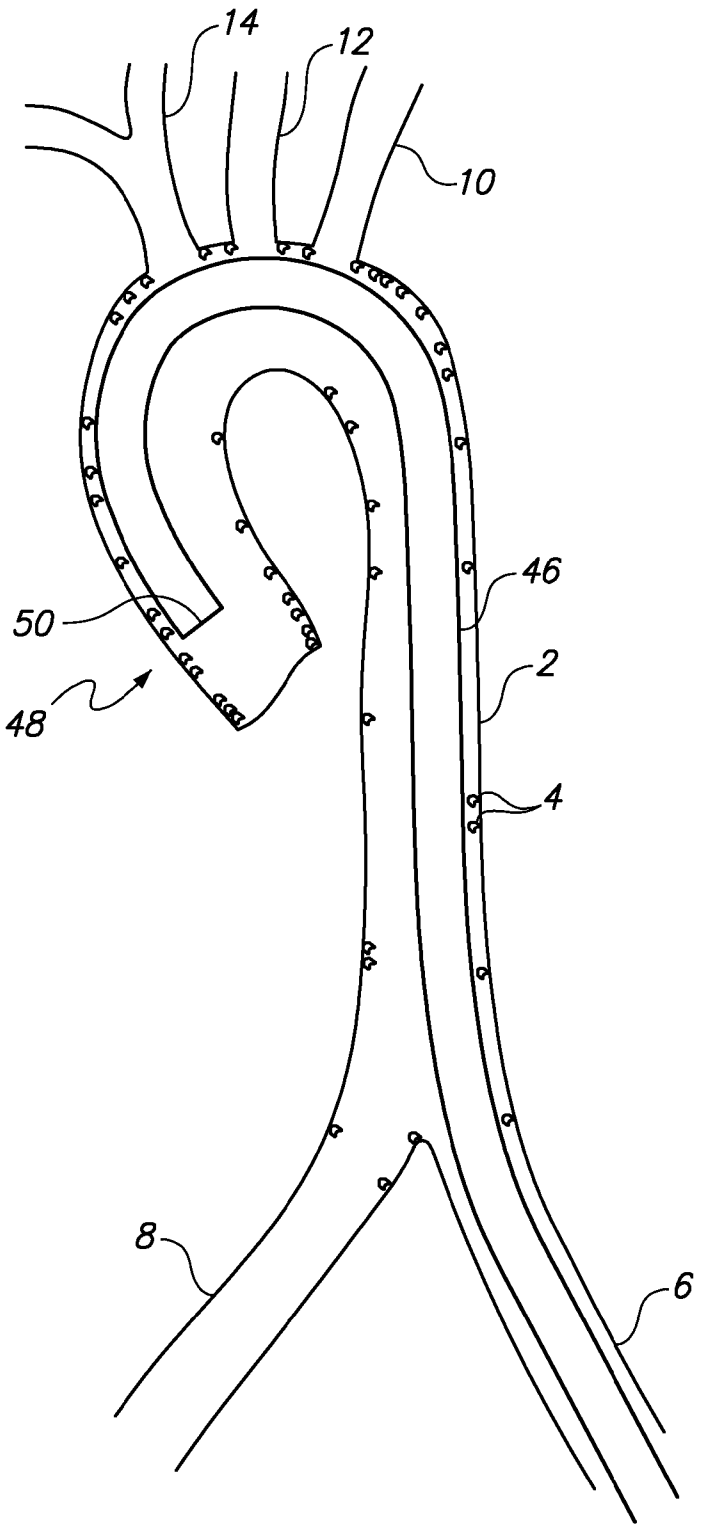


FIG. 2E

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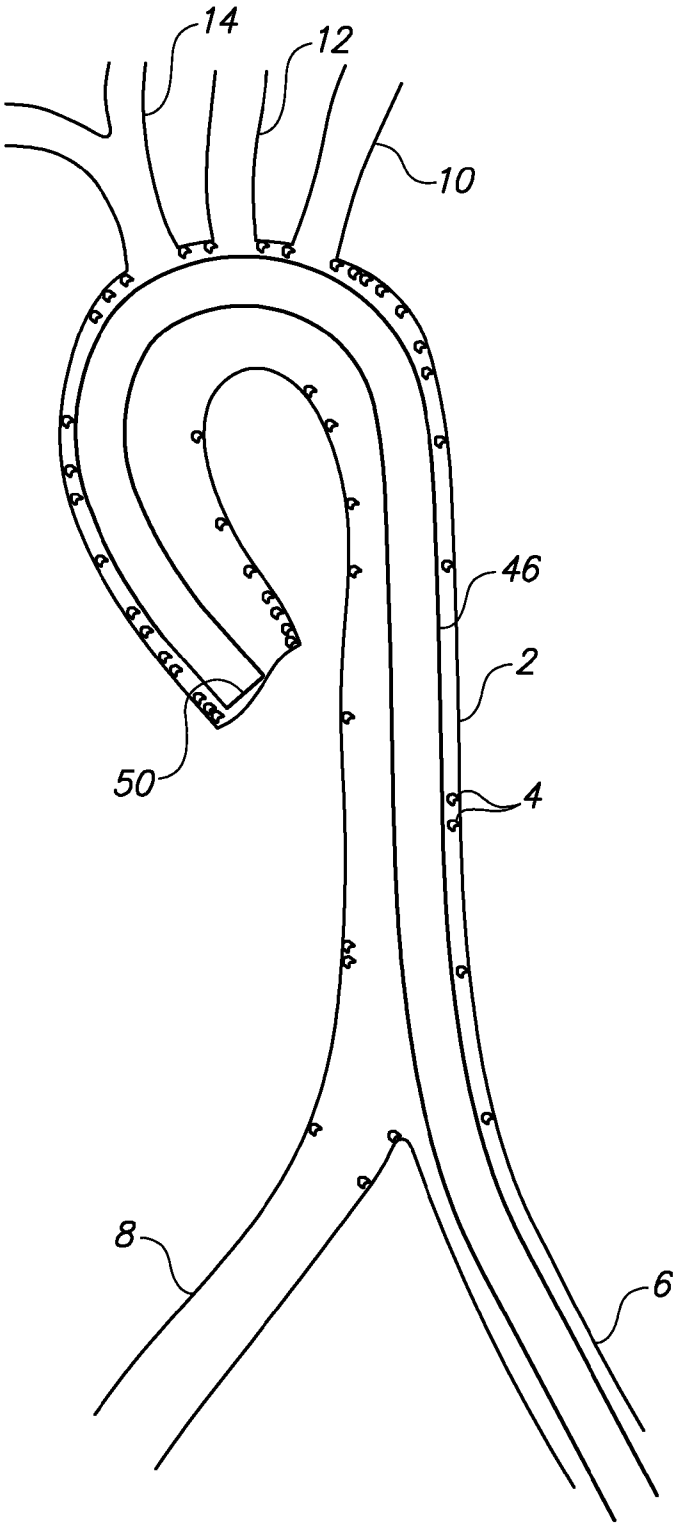


FIG. 2F

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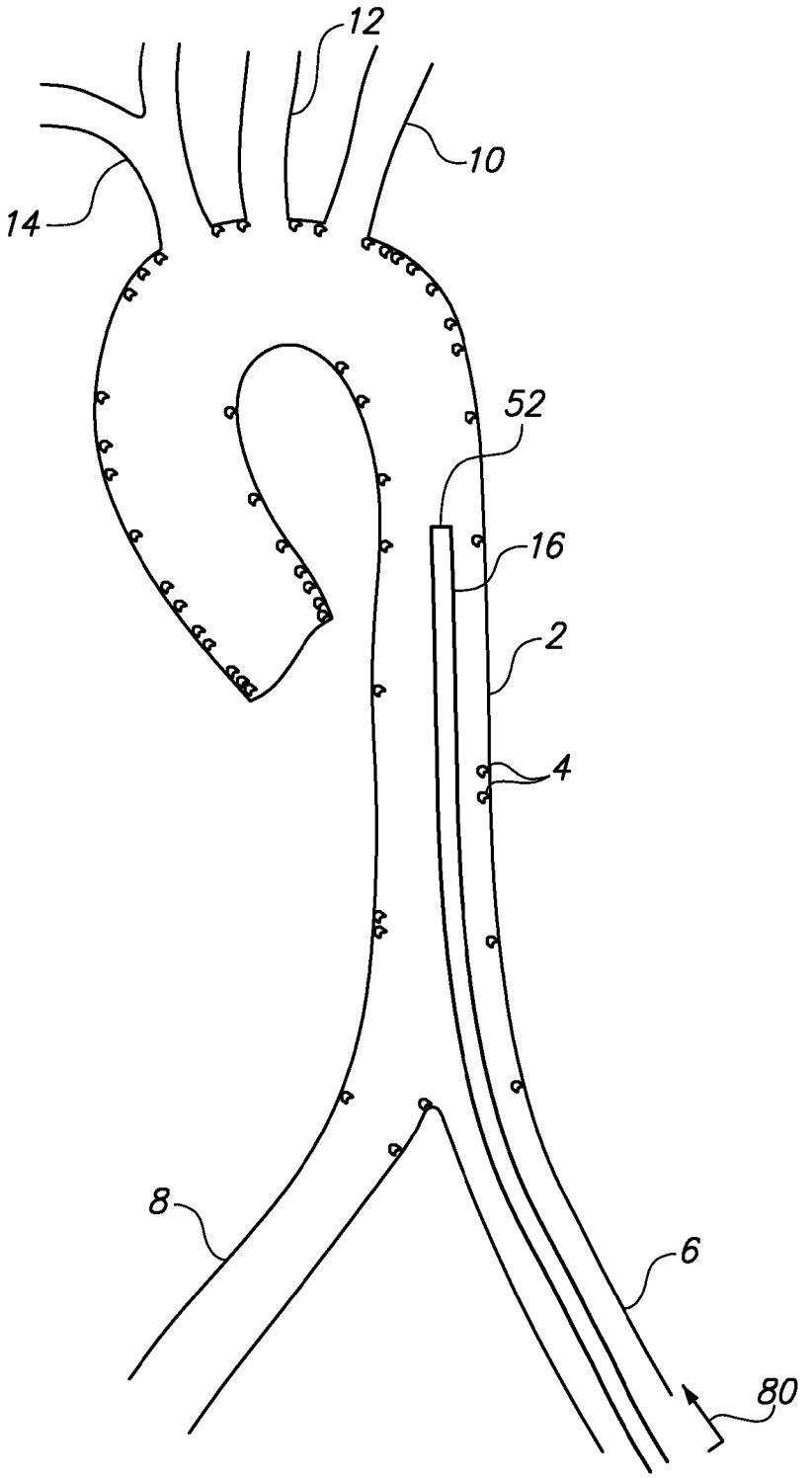


FIG. 3A

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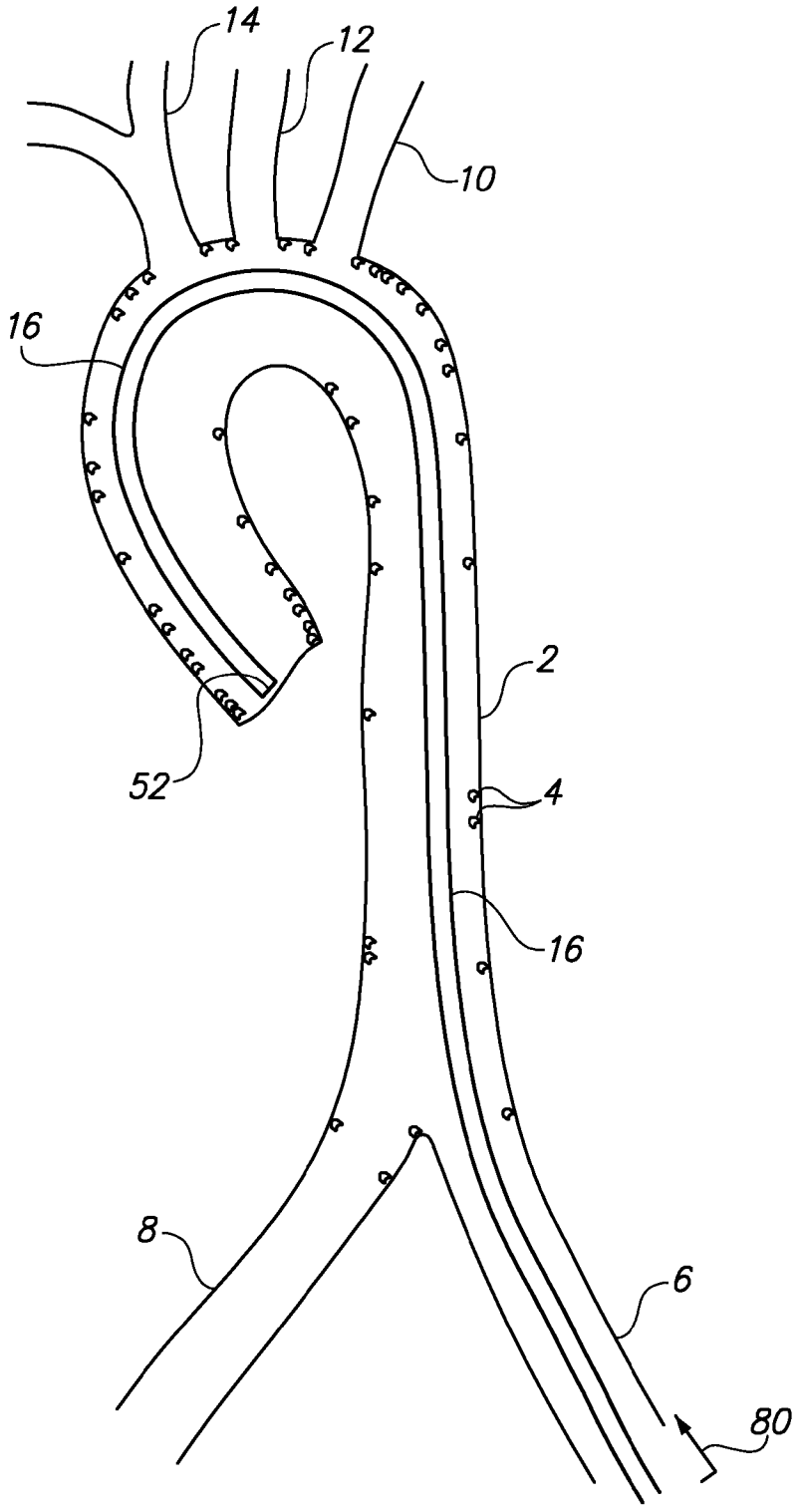


FIG. 3B

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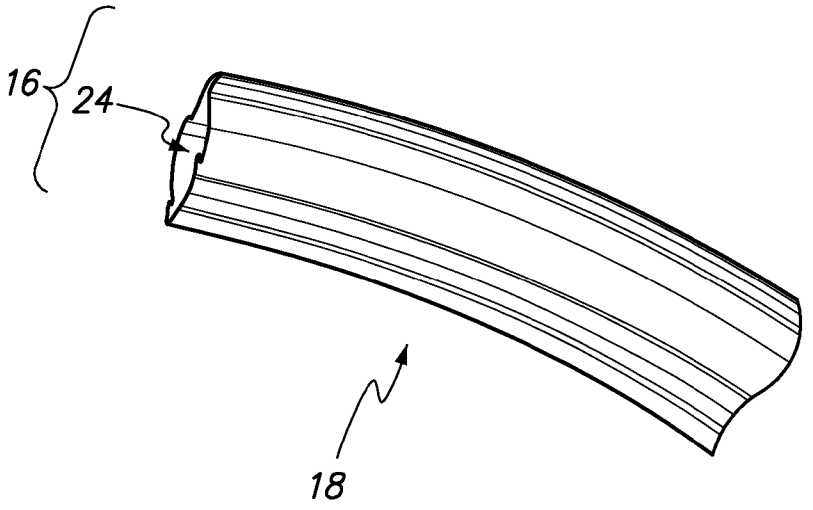


FIG. 3C

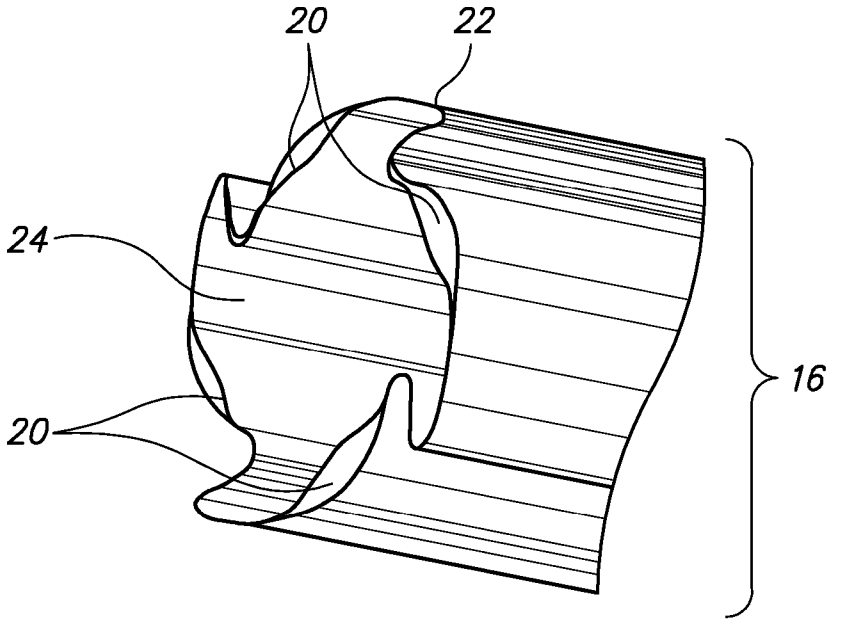


FIG. 3D

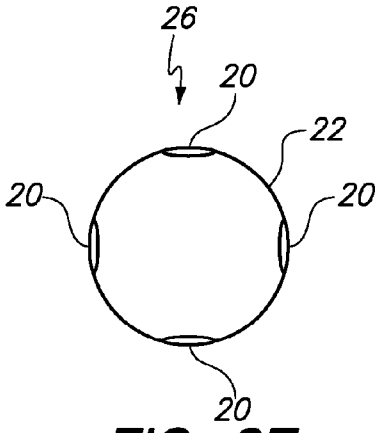


FIG. 3E

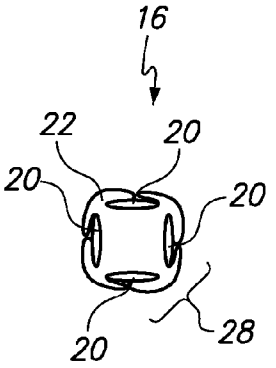


FIG. 3F

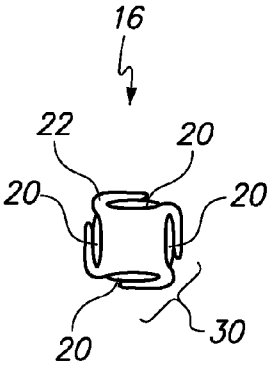


FIG. 3G

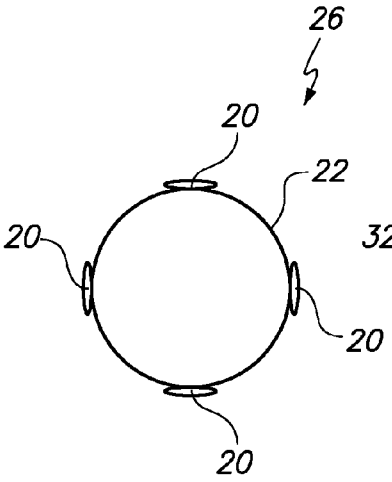


FIG. 3H

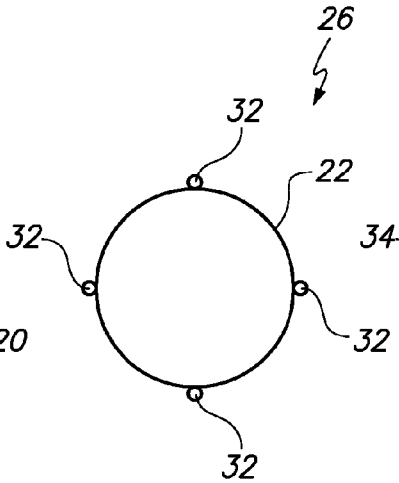


FIG. 3I

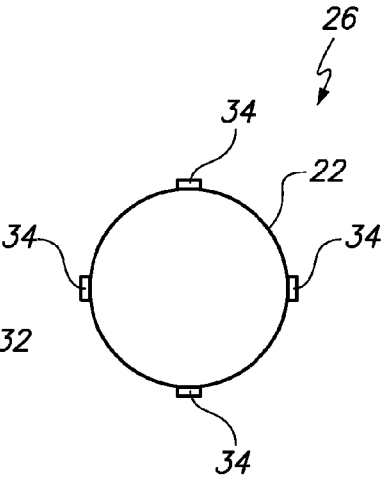


FIG. 3J

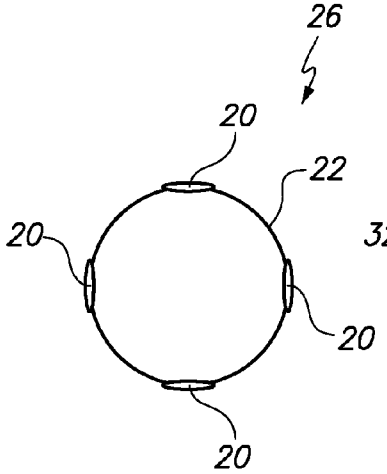


FIG. 3K

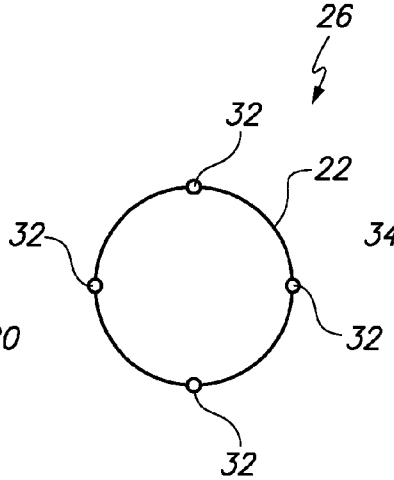


FIG. 3L

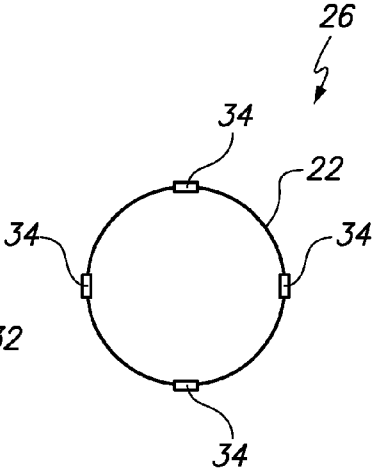


FIG. 3M

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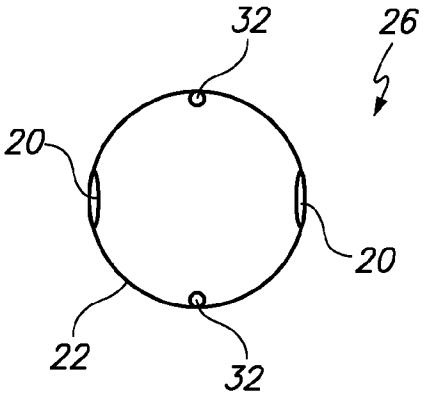


FIG. 3N

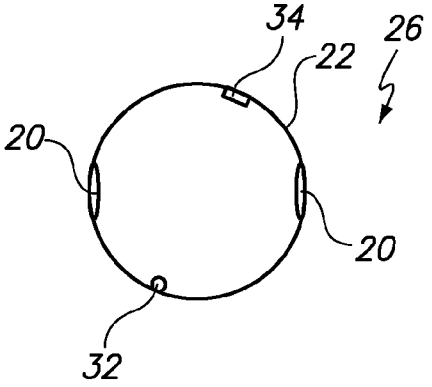


FIG. 3O

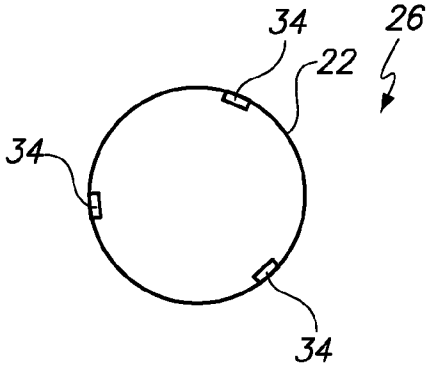


FIG. 3P

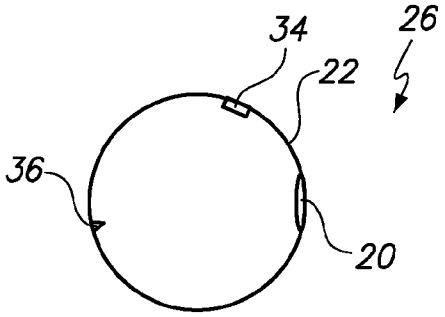


FIG. 3Q

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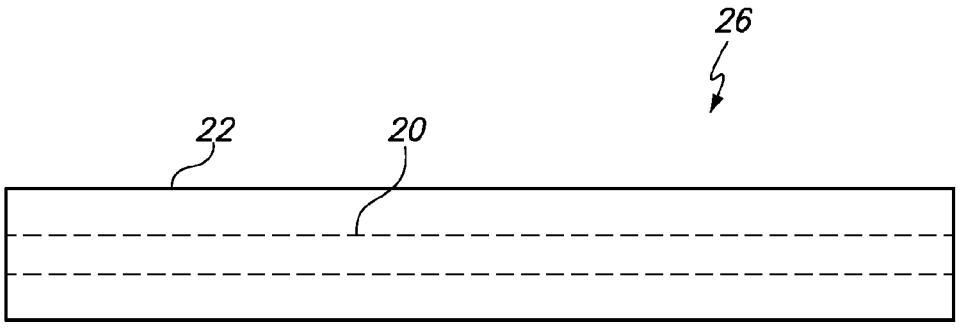


FIG. 3R

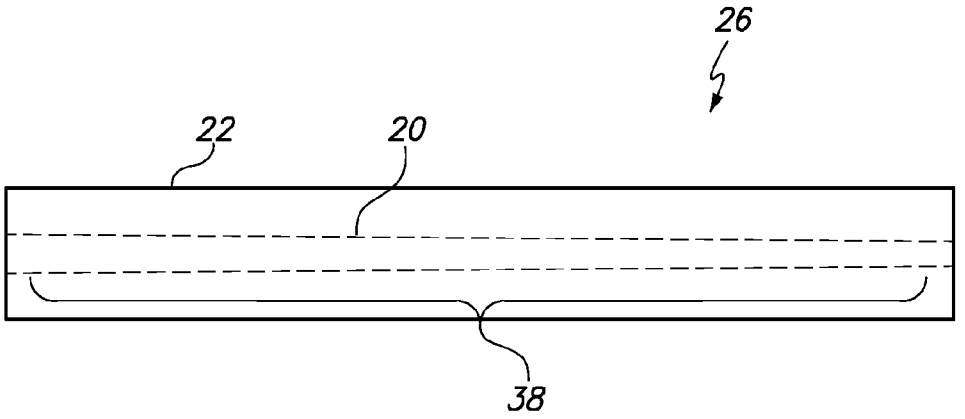


FIG. 3S

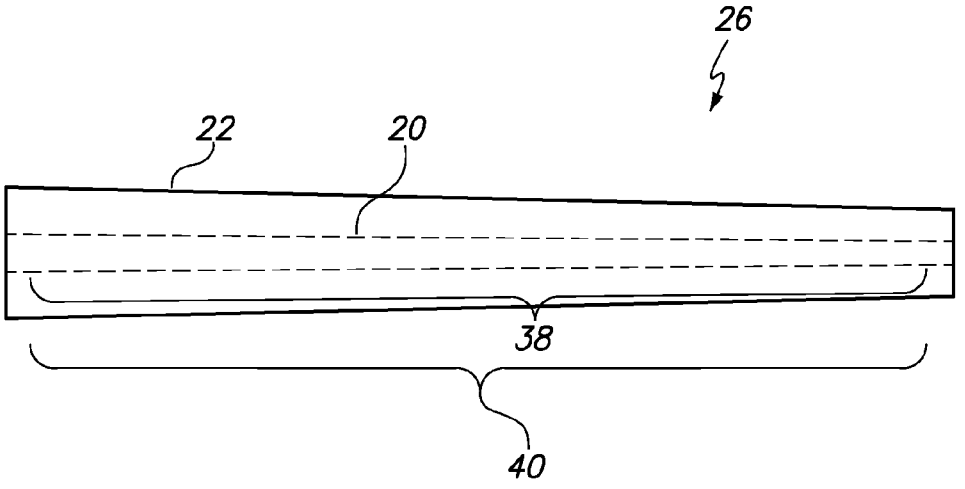


FIG. 3T

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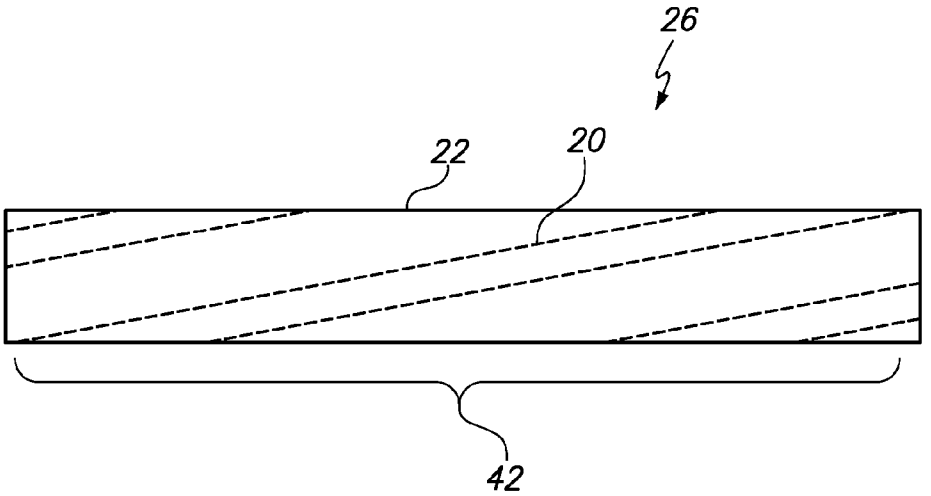


FIG. 3U

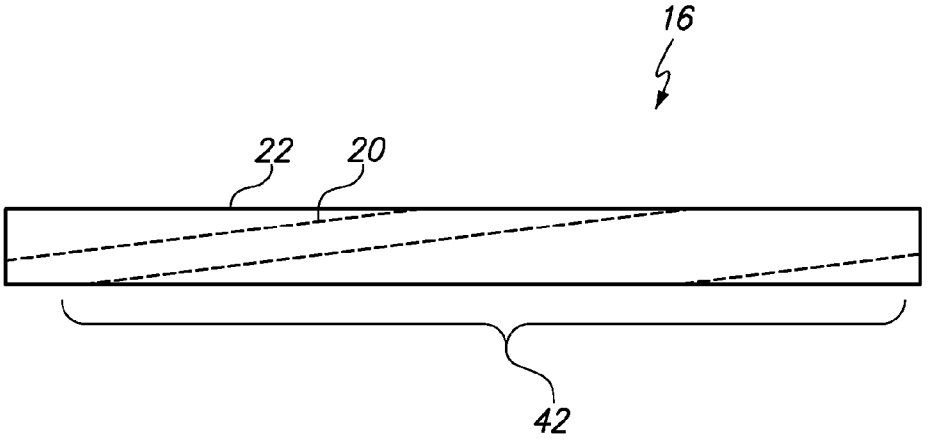


FIG. 3V

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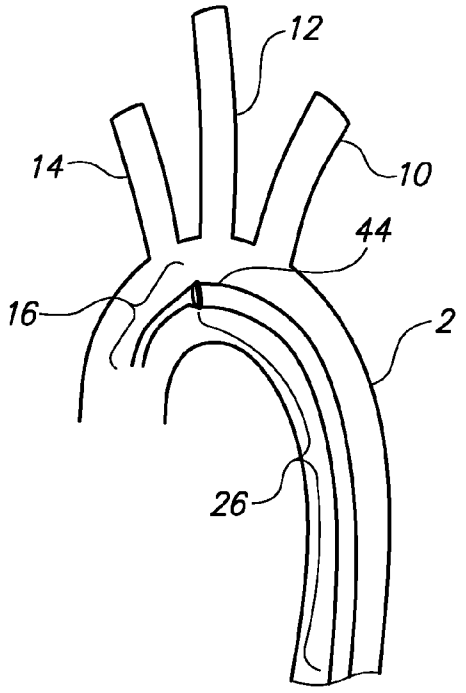


FIG. 3W

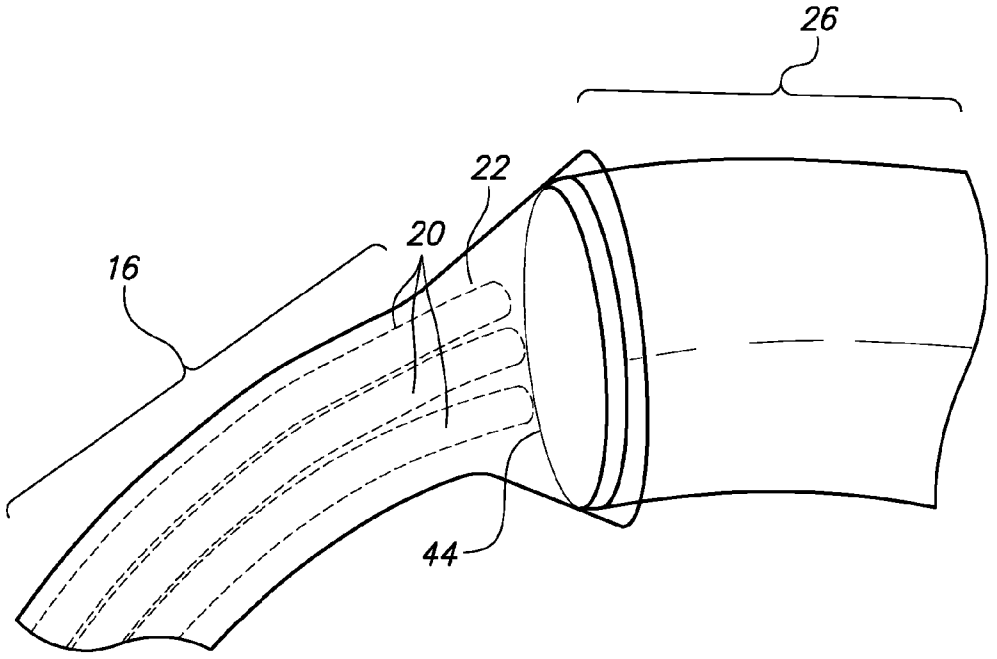


FIG. 3X

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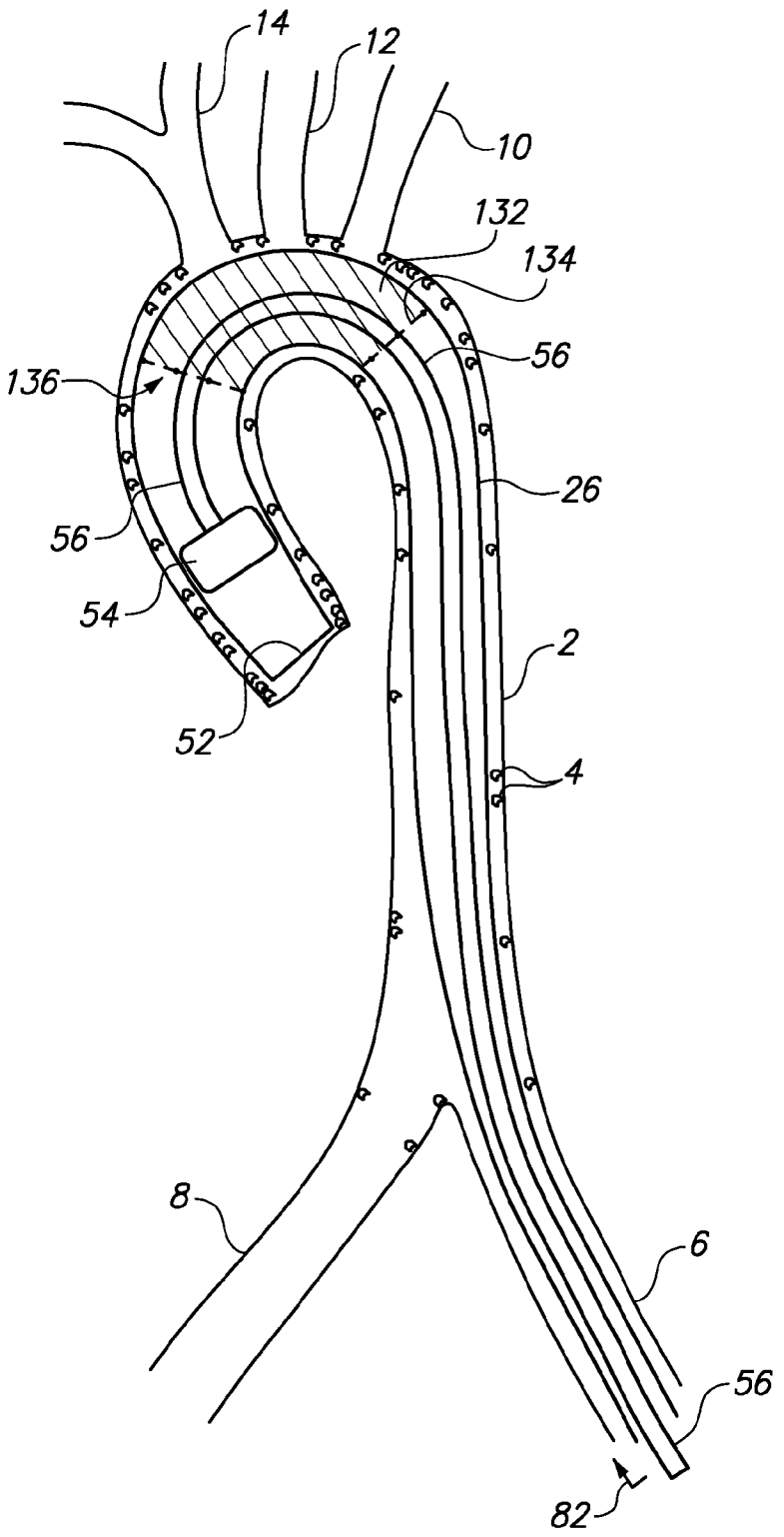


FIG. 3Y

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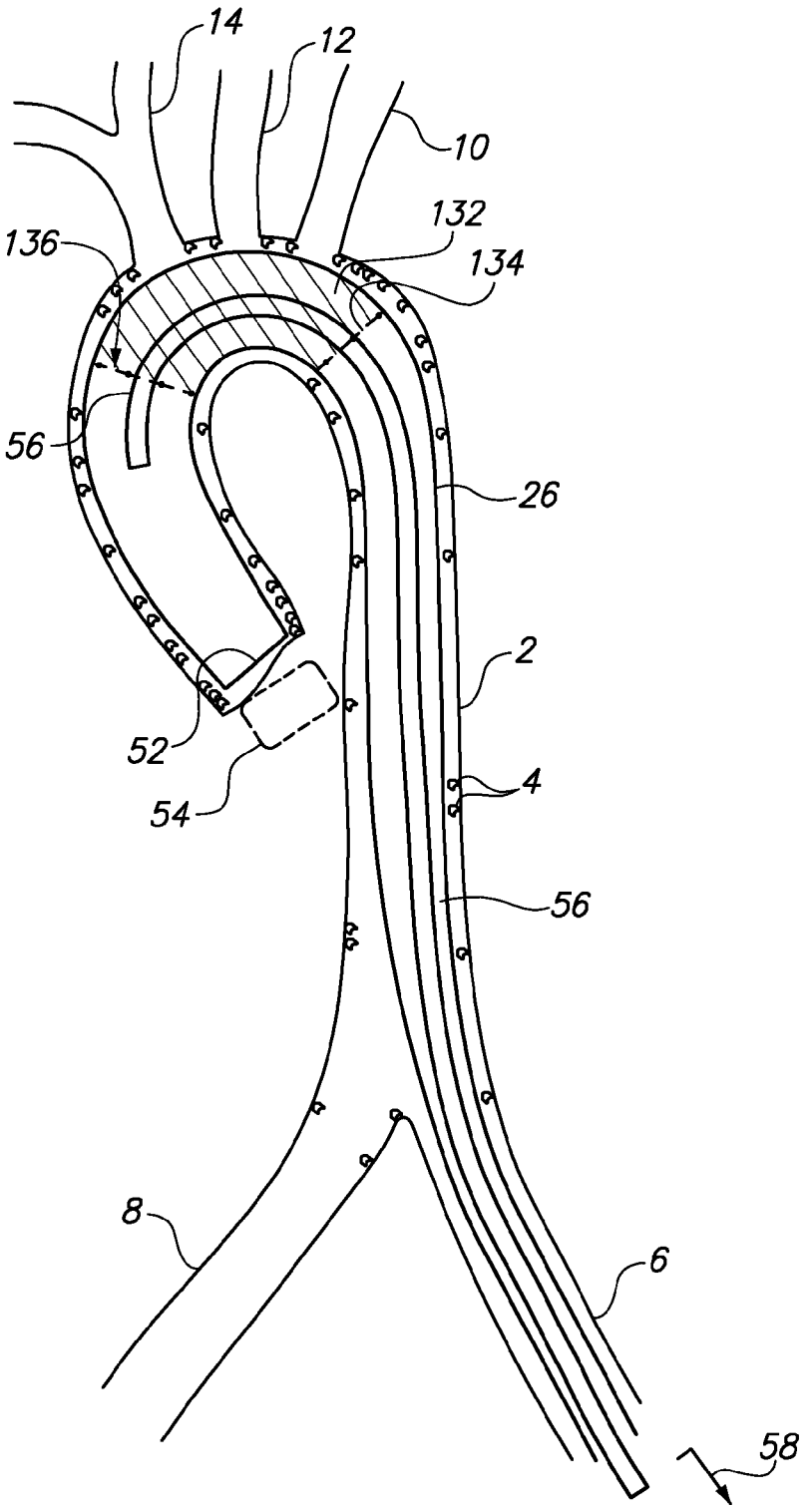


FIG. 3Z

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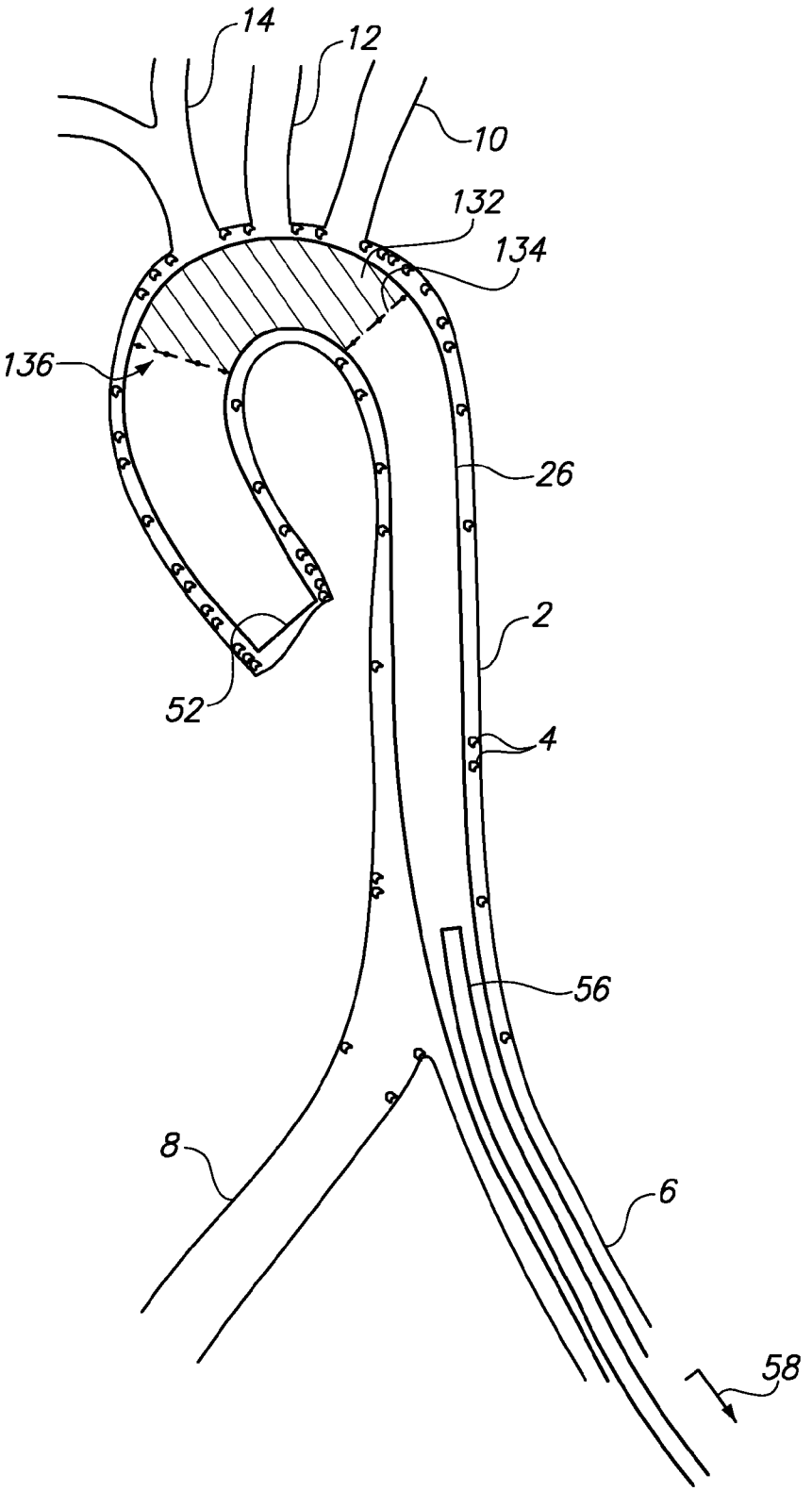


FIG. 3Z-1

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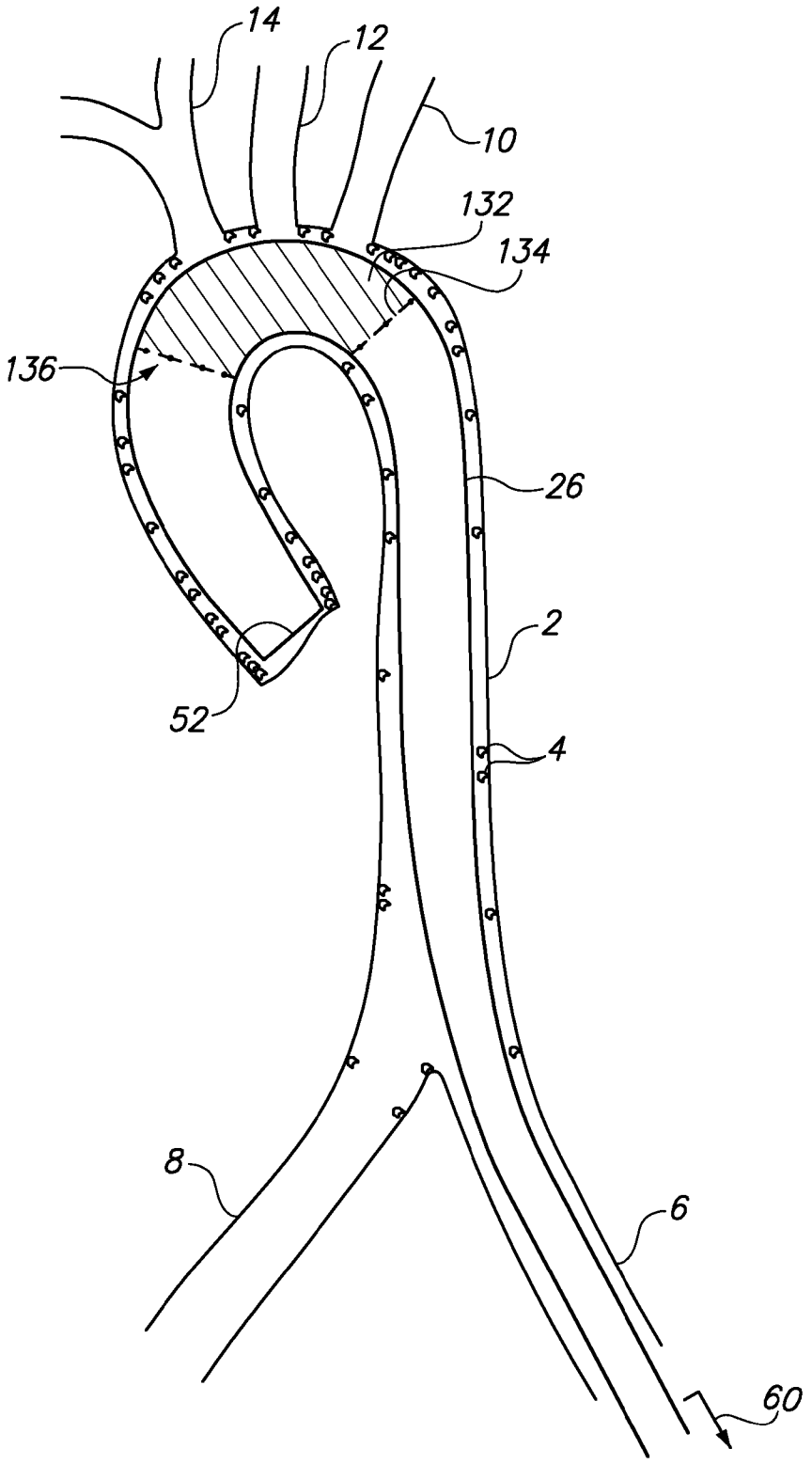


FIG. 3Z-2

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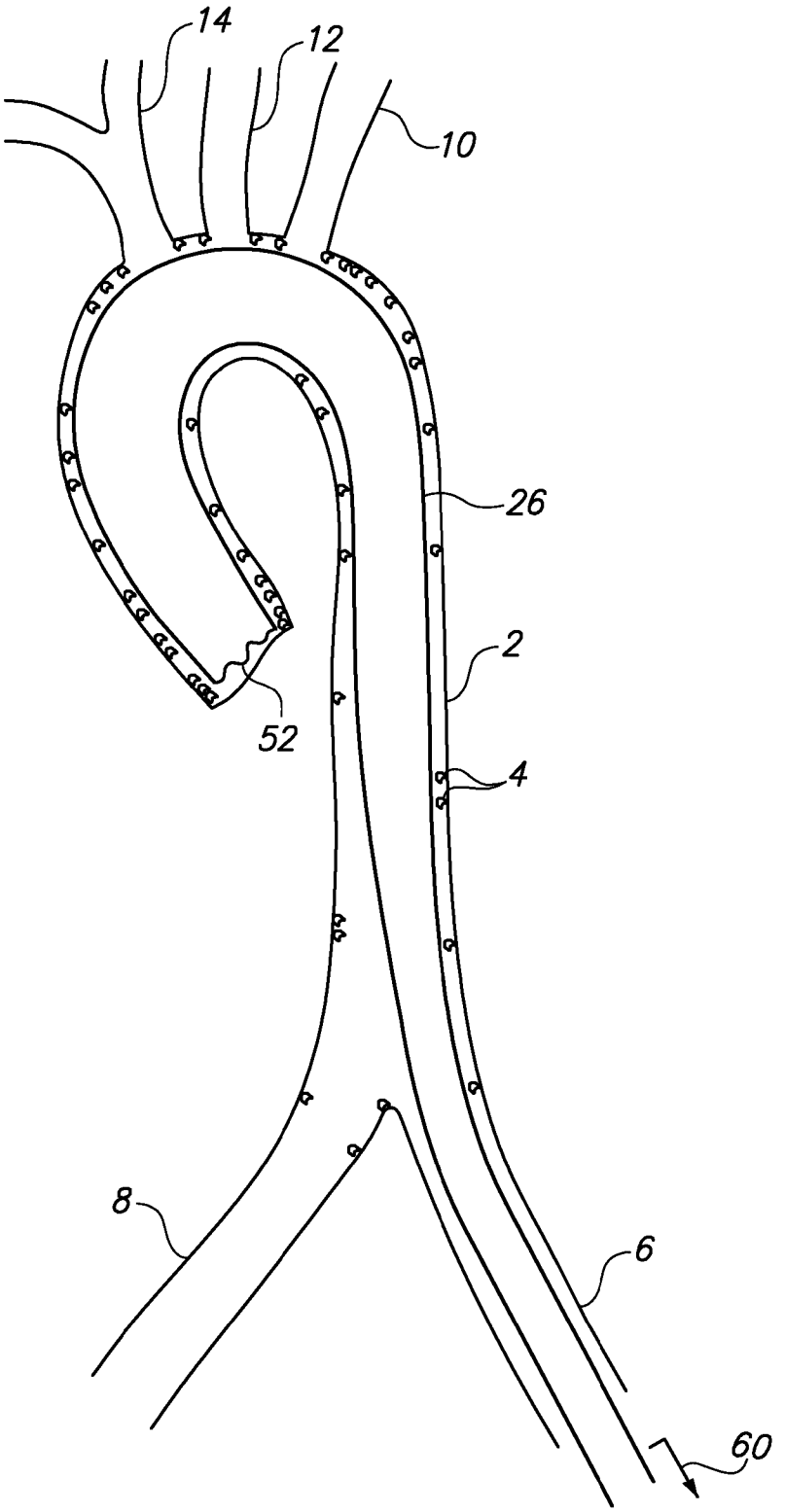


FIG. 3Z-3

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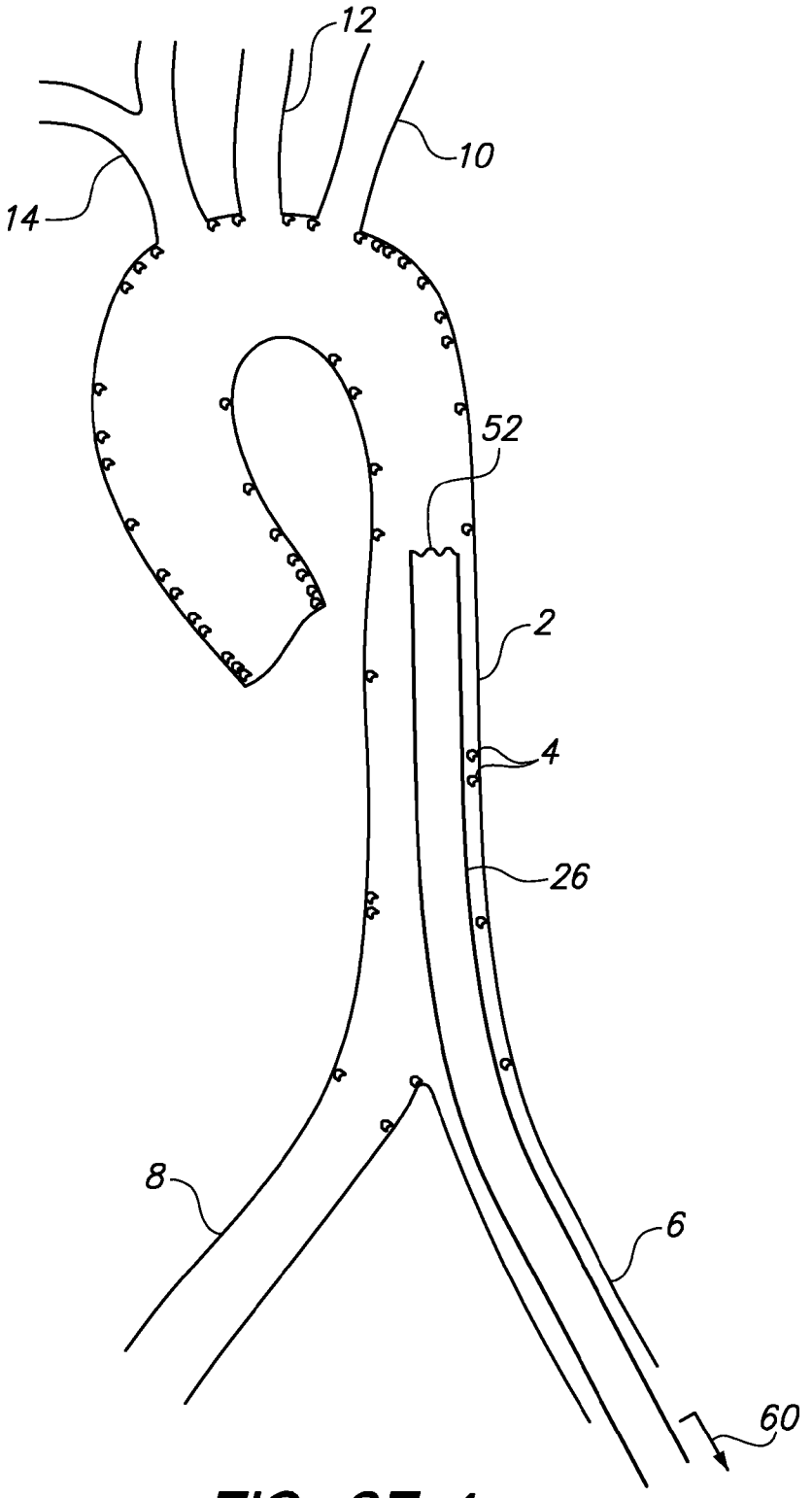


FIG. 3Z-4

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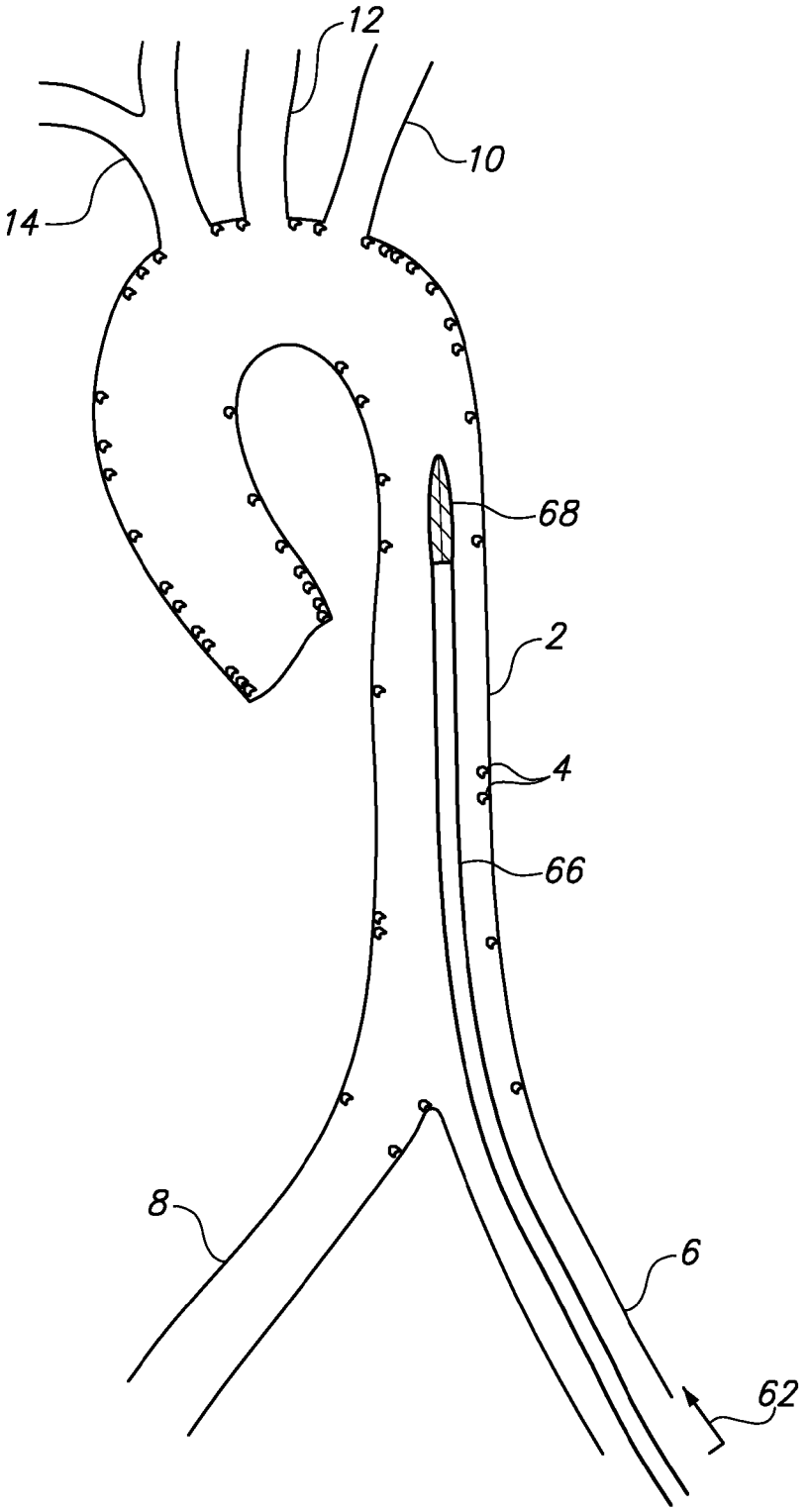


FIG. 4A

Date Reçue/Date Received 2020-09-03

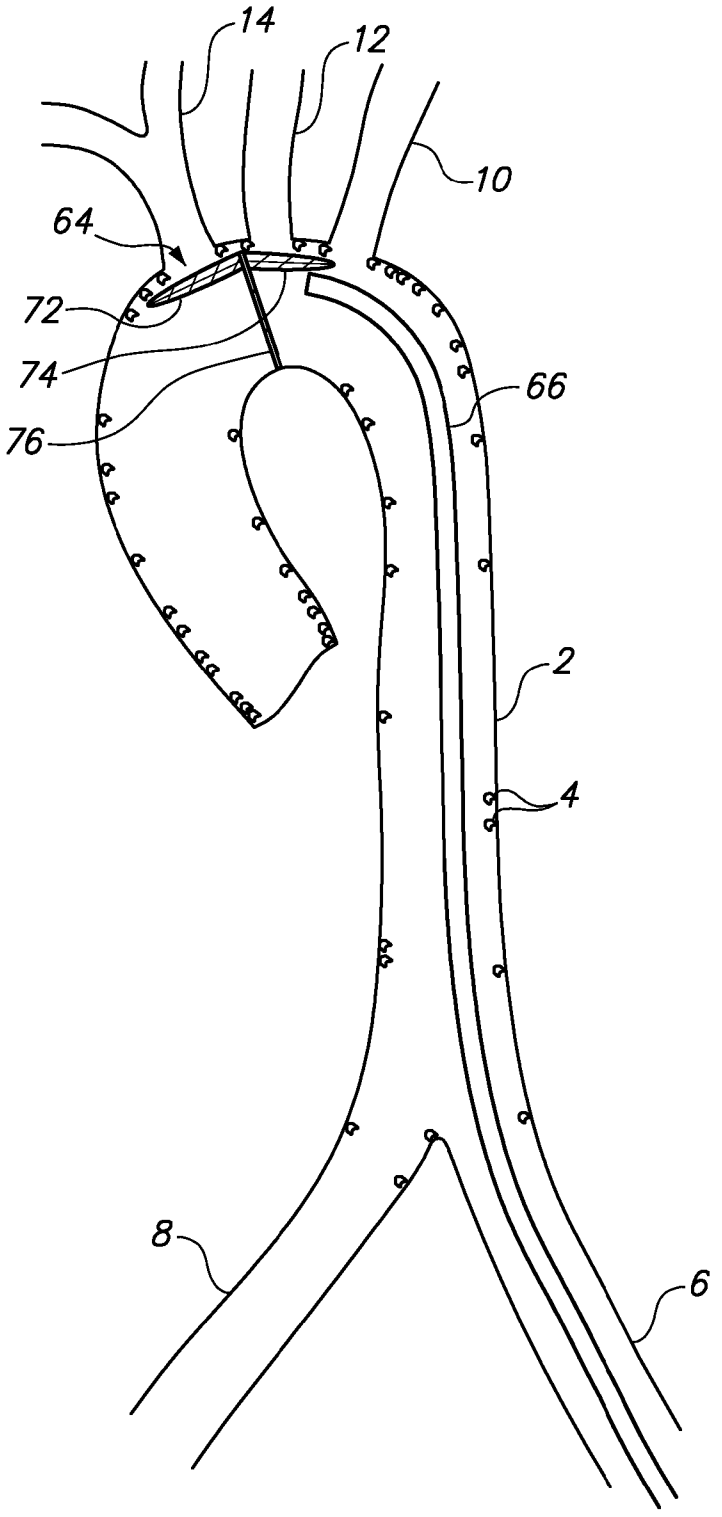


FIG. 4B

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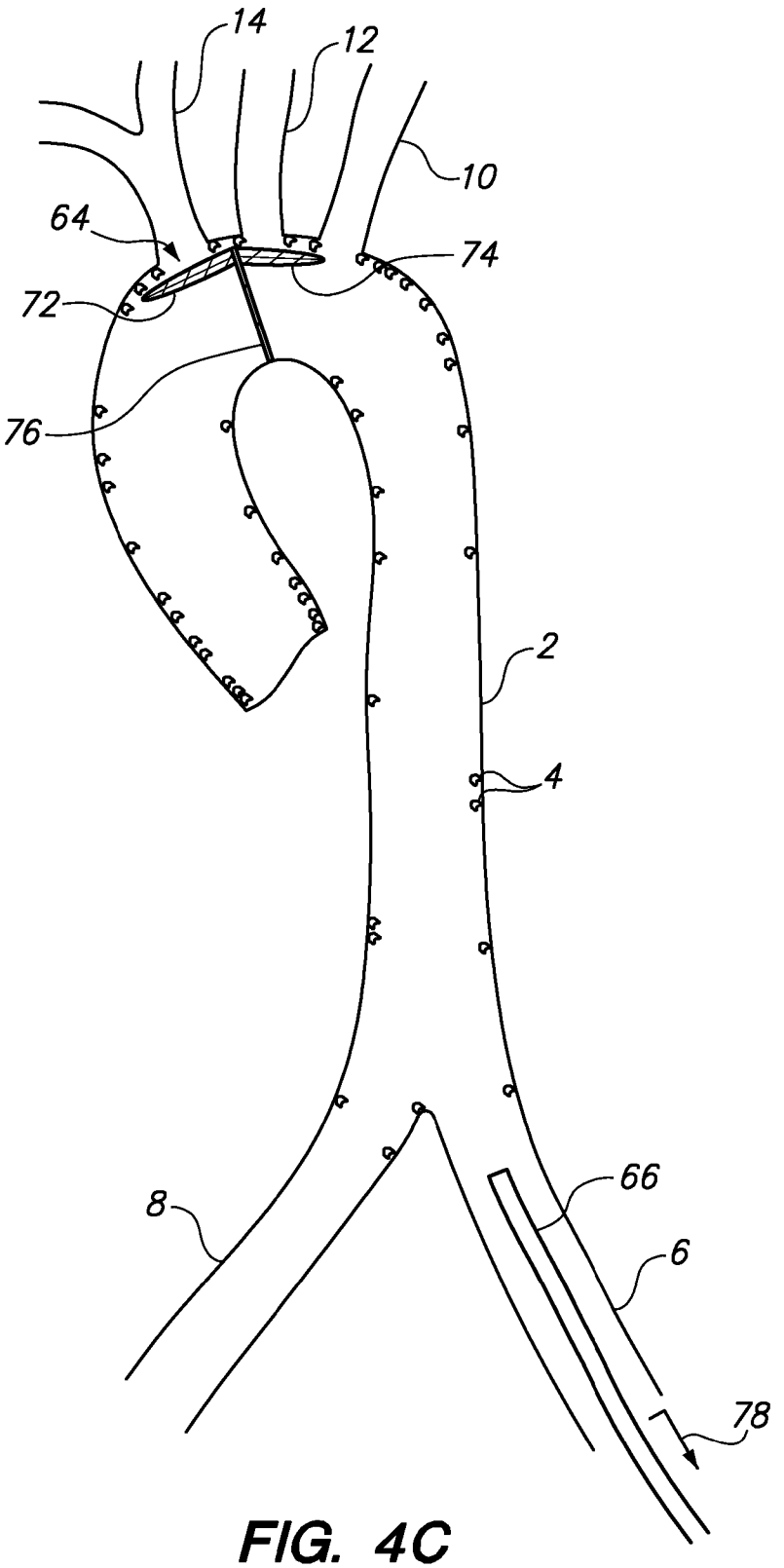


FIG. 4C

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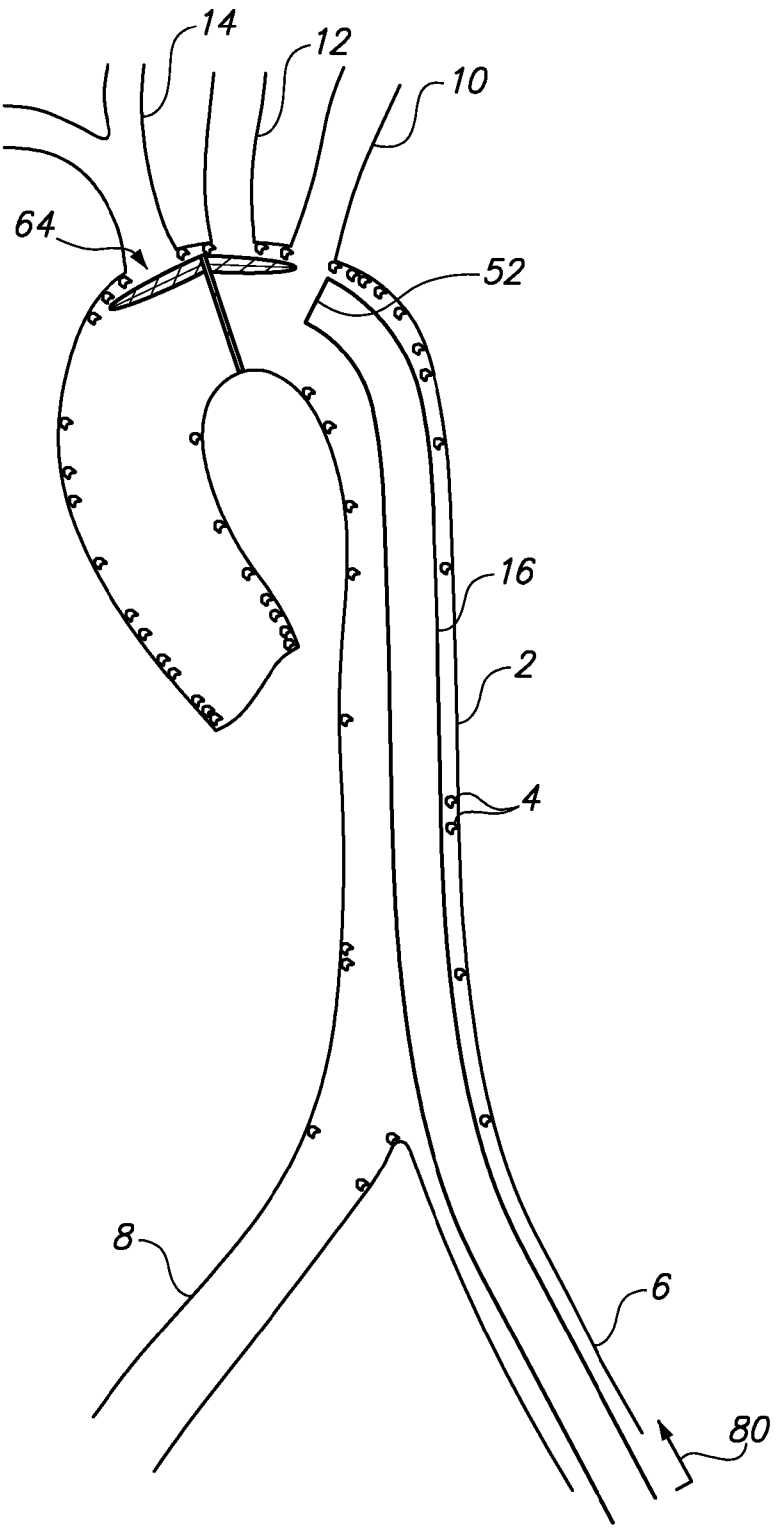


FIG. 4D

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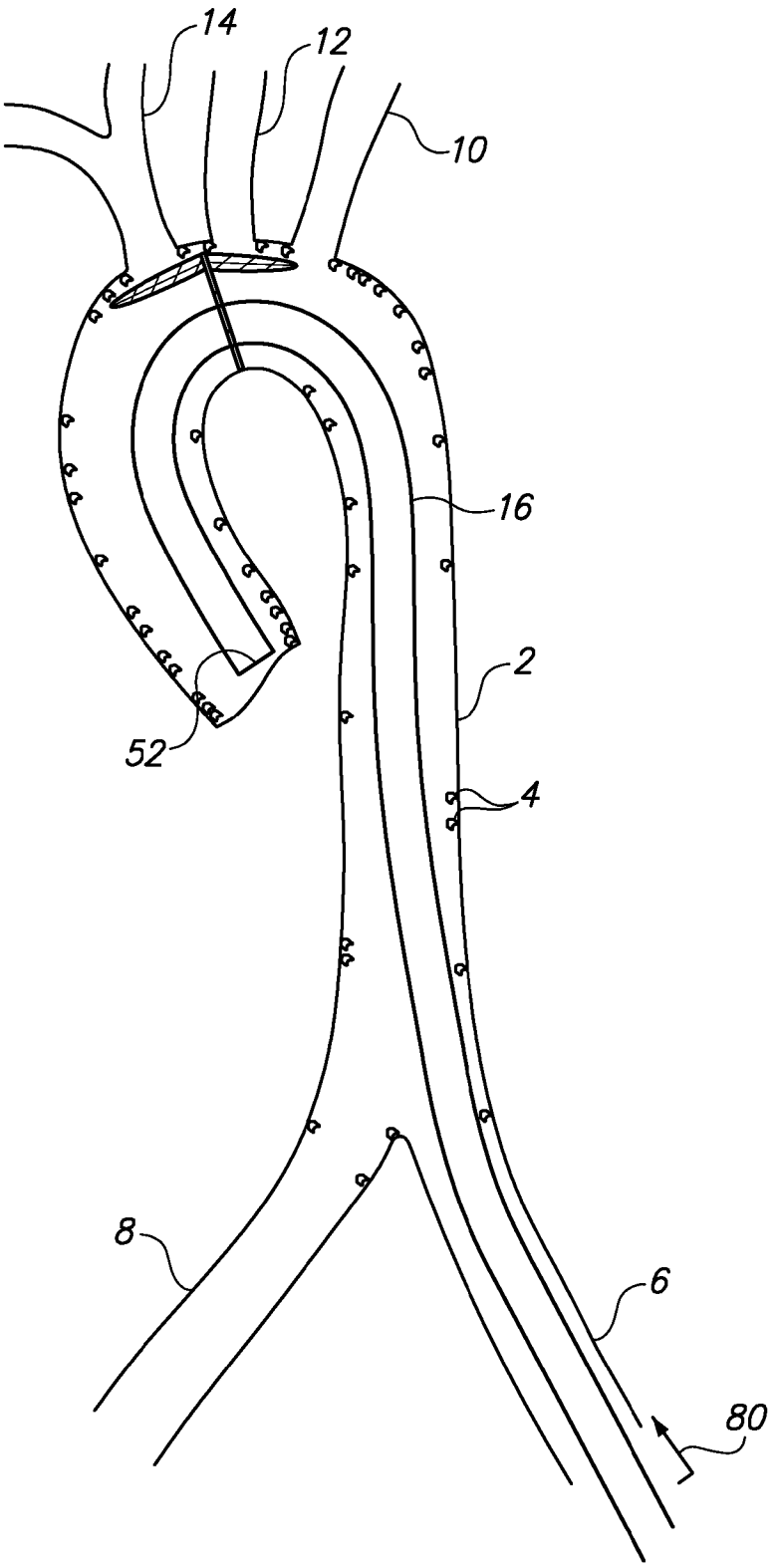


FIG. 4E

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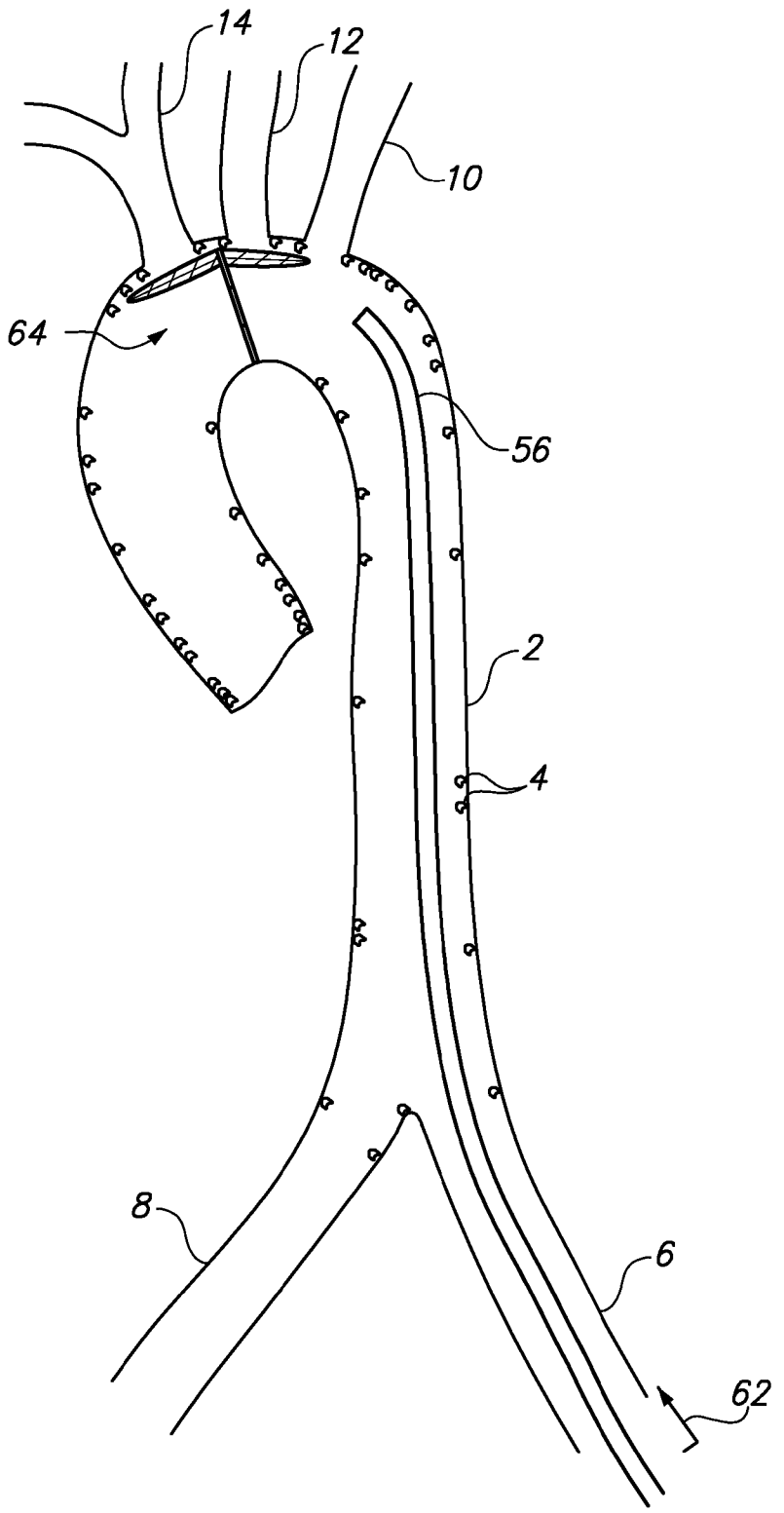


FIG. 4F

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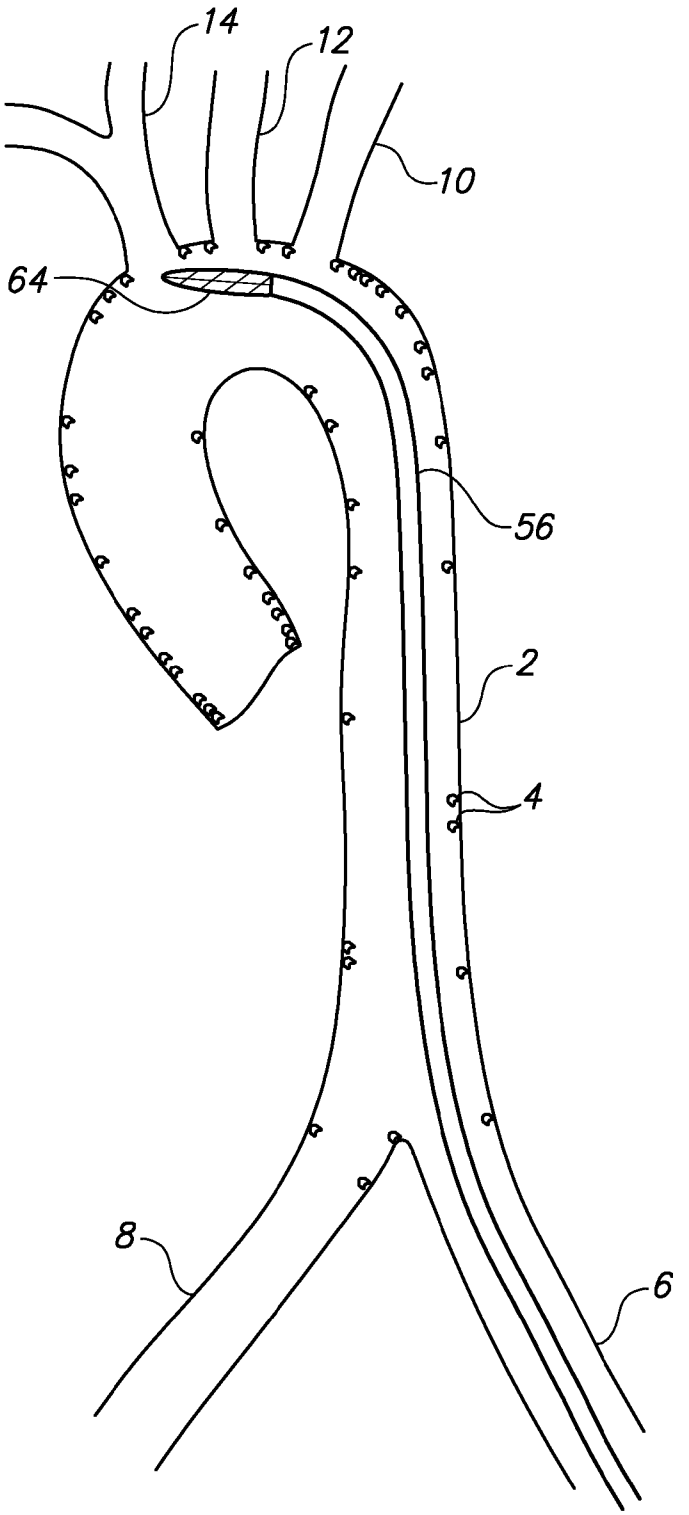


FIG. 4G

Date Reçue/Date Received 2020-09-03

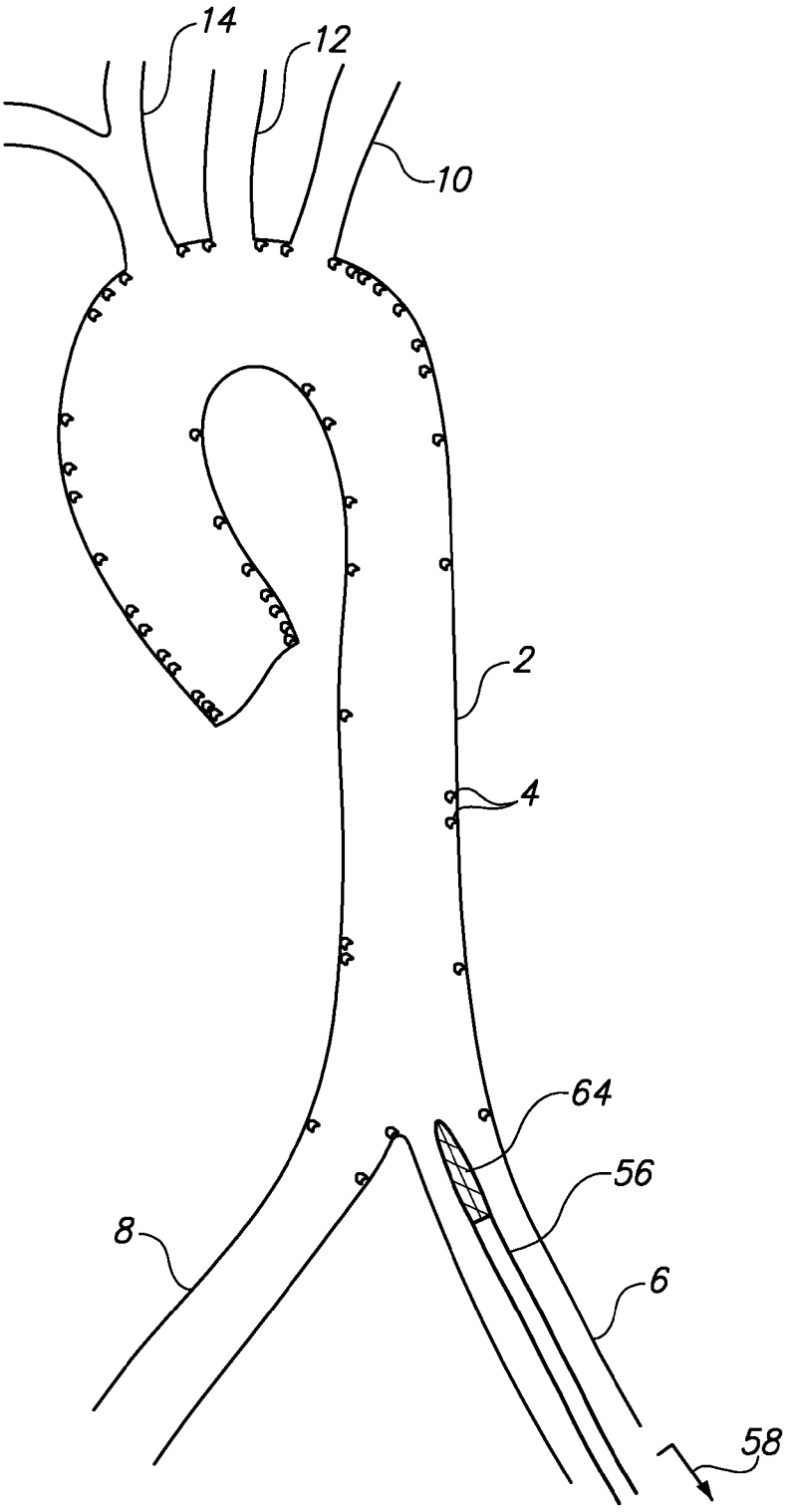


FIG. 4H

Date Reçue/Date Received 2020-09-03

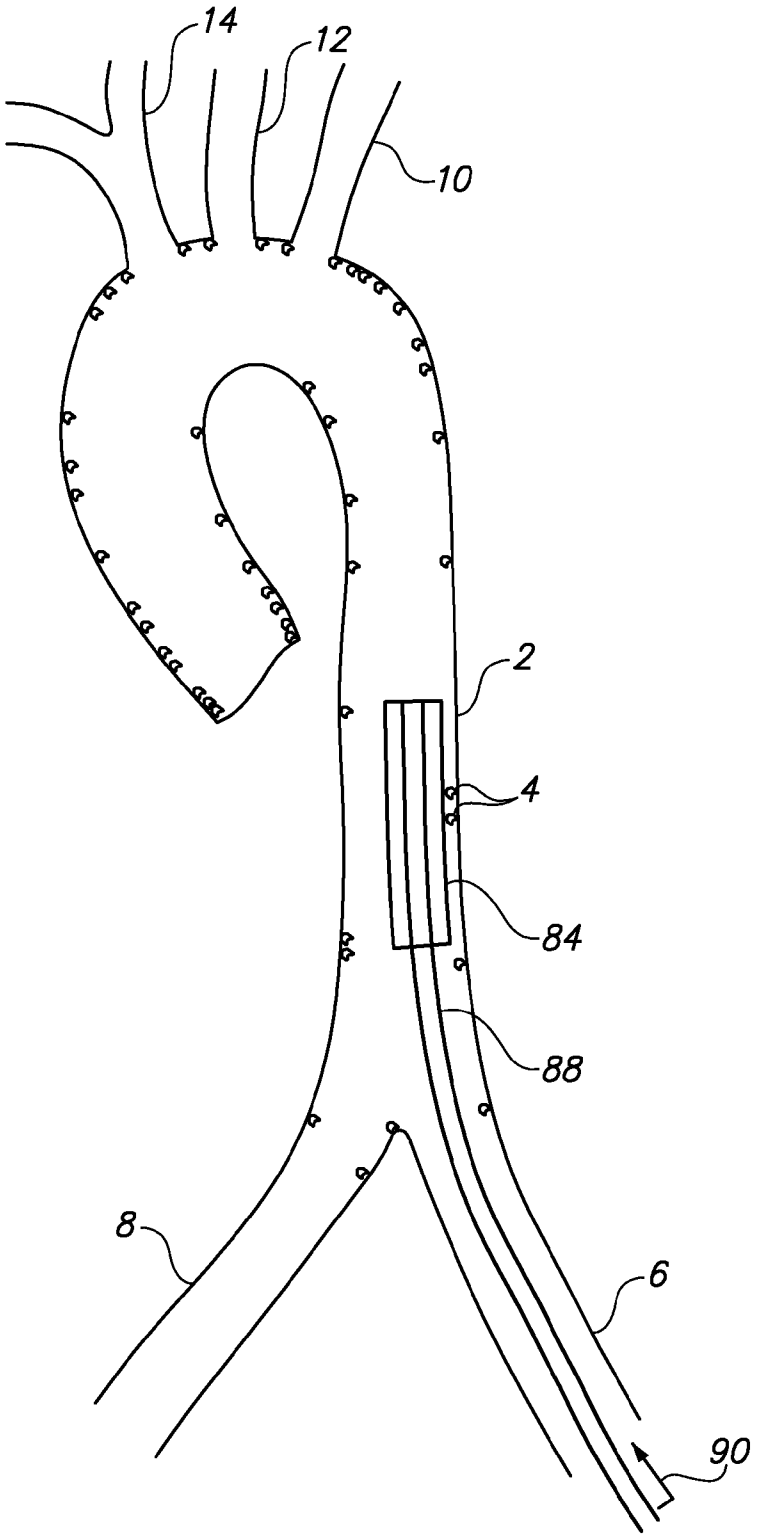


FIG. 5A

Date Reçue/Date Received 2020-09-03

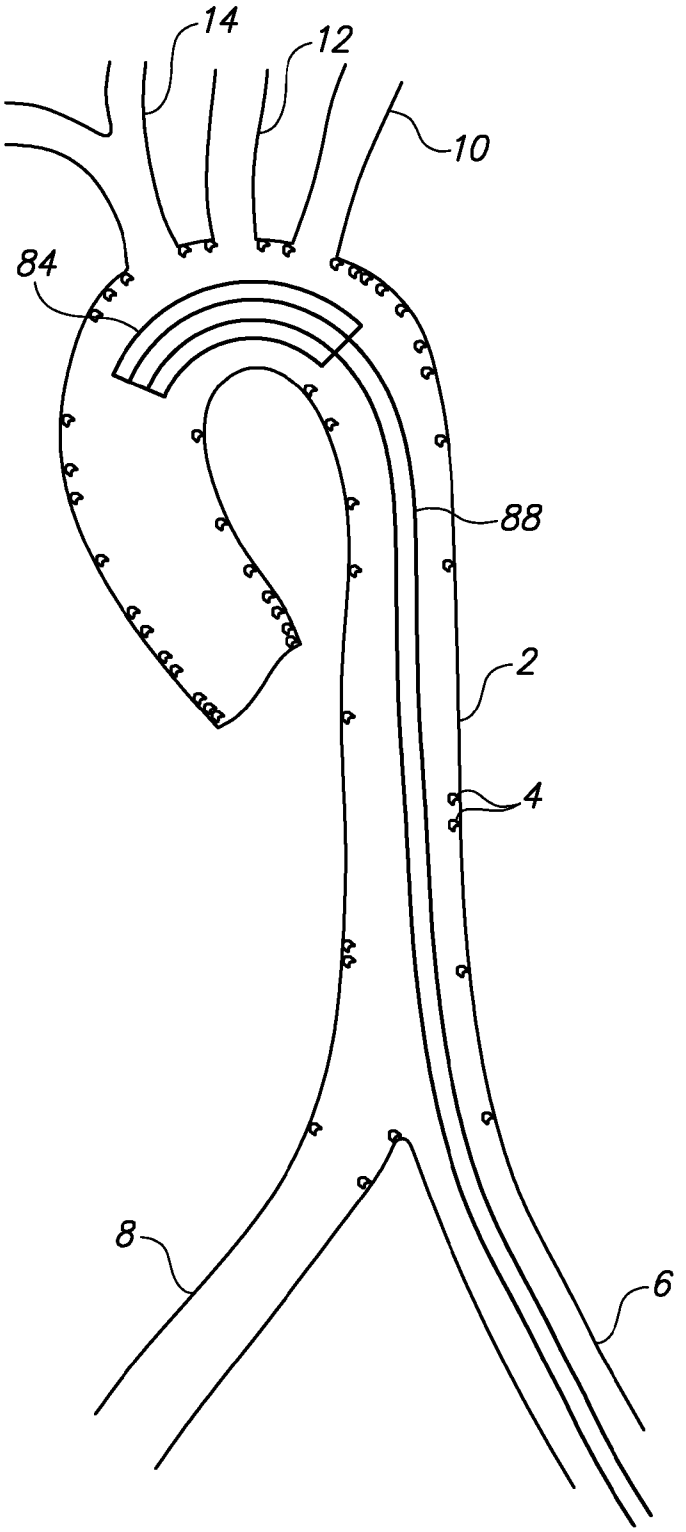


FIG. 5B

Date Reçue/Date Received 2020-09-03

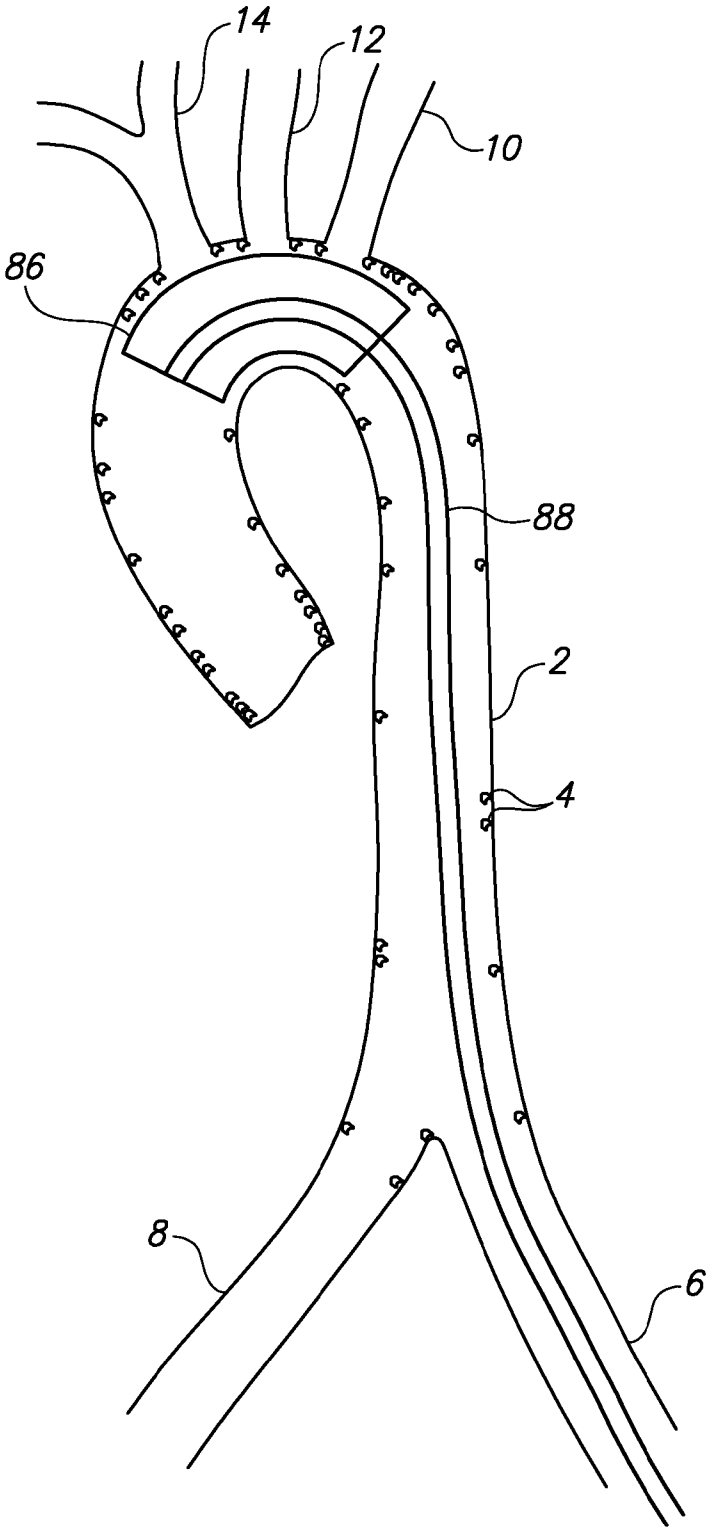


FIG. 5C

Date Reçue/Date Received 2020-09-03

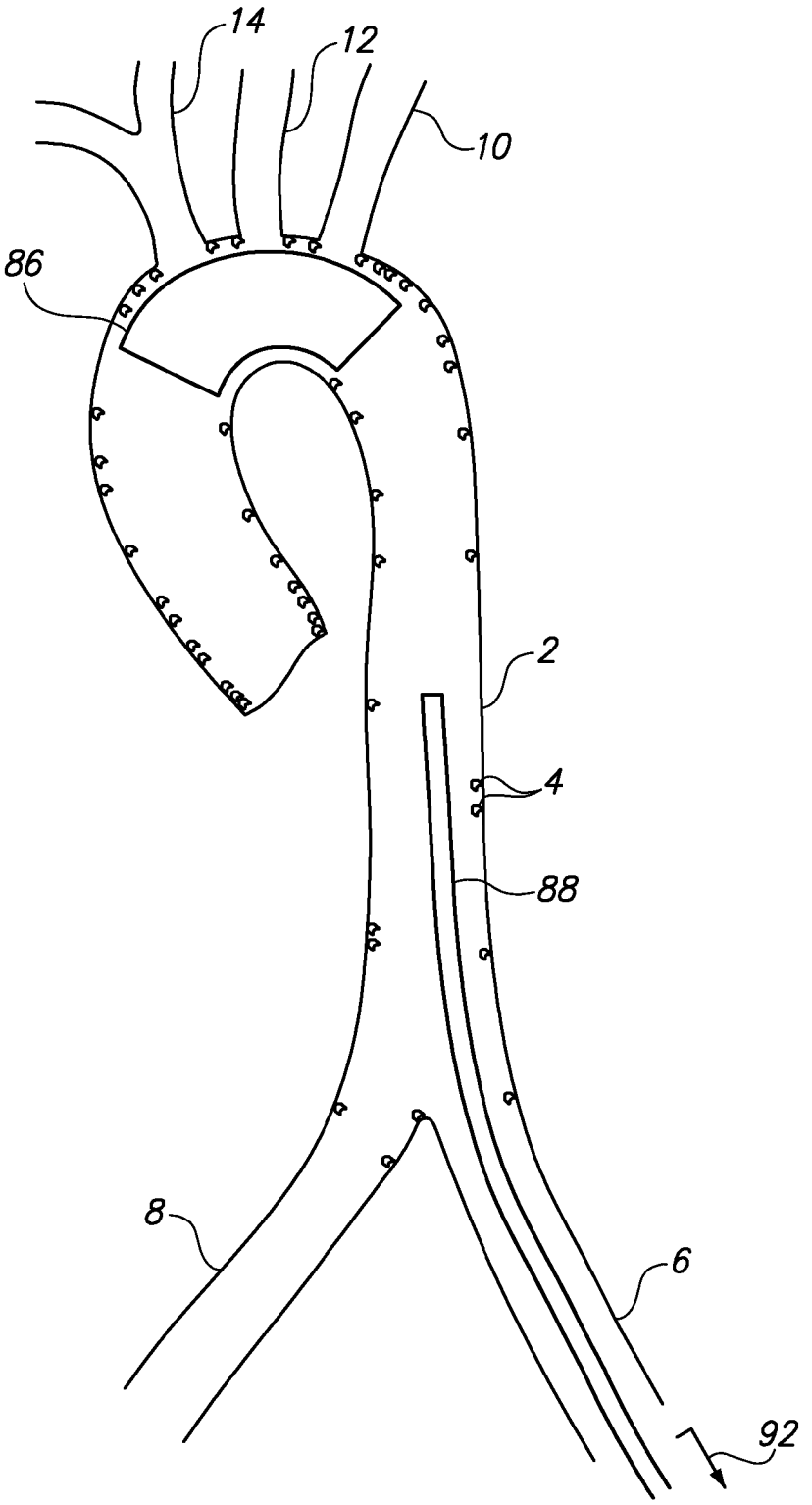


FIG. 5D

Date Reçue/Date Received 2020-09-03

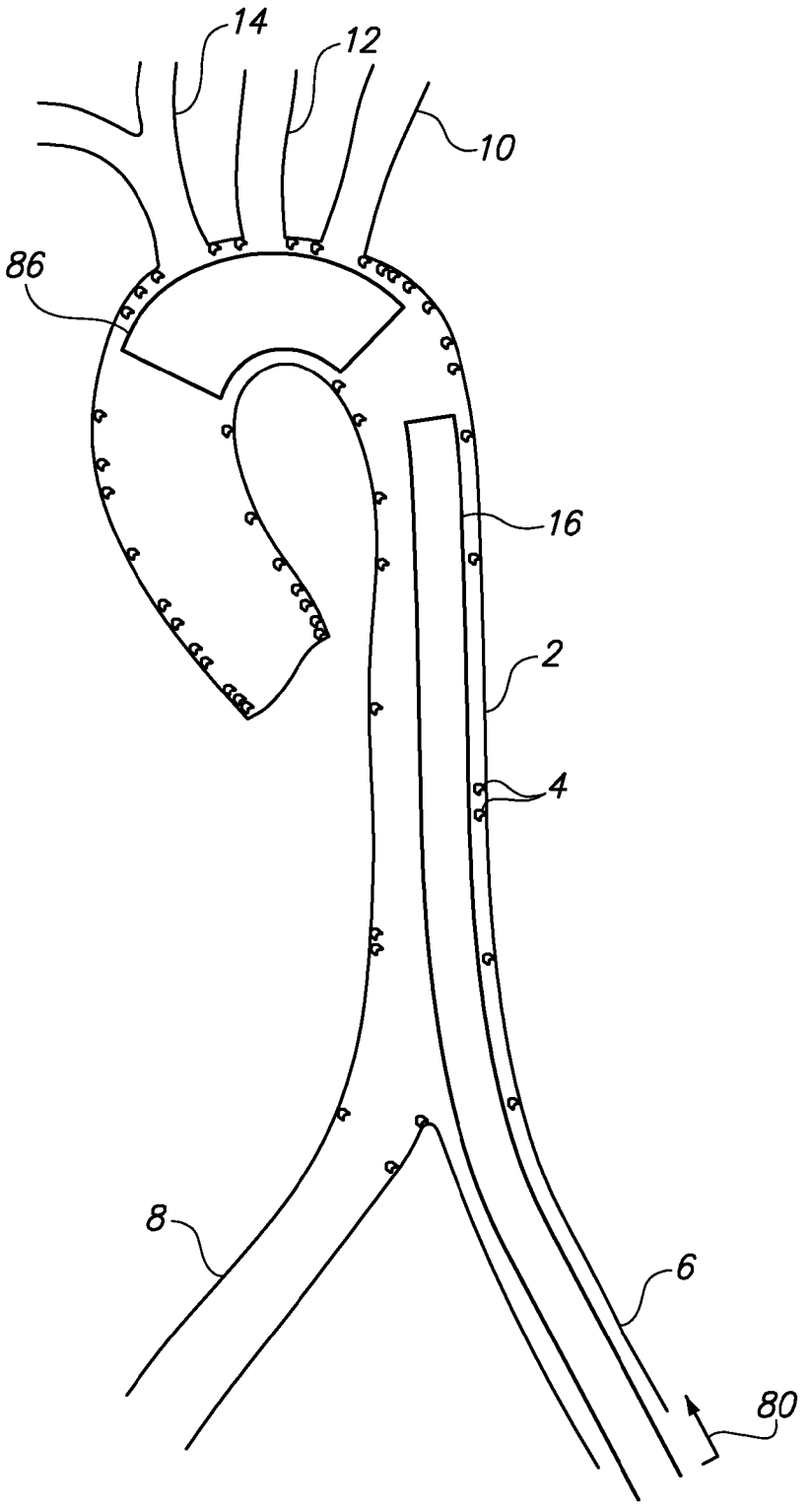


FIG. 5E

Date Reçue/Date Received 2020-09-03

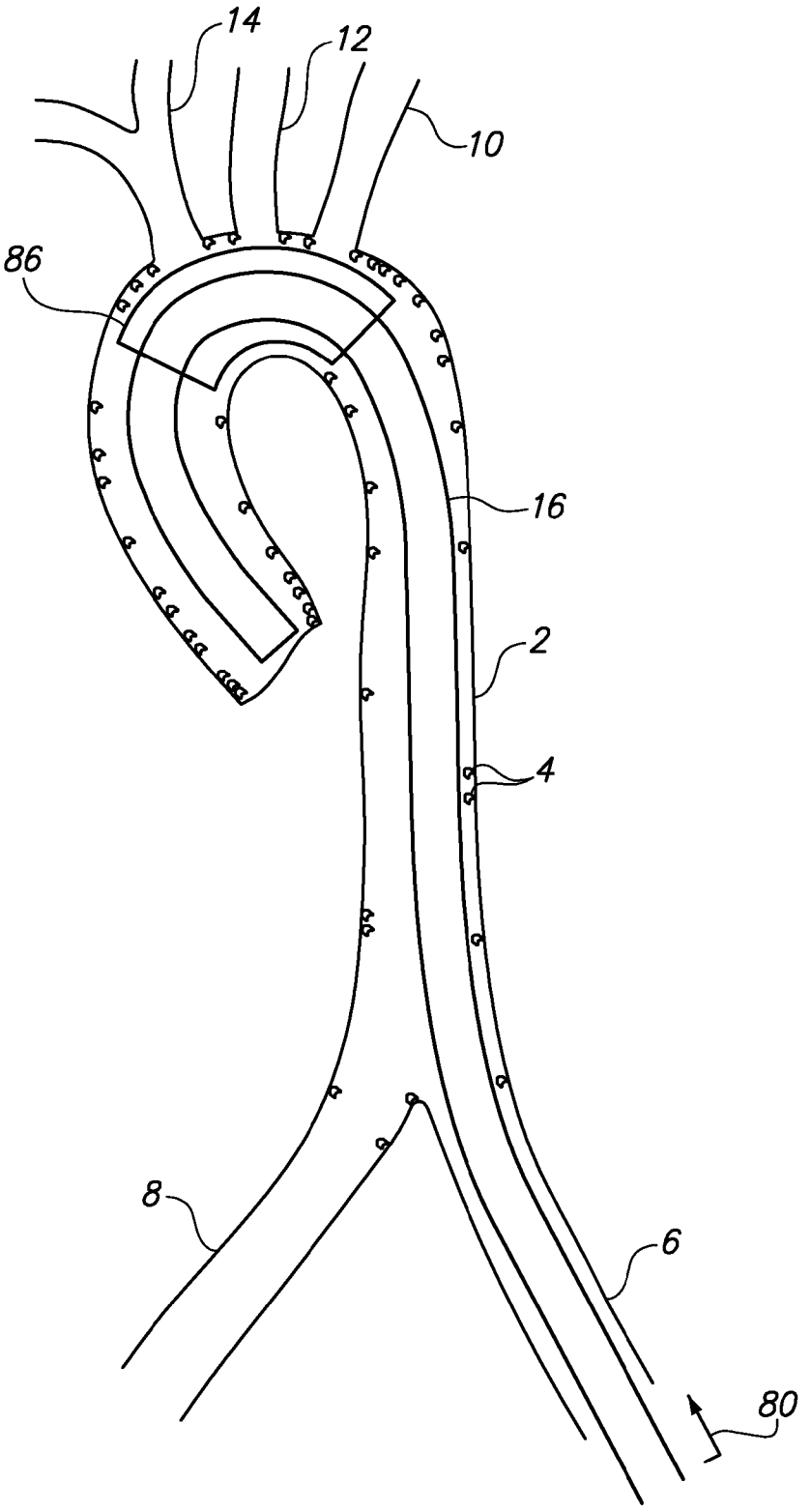


FIG. 5F

Date Reçue/Date Received 2020-09-03

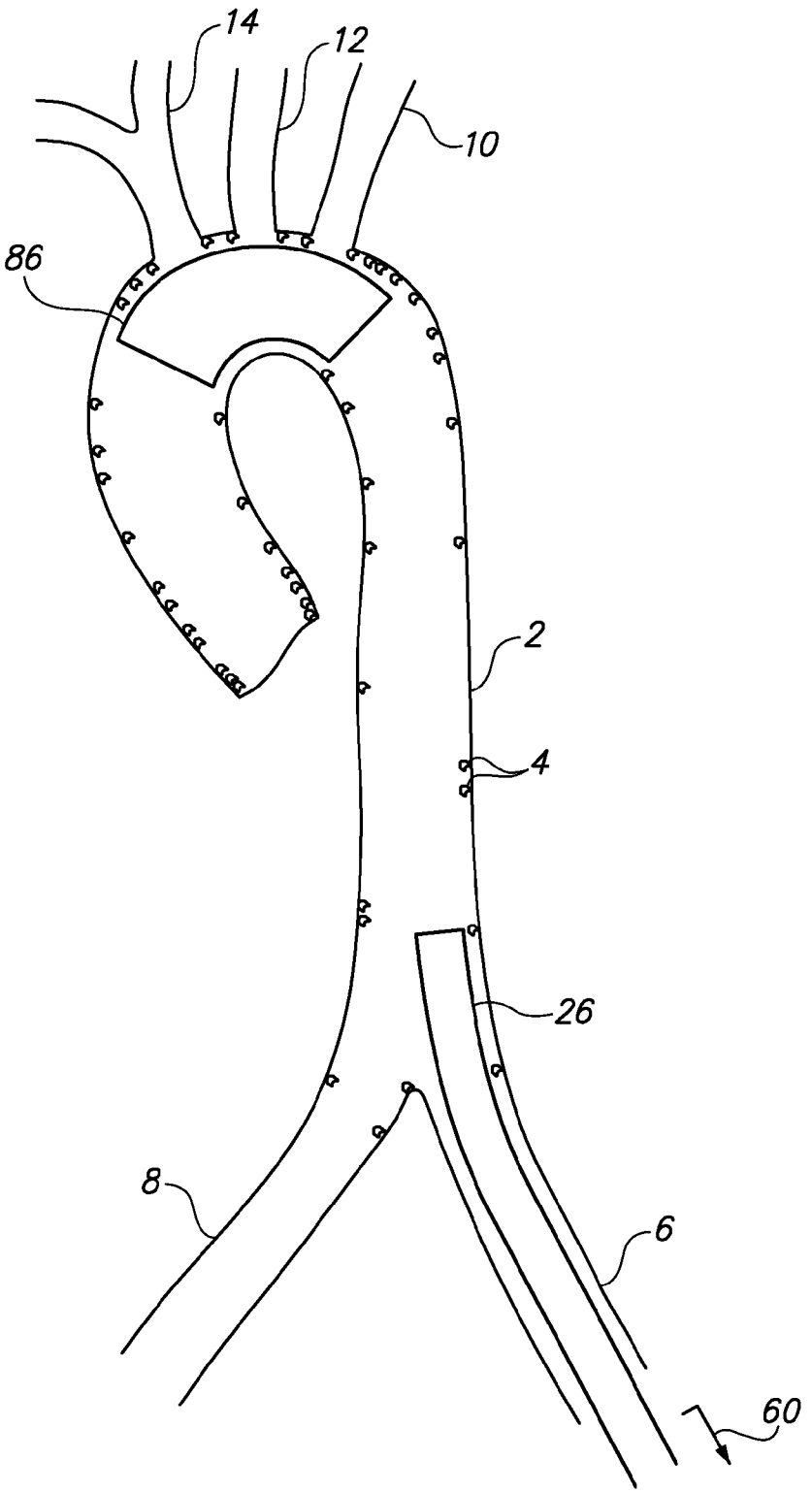


FIG. 5G

Date Reçue/Date Received 2020-09-03

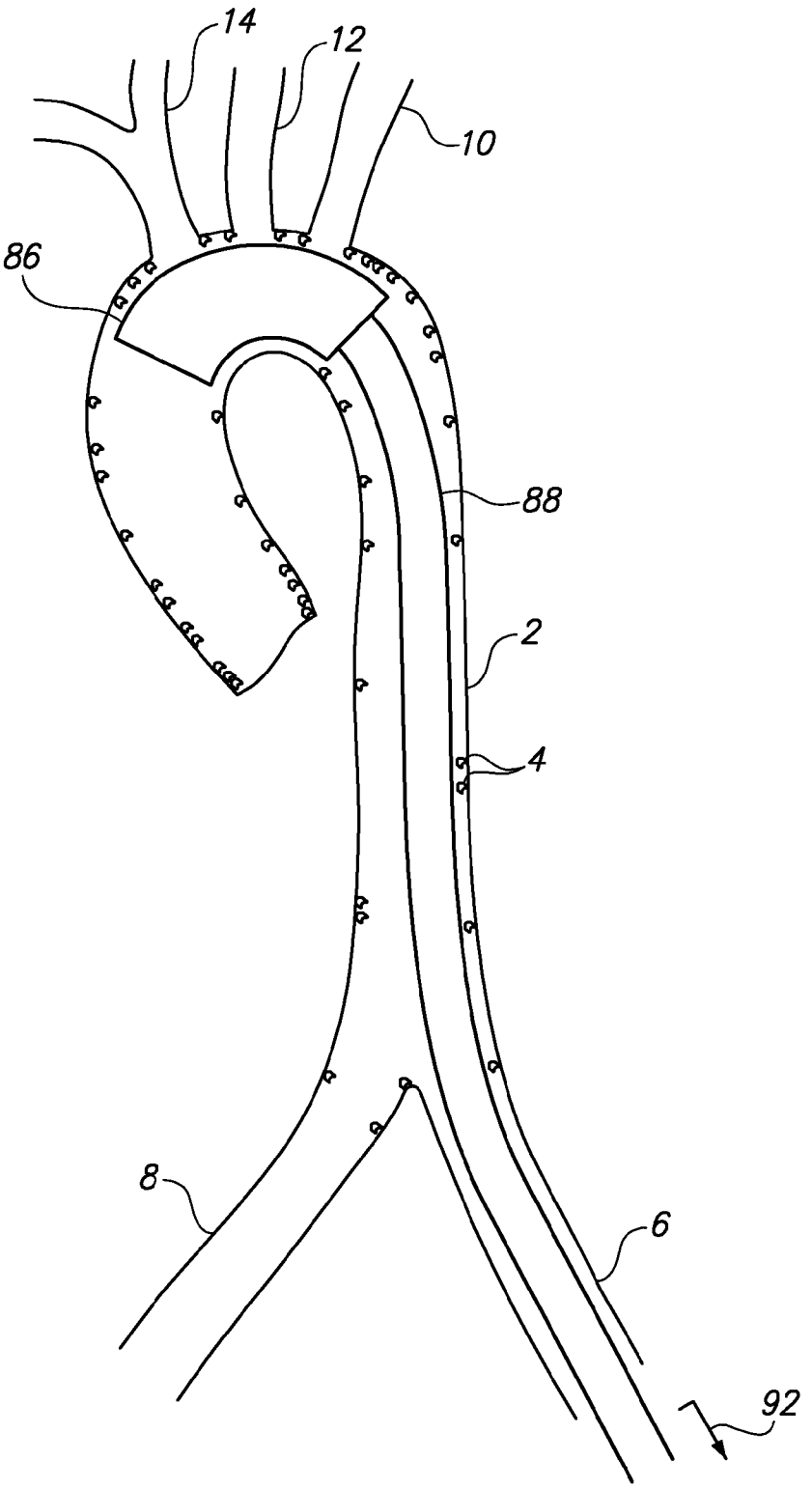


FIG. 5H

Date Reçue/Date Received 2020-09-03

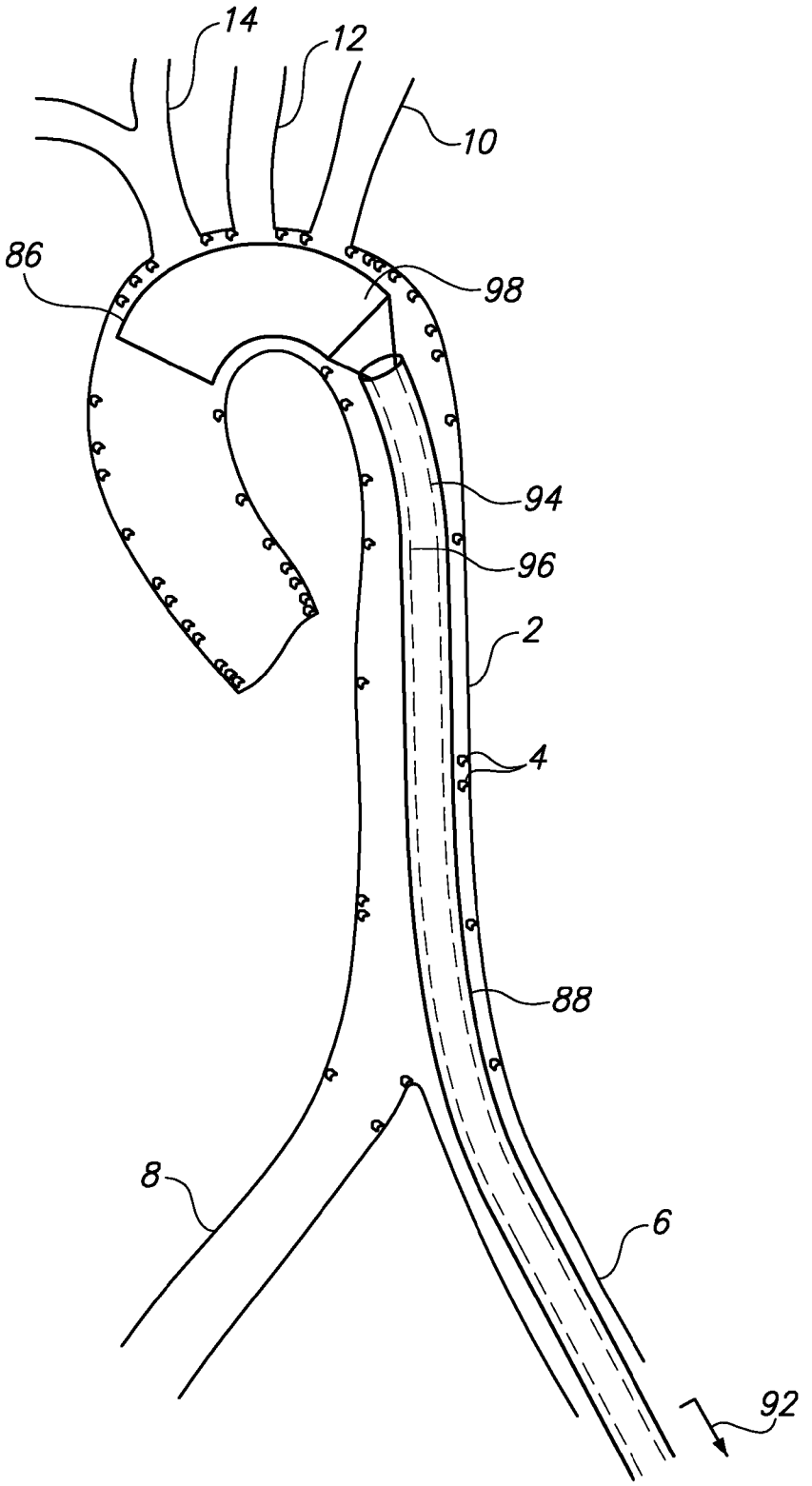


FIG. 5I

Date Reçue/Date Received 2020-09-03

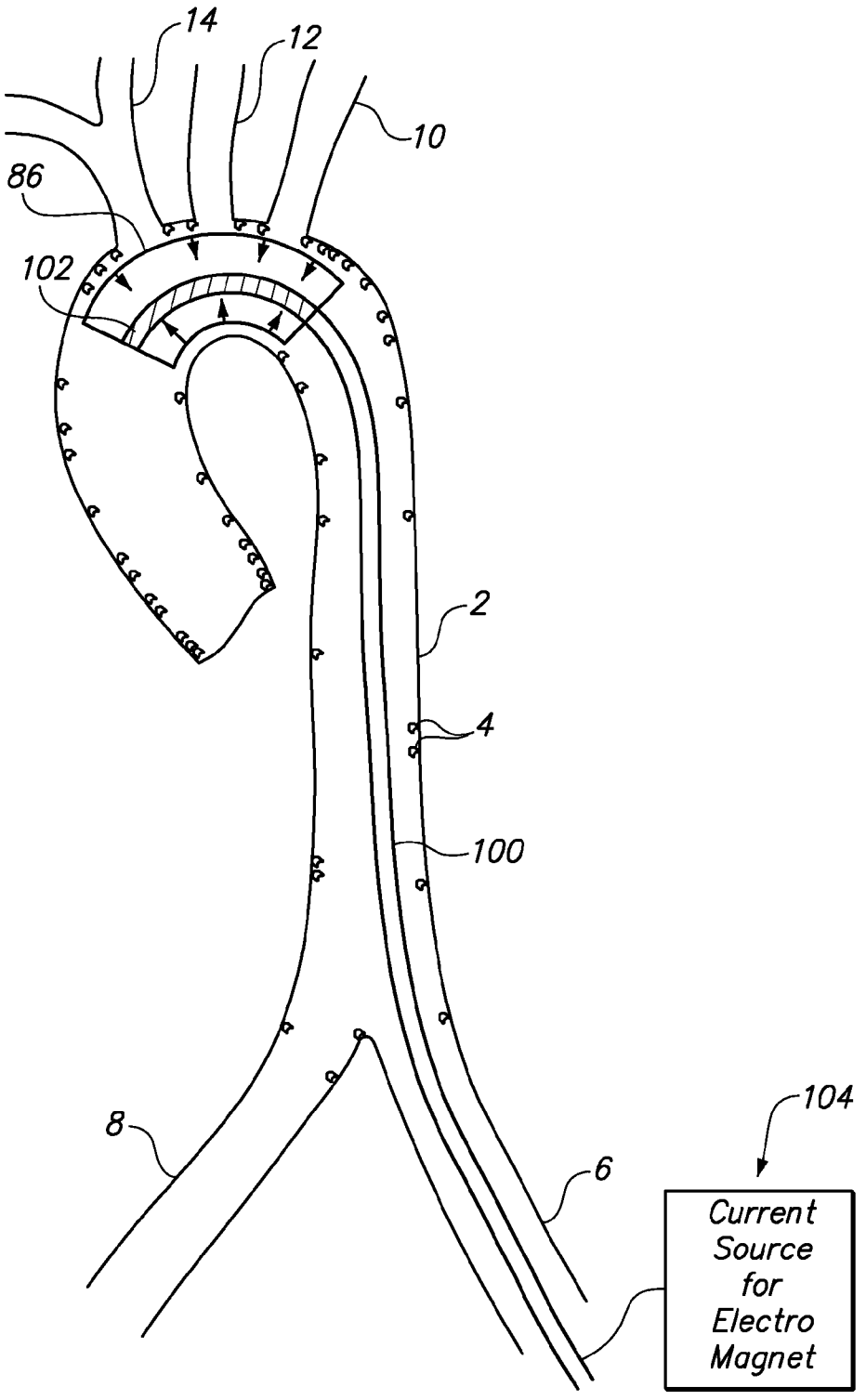


FIG. 5J

Date Reçue/Date Received 2020-09-03

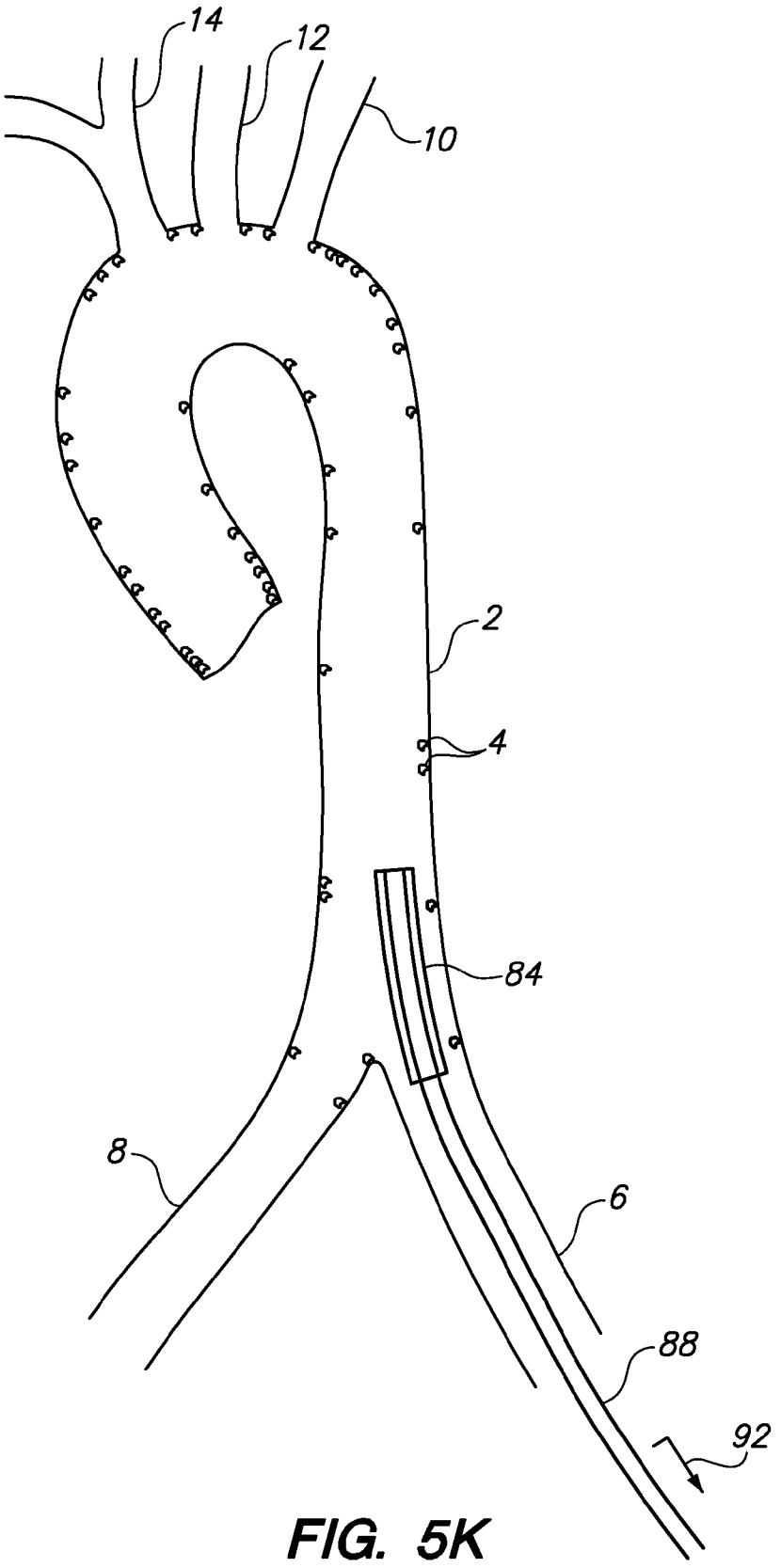


FIG. 5K

Date Reçue/Date Received 2020-09-03

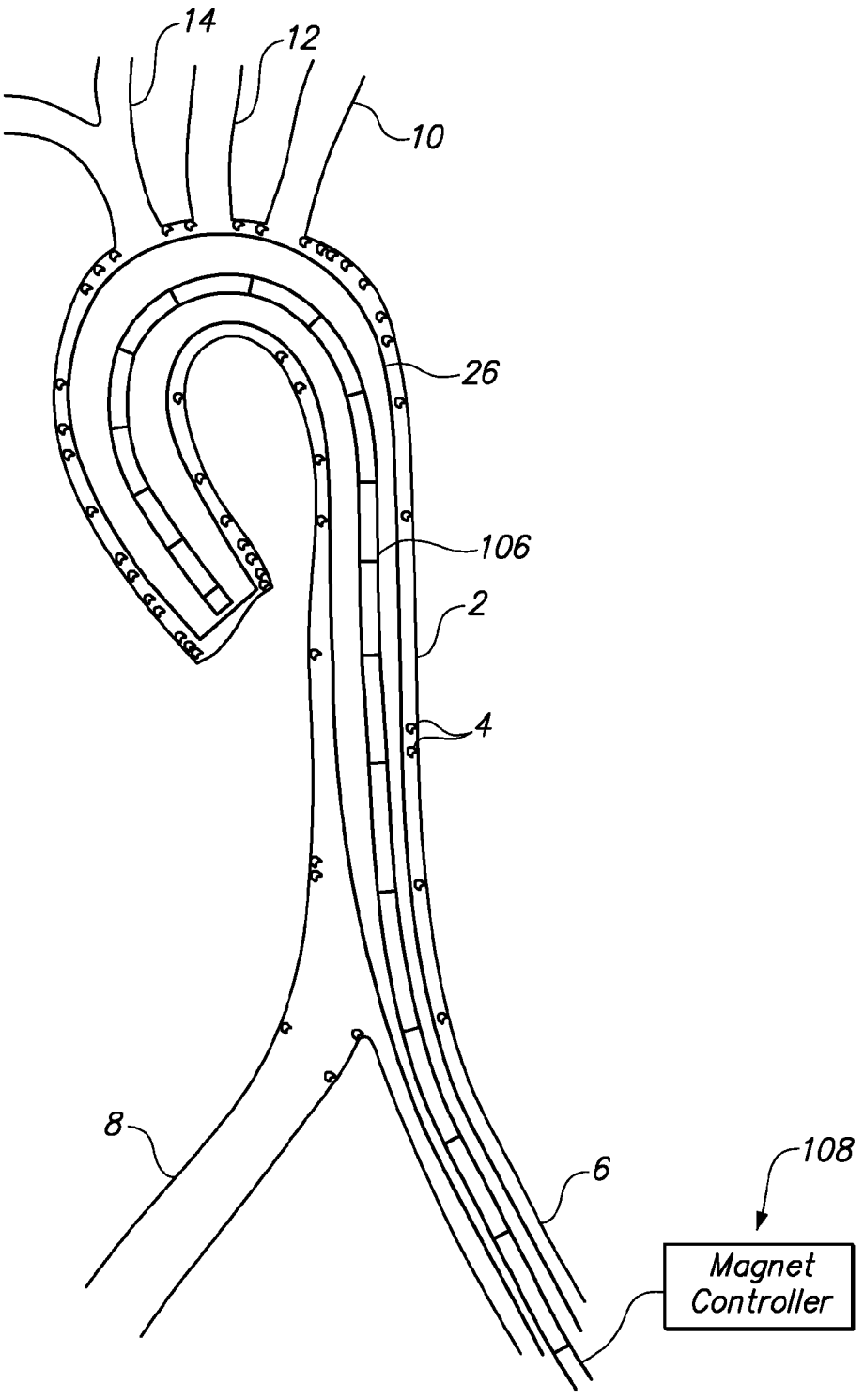


FIG. 6

Date Reçue/Date Received 2020-09-03

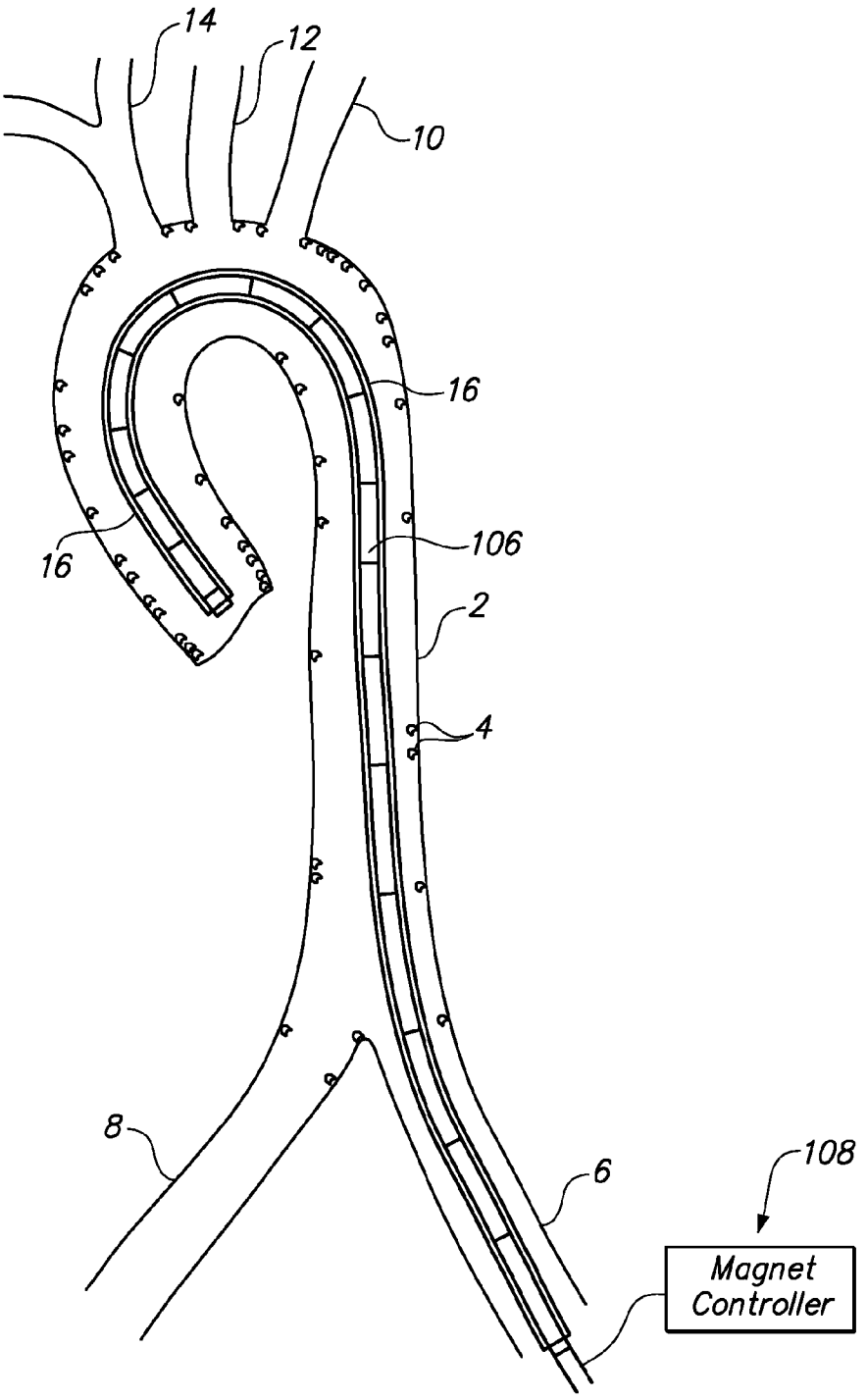


FIG. 7

Date Reçue/Date Received 2020-09-03

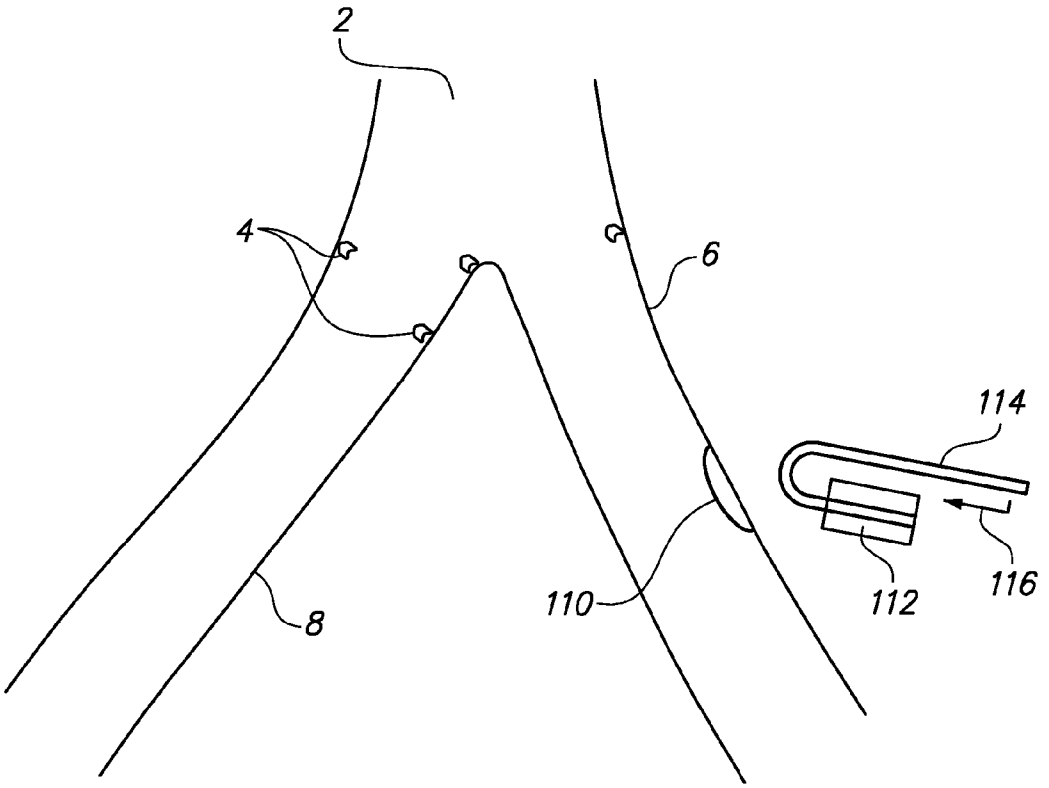


FIG. 8A

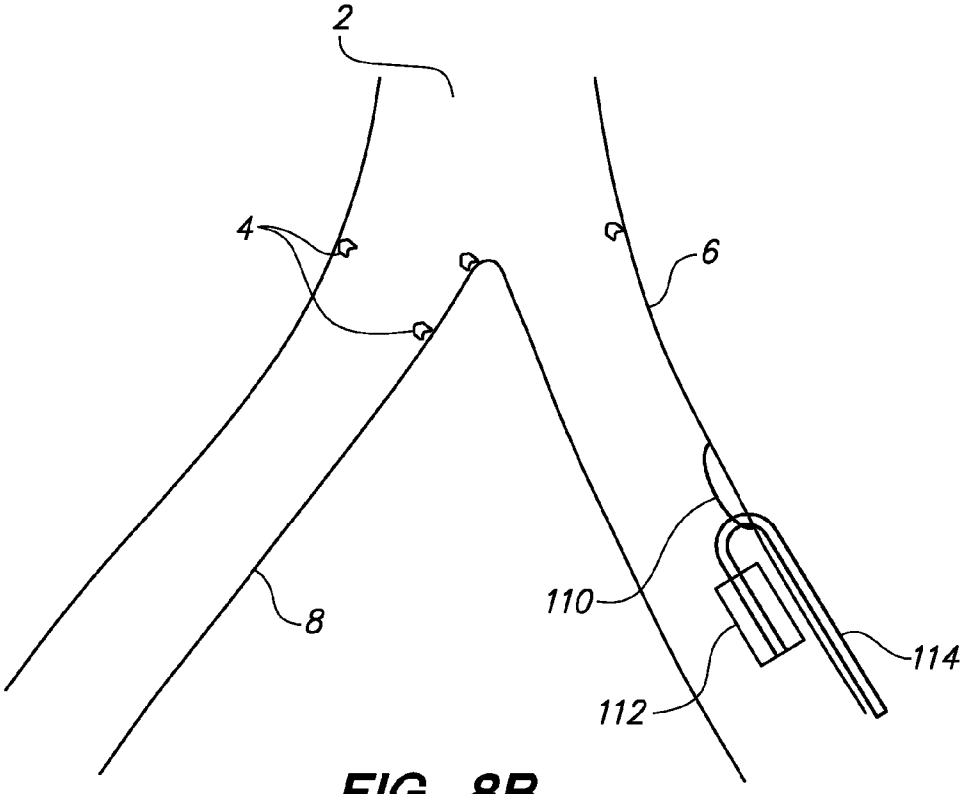


FIG. 8B

Date Reçue/Date Received 2020-09-03

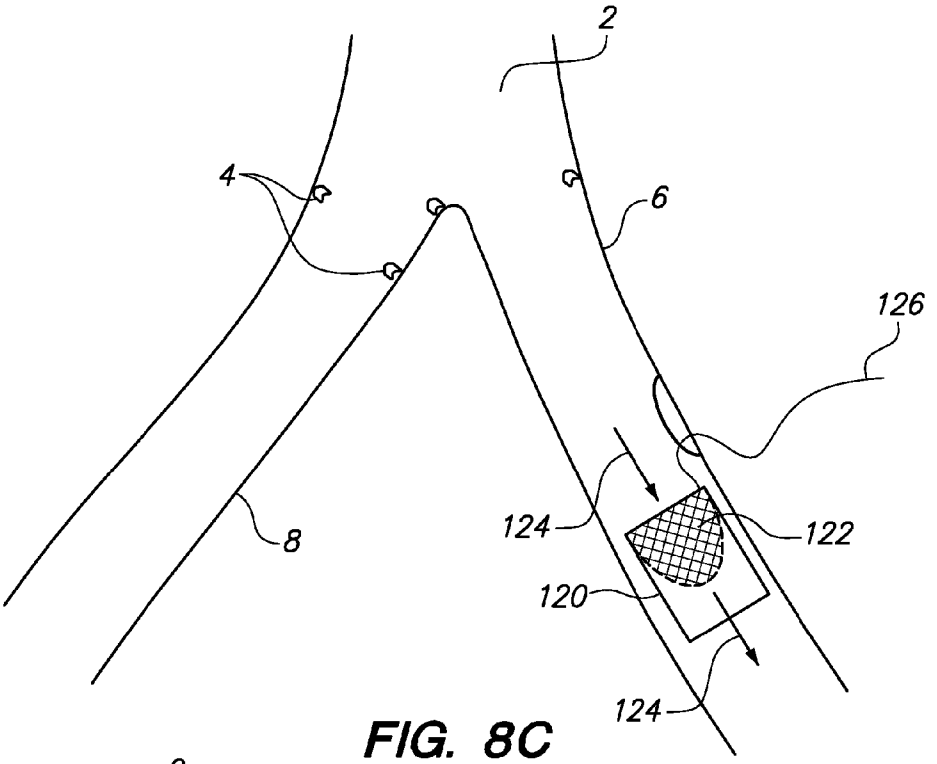


FIG. 8C

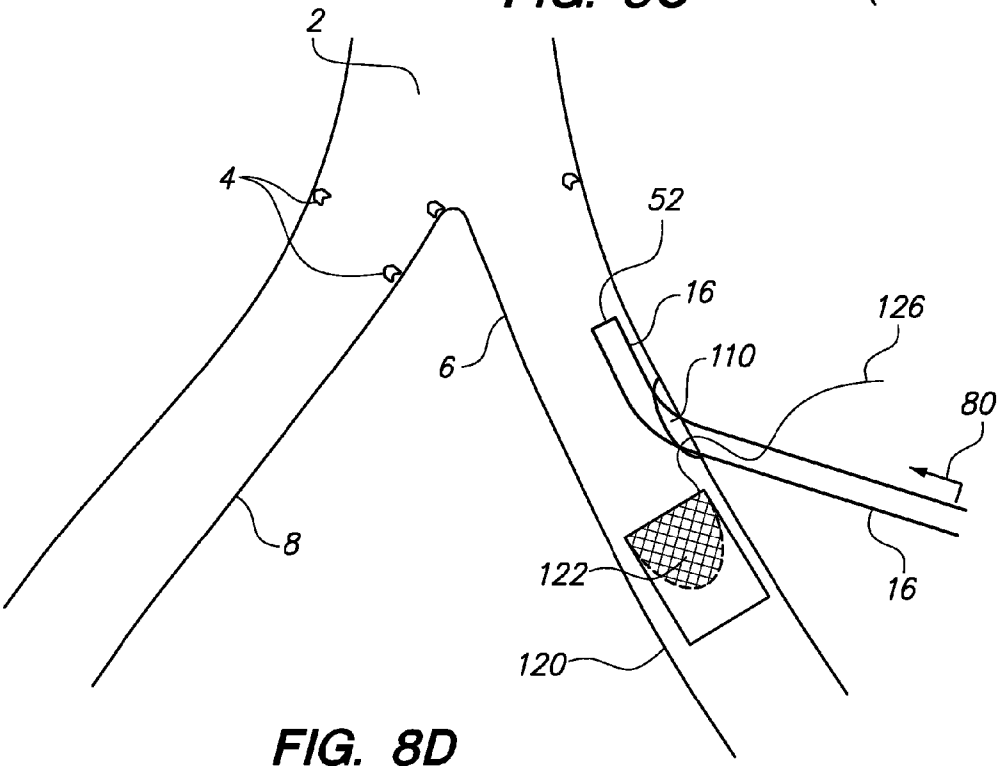


FIG. 8D

Date Reçue/Date Received 2020-09-03

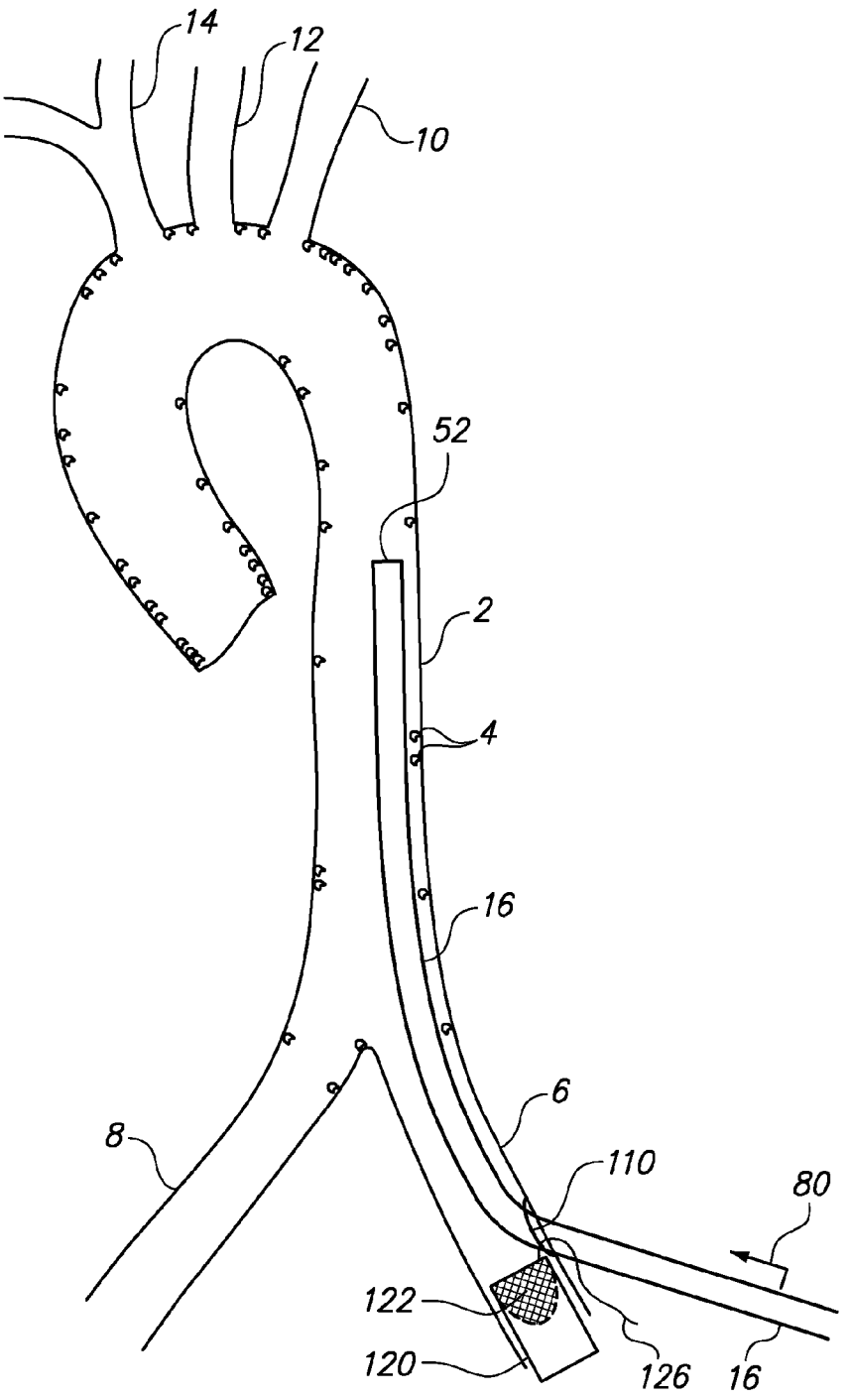


FIG. 8E

Date Reçue/Date Received 2020-09-03

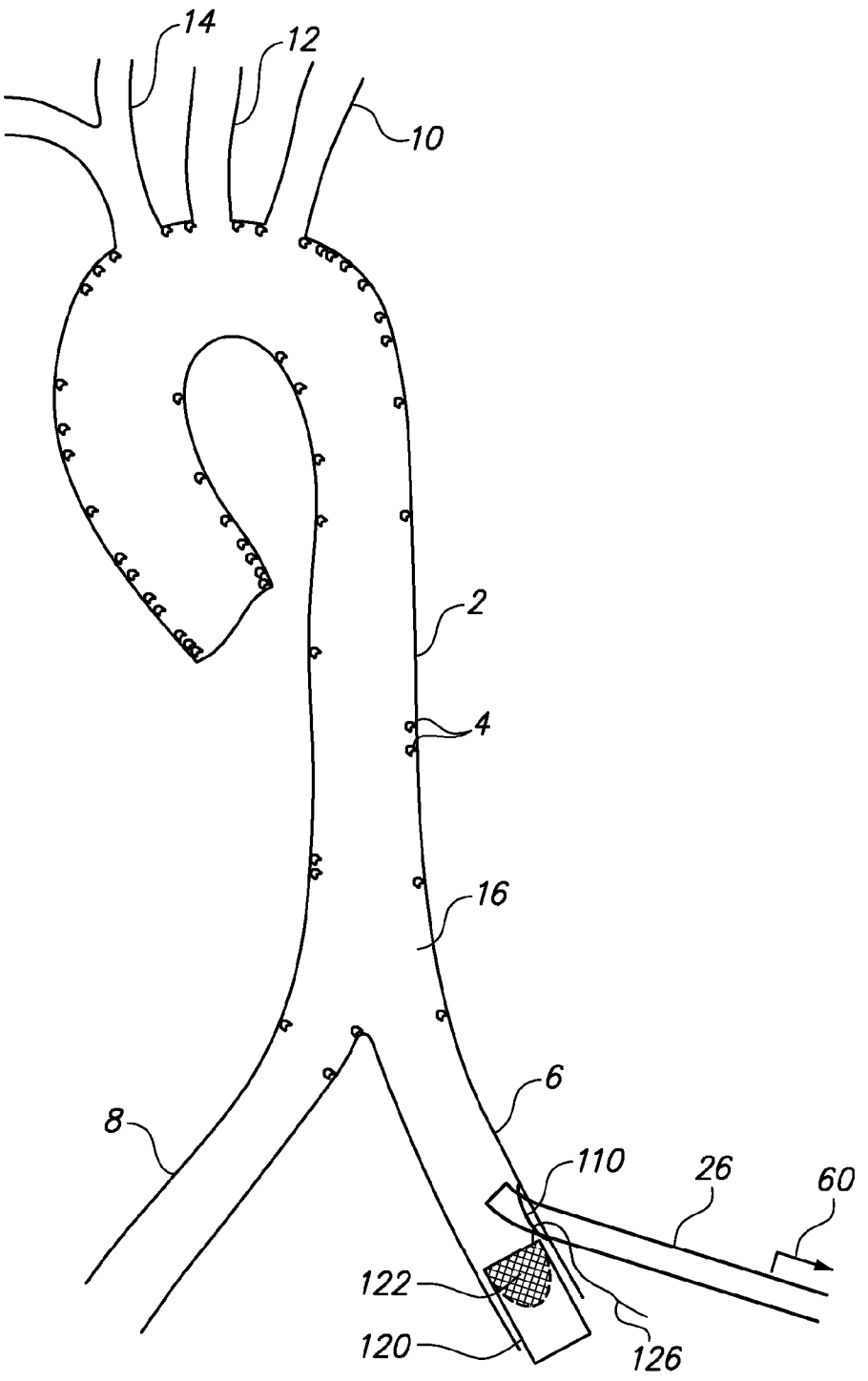


FIG. 8F

Date Reçue/Date Received 2020-09-03

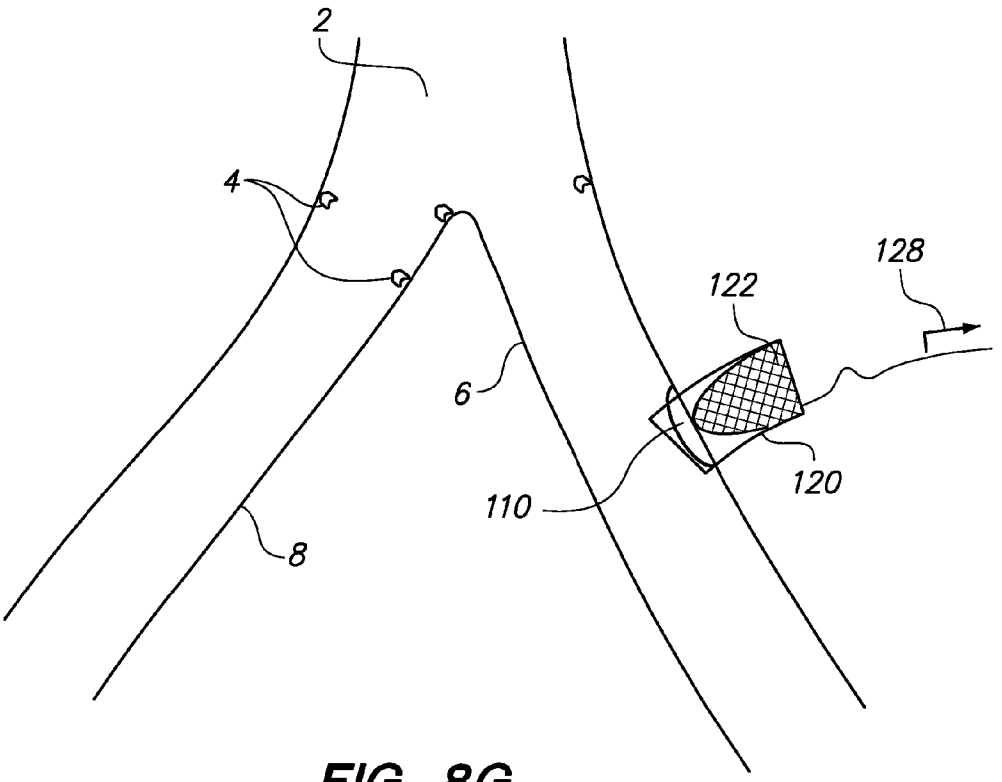


FIG. 8G

Date Reçue/Date Received 2020-09-03

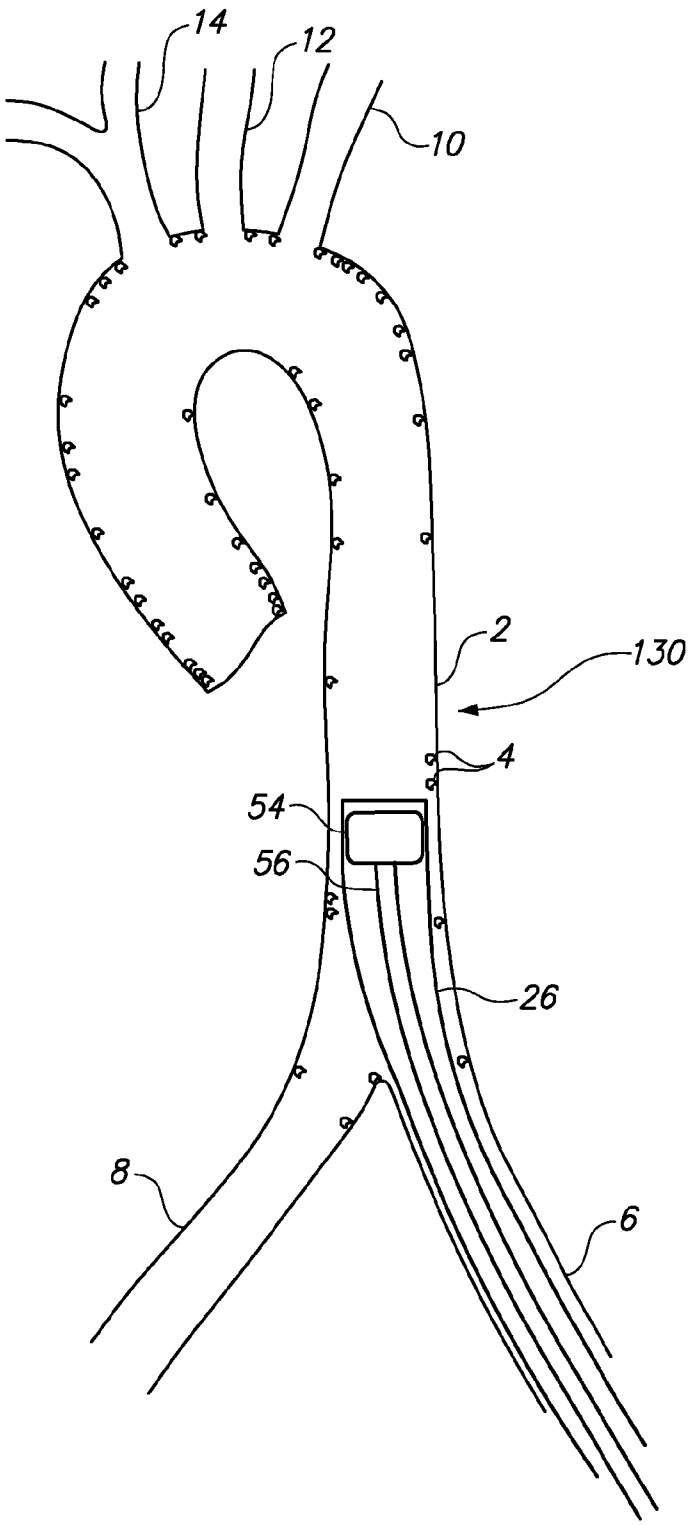


FIG. 9

Date Reçue/Date Received 2020-09-03

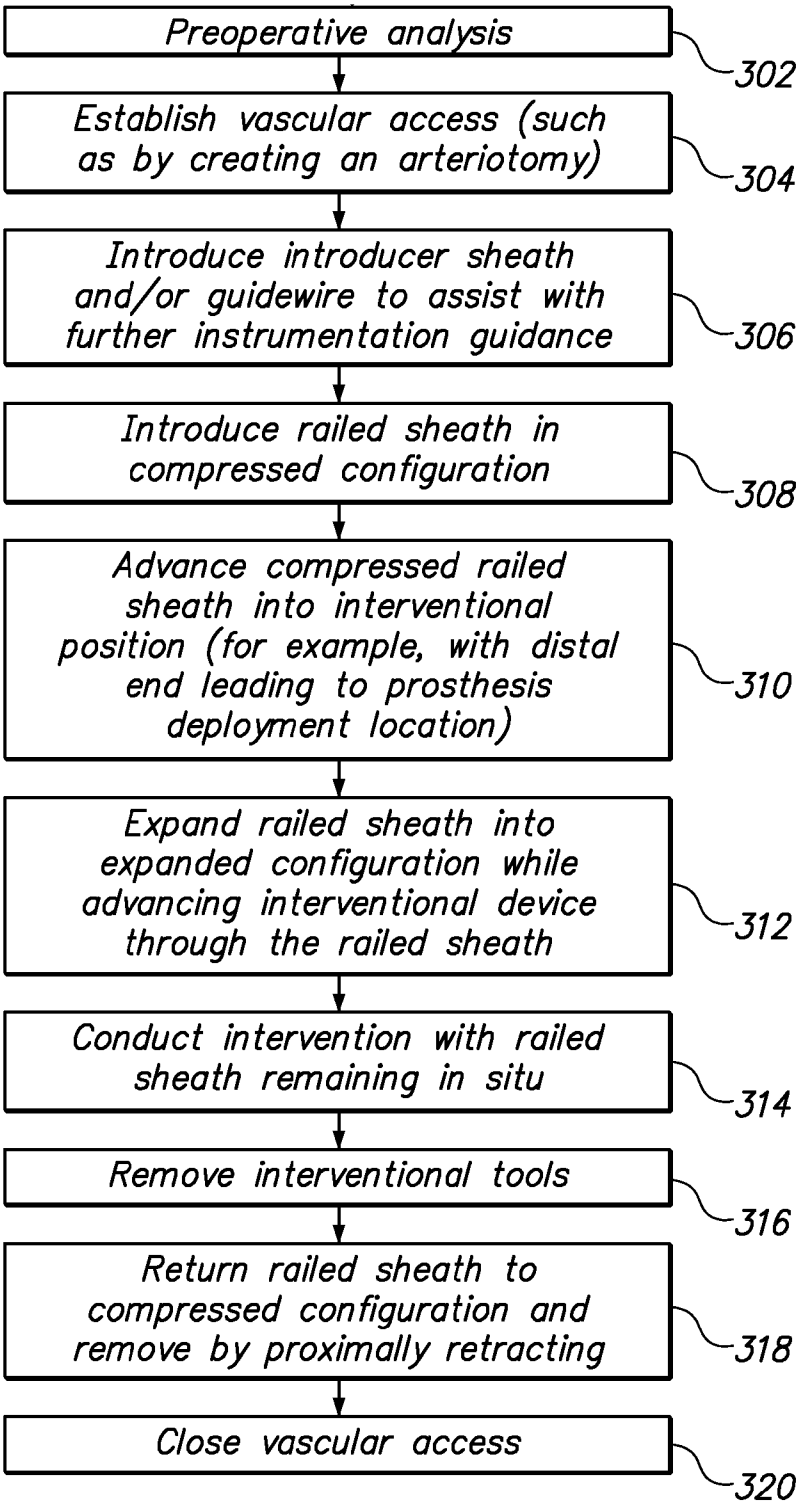


FIG. 10

Date Reçue/Date Received 2020-09-03

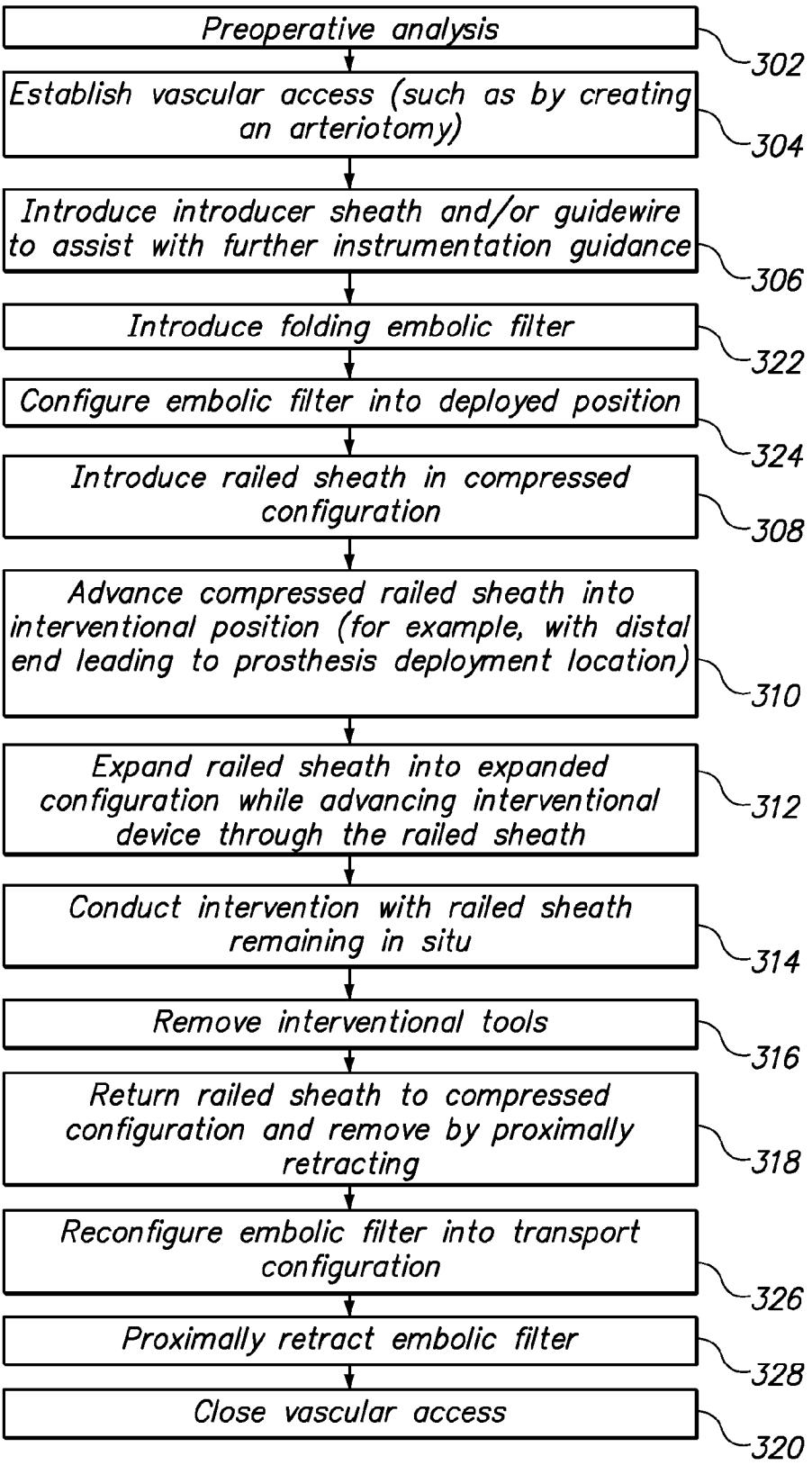


FIG. 11

Date Reçue/Date Received 2020-09-03

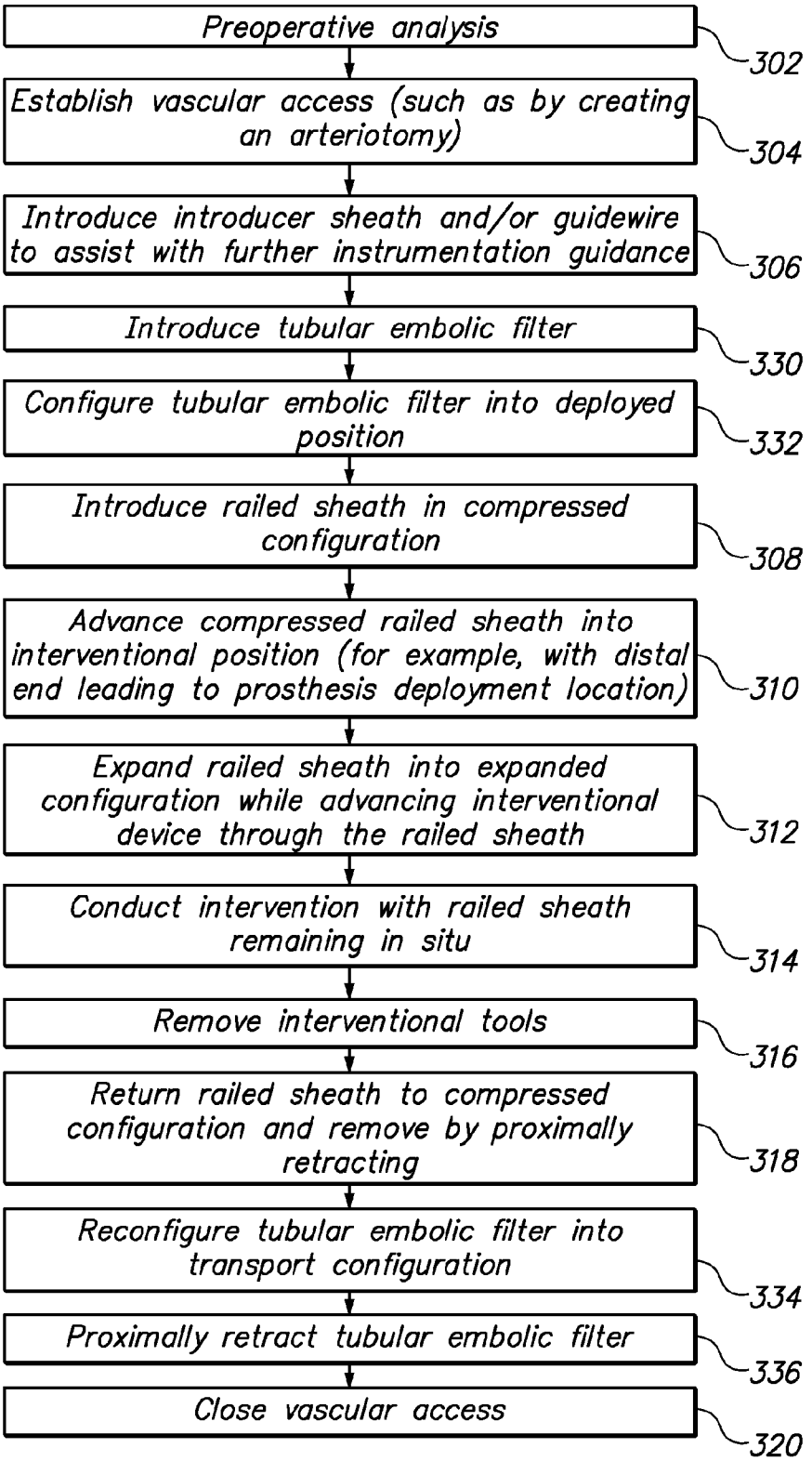


FIG. 12

Date Reçue/Date Received 2020-09-03

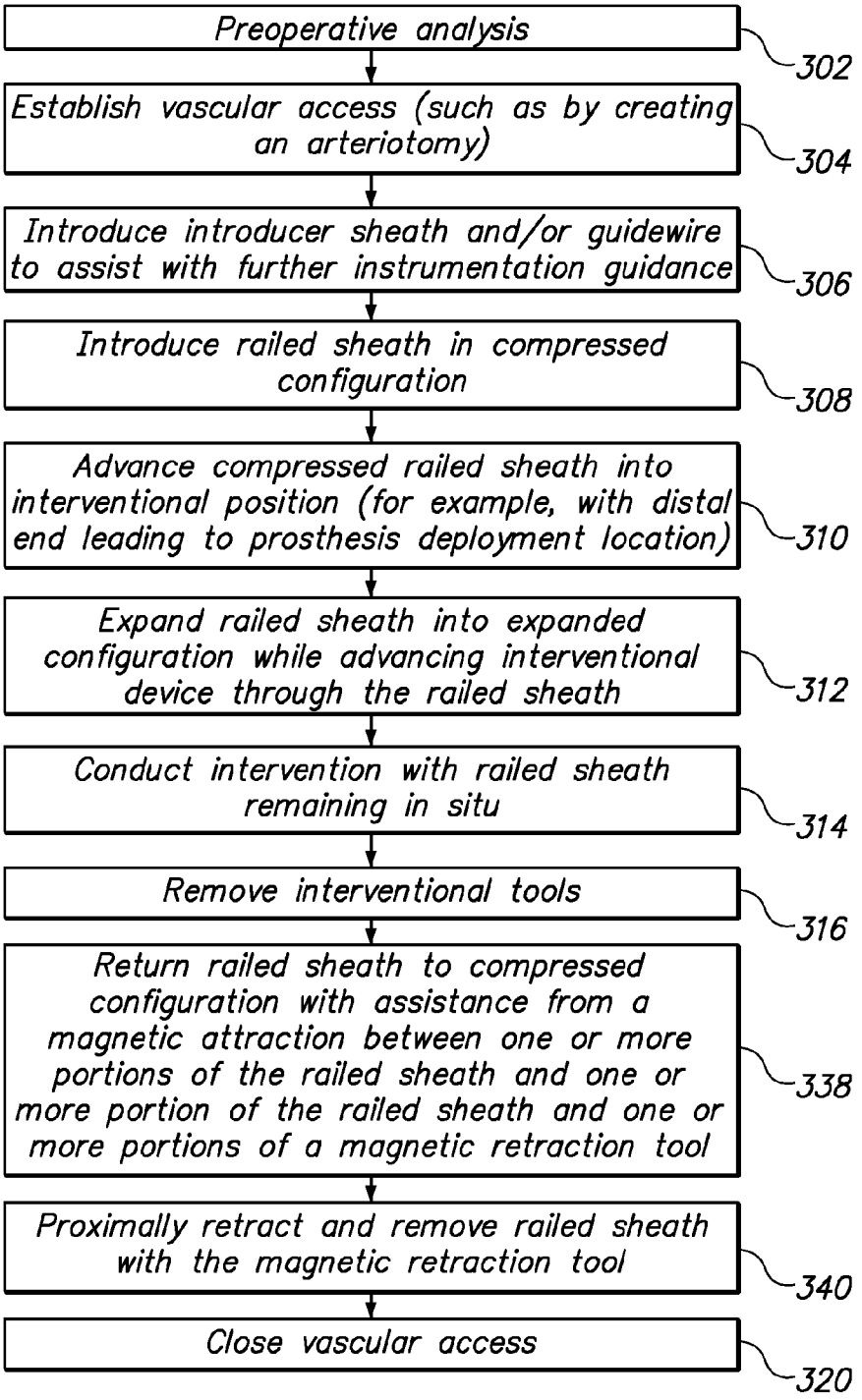


FIG. 13

Date Reçue/Date Received 2020-09-03

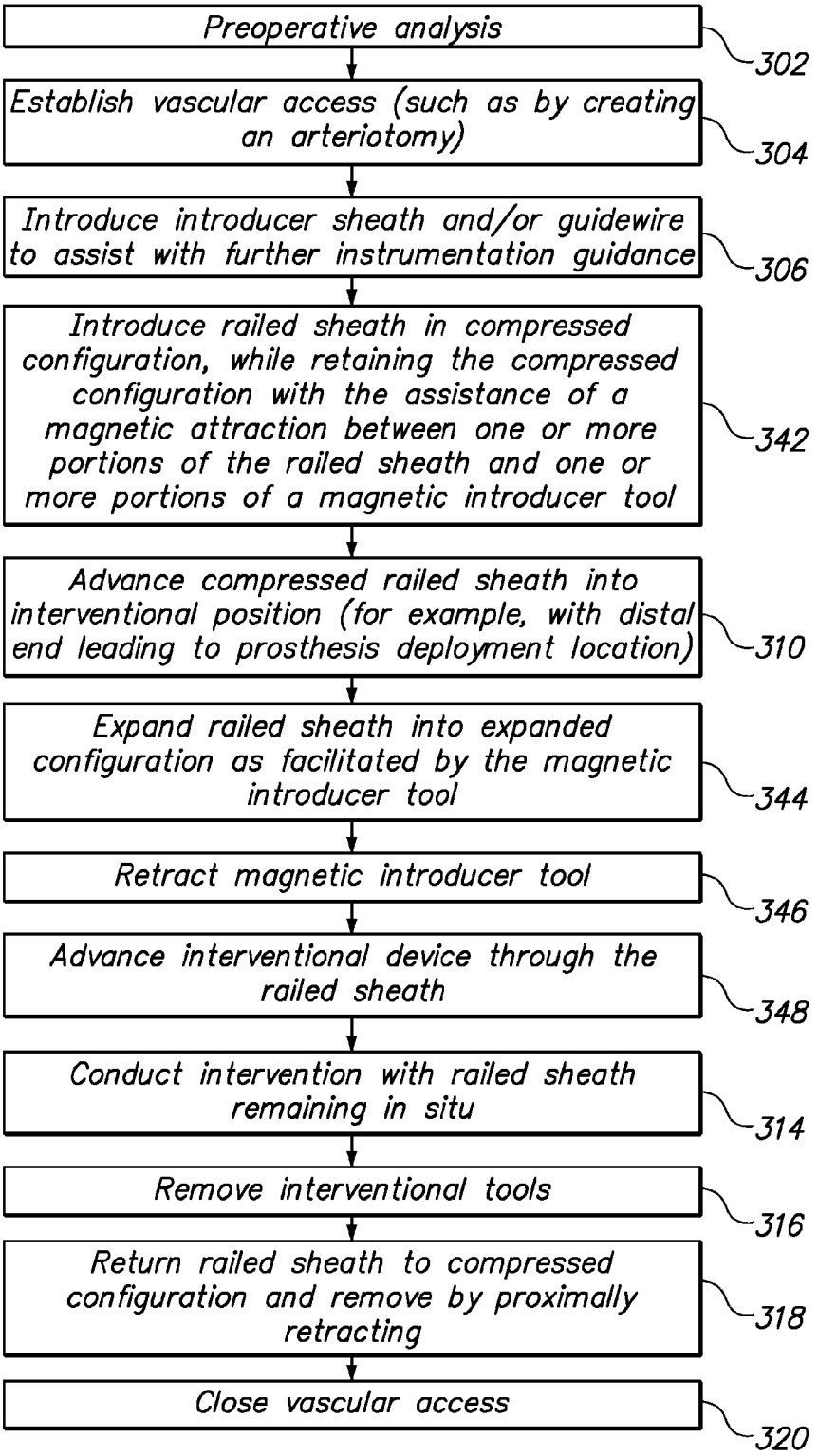


FIG. 14

Date Reçue/Date Received 2020-09-03

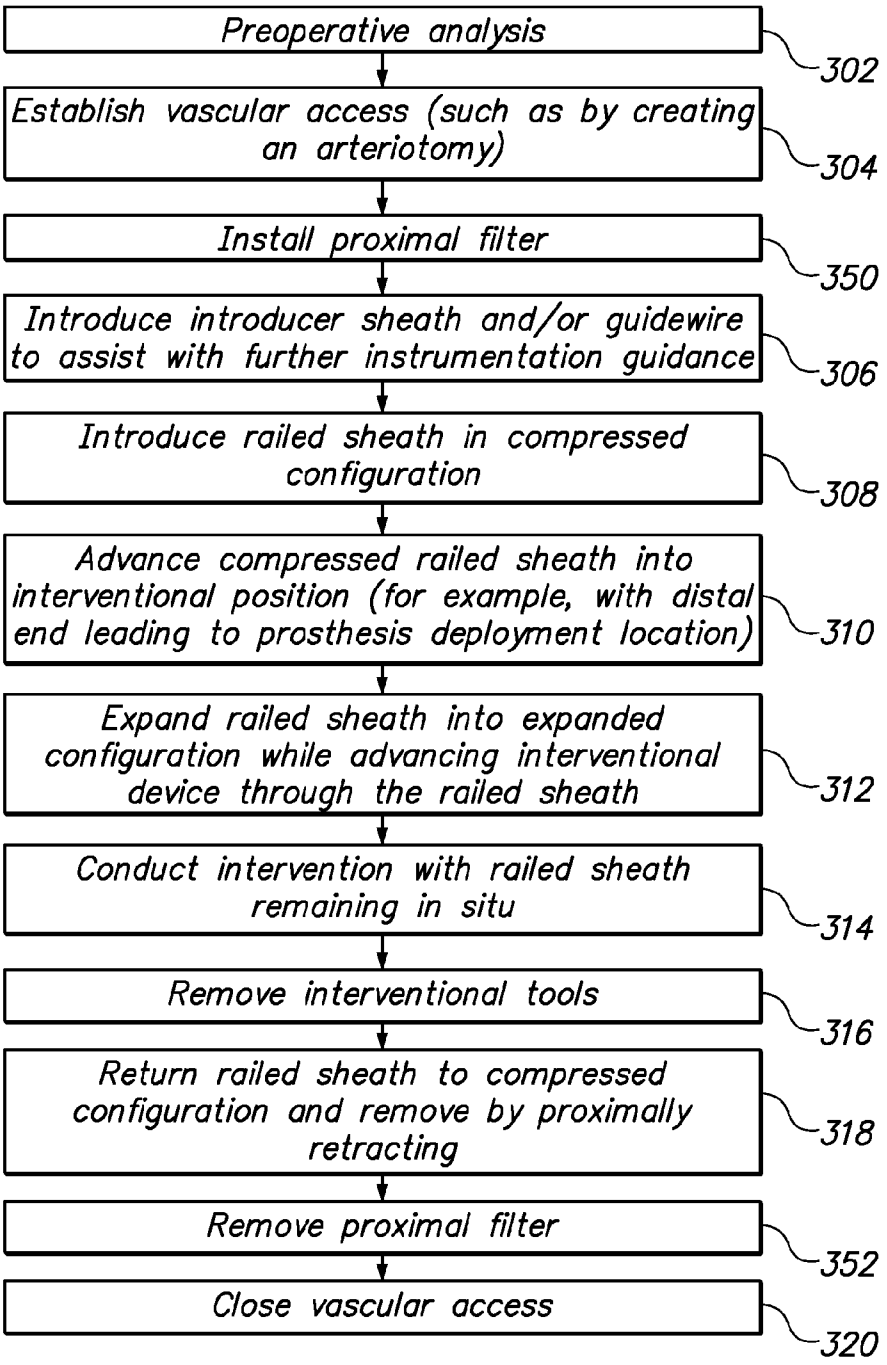


FIG. 15

Date Reçue/Date Received 2020-09-03

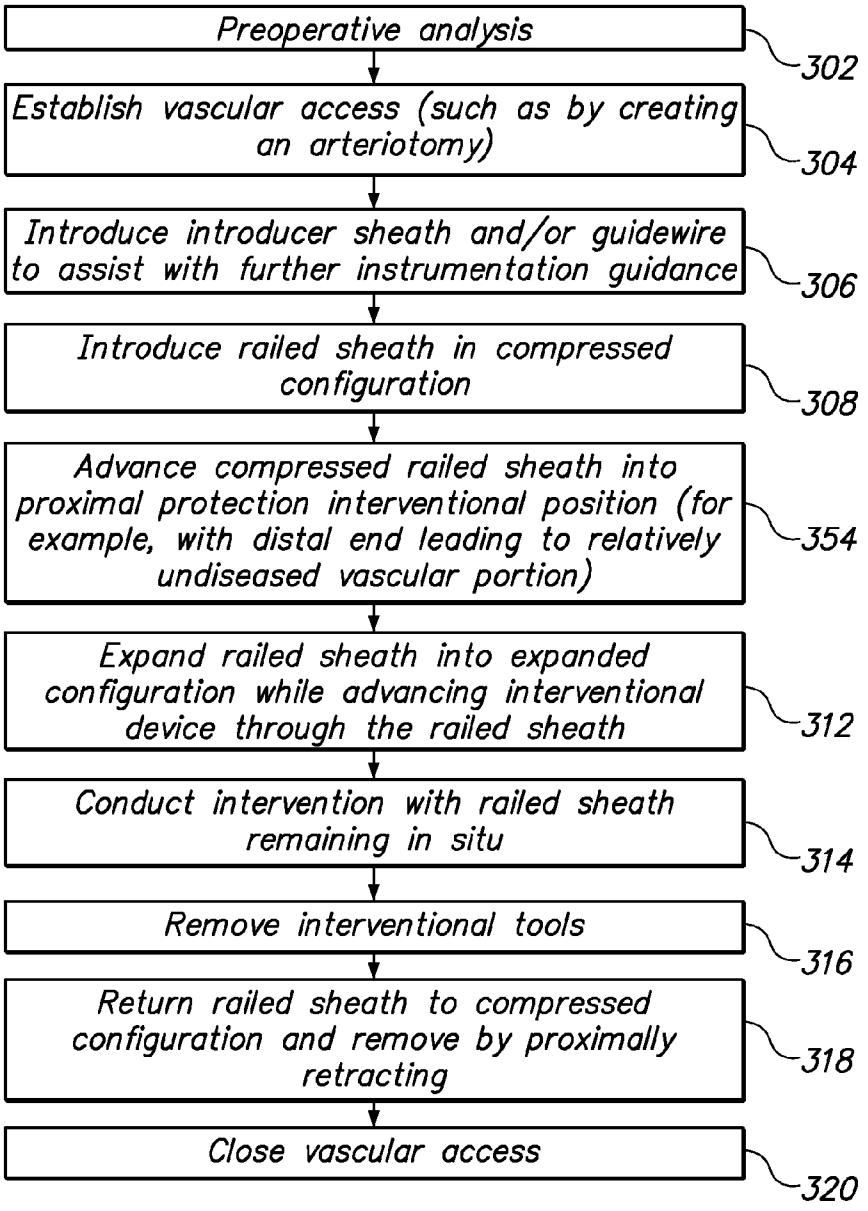


FIG. 16

Date Reçue/Date Received 2020-09-03

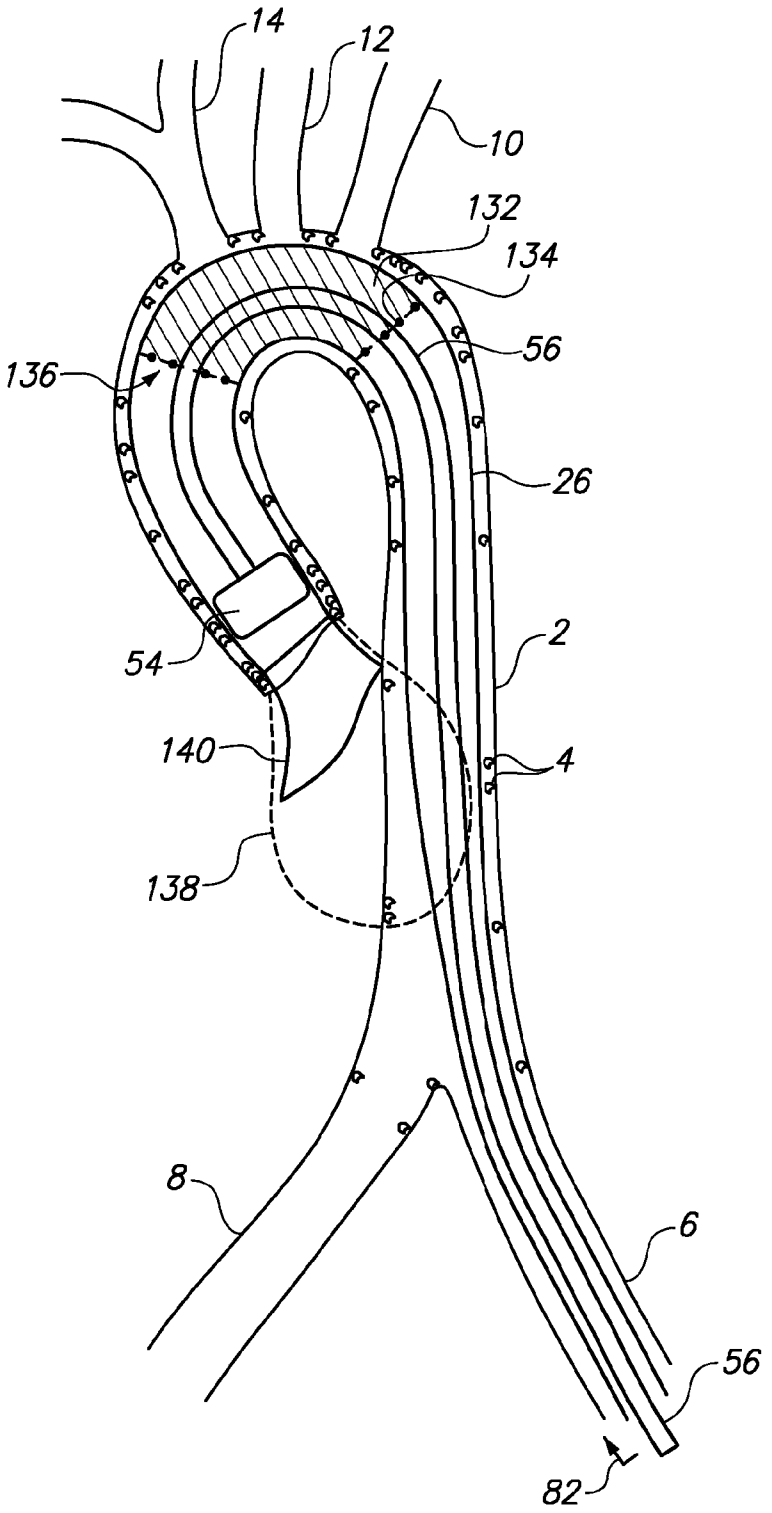


FIG. 17A

Date Reçue/Date Received 2020-09-03

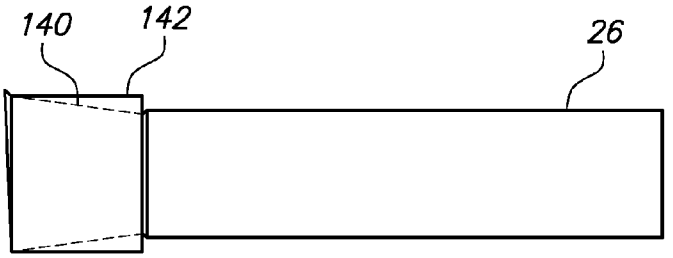


FIG. 17B

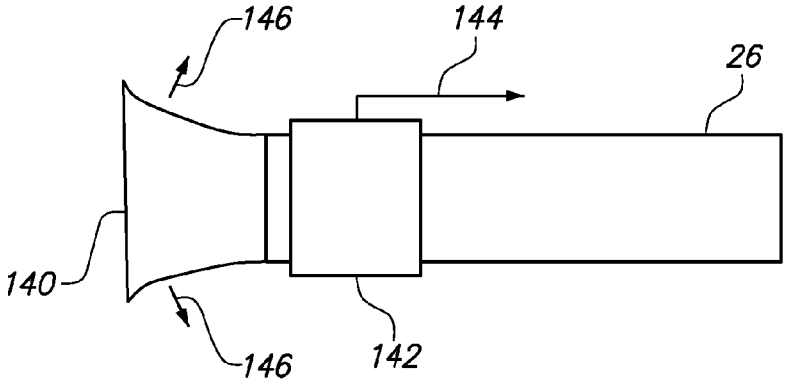


FIG. 17C

Date Reçue/Date Received 2020-09-03

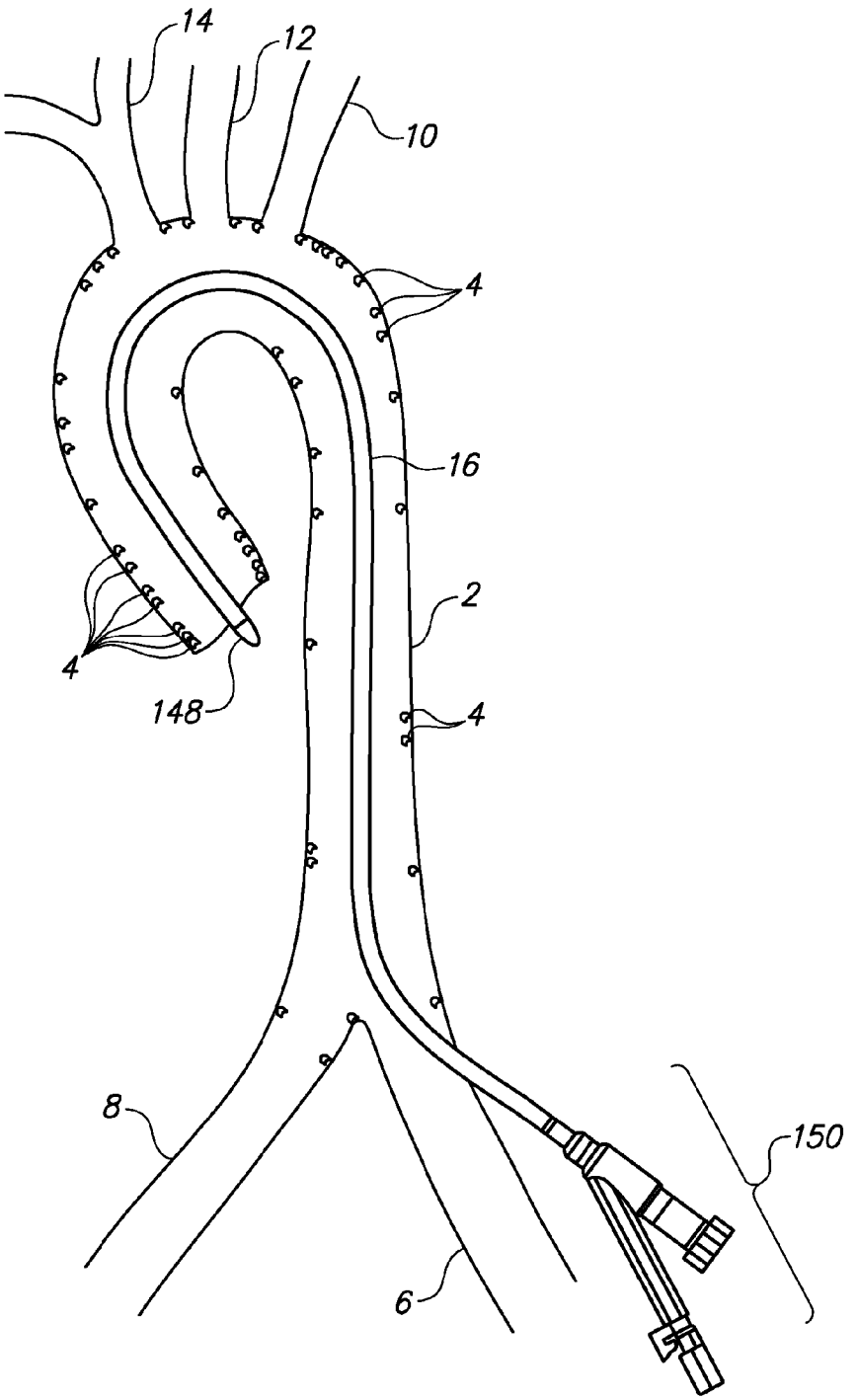


FIG. 18A

Date Reçue/Date Received 2020-09-03

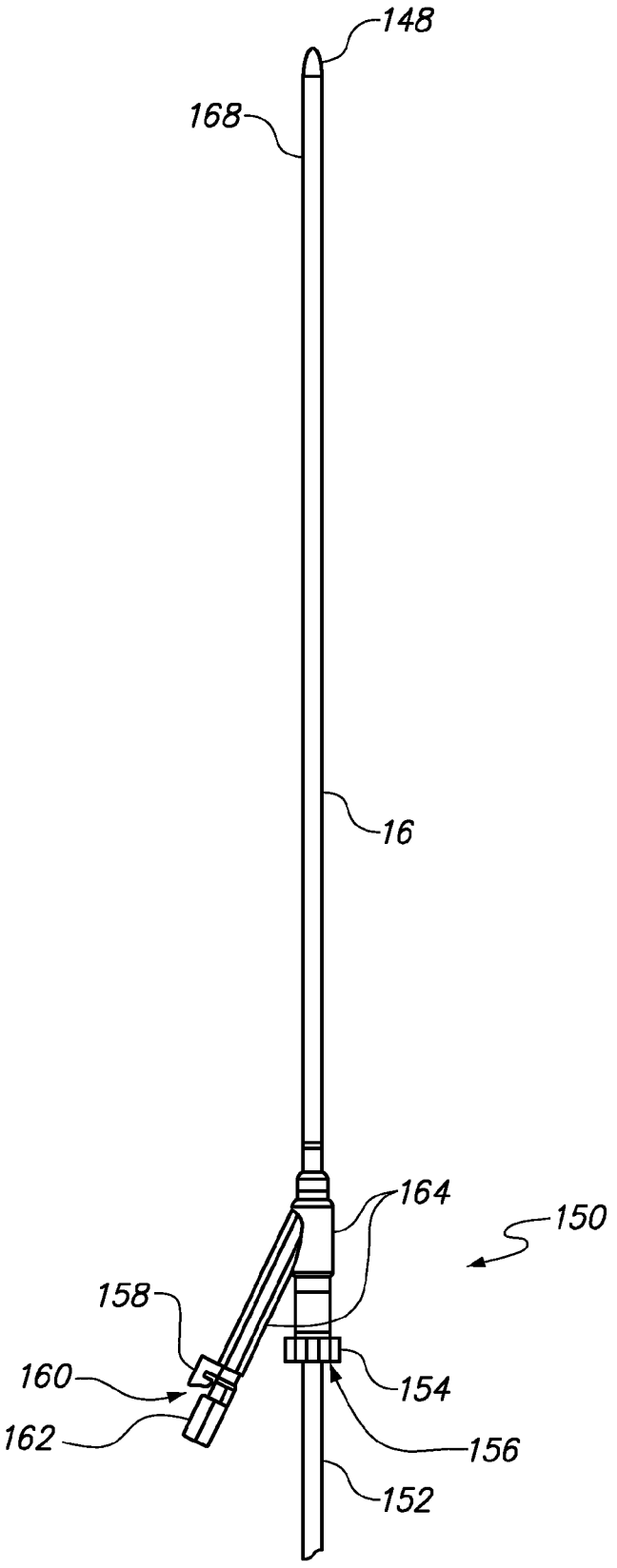


FIG. 18B

Date Reçue/Date Received 2020-09-03

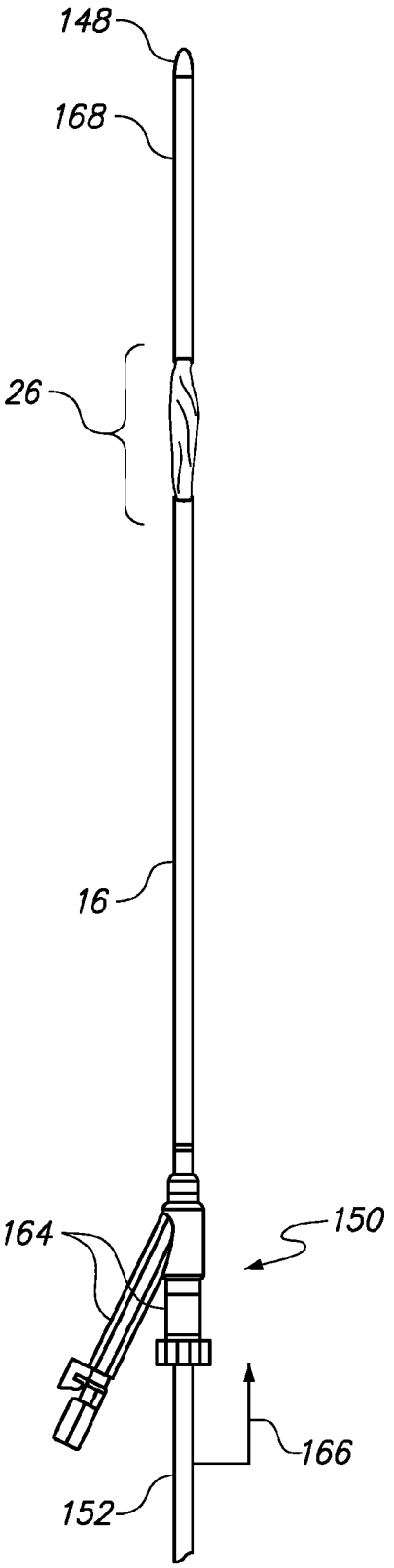


FIG. 18C

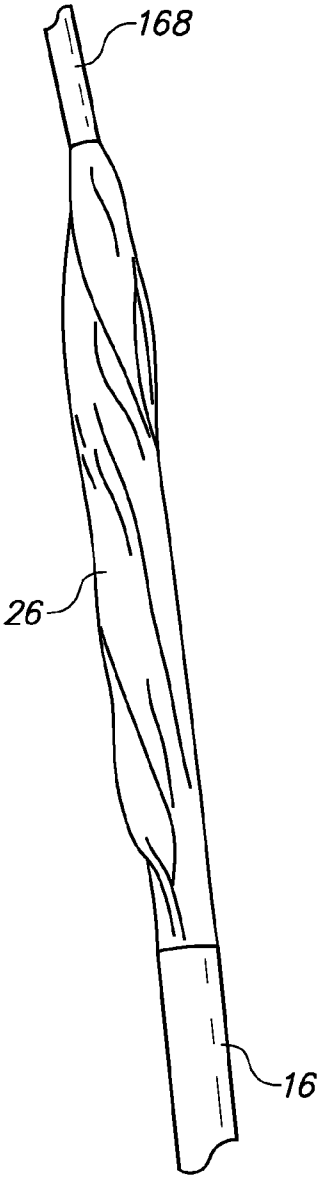


FIG. 18D

Date Reçue/Date Received 2020-09-03

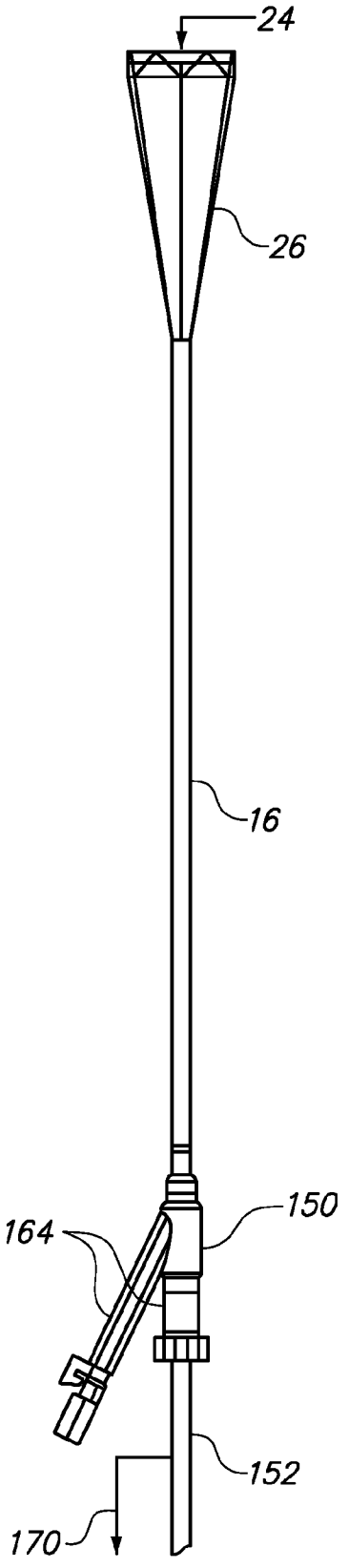


FIG. 18E

Date Reçue/Date Received 2020-09-03

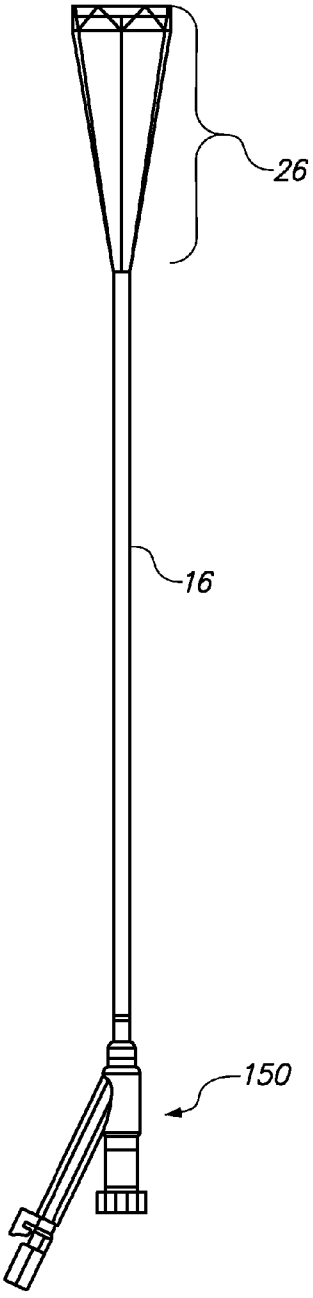


FIG. 18F

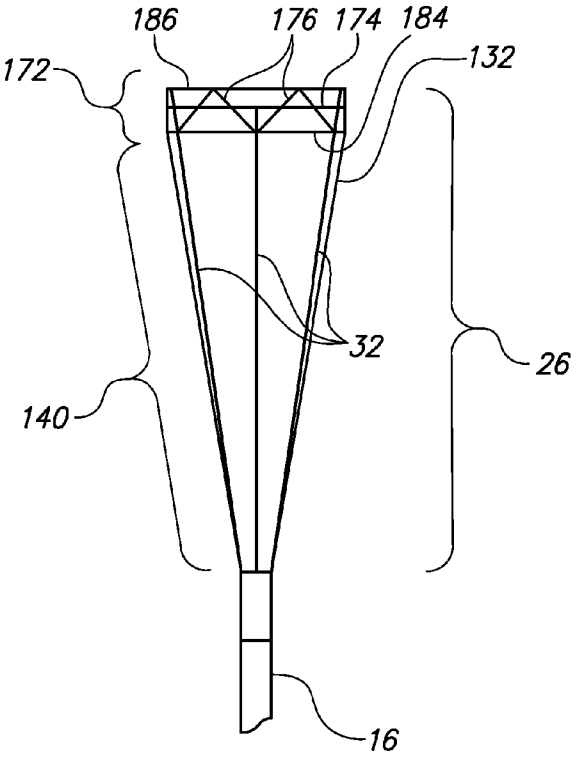


FIG. 18G

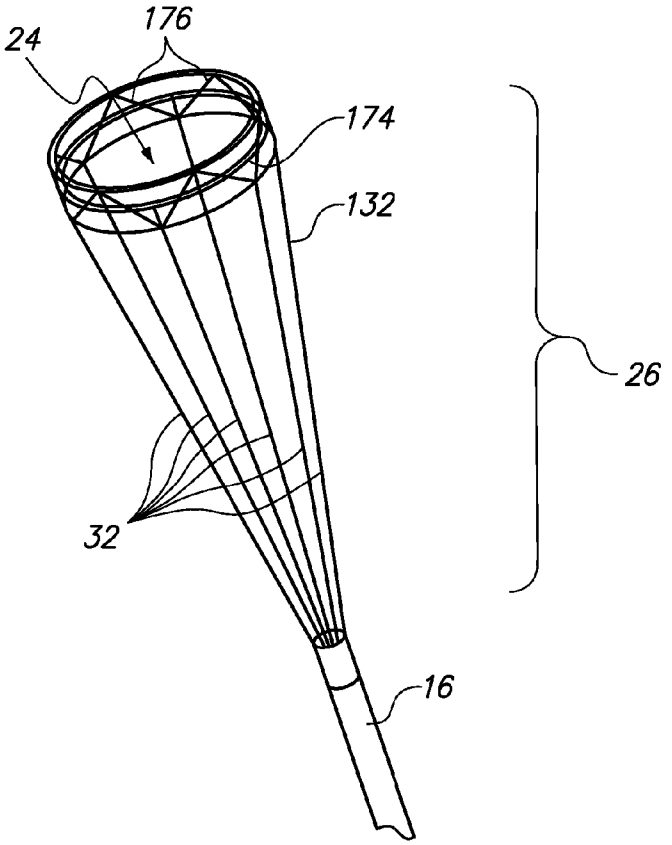


FIG. 18H

Date Reçue/Date Received 2020-09-03

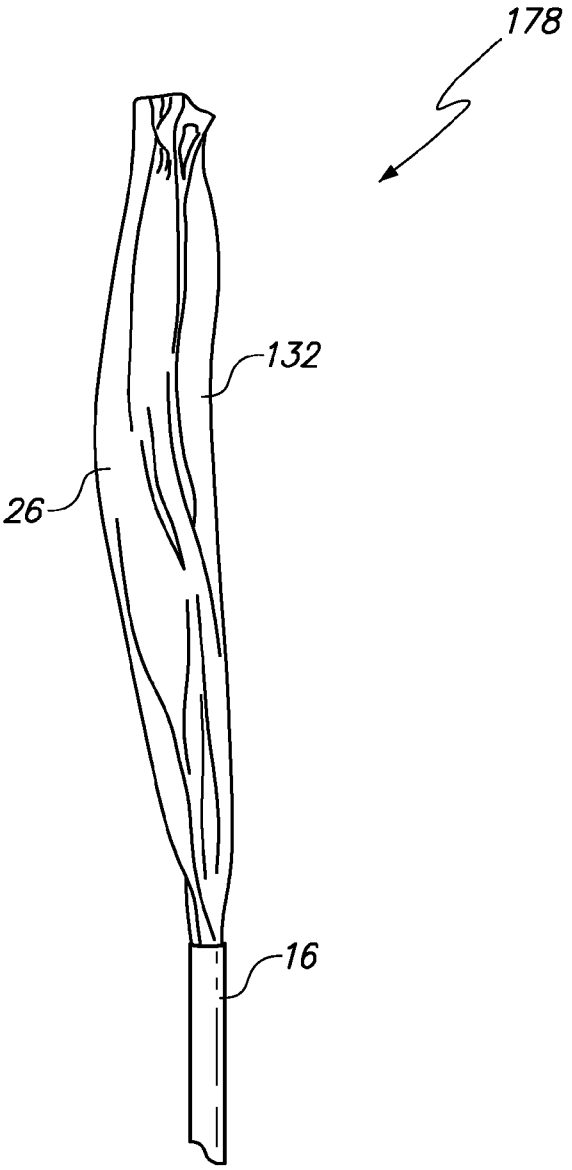


FIG. 18I

Date Reçue/Date Received 2020-09-03

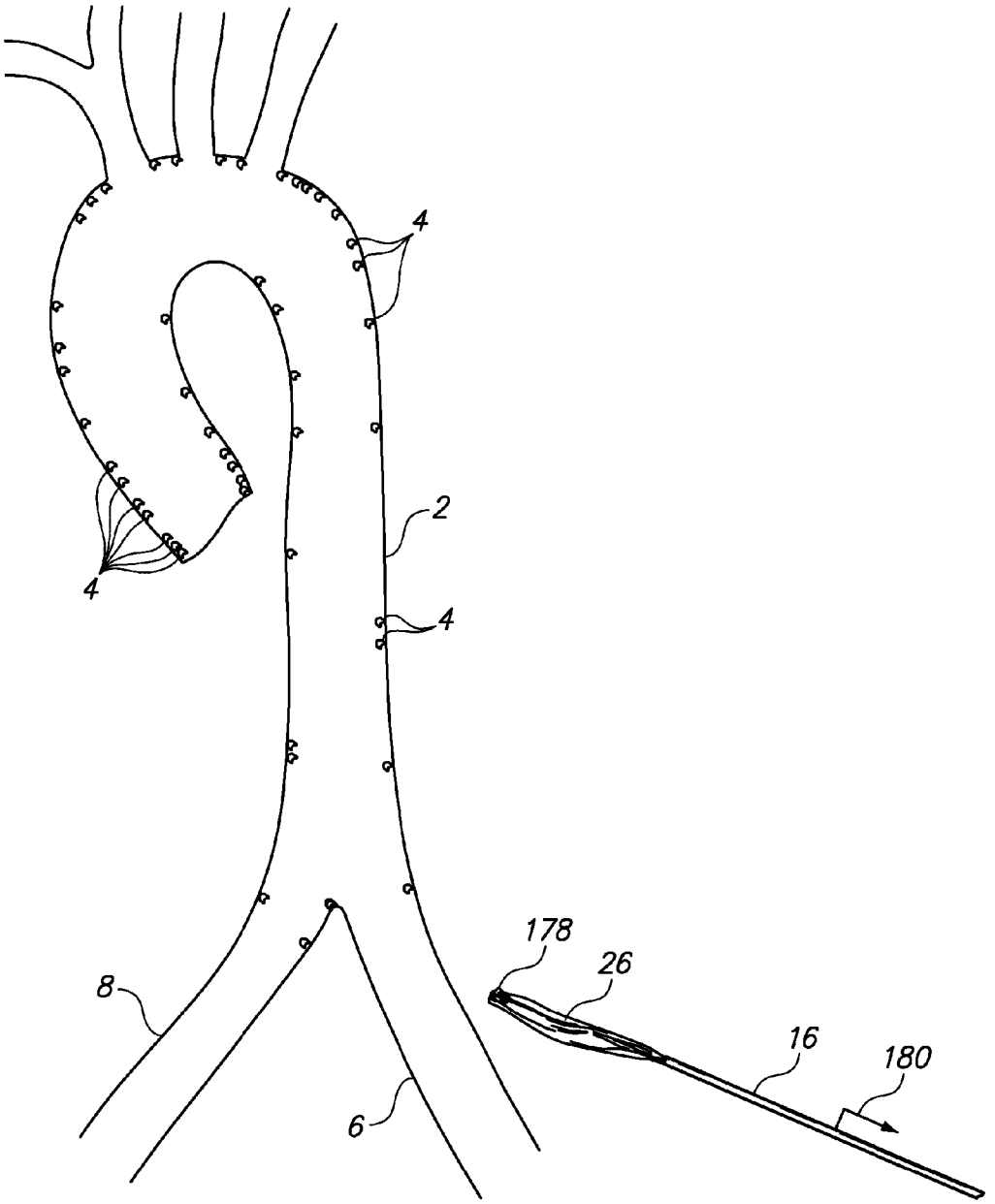


FIG. 18J

Date Reçue/Date Received 2020-09-03

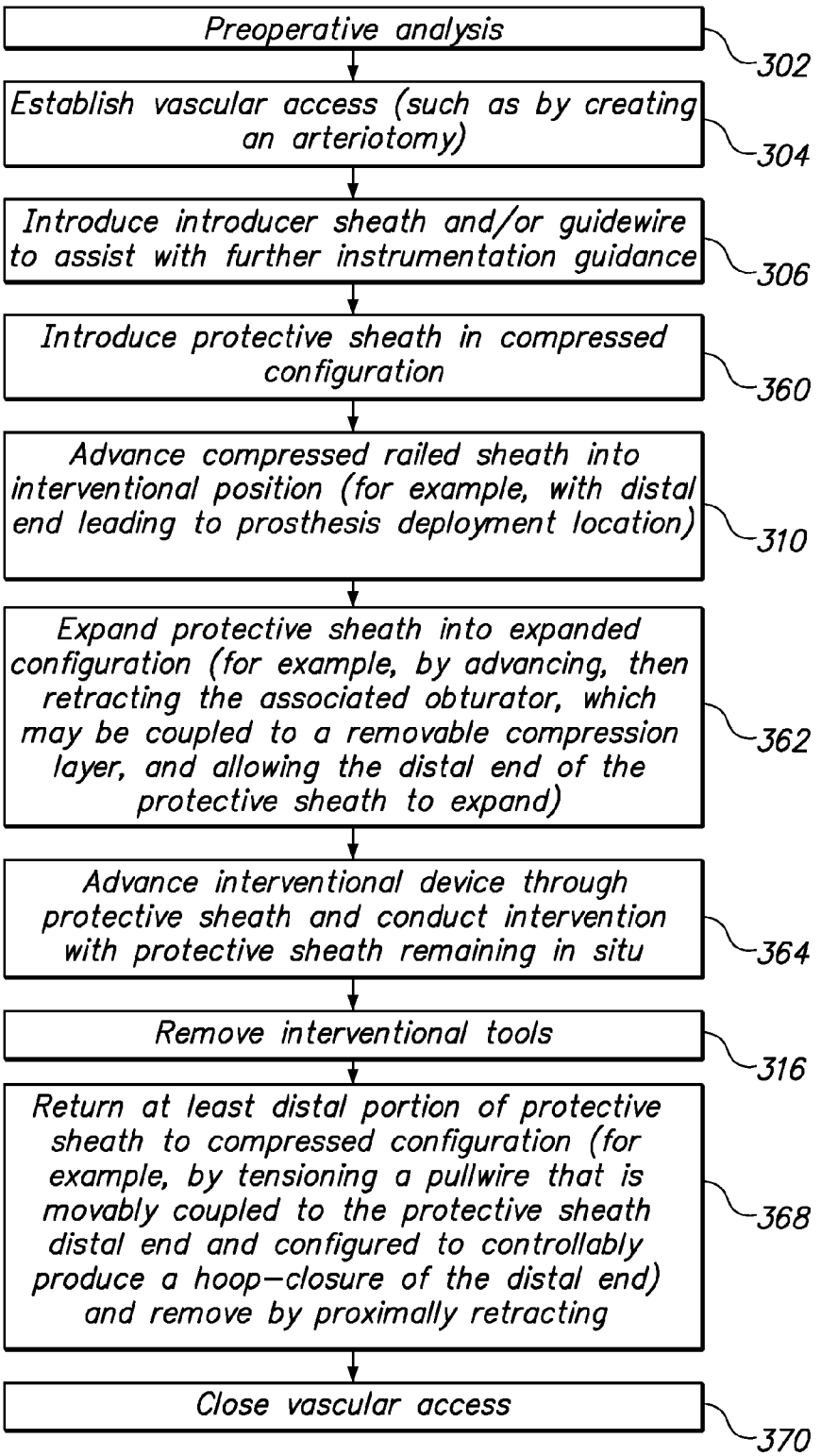
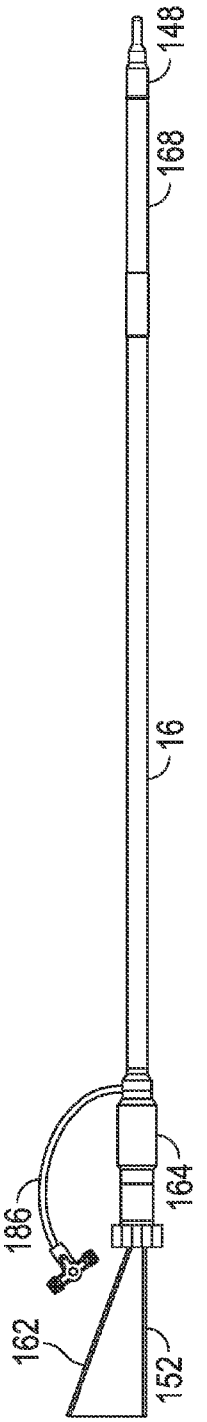


FIG. 19

Date Reçue/Date Received 2020-09-03



20A

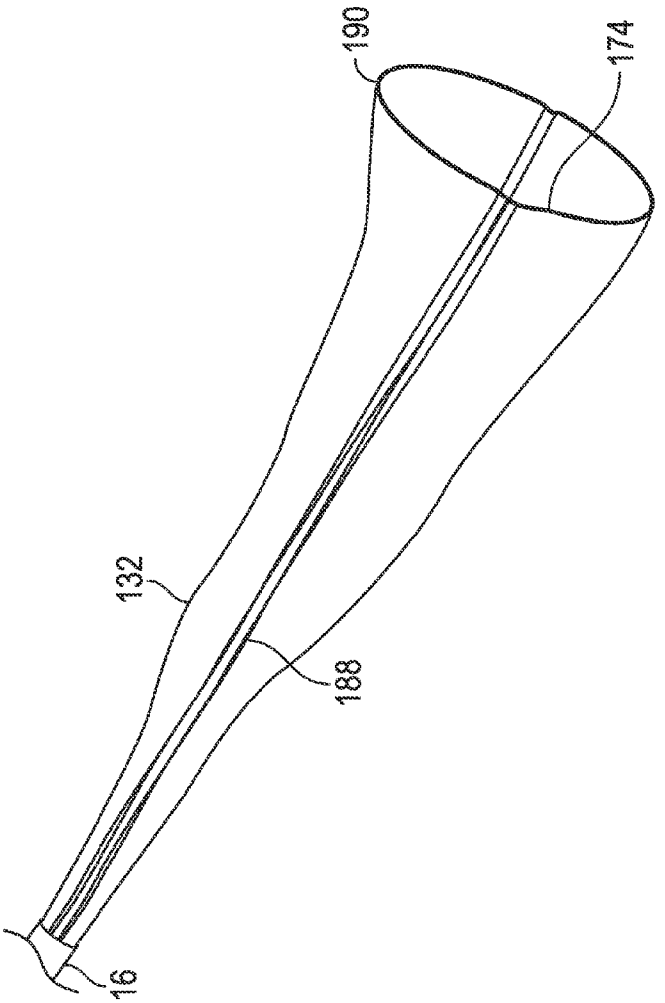


FIG. 20B

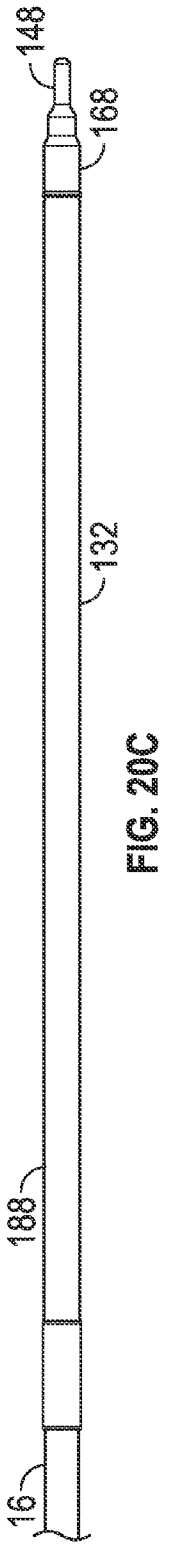


FIG. 20C

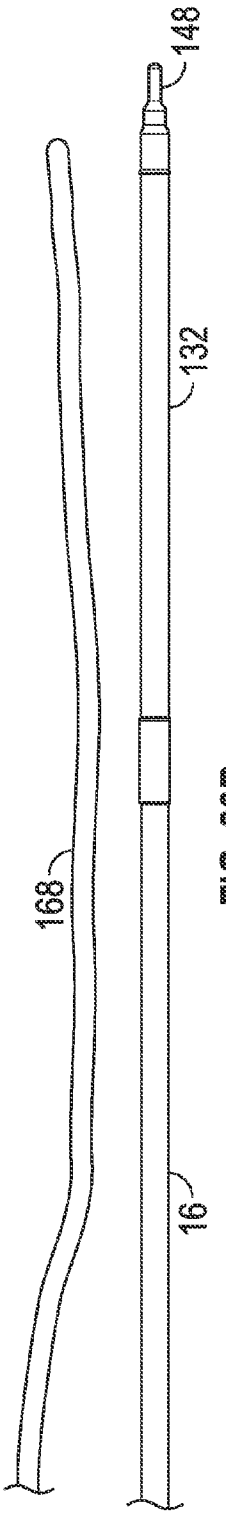


FIG. 20D

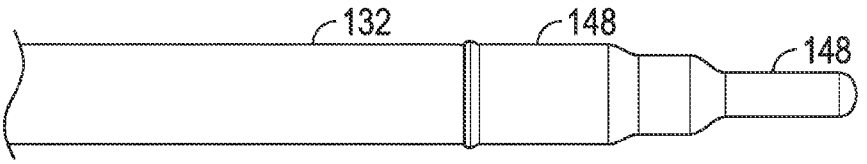


FIG. 20E

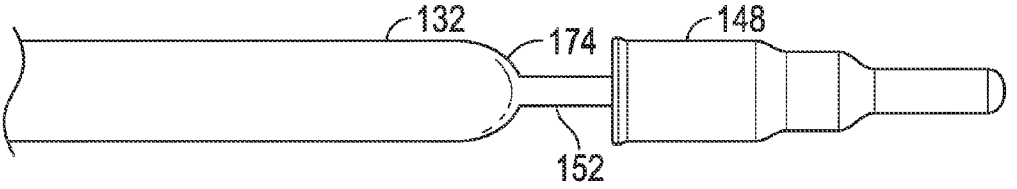


FIG. 20F

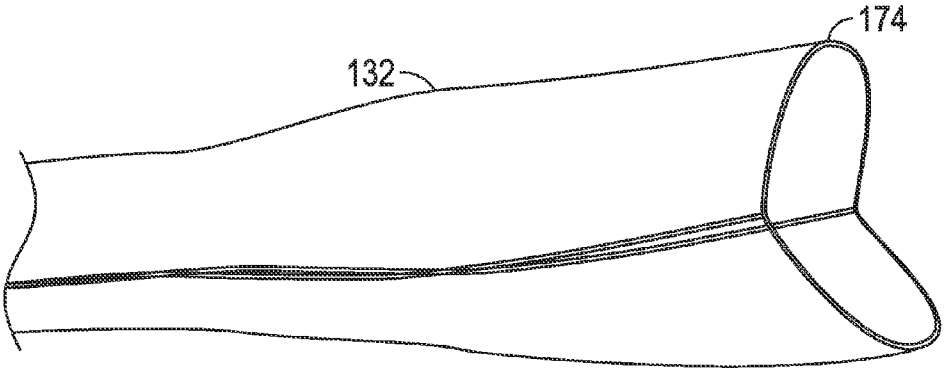


FIG. 20G

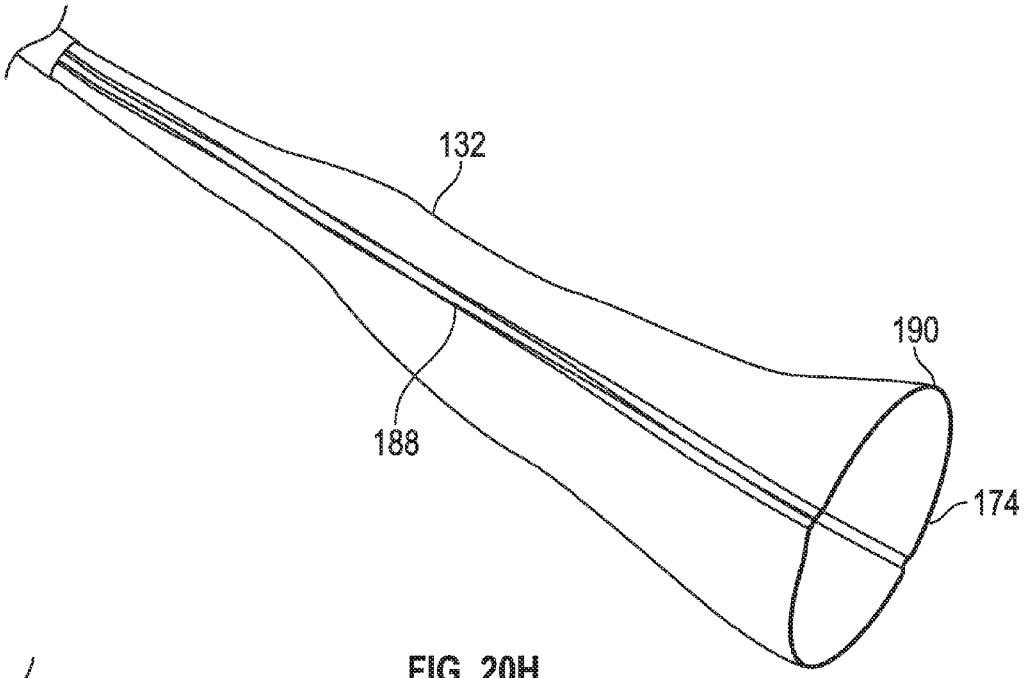


FIG. 20H

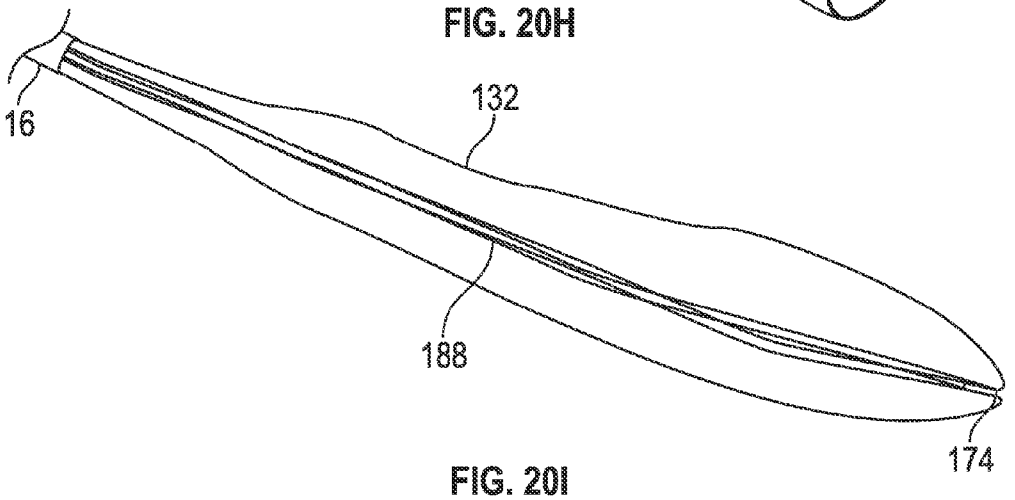


FIG. 20I

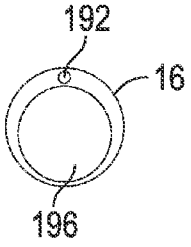


FIG. 20J

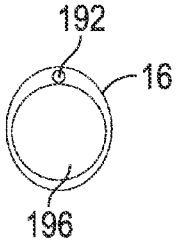


FIG. 20K

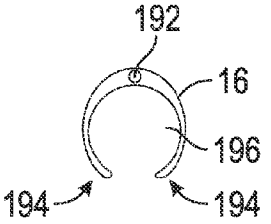


FIG. 20L

Date Reçue/Date Received 2020-09-03

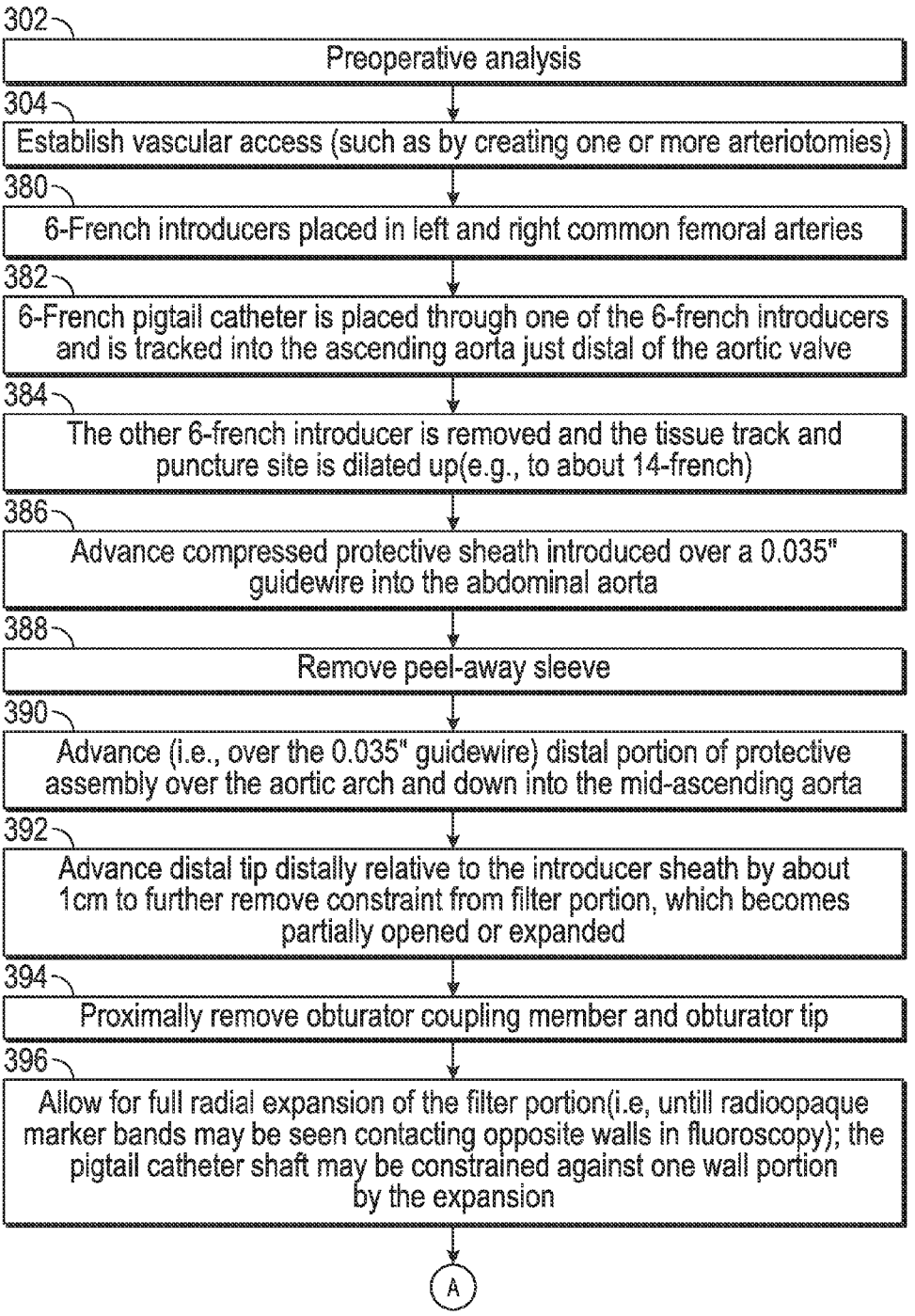


FIG. 21

Date Reçue/Date Received 2020-09-03

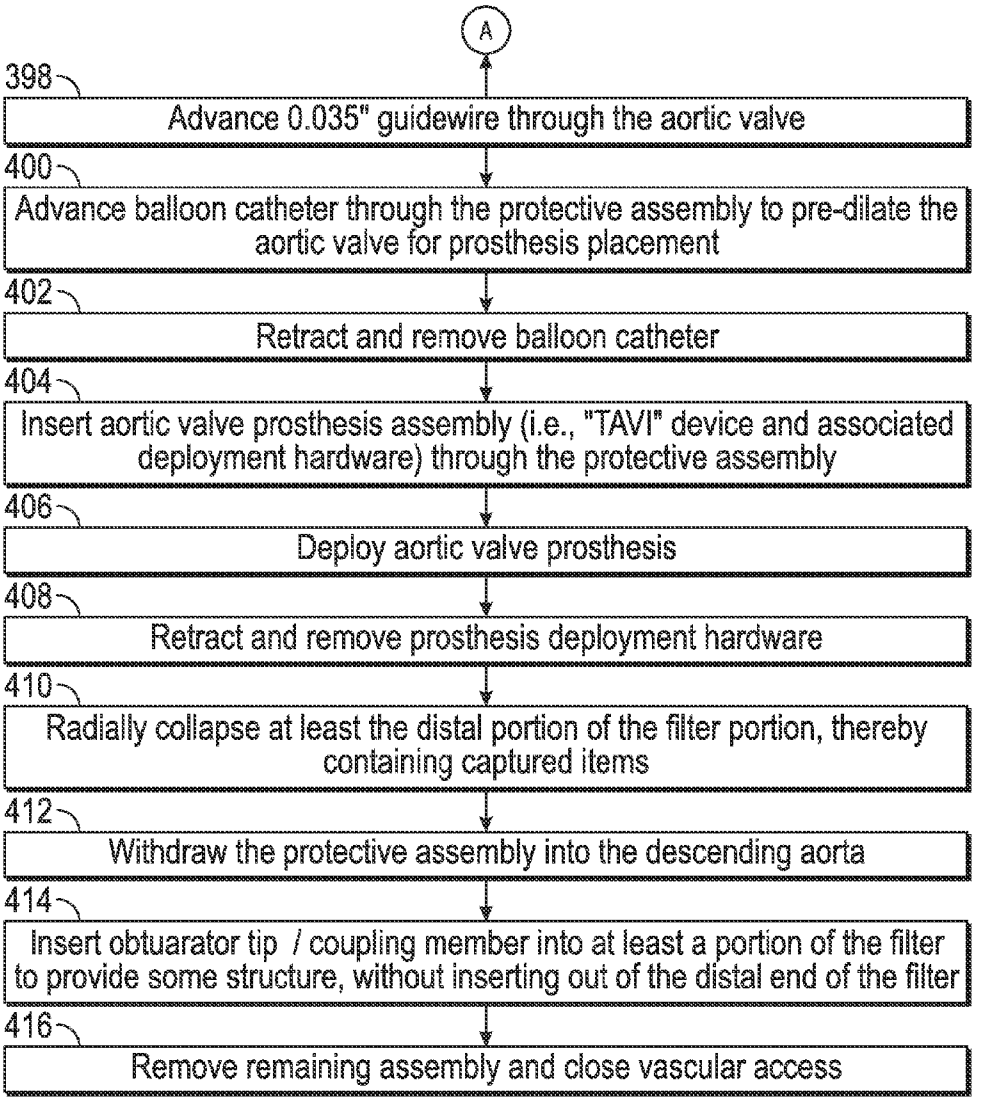
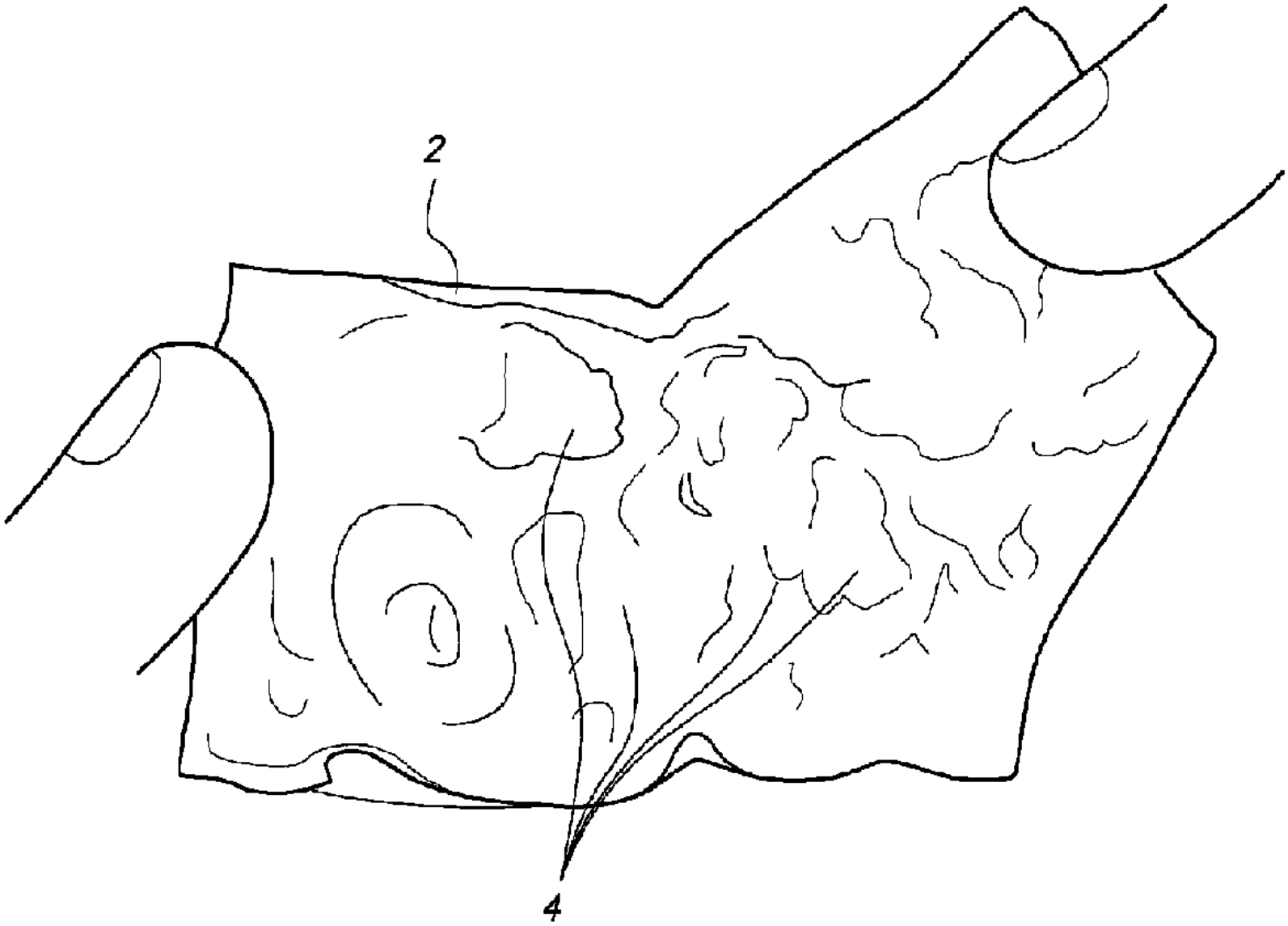


FIG. 21
(Continued)

Date Reçue/Date Received 2020-09-03


2
4