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(54) **COMPONENTS, SYSTEMS, AND METHODS FOR FORMING ANASTOMOSES USING MAGNETISM OR OTHER COUPLING MEANS**

continuation-in-part of application No. 09/638,805, filed on Aug. 12, 2000, now Pat. No. 6,719,768, which is a continuation-in-part of application No. 09/562,599, filed on Apr. 29, 2000, now Pat. No. 6,352,543.

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(57) **ABSTRACT**

Anastomotic components may be attached to hollow bodies or vessels by magnetic or mechanical force to create an anastomosis, form a port in a vessel, or repair a diseased vessel lumen. Anastomoses are created by coupling a first connection to an end of a vessel and then attracting it to a second connector secured to the side wall of another vessel. The connection between the first and second connectors may be solidly magnetic, solely mechanical, or a combination thereof. Also disclosed are methods and devices for treating diseased vessel lumens, for example abdominal aortic aneurysm. A plurality of docking members is attached to the vessel at solicited positions, and then one or more grafts is secured to the docking members in any suitable manner.

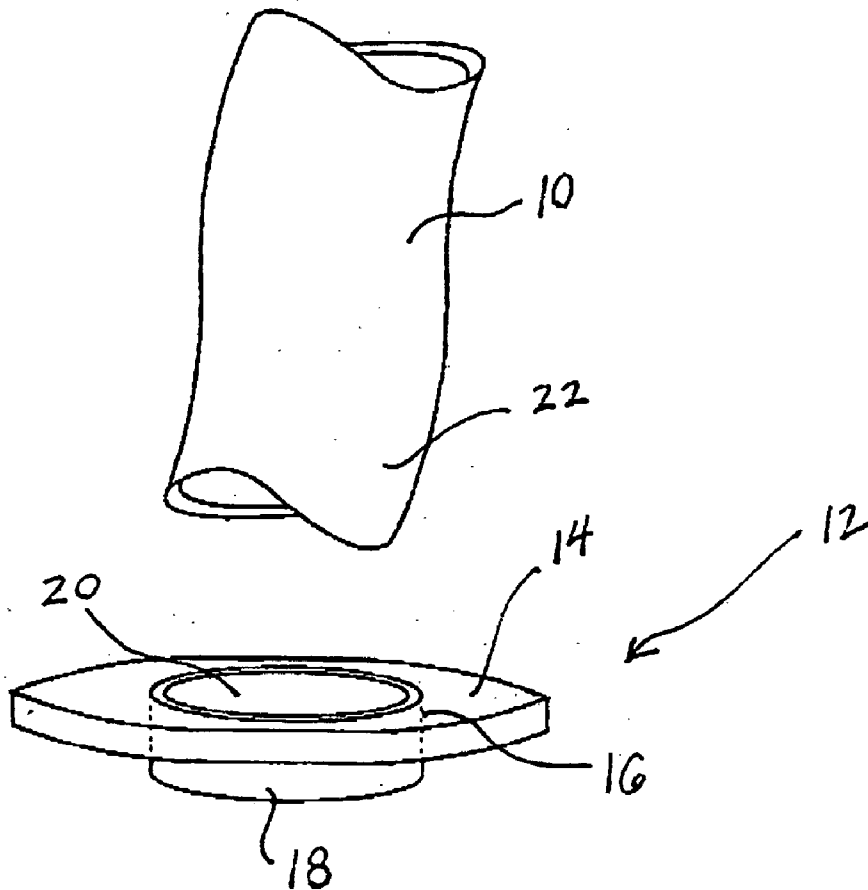
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(21) Appl. No.: **11/818,360**

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(63) Continuation of application No. 10/444,501, filed on May 23, 2003, now Pat. No. 7,241,300, which is a



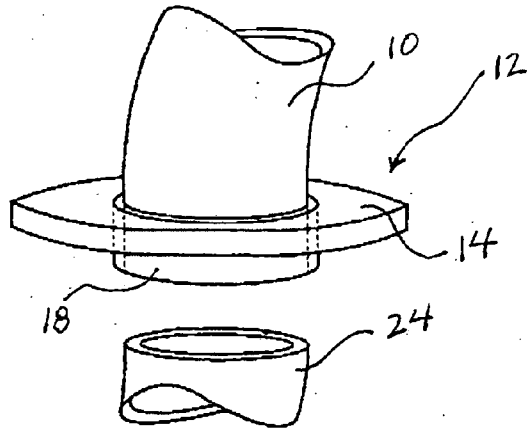
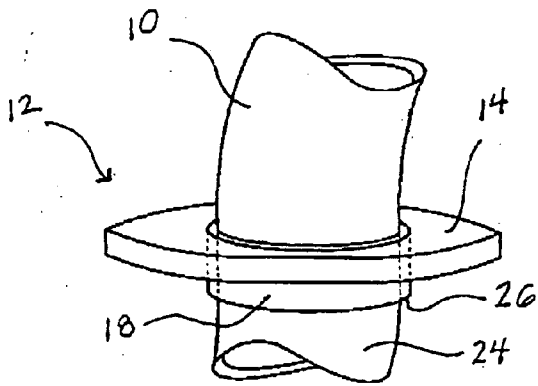
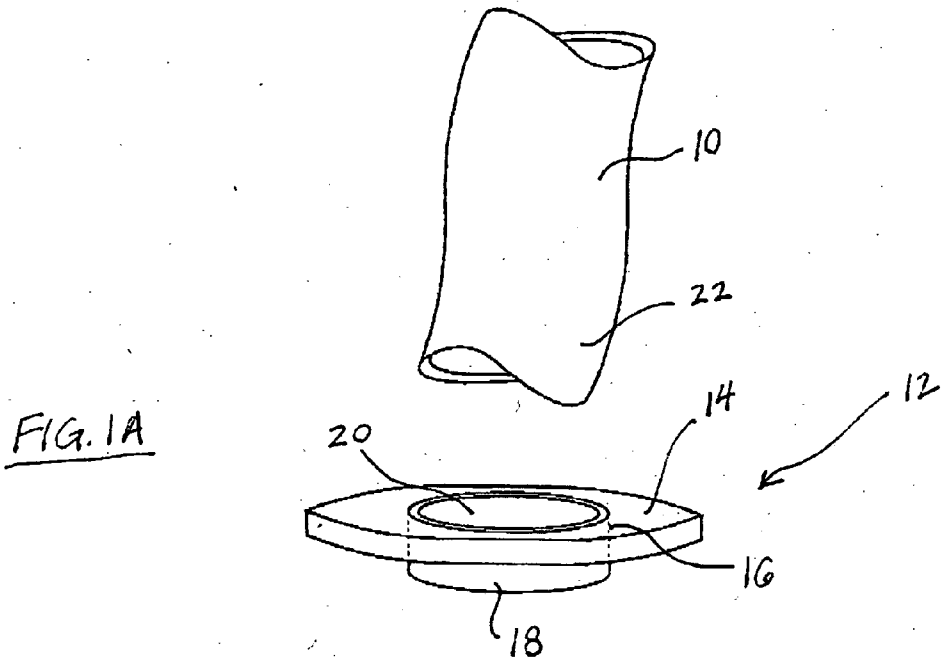


FIG. 2A

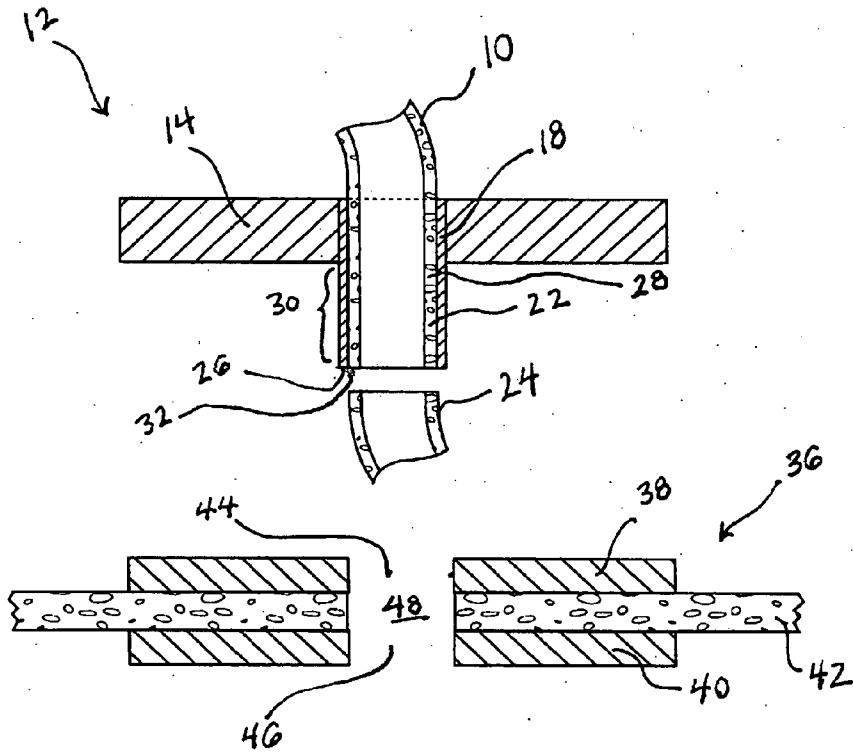


FIG. 2B

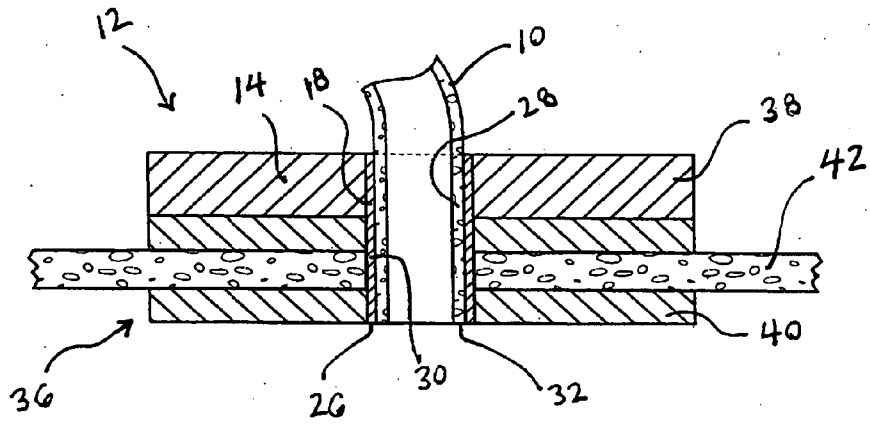
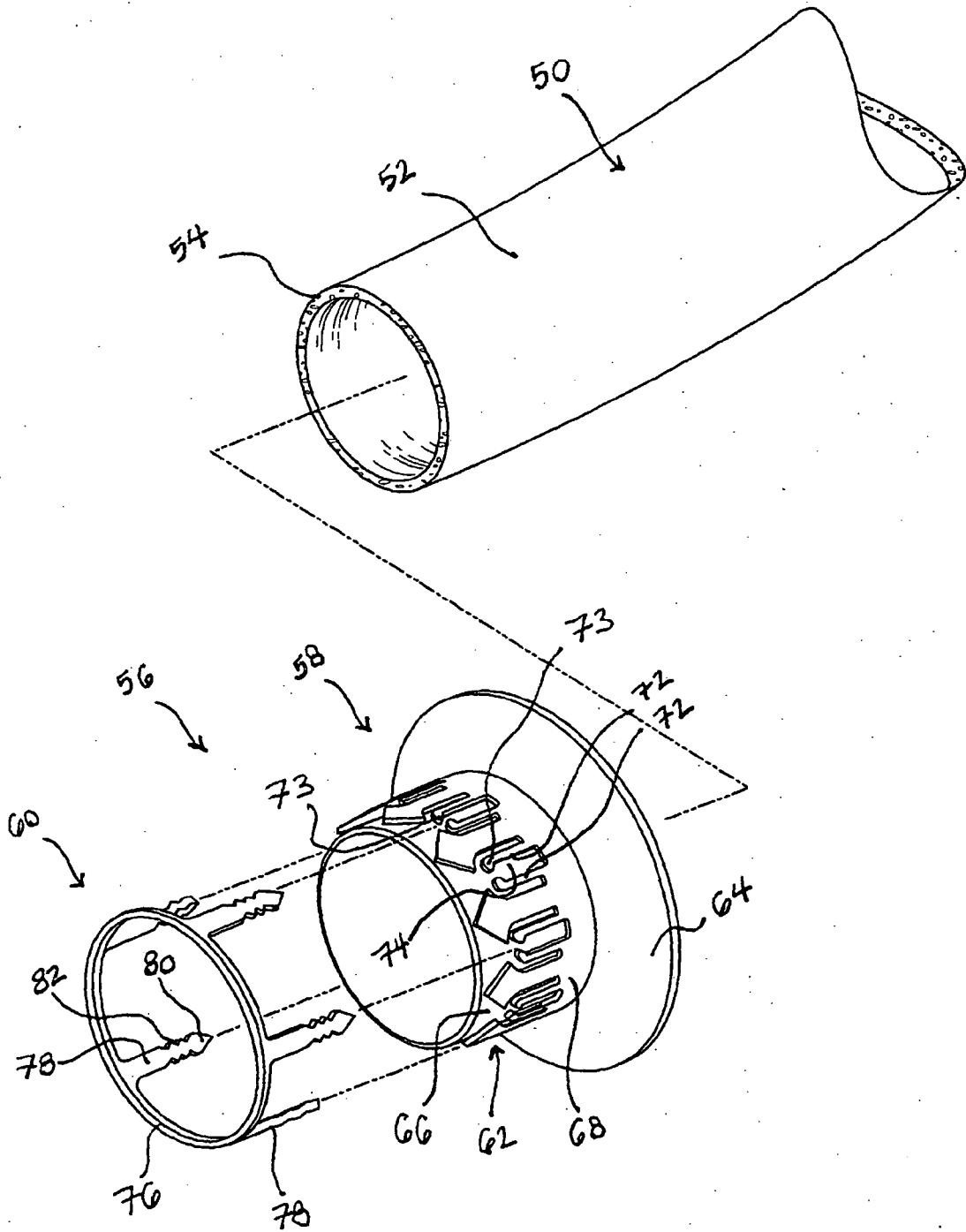


FIG. 3A



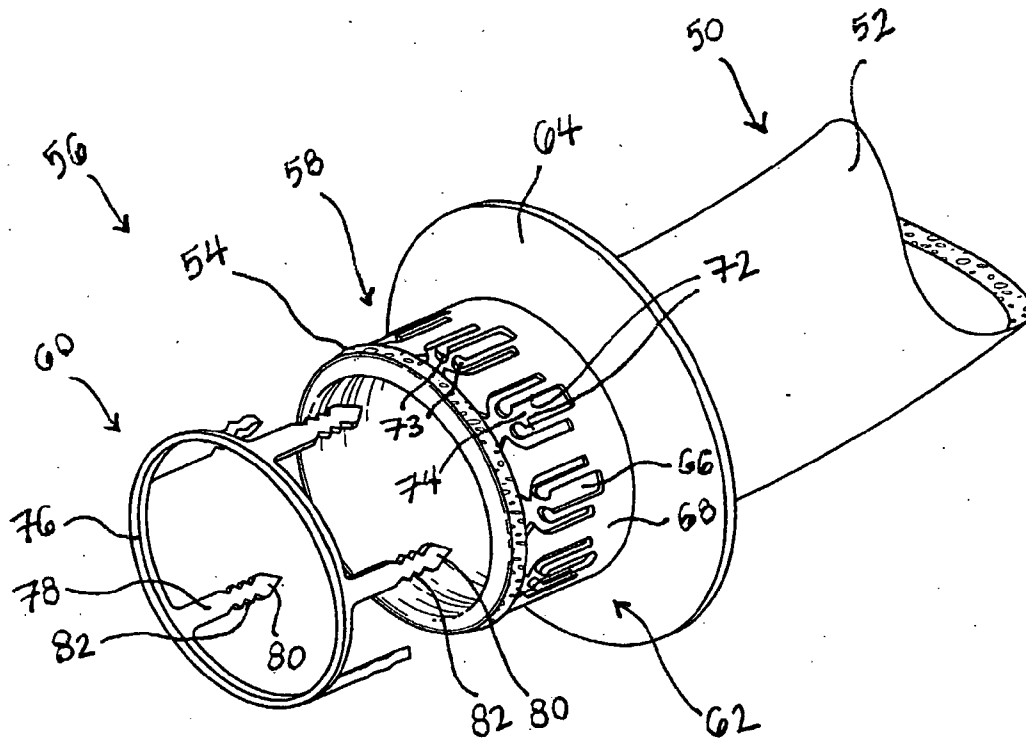


FIG. 3B

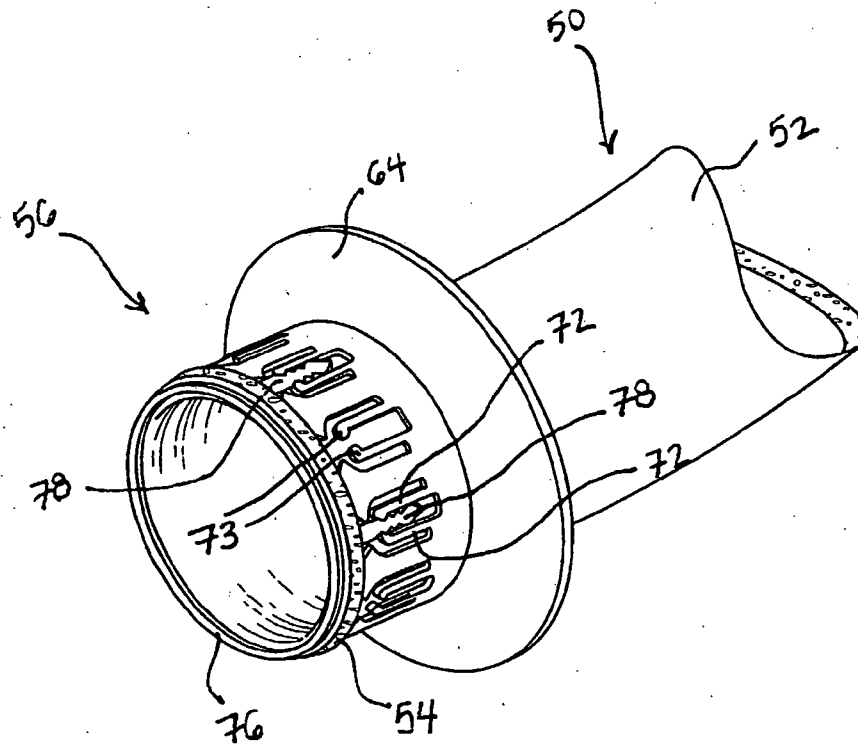


FIG. 3C

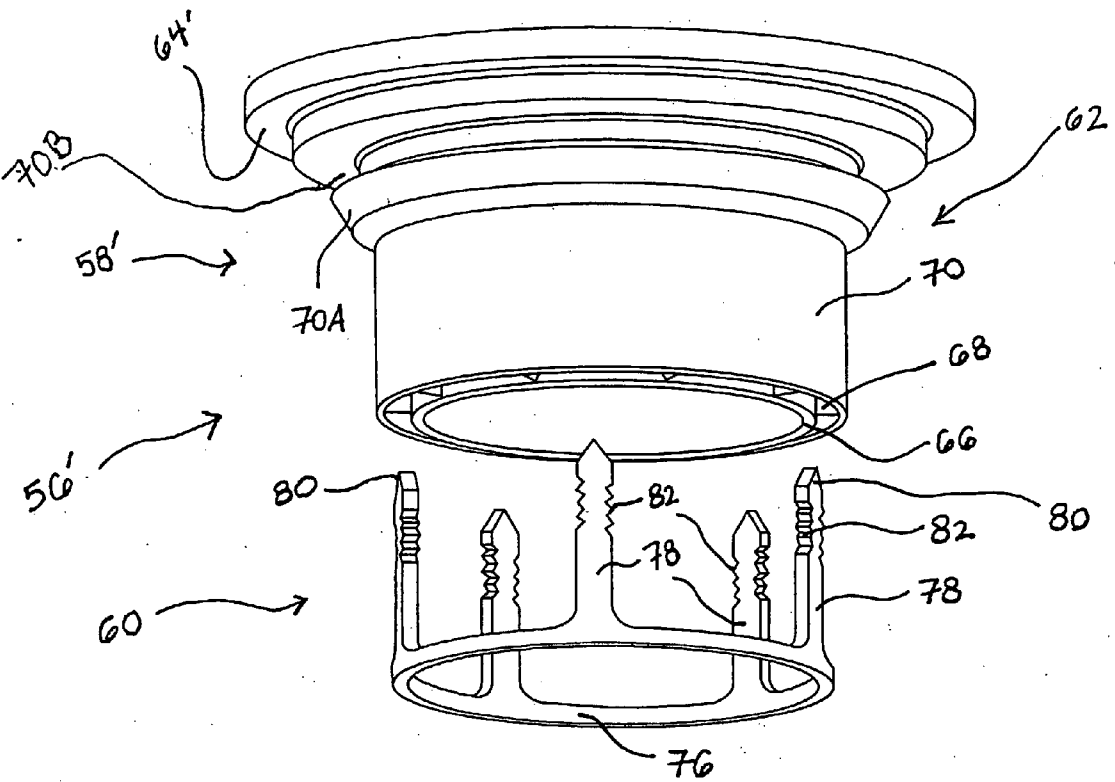


FIG. 4A

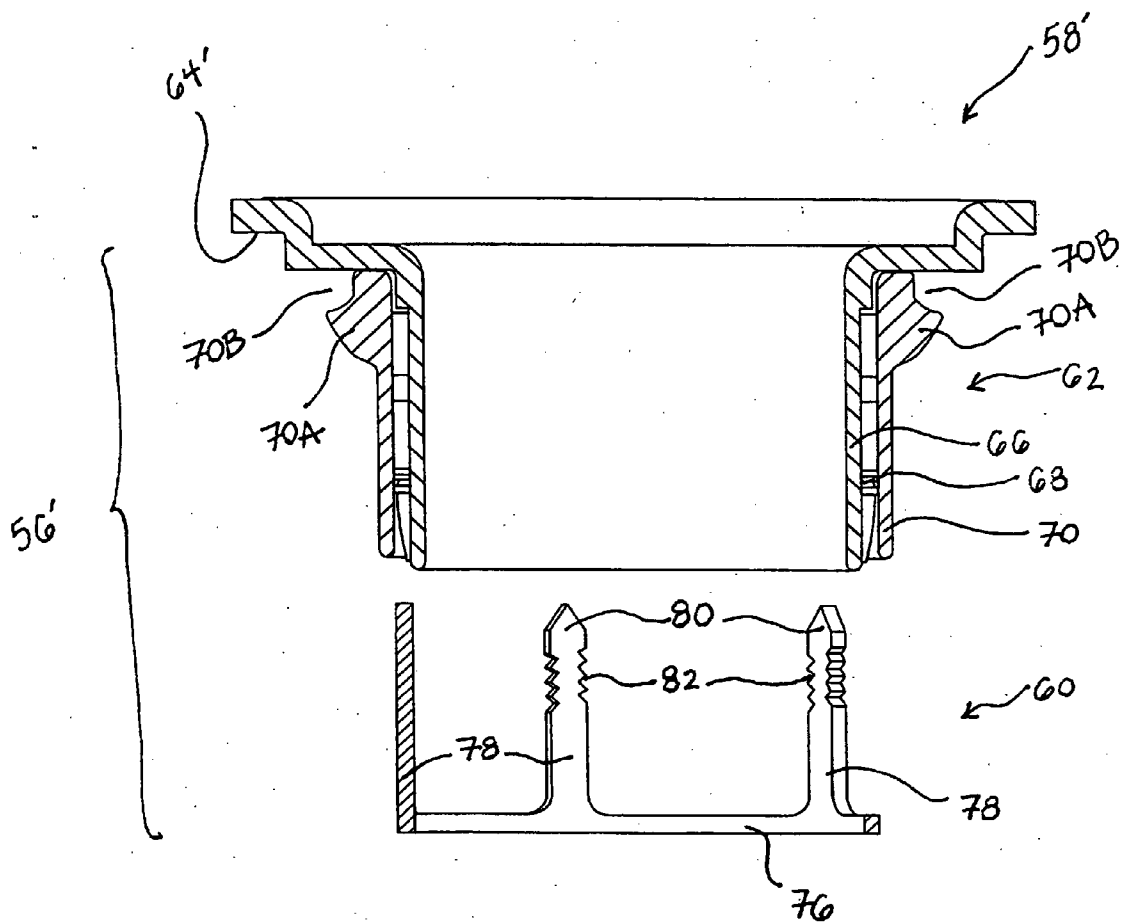


FIG. 4B

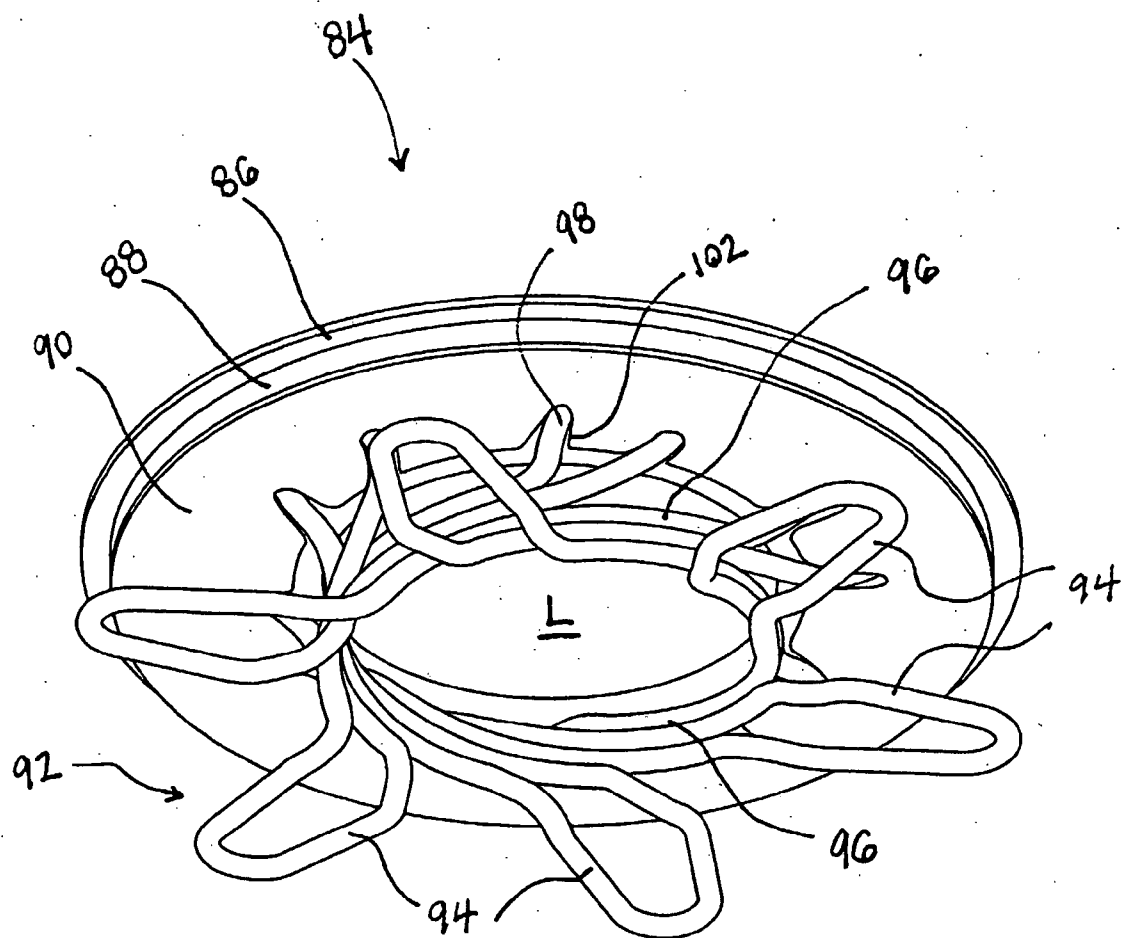


FIG. 5

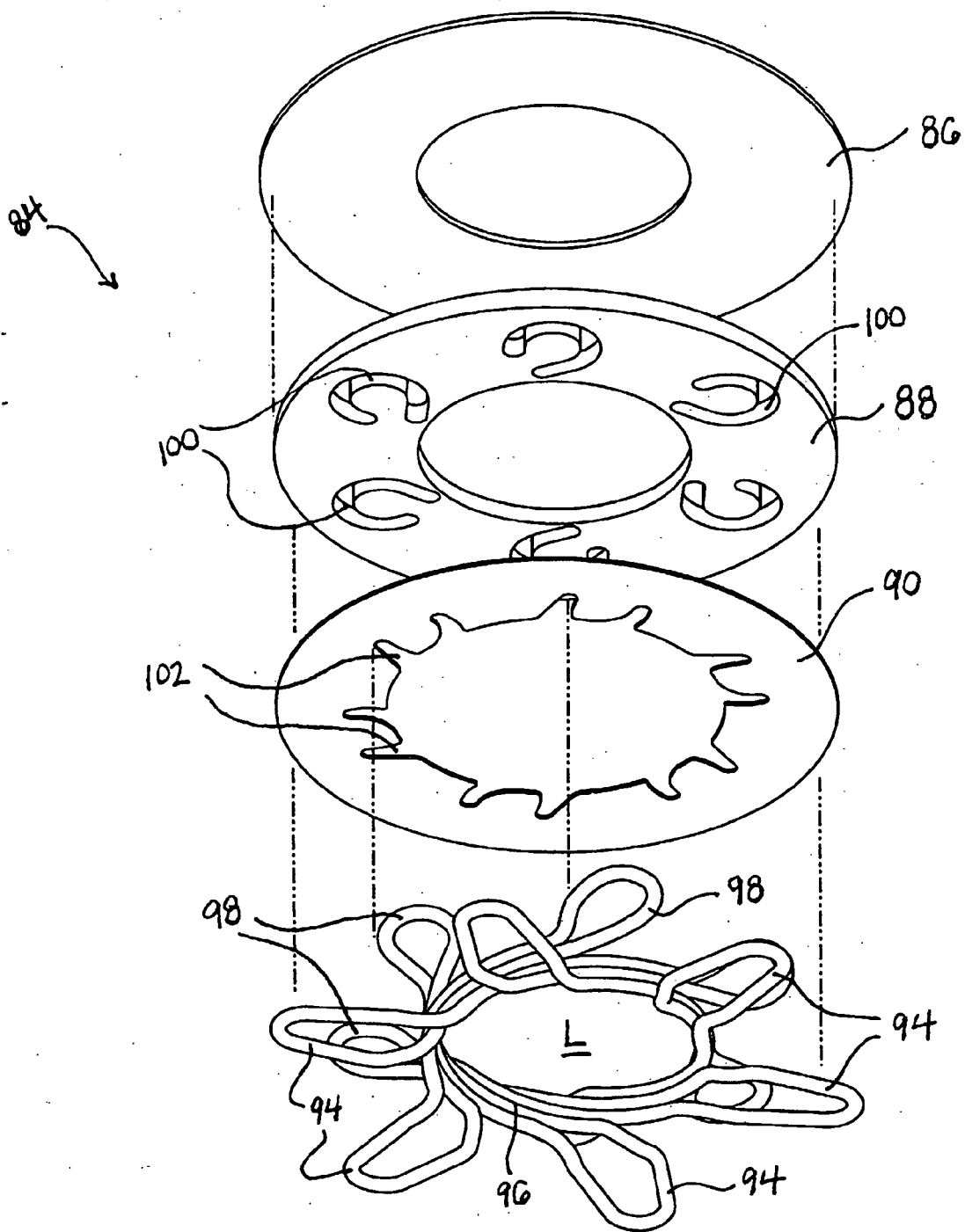


FIG. 6

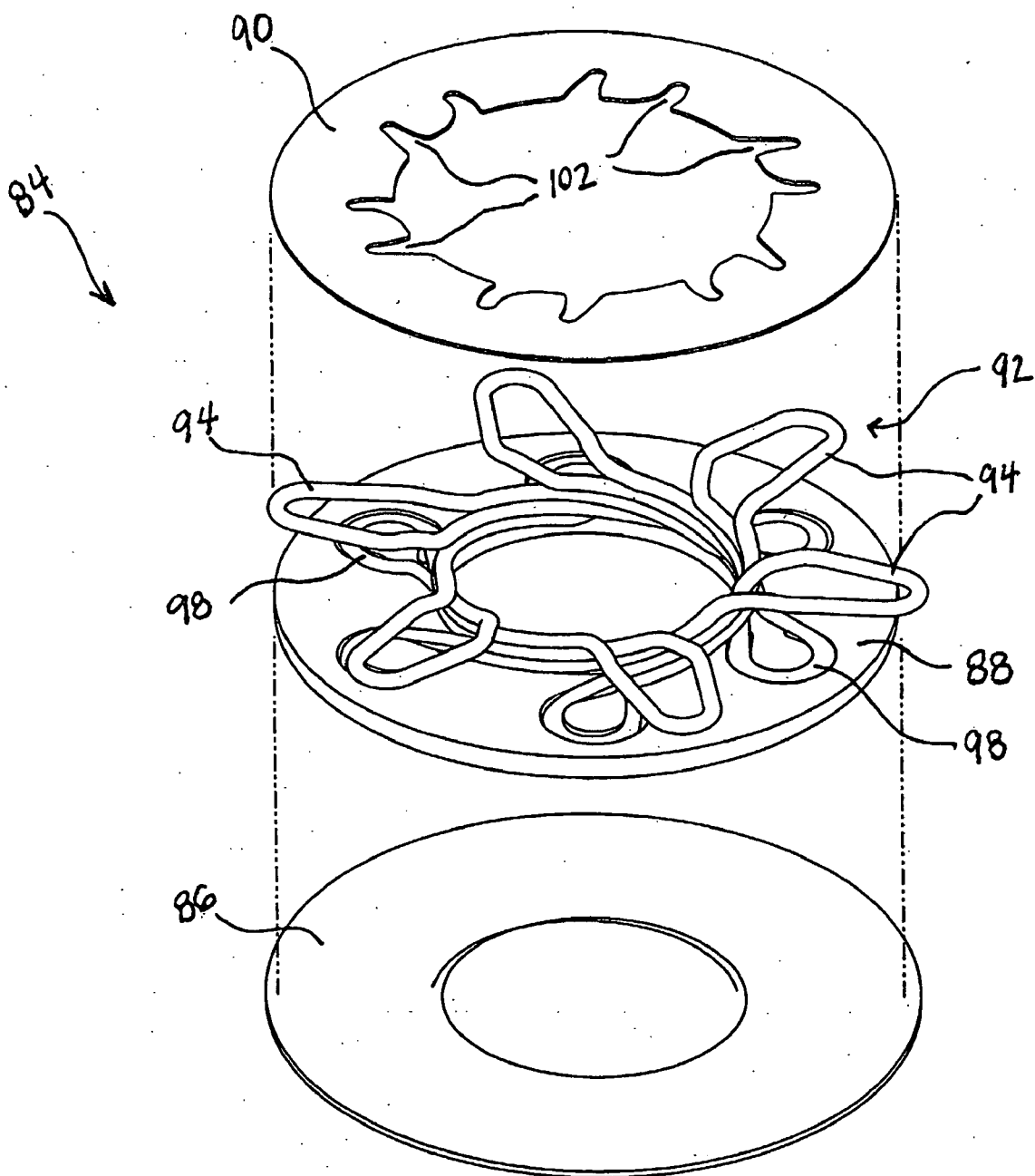


FIG. 7

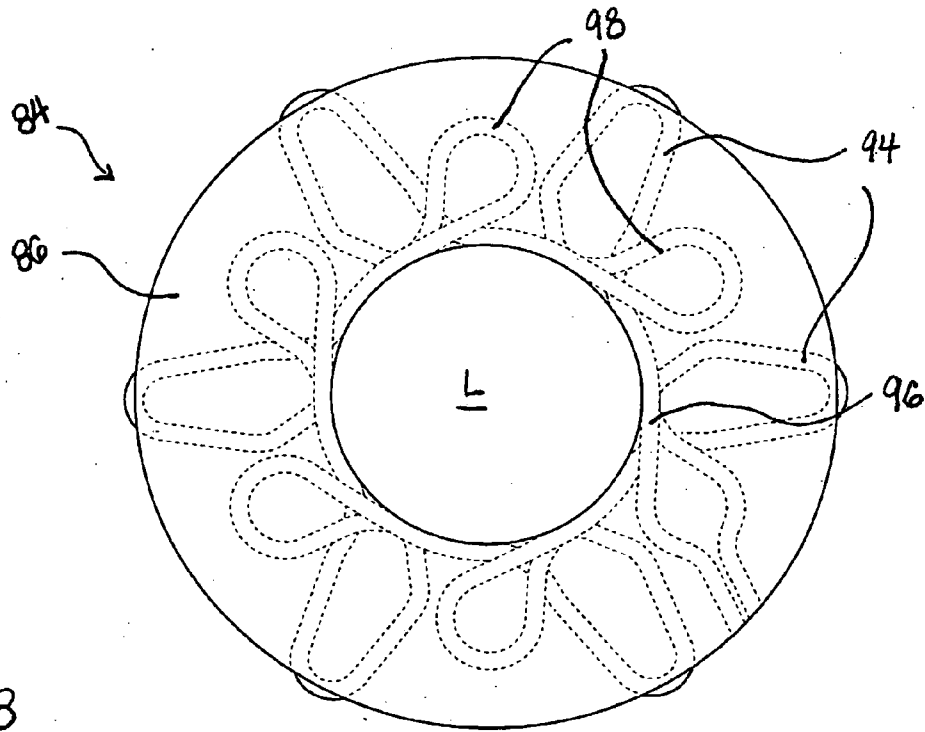


FIG. 8

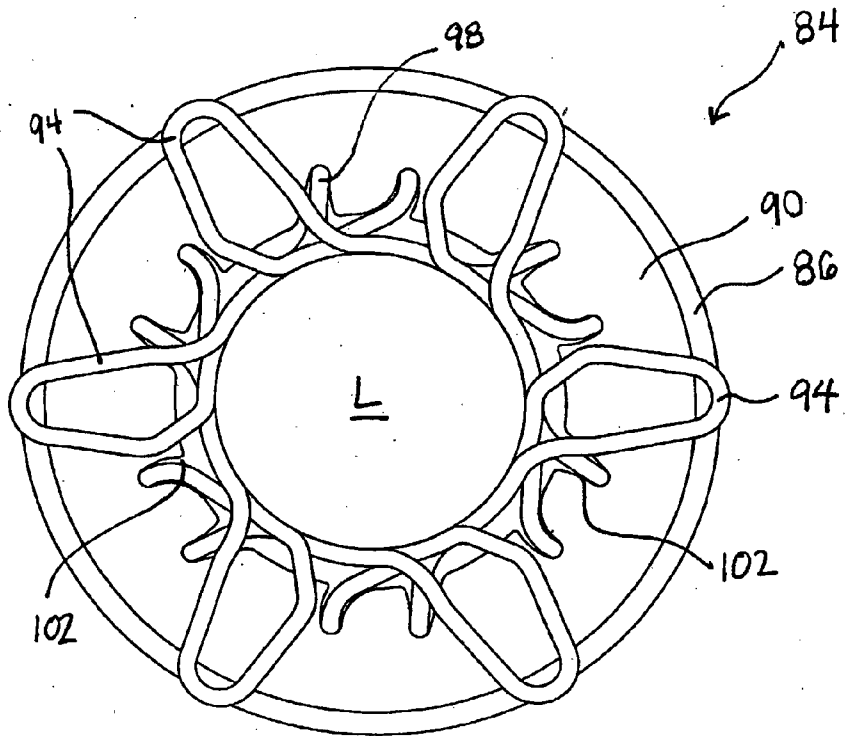


FIG. 9

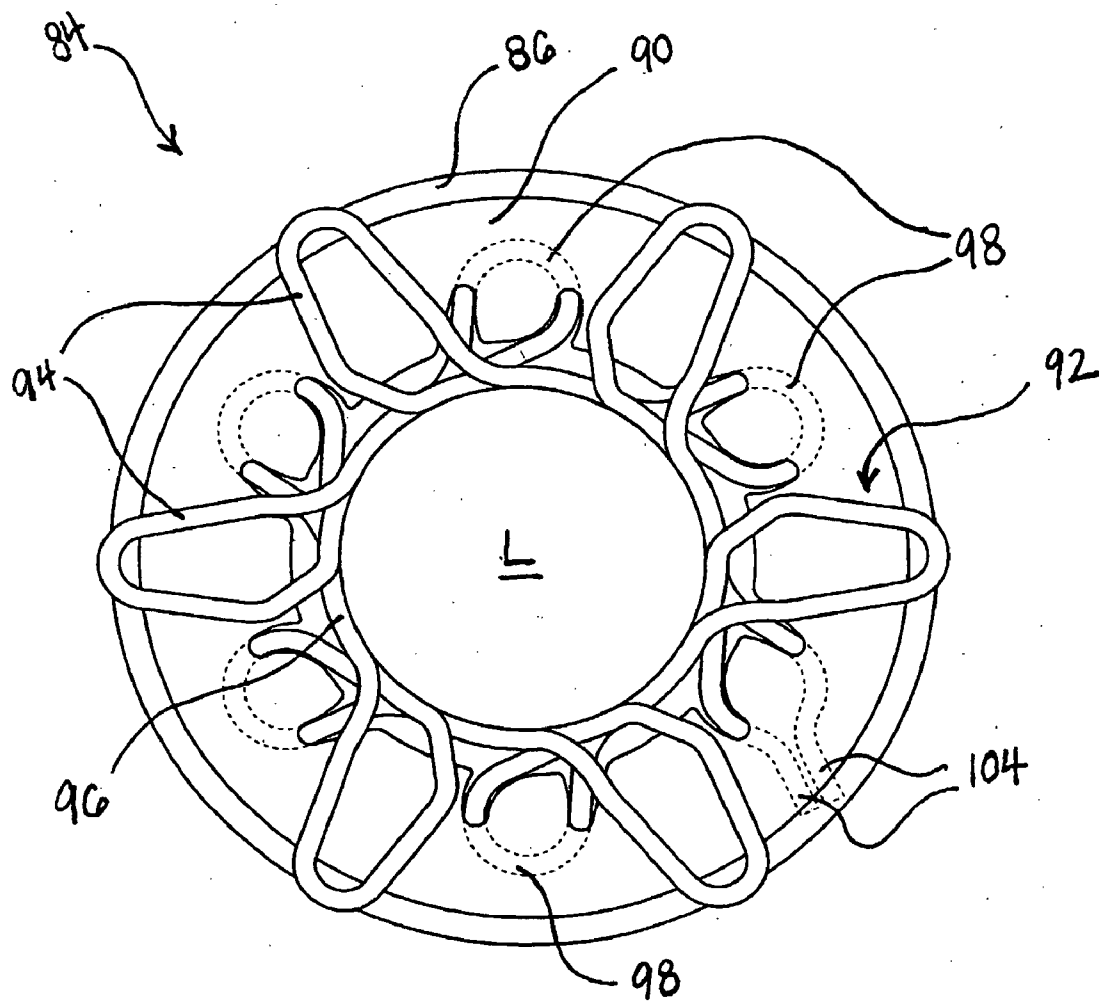


FIG. 10

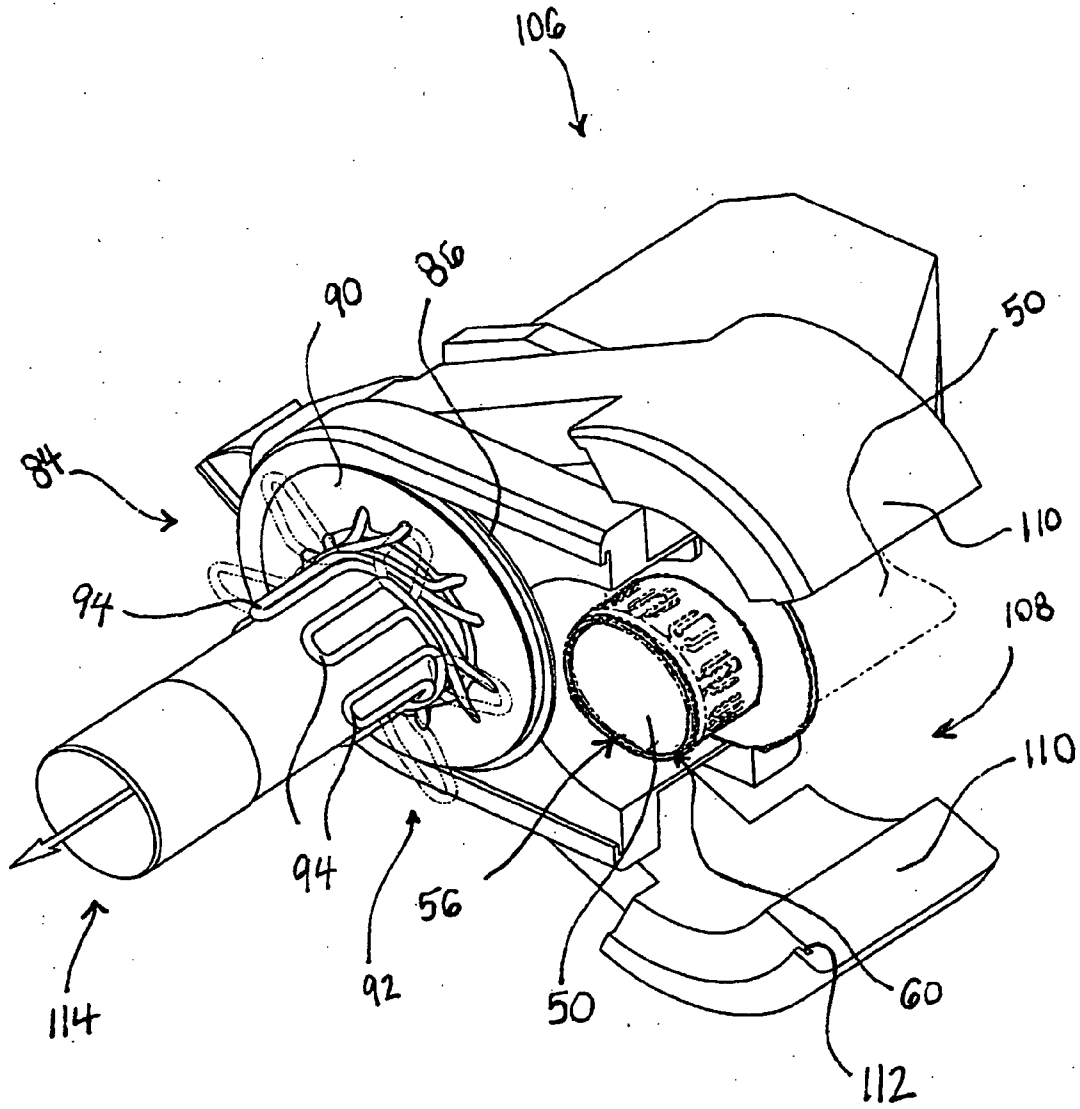


FIG. 11

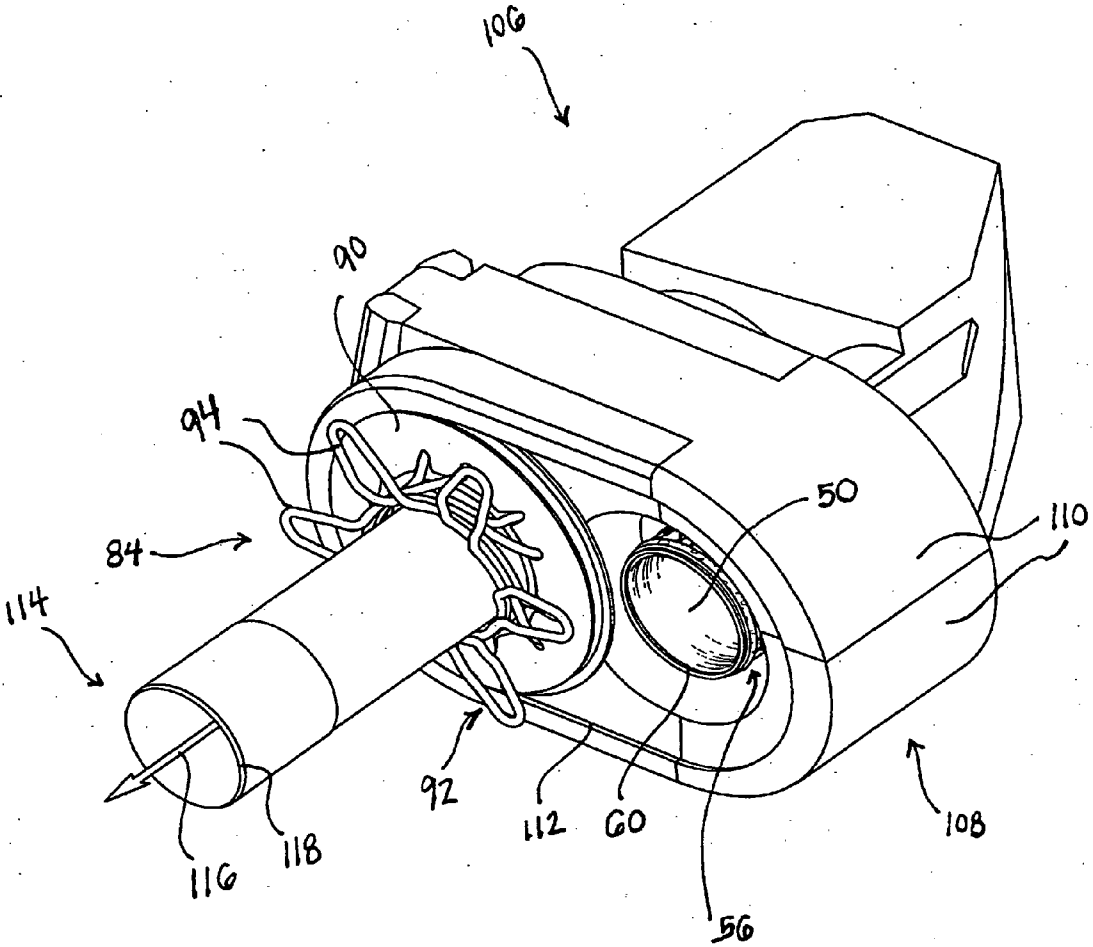


FIG. 12

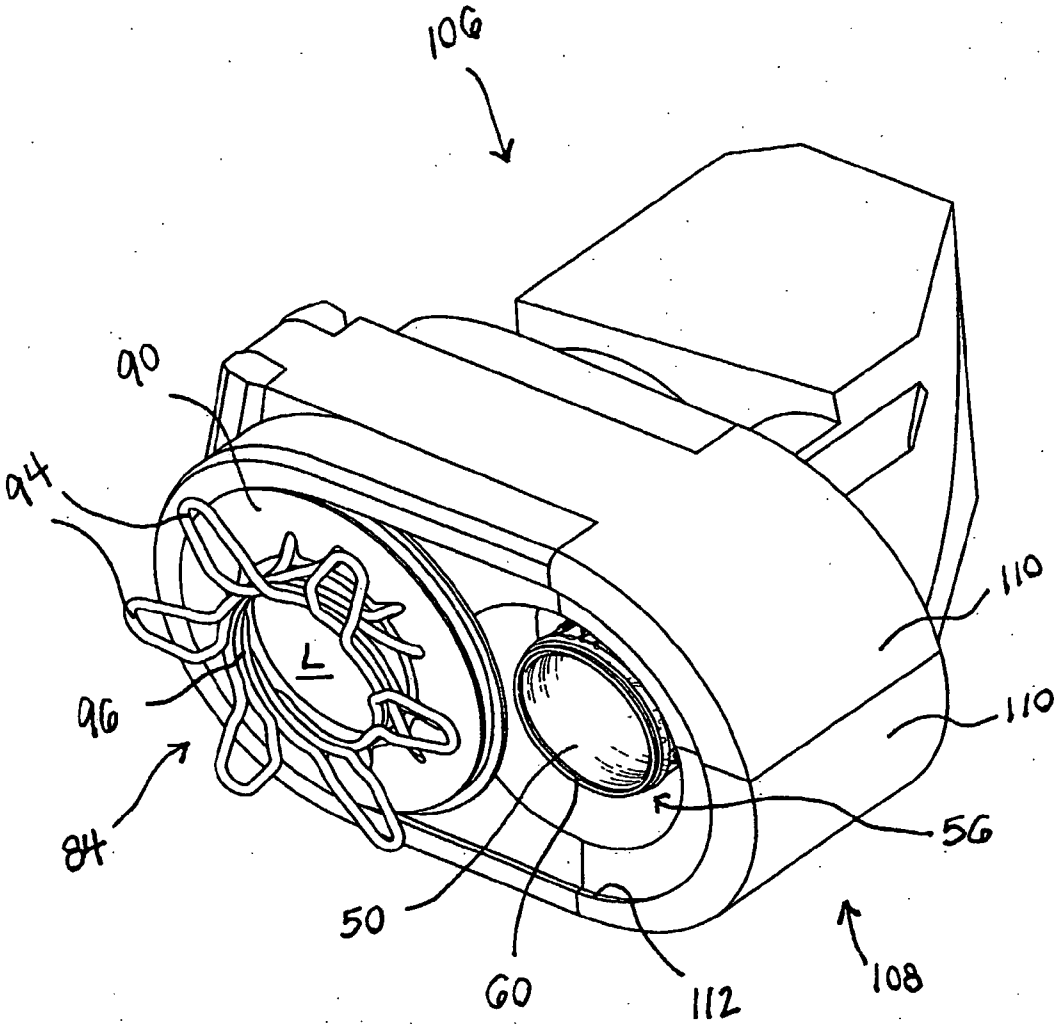


FIG. 13

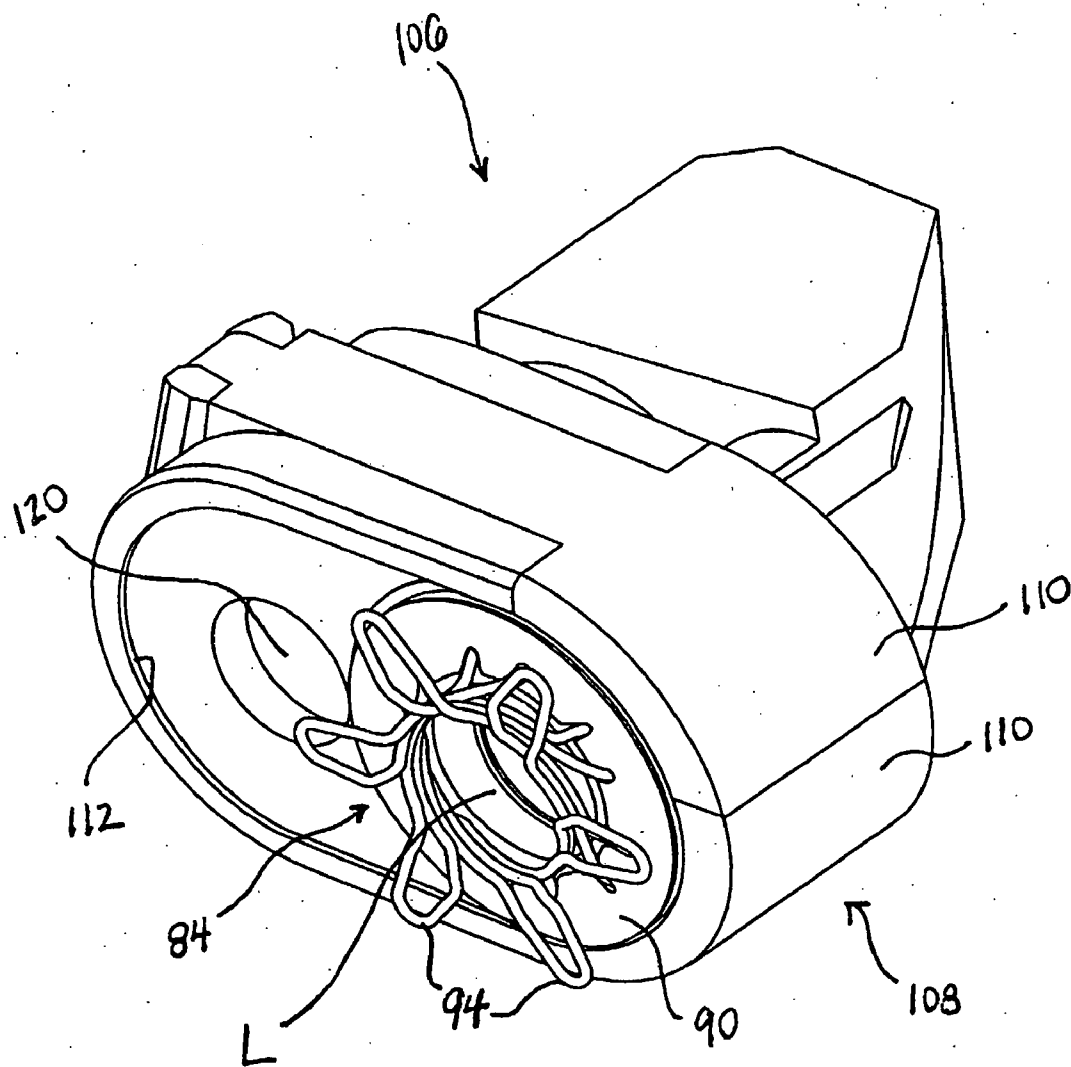


FIG. 14

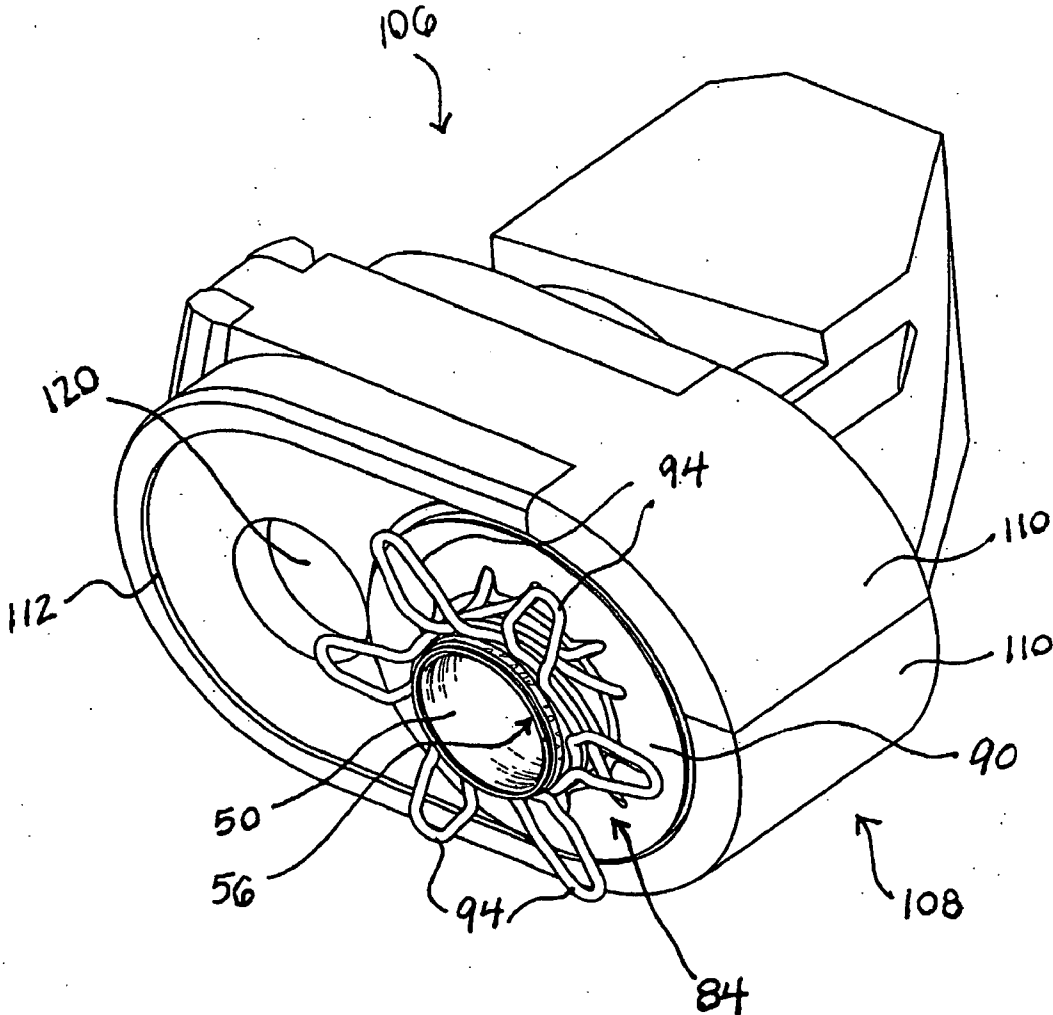


FIG. 15

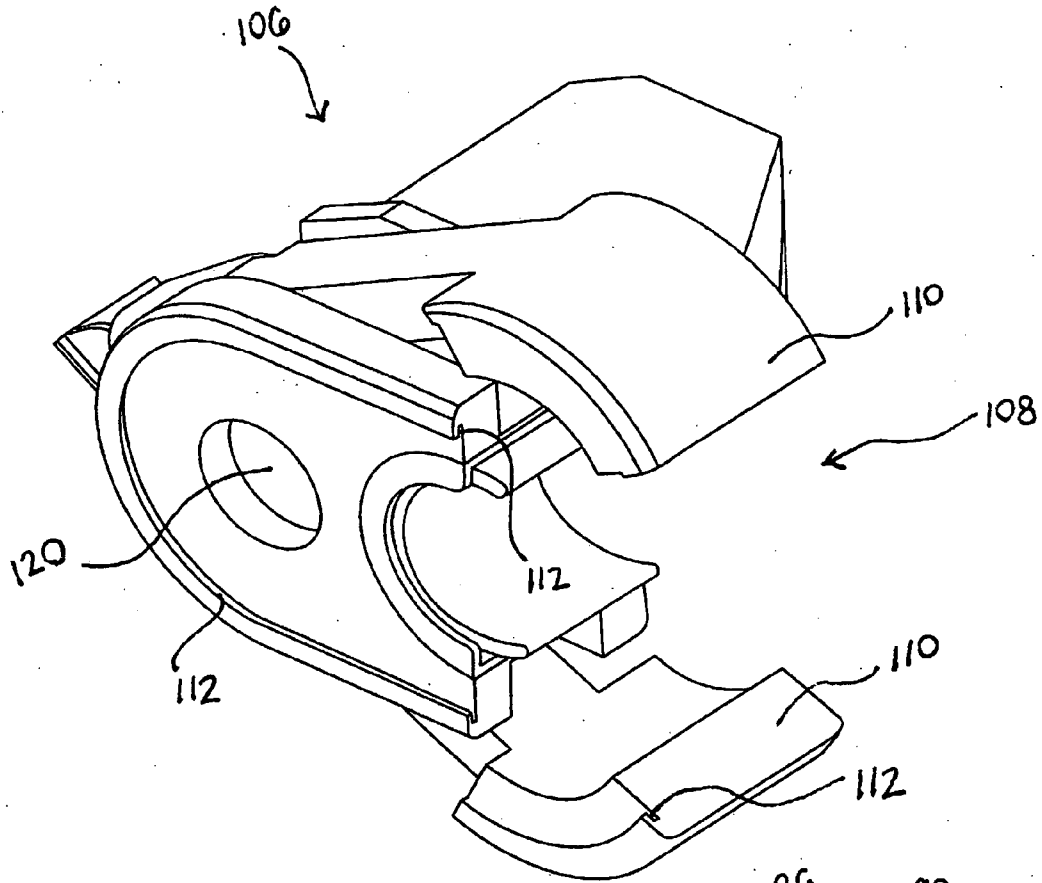
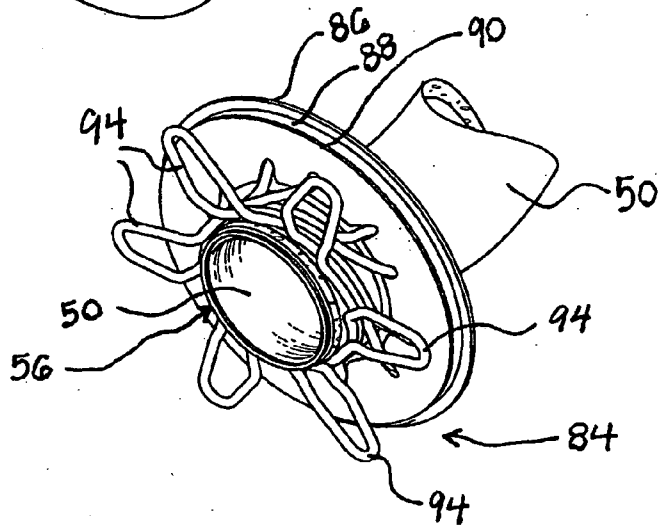


FIG. 16



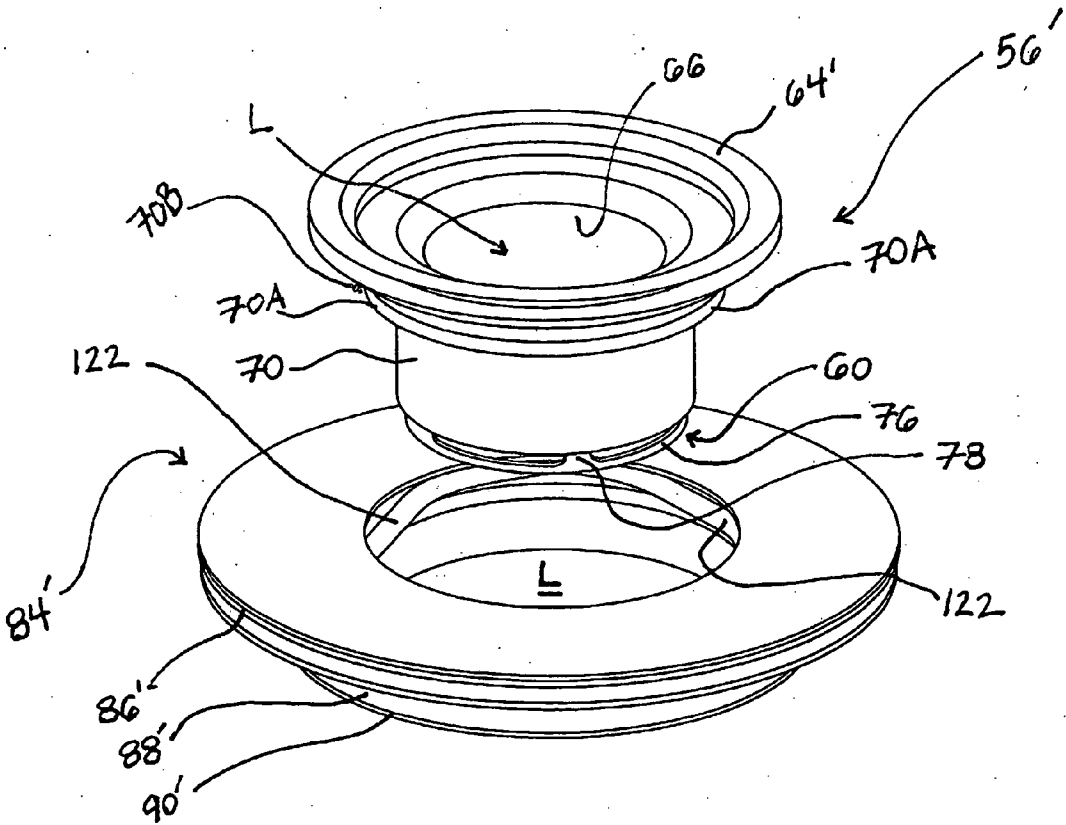


FIG. 17

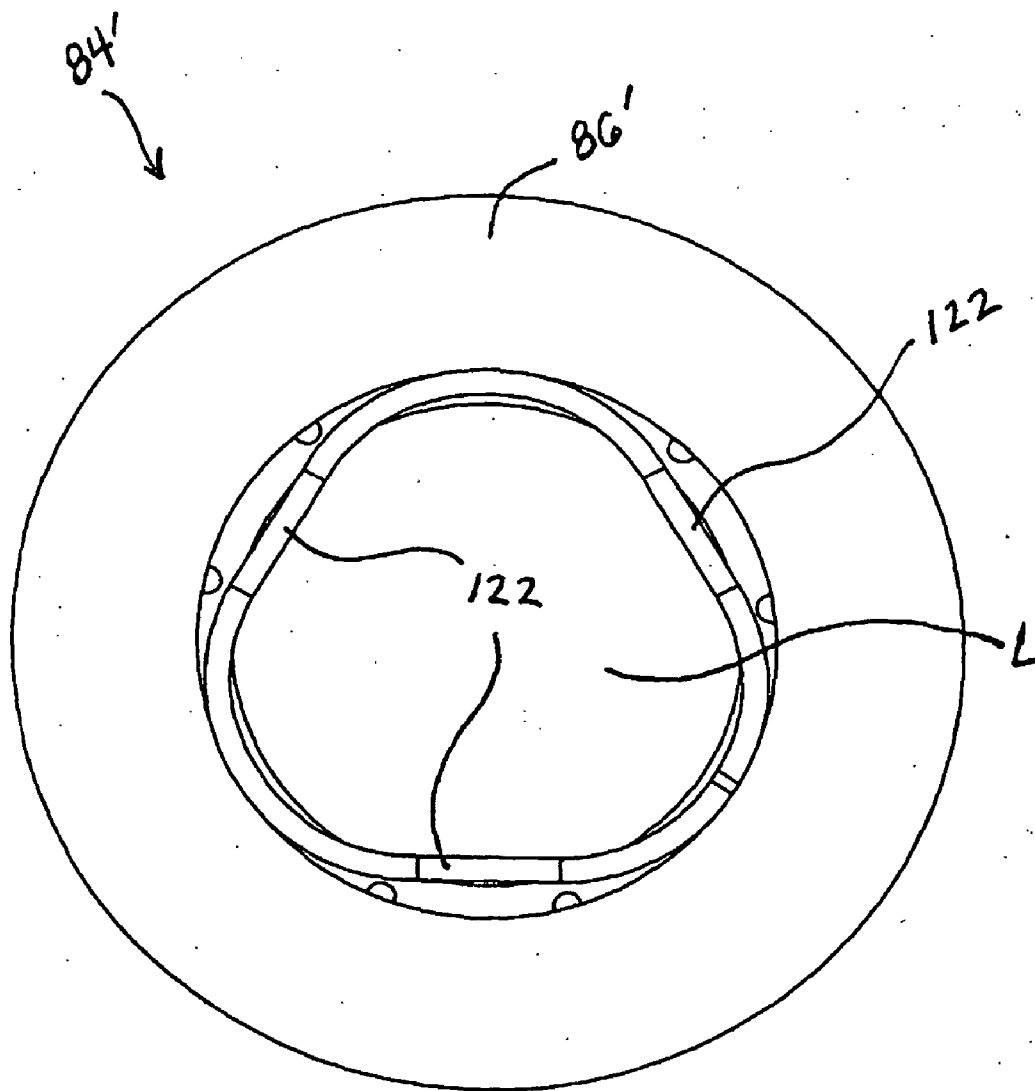


FIG. 18

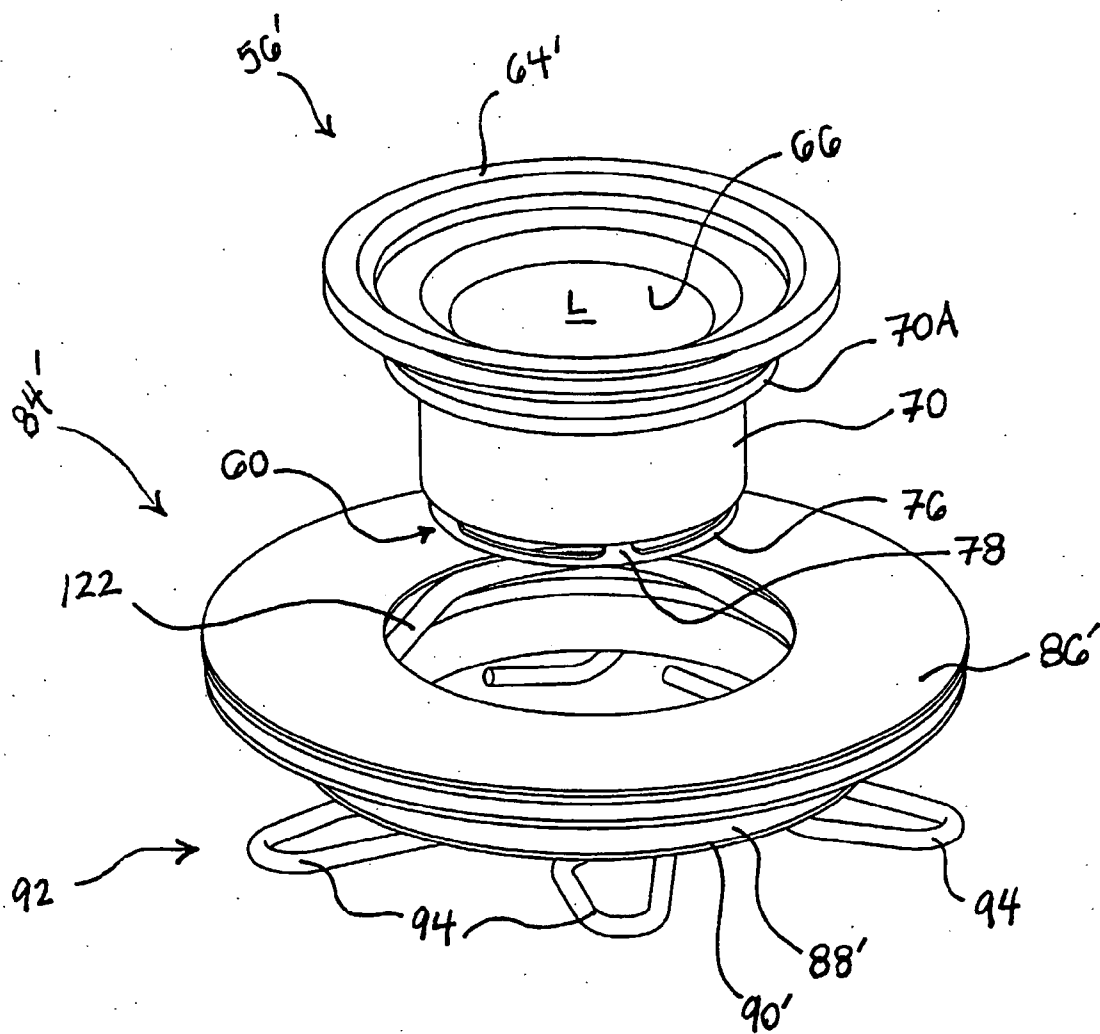


FIG. 19

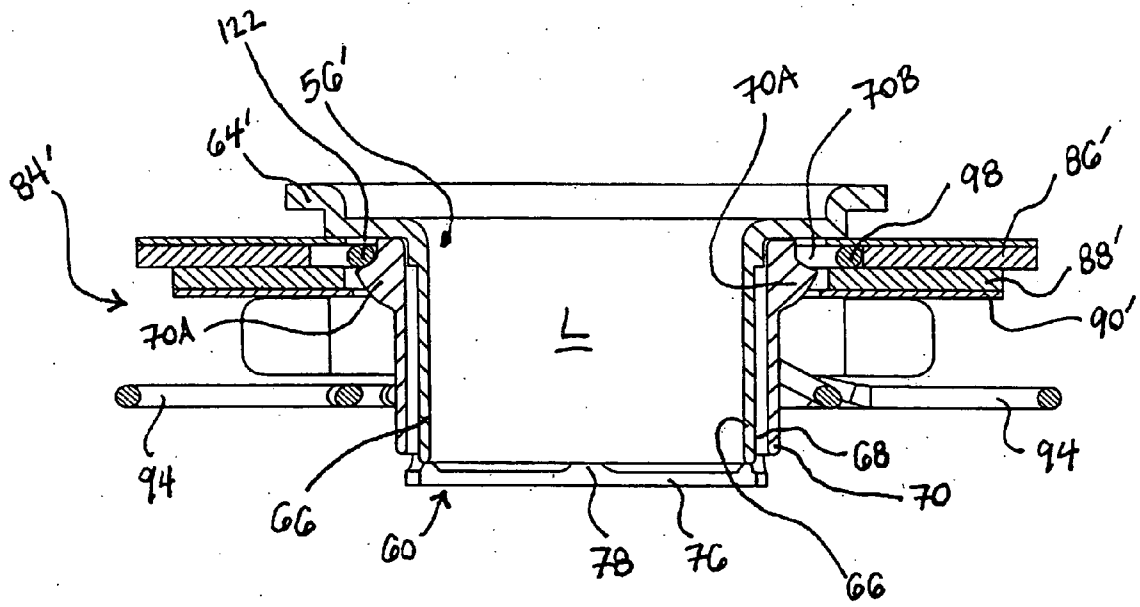


FIG. 20

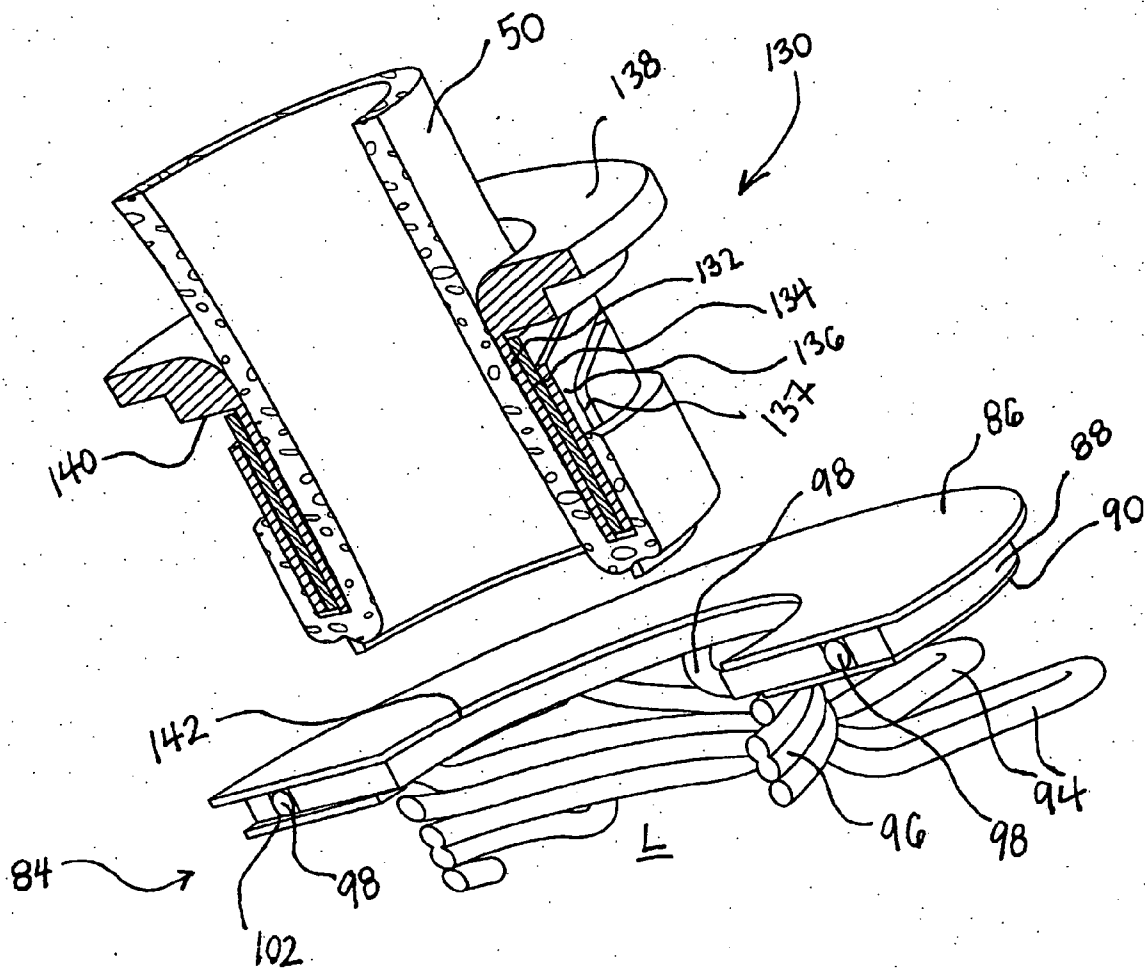


FIG. 21

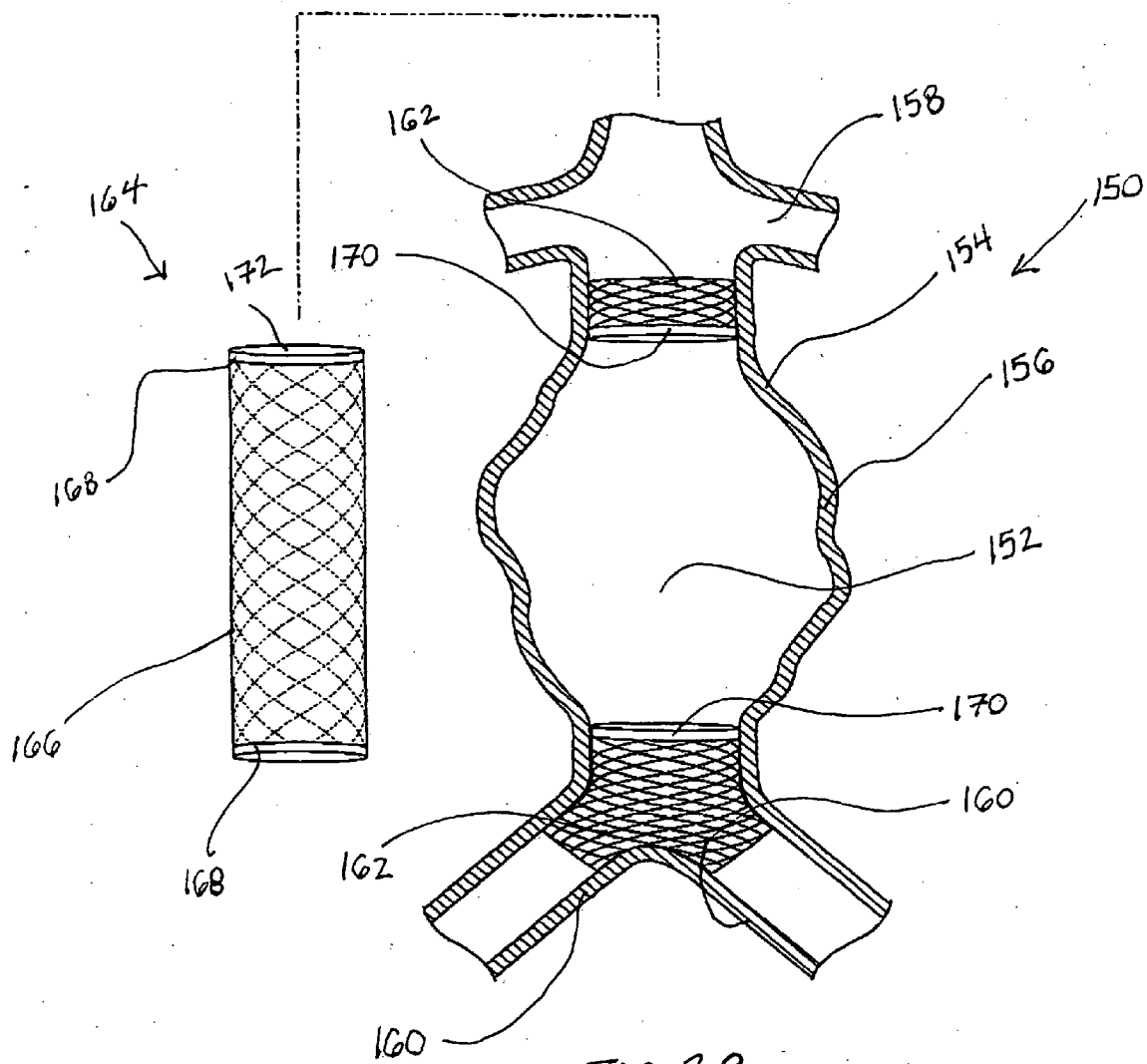


FIG. 22

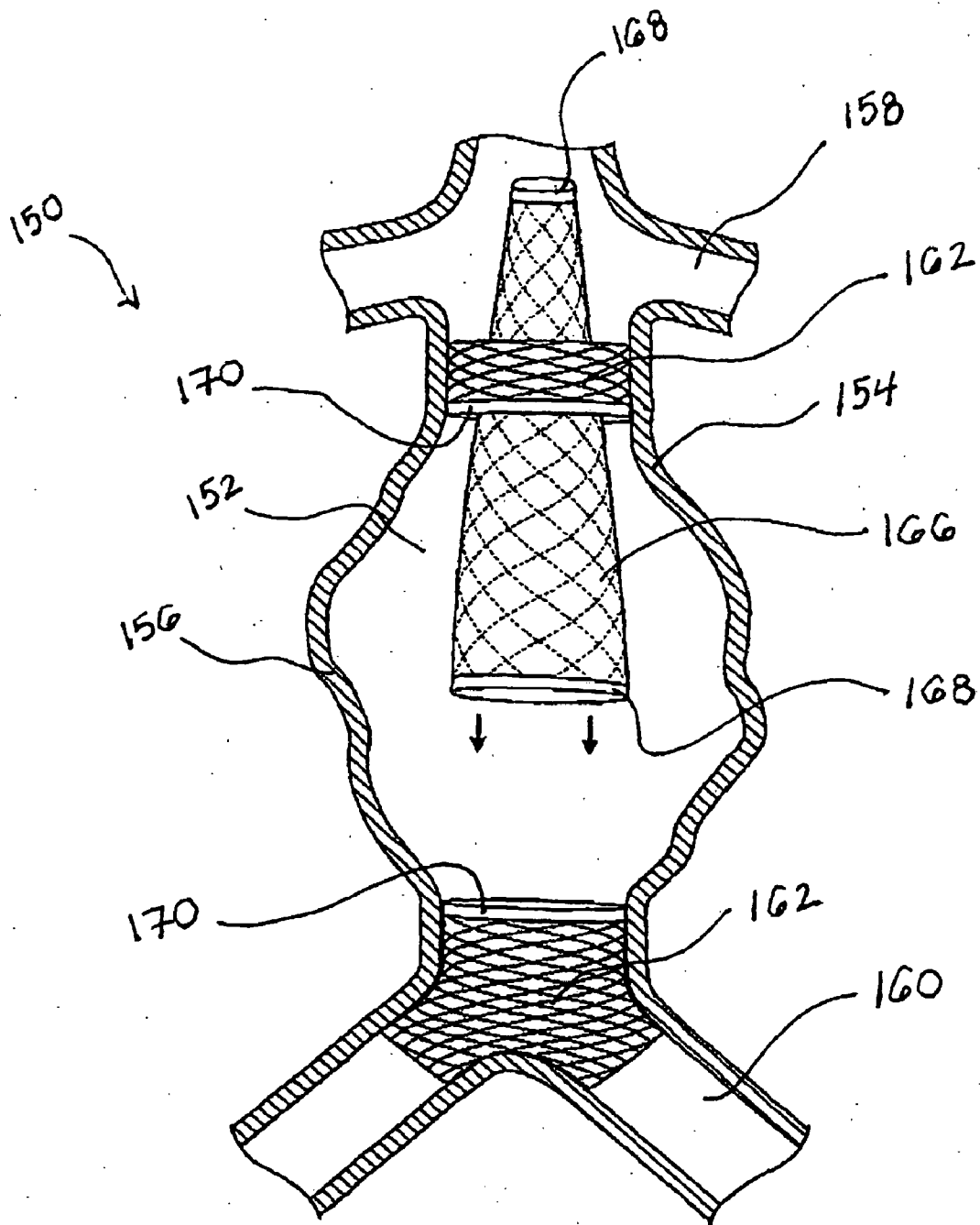


FIG. 23A

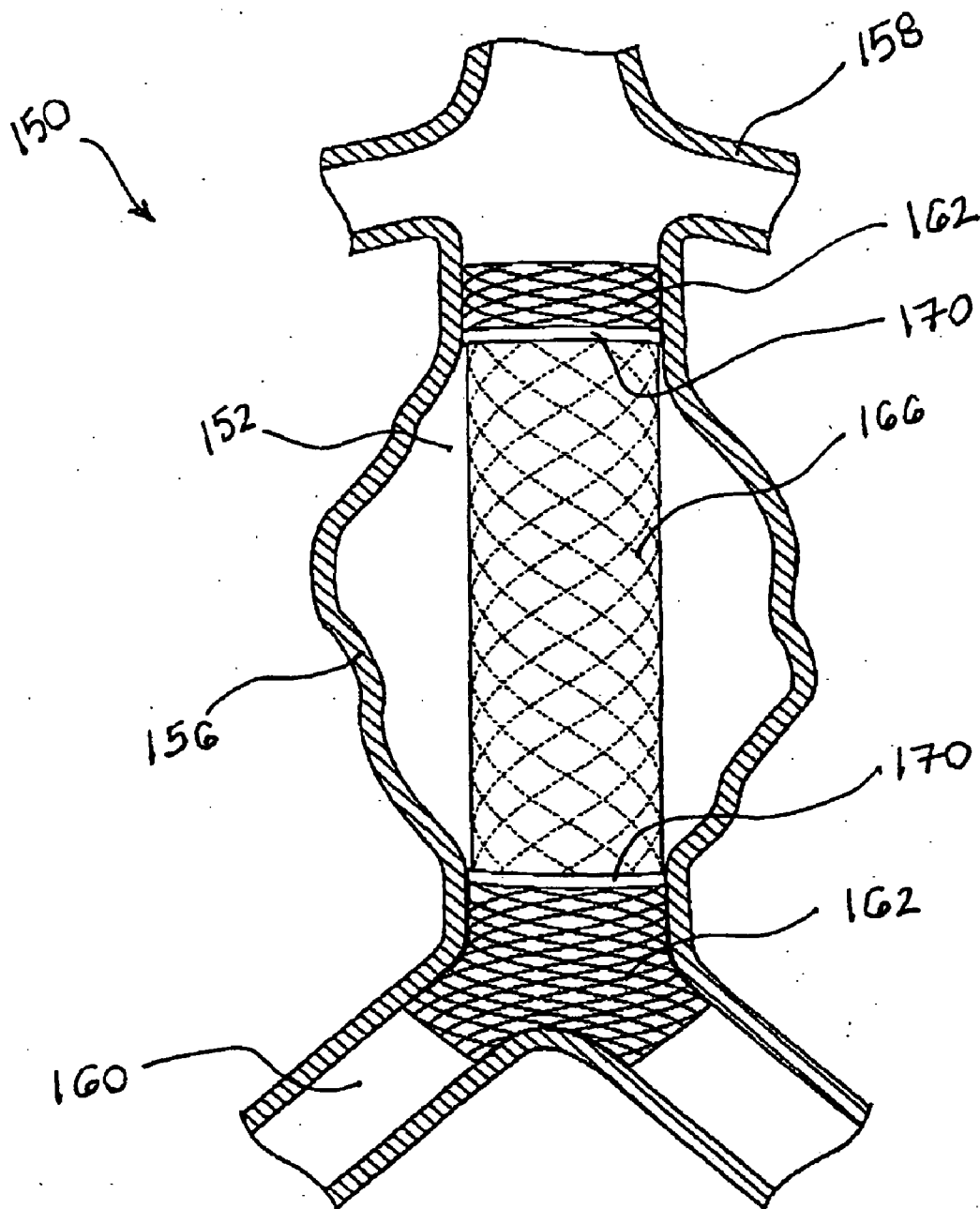
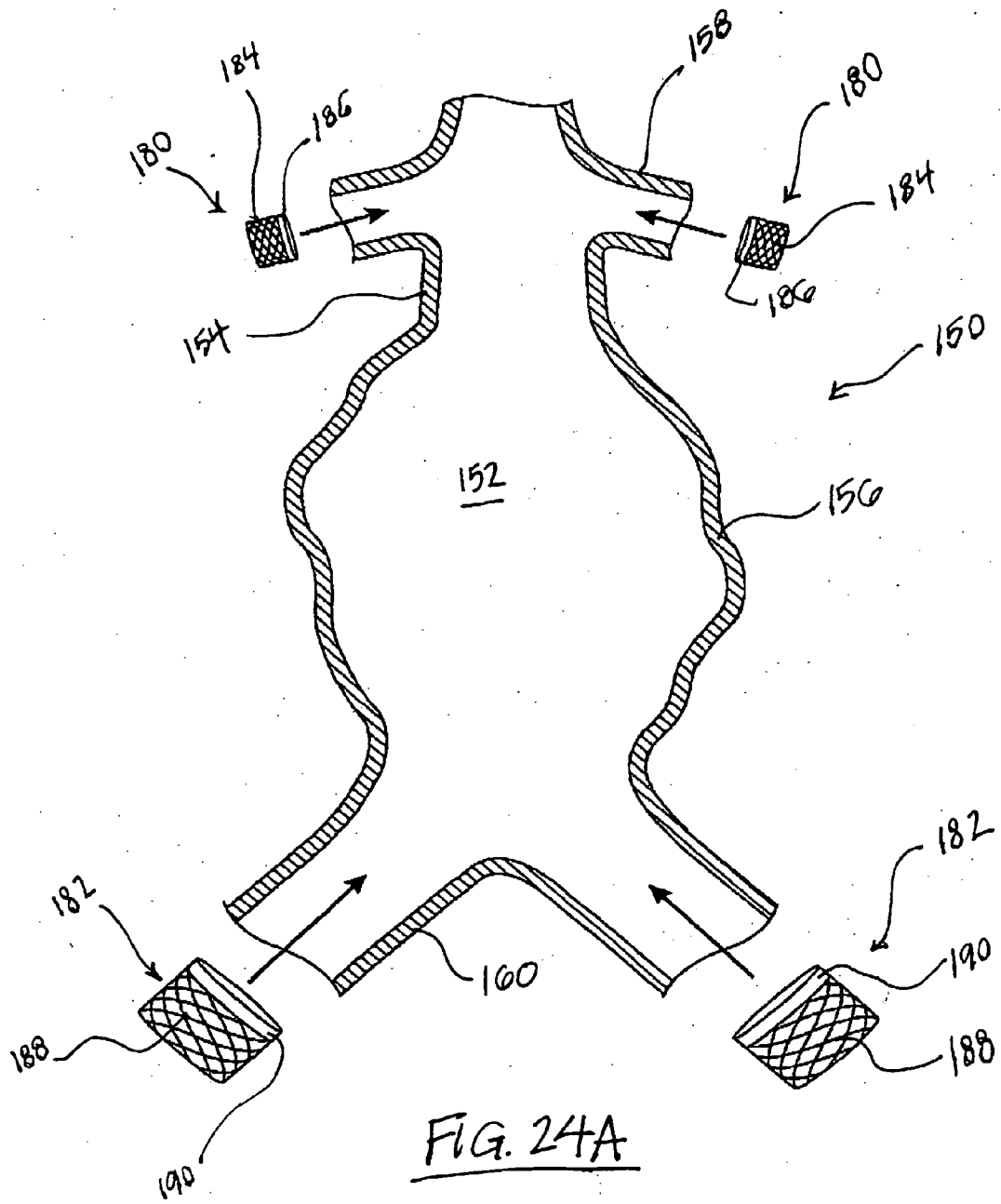


FIG. 23B



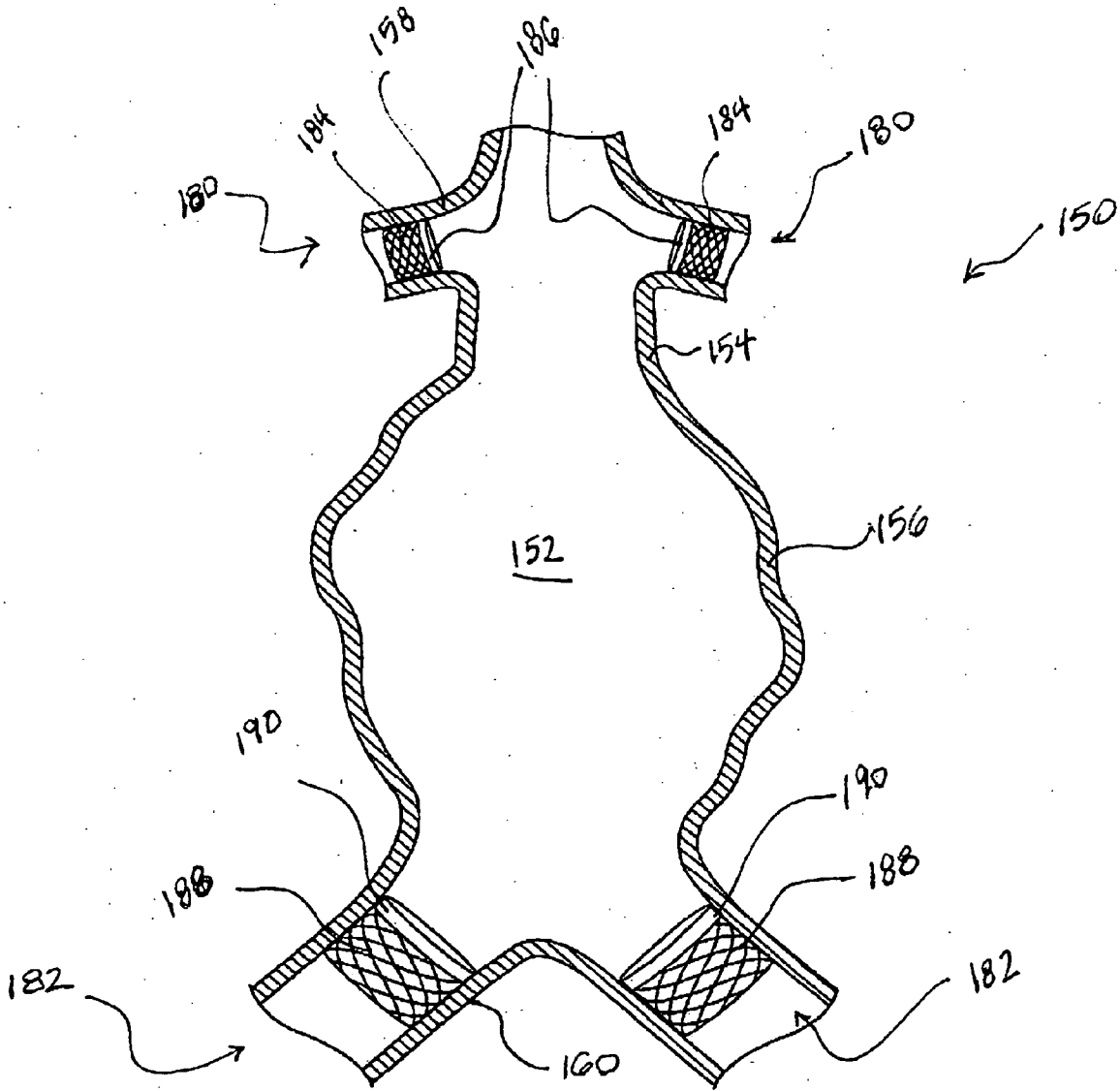
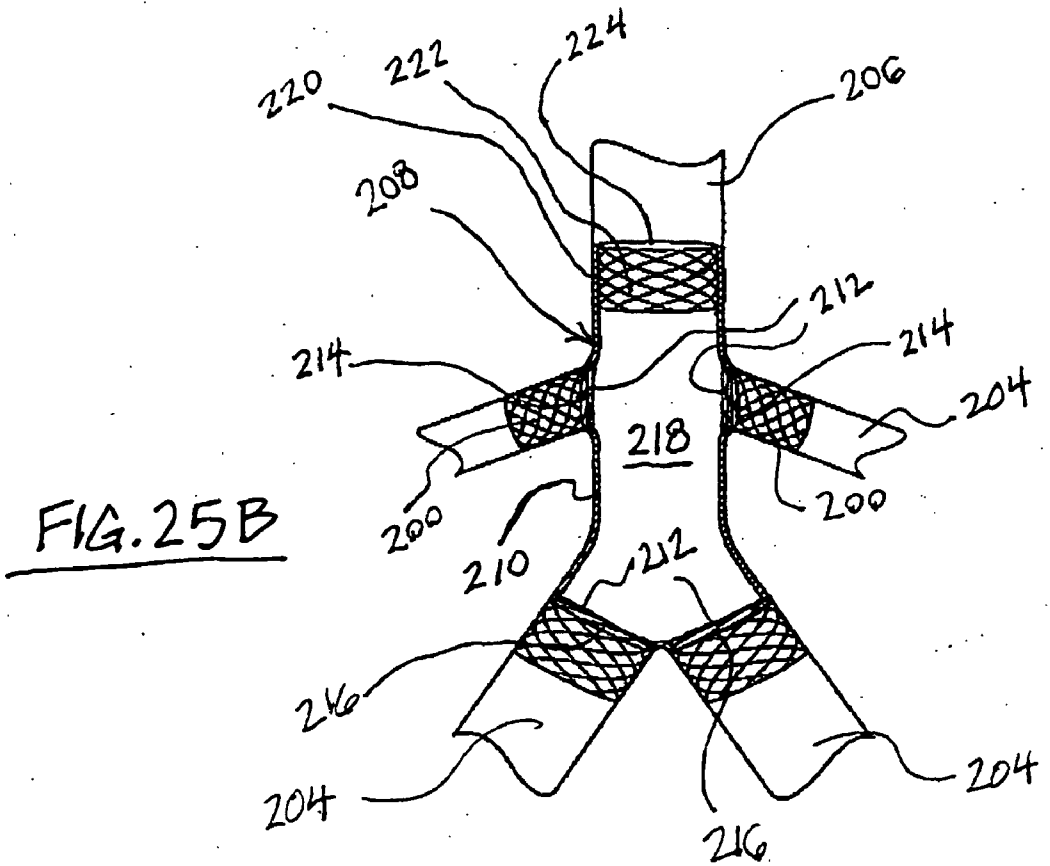
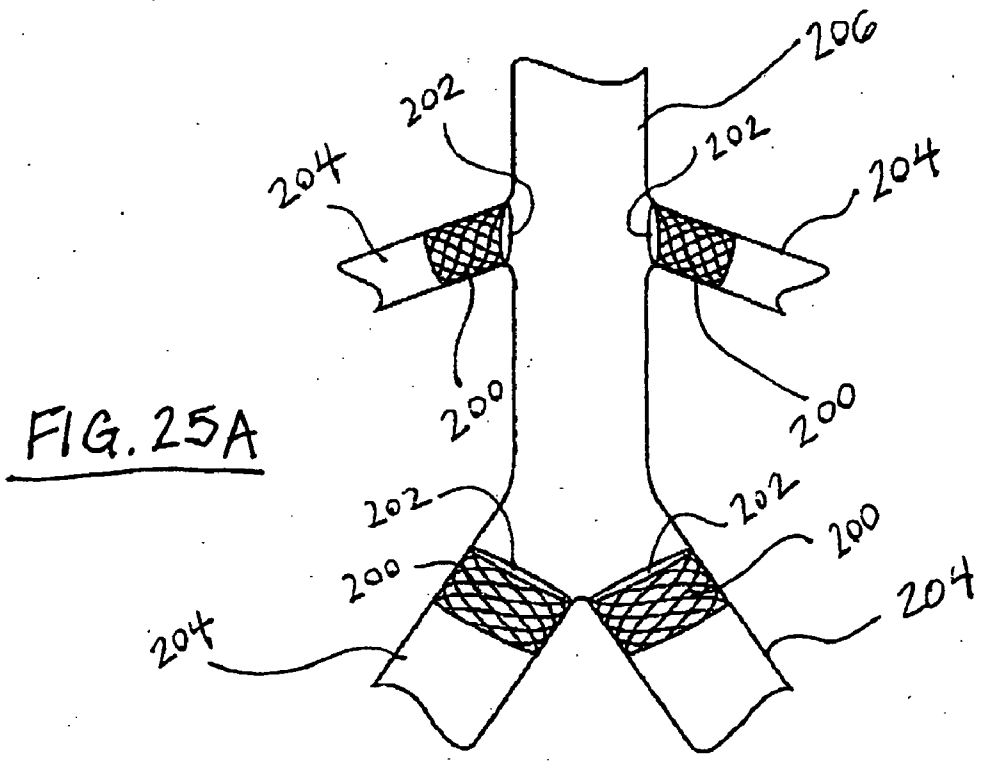
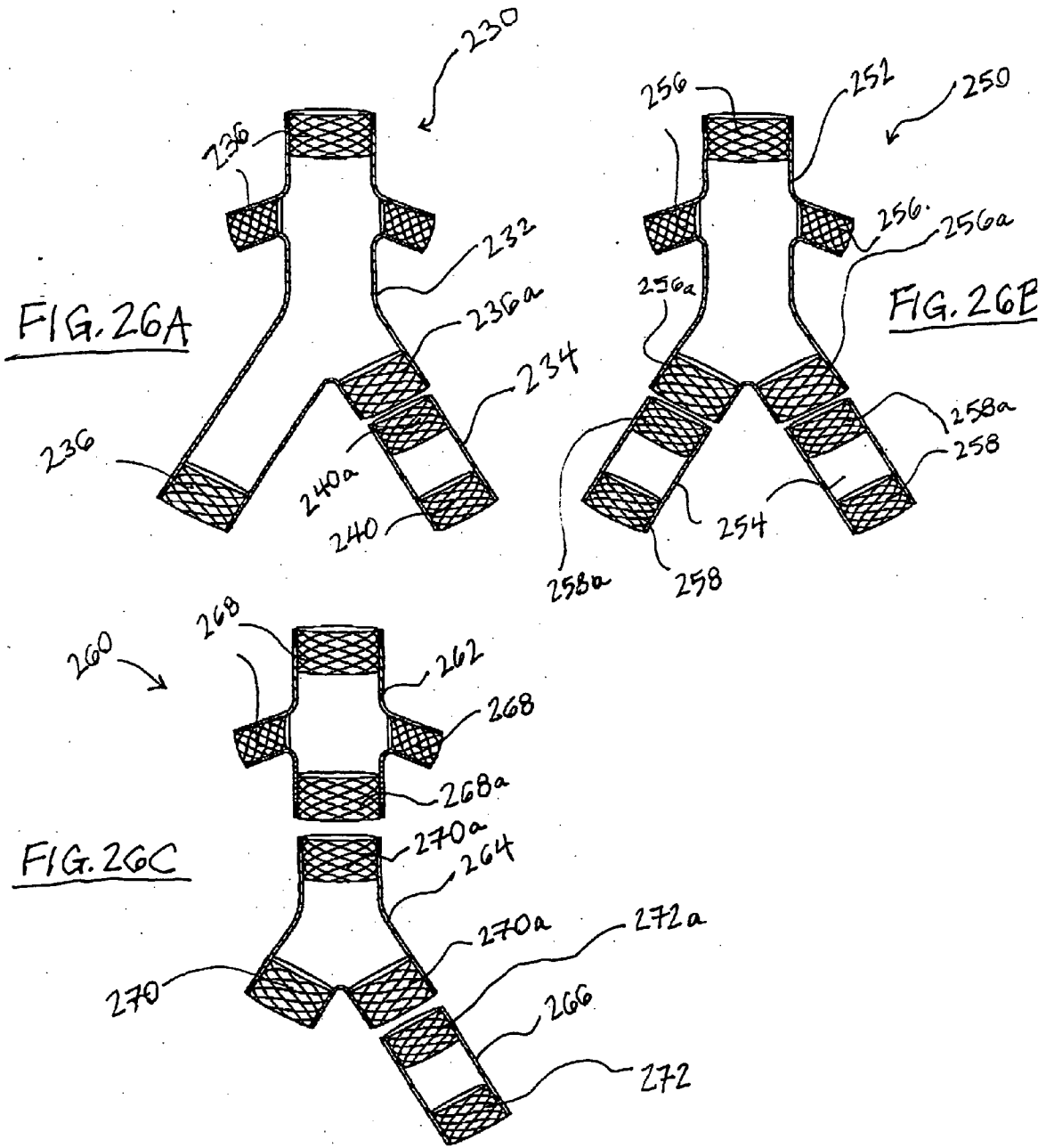


FIG. 24B





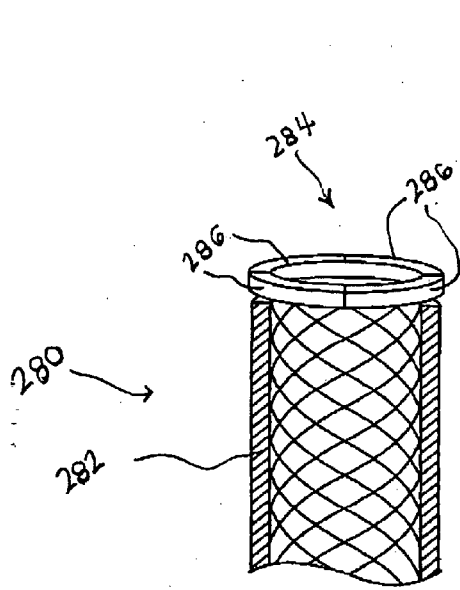


FIG. 27A

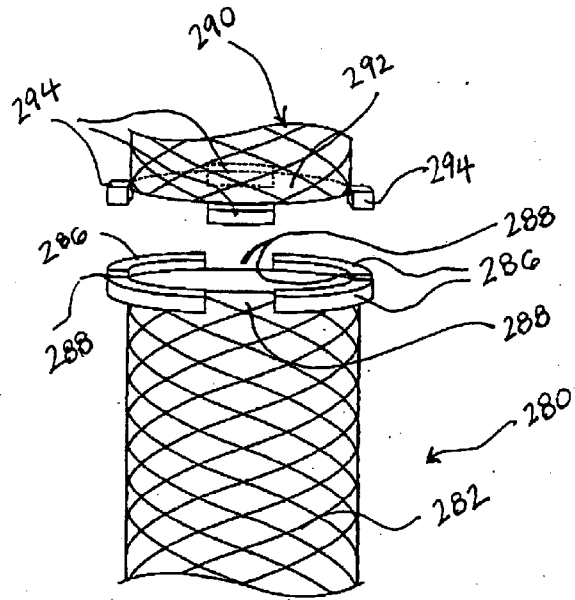


FIG. 27B

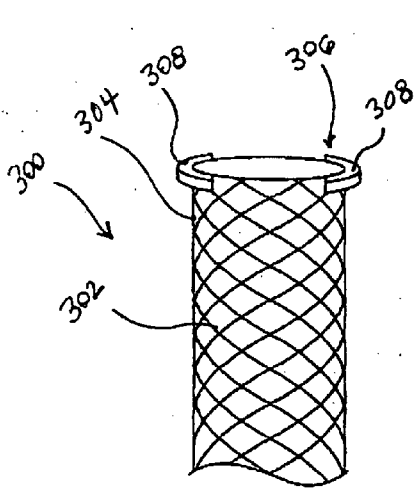


FIG. 27C

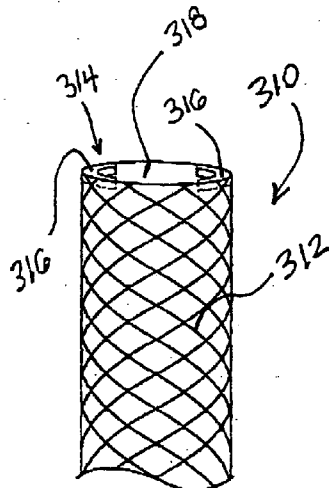


FIG. 27D

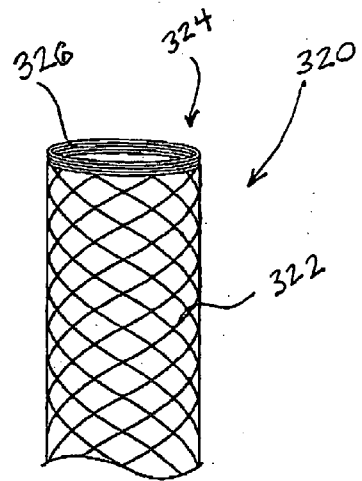


FIG. 27E

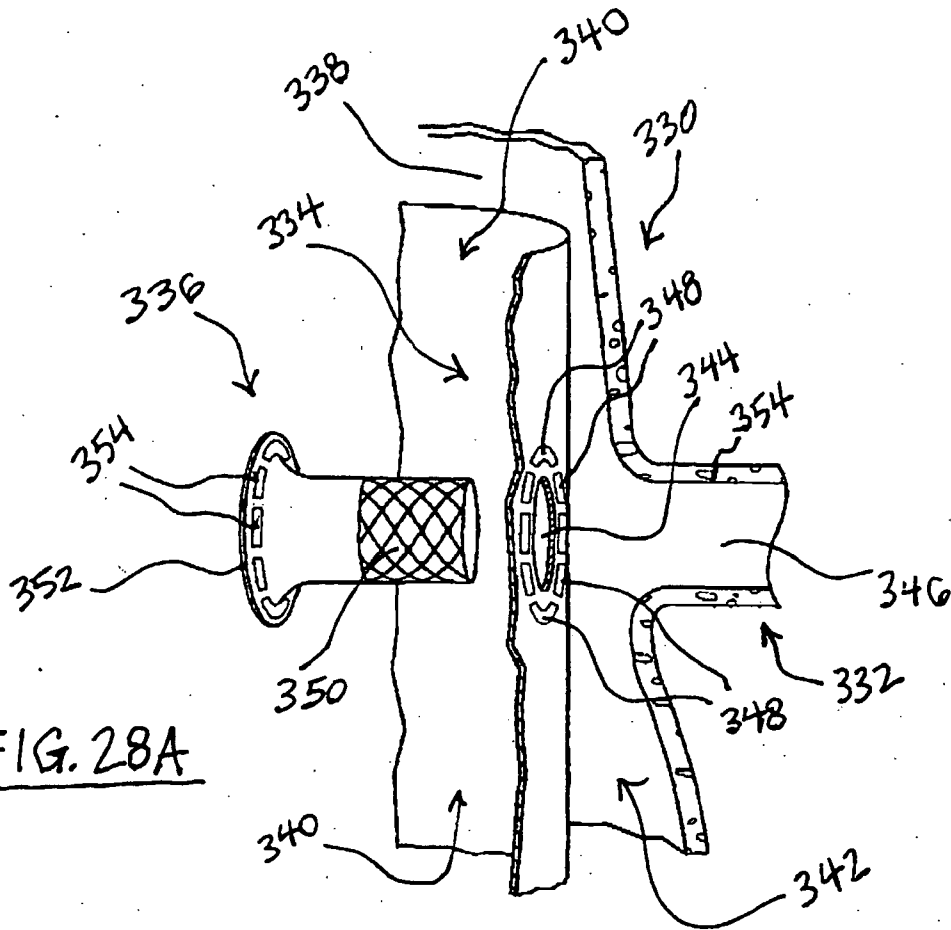


FIG. 28A

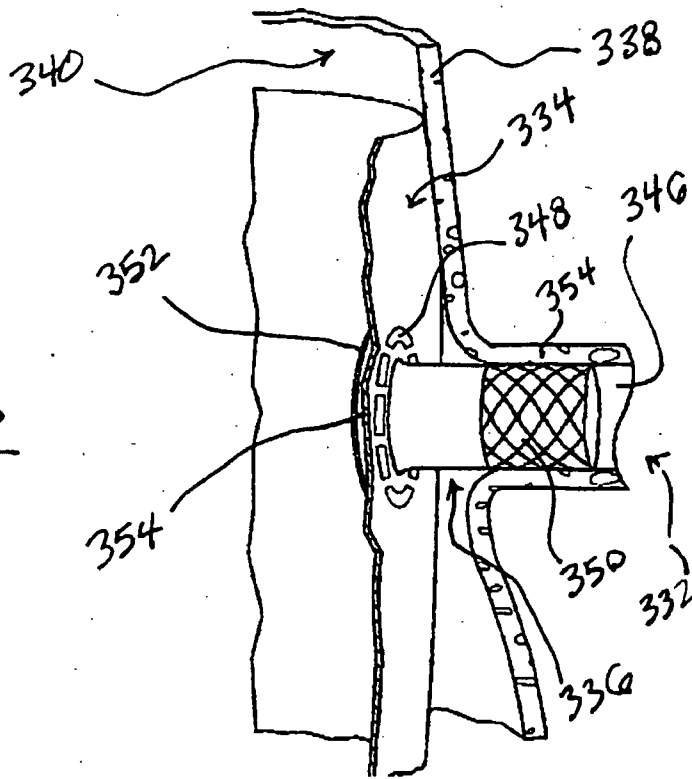


FIG. 28B

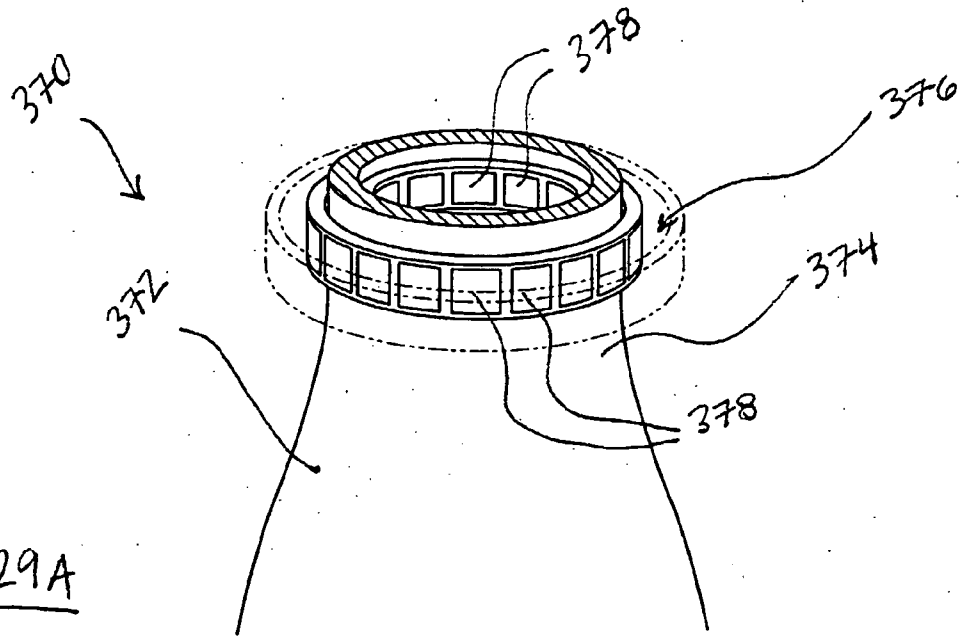


FIG. 29A

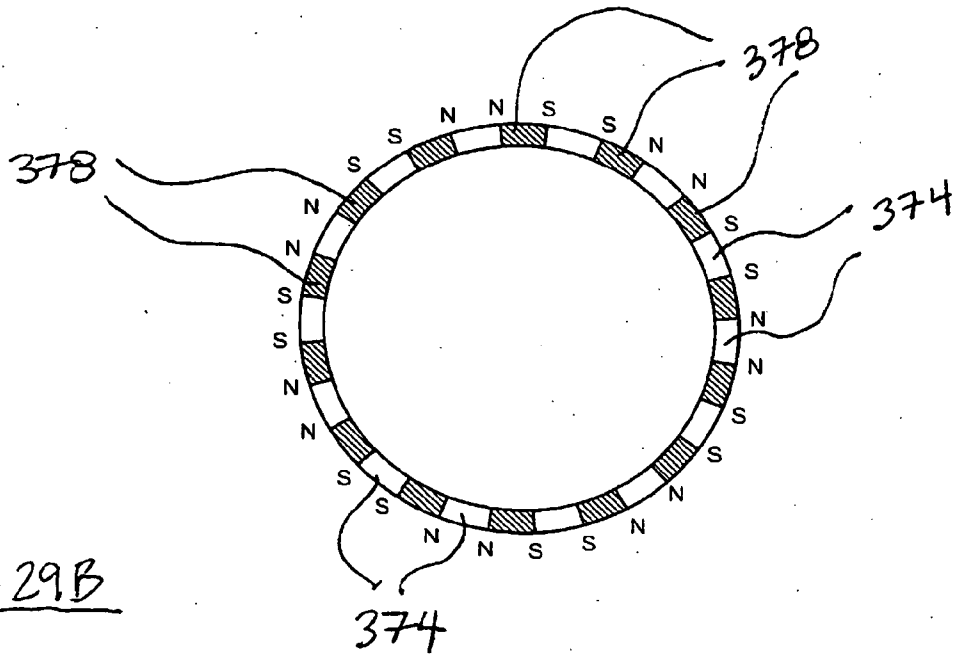


FIG. 29B

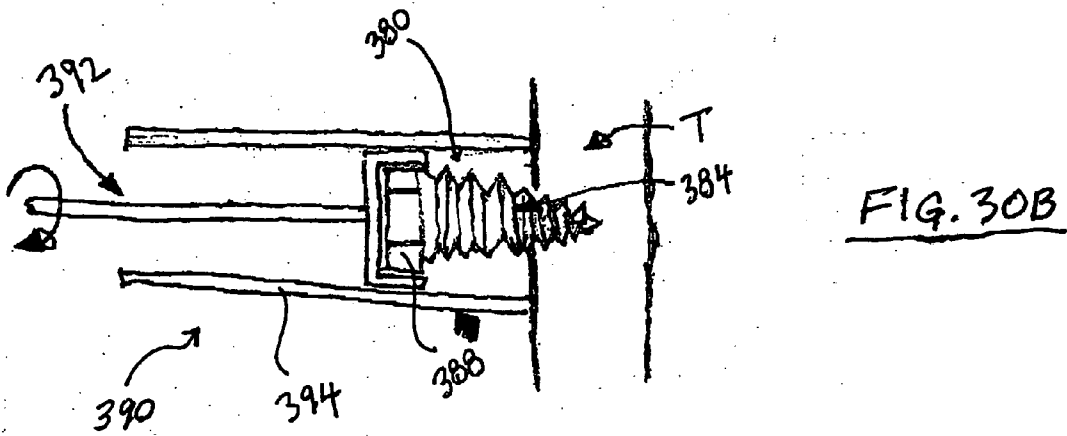
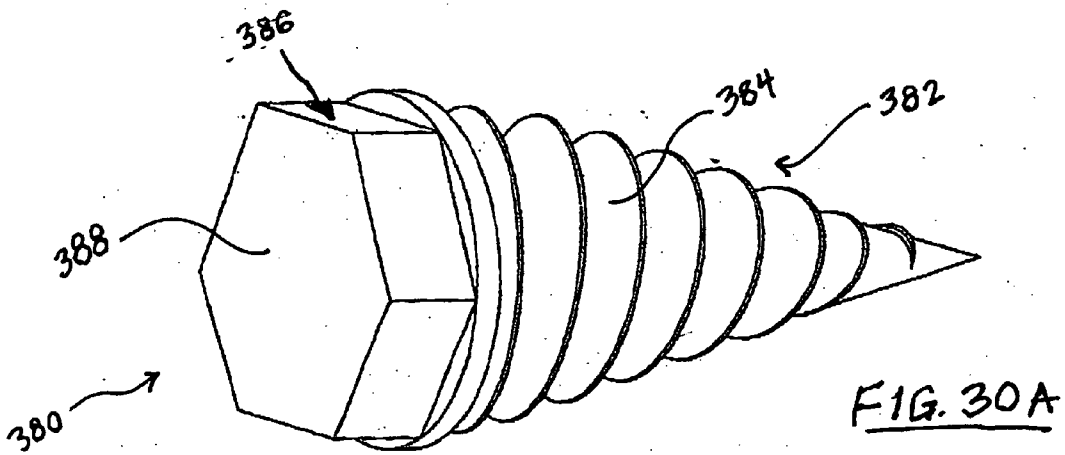
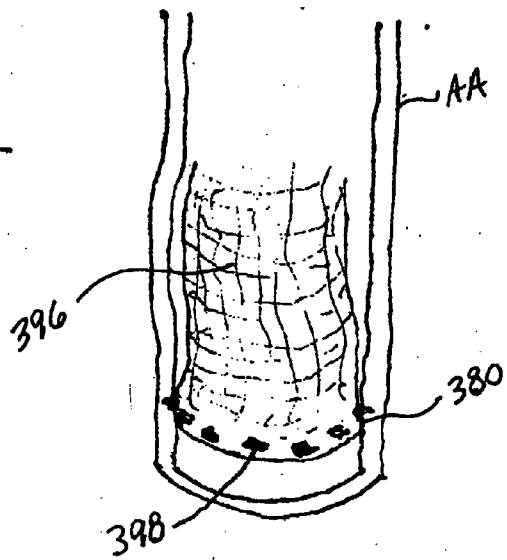


FIG. 31



COMPONENTS, SYSTEMS, AND METHODS FOR FORMING ANASTOMOSES USING MAGNETISM OR OTHER COUPLING MEANS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of application Ser. No. 09/638,805, filed Aug. 12, 2000, which is a continuation-in-part of application Ser. No. 09/562,599, filed Apr. 29, 2000, now U.S. Pat. No. 6,352,543. This application also claims priority from provisional application Ser. No. 60/255,635, filed Dec. 13, 2000, and application Ser. No. 09/851,400, filed May 7, 2001. The entire disclosure of each of the above-referenced patent applications is expressly incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The invention relates to treating hollow anatomical structures having a lumen. More specifically, the invention relates to treating one or more diseased body lumens, creating anastomoses between such hollow body structures, and using magnetism to secure anastomotic components to such structures, for example, in conjunction with creating an anastomosis.

[0004] 2. Description of Related Art

[0005] Despite the considerable advances that have been realized in both interventional cardiology and cardiovascular surgery, heart disease remains the leading cause of death throughout much of the world. Coronary artery disease, or arteriosclerosis, is the single leading cause of death in the United States today. As a result, those in the cardiovascular field continue to search for new treatments and improvements to existing treatments.

[0006] Coronary artery disease is currently treated by interventional-procedures such as percutaneous transluminal coronary angioplasty (PTCA), coronary stenting and atherectomy, as well as surgical procedures including coronary artery bypass grafting (CABG). The goal of these procedures is to reestablish or improve blood flow through occluded (or partially occluded) coronary arteries, and is accomplished, for example, by enlarging the blood flow lumen of the artery or forming a bypass that allows blood to circumvent the occlusion. What procedure(s) is used typically depends on the severity and location of the blockage. When successful, these procedures restore blood flow to myocardial tissue that had not been sufficiently perfused due to the occlusion.

[0007] Another proposed treatment places the target vessel, e.g., a coronary artery, in direct fluid communication with a heart chamber containing blood, for example, the left ventricle. Blood flows from the ventricle into a conduit that is in fluid communication with the artery; as such, this treatment may be described as a ventricular bypass procedure. Benefits of this procedure include obviating the need to manipulate the aorta, for example, as is done when a side-biting clamp is used in a typical CABG procedure to create a proximal anastomosis between the bypass graft and the aorta. Clamping or otherwise manipulating the aorta places the patient at risk in some cases due to the likelihood that such manipulation will release embolic material into the

bloodstream. Some challenges associated with this procedure include delivering and deploying the conduit in the patient's body in proper position with respect to the heart chamber and the coronary vessel.

[0008] A particularly challenging task that must be performed during many of these and other revascularization procedures is suturing one hollow structure to another hollow structure. For instance, one end of a graft vessel is sutured to a source of blood, such as the aorta, a heart chamber or another blood vessel, while another end of the graft vessel is sutured to a target vessel, such as a coronary artery having an occluded lumen. The small diameter of the hollow structures involved, typically from 1 mm to 4 mm, makes forming a handsewn anastomosis a highly technical and time-consuming procedure. The difficulty in forming the sutured anastomosis is exacerbated when access to the target vessel is restricted or limited, as in a minimally invasive or percutaneous procedure. This problem can also arise in non-cardiovascular applications that utilize handsewn anastomoses, for example, treating peripheral vascular disease or injury, creating AV (arteriovenous) shunts, etc.

[0009] While those in the art have proposed various anastomotic coupling, none has performed well enough to receive any significant level of acceptance in the field. Many of the proposed couplings penetrate or damage the wall of the hollow structures, do not remain patent, fail to produce a fluid-tight seal between the conduit and vessel, or are simply too cumbersome and difficult to deliver or deploy.

[0010] It should be noted, though, that a more recently proposed technology which uses magnetism to treat hollow anatomical structures has enjoyed clinical success in creating an anastomosis between a graft blood vessel and a coronary artery. This anastomotic technology, which was developed by Ventrica, Inc., of Fremont, Calif., and is referred to as the MVP™ (Magnetic Vascular Positioner) anastomotic system, provides considerable benefits over other proposed technologies. Nevertheless, there remains room in the art for improvement with respect to a number of technological and procedural areas.

[0011] For example, it is desirable to maximize the ability of the technology to be used in a minimally invasive manner, such as in a procedure performed by a robotic system. As another example, it is desirable to minimize the amount of foreign material in the blood flow path so as to decrease the chance of thrombosis. Achieving this goal, however, must be balanced with the need to form a secure, connection between the anastomotic components, or between a component and a hollow body structure.

SUMMARY OF THE INVENTION

[0012] One embodiment of the invention provides a method for forming an anastomosis between two blood vessels using magnetism and includes steps of securing a first component to a first blood vessel and securing a second component to a side wall of a second blood vessel in alignment with an opening in the side wall. Further steps include placing the first component in contact with at least one of the second component and the side wall of the second blood vessel, positioning an intimal surface of the first blood vessel adjacent an intimal surface of the second blood vessel, and using magnetism to couple the first and second components.

[0013] Another embodiment of the invention provides a method for forming an anastomosis between two blood vessels with steps of securing a first component to an end portion of a first blood vessel securing a second component to a side wall of a second blood vessel with an opening in the second component substantially aligned with an opening in the side wall, placing the first component and the end portion of the first blood vessel through the opening in the second component and the opening in the side wall of the second blood vessel, and coupling the first and second components to form an anastomosis between the first and second blood vessels. Another embodiment of the invention provides a method with steps of providing an anastomotic component including a sleeve defining a lumen, securing an end portion of a blood vessel to the anastomotic component by passing the end portion through the sleeve, placing an edge of the blood vessel in substantial alignment with an edge of the anastomotic component, and passing a fastener through the end portion of the blood vessel and into locking engagement with the sleeve, the fastener leaving an exposed intimal surface that extends substantially around the sleeve.

[0014] Another embodiment of the invention provides a method for securing an anastomotic component to a side wall of a blood vessel and has steps of providing an anastomotic component including a non-expandable portion and an expandable portion, the anastomotic component comprising a wire shaped to define a lumen and multiple tissue engaging portions, forming an opening in a side wall of a blood vessel, collapsing the expandable portion of the anastomotic component by collapsing the wire, expanding the expandable portion of the anastomotic component by expanding the wire, and securing the anastomotic component to the blood vessel by engaging the tissue engaging portions with the vessel side wall.

[0015] Another embodiment of the invention provides a method for treating a lumen defined by a hollow structure in a patient's body and includes steps of providing a docking member configured to be secured to tissue, providing a prosthesis configured to be magnetically coupled to the docking member, the prosthesis having a lumen, securing the docking member to a vessel in a patient's body, the vessel having a lumen with a diseased portion, and magnetically coupling the prosthesis to the docking member to place the prosthesis lumen in sealing engagement with the vessel lumen.

[0016] Still another embodiment of the invention provides a method for repairing an aneurysm located in a patient's body lumen and includes steps of providing a prosthesis having an outer surface and a lumen, locating a body lumen having an aneurysm, placing the prosthesis in a desired position with respect to the aneurysm so that the prosthesis lumen sealingly engages the body lumen, and using magnetism to secure the prosthesis in the selected position.

[0017] Yet another embodiment of the invention provides an anastomotic component including a sleeve having a lumen adapted to receive a first vessel, and a plate extending away from the sleeve, the plate having an opening communicating with the sleeve lumen wherein at least one of the sleeve and plate includes a locking portion configured to lockingly engage another anastomotic component secured to a second vessel.

BRIEF DESCRIPTION OF THE DRAWING
FIGURES

[0018] Other features, benefits and advantages of the invention will become apparent from the following detailed description of preferred embodiments thereof, taken in conjunction with the accompanying Figures, wherein:

[0019] FIGS. 1A-1C are sequential perspective views showing a vessel being attached to an anastomotic component according to one embodiment of the invention;

[0020] FIGS. 2A-2B are sectional views corresponding to FIGS. 1A and 1C, wherein a second anastomotic component provided on a target vessel is coupled to the anastomotic component shown in FIG. 1A;

[0021] FIG. 3A is an exploded perspective view of a vessel and an anastomotic component constructed according to another embodiment of the invention;

[0022] FIGS. 3B and 3C show the anastomotic component of FIG. 3A being attached to the end of the vessel;

[0023] FIG. 4A is an exploded perspective view of the anastomotic component shown in FIGS. 3B and 3C.

[0024] FIG. 4B is an elevation view, in section, of the anastomotic component shown in FIG. 4A;

[0025] FIG. 5 is a lower plan view of an anastomotic component constructed according to another embodiment of the invention;

[0026] FIG. 6 is an exploded perspective view of the anastomotic component shown in FIG. 5;

[0027] FIG. 7 is a perspective view of the anastomotic component shown in FIGS. 5 and 6 partially assembled;

[0028] FIG. 8 is an upper plan view of the anastomotic component shown in FIG. 7;

[0029] FIG. 9 is a lower plan view of the anastomotic component shown in FIG. 7;

[0030] FIG. 10 is a lower plan view of the anastomotic component shown in FIG. 9 with securing portions of the component being indicated in phantom;

[0031] FIG. 11 is a perspective view of a delivery device constructed according to one embodiment of the invention, wherein the anastomotic components shown in FIGS. 1-10 are loaded on the device;

[0032] FIG. 12 is a perspective view showing the delivery device closed with the first and second anastomotic components locked in place, wherein the device includes a tissue removal mechanism;

[0033] FIG. 13 is a perspective view of the delivery device shown in FIG. 12 after the tissue removal mechanism has been removed from the delivery device;

[0034] FIG. 14 is a perspective view showing the delivery device of FIG. 13 shifted relative to the second anastomotic component;

[0035] FIG. 15 is a perspective view showing the first anastomotic component moved into locking engagement with the second anastomotic component;

[0036] FIG. 16 shows the delivery device opened to release the now-coupled first and second anastomotic components.

[0037] FIG. 17 is an exploded perspective view showing first and second anastomotic components constructed according to another embodiment of the invention;

[0038] FIG. 18 is an upper plan view of the second anastomotic component shown in FIG. 17;

[0039] FIG. 19 is a perspective view corresponding to FIG. 17 wherein the second anastomotic component has been actuated to its tissue securing position;

[0040] FIG. 20 is a sectional view showing the first and second components of FIG. 19 coupled;

[0041] FIG. 21 is an exploded perspective view, in section, of the two components shown in FIG. 18 modified according to another embodiment of the invention;

[0042] FIGS. 22, 23A and 23B are sequential perspective views, partially in section, showing a device constructed according to another embodiment of the invention being used to treat a diseased lumen in a patient's body;

[0043] FIGS. 24A and 24B are sequential perspective views, in section, showing a device constricted according to another embodiment of the invention being used to repair a body lumen;

[0044] FIGS. 25A and 25B are sequential perspective views showing the device of FIGS. 24A-24B being used to secure a vascular prosthesis to a vessel;

[0045] FIGS. 26A-26C are elevation views, in section, of lumen repair devices constructed according to the other embodiments of the invention;

[0046] FIGS. 27A-27E are elevation views, in section, of lumen repair devices constructed according to the other embodiments of the invention;

[0047] FIGS. 28A-28B and 29A-29B are perspective sectional views showing a vessel repair device constructed according to another embodiment of the invention; and

[0048] FIGS. 30A-30B and 31 are views showing magnetic components constructed according to another embodiment of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0049] With reference to FIGS. 1A-1C, a first embodiment of the invention is shown alongside a first vessel, organ, or part thereof, indicated by reference numeral 10. The various embodiments may be used to form an anastomosis between vessels, organs, or any anatomical structure having a lumen, for example. The invention also encompasses devices and methods for repairing a diseased body lumen.

[0050] It will be appreciated that the invention has applications beyond the specific uses mentioned above. Additional exemplary applications for the invention are disclosed in the aforementioned priority applications, the entire subject matter of each application being expressly incorporated herein by reference.

[0051] A first anastomotic component 12 comprises a body which, in the illustrated embodiment, is an annular

member 14 having an opening 16. The anastomotic component 12 also includes a sleeve 18 with a lumen 20 (FIG. 1A). An end portion 22 of the first vessel 10 is passed through the lumen 20 of the sleeve 18 (FIG. 1B), and a portion 24 of the vessel 10 that extends beyond the sleeve 18 is trimmed even with the sleeve end 26 (FIG. 1C). It will be appreciated that the first vessel 10 and the anastomotic component 12 may be secured in a different relative position than that shown in FIG. 1C. For example, the end of the vessel 10 may extend beyond and be everted (not shown) over the end 26 of the sleeve 18.

[0052] The vessel 10 may be attached to the anastomotic component 12, and preferably the sleeve 18, by any suitable means, e.g., adhesive, staples, clips, pins, suture, etc. FIG. 2A shows the first anastomotic component 12 secured to the first vessel 10. As can be seen, a portion 28 of the vessel 10 extends along the length of the sleeve 18. In this embodiment, the exterior of the vessel portion 28 is partially or entirely adhesively secured to the inner surface of the sleeve 18. A portion 30 of the sleeve 18 extends beyond the annular member 14 and terminates at the vessel end 32. This exposes an intimal surface 32 of the first vessel 10 at the end 26 of the sleeve 18 of the component 12 (FIG. 2A).

[0053] FIG. 2A also shows a second anastomotic component 36 positioned next to the first component 12. The second component 36 comprises a pair of annular members 38, 40, disposed on opposite surfaces of the wall of a second vessel 42. In this embodiment, magnetic force secures the second component members 38, 40 to the second vessel 42; magnetic force also secures the first and second anastomotic components 12, 36 together to form the anastomosis. It should be recognized that magnetic force or nonmagnetic force (or a combination of the two) may be used to secure one or both anastomotic components to a respective vessel, or to couple the two components together to place the vessels in communication.

[0054] As seen in FIG. 2A, the members 38, 40 of the second component have respective openings 44, 46 that are aligned with an opening 48 in the wall of second vessel 42. The first anastomotic component 12 is magnetically coupled to the second anastomotic component 36, with the annular member 14 engaging the annular member 38 (FIG. 2B). The extended portion 30 of the sleeve 18 is positioned through the openings 44, 46 of the second component members 38, 40 and through the opening 48 in the side wall of the second vessel 42. The first and second components 12, 36 are preferably sized and configured to leave a relatively small amount of foreign material in the blood flow path. In this embodiment, essentially only the material of the second component member 40 is exposed to blood, as shown in FIG. 2B. Minimizing the amount of foreign material in the blood flow path is desirable because it decreases the possibility of thrombosis and thus improves patency of the anastomotic connection.

[0055] In the illustrated embodiment, the thickness T1 of the second component, including the thickness of the second vessel wall 42, is equal (or approximately equal) to the length L1 of the extended portion 30 of the first component 12. As a result, as shown in FIG. 2B, the end 26 of the sleeve 18 and the intimal surface 32 of first vessel 10 are substantially flush with the inner surface of the annular member 40. This configuration allows the first vessel 10 to extend only

through the members **38, 40** and the second vessel wall **42**, thereby removing the members **38, 40** from the blood flow path.

[0056] As noted above, magnetic or nonmagnetic force may be used to secure the anastomotic components of the invention to a selected vessel. With reference to FIG. 3A through FIG. 4B, an embodiment using a mechanical, non-magnetic attachment will be described.

[0057] FIGS. 3A-3C show a first vessel **50** having a sidewall **52** and an end **54**. An anastomotic component **56** comprises a base **58** and a locking member for securing the base **58** to the vessel **50**. In the illustrated embodiment, the locking member is in the form of a fastener **60**. The fastener **60** and the base **58** are configured to lock together, preferably in any of a plurality of positions, so as to attach the vessel **50** to the base **58**.

[0058] Referring to FIG. 3A, the base **58** comprises a collar **62** extending from an annular plate **64**. The illustrated collar **62** has multiple layers, namely, an inner sleeve **66**, a middle sleeve **68** and an outer sleeve (omitted from FIGS. 3A-3C for clarity, but designated by reference numeral **70** in FIGS. 4A and 4B). The inner sleeve **66** is sized and configured to receive the vessel **50**. The middle sleeve **68** is configured to lockingly engage the fastener **60**. The outer sleeve **70** provides a cover and, preferably, means (FIGS. 4A and 4B) for securing the anastomotic component **56** to another anastomotic component (not shown).

[0059] The middle sleeve **68** of the collar **62** has a plurality of paired arms **72**, each pair is defining a space **74**. The fastener **60** comprises a base **76** and a plurality of prongs **78** configured to enter the spaces **74**. Each prong **78** has an end **80** and multiple locking elements **82**. The locking elements **82** carried by the prongs **78** engage the ends **73** of the arms **72** to lock the fastener **60** to the base **58**. It will be appreciated that the specific manner of locking the base **58** and fastener **60** together may be different from that shown. As an example, rather than using an integrally formed fastener with several prongs **78**, a plurality of individual, discrete prongs (e.g., staples) could be used to secure the base **58** to the vessel **50**.

[0060] The manner in which the first anastomotic component **56** is secured to the vessel **50** will now be described. The end **54** of the vessel **50** is passed through the bore of the plate **64** and the inner sleeve **66** to a position adjacent the end of the collar **62**. The end **54** of vessel **50** may be turned outwardly, as shown in FIG. 3B, which exposes the intimal surface of the vessel. It will be understood that the end **54** of the vessel **50** could also be turned and everted over the collar **62**, i.e., back toward the plate **64**, rather than simply flared over the end of the collar **62**, as shown in FIGS. 3B-3C.

[0061] Referring to FIG. 3C, the fastener **60** is moved toward the base **58** and the sharpened ends **80** of the prongs **78** pass through the tissue of vessel **50**. Each prong end **80** then enters the space **74** between a pair of arms **72**. The prong locking elements **82** lockingly engage the ends **73** of the arms **72** in ratchet-like fashion. The fastener **60** is moved farther toward the base **58** until the fastener base **76** presses the vessel end **54** against the end of the collar **62**, and in particular against the ends of the middle and outer sleeves **66, 68**. The prong locking elements **82** and the arm ends **73**

maintain the base **58** and fastener **60** in the desired relative position vis-à-vis the vessel **50**.

[0062] FIGS. 4A-4B show the locking relationship between the fastener **60** and an anastomotic component that is designated by reference numeral **56'** in view of structural differences from the anastomotic component **56** shown in FIGS. 3A-3C. In particular, the anastomotic component **56'** of FIGS. 4A-4B is provided with a coupling mechanism (described below) that locks with a complementary mechanism on another component. It should be noted that the specific construction of either component may be varied from the exemplary configurations illustrated in the Figures.

[0063] FIGS. 4A-4B show the multiple sleeves of the collar **62** of the base **58'**. In particular, FIG. 4B shows the sleeves **66, 68, 70** and how they cooperate to lockingly receive and engage the prongs **78** of fastener **60**. The means for coupling the component **56** to another component are, in the illustrated embodiment, carried by the outer sleeve **70** and comprises a rim **70A** extending around the collar **62**. The rim **70A** cooperates with the plate **64'** (modified from the plate **64** of FIGS. 3A-3C) to form a recess **70B**. This recess **70B** is configured to engage a portion of another anastomotic component (not shown) in a snap-fit manner to create a fluid-tight anastomotic connection. These Figures show only one possible means for coupling the anastomotic component **56** to a second anastomotic component (not shown).

[0064] The anastomotic components of the embodiments of FIGS. 1A-2B and FIGS. 3A-4B are adapted to be secured to the end of a vessel and may be used to create various types of anastomoses (e.g., end-to-side or end-to-end). The present invention also encompasses anastomotic components that are designed to be secured to the side wall of a vessel (rather than its end). An exemplary embodiment of such a component will be described with respect to FIGS. 5-10.

[0065] FIG. 5 is an assembly view of an anastomotic component **84** which is configured to be secured to the sidewall of a vessel according to one embodiment of the invention. The anastomotic component **84** comprises a base **86**, a body **88** and a retention plate **90**. The component **84** is provided with a vessel attachment mechanism which, in the illustrated embodiment comprises a wireform coupling structure **92**. The coupling structure **92** includes a plurality of vessel engagement members preferably in the form of a plurality of first wire loops **94**. The first wire loops **94** extend from one end of a coil portion **96**, which defines a lumen **L** passing through the component. A plurality of second wire loops **98** extend from the other end of the coil portion **96** (FIG. 6). The second set of wire loops **98** is used to secure the coil portion **96** and coupling structure **92** to the base **86** and body **88** of the anastomotic component **84**.

[0066] The coupling structure **92** is formed to permit the first, vessel-engaging loops **94** to selectively collapse and expand, as explained below. FIGS. 5-10 show the coupling structure **92** with the vessel engaging loops **94** in their expanded, unbiased orientation. FIG. 11 shows the coupling structure **92** with the vessel engaging loops **94** biased to their collapsed or low profile orientation. In the illustrated embodiment, the loops **94** assume an axial position that is generally parallel to the lumen **L** of the anastomotic component **84**; however, it will be appreciated that the loops **94** could be collapsed in a different manner or to a different extent than shown in the figures.

[0067] FIG. 6 shows one preferred manner of constructing the anastomotic component 84 it will be recognized, of course, that the specific configuration shown and described herein is made for sake of example and for purposes of making a complete disclosure, and is not intended to limit the scope of the present invention as defined by the claims.

[0068] Referring to FIG. 6, the base 86, body 88, retention plate 90 and coupling structure 92 of the anastomotic component 84 are annularly shaped so that when assembled they form a lumen L (FIG. 5) that extends through the component 84. The second set of wire loops 98 of the coupling structure 92 are positioned within complementarily-shaped openings 100 formed in the body 88 (FIG. 7). The ends 104 of the coil that forms portion 96 and loops 94, 98 sit in corresponding grooves in the body 88. The body 88 is then attached to base 86, and the retention plate 90 is placed over the tissue-engaging loops 94, preferably while the loops 94 are biased to their collapsed orientation (FIG. 11).

[0069] The retention plate 90 has a plurality of slots 102 (FIG. 6) that are positioned to overlie the openings 100 in the body 88. The slots 102 receive the legs of each loop 98 and position the loops 94 away from the retention plate 90, as shown best in FIGS. 5, 7 and 10. FIG. 9 shows the retention plate 90 secured to the remaining elements of the anastomotic component 84.

[0070] FIGS. 11-16 show the anastomotic component 56 of FIGS. 3A-4B after it has been secured to the end of the vessel 50 (shown in phantom). These Figures also show the anastomotic component 84 of FIGS. 5-10 prior to its attachment to the side wall of a vessel (not shown). The two components 56 and 84 are mounted in a delivery device 106 arranged to deploy one or both components to form the anastomosis. The exemplary embodiment connects two vessels via an end-to-side anastomosis; however, it should be appreciated that the invention may be used to make other types of connections, for example, end-to-end and side-to-side anastomoses.

[0071] The delivery device 106 includes a cradle 108 which receives the first anastomotic component 56 and the first vessel 50. The cradle 108 comprises a pair of jaws 110 movable between open (FIG. 11) and closed (FIG. 12) positions in order to mount the first anastomotic component 56 and vessel 50 in the delivery device 106. FIG. 11 shows the second anastomotic component 84 with the tissue engaging loops 94 of the coupling structure 92 collapsed for delivery, while FIG. 12 shows the coupling structure 92 expanded for engaging tissue (now shown)

[0072] As shown in FIGS. 11 and 12, the delivery device 106 may include a tissue removal mechanism 114 for forming an opening in a vessel that is placed in communication with the lumen L (FIG. 13) of the anastomotic component 84. The tissue removal mechanism 114 comprises a tissue holding element in the form of a barbed needle 116, and a tissue cutting tube 118 that is rotated in order to remove a desired amount of tissue. The tissue holding element is retractable in order to retract the needle 116 and pull the cut tissue into the tube 118 for removal. The means for moving the needle 116 and cutting tube 118 axially, and for rotating the tube 118, are not shown but may comprise any suitable drive or transmission assembly. The mechanism 114 is slidably disposed in a bore 120 in the delivery device 106 (FIG. 12).

[0073] The tissue removal mechanism 114 is removed from device 106 (FIG. 13) after forming an opening in the vessel, and the second anastomotic component 84 is secured to the vessel (not shown) by expanding the helical loops 94. The second anastomotic component 84 is then aligned with the first component 56 by moving the device 106 and first component 56 relative to the second component 84 (and the second vessel). The two anastomotic components 56, 84 are initially unaligned, as shown in FIGS. 11-13. The delivery device 106 is moved from the position shown in FIG. 13 to the position shown in FIG. 14, which shifts the first anastomotic component 56 and first vessel 50 into alignment with the second anastomotic component 84.

[0074] The jaws 110 of the cradle 108 are provided with grooves 112 (FIG. 11) configured to receive the base 86 of the second anastomotic component 84 in a sliding manner. This facilitates controlled movement of the device 106 with respect to the second anastomotic component 84, from the position shown in FIG. 13 to the position shown in FIG. 14.

[0075] After being aligned, the first and second anastomotic components 56, 84 are secured to each other to place the lumens of the first and second vessels in communication and complete the anastomosis. In the illustrated embodiment, this is accomplished by moving the first anastomotic component 56 distally from the position shown in FIG. 14 to the position shown in FIG. 15, which moves component 56 into engagement with the second anastomotic component 84, as shown in FIG. 14. More specifically, the collar 62 of the first anastomotic component 56 is moved into the lumen L of the second anastomotic component 84 and enters the coil portion 96 of the wireform coupling structure 92. This moves the plate 64, 64' of the first anastomotic component 56, 56' next to, and preferably against, the exterior of the base 86 of the second anastomotic component 84.

[0076] FIG. 16 shows the delivery device 106 after the jaws 110 of cradle 108 have been opened to release the first and second anastomotic components 56, 84. The grooves 112 of the device 106 release the base 86 of the second anastomotic component 84, which has been secured to its vessel. The delivery device 106 is removed from coupled components 56, 84, leaving the two vessels in communication to complete the anastomosis.

[0077] The anastomotic components of the invention may be secured together by any suitable means which, as noted above, may use mechanical or magnetic force (or both) to achieve coupling. In the illustrated embodiment, the anastomotic components are secured to the vessels as they are secured to each other, namely, mechanically. In another embodiment, for instance, the first component is attached to its vessel mechanically but is coupled to the second component magnetically, for example, in accordance with any of the teachings in the aforementioned priority applications. An exemplary mechanism for securing the anastomotic components will now be described with respect to FIGS. 17-21.

[0078] FIG. 17 shows the first anastomotic component 56', which includes the modified plate 64' and rim 70 that define the recess 70B. The construction of the anastomotic component 56' is described above with respect to FIGS. 4A and 4B. The second anastomotic component is designated by reference numeral 84' as it, unlike the component 84, includes a mechanism for coupling the components. The illustrated mechanism is in the form of spring wires 122

which are located around the lumen L of the component 84'. See FIG. 18. FIG. 19 shows the first and second components 56', 84' of FIG. 17 after the component 84' has been deployed and the wire loops 94 are in their expanded orientation.

[0079] FIG. 20 shows the first and second anastomotic components 56', 84' after they have been coupled, which, in this example, is done mechanically. As can be seen the spring wires 122 are received within the recesses 70B, preferably in tight locking fashion, for example, via a spring or snap fit engagement. Other possible locking mechanisms may of course be used.

[0080] FIG. 21 shows one alternative coupling mechanism or structure carried by a first anastomotic component 130. Specifically, the component 130 includes a multilayer collar comprising an inner layer 132, a middle layer 134 and an outer layer 136. The inner layer 132 is carried by a plate 138, and surface 140 is configured to rest on the plate 86 of the component 84. The outer layer 136 has one or more slots or grooves 137 configured to lockingly engage structure carried by the second anastomotic component 84. The second anastomotic component 84 includes plate 86 with an edge 142 (FIG. 21) that is received in some or all of the slot(s) 137 in the outer layer 136 of the first anastomotic component 130. It will be appreciated that the exact manner that the plate 86 engages the slot(s) 137 may vary widely while still providing a secure, sealed connection.

[0081] Additional aspects of the invention will be described with respect to FIG. 22 through FIG. 29B, which show various systems, devices and methods for treating body lumens, i.e., hollow anatomical structures having a lumen, for example, a blood vessel. FIG. 22 shows a body structure in the form of a blood vessel, and more specifically, the abdominal aorta. The vessel is designated generally by the reference numeral 150 and includes a lumen 152 defined by a wall 154. The wall 154 has an aneurysm 156 where the lumen 152 is enlarged and the wall 154 is thinner (although not in the Figures). The vessel 150 has side branches 158 and a Y-shaped section 160.

[0082] FIG. 22 also shows a pair of docking devices 162 secured to the wall 154 of the vessel 150, the devices being in the form of mesh structures expanded against the surface of the vessel wall 154. Also shown is a device 164 preferably in the form of a stent graft with a body 166 and attachment members 168 configured to engage attachment members 170 provided on the docking devices 162.

[0083] FIGS. 23A and 23B show the stent graft 166 being collapsed for delivery into the lumen 152 of the vessel 150. After being passed into the lumen 152 the graft body 166 is expanded and the attachment members 168 are coupled to the attachment members 170 of the docking devices 162. In the illustrated embodiment, the attachment members 168 and the members 170 are magnetically attracted so that upon being moved into proximity to each other they become securely connected. As a result, as shown in FIG. 23B, the device 164 extends through the aneurysmal section of the vessel 150 so that its lumen 172 replaces the diseased lumen. The docking devices 162 are in sealing contact with the vessel wall 154 and the stent graft 166 is in sealing contact with the docking devices. As such, blood flow past the aneurysm must take place through lumen 172 of the prosthesis.

[0084] FIGS. 24A and 24B show another embodiment of the invention comprising a pair of proximal docking members 180 and a pair of distal docking members 182. The docking members 180 and 182 are shown in conjunction with the vessel 150 of FIG. 22 and FIGS. 23A-23B and may be constructed in any suitable manner that facilitates their attachment to a vessel wall, for instance, expansion against the vessel wall as described above with respect to the docking members 162 of the previous embodiment.

[0085] The proximal docking members each have a stent-like body 184 and an attachment portion 186, while the distal members each have a stent-like body 188 with an attachment portion 190. FIG. 24B shows the four docking members 180, 182 with members 180 secured to side branches 158 and members 182 secured to the Y-shaped section 160 of the vessel 150. The number and position of docking members used may vary upon application or user preference. Two different, exemplary approaches are shown in FIGS. 23B and 24B. Once the docking members 180 and 182 have been attached to the vessel wall in a secure sealed fashion as shown in FIG. 24B, a vascular prosthesis (not shown) is secured to the respective attachment portions 186, 190 of the members 180 and 182.

[0086] FIG. 25A shows another configuration wherein several docking members 200 are constructed and used much in the manner described above. Each docking member 200 has attachment portions 202 and is attached to a side branch 204 of the vessel 206. FIG. 25B shows the vessel 206 after a vascular prosthesis 208 has been secured to the docking members 200. The exemplary prosthesis 208 comprises a graft body 210 with attachment structure 212 provided adjacent proximal and distal openings 214, 216 of the graft. The graft attachment structure 212 is secured to complementarily-formed attachment portions 202 of the docking members 200 to sealingly connect the graft lumen 218 with the lumens of all four side branches 204, as shown in FIG. 25B. The diseased lumen L of the vessel 206 is thereby replaced by the lumen 218 of the graft body 210.

[0087] The means for connecting the docket member attachment portions 202 and the graft attachment structures 212 may utilize magnetic force, mechanical force, or a combination of the two. In the illustrated embodiment, the docking members 200 are provided with permanent magnets configured to be coupled to corresponding permanent magnets on the prosthesis 208. In addition, a proximal end 220 of the graft body 210 is provided with an additional coupling device 222 having an opening 224, the device 222 being expanded securely against the wall of vessel 206.

[0088] FIGS. 26A-26C show for sake of example, various vascular graft configurations according to other embodiments of the invention. The illustrated grafts are suitable for use with diseased vessels with or without side branches. FIG. 26A shows a graft 230 comprising first and second portions 232, 234 which are fixed to a vessel and joined in fluid communication. The first portion 232 has attachment members 236 while the second portion 238 has attachment members 240, the use of which is explained above. The two portions 232 and 234 are attached by providing mating members 236a and 240a thereon.

[0089] FIG. 26B shows a prosthesis or graft 250 having a first portion 252 and a second portion 254 attachable thereto. The first portion 252 has multiple attachment portions 256

(including main and several side branches or lumens). The second portions **254** each have attachment portions **258** and an attachment portion **258a**, the latter being securable to mating portions **256a** provided on two legs of the first portion **252** of the graft **250**.

[0090] FIG. **26C** shows a prosthesis **260** with first, second and third portions **262**, **264** and **266**, which are attachable to each other in a secure, sealing manner. The three portions **262**, **264** and **266** of the graft **260** are respectively provided with several attachment portions **268**, **270** and **272**, which includes portions **268a**, **270a**, and **272a**, for connecting the graft portions, **262**, **264**, and **266** to each other via securely via magnetic or mechanical means.

[0091] FIGS. **27A-27E** show various docking members constructed according to additional embodiments of the invention. The docking members have an expandable body to allow engagement with a vessel wall (not shown) in order to secure the member thereto. It will be recognized that other ways of securing a docking member to a vessel may be used without departing from the principles of the present invention.

[0092] FIG. **27A** shows a docking member **280** with a collapsed body **282** and prosthesis attachment structure **284** comprising sections **206** of a suitable magnetic material. The sections **286** are relatively movable to and from the position of FIG. **27A**. The body **282** of the docking members **280** is expanded to the position of FIG. **27B** and into engagement with a vessel wall (not shown). This moves the sections **286** of the attachment structure **284** away from each other to the position of FIG. **27B**, which forms a plurality of gaps **288** between adjacent sections **286**.

[0093] FIG. **27B** also shows a portion of a prosthesis such as a vascular graft **290**. One end **292** of the graft **290** is provided with a plurality of attachment members **294** spaced from each other and sized to be received in the gaps **288** of the docking member sections **286**. The members **294** are placed in the gaps **288** to mechanically and magnetically couple the docking member **280** and the graft **290**.

[0094] FIG. **27C** shows a docking member **300** with an expandable body **302** and an end **304** provided with attachment structure **306**. The attachment structure **306** comprises a plurality of sections **308** which engages corresponding structure on a graft (not shown) to fix the graft to the docking member **300**, for example, via magnetic, mechanical or other means.

[0095] FIG. **27D** shows a docking member **310** comprising an expandable body **312** and attachment structure **314** at one end thereof. The structure **314** is similar to the structure **306** of the previous embodiment in that it includes the plurality of spaced sections **316**. The attachment sections **316**, though, are disposed within the lumen **318** of the body **312** of the docking member **310**. A graft (not shown) having mating attachment structures (i.e., spaced segments) is then secured to the member **310**, much in the same manner as discussed above.

[0096] FIG. **27E** shows a docking member **320** comprising an expandable body **322** and attachment structure **324** at an end thereof. The attachment structure **324** is in the form of ferromagnetic element **326** which may be, for example, a steel coil **326** capable of being compressed and expanded.

The coiled element **326** is preferably ferromagnetic for being magnetically coupled to a graft-carried magnet (not shown).

[0097] FIGS. **28A-28B** show another embodiment of the invention for use in securing a prosthesis to a vessel that is diseased at or near a side branch. An exemplary vessel **330** with a side branch **332** is shown in FIG. **28A** along with a prosthesis or graft **334** and a prosthesis fixation device **336**. The graft **334** is preferably tubular and is configured to be secured to the wall **338** of vessel **330** such that the lumen **340** of the graft **334** replaces the diseased lumen **342** of the vessel **330**.

[0098] The graft **334** has an opening **344** sized and configured for alignment with the lumen **346** of the vessel-side branch **332** once the graft **334** has been secured to the vessel **330**. The area surrounding or adjacent to the **344** of graft **334** is provided with one or more attachment members **348** for securing the graft to the fixation device **336**, as explained below. As shown in FIG. **28A**, the fixation device **336** comprises a tubular graft body **350** with a flared end **352**. The graft body **350**, in whole or in part, is expandable, for example, as described above with respect to docking members of the previous embodiments. The tubular graft body **350** passes through the opening **344** in the graft **334** and is expanded against the wall **354** of the side branch **332** to secure the graft **350** to the vessels as shown in FIG. **28B**.

[0099] This places the lumen **346** of the side branch **332** in sealing communication with the lumen **340** of the graft body **350**, which itself is in sealing communication with the lumen **340** of the graft **334** and the lumen **342** of the vessel **330**. The flared end **352** of the graft fixation device **336** includes attachment structure in the form of segments or portions **354** configured and arranged to be coupled with the attachment portions **348** provided on the graft **334** (as shown in FIG. **28B**).

[0100] FIGS. **29A-29B** show still another embodiment of the invention that provides a collapsible/expandable prosthesis or graft for use in treating a diseased vessel. The illustrated graft **370** comprises a tubular body **372** with at least one end **374** thereof provided with an attachment structure **376** for securing the graft end **374** to a docking member that has been placed in a desired position with respect to a vessel (not shown). The body **372** of the graft **370** may comprise only graft material, such as EPTFE, or graft material reinforced by suitable means, for example a stent.

[0101] FIG. **29A** shows the end of **374** of the graft body **372** in its collapsed orientation. The attachment structure **376** comprises a plurality of permanent magnets **378** which, in the collapsed orientation of FIG. **29A**, are disposed next to each other. The polarity of the magnets **378** is shown in FIG. **29B**, which also shows the graft body **372** disposed between adjacent magnets **378**. For delivery and docking the end **374** of graft **370** is collapsed (FIG. **29A**) and then expanded (FIG. **29B**) into engagement with corresponding attachment structure carried by the docking members. The magnets **378** repel each other such that the graft end **374** assumes the position of FIG. **29B** (when unbiased). The magnets **378** place the graft in the desired position and sever to secure the graft **370** to a docking member (not shown). It will be recognized that the illustrated structure for securing a graft to a docking member represents only one of many possible constructions.

[0102] FIGS. 30A-30B show a component 380 comprising an attachment portion 382 that is preferably in the form of screw threads 384. The component has a coupling portion 386 preferably comprising a permanent magnet 388. The threads 384 are used to fix the component 380 to tissue (or bone, etc.) so as to present the magnet 388 for coupling to a prosthesis (not shown), another component, etc. The attachment portion 382 and coupling portion 386 may be separate elements that are fixed to one another, or they be integrally formed with the component; which is preferably provided with a corrosion-resistant biocompatible coating or layer.

[0103] FIG. 30B shows an exemplary delivery device 390 for deploying the component 380. The device includes a drive shaft 392 and a catheter sheath 394 and may be used in a minimally invasive manner to deliver the component 380. This embodiment may be used in many applications, e.g., AAA repair, percutaneous valve repair, etc. FIG. 31 shows a plurality of components 380 fixed to a hollow body, such as the abdominal aorta AA, in a desired pattern. A prosthesis, such as stent graft 396, has members 398 that are magnetically coupled to the magnets 388 of components 380, which couples the prosthesis to the aorta, as shown in FIG. 31.

[0104] Other features, aspects and advantages of the invention beyond those specifically discussed will be apparent to those skilled in the art. Modifications, alterations and variations of the illustrated embodiments may be made without departing from the spirit of the invention.

1. A method for forming an anastomosis between two blood vessels using magnetism, the method comprising the steps of:

- securing a first component to a first blood vessel;
- securing a second component to a side wall of a second blood vessel with an opening in the second component substantially aligned with an opening in the side wall of the second blood vessel;
- placing the first component in contact with at least one of the second component and the side wall of the second blood vessel;
- positioning an intimal surface of the first blood vessel adjacent an intimal surface of the second blood vessel; and
- using magnetism to couple the first and second components and form an anastomosis between the first and second blood vessels.

2-37. (canceled)

38. A method for forming an anastomosis between two blood vessels, the method comprising the steps of:

- securing a first component to an end portion of a first blood vessel, wherein the first component and the end portion of the first blood vessel have substantially the same length and an intimal surface of the first blood vessel is uncovered by the first component;
- securing a second component to a side wall of a second blood vessel with an opening in the second component substantially aligned with an opening in the side wall of the second blood vessel;

placing the first component and the end portion of the first blood vessel through the opening in the second component and the opening in the side wall of the second blood vessel, wherein the uncovered intimal surface of the first blood vessel is disposed adjacent an intimal surface of the side wall of the second blood vessel; and

coupling the first and second components to form an anastomosis between the first and second blood vessels.

39. A method for securing an anastomotic component to an end of a blood vessel, the method comprising steps of:

providing an anastomotic component including a sleeve defining a lumen;

securing an end portion of a blood vessel to the anastomotic component by passing the end portion through the lumen of the sleeve;

placing an edge of the blood vessel in substantial alignment with an edge of the anastomotic component; and

passing a fastener through the end portion of the blood vessel and into locking engagement with the sleeve, the fastener leaving an exposed intimal surface that extends substantially around the sleeve.

40. A method for securing an anastomotic component to a side wall of a blood vessel, the method comprising steps of:

providing an anastomotic component including a non-expandable portion and an expandable portion, the anastomotic component comprising a wire shaped to define a lumen and multiple tissue engaging portions;

forming an opening in a side wall of a blood vessel;

collapsing the expandable portion of the anastomotic component by collapsing the wire;

expanding the expandable portion of the anastomotic component by expanding the wire; and

securing the anastomotic component to the blood vessel by engaging the tissue engaging portions with the side wall of the blood vessel.

41. A method for treating a lumen defined by a hollow structure in a patient's body, the method comprising steps of:

providing a docking member configured to be secured to tissue;

providing a prosthesis configured to be magnetically coupled to the docking member, the prosthesis having a lumen;

securing the docking member to a vessel in a patient's body, the vessel having a lumen with a diseased portion; and

magnetically coupling the prosthesis to the docking member to place the prosthesis lumen in sealing engagement with the vessel lumen.

42. A method for repairing an aneurysm using magnetism, the aneurysm being located in a patient's body lumen, the method comprising steps of:

providing a prosthesis having an outer surface and a lumen;

locating a body lumen having an aneurysm;

placing the prosthesis in a desired position with respect to the aneurysm so that the prosthesis lumen sealingly engages the body lumen; and

using magnetism to secure the prosthesis in the selected position.

43. An anastomotic component comprising:

a sleeve having a lumen adapted to receive a first vessel;

a plate extending away from the sleeve, the plate having an opening communicating with the sleeve lumen;

at least one of the sleeve and plate including a locking portion configured to lockingly engage another anastomotic component secured to a second vessel.

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