

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
2 October 2008 (02.10.2008)

PCT

(10) International Publication Number
WO 2008/118670 A2

(51) International Patent Classification:
A61F 2/06 (2006.01)

(21) International Application Number:
PCT/US2008/057202

(22) International Filing Date: 17 March 2008 (17.03.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/689,927 22 March 2007 (22.03.2007) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

Published:

— without international search report and to be republished upon receipt of that report

(54) Title: DEVICES AND METHODS FOR CONTROLLING EXPANDABLE PROSTHESES DURING DEPLOYMENT

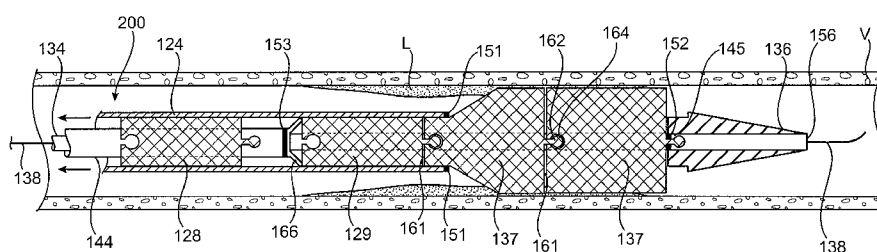


FIG. 2D

(57) Abstract: A catheter for delivering a prosthesis to a treatment site in a body lumen comprises an elongate flexible member and a sheath slidably disposed thereover. A plurality of self-expanding tubular prostheses are carried in axially spaced apart locations along the elongate member, within the sheath. The prostheses may be selectively interlocked with one another and are constrained by the sheath in a radially contracted configuration. The prostheses are separately releasable from the sheath when the sheath is retracted relative to the elongate member. The catheter also has a pusher member slidably disposed along the elongate member within the sheath. The pusher is adapted to move past the prostheses in a first direction without displacing the prostheses, while in a second direction the pusher engages a selected prosthesis so as to move the prosthesis with the pusher to interlock the selected prosthesis with a second prosthesis.

DEVICES AND METHODS FOR CONTROLLING EXPANDABLE PROSTHESES DURING DEPLOYMENT

BACKGROUND OF THE INVENTION

5 [0001] 1. Field of the Invention. This invention relates generally to medical apparatus and methods, and more specifically to vascular catheters, stents and stent delivery systems for use in the coronary and peripheral arteries as well as other vessels and body lumens.

[0002] Stenting is an important treatment option for patients with occlusive disease in the vasculature as well as other systems such as the biliary tract. The stenting procedure involves
10 placing a tubular prosthesis at the site of a lesion, typically within a diseased artery. The procedure is performed in order to maintain the patency of the artery and is often performed after a primary treatment such as angioplasty. Early stent results suffered from high rates of restenosis, i.e. the tendency for the stented vessel, such as an artery, to become re-occluded following stent implantation. However, in recent years, restenosis rates have decreased
15 substantially, due to many improvements in stent delivery, stent technology as well as the use of drugs. As a result, the number of stent related procedures being performed worldwide continues to dramatically increase.

[0003] Stents are typically either self-expanding or balloon expandable and they are delivered to the arteries using long, flexible vascular catheters typically inserted
20 percutaneously through the patient's femoral artery. For balloon expandable stents, the stents are usually mounted over a balloon on the delivery catheter, thus, when the balloon is inflated, it expands which correspondingly expands and deforms the stent to the desired diameter. The balloon can then be deflated and removed, leaving the stent in place. For self-expanding stents, the stent is released from the delivery catheter and it resiliently expands
25 into engagement with the vessel wall. Self-expanding stents are often used in the peripheral vascular system since they are more resilient than balloon expandable stents. Resilient stents are better suited for implantation into regions of the body closer to the body's surface, such as a peripheral artery, since the stent's resilience helps minimize damage or crushing caused by body movement or externally applied forces.

[0004] Self-expanding stents may also be used in the coronary arteries and may provide advantages over balloon expandable stents. Balloon expandable stents are typically expanded with a balloon having a constant diameter and therefore the expanded stent may not conform well to a coronary artery having variations in diameter due to tortuosity or taper. Therefore, there is a potential for gaps between the outer stent surface and the inner surface of the artery wall. These gaps may lead to thrombus formation and recently, there has been concern that this effect is pronounced in drug eluting stents because the drug delays endothelialization of the stent surface, allowing the gaps to remain for a longer period of time. Self-expanding stents expand until the outer stent surface is constrained by contact with a vessel wall. Therefore, gaps between the stent and the arterial wall are minimized thus helping to reduce thrombus formation. Companies such as Devax (Irvine, CA) and Cardiomind (Sunnyvale, CA) are developing self-expanding stents for implantation into the coronary arteries.

[0005] Current stent delivery technology suffers from a number of drawbacks which can make delivery of stents challenging. In particular, current stent delivery catheters often employ stents having fixed lengths. The proper selection of fixed length stents requires accurate knowledge of the lesion length being treated. While lesion length may be measured prior to stent deployment using angiography and fluoroscopy, these measurements are often inaccurate. Thus, if an incorrectly sized stent is introduced to a treatment site, it must be removed from the patient along with the delivery catheter and replaced with a different device having the correct stent size. This prolongs the procedure, increases waste and results in a more costly procedure.

[0006] Additionally, and especially in the case of peripheral vascular disease, lesions are often long and diffuse. A single long stent may be deployed to treat a single lesion or to span multiple lesions, however this is not optimal since longer stents tend to have higher fracture and restenosis rates as compared with shorter stents. Therefore, placement of multiple shorter stents in a long lesion may be advantageous instead of deploying a single long length stent.

[0007] The use of "custom length" stents as an alternative to fixed length stents has been proposed. One such approach for providing a custom length stent has been to use segmented stents for treatment in which only some of the stents are deployed for treatment. Several exemplary systems are described in several copending, commonly assigned applications which are listed below. In these systems, the stent segments are deployed by selective

advancement over the delivery catheter. After delivering an initial group of segments, the catheter may be repositioned to a new treatment site and a further group of segments can then be deployed. These systems enable treatment of multiple lesions with a single device and may contain up to fifty segments.

- 5 [0008] While this technology represents a significant improvement over earlier stent delivery systems, in the case of self-expanding stents, accurate delivery of the stents to a treatment site can present other challenges. Because self-expanding stent segments tend to rapidly spring open upon deployment, it is difficult to control their placement. In some cases, the stents may actually eject or "watermelon seed" away from the delivery catheter.
- 10 Therefore, a delivery system that allows more precise control of stent deployment and placement is desirable.

- [0009] Another challenge with existing "custom length" stent delivery systems is that to deliver multiple stent segments to multiple lesion sites requires an intricate delivery system that can be somewhat complex to use. Thus, a simpler delivery system that allows length
- 15 customization is desirable, especially for use in treating long lesions in the peripheral and coronary vasculature.

- [0010] For the reasons above, as well as others, it would be desirable to provide improved prosthetic stents and delivery catheters. It would be particularly desirable to provide catheters which enable stent length to be customized using multiple stent segments. It is also
- 20 desirable to provide a delivery system that is flexible and can track torturous vessels and that has a simple construction and is less costly and easy to use in deploying a selectable number of stent segments to a treatment site. It is further desirable to provide a stent delivery catheter that can control the delivery and placement of self-expanding stents in the peripheral and coronary vascular system.

- 25 [0011] 2. Description of the Background Art. Prior publications describing catheters for delivering multiple segmented stents include: U.S. Publication Nos. 2004/0098081, 2005/0149159, 2004/0093061, 2005/0010276, 2005/0038505, 2004/0186551 and 2003/013266. Prior related unpublished co-pending U.S. patent applications include serial number 11/148,713, filed June 8, 2005 (Attorney Docket No. 14592.4002), entitled "Devices
- 30 and Methods for Operating and Controlling Interventional Apparatus"; serial number 11/148,545, filed June 8, 2005 (Attorney Docket No. 14592.4005), entitled "Apparatus and Methods for Deployment of Multiple Custom-Length Prosthesis"; serial number 11/344,464,

filed January 30, 2006 (Attorney Docket No. 021629-003500US), entitled "Apparatus and Methods for Deployment of Custom-Length Prostheses"; serial number 60/784,309, filed March 20, 2006 (Attorney Docket No. 021629-003600US), entitled "Apparatus and Methods for Deployment of Linked Prosthetic Segments"; serial number 11/469,773 filed September 1, 2006 (Attorney Docket No. 021629-004000US), entitled "Custom Length Stent Apparatus"; and serial number 11/462,951, filed August 7, 2006 (Attorney Docket No. 021629-004100US), entitled "Custom Length Stent Apparatus." The full disclosures of each of these patents and applications are incorporated herein by reference.

BRIEF SUMMARY OF THE INVENTION

[0012] The invention generally provides for the delivery of self-expanding prostheses with a flexible delivery catheter capable of navigating vessels such as the peripheral and coronary arteries. The delivery catheter permits controlled deployment of a selectable number of prosthetic segments at a treatment site, thus allowing customization of prosthesis length while the delivery catheter is in a body lumen at a treatment site. Customization of prosthesis length *in situ* permits better matching of the prosthesis length to the lesion length being treated.

[0013] The terms "stent" and "stenting" are defined to include any of the array of expandable prostheses and scaffolds which are introduced into a lumen at a target treatment site and expanded *in situ* thereby exerting a radially outward force against the lumen wall. The prosthesis of the present invention comprises a closed or an open lattice structure and is typically fabricated from an elastic material or self-expanding material, including superelastic materials such as nickel-titanium alloys like Nitinol, or spring temper stainless steels or polymers, and the lattice structures are commonly constrained radially during delivery and upon deployment the constraining structure is removed, allowing the prosthesis to "self-expand" at the target site. The terms "stent," "prosthesis," "prosthetic segment" and "stent segment" refer broadly to all radially expansible stents, grafts, and other scaffold-like structures which are intended for deployment within a body lumen.

[0014] In a first aspect of the present invention, a catheter for delivering a prosthesis to a treatment site in a body lumen comprises an elongate flexible member having a proximal end and a distal end. A sheath is slidably disposed over the elongate flexible member and a plurality of self-expanding tubular prostheses are carried in axially spaced-apart locations

along the elongate flexible member, within the sheath. The plurality of self-expanding tubular prostheses are adapted to be selectively interlocked with one another and they are constrained by the sheath in a radially contracted configuration. The prostheses are separately releasable from the sheath as the sheath is retracted relative to the elongate flexible member.

[0015] The catheter also includes a pusher member that is slidably disposed along the elongate flexible member within the sheath and the pusher is adapted to move past the prostheses in a first direction, usually without displacing the prostheses. In a second direction, the pusher member engages a selected prosthesis and the pusher can move the prosthesis so as to interlock the selected prosthesis with a second prosthesis. The pusher member may have an engagement member which is deflectable radially inward by contact with the prostheses when moved in the first direction while in the second direction the engagement member engages the prostheses selected for deployment. Sometimes the engagement member may comprise a plurality of flexible fingers that extend radially outward from the pusher member. The pusher member often may exert substantially greater axial force against the plurality of self-expanding tubular prostheses when the pusher member is advanced distally than when the pusher member is retracted proximally.

[0016] Sometimes the catheter comprises a stopping element that is axially disposed along the elongate flexible member. The stopping element is adapted to prevent the plurality of self-expanding tubular prostheses from being displaced past the distal end of the elongate flexible member when the pusher member is advanced distally. The catheter may also comprise a handle that is usually near the proximal end of the elongate flexible member and the handle usually has a control mechanism adapted to move the sheath and pusher member. Sometimes the catheter may also include a central lumen disposed within the elongate shaft that can carry a guidewire.

[0017] In another aspect of the present invention, a method for delivering a prosthesis to a body lumen having a lesion with a length comprises introducing into the body lumen one or more self-expanding tubular prostheses. The prostheses are carried at axially spaced apart locations along an elongate flexible member and they are constrained in a contracted configuration within a sheath. Selecting a first group of the tubular prostheses for delivery picks a first group of prostheses that has a combined length substantially traversing the lesion. Bringing the first group into engagement with each other within the sheath interlocks

prostheses in the first group with one another and uncovering the first group from the sheath removes the constraint from the first group so they may expand at the first treatment site while a second group of prostheses is retained within the sheath. Sometimes the method may further comprise selecting one or more additional self-expanding tubular prostheses and bringing them into to engagement with the first group within the sheath so that the additional prostheses interlock with the first group.

[0018] Selecting a first group of prostheses may comprise proximally retracting a pusher member. The pusher member often has a flexible engagement member that is deflected by the prostheses as the pusher member is retracted proximally. Bringing the first group into engagement with each other may comprise engaging at least one of the first group of prostheses with a pusher member and advancing the pusher member distally. Bringing the first group into engagement with each other may also comprise stopping the first group of prostheses from moving distally with a stopping element that is disposed on the elongate flexible member. Engaging the at least one prosthesis may include engaging the prosthesis with a flexible engagement member that is disposed on the pusher member and uncovering the first group can involve proximally retracting the sheath. The method may also comprise releasing a therapeutic agent from the first group of prostheses after expansion at the treatment site. Often, the therapeutic agent may comprise an anti-restenosis agent.

[0019] In still another aspect of the present invention, a self-expanding tubular prosthesis comprises a plurality of self-expanding tubular rings that have a plurality of axial struts and a plurality of connectors coupling adjacent struts together. The axial struts and connectors also may form a plurality of substantially parallel and spaced apart columns of open cells. The axial struts and connectors often form a substantially zig-zag pattern and a bridge member couples adjacent tubular rings together. A plurality of bridges, which may be sigmoidally shaped may join the columns of open cells or rings together. Sometimes the connectors are U-shaped and often the columns of open cells are out of phase with an adjacent column. The prosthesis is usually adapted to be interlocked with an adjacent prosthesis when pressed together and the prostheses remain interlocked with one another even after radial self-expansion. The prosthesis often may have an interlocking tab on one end of the tubular rings that is adapted to interlock with an adjacent tubular ring when the rings are pressed together.

[0020] The interlocking tab may comprise a strut that defines an aperture which is adapted to hold a radiopaque marker. The bridge may be coupled to a connector and have an axially

extending strut that joins the bridge with the connector. The bridge may connect to an apex of the connector, which may be U-shaped. The interlocking tab may comprise a narrow neck region and an enlarged head region which may be C-shaped. The enlarged head region may have an arcuate strut defining a narrow inlet portion and a wider receiving portion. The receiving portion is usually adapted to receive and interlock with an interlocking tab on an adjacent ring.

[0021] The enlarged head region may have a plurality of arcuate struts that are coupled to the ring with a plurality of axial struts and the neck region may comprise a plurality of axial struts. The enlarged head region may also comprise an arcuate strut that forms a C-shape and that is coupled to the ring with an axial strut.

[0022] The prosthesis may also have a female receiving tab on an end of the prosthesis opposite of the interlocking tab. The female tab may include an arcuate strut that defines a receptacle, sometimes C-shaped, which can receive and interlock with an enlarged head of an adjacent prosthesis. The arcuate strut may be coupled to a ring with an axial strut. The female tab may also comprise an arcuate strut that defines an aperture which can hold a radiopaque marker. The prosthesis may further comprise a therapeutic agent that is carried on the prosthesis and that may be released therefrom. Often, the therapeutic agent comprises an anti-restenosis agent. The prosthesis often has an overall length in the range from about 5 mm to about 50 mm. Sometimes each of the prostheses have the same length, although sometimes at least one of the prostheses may have a different length than another of the prostheses.

[0023] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Fig. 1A is a perspective view of an over-the-wire stent delivery catheter in accordance with one embodiment of the present invention.

[0025] Fig. 1B is a cross section of the distal end of the stent delivery catheter illustrated in Fig. 1A.

[0026] Fig. 1C is a perspective view of a stent delivery catheter in accordance with another embodiment of the present invention.

[0027] Figs. 2A-2E illustrate selection and deployment of prostheses in accordance with an exemplary embodiment.

[0028] Fig. 3A shows a top view of a prosthesis after it has been unrolled and flattened.

[0029] Fig. 3B shows interlocking of two of the prostheses illustrated in Fig. 3A.

5 [0030] Fig. 3C shows interlocking of two of the prostheses illustrated in Fig. 3A after expansion.

[0031] Fig. 3D highlights the interlocking of prostheses shown in Fig. 3C.

[0032] Fig. 4A shows a top view of another embodiment of a prosthesis after it has been unrolled and flattened.

10 [0033] Fig. 4B shows interlocking of two of the prostheses illustrated in Fig. 4A.

[0034] Fig. 5A shows a top view of still another embodiment of a prosthesis after it has been unrolled and flattened.

[0035] Fig. 5B shows interlocking of two of the prostheses illustrated in Fig. 5A.

DETAILED DESCRIPTION OF THE INVENTION

15 [0036] In the drawings like numerals describe substantially similar components. Referring now to Fig. 1A, a preferred embodiment of an over-the-wire prosthesis delivery catheter 50 comprises a catheter shaft 120 which includes a sheath 124 slidably disposed over a pusher tube 144 which is in turn slidably disposed over an inner shaft 134 (seen in Fig. 1B). A prosthesis 126 is carried near the distal end of the catheter shaft 120 and is covered by sheath 124. Pusher tube 144 is adapted to move past the prosthesis 126 in one direction and to push prosthesis 126 in a second direction and this will be described in greater detail below. A tapered nosecone 136 having a distal exit port 156, composed of a soft elastomeric material to minimize trauma to the vessel during advancement of the delivery catheter 50, is attached to the inner shaft 134 distally of the prosthesis 126. Prosthesis 126 preferably comprises a plurality of self-expanding prostheses 128 mounted under sheath 124 and disposed over inner shaft 134. Sheath 124 covers the self-expanding prostheses 128 and constrains them in a radially contracted configuration until the delivery catheter 50 has been properly positioned at a treatment site. A radiopaque marker 152 (Fig. 1B) near the proximal end of nosecone 136 or optionally a radiopaque marker 151 near the distal end of sheath 124 and a radiopaque marker 153 near the distal end of pusher tube 144 help the operator visualize the delivery

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catheter under a fluoroscope during a stent procedure. Radiopaque marker 153 also helps the operator to view the distance the pusher 144 has been retracted relative to the radiopaque marker 152 adjacent to nosecone 136. This helps the operator determine how many prostheses 128 to deploy and will be discussed in greater detail below.

5 [0037] As shown in Fig. 1A, handle 106 is attached to a proximal end 112 of the outer sheath 124. The handle 106 performs several functions, including retracting and advancing outer sheath 124 and pusher tube 144 thereby allowing selection and exposure of prosthetic segments 128 so that they may self-expand and be deployed. A guidewire 138 is positioned slidably through adapter 108 of handle 106 and extends through inner lumen 135, exiting
10 distal port 156.

[0038] Handle 106 includes a housing 110 which encloses the internal components of the handle 106. Handle 106 allows a physician operator to advance or retract outer sheath 124 and pusher tube 144. The amount of retraction of sheath 124 and pusher tube 144 determine the number of individual prostheses 128 to be deployed thereby establishing the overall
15 length of the prosthesis 126 while ensuring accurate delivery of the individual prostheses 128. The inner shaft 134 is preferably fixed to the handle housing 110, while both outer sheath 124 and pusher tube 144 are coupled to slide mechanisms 102 and 140, respectively. Slide mechanisms 102 and 140 allow both the outer sheath 124 and pusher tube 144 to be retracted and advanced relative to handle 106. Optionally, a single slide mechanism could be used to
20 control motion of the outer sheath 124 and pusher tube 144. Other handle embodiments are described in U.S. Patent Application No. 11/614,271 (Attorney Docket No. 021629-002210US), the entire contents of which are hereby incorporated by reference.

[0039] The slide mechanism 102 translates along calibrated slot 104. Slide mechanism 102 is coupled with outer sheath 124. Slide mechanism 102 is adapted to retract the outer sheath
25 124 a selected distance so that the self-expanding tubular prostheses 128 may be exposed for delivery. As sheath 124 is retracted, the distal most section of prosthesis 128 begins to expand. Additional details on the operation of sheath 124 and pusher 144 are described below. The slide mechanism 102 may include optional visual markers 148 that allow an operator to easily determine the length or number of prostheses that have been exposed. In
30 preferred embodiments, slide mechanism 102 may have detents or a ratchet that provides audible or tactile feedback to the operator to facilitate operation of the stent delivery catheter
50 without requiring direct visualization during operation.

[0040] Handle 106 also comprises a second control mechanism 140 that translates along calibrated slot 142. Slide mechanism 140 is coupled with the pusher tube 144 and is adapted to retract or advance pusher tube 144 independently of outer sheath 124. Retracting pusher tube 144 allows the number of prostheses 128 to be selected for deployment. Advancement of pusher tube 144 advances the prostheses 128 distally and couples the prostheses 128 together. Slide mechanism 140 may also include optional visual markers 150 that help the physician determine the position of the pusher tube 144 or the number of prostheses 128 selected for deployment or the total length thereof. Additionally, the slide mechanism 140 may comprise detents or a ratchet that further assists physician operation by providing audible or tactile feedback. Further details on operation of the pusher tube 144 and the outer sheath 124 are discussed below.

[0041] Handle 106 also permits connection of an external fluid source via adapter 108 attached to the proximal end of handle 106. Fluid may then be injected at the proximal handle end and infused along a lumen in inner shaft 134 into a patient via distal port 156 or other infusion ports (not shown) near the distal end of the delivery catheter 50. The adaptor 108, preferably a Luer connector, is configured to be fluidly coupled with a fluid source such as a syringe or intravenous bag. In alternative embodiments adaptor 108 may be fluidly connected to an inflation lumen 135 in inner shaft 134 which is connected to an optional inflatable balloon (not shown) near the distal end of the catheter 50. An inflation device which may be any commercially available balloon inflation device such as those sold under the trade name "IndeflatorTM," manufactured by Abbott (formerly Guidant Corporation of Santa Clara, CA) may then be connected to adaptor 108 to deliver an inflation fluid to the balloon.

[0042] Additional details on materials and construction of other suitable handles and control mechanisms are described in co-pending U.S. Patent Application No. 11/148,713, filed June 8, 2005, (Attorney Docket No. 14592.4002), entitled "Devices and Methods for Operating and Controlling Interventional Apparatus," and co-pending United States Publication No. 2005/0149159, entitled "Devices and Methods for Controlling and Indicating the Length of an Interventional Element," and Application No. 11/614,271, filed December 21, 2006, (Attorney Docket No. 021629-002210US, formerly 021629-003800US), entitled "Custom Length Stent Apparatus," the full disclosures of which are incorporated herein by reference.

[0043] Outer sheath 124 may be composed of any of a variety of biocompatible materials, such as but not limited to a polymer like PTFE, FEP, polyimide, Nylon or Pebax, and may be reinforced with a metallic or polymeric braid to resist radial expansion of self-expanding prostheses 128. Similar materials may also be used for the inner shaft 134. Both the inner
5 shaft 134 and outer sheath 124 may also be fabricated from metals such as stainless steel or nickel-titanium alloys like nitinol.

[0044] Pusher tube 144 is seen in Fig. 1B. Pusher tube 144 is an elongate tube having a central lumen that is slidably disposed over inner shaft 134 and under outer sheath 124. The proximal end of pusher tube 144 is coupled with handle 106 as discussed above. The distal
10 end of pusher tube 144 is adapted to slide under prostheses 128 when pusher tube 144 is retracted and to engage a prosthesis 128 and move it distally when pusher tube 144 is advanced distally. The pusher tube 144 therefore selects the number of prostheses 128 for delivery and provides enough force to interlock prostheses 128 together as will be discussed below. Pusher tube 144 is often an extruded polymer tube, manufactured from similar materials as the outer sheath 124
15 or inner shaft 134. The distal tip of pusher tube 144 typically comprises resilient fingers 166 which may be a polymer or a metal ring with resilient fingers 166 formed from metals such as spring temper stainless steel or nickel-titanium alloy such as nitinol bonded or welded to the distal end of pusher tube 144. Pusher tube 144 may also be made from nitinol tubing with resilient fingers on the distal end.

[0045] Additional aspects of the luminal prosthesis delivery system are described in U.S. Patent Application Serial No. 10/306,813, filed November 27, 2002 (Attorney Docket No. 021629-000320US); U.S. Patent Application Serial No. 10/637,713, filed August 8, 2003 (Attorney Docket No. 021629-000340US); U.S. Patent Application Serial No. 10/738,666, filed December 16, 2003 (Attorney Docket No. 021629-000510US); and U.S. Patent
25 Application Serial No. 11/104,305, filed April 11, 2005 (Attorney Docket No. 021629-003300US); the full disclosures of which are hereby incorporated by reference.

[0046] Fig. 1C illustrates another embodiment of a prosthesis delivery catheter 100 similar to delivery catheter 50 described in Fig. 1A, except that delivery catheter 100 now comprises a guidewire tube and is not a simple over the wire catheter. Delivery catheter 100 comprises
30 a catheter shaft 120 which includes a sheath 124 slidably disposed over a pusher tube 144 which is in turn slidably disposed over an inner shaft 134 (seen in Fig. 2A). A prosthesis 126 is carried near the distal end of the catheter shaft 120 and is covered by sheath 124. Pusher

tube 144 is adapted to move past the prosthesis 126 in one direction and to push prosthesis 126 in a second direction as described further below. A tapered nosecone 136 having a distal exit port 156, composed of a soft elastomeric material to minimize trauma to the vessel during advancement of the delivery catheter 50, is attached to the inner shaft 134 distally of the prosthesis 126. Prosthesis 126 preferably comprises a plurality of self-expanding prostheses 128 mounted under sheath 124 and disposed over inner shaft 134. Sheath 124 covers the self-expanding prostheses 128 and constrains them in a radially contracted configuration until the delivery catheter 100 has been properly positioned at a treatment site. A radiopaque marker 152 (Fig. 2A) near the proximal end of nosecone 136 or optionally a radiopaque marker 151 near the distal end of sheath 124 and a radiopaque marker 153 near the distal end of pusher tube 144 help the operator visualize the delivery catheter under a fluoroscope during a stent procedure. Radiopaque marker 153 also helps the operator to view the distance the pusher 144 has been retracted relative to the radiopaque marker 152 adjacent to nosecone 136. This helps the operator determine how many prostheses 128 to deploy and will be discussed in greater detail below.

[0047] A guidewire tube 122 is slidably positioned through sheath 124 and inner shaft 134 proximal to the prosthesis 126. A guidewire 138 is positioned slidably through guidewire tube 122 and nosecone 136 and exits a distal exit port 156, extending distally thereof. Additional details on guidewire tube 122 are disclosed in copending U.S. Patent Application No. 10/814,581 (Attorney Docket No. 021629-001000US), the entire contents of which are hereby incorporated by reference.

[0048] As shown in Fig. 1C, a handle 106 is attached to a proximal end 112 of the outer sheath 124. The handle 106 generally takes the same form as handle 106 which was previously described above with reference to Fig. 1A and controls the movement of outer sheath 124 and pusher tube 144. Fig. 1C shows two sliders 102, 140 used to control sheath 124 and pusher 144, however, optionally, a single slide mechanism could be used to control motion of the outer sheath 124 and pusher tube 144. Other handle embodiments are described in U.S. Patent Application No. 11/614,271 (Attorney Docket No. 021629-002210US), the entire contents of which have previously been incorporated by reference. Additional details on materials and construction of other suitable handles and control mechanisms have also been described in co-pending U.S. Patent Application No. 11/148,713, filed June 8, 2005, (Attorney Docket No. 14592.4002), entitled "Devices and Methods for Operating and Controlling Interventional Apparatus," as well as co-pending United States

Publication No. 2005/0149159, entitled "Devices and Methods for Controlling and Indicating the Length of an Interventional Element," the full disclosures of which are incorporated herein by reference.

[0049] Both outer sheath 124 and guidewire 138 each extend through a slider assembly 132 slidably disposed on the catheter body 120 at a point between its handle 106 and prostheses 128. The slider assembly 132 is adapted for insertion into and sealing with a hemostasis valve, such as on an introducer sheath or guiding catheter, while still allowing relative movement of the outer sheath 124 relative to the slider assembly 132. The slider assembly 132 includes a slider tube 118, a slider body 116, and a slider cap 114.

[0050] Outer sheath 124 may be composed of any of a variety of biocompatible materials, such as but not limited to a polymer like PTFE, FEP, polyimide, Nylon or Pebax, and may be reinforced with a metallic or polymeric braid to resist radial expansion of self-expanding prostheses 128. Similar materials may also be used for the inner shaft 134. Both the inner shaft 134 and outer sheath 124 may also be fabricated from metals such as stainless steel or nickel-titanium alloys like nitinol.

[0051] Pusher tube 144 is seen in Fig. 2A. Pusher tube 144 generally takes the same form as pusher 144 in Fig. 1B and is an elongate tube having a central lumen that is slidably disposed over inner shaft 134 and under outer sheath 124. The proximal end of pusher tube 144 is coupled with handle 106 as discussed above. The distal end of pusher 144 is adapted to slide under prostheses 128 when pusher 144 is retracted and to engage a prosthesis 128 and move it distally when pusher 144 is advanced distally. The pusher 144 therefore selects the number of prostheses 128 for delivery and provides enough force to interlock prostheses 128 together as will be discussed below. Pusher tube 144 may be fabricated similarly as previously described.

[0052] Additional aspects of the luminal prosthesis delivery system are described in U.S. Patent Application Serial No. 10/306,813, filed November 27, 2002 (Attorney Docket No. 021629-000320US); U.S. Patent Application Serial No. 10/637,713, filed August 8, 2003 (Attorney Docket No. 021629-000340US); U.S. Patent Application Serial No. 10/738,666, filed December 16, 2003 (Attorney Docket No. 021629-000510US); and U.S. Patent Application Serial No. 11/104,305, filed April 11, 2005 (Attorney Docket No. 021629-003300US); the full disclosures of which are hereby incorporated by reference.

[0053] Prosthesis 126 in Figs. 1A-1C is composed of one or more prostheses 128.

Prostheses 128 are disposed over the inner shaft 134 and under sheath 124. Each prosthesis or segment 128 has interlocking tabs on each end and is about 3-50 mm in length, more

typically about 10-30 mm in length and preferably being about 15-25 mm in length. Usually

2-20, more typically 2-15 and preferably 5-10 prostheses 128 are positioned axially over the inner shaft 134. Prostheses 128 are preferably positioned with a spacing in between

prostheses 128. The spacing is typically between about 0.5 mm and about 1 mm. During

selection and deployment of the prostheses 128, the prostheses 128 selected for deployment are pressed together so that interlocking tabs engage and the prostheses 128 are coupled

together. Thus, prostheses 128 may be deployed individually or in groups of two or more at a single treatment site within the vessel lumen.

[0054] In preferred embodiments the adjacent ends have axially extending members that interleave and engage with one another. In an embodiment seen in Fig. 3A, the geometry of

prosthesis 300 is illustrated in an unexpanded configuration, unrolled and flattened out for

clarity. In Fig. 3A, prosthesis 300 comprises eleven substantially parallel columns 302a,

302b, 302c, 302d, 302e, 302f, 302g, 302h, 302i, 302j, 302k of open cells 326, spaced apart by a gap 330 and formed around a central axis 324 so that prosthesis 300 has a tubular or

cylindrical shape. Each column 302a, 302b, 302c, 302d, 302e, 302f, 302g, 302h, 302i, 302j,

302k is formed from an undulating or sinusoidal or zig-zag or wave pattern 318. The wave

pattern 318 is comprised of substantially axial struts 320 joined together by a U-shaped connector 322. The struts 320 are generally parallel to the central axis 324.

[0055] In this embodiment, each wave pattern 318 repeats itself sixteen times in each of

the eleven parallel columns 302a, 302b, 302c, 302d, 302e, 302f, 302g, 302h, 302i, 302j, 302k of open cells 326, although this number is not intended to be limiting. The number of rows of

cells may be increased to provide increased scaffolding of the lumen wall or the number of rows may be decreased to minimize the amount of metal in the prosthesis which contacts the

lumen wall. The wave pattern 318 in each column is out-of-phase with the adjacent column, therefore the peak of one wave pattern 318 is adjacent to the trough of a wave 318 pattern in

an adjacent column. In addition, the parallel columns 302a, 302b, 302c, 302d, 302e, 302f,

302g, 302h, 302i, 302j, 302k of open cells 326 are joined together by a sigmoidal shaped connector 328 which joins the ends of U-shaped connector 322 together.

[0056] The sigmoidal connector 328 generally attaches to the apex of the U-shaped connector 322. Also, the sigmoidal shaped connector 328 attaches generally to every fourth U-shaped connector 322, in each column 302a, 302b, 302c, 302d, 302e, 302f, 302g, 302h, 302i, 302j, 302k, thus there are four sigmoidal shaped connectors 328 between each column 302a, 302b, 302c, 302d, 302e, 302f, 302g, 302h, 302i, 302j, 302k of open cells 326. Additionally, the slope of the sigmoidal shaped connectors 328 generally slopes downward between columns 302a, 302b, 302c, 302d, 302e, 302f, 302g, 302h, 302i, 302j, 302k of open cells 326. For example, the sigmoidal shaped connector 328 between column 302a and 302b is attached to U-shaped connector 322 in column 302a at a point generally at the apex of the U-shaped connector 322 and substantially parallel to the axial struts 320. The sigmoidal connector 328 slopes downward toward the adjacent U-shaped connector 322 in adjacent column 302b and attaches to the adjacent U-shaped connector 322 at a point generally at the apex of U-shaped connector 322 and substantially parallel to the axial struts 320. The sigmoidal shaped connector 322 between columns 302b and 302c similarly joins U-shaped connectors 322, sloping downward. This pattern repeats across the prosthesis 300 so that there are ten sets of sigmoidal shaped connectors 328 with downward slopes. Additionally, sigmoidal shaped connectors 322 are staggered such that across any row of open cells 326, a sigmoidal shaped connector 322 couples columns of open cells 326 every fourth gap 330.

[0057] Both ends of prosthesis 300 also comprise locking tabs 332 having a narrow neck portion 333 and a wider head portion 335 defined by curved strut 338. Each locking tab 332 is joined to the body of the prosthesis 300 by an axial strut 340 which join to every fourth U-shaped connector 322 at its apex. Strut 338 defines a U-shape or C-shape with enlarged and rounded tips 337 that define a receptacle 339 therein. In some embodiments, the receptacle 339 may be fitted with an optional radiopaque marker 341 to enhance visibility of the prosthesis under a fluoroscope. A space 342 is disposed between ends of locking tabs 332, defined by a narrow inlet portion 343 and a wider receiver portion 345 adapted to receive the rounded tip 337 on a locking tab 332 from an adjacent prosthesis 300. Locking tabs 332 on the opposite end of prosthesis 300 are circumferentially offset with respect to the first end so that adjacent prostheses may interleave and engage with one another. Fig. 3B illustrates how the ends of prostheses 300 with locking tabs 332 engage one another.

[0058] Fig. 3C illustrates prosthesis 300 of Figs. 3A-3B in the expanded configuration and interlocked with an adjacent expanded prosthesis 300. In the expanded configuration, U-shaped connectors 322 deflect outwardly, expanding cells 326. Struts 320, while still

substantially straight, are no longer horizontal and thus the period of the sinusoidal-like wave pattern forming each cell 326 has increased and become more angular to form more of a zig-zag, thereby increasing the diameter of the prosthesis. Cells 326 which originally appear as a series of horizontally oriented ovals, now appear as a series of triangles or diamonds.

- 5 Sigmoidal connectors 328 maintain the spacing 330 between columns of cells 318. Additionally, locking tabs 332 remain coupled between adjacent prostheses 300 even after expansion. Fig. 3D highlights the coupling of locking tabs 332 between adjacent prostheses 300 after expansion.

[0059] Fig. 4A illustrates another embodiment of a prosthesis 400 in the unexpanded configuration, unrolled and flattened out for clarity. This embodiment is similar to the
10 embodiment in Figs. 3A-3D with the major difference being that this embodiment has fewer columns of open cells and different interlocking tabs on either end of the prosthesis.

[0060] Fig. 4A shows a preferred embodiment of a prosthesis illustrated in the unexpanded configuration, unrolled and flattened out for clarity. Prosthesis 400 comprises nine
15 substantially parallel columns of 402a, 402b, 402c, 403d, 402e, 402f, 402g, 402h and 402i of open cells 426, spaced apart by a gap 430 and formed around a central axis 424 so that prosthesis 400 has a tubular or cylindrical shape. Each column 402a, 402b, 402c, 403d, 402e, 402f, 402g, 402h and 402i is formed from an undulating or sinusoidal or zig-zag or wave pattern 418. The wave pattern 418 is comprised of substantially axial struts 420 joined
20 together by a U-shaped connector 422. The struts 420 are generally parallel to the central axis 424.

[0061] In this embodiment, each wave pattern 418 repeats itself sixteen times in each of the nine parallel columns 402a, 402b, 402c, 403d, 402e, 402f, 402g, 402h and 402i of open cells 426, although this number is not intended to be limiting. The number of rows of cells
25 426 may be increased to provide increased scaffolding of the lumen wall or the number of rows may be decreased to minimize the amount of metal in the prosthesis which contacts the lumen wall. The wave pattern 418 in each column is out-of-phase with the adjacent column, therefore the peak of one wave pattern 418 is adjacent to the trough of a wave 418 pattern in an adjacent column. In addition, the parallel columns 402a, 402b, 402c, 403d, 402e, 402f,
30 402g, 402h and 402i of open cells 426 are joined together by a sigmoidal shaped connector 428 which joins the ends of U-shaped connector 422 together.

[0062] The sigmoidal connector 428 generally attaches to the apex of the U-shaped connector 422. Also, the sigmoidal shaped connector 428 attaches generally to every fourth U-shaped connector 422, in each column 402a, 402b, 402c, 403d, 402e, 402f, 402g, 402h and 402i, thus there are four sigmoidal shaped connectors 428 between each column 402a, 402b, 402c, 403d, 402e, 402f, 402g, 402h and 402i of open cells 426. Additionally, the slope of the sigmoidal shaped connectors 428 generally slopes downward between columns 402a, 402b, 402c, 403d, 402e, 402f, 402g, 402h and 402i open cells 426. For example, the sigmoidal shaped connector 428 between column 402a and 402b is attached to U-shaped connector 422 in column 402a at a point generally at the apex of the U-shaped connector 422 and substantially parallel to the axial struts 420. The sigmoidal connector 428 slopes downward toward the adjacent U-shaped connector 422 in adjacent column 402b and attaches to the adjacent U-shaped connector 422 at a point generally at the apex of U-shaped connector 422 and substantially parallel to the axial struts 420. The sigmoidal shaped connector 422 between columns 402b and 402c similarly joins U-shaped connectors 422, sloping downward. This pattern repeats across the prosthesis 400 so that there are eight sets of sigmoidal shaped connectors 428 with downward slopes. Additionally, sigmoidal shaped connectors 422 are staggered such that across any row of open cells 426, a sigmoidal shaped connector 422 couples columns of open cells 426 every fourth gap 330.

[0063] Both ends of prosthesis 400 comprise interlocking tabs. One end of prosthesis 400 has a locking male tab 432 and the opposite end has a female receiving tab 436. Male tab 432 has a wider head portion 434 defined by arcuate strut 438 unconnected at one end so that it may flex and a narrow neck portion 433 defined by axial strut 436. Axial struts 436 couple the male locking tab 432 to adjacent U-shaped connectors 422 and therefore there also is a spacing 442 between axial struts 436. Female receiving tab 436 also has an enlarged head portion 444 and a narrower neck portion 446. The head portion 444 is formed from arcuate struts 448 shaped like a "C" or a "U," and having bulbous tips 450. The arcuate struts 448 form a receptacle 454 which is adapted to interlock with the enlarged head portion 434 of male locking tab 432. The neck portion is formed from a wide strut 452 which joins with adjacent axial struts 420, replacing the U-shaped connector 422. Female tabs 436 are staggered relative to male tabs 432 so that adjacent prostheses may interlock with each other. Fig. 4B illustrates how the ends of prostheses 400 with tabs 432 and 436 engage one another.

[0064] Fig. 5A shows another embodiment of an interlocking prosthesis 500 in the unexpanded configuration, unrolled and flattened out for clarity. This embodiment is similar

to that shown in Figs. 4A-4B with the major difference being the interlocking tabs on either end of the prosthesis 500. The overall geometry of prosthesis 500 is the same as prosthesis 400 above. For example, prosthesis 500 also has nine substantially parallel columns 502a, 502b, 502c, 502d, 502e, 502f, 502g, 502h and 502i of open cells 526 spaced apart by a gap 530 and formed around a central axis 524 so that prosthesis 500 has a tubular or cylindrical shape. Each column 502a, 502b, 502c, 502d, 502e, 502f, 502g, 502h and 502i has the same undulating wave pattern 418 as prosthesis 400 with a sigmoidal connector 528 coupling the nine columns 502a, 502b, 502c, 502d, 502e, 502f, 502g, 502h and 502i together. Other aspects of the sigmoidal connector 528 are generally the same as sigmoidal connector 428 described above with respect to Figs. 4A-4B.

[0065] Both ends of prosthesis 500 comprise interlocking tabs. One end of prosthesis 500 has a locking male tab 532 and the opposite end has a female receiving tab 536. Male tab 532 has a wider head portion 534 defined by an arcuate strut 538 forming a "C" shape and having free ends 539 that may flex, and a narrow neck portion 533 defined by an axial strut 536. The axial strut 536 is coupled with the C-shaped arcuate strut 538 approximately at the center of the concave portion of the "C." The axial strut 536 couples the male locking tab 532 to the prosthesis 500 at the apex of U-shaped connector 522 in open cell 526. There are four male locking tabs 532 on one end of prosthesis 500, spaced apart every four rows of open cells 526.

[0066] The opposite end of prosthesis 500 has a female receiving tab 536 which includes an enlarged head portion 544 and a narrower neck portion 546. The head portion 544 is formed from an arcuate strut 548 shaped like a "C" or a "U," and having enlarged tips 550 defining a receptacle 551 therein. An optional radiopaque marker 553 may be press-fit, welded or bonded into receptacle 551. Radiopaque markers are commonly fabricated from gold, platinum, iridium or tantalum. The arcuate strut 548 forms another receptacle 554 having a narrow inlet portion 560 and a wider receiver portion 562 which is adapted to interlock with the enlarged head portion 534 of male locking tab 532. The neck portion 546 is formed from a strut 552 which joins with the adjacent axial struts 520 which form open cells 526. Strut 552 joins with strut 520 at the apex of U-shaped connector 522. Female receiving tabs 536 are staggered with respect to male tabs 532 so that adjacent prostheses 500 may interlock with each other. Prostheses 500 interlock with one another by pressing them together. Fig. 5B illustrates how the ends of prostheses 500 with tabs 532 and 536 engage one another.

[0067] Other interleaving stent embodiments are described in copending U.S. Patent Application No. 10/738,666 filed December 16, 2003 (Attorney Docket No. 021629-000510US); U.S. Patent Application No. 10/957,079 filed September 30, 2004 (Attorney Docket No. 021629-002710US); and U.S. Provisional Application No. 60/784,309 filed March 20, 2006 (Attorney Docket No. 021629-003600US), the entire contents of which are incorporated herein by reference.

[0068] Prostheses 128 are preferably composed of an elastic or superelastic shape memory alloy such as Nitinol so that the prostheses 128 resiliently self-expand upon release into a vessel by retraction of the sheath 124. Other possible materials include a spring temper metal such as stainless steel, cobalt-chromium or ELGILOY™ so the prostheses 128 may self-expand in the body lumen at the target treatment site. In the case of self-expanding prostheses 128, an inflation balloon is not required but may still be used for predilation of a lesion or augmenting expansion of the self-expanding stent segments 128 (e.g. postdilation or tacking). Other materials such as biocompatible polymers may be used to fabricate prosthetic stent segments that self-expand, and these materials may further include bioabsorbable or bioerodable properties.

[0069] In other embodiments, prostheses 128 may have any of a variety of common constructions, such as but not limited to those described in U.S. Patent Application Serial No. 10/738,666 filed December 16, 2003 (Attorney Docket No. 02169-000510US), which was previously incorporated by reference. Constructions may include for example, closed cell constructions including expansible ovals, ellipses, box structures, expandable diamond structures, etc. In addition, the closed cells may have complex slotted geometries such as H-shaped slots, I-shaped slots, J-shaped slots, etc. Suitable open cell structures include zig-zag structures, serpentine structures, and the like. Such conventional stent structures are well described in the patent and medical literature. Specific examples of suitable stent structures are described in the following U.S. Patents, the full disclosures of which are incorporated herein by reference: U.S. Patent Nos.: 6,315,794; 5,980,552; 5,836,964; 5,527,354; 5,421,955; 4,886,062; and 4,776,337.

[0070] In preferred embodiments, prosthetic stent segments 128 may be coated, impregnated, infused or otherwise coupled with one or more drugs that inhibit restenosis, such as Rapamycin, Everolimus, Biolimus A9, Paclitaxel, analogs, prodrugs, or derivatives of the aforementioned, or other suitable agents, preferably carried in a durable or bioerodable

carrier of polymeric or other suitable material. Alternatively, stent segments 128 may be coated with other types of drugs or therapeutic materials such as antibiotics, thrombolytics, anti-thrombotics, anti-inflammatories, cytotoxic agents, anti-proliferative agents, vasodilators, gene therapy agents, radioactive agents, immunosuppressants, chemotherapeutics, endothelial cell attractors or promoters and/or stem cells. Such materials may be coated over all or a portion of the surface of stent segments 128, or stent segments 128 may have a porous structure or include apertures, holes, channels, or other features in which such materials may be deposited.

[0071] Referring now to Figs. 2A-2E, the deployment of selected prostheses to treat a lesion is shown in accordance with an exemplary embodiment. While the embodiment will be described in the context of a femoral artery stent procedure, it should be understood that the invention may be employed in any variety of coronary or peripheral arteries, blood vessels and other body lumens in which stents or tubular prostheses are deployed, including the carotid and iliac arteries, other arteries or veins, as well as non-vascular body lumens such as the ureter, urethra, fallopian tubes, the hepatic and biliary duct and the like. The delivery catheter is introduced into a treatment vessel first, by placing an introducer sheath (not illustrated) into the target peripheral artery, typically using a percutaneous procedure such as the Seldinger technique or by surgical cutdown. In this exemplary embodiment, the target vessel is a femoral artery. The introducer sheath is then advanced slightly into the femoral artery. A guidewire 138 is then inserted through the introducer and advanced into the target vessel V where a lesion L to be treated is located. The proximal end of guidewire 138 is then inserted through distal port 156 of nosecone 138 and through inner lumen 135 of inner shaft 134, exiting handle 106 at adapter 108 which is outside the patient's body. Optionally, a guide catheter may also be employed.

[0072] Fig. 2A shows a stent delivery catheter 200 slidably advanced over the guidewire 138 into the vessel V so that nosecone 138 is distal to lesion L. Self-expanding tubular prostheses 128 having ends spaced apart are disposed over inner shaft 134 and constrained by outer sheath 124. In this embodiment, four prostheses 128 are carried by the stent delivery catheter 200, although this is not intended to be limiting. The number of prostheses may be varied to accommodate different lesion lengths.

[0073] Outer sheath 124 has a high hoop strength near the distal end such that the outer sheath 124 is able to prevent the self-expanding prostheses 128 from expanding when the

outer sheath 124 is disposed thereover. This may be accomplished by using an outer sheath 124 with a suitable wall thickness or the sheath 124 may also have a distal portion formed from a metal or polymer reinforced with a metallic or polymeric braid to resist radial expansion of the self-expanding prostheses 128.

- 5 [0074] In this embodiment, each prosthesis 128 has a length approximately 20 mm long. Thus the delivery catheter 200 is adapted to deliver a prosthesis having a total length from about 20 mm long, up to 80 mm long, in 20 mm increments. Other lengths and quantities of prostheses 128 may be employed and this exemplary embodiment is not meant to limit the scope of the present invention.
- 10 [0075] Radiopaque marker 152 is disposed near the proximal end of nosecone 138 or alternatively, radiopaque marker 152 may be disposed on inner shaft 134 near the proximal end of nosecone 138. Radiopaque marker 153 is disposed near the distal end of pusher 144. Radiopaque markers are typically fabricated from gold, platinum, iridium or tantalum and are well known in the art. Radiopaque markers 152 and 153 help an operator to visualize the tip
- 15 of delivery catheter 200 under fluoroscopy as well as determining the number of prostheses 128 to deploy to traverse the lesion L. In some embodiments, an optional radiopaque marker 151 may be disposed near the distal end of outer sheath 124 so that sheath position may also be observed under fluoroscopy. Pusher tube 144 is also seen in Fig. 2A disposed over inner shaft 134. The distal end pusher tube 144 comprise several resilient fingers 166 which
- 20 radially extend outward such that pusher tube 144 may be retracted proximally past prostheses 128 but when pusher 144 is advanced distally, the resilient fingers 166 engage a prosthesis 128 so that the prosthesis 128 is advanced distally as the pusher 144 is advanced. Distal motion of prosthesis 128 allows adjacent prostheses 128 having interlocking tabs 162 to engage with receptacle 164, eliminating gap 160. Pusher tube 144 also serves as a
- 25 backstop to prevent proximal motion of prostheses 128. Additional details on these elements will be discussed in greater detail below, with respect to Figs. 2B-2E.

- [0076] Referring now to Fig. 2B, the lesion L to be treated is typically visualized by introducing contrast media into the target vessel V and observing the resulting image under a fluoroscope. Radiopaque markers 152, 153 and optional radiopaque marker 151 are used to
- 30 help visualized the position of the delivery catheter 200 relative to the lesion L as well as to visualize the length of prostheses 129 selected for deployment relative to the target lesion L. Radiopaque marker 152 is typically disposed near the proximal end of nosecone 136 but in

alternative embodiments marker 152 may also be disposed on the inner shaft 134 near the proximal end of nosecone 136. Delivery catheter 200 is advanced until radiopaque marker 152 is near the distal edge of lesion L. Pusher 144 will later be retracted proximally until it is near the proximal end of lesion L. The lesion therefore traverses the region between radiopaque markers 152 and 153. An optional radiopaque marker 151 disposed near the distal end of outer sheath 124 allows the user to observed sheath position during the stenting procedure.

[0077] In Fig. 2B, pusher tube 144 is retracted proximally until radiopaque marker 153 is near the proximal edge of lesion L. The distal end 166 pusher tube 144 comprises a plurality of resilient, radially extending inclined fingers 166, thus pusher tube 144 may be retracted proximally under prostheses 128 without displacing them. Retracting pusher 144 selects the number of prostheses 129 to be deployed and that will provide a total prosthesis 126 length that traverses the length of lesion L. Pusher 144 tube extends to the proximal end of delivery catheter 200 and retraction of pusher tube 144 is accomplished using a control mechanism such as slider 140 in Figs. 1A or 1C.

[0078] In Fig. 2C, prostheses 129 are advanced distally until they engage and interlock with one another. Pusher tube 144 is advanced distally until it engages the proximal-most end of the proximal prosthesis 129 selected for delivery. The distal end of pusher tube 144 has resilient and radially extending inclined fingers 166. Advancing pusher tube 144 distally causes the fingers 166 to engage with the proximal-most prosthesis 129 selected for delivery. Further advancement of pusher tube 144 advances the selected prostheses 129 until the distal-most prosthesis 129 of those selected butts up against the proximal end of nose cone 136. Nosecone 136 has a recessed region 145 in which interlocking tab 162 may be received so that the distal-most prosthesis 129 can fit flush against nosecone 136. As pusher tube 144 is advanced, prostheses 129 selected for deployment bunch up together until locking tabs 162 engage and interlock with receivers 164 on an adjacent prosthesis 129. The gap 160 that existed between prostheses 128 prior to deployment therefore is reduced significantly to a slight gap or no gap 161 as prosthesis 129 ends are engaged with one another during deployment. Additionally, if after pushing prostheses 129 together, a longer total length is required, the steps illustrated in Figs. 2B-2C may be repeated in order to create a longer “stent train.”

[0079] In Fig. 2D, the constraint covering prostheses 129 selected for deployment is removed. In Fig. 2D, outer sheath 124 is retracted proximally. Retraction of outer sheath 124 is accomplished using a control mechanism such as slider 102 in Figs. 1A or 1C.

Retracting outer sheath 124 removes the constraint and exposes prostheses 129, allowing them to self-expand into lesion L. As outer sheath 124 is retracted, the exposed portion of prostheses 129 self-expand to a final shape 137 matching lesion L. Prosthesis 129 is prevented from jumping or “watermelon seeding” away from delivery catheter 200 because the prosthesis 129 being deployed is interlocked with an adjacent prosthesis 129 maintained in the delivery catheter 200 and constrained by outer sheath 124. The position of the outer sheath 124 may be monitored by the operator by visualizing an optional radiopaque marker 151 on the distal end of outer sheath 124, or the operator may determine sheath position by observing the position of slider 102. Pusher tube 144 also serves as a backstop to prevent proximal displacement of prostheses 129 that might occur as a result of outer sheath 124 passing distally thereover.

[0080] In Fig. 2E, outer sheath 124 is retracted proximally until all prostheses 129 selected for deployment are unconstrained and they self-expand into the lesion L. If an additional prosthesis 128 is required to treat the lesion L, the pusher tube 144 may be retracted proximally so as to select an additional prosthesis 128 and it may be deployed in similar manner to that previously described. Once all prostheses 129 have been deployed, outer sheath 124 may be advanced distally until it engages nosecone 136 and the entire delivery catheter 200 may be removed from the treatment site. Alternatively, inner shaft 134 may be retracted into outer sheath 124 until nosecone 136 engages outer sheath 124 and then the entire delivery catheter 200 may be withdrawn.

[0081] While the exemplary embodiments have been described in some detail for clarity of understanding and by way of example, a variety of additional modifications, adaptations and changes may be clear to those of skill in the art. Hence, the scope of the present invention is limited solely by the appended claims.

WHAT IS CLAIMED IS:

1 1. A catheter for delivering a prosthesis to a treatment site in a body
2 lumen, the catheter comprising:
3 an elongate flexible member having a proximal end and a distal end;
4 a sheath slidably disposed over the elongate flexible member;
5 a plurality of self-expanding tubular prostheses carried in axially spaced-apart
6 locations along the elongate flexible member and within the sheath, the plurality of self-
7 expanding tubular prostheses adapted to be selectively interlocked with one another and
8 constrained by the sheath in a radially contracted configuration, the prostheses being
9 separately releasable from the sheath as the sheath is retracted relative to the elongate flexible
10 member; and

11 a pusher member slidably disposed along the elongate flexible member within
12 the sheath, the pusher member adapted to move past the prostheses in a first direction, while
13 in a second direction the pusher member engages a selected prosthesis so as to move the
14 prosthesis with the pusher member to interlock the selected prosthesis with a second
15 prosthesis.

1 2. The catheter of claim 1, further comprising a stopping element axially
2 disposed along the elongate flexible member, the stopping element adapted to prevent the
3 plurality of self-expanding tubular prostheses from being displaced past the distal end of the
4 elongate flexible member when the pusher member is advanced distally.

1 3. The catheter of claim 1, further comprising a handle near the proximal
2 end of the elongate flexible member and having a control mechanism adapted to move the
3 sheath and pusher member.

1 4. The catheter of claim 1, wherein the pusher member is adapted to
2 move past the prostheses in a first direction without displacement thereof.

1 5. The catheter of claim 1, wherein the pusher member is slidable through
2 the prostheses and comprises a plurality of fingers projecting radially outwardly so as to slide
3 past the prostheses in a first direction while in a second direction the fingers engage the
4 selected prosthesis.

1 6. The catheter of claim 1, wherein the pusher member has an
2 engagement member which is deflectable radially inward by contact with the prostheses
3 when moved in the first direction.

1 7. The catheter of claim 6, wherein the engagement member comprises a
2 plurality of flexible fingers extending radially outward from the pusher member.

1 8. The catheter of claim 1, wherein the pusher member exerts
2 substantially greater axial force against the plurality of self-expanding tubular prostheses
3 when the pusher member is advanced distally than when the pusher member is retracted
4 proximally.

1 9. The catheter of claim 1, further comprising a central lumen disposed
2 within the elongate shaft and adapted to carry a guidewire.

1 10. The catheter of claim 1, wherein the plurality of self-expanding
2 tubular prostheses carry a therapeutic agent adapted to be released therefrom.

1 11. The catheter of claim 10, wherein the therapeutic agent comprises an
2 anti-restenosis agent.

1 12. The catheter of claim 1, wherein the plurality of self-expanding
2 tubular prostheses have a length in the range of about 5 mm to about 50 mm.

1 13. The catheter of claim 1, wherein each of the plurality of tubular self-
2 expanding prostheses has the same length.

1 14. The catheter of claim 1, wherein at least one of the plurality of self-
2 expanding tubular prostheses has a different length than at least another of the prostheses.

1 15. The catheter of claim 1, wherein the prostheses are adapted to be
2 interlocked with one another when pressed together.

1 16. The catheter of claim 15, wherein the prostheses are adapted to remain
2 interlocked with one another after radially expanding.

1 17. The catheter of claim 1, wherein the prostheses comprise a plurality of
2 substantially parallel columns of open cells, the columns spaced apart and formed from a zig-
3 zag pattern of substantially axial struts joined together with a connector.

1 18. The catheter of claim 17, wherein a plurality of bridges join the
2 columns of open cells together.

1 19. The catheter of claim 18, wherein the bridges are sigmoidally shaped.

1 20. The catheter of claim 1, wherein the prostheses comprise an
2 interlocking tab disposed on a first end of the prostheses and adapted to interlock with an
3 adjacent prosthesis.

1 21. The catheter of claim 20, wherein the interlocking tab comprises an
2 enlarged head region and a narrower neck region.

1 22. The catheter of claim 21, wherein the enlarged head region comprises
2 an arcuate strut defining a narrow inlet portion and a wider receiving portion, the receiving
3 portion adapted to receive and interlock with an interlocking tab on an adjacent prosthesis.

1 23. The catheter of claim 21, wherein the enlarged head is C-shaped.

1 24. The catheter of claim 20, wherein the interlocking tab comprises a strut
2 defining an aperture.

1 25. The catheter of claim 24, wherein the aperture is adapted to hold a
2 radiopaque marker.

1 26. The catheter of claim 21, wherein the enlarged head comprises a
2 plurality of arcuate struts coupled to the prosthesis with a plurality of axial struts.

1 27. The catheter of claim 21, wherein the neck comprises a plurality of
2 axial struts.

1 28. The catheter of claim 21, wherein the enlarged head comprises an
2 arcuate strut forming a C-shape coupled to the prosthesis with an axial strut.

1 29. The catheter of claim 1, wherein the prostheses further comprise a
2 female receiving tab on an opposite end of the prosthesis as the interlocking tab.

1 30. The catheter of claim 29, wherein the female tab comprises an arcuate
2 strut defining a receptacle, the receptacle adapted to receive and interlock with an enlarged
3 head of an adjacent prosthesis and wherein the arcuate strut is coupled to the prostheses with
4 an axial strut.

1 31. The catheter of claim 30, wherein the receptacle is C-shaped.

1 32. The catheter of claim 29, wherein the female tab comprises an arcuate
2 strut defining an aperture, the aperture adapted to hold a radiopaque marker.

1 33. The catheter of claim 17, wherein the connector comprises a U-shaped
2 portion.

1 34. The catheter of claim 17, wherein the open cells in a first column are
2 out of phase with the open cells in an adjacent column.

1 35. A method for delivering a prosthesis to a body lumen, the method
2 comprising:
3 introducing into the body lumen one or more self-expanding tubular
4 prostheses carried at axially spaced apart locations along an elongate flexible member and
5 constrained in a contracted configuration within a sheath, the body lumen having a lesion
6 with a lesion length;
7 selecting a first group of the self-expanding tubular prostheses for delivery, the
8 first group having a combined length that substantially traverses the lesion length;
9 bringing the first group into engagement with each other within the sheath so
10 that prostheses in the first group interlock with one another; and
11 uncovering the first group from the sheath so that they are unconstrained from
12 expansion, wherein the first group expands at the first treatment site.

1 36. The method of claim 35, wherein the first group expands at the first
2 treatment site while at least a second group of prostheses is retained within the sheath.

1 37. The method of claim 35, further comprising:

2 selecting one or more additional self-expanding tubular prostheses; and
3 bringing the additional self-expanding tubular prostheses into engagement
4 with the first group within the sheath so that the additional prostheses interlock with the first
5 group.

1 38. The method of claim 35, wherein selecting a first group comprises
2 proximally retracting a pusher member.

1 39. The method of claim 35, wherein the pusher member has a flexible
2 engagement member that is deflected by the prostheses as the pusher member is retracted
3 proximally.

1 40. The method of claim 35, wherein bringing the first group into
2 engagement with each other comprises engaging at least one of the first group of prostheses
3 with a pusher member and advancing the pusher member distally.

1 41. The method of claim 35, wherein engaging the at least one prosthesis
2 comprises engaging the prosthesis with a flexible engagement member disposed on the
3 pusher member.

1 42. The method of claim 35, wherein bringing the first group into
2 engagement with each other comprises stopping the first group of prostheses from moving
3 distally with a stopping element disposed on the elongate flexible member.

1 43. The method of claim 35, wherein uncovering the first group comprises
2 proximally retracting the sheath.

1 44. The method of claim 35, further comprising releasing a therapeutic
2 agent from the first group after expansion at the treatment site.

1 45. The method of claim 44, wherein the therapeutic agent comprises an
2 anti-restenosis agent.

1 46. The method of claim 35, wherein the plurality of self-expanding
2 tubular prostheses have a length in the range of about 5 mm to about 50 mm.

1 47. The method of claim 35, wherein each of the plurality of self-
2 expanding tubular prostheses has the same length.

1 48. The method of claim 35, wherein at least one of the plurality of self-
2 expanding tubular prostheses has a different length than at least another of the prostheses.

1 49. The method of claim 35, wherein the prosthesis comprises a plurality
2 of substantially parallel columns of open cells, the columns spaced apart and formed from a
3 zig-zag pattern of substantially axial struts joined together with a connector.

1 50. The method of claim 35, wherein a plurality of bridges join the
2 columns of open cells together.

1 51. The method of claim 50, wherein the bridges are sigmoidally shaped.

1 52. The method of claim 35, wherein a prosthesis comprises an
2 interlocking tab disposed on a first end of the prosthesis and adapted to interlock with an
3 adjacent prosthesis.

1 53. The method of claim 52, wherein the prosthesis comprises a mating tab
2 disposed on a second end of the prosthesis opposite the first end, the mating tab adapted to
3 interlock with an interlocking tab on an adjacent prosthesis.

1 54. The method of claim 52, wherein the interlocking tab comprises one or
2 more struts defining an aperture therein.

1 55. The method of claim 52, wherein the interlocking tab comprises a
2 radiopaque marker.

1 56. The method of claim 49, wherein the connector comprises a U-shaped
2 portion.

1 57. The method of claim 49, wherein the open cells in a first column are
2 out of phase with the open cells in an adjacent column.

1 58. A self-expanding tubular prosthesis comprising:
2 a plurality of self-expanding tubular rings having a plurality of axial struts and
3 a plurality of connectors coupling adjacent struts together, the axial struts and connectors
4 forming a substantially zig-zag pattern;
5 a bridge member coupling adjacent tubular rings together; and

6 an interlocking tab on one end of the prosthesis coupled to a tubular ring, the
7 interlocking tab adapted to interlock with an adjacent prosthesis when the prostheses are
8 pressed together and wherein adjacent prostheses remain interlocked after they have self-
9 expanded.

1 59. The prosthesis of claim 58, wherein the connectors are substantially U-
2 shaped.

1 60. The prosthesis of claim 58, wherein the bridge member is sigmoidal-
2 shaped.

1 61. The prosthesis of claim 58, wherein the bridge is coupled to a
2 connector.

1 62. The prosthesis of claim 58, wherein the bridge comprises an axially
2 extending strut that joins the bridge with the connector.

1 63. The prosthesis of claim 58, wherein the bridge connects to an apex of
2 the connector.

1 64. The prosthesis of claim 58, wherein the interlocking tab comprises an
2 enlarged head region and a narrower neck region.

1 65. The prosthesis of claim 64, wherein the enlarged head region
2 comprises an arcuate strut defining a narrow inlet portion and a wider receiving portion, the
3 receiving portion adapted to receive and interlock with an interlocking tab on an adjacent
4 ring.

1 66. The prosthesis of claim 64, wherein the enlarged head is C-shaped.

1 67. The prosthesis of claim 58, wherein the interlocking tab comprises a
2 strut defining an aperture, the aperture adapted to hold a radiopaque marker.

1 68. The prosthesis of claim 64, wherein the enlarged head region
2 comprises a plurality of arcuate struts coupled to the prosthesis with a plurality of axial struts.

1 69. The prosthesis of claim 64, wherein the neck region comprises a
2 plurality of axial struts.

1 70. The prosthesis of claim 64, wherein the enlarged head region
2 comprises an arcuate strut forming a C-shape coupled to the prosthesis with an axial strut.

1 71. The prosthesis of claim 58, further comprising a female receiving tab
2 on an end of the prosthesis opposite of the interlocking tab.

1 72. The prosthesis of claim 71, wherein the female tab comprises an
2 arcuate strut defining a receptacle, the receptacle adapted to receive and interlock with an
3 enlarged head of an adjacent prosthesis and wherein the arcuate strut is coupled to the
4 prosthesis with an axial strut.

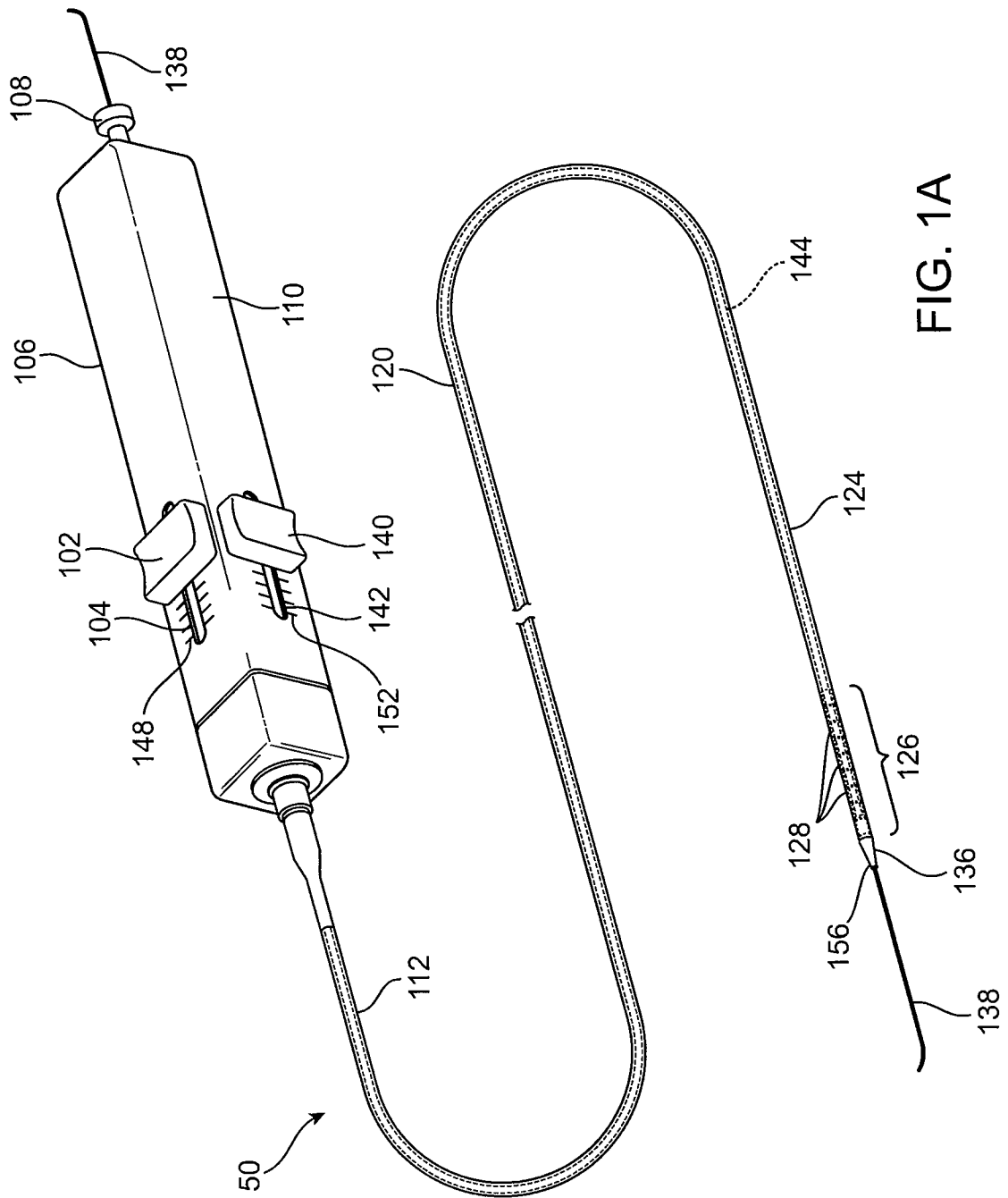
1 73. The prosthesis of claim 72, wherein the receptacle is C-shaped.

1 74. The prosthesis of claim 71, wherein the female tab comprises an
2 arcuate strut defining an aperture, the aperture adapted to hold a radiopaque marker.

1 75. The prosthesis of claim 58, further comprising a therapeutic agent
2 carried on the prosthesis and adapted to be released therefrom.

1 76. The prosthesis of claim 75, wherein the therapeutic agent comprises an
2 anti-restenosis agent.

1 77. The prosthesis of claim 58, wherein the prosthesis has an overall length
2 in the range from about 5 mm to about 50 mm.



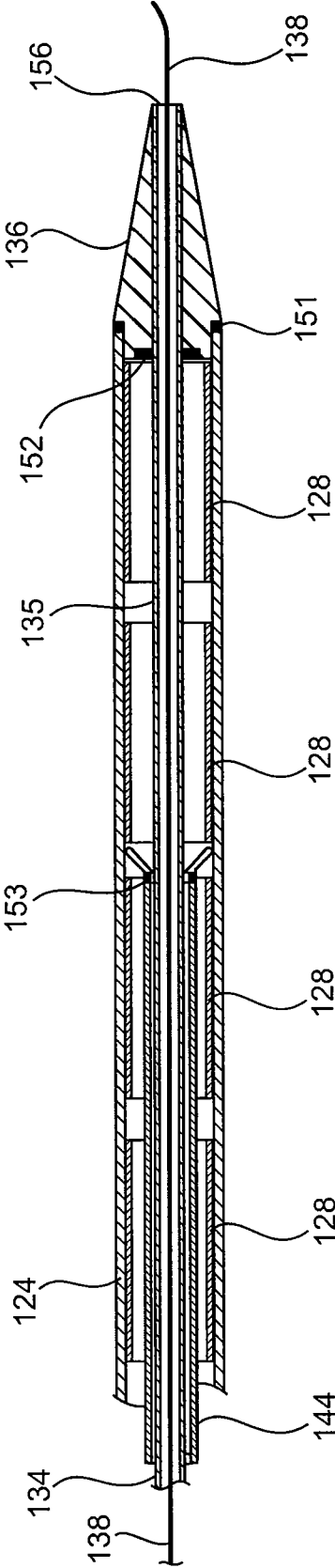
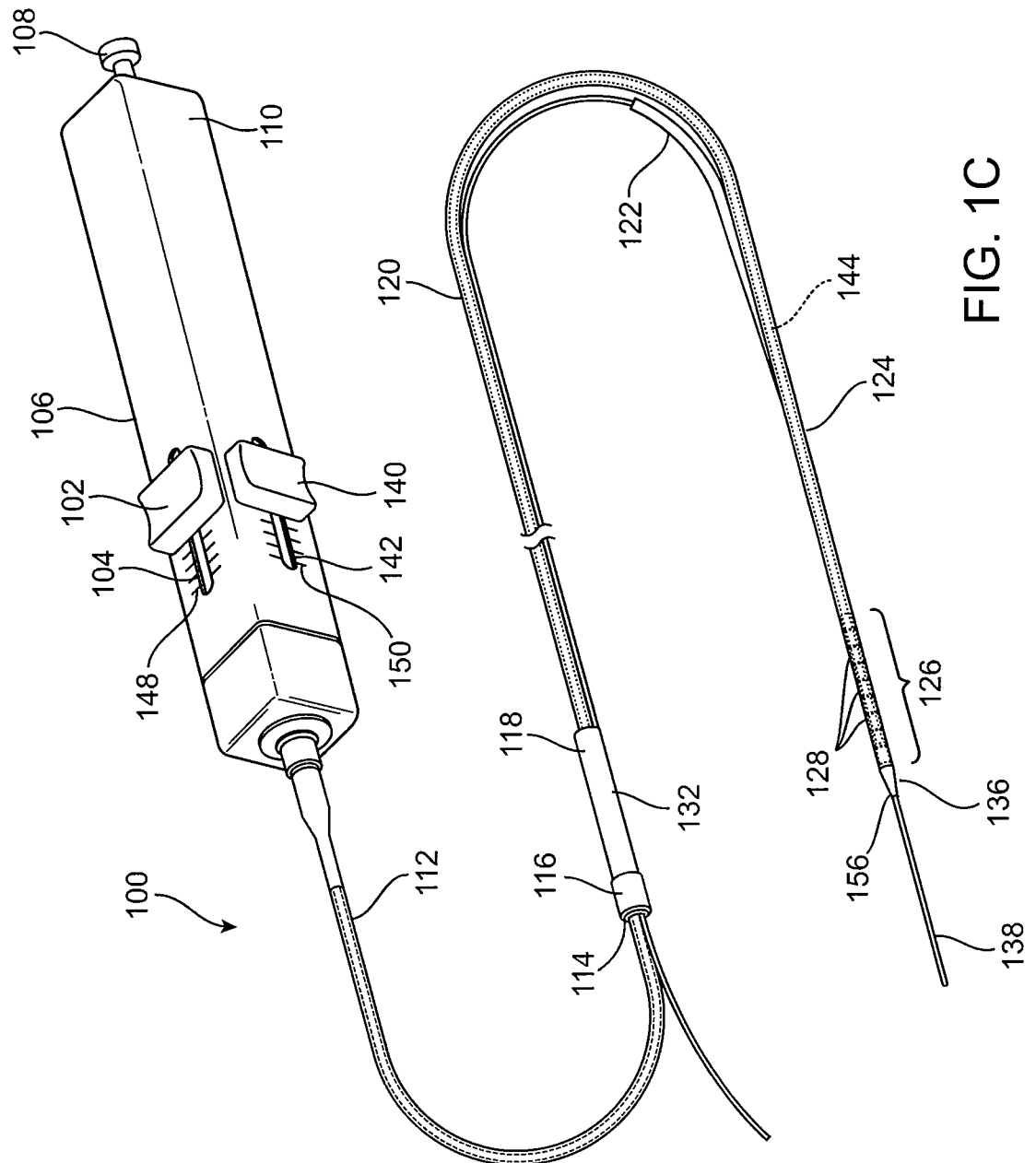


FIG. 1B



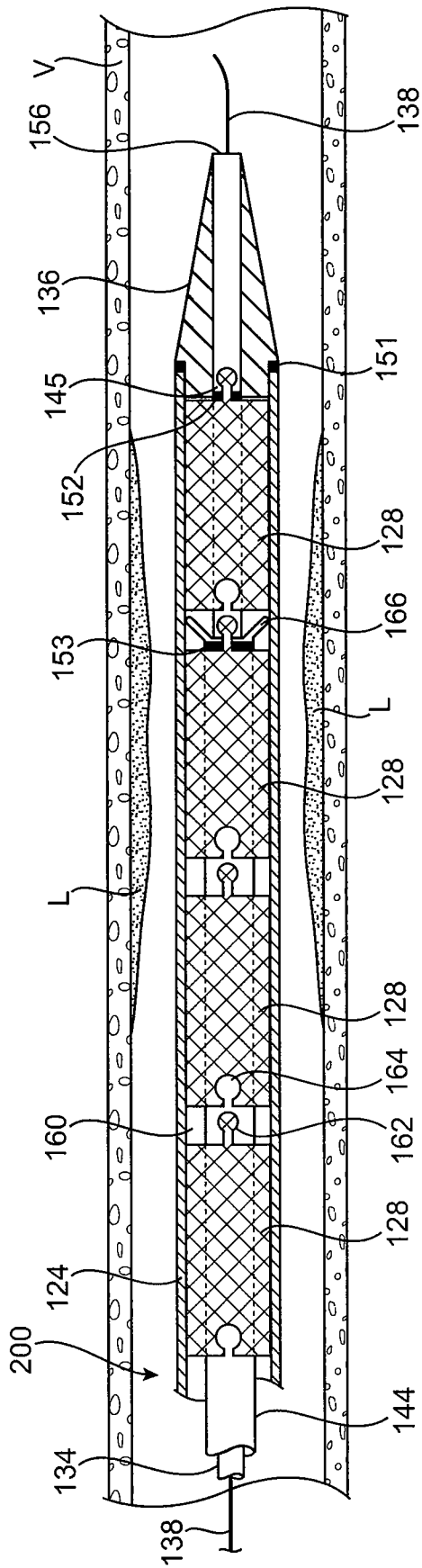


FIG. 2A

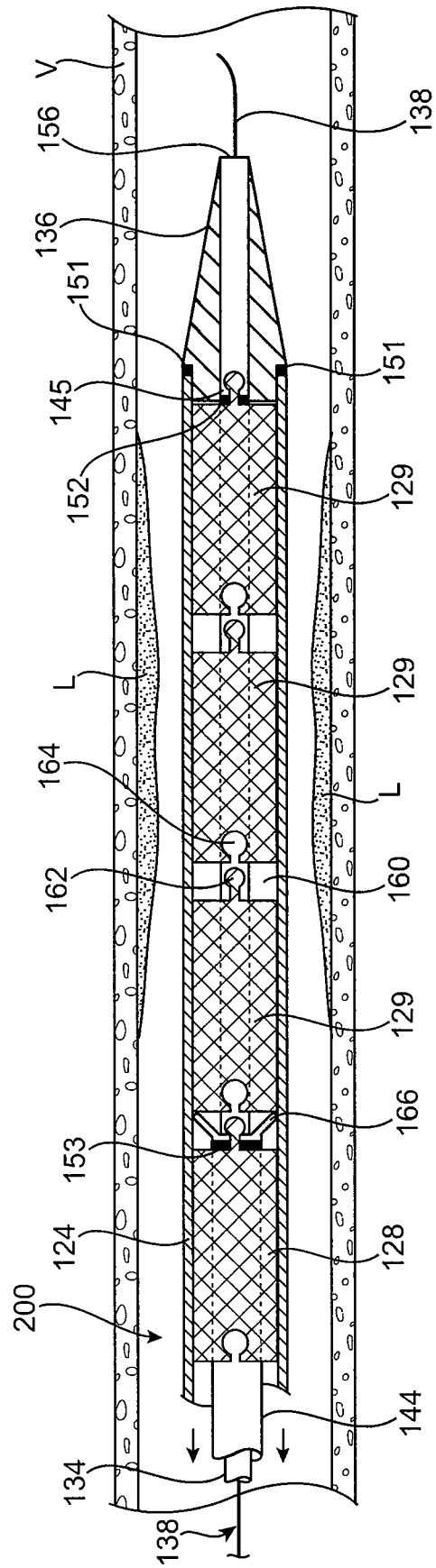


FIG. 2B

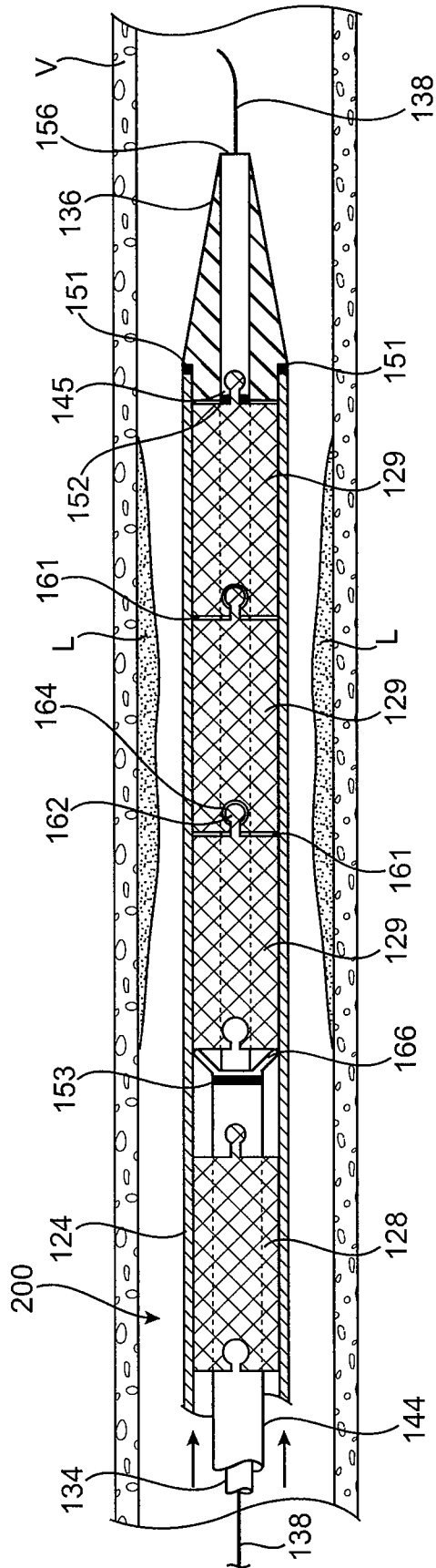


FIG. 2C

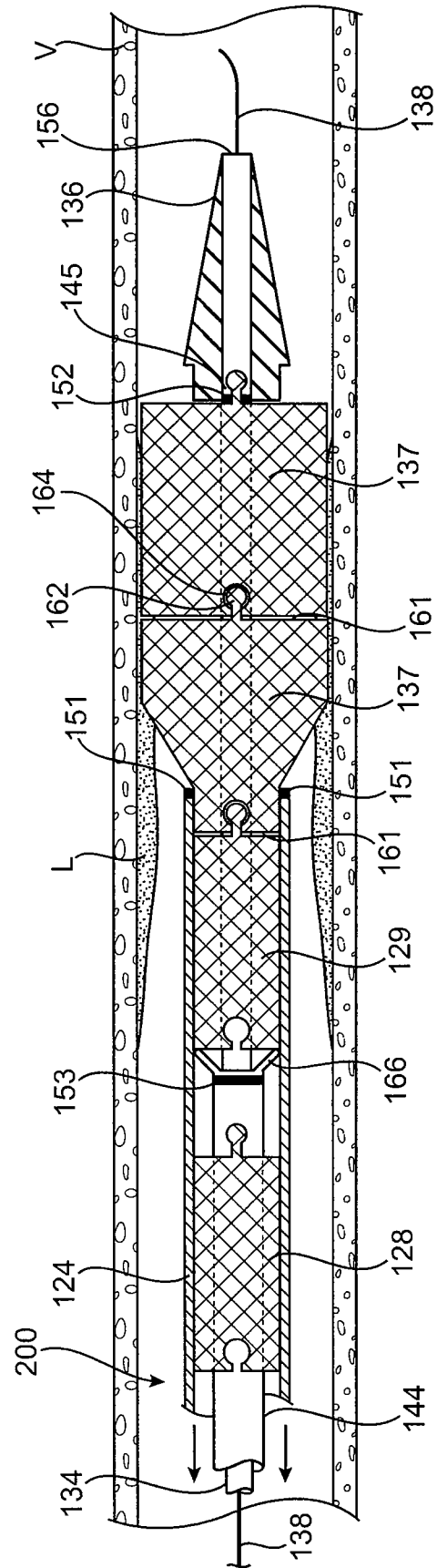


FIG. 2D

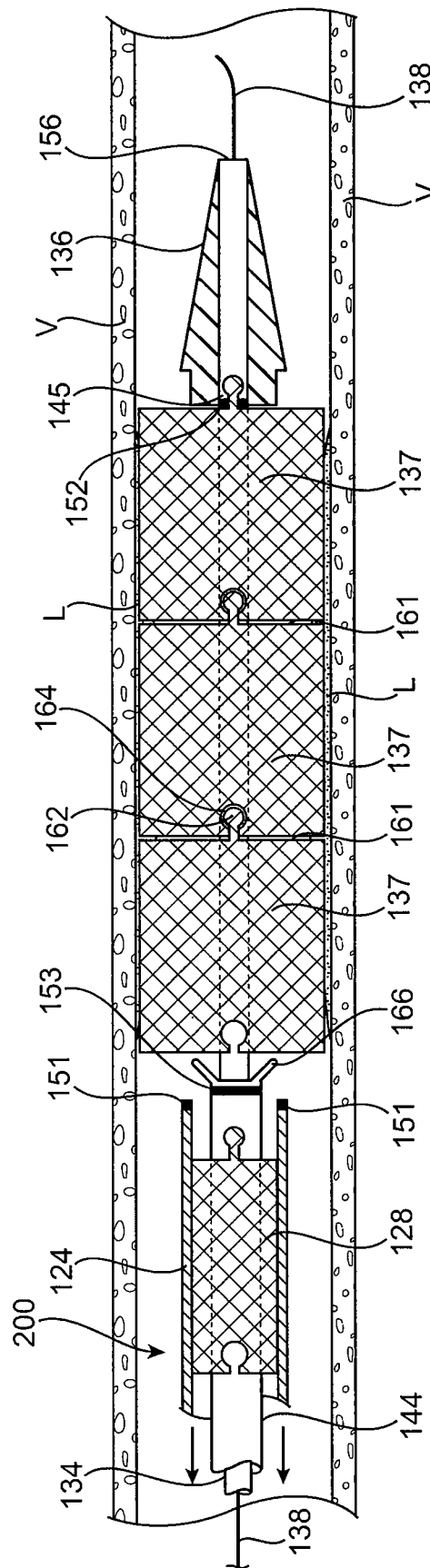


FIG. 2E

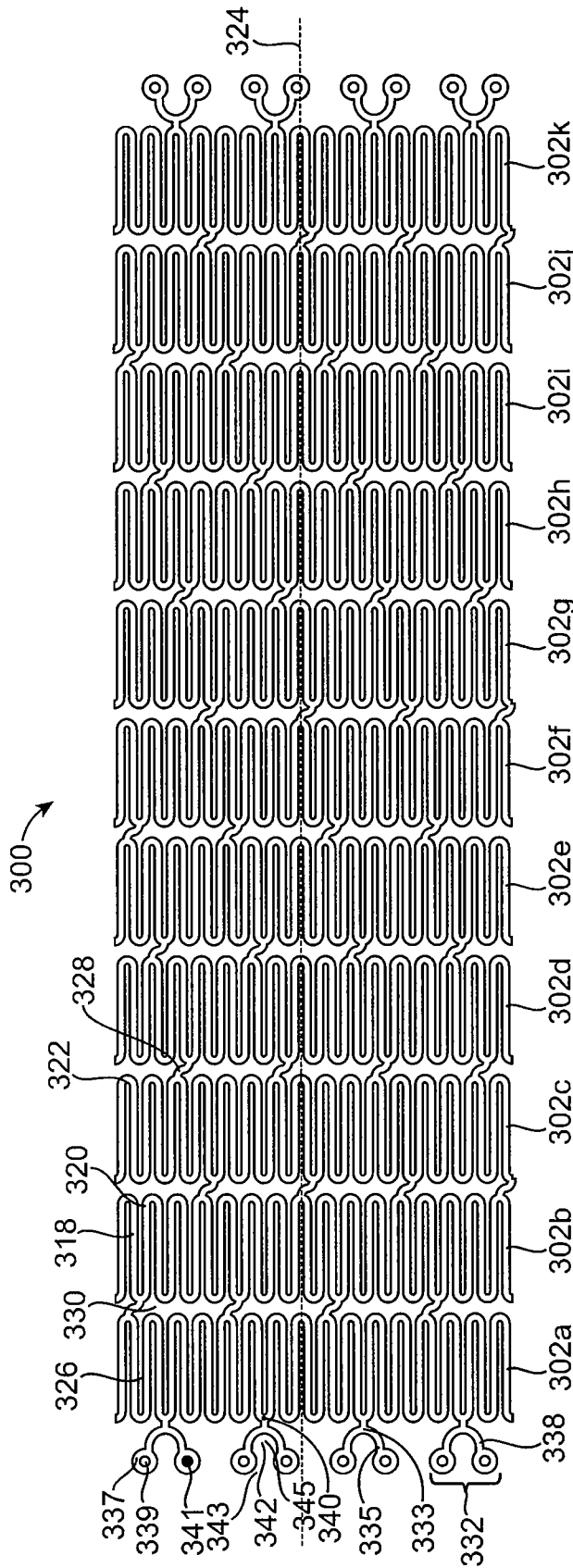


FIG. 3A

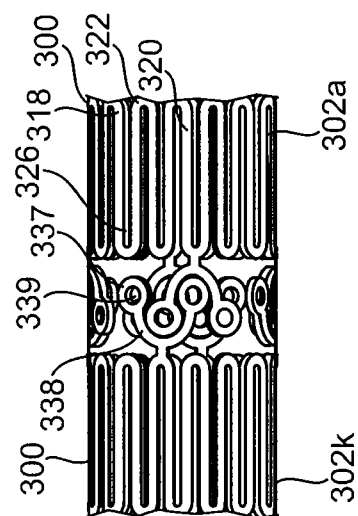


FIG. 3B

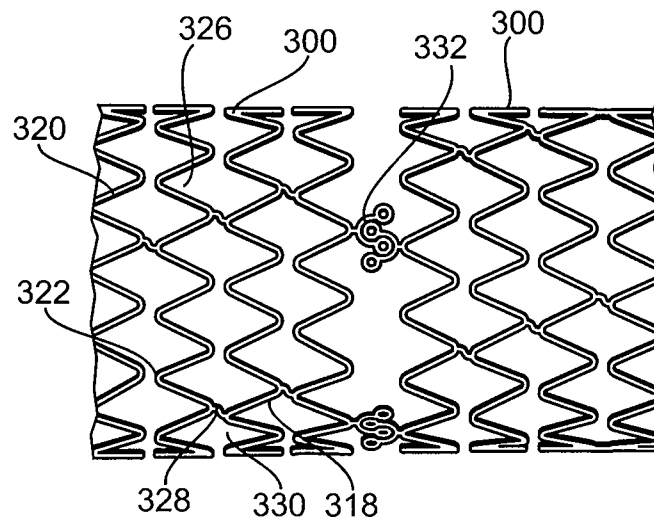


FIG. 3C

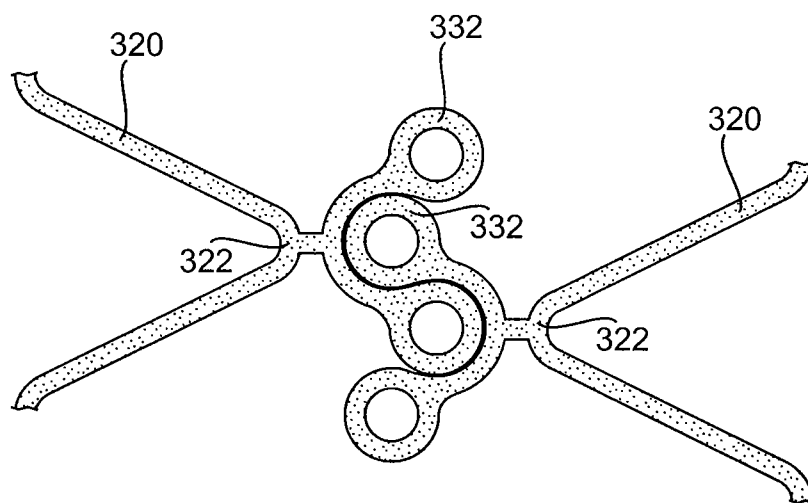


FIG. 3D

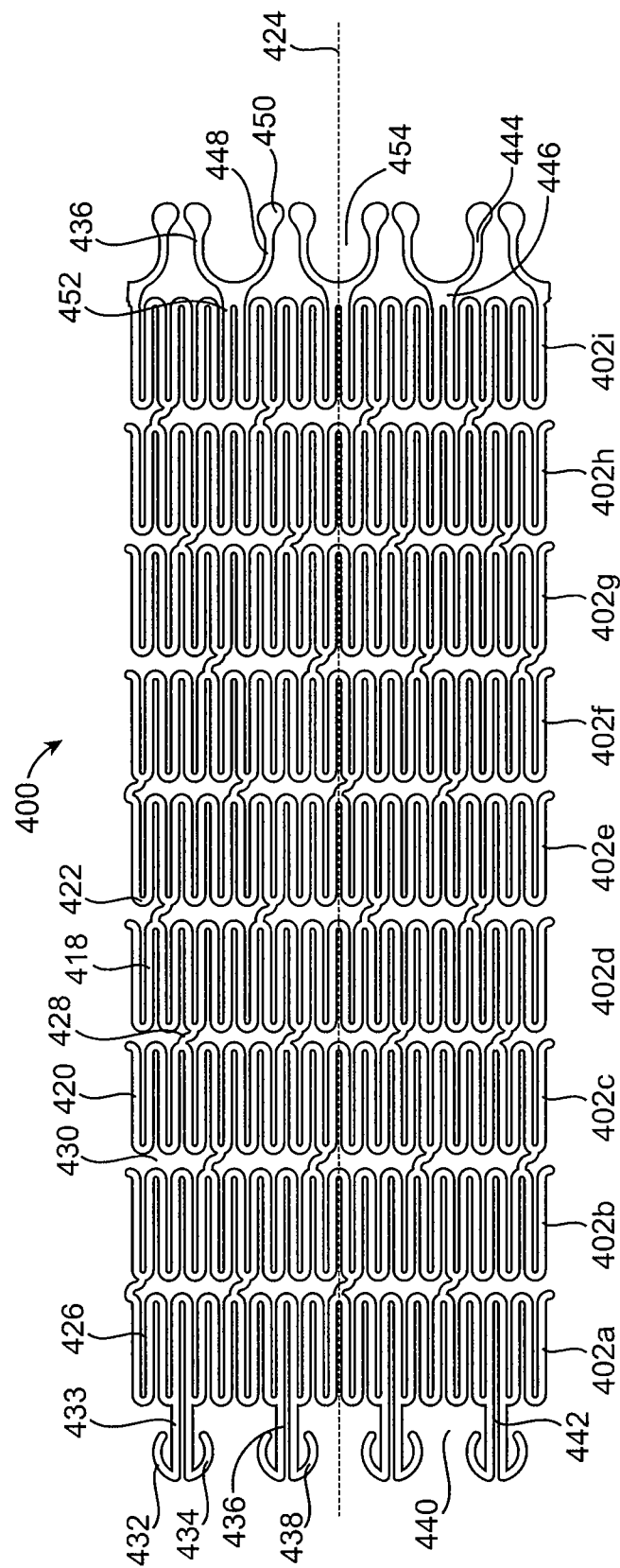


FIG. 4A

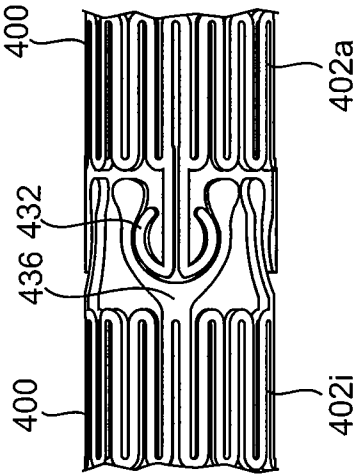


FIG. 4B

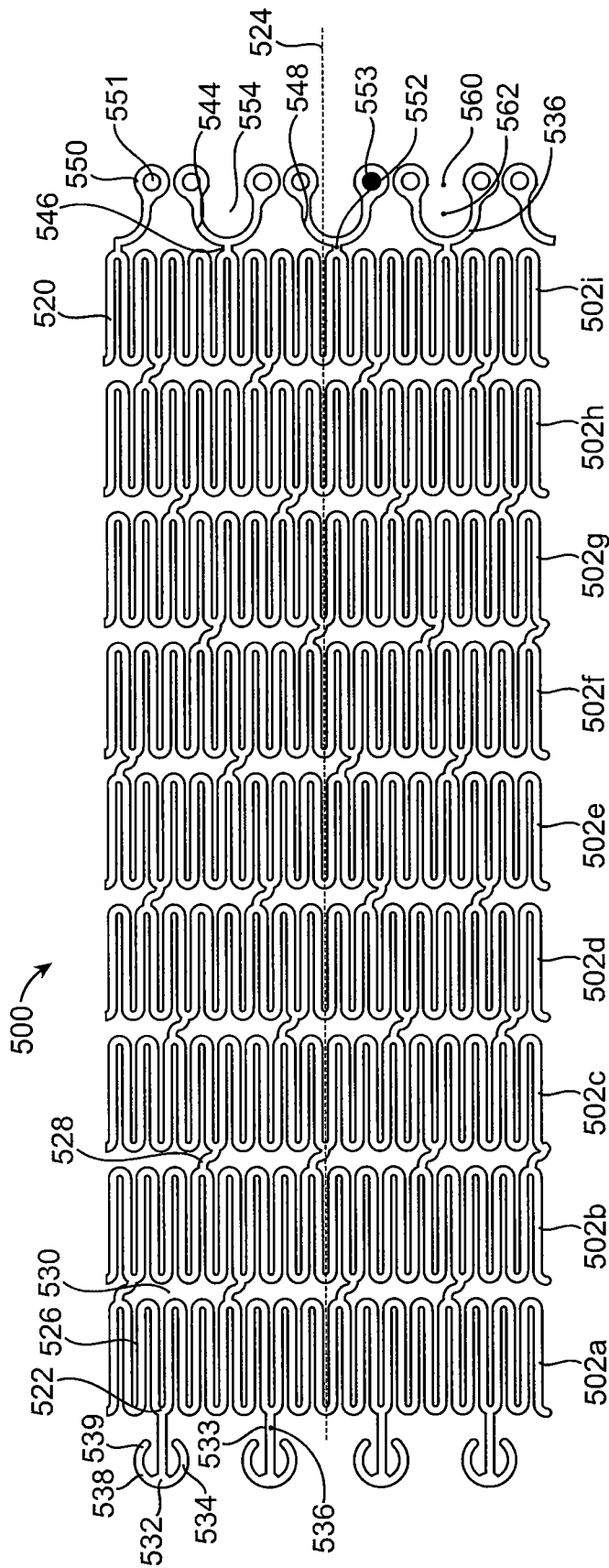


FIG. 5A

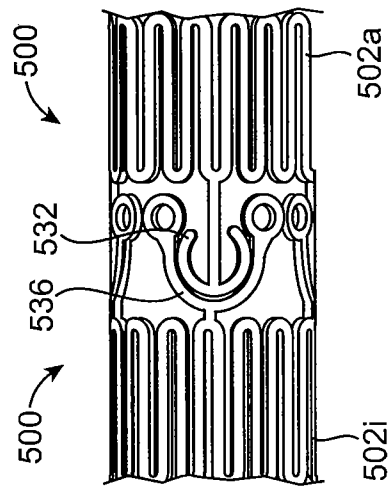


FIG. 5B