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(71) **Applicant** *(for all designated States except US)*: **REVA MEDICAL, INC.** [US/US]; 5751 Copley Drive, Suite B, San Diego, CA 92111 (US).

(72) **Inventors; and**

(75) **Inventors/Applicants** *(for US only)*: **MORRIS, Andrew** [US/US]; 7924 Valdosta Avenue, San Diego, CA 92126 (US). **SCHMID, Eric** [US/US]; 12248 Meadow Grass Court, San Diego, CA 92128 (US). **SHERIFF, Jeffrey** [US/US]; 1324 Skyridge Court, San Marcos, CA 92078 (US). **FELKINS, Brandon** [US/US]; 540 El Granada Boulevard, Half Moon Bay, CA 94019 (US).

(74) **Agent**: **ALTMAN, Daniel, E.**; Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, CA 92614 (US).

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(54) **Title**: AXIALLY NESTED SLIDE AND LOCK EXPANDABLE DEVICE

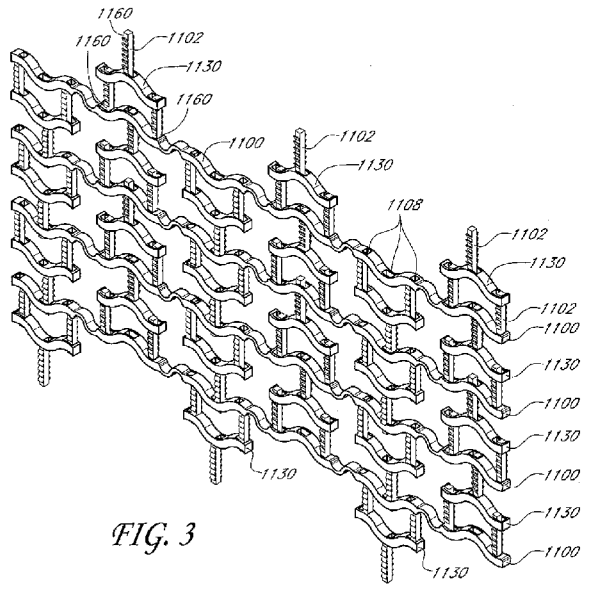

FIG. 3

(57) **Abstract**: Expandable medical implants are provided for maintaining support of a body lumen. For example, an axially nested, expandable, slide and lock vascular device is provided for enlarging an occluded portion of a vessel. The axially nested vascular device can achieve both competitive crossing profiles while maintaining other key features, such as radial strength and luminal patency. The collapsed profile can also be made very thin without compromising radial strength. Thus, the vascular device can advantageously be deployed in small and difficult to reach areas or vessels. The axial nesting substantially eliminates radial overlap between mating structural elements thereby desirably allowing for a low, uniform profile.

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AXIALLY NESTED SLIDE AND LOCK EXPANDABLE DEVICE

Background

Field of the Inventions

[0001] The inventions relate generally to expandable medical implants for maintaining support of a body lumen. More particularly, the inventions relate to a predominantly axially nested, diametrically expandable, slide and lock device for enlarging a portion of a body lumen.

Description of the Related Art

[0002] Stents or expandable stent grafts are implanted in a variety of body lumens in an effort to maintain their patency. The body lumens no matter how large or small may be vascular and nonvascular. These devices are typically intraluminally implanted by use of a catheter, which is inserted at an easily accessible location and then advanced to the deployment site. The stent is initially in a radially compressed or collapsed state to enable it to be maneuvered through the lumen. Once in position, the stent is deployed which, depending on its configuration, may be achieved either automatically or manually, by for example, the inflation of a balloon about which the stent is carried on the catheter.

[0003] An important and frequent use of stents is the treatment of blood vessels in situations where part of the vessel wall or stenotic plaque blocks or occludes fluid flow in the vessel. Often, a balloon catheter is utilized in a percutaneous transluminal coronary angioplasty procedure to enlarge the occluded portion of the vessel. However, the dilation of the occlusion can cause fissuring of atherosclerotic plaque and damage to the endothelium and underlying smooth muscle cell layer, potentially leading to immediate problems from flap formation or perforations in the vessel wall, as well as long-term problems with restenosis of the dilated vessel. Implantation of stents can provide support for such problems and prevent re-closure of the vessel or provide patch repair for a perforated vessel. Further, the stent may overcome the tendency of diseased vessel walls to collapse, thereby maintaining a more normal flow of blood through that

vessel. Stents are also now being used in other clinical conditions such as in patients with unstable vulnerable plaque lesions.

[0004] As stents are normally employed to hold open an otherwise blocked, constricted or occluded lumen, a stent must exhibit sufficient radial or hoop strength in its expanded state to effectively counter the anticipated forces. It is, however, simultaneously necessary for the stent to be as compact as possible in its collapsed state in order to facilitate its advancement through the lumen. As a result, it is advantageous for a stent to have as large an expansion ratio as possible.

[0005] An additional consideration is the longitudinal flexibility of the device. Such characteristic is important not only in maneuvering the stent into position, which may require the traversal of substantial convolutions of the vasculature, but also to better conform to any curvature of the vasculature at the deployment site. At the same time it is, however, necessary for the stent to nonetheless exhibit sufficient radial strength to provide the necessary support for the lumen walls upon deployment.

[0006] Another problem inherent in many prior art stent configurations is the longitudinal contraction that such structures typically undergo as they are radially expanded. This not only reduces the effective length of the stent in its deployed state but may cause abrasion trauma to be inflicted on the vessel walls during expansion.

[0007] A number of very different approaches have been previously devised in an effort to address these various requirements. A popular approach calls for the stent to be constructed wholly of wire. The wire is bent, woven and/or coiled to define a generally cylindrical structure in a configuration that has the ability to undergo radial expansion.

[0008] As an alternative to wire-based structures, stents have been constructed from tube stock. By selectively removing material from such tubular starting material, a desired degree of flexibility and expandability can be imparted to the structure. Etching techniques as well as laser-cutting processes are utilized to remove material from the tube. Laser cutting provides for a high degree of precision and accuracy with which very well defined patterns of material can be removed from the tube to conversely leave very precisely and accurately defined patterns of material in tact. The performance of such stent is very much a function of the pattern of material which remains (i.e., design) and material thickness. The selection of a particular pattern has a profound effect on the

coverage area, expansion ratio and strength of the resulting stent as well as its longitudinal flexibility and longitudinal dimensional stability during expansion.

[0009] While the tube-based stents offer many advantages over the wire-based designs, it is nonetheless desirable to improve upon such designs in an effort to further enhance longitudinal flexibility and longitudinal dimensional stability during radial expansion without sacrificing radial hoop strength.

[0010] One stent design described by Fordenbacher, see e.g., U.S. Patent Nos. 5,549,662 and 5,733,328, employs a plurality of elongated parallel stent components, each having a longitudinal backbone that spans the entire axial length of the stent and a plurality of opposing circumferential elements or fingers extending therefrom. The circumferential elements from one stent component weave into paired slots in the longitudinal backbone of an adjacent stent component. This weave-like interlocking configuration, wherein a circumferential element passes through the first slot in a pair and then weaves back through the second slot in the pair, is essential to Fordenbacher's goal of permitting radial expansion without material deformation. In addition, sufficient members of circumferential elements in the Fordenbacher stent may provide adequate scaffolding. Unfortunately, the circumferential elements have free ends, protruding from the paired slots. Moreover, the circumferential elements weaving through the paired slots also necessarily stand off from the lumen wall. Both the free ends and the stand off may pose significant risks of thrombosis and/or restenosis. Moreover, this stent design would tend to be rather inflexible as a result of the plurality of longitudinal backbones.

[0011] Some stents employ "jelly roll" designs, wherein a sheet is rolled upon itself with a high degree of overlap in the collapsed state and a decreasing overlap as the stent unrolls to an expanded state. Examples of such designs are described in U.S. Patent Nos. 5,421,955 to Lau, 5,441,515 and 5,618,299 to Khosravi, and 5,443,500 to Sigwart. The disadvantage of these designs is that they tend to exhibit very poor longitudinal flexibility. In a modified design that exhibits improved longitudinal flexibility, multiple short rolls are coupled longitudinally. See e.g., U.S. Patent Nos. 5,649,977 to Campbell and 5,643,314 and 5,735,872 to Carpenter. However, these coupled rolls lack vessel support between adjacent rolls. Furthermore, these designs exhibit extensive overlapping of stent elements in multiple layers, which makes the delivery profile rather thick.

[0012] Various types of stents, including those referenced above, are often described based on their means for expansion. Balloon expandable stents are

manufactured in the collapsed condition and are expanded to a desired diameter with a balloon. Although balloon expandable stents are the first stent type to be widely used in clinical applications, it is well recognized that balloon expandable stents have a variety of shortcomings which may limit their effectiveness in many important applications. For example, balloon expandable stents often exhibit substantial recoil (i.e., a reduction in diameter) immediately following deflation of the inflatable balloon. Accordingly, it may be necessary to over-inflate the balloon during deployment of the stent to compensate for the subsequent recoil. This is disadvantageous because it has been found that over-inflation may damage the blood vessel. Furthermore, a deployed balloon expandable stent may exhibit chronic recoil over time, thereby reducing the patency of the lumen. Still further, balloon expandable stents often exhibit foreshortening (i.e., a reduction in length) during expansion, thereby creating undesirable stresses along the vessel wall and making stent placement less precise. Still further, many balloon expandable stents, such as the original Palmaz-Schatz stent and later variations, are configured with an expandable mesh having relatively jagged terminal prongs, which increases the risk of injury to the vessel, thrombosis and/or restenosis.

[0013] Self-expanding stents are manufactured with a diameter approximately equal to, or larger than, the vessel diameter and are collapsed and constrained at a smaller diameter for delivery to the treatment site. Self-expanding stents are commonly placed within a sheath or sleeve to constrain the stent in the collapsed condition during delivery. After the treatment site is reached, the constraint mechanism is removed and the stent self-expands to the expanded condition. Most commonly, self-expanding stents are made of Nitinol or other shape memory alloy.

[0014] In summary, although a wide variety of stents have been proposed over the years for maintaining the patency of a body lumen, none of the existing stent designs has been capable of overcoming most or all of the above described shortcomings. As a result, clinicians are forced to weigh advantages against shortcomings when selecting a stent type to use in a particular application. Accordingly, there remains a need for an improved stent: one that is compact and flexible enough when collapsed to permit uncomplicated delivery to the affected area; one that is sufficiently flexible upon deployment to conform to the shape of the affected body lumen; one that expands uniformly to a desired diameter, without change in length; one that maintains the

expanded size, without significant recoil; and one that has sufficient scaffolding to provide a clear through-lumen.

Summary

[0015] For purposes of summarizing the inventions, certain aspects, advantages and novel features of the inventions have been described herein above. Of course, it is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment of the inventions. Thus, the inventions may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught or suggested herein without necessarily achieving other advantages as may be taught or suggested herein.

[0016] Some embodiments provide a diametrically expanding, slide and lock vascular device, prosthesis or stent comprising elements or members that do not substantially overlap each other in the radial direction, i.e., do not lay (nest) upon each other in the deployed state. In the nested (non-expanded, undeployed, predilated) position, the radial thickness of two overlapping elements is less than about two times the nominal material thickness. Overlap in the non-deployed state is generally acceptable as long a suitable crossing profile is achieved while in the deployed state there is desirably substantially no, minimal or reduced overlap.

[0017] During manufacture and assembly of the axially nested embodiments, the device structural elements are substantially majorly or primarily positioned side by side (axially) in the predilated or non-expanded state to substantially reduce or minimize the device crossing profile and bulk in both the undeployed (non-expanded, predilated) and deployed (expanded, dilated) states. Advantageously, by substantially reducing or eliminating the excess bulk typically encountered with a radially nesting device design, embodiments of the inventions can be used to achieve competitive devices and crossing profiles with a wide variety of materials at a wide variety of thicknesses, thereby desirably allowing for optimum device design and performance.

[0018] Many conventional slide and lock vascular devices comprise elements that overlap each other in the radial direction, i.e., lay upon each other. This feature can limit that thickness of material that can be employed as well as the number of elements that can be employed. As the thickness or element number increases, competitive features of the device may be compromised, such as crossing profile. To provide acceptable

crossing profiles, the thicknesses and the number of elements employed in these radially nesting devices is often reduced, which can have an impact on such features as reliability and device radial strength.

[0019] Embodiments of the inventions provide an axially nested vascular device to achieve both competitive crossing profiles while maintaining other key features, such as, for example, radial strength and luminal patency. Advantageously, an axially nested device design allows for use of thicker materials to maintain radial strength, as needed or desired.

[0020] Embodiments of the inventions can utilize a number of features to create slide and lock mechanisms that allow for controlled and predictable device expansion. For example, deflectable and non-deflectable elements and members can be employed to achieve desired deployment and lock out performance. The skilled artisan will appreciate that a variety of mechanisms, features and/or geometries can readily be included to achieve the desired deployment and lock out performance. For example, mechanisms can be employed that incorporate the bulk of the structural element, or smaller localized sub-elements can be employed.

[0021] Some embodiments provide a slide-and-lock stent that comprises a tubular member that is expandable from a collapsed state to an expanded state. The tubular member comprises at least one slide-and-lock section, comprising separate first and second axially nested, slidably coupled structural elements, at least one of which comprises a deflectable structure configured to deflect during expansion from the collapsed state to the expanded state, thereby resisting recoil, and wherein no portion of either structural elements weaves through paired slots in the other structural element.

[0022] In optional embodiments, the deflectable structure is configured to deflect axially. Alternatively, the deflectable structure is configured to deflect radially.

[0023] Embodiments of the inventions provide an improved stent: one that desirably is small enough and flexible enough when collapsed to permit uncomplicated delivery to the affected area; one that is sufficiently flexible upon deployment to conform to the shape of the affected body lumen; one that expands uniformly to a desired diameter, without change in length; one that maintains the expanded size, without significant recoil; one that has sufficient scaffolding to provide a clear through-lumen; one that supports endothelialization or covering of the stent with vessel lining, which in turn minimizes the

risk of thrombosis; and one that has a greater capacity to deliver therapeutic agents to minimize injury, treat restenosis and other vascular diseases.

[0024] Stents in accordance with optional embodiments can be fabricated or created using a wide variety of manufacturing methods, techniques and procedures. These include, but are not limited to, lasing, laser processing, milling, stamping, forming, casting, molding, laminating, bonding, welding, adhesively fixing, and the like, among others.

[0025] In optional embodiments, stent features and mechanisms are created in a generally two dimensional geometry and further processed, for example by utilizing, but not limited to, bonding, lamination and the like, into three dimensional designs and features. In other embodiments, stent features and mechanisms are directly created into three dimensional shapes, for example by utilizing, but not limited to, processes such as injection molding and the like.

[0026] In optional embodiments of the above-described stents, the stent further comprises a material selected from the group consisting of metal and polymer. Optionally, the polymer comprises a bioresorbable polymer. More preferably, the polymer comprises a radiopaque, bioresorbable polymer. In one aspect, the polymer forms a coating on at least a portion of the stent. The polymer coating may further comprise a biocompatible, bioresorbable polymer adapted to promote a selected biological response.In accordance with an embodiment, there is provided an axially nested stent that can be expanded from an axially nested unexpanded state to an expanded state. The stent can comprise a tubular member having longitudinal and circumferential axes. The tubular member can comprise a plurality of elongate linkage sections and at least one interconnector module. The plurality of elongate linkage sections can be circumferentially disposed about the longitudinal axis. Each linkage section can comprise at least one engagement aperture disposed in the linkage section. The engagement aperture can be disposed through the linkage section in a circumferential direction. Further, the at least one interconnector module can extend intermediate the engagement apetures of at least two linkage sections. The interconnector module can be generally aligned with the circumferential axis of the tubular member. The interconnector module can be configured to allow one-way slidable movement of the linkage sections relative to the interconnector module during expansion of the stent from the axially nested unexpanded state to the expanded state.

[0027] In a modified embodiment, each linkage section can comprise a plurality of link elements interconnected via flexible sections. The link elements can each define proximal and distal ends. The flexible sections can extend intermediate the proximal end of a given link element and the distal end of another given link element to interconnect the plurality of link elements in an end-to-end manner. Further, the at least one engagement aperture can be disposed in at least one link element of the linkage section, and the engagement aperture can be disposed through the link element in a circumferential direction.

[0028] In another modified embodiment, at least first, second, and third elongate linkage sections can be circumferentially spaced apart from each other and connected via a plurality of interconnector modules. The interconnector modules can connect the first and second elongate linkage sections being longitudinally spaced apart from the interconnector modules connecting the second and third elongate linkage sections. Further, the elongate linkage sections can be formed separately from the at least one interconnector module.

[0029] In yet another modified embodiment, at least first, second, and third elongate linkage sections can be circumferentially spaced apart from each other to form the tubular member. Wherein the tubular member comprises respective interconnector modules being at least partially circumferentially interposed between respective circumferentially adjacent elongate linkage sections. In some embodiments, the interconnector modules can connect the first and second elongate linkage sections and the interconnector modules can connect the second and third elongate linkage sections at least partially define an outer surface of the tubular member.

[0030] In additional embodiments, in the expanded state, an end of the at least one interconnector module can be at least partially received into a respective engagement aperture. Further, in some embodiments, in the expanded state, an end of the at least one interconnector module can be substantially fixed relative to a respective engagement aperture. In some embodiments, in the radially nested unexpanded state, the at least one interconnector module can be circumferentially nested within the tubular member.

[0031] According to some embodiments, the stent can further comprise at least one interlink that can be circumferentially disposed about the longitudinal axis of the tubular member and being interposed between adjacent linkage sections. The interlink can have an elongate interlink body that can be configured with an interconnector module

extending from a first side of the interlink body. In this regard, the interlink can be configured with at least one interconnector module extending from a second side thereof.

[0032] In some embodiments, the interconnector module can comprise a plurality of teeth disposed along at least one of top and bottom surfaces thereof to engage the engagement aperture of the link element for facilitating one-way expansion of the stent. The teeth can comprise a flexible oblique projection extending from the top surface of the interconnector module. Further, the teeth can comprise paddles having a free end and a fixed end being coupled to the interconnector module. The paddles can be operative to deflect during passage of the interconnector module through the engagement aperture and to return to an engaged position upon exiting the engagement aperture to facilitate one-way expansion of the stent.

[0033] In accordance with some embodiments, the interconnector module can interconnect two adjacent linkage sections. In this regard, a length of the interconnector module can define a maximum distance between the linkage sections. Further some embodiments can be configured such that the interconnection member comprises a stop member for limiting expansion of the stent. In this regard, the engagement aperture of the linkage section can define a first passing profile and the stop member can define a second passing profile being greater than the first passing profile.

[0034] In accordance with yet additional modified embodiments, each linkage section can further comprise a plurality of link modules that can define an A-frame and opposing lateral wings and a flexible section that can extend intermediate the lateral wing of a given link module and the lateral wing of another given link module to interconnect the plurality of link modules in an end-to-end manner. In this regard, the at least one engagement aperture can be disposed in the A-frame of the link module of the linkage section. Further, the engagement aperture can be disposed through the link module in a circumferential direction. Additionally, the at least one interconnector module can be circumferentially disposed about the longitudinal axis with a respective interconnector module being interposed between adjacent linkage sections. The interconnector module can comprise a plurality of interconnection members extending intermediate the engagement apetures of the adjacent linkage sections. The interconnection members can be generally aligned with the circumferential axis of the tubular member. The interconnection members can be configured to allow one-way slidable movement of the

linkage sections relative to the interconnection member during expansion of the stent from the axially nested unexpanded state to the expanded state.

[0035] In some embodiments, the interconnection member can include a plurality of teeth disposed along at least one side surface thereof to engage the engagement aperture of the link module for facilitating one-way expansion of the stent. The teeth can comprise a flexible oblique projection extending from the both side surfaces of the interconnection member. Further, the teeth can comprise paddles having a free end and a fixed end being coupled to the interconnection member. The paddles can be operative to deflect during passage of the interconnection member through the engagement aperture and to return to an engaged position upon exiting the engagement aperture to facilitate one-way expansion of the stent.

[0036] In addition, some embodiments can be configured such that the interconnector modules comprise first and second sides. Further, the number of interconnection members extending from the first side can be double the number of interconnection members extending from the second side. The link modules of a given linkage section can also be generally longitudinally aligned with the link modules of another given linkage section.

[0037] A method for re-treatment of a body lumen is disclosed in accordance with another embodiment of the present inventions. The method comprises the steps of: deploying to a region of the body lumen any of the above described stents, wherein the stent is made from a bioresorbable polymer, and resides at the region for a period of time; and administering to the region, after the period of time, a second treatment, such as for example, treatments selected from the group consisting of a second stent of any kind, angioplasty, arthrectomy, surgical bypass, radiation, ablation, local drug infusion, etc., or any subsequent intervention or treatment.

[0038] In optional embodiments of the above-described stents, the stent further comprises a therapeutic agent.

[0039] In optional embodiments of the above-described stents, the stent further comprises a layered material. Optionally, the layered material comprises a bioresorbable polymer.

[0040] One key design aspect of embodiments of a slide and lock vascular device is its deployment ratio, that is, the ratio of final maximum diameter to initial compacted diameter. Depending upon the particular design being pursued or the

application being addressed, the deployment ratio may vary. Advantageously, the stent of embodiments of the inventions allows the number of elements to be increased or decreased, that is, varied, as needed or desired, to achieve optimization of the deployment ratio as well as device performance, crossing profile, flexibility, among others. This desirably adds to the device versatility and utility.

[0041] In optional embodiments of the above-described stents, a cross-sectional geometry of at least a portion of the stent is tapered so as to produce generally desirable blood flow characteristics when the stent is placed in a blood vessel lumen.

[0042] In optional embodiments of the above-described stents, the stent further comprises a retractable sheath sized for enclosing the tubular member during delivery to a treatment site.

[0043] In optional embodiments of the above-described stents, the stent further comprises a solid wall region. The solid wall region may further comprise an opening.

[0044] In optional embodiments of the above-described stents, the stent further comprises a polymeric sheath.

[0045] A system for treating a site within a vessel is also disclosed. The system comprises a catheter having a deployment means, and any of the above-described stents, wherein the catheter is adapted to deliver the stent to the site and the deployment means is adapted to deploy the stent. In preferred variations, the catheter is selected from the group consisting of over-the-wire catheters, coaxial rapid-exchange catheters, and multi-exchange delivery catheters.

[0046] All of these embodiments are intended to be within the scope of the inventions herein disclosed. These and other embodiments of the inventions will become readily apparent to those skilled in the art from the following detailed description of the optional embodiments having reference to the attached figures, the inventions not being limited to any particular optional embodiment(s) disclosed.

Brief Description of the Drawings

[0047] Having thus summarized the general nature of the inventions and some of its features and advantages, certain optional embodiments and modifications thereof will become apparent to those skilled in the art from the detailed description herein having reference to the figures that follow, of which:

[0048] **FIG. 1A** is a simplified schematic end view of an axially nested slide and lock stent illustrating features and advantages in accordance with an embodiment of the inventions.

[0049] **FIG. 1B** is a simplified schematic side view of an axially nested slide and lock stent illustrating features and advantages in accordance with another embodiment of the inventions.

[0050] **FIG. 2** is a planar view of an axially nested slide and lock stent in a nested state illustrating features and advantages in accordance with another embodiment of the inventions.

[0051] **FIG. 3** is a perspective view of the axially nested slide and lock stent of Figure 2 in an expanded state.

[0052] **FIG. 4A** is a top view of an elongate linkage section of the axially nested stent of Figure 4, in accordance with an embodiment.

[0053] **FIG. 4B** is a side view of the elongate linkage section of Figure 4A.

[0054] **FIG. 5A** is a top view of an interconnection member of the stent of Figure 4, in accordance with an embodiment.

[0055] **FIG. 5B** is a side view of the interconnection member of Figure 5A.

[0056] **FIG. 6A** is a side view of the stent shown in a nested state as in Figure 2.

[0057] **FIG. 6B** is a side view of the stent shown in an expanded state as in Figure 3.

[0058] **FIG. 7** is a partial perspective view of an embodiment of the stent illustrating stop members for limiting expansion of the stent.

[0059] **FIG. 8** is a perspective view of another axially nested slide and lock stent in a nested state illustrating features and advantages in accordance with another embodiment of the inventions.

[0060] **FIG. 9** is a perspective view of the axially nested slide and lock stent of Figure 8 in an expanded state.

Detailed Description

[0061] While the description sets forth various embodiment specific details, it will be appreciated that the description is illustrative only and should not be construed in any way as limiting the inventions. Furthermore, various applications of the inventions,

and modifications thereto, which may occur to those who are skilled in the art, are also encompassed by the general concepts described herein.

[0062] The term "stent" is used herein to designate embodiments for placement in (1) vascular body lumens (i.e., arteries and/or veins) such as coronary vessels, neurovascular vessels and peripheral vessels for instance renal, iliac, femoral, popliteal, subclavian and carotid; and in (2) nonvascular body lumens such as those treated currently i.e., digestive lumens (e.g., gastrointestinal, duodenum and esophagus, biliary ducts), respiratory lumens (e.g., tracheal and bronchial), and urinary lumens (e.g., urethra); (3) additionally such embodiments may be useful in lumens of other body systems such as the reproductive, endocrine, hematopoietic and/or the integumentary, musculoskeletal/orthopedic and nervous systems (including auditory and ophthalmic applications); and, (4) finally, stent embodiments may be useful for expanding an obstructed lumen and for inducing an obstruction (e.g., as in the case of aneurysms).

[0063] In the following description of the present inventions, the term "stent" may be used interchangeably with the term "prosthesis" and should be interpreted broadly to include a wide variety of devices configured for supporting a segment of a body passageway. Furthermore, it should be understood that the term "body passageway" encompasses any lumen or duct within a body, such as those described herein.

[0064] Still further, it should be understood that the term "shape-memory material" is a broad term that includes a variety of known shape memory alloys, such as nickel-titanium alloys, as well as any other materials that return to a previously defined shape after undergoing substantial plastic deformation.

[0065] In one optional embodiment, the assembled stent generally comprises a tubular member having a length in the longitudinal axis and a diameter in the circumferential axis sized for insertion into the body lumen. The tubular member is optionally formed with a "clear through-lumen," which is defined as having little or no structure protruding into the lumen in either the collapsed or expanded condition.

[0066] In many of the embodiments illustrated and described herein, the intraluminal stent is optionally provided with "slide-and-lock elements" generally referred to herein as "axial elements." The axial elements are slidably interconnected with circumferentially adjacent axial elements in a manner wherein the stent exhibits mono-directional axial expansion from an axially collapsed state to an axially expanded state, e.g., during deployment. The axial elements are optionally configured to provide a

ratcheting effect such that the stent is maintained (i.e., "locked-out") in the expanded diameter after deployment within the body passage. More particularly, the structures (e.g., axial elements) may flex or bend; however, unlike conventional balloon expandable stents, no substantial plastic deformation of the elements are required during expansion of the stent from a collapsed diameter to an expanded diameter. Elements of this type are generally referred to herein as "non-deforming elements." Accordingly, the term "non-deforming element" is intended to generally describe a structure that substantially maintains its original dimensions (i.e., length and width) during deployment of the stent. Each axial element is optionally formed as a flat sheet that is cut or otherwise shaped to provide a slide-and-lock mechanism.

[0067] The phrase "weaves through paired slots" has the meaning described in U.S. Patent Nos. 5,549,662 and 5,733,328. As used herein, this phrase describes a particular slidable coupling or articulation between stent components, wherein a portion of one stent component passes through one of a pair of slots in another stent component, and then passes back through the second of the pair of slots, creating a weave-like interlocking configuration. Optional embodiments of the present inventions employ slidable couplings or articulations between stent components that avoid weave-like configurations, such that in these optional embodiments, no portion of a stent component weaves through paired slots in another stent component.

[0068] The term "radial strength," as used herein, describes the external pressure that a stent is able to withstand without incurring clinically significant damage. Due to their high radial strength, balloon expandable stents are commonly used in the coronary arteries to ensure patency of the vessel. During deployment in a body lumen, the inflation of the balloon can be regulated for expanding the stent to a particular desired diameter. Accordingly, balloon expandable stents may be used in applications wherein precise placement and sizing are important. Balloon expandable stents may be used for direct stenting applications, where there is no pre-dilation of the vessel before stent deployment, or in prosthetic applications, following a pre-dilation procedure (e.g., balloon angioplasty). During direct stenting, the expansion of the inflatable balloon dilates the vessel while also expanding the stent.

[0069] In another optional embodiment, the stent further comprises a tubular member formed from a biocompatible and optionally, bioresorbable polymer, such as those disclosed in co-pending U.S. Application No. 10/952,202; incorporated herein in its

entirety by reference. It is also understood that the various polymer formulae employed may include homopolymers and heteropolymers, which includes stereoisomers. Homopolymer is used herein to designate a polymer comprised of all the same type of monomers. Heteropolymer is used herein to designate a polymer comprised of two or more different types of monomer which is also called a co-polymer. A heteropolymer or co-polymer may be of a kind known as block, random and alternating. Further with respect to the presentation of the various polymer formulae, products according to embodiments of the present inventions may be comprised of a homopolymer, heteropolymer and/or a blend of such polymers.

[0070] The term "bioresorbable" is used herein to designate polymers that undergo biodegradation (through the action of water and/or enzymes to be chemically degraded) and at least some of the degradation products are eliminated and/or absorbed by the body. The term "radiopaque" is used herein to designate an object or material comprising the object visible by in vivo analysis techniques for imaging such as, but not limited to, methods such as x-ray radiography, fluoroscopy, other forms of radiation, MRI, electromagnetic energy, structural imaging (such as computed or computerized tomography), and functional imaging (such as ultrasonography). The term, "inherently radiopaque", is used herein to designate polymer that is intrinsically radiopaque due to the covalent bonding of halogen species to the polymer. Accordingly, the term does encompass a polymer which is simply blended with a halogenated species or other radiopacifying agents such as metals and their complexes.

[0071] In another optional embodiment, the stent further comprises an amount of a therapeutic agent (for example, a pharmaceutical agent and/or a biologic agent) sufficient to exert a selected therapeutic effect. The term "pharmaceutical agent," as used herein, encompasses a substance intended for mitigation, treatment, or prevention of disease that stimulates a specific physiologic (metabolic) response. The term "biological agent," as used herein, encompasses any substance that possesses structural and/or functional activity in a biological system, including without limitation, organ, tissue or cell based derivatives, cells, viruses, vectors, nucleic acids (animal, plant, microbial, and viral) that are natural and recombinant and synthetic in origin and of any sequence and size, antibodies, polynucleotides, oligonucleotides, cDNA's, oncogenes, proteins, peptides, amino acids, lipoproteins, glycoproteins, lipids, carbohydrates, polysaccharides, lipids, liposomes, or other cellular components or organelles for instance receptors and

ligands. Further the term "biological agent," as used herein, includes virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of diseases or injuries of man (per Section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)). Further the term "biological agent" may include 1) "biomolecule," as used herein, encompassing a biologically active peptide, protein, carbohydrate, vitamin, lipid, or nucleic acid produced by and purified from naturally occurring or recombinant organisms, tissues or cell lines or synthetic analogs of such molecules, including antibodies, growth factors, interleukins and interferons; 2) "genetic material" as used herein, encompassing nucleic acid (either deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), genetic element, gene, factor, allele, operon, structural gene, regulator gene, operator gene, gene complement, genome, genetic code, codon, anticodon, messenger RNA (mRNA), transfer RNA (tRNA), ribosomal extrachromosomal genetic element, plasmagene, plasmid, transposon, gene mutation, gene sequence, exon, intron, and, 3) "processed biologics," as used herein, such as cells, tissues or organs that have undergone manipulation. The therapeutic agent may also include vitamin or mineral substances or other natural elements.

[0072] In some embodiments, the design features of the axial elements can be varied to customize the functional features of strength, compliance, radius of curvature at deployment and expansion ratio. In some embodiments, the stent comprises a resorbable material and vanishes when its job is done. In some embodiments, the stent serves as a therapeutic delivery platform.

[0073] The stent optionally comprises at least one longitudinal module, which consists of a series of axial elements, including one or more slide-and-lock axial elements and optionally one or more passive axial elements, linked in the longitudinal axis by flexible coupling portions. In such an embodiment, the axial elements from two or more similar longitudinal modules are slidably connected to circumferentially adjacent axial elements. Of course, single module (or jellyroll-type) embodiments are also encompassed within the scope of the present disclosure. Each module can be a discrete, unitary structure that does not stretch or otherwise exhibit any substantial permanent deformation during stent deployment.

[0074] Some embodiments relate to an axially expandable stent used to open, or to expand a targeted area in a body lumen. In some embodiments, the assembled stent

comprises a tubular member having a length in the longitudinal axis and a diameter in the circumferential or axial axis, of appropriate size to be inserted into the body lumen. The length and diameter of the tubular member may vary considerably for deployment in different selected target lumens depending on the number and configuration of the structural components, described below. The tubular member is adjustable from at least a first collapsed diameter to at least a second expanded diameter. One or more stops and engaging elements or tabs are incorporated into the structural components of the tubular member whereby recoil (i.e., collapse from an expanded diameter to a more collapsed diameter) is minimized to less than about 5%.

[0075] Stents according to aspects of the present inventions are optionally formed with walls for providing a low crossing profile and for allowing excellent longitudinal flexibility. In optional embodiments, the wall thickness is about 0.0001 inches to about 0.0250 inches, and optionally about 0.0010 to about 0.0100 inches. However, the wall thickness depends, at least in part, on the selected material. For example, the thickness may be less than about 0.0080 inches for plastic and degradable materials and may be less than about 0.0020 inches for metal materials. More particularly, for a 3.00 mm stent application, when a plastic material is used, the thickness is optionally in the range of about 0.0040 inches to about 0.0085 inches. However, a stent having various diameters may employ different thicknesses for biliary and other peripheral vascular applications. The above thickness ranges have been found to provide beneficial characteristics through all aspects of the device including assembly and deployment. However, it will be appreciated that the above thickness ranges should not be limiting with respect to the scope of the inventions and that the teachings of the present inventions may be applied to devices having dimensions not discussed herein.

[0076] Some aspects are also disclosed in co-pending U.S. Patent Application Nos. 11/016,269, 60/601,526, 10/655,338, 10/773,756, 10/897,235; each of which is incorporated herein in its entirety by reference thereto.

[0077] Optional embodiments of the inventions described herein relate generally to expandable medical implants for maintaining support of a body lumen and, in particular, to an axially nested, diametrically expandable, slide and lock vascular device for enlarging an occluded portion of a vessel.

[0078] While the description sets forth various details, it will be appreciated that the description is illustrative only and should not be construed in any way as limiting

the inventions. Furthermore, various applications of the inventions, and modifications thereto, which may occur to those who are skilled in the art, are also encompassed by the general concepts described herein.

[0079] Some embodiments relate to an expandable stent having a plurality of longitudinally arranged sections, segments or frames. The sections have a plurality of axially nesting sliding and locking elements permitting one-way sliding of the elements from a collapsed diameter to an expanded/deployed diameter, but inhibiting recoil from the expanded diameter. In some embodiments, the stent comprises a polymer and is fabricated by a combination of laminating and laser cutting a plurality of layers. Advantageously, the stent substantially reduces or minimizes overlap between the structural elements and thus desirably reduces the effective wall thickness of the stent. Another advantage is that the stent design elements and interlocks can be varied to customize the functional features of strength, compliance, radius of curvature at deployment and expansion ratio. In some embodiments, the stent comprises a resorbable material and vanishes when its job is done. In some embodiments, the stent serves as a delivery platform for therapeutic agents such as pharmaceutical compounds or biological materials.

[0080] Some embodiments relate to a radially expandable stent used to open, or to expand a targeted area in a body lumen. Some embodiments relate to a radially expandable stent used as a drug delivery platform to treat vascular conditions. In some embodiments, the assembled stent comprises a tubular member having a length in the longitudinal axis and a diameter in the radial axis, of appropriate size to be inserted into the body lumen. The length and diameter of the tubular member may vary considerably for deployment in different selected target lumens depending on the number and configuration of the structural components, described below.

[0081] The tubular member in accordance with some embodiments has a "clear through-lumen," which is defined as having no structural elements protruding into the lumen in either the collapsed or expanded diameters. Further, the tubular member has smooth marginal edges to minimize the trauma of edge effects. The tubular member is optionally thin-walled (wall thickness depending on the selected materials and intended vessel size to be treated ranging from less than about 0.009 inches for plastic and resorbable materials to less than about 0.0008 inches for metal materials) and flexible to facilitate delivery to small vessels and through tortuous vasculature. The thin walled

design can also minimize blood turbulence and thus risk of thrombosis. The thin profile of the deployed tubular member in accordance with some embodiments also facilitates more rapid endothelialization of the stent.

[0082] Some features and arrangements of embodiments of stents are disclosed in U.S. Patent Nos. 6,033,436, 6,224,626 and 6,623,521 each issued to Steinke, the disclosures of each one of which are hereby incorporated in their entirety by reference thereto.

Embodiments and Design Features

[0083] Figure 1A schematically depicts an end view of one embodiment of a vascular device, prosthesis or stent 10' generally comprising one or more longitudinally arranged sections, segments or frames 12'. Each section 12' includes two or more structural elements 14' that are radially or circumferentially coupled to other structural elements 14' of the same section 12' by one-way slide and lock articulating mechanisms 16'.

[0084] The articulating mechanisms 16' allow one-way expansion of the section 12' from a first collapsed diameter to a second expanded diameter. During expansion, there is circumferential relative motion between the structural elements 14' as generally shown by arrows 18' such that one or both of the structural elements 14' slidably move apart.

[0085] As described in more detail below, even though the structural elements 14' of the same section 12' are radially or circumferentially coupled, the sections 12' and structural elements 14' are designed and configured such that there is minimal or reduced overlapping in the radial or circumferential direction between the structural elements 14' in both the non-expanded and expanded states. Thus, the structural elements 14' are referred to as being axially, longitudinally or non-radially nested.

[0086] Figure 1B schematically depicts a side view of another embodiment of a vascular device, prosthesis or stent 10" generally comprising two or more longitudinally arranged sections, segments or frames 12". Each section 12" includes one or more structural elements 14". Structural elements 14" of adjacent sections 12" are axially or longitudinally coupled to one another by one-way slide and lock articulating mechanisms 16".

[0087] The articulating mechanisms 16" allow one-way expansion of the sections 12" from a first collapsed diameter to a second expanded diameter. During expansion, there is circumferential relative motion between the structural elements 14" as generally shown by arrows 18" such that one or both of the structural elements 14" slidably move.

[0088] As described in more detail below, the axial or longitudinal coupling between the structural elements 14" of adjacent sections 12", and the design and configuration of the sections 12" and structural elements 14" are such that there is minimal or reduced overlapping in the radial or circumferential direction between the structural elements 14'' in both the non-expanded and expanded states. Thus, the structural elements 14" are referred to as being axially, longitudinally or non-radially nested.

[0089] Advantageously, the axially nested embodiments of Figures 1A and 1B, and others as described, taught or suggested herein, allow suitable crossing profiles (e.g. luminal size) while maintaining desirable radial strength and luminal patency. In the non-expanded state, there is also minimal or reduced overlap between structural elements, so that the luminal size facilitates insertion of a guiding catheter balloon or the like to expand the vascular device. The collapsed profile can also be made very thin without compromising radial strength. Thus, the stent of embodiments of the inventions can be deployed in small and difficult to reach vessels, such as the intercranial vessels distal to the carotids and the remote coronary vessels.

[0090] The axially nested embodiments of Figures 1A and 1B, and others as described, taught or suggested herein advantageously significantly minimizes radial stacking (overlap), thus reducing material thickness of the stent in the nondeployed and deployed configurations and thus desirably reduces the effective wall thickness of the deployed stent. Stated differently, the stent substantially eliminates radial overlap between mating structural elements thereby desirably allowing for a low, uniform profile.

[0091] Referring now to Figures 2-7, an embodiment of an axially nested stent is shown. The stent can comprise a tubular member having longitudinal and circumferential axes and that is expandable from a collapsed or axially nested unexpanded state to an expanded state. As shown in Figure 2, in an embodiment, the tubular member can comprise a plurality of elongate linkage sections 1100 and at least one interconnection member 1102 that can be used to interconnect the linkage sections 1100. The linkage

sections 1100 can be oriented to be substantially parallel with a longitudinal axis 1101; thus, when in an assembled state, the linkage sections 1100 can be circumferentially disposed about the longitudinal axis 1101, and can thereby form the tubular member. Nevertheless, it is also noted that the linkage sections 1100 need not be oriented substantially parallel about the longitudinal axis 1101, but that other configurations can be developed that enable the linkage sections 1100 to be oriented substantially skew with respect to the longitudinal axis 1101 of the tubular member.

[0092] Figure 2 illustrates a portion of the stent showing the linkage sections 1100 in the axially nested unexpanded or collapsed state. As such, the linkage sections 1100 can be disposed substantially adjacent to one another. However, it is also contemplated that the linkage sections 1100 can be separated from each other in the unexpanded state. As shown in Figure 3, the stent can achieve the expanded state when the linkage sections 1100 are radially separated from each other.

[0093] In some embodiments, the linkage sections 1100 can be separated at a maximum distance generally defined by the length and configuration of the interconnection member 1102. For example, the interconnection member 1102 can be configured to include stop members at a distal end thereof or other features that limit the total expansion of the stent by limiting the relative movement of the interconnection member 1102 relative to the linkage section 1100. Stop members in some embodiments are discussed further below.

[0094] Thus, in some embodiments, the linkage sections 1100 can be separated at a distance just less than the length of an interconnection member 1102. In other embodiments, as shown in Figure 3, the stent can be configured such that the linkage sections 1100 are separated from one another at a maximum distance that is greater than the length of an individual interconnection member 1102. For example, the stent can comprise an intermediate member having a plurality of interconnection members 1102 extending therefrom to provide greater expansion for the stent. Such embodiments will be described in greater detail below with reference to Figure 3.

[0095] In accordance with an aspect of some embodiments, the linkage sections 1100 can comprise a plurality of link elements 1104, a flexible section 1106 extending intermediate the link elements 1104, and at least one engagement aperture 1108 (shown in Figures 3-4B). The link elements 1104 can be generally elongate. The link

elements 1104 can also be generally straight; however, the link elements 1104 can be arcuately shaped, zig-zag, or can define multifarious geometrical shapes.

[0096] Further, the link elements 1104 can define an overall length that is substantially greater than its overall width. However, it is also contemplated that the overall width can be approximately equal to or greater than the overall length. The link elements 1104 can define a first end 1110 and a second end 1112. In some embodiments, the flexible section 1106 can be configured to extend intermediate a first end 1110' of a given link element 1104' and the second end 1112 of the link element 1104. Thus, the link elements 1104, 1104' can be interconnected in an end-to-end manner.

[0097] In some embodiments, such as those shown in Figures 2-4B, the linkage section 1100 can be configured in a curvilinear design and the linkage sections 1100 can be at least partially axially nestable when positioned adjacent to each other in the unexpanded state. Further, the flexible sections 1106 can also be configured to be curvilinear, which may facilitate flexibility of the stent with respect to the longitudinal axis thereof. Thus, the stent can flex so as to conform to the shape of a body lumen into which it is implanted. Accordingly then, the linkage sections 1100 can allow the stent to assume configurations other than that of a right circular cylinder.

[0098] Referring to Figures 4A-4B, the engagement apertures 1108 of the linkage sections 1100 can be disposed through at least one link element 1104 in a circumferential direction 1120. In some embodiments, the engagement aperture 1108 can be a through-hole that passes from a first side 1122 of the link element 1104 to a second side 1124 of the link element 1104. However, it is also contemplated that the engagement aperture 1108 can be configured as a slot or groove into which at least a portion of the interconnection member 1102 can be received.

[0099] As shown in Figures 2-4B, some embodiments of the stent can be configured such that the link elements 1104 each include a plurality of engagement apertures 1108. Although the link elements 1104 are shown as including three engagements apertures 1108, it is contemplated that a pair of engagement apertures 1108 or even a single engagement aperture 1108 can be used. Such design modifications can be performed in response to the overall configuration and design requirements of the stent.

[0100] The interconnection member 1102 can be configured to be received into the engagement aperture 1108 of the linkage section 1104. In some embodiments,

the interconnection member 1102 can extend from one link element toward the engagement aperture 1108 of another link element 1104. In yet other embodiments, the stent can be configured to include an intermediate or interlink member 1130 to which the interconnection member 1102 can be attached. Thus, as will be described in greater detail below, the interlink member 1130 can be positioned intermediate adjacent linkage sections 1100 and be configured such that a plurality of interconnection members 1102 extend from the interlink members 1130 into the engagement apertures 1108 of the linkage elements 1104 of the linkage sections 1100.

[0101] Referring now to figures 5A-5B, an embodiment of the interlink member 1130 is shown. The interlink member 1130 can include an interlink body 1132 having first and second sides 1134, 1136. The interlink body 1132 can be configured to define a shape that complements the shape or configuration of the link element 1104 of the linkage section 1100. The interlink member 1130 can be configured to be nestable intermediate adjacent linkage sections 1100. In some embodiments, the interlink member 1130 can be positioned intermediate adjacent link elements 1104 of adjacent linkage sections 1100. However, it is also contemplated that the interlink member 1130 can span between multiple link elements 1104 of linkage sections 1100. Thus, although Figures 2-3 illustrate a single interlink member 1130 disposed intermediate adjacent interlink elements 1104, it is contemplated that the interlink element 1130 can extend along the longitudinal axis 1101 so as to be interposed between pairs of linkage elements 1104 of adjacent linkage sections 1100.

[0102] Figure 5A also illustrates that at least one interconnection member 1102 can extend from the interlink member 1130. As such, one or more interconnection members 1102 can extend from either of the first and second sides 1134, 1136, to facilitate the interconnection of adjacent linkage sections 1100.

[0103] In the embodiment shown in Figure 5A, the interlink body 1132 can be configured to conform substantially to the shape of a sinusoidal curve with an engagement member 1102 extending from a central crest 1140 of the interlink body and a pair of interconnection members 1102 extending from the respective end troughs 1142 of the interlink body. Such a configuration can be advantageous in an embodiment such as that illustrated in Figures 2-3 due to the unique configuration of the linkage sections 1100 which utilize link elements 1104 that are alternately configured to conform to the shape of a sinusoidal curve and a co-sinusoidal curve. Thus, as shown in Figure 3, along the

longitudinal axis, the interlink member 1130 can similarly be alternately positioned to conform to the shape of the linkage sections 1100.

[0104] In some embodiments, the stent can achieve a uniform longitudinal spacing of the interconnection members 1102. Nevertheless, other configurations can be employed that likewise achieve uniform spacing of the linkage sections 1100 and the interconnection members 1102. In this regard, it is contemplated that the linkage sections 1100, the interlink members 1130 and the interconnection members 1102 can be configured to provide a substantially symmetrical design that can distribute forces and stresses evenly throughout the stent.

[0105] Referring again to Figures 5A-5B, the interconnection member can include a ratcheting means 1150. The ratcheting means 1150 can be configured to engage the engagement apertures 1108 of the link elements 1104 to allow one-way movement of the interconnection member 1102 relative to the link element 1104. In this manner, the interconnection member 1102 can therefore facilitate the expansion of the stent, but nevertheless prevent the stent from collapsing from the expanded state.

[0106] In some embodiments, such as that illustrated in Figure 5B, the ratcheting means 1150 can include a plurality of teeth 1152 disposed along at least one of a top surface 1154 and a bottom surface 1156 of the interconnection member 1102. Optionally, the teeth 1152 are disposed along both the top and bottom surfaces 1154, 1156 of the interconnection member 1102. Additionally, it is contemplated that the shape of the teeth 1152 can be configured to facilitate expansion of the stent using very minimal expansive force, while being configured to withstand substantial compressive forces to prevent collapse of the stent. In this regard, each of the teeth 1152 can be configured as a projection extending from the interconnection member 1102 that tapers towards its distal end either in the widthwise or lengthwise dimension.

[0107] In some embodiments, each of the teeth 1152 can be shaped substantially as a right triangle or an oblique triangle, when seen from a side view such as the view in Figure 5B. Further, as illustrated in Figure 5B, each of the teeth 1152 can be configured as an oblique projection shaped as a paddle that has a distal free end and a proximal fixed end that is coupled to the interconnection member 1102. In this regard, the distal free end of the paddles can be configured to deflect in a substantially radial direction as the interconnection member 1102 passes through the engagement aperture 1108 during expansion of the stent. However, after the paddle exits the engagement

aperture 1108 the paddle can be configured to be resilient to thereby return to an engaged position and thereby prevent the interconnection member 1102 from reversing its movement. Thus, the interconnection member 1108 can provide one-way movement of the interconnection member 1102 relative to the engagement aperture 1108. In such an embodiment, it is contemplated that the paddle or tooth 1152 can easily radially deflect to allow the expansion of the stent while engaging the engagement aperture 1108 to prevent collapsing of the stent.

[0108] Referring again to Figure 3, it is contemplated that when the stent achieves a fully expanded state, a distal end 1160 of the interconnection member 1102 can be configured to be received into and become substantially fixed relative to the respective engagement aperture 1108. Thus, the movement of the interconnection member 1102 relative to the engagement aperture 1108 can be limited such as by the stop element mentioned above, thus preventing the interconnection member 1102 from exiting the engagement aperture 1108 after the stent becomes fully expanded. The stop members can optionally be configured as those shown in Figure 7.

[0109] Figures 6A-6B illustrate side views of the stent in an axially nested unexpanded or collapsed state and expanded state, respectively. Figure 6A shows a linkage section 1100 and an adjacent linkage section 1100' as well as an interlink member 1130 interposed between the linkage sections 1100, 1100'. As also shown in Figure 6A, another interlink member 1130' is disposed adjacent linkage section 1100'. In this regard, as shown in Figure 3, adjacent interlink members 1130 can be configured such that the interconnection members 1102 are offset from each other. The interconnection members 1102 each extend in opposing circumferential directions and are received into engagement apertures (not shown) of the linkage sections 1100, 1100'. In such an embodiment, the interconnection members 1102 and linkage sections 1100 can move relative to each other in a common circumferential layer (which is illustrated as planar in Figures 6A-B). Thus, these components can be axially nested within each other.

[0110] Additionally, with reference to Figures 3, 5A, and 6A-6B, the interconnection member 1102 extending from the central crest 1140 of interlink member 1130 in Figure 6A can be longitudinally offset from the interconnection member 1102 of interlink member 1130 in Figure 6A can be longitudinally offset from the interconnection member 1102' extending from the central crest of the interlink member 1130'. The offset configuration of the interconnection members of adjacent interlink members can allow the

interconnection member to be of a greater length so as to increase the ratio of the circumference of the stent in the expanded state to the circumference of the stent in the unexpanded state. Further, the offset configuration also provides for more uniform and stable structural properties in the stent.

[0111] In this regard, it is contemplated that the interlink member can also include apertures corresponding to each interconnection member of the interlink member and that are configured to receive at least a portion of respective interconnection members of adjacent interlink members. Such an embodiment is illustrated generally in Figures 2 and 3. Thus, the length of the interconnection member 1102 can be maximized by including corresponding apertures in adjacent interlink members such that when the stent is in the collapsed or unexpanded state, the interconnection members can be received into such apertures.

[0112] Furthermore, Figures 6A-6B also illustrate an aspect of various embodiments disclosed herein, which is that the linkage sections 1100, 1100' and the interlink members 1130, 1130' as well as the interconnection members 1102, 1102' can be configured such that in the unexpanded state, all of the elements of the stent are substantially axially nested. In some embodiments, this feature can generally eliminate any radially protruding elements that would otherwise disrupt fluid flow through the interior of the stent or cause the stent to snag as it is placed into the body lumen.

[0113] As mentioned above, some embodiments of the stent can comprise stop members in order to limit expansion of the stent. For example, as shown in the embodiment of Figure 7, shown in an expanded state, the stent can comprise a linkage section 1180 and an interlink member 1182. The interlink member 1182 can comprise one or more interconnection members 1184 having stop members 1186 disposed at distal ends thereof. Further, the linkage section 1180 can comprise one or more engagement apertures 1188. Further, the interlink member 1182 can comprise one or more alignment apertures 1192.

[0114] The interconnection member 1184 can comprise an elongate body with a cross-sectional dimension or passing profile that is different from the passing profile of the stop member 1186. The passing profile of the body of the interconnection member 1184, including in some embodiments, teeth 1190, can be smaller than passing profiles of the engagement aperture 1188 and the alignment aperture 1192. In this manner, the body of the interconnection member 1184 can freely move through both of the engagement

aperture 1188 and the alignment aperture 1192. The stop member 1186 of the interconnection member 1184 can define a passing profile that is smaller in size that the passing profile of the alignment aperture 1192. However, the passing profile of the stop member 1186 can be larger than the passing profile of the engagement aperture 1188. Thus, the interconnection member 1184 can slide through the engagement aperture 1188 and the alignment aperture 1192 until the movement of the interconnection member 1184 is impeded due to the larger profile of the stop member 1186 than the engagement aperture 1188. In this manner, the engagement aperture 1188 can prevent further movement of the interconnection member 1184 relative to the linkage section 1180.

[0115] Thus, in some embodiments, it is contemplated that motion of the interconnection member can also be limited by the use of an enlarged distal end that interacts with the engagement aperture of the linkage section. Although Figure 7 illustrates that only the linkage section has engagement apertures and that only the interlink member has alignment apertures and interconnection members, it is contemplated that the interconnection member and the linkage section can both comprise one or more alignment apertures, one or more engagement apertures, and one or more interconnection members. In some embodiments, the stent can comprise a series of common, repeating elements that comprise one or more alignment apertures, one or more engagement apertures, and one or more interconnection members. In other words, it is contemplated that instead of have both interlink members and linkage sections, the stent could comprise a single linkage member that repeats and is interconnected to adjacent linkage members to form the circumference of the stent.

[0116] Referring now to Figures 8-9, another embodiment of an axially nested stent is shown. As with the embodiment illustrated in Figures 2-6B, the embodiment of the stent shown in Figures 8-9 illustrates only a portion of the stent which can be formed to comprise a tubular member having longitudinal and circumferential axes. Similarly, the stent can be expandable from a collapsed or axially nested unexpanded state to an expanded state. As shown in Figure 8, in an embodiment, the tubular member can comprise a plurality of elongate linkage sections 1200 and at least one interconnector module 1202 that can be used to interconnect the linkage sections 1200.

[0117] The linkage sections 1200 can be arranged to be substantially parallel with a longitudinal axis 1204; thus, when in an assembled state, the linkage sections 1200 can be circumferentially disposed about the longitudinal axis 1204, and can thereby form

the tubular member. Nevertheless, it is also noted that the linkage sections 1200 need not be oriented substantially parallel about the longitudinal axis 1204, but that other configurations can be developed that enable the linkage sections 1200 to be oriented substantially skew with respect to the longitudinal axis 1204 of the tubular member.

[0118] The embodiment of the stent illustrated in Figures 8-9 provides for a narrow profile and modular construction. As shown, the linkage sections 1200 can comprise a plurality of link modules 1210 that are interconnected via a plurality of respective flexible sections 1212. The flexible sections 1212 can extend intermediate side portions of adjacent link modules 1210. The flexible sections 1212 are optionally curvilinear to facilitate conformance of the shape of the stent and movement of the modules 1210 thereof during placement and expansion of the stent. Nevertheless, the flexible sections 1212 can be linear or have any variety of bends or angles along their length. Furthermore, in some embodiments, the flexible sections 1212 can extend intermediate other portions of the modules 1210, such as corners thereof.

[0119] The linkage section 1200 can be configured to include a plurality of engagement apertures 1220. The engagement apertures 1220 of the linkage section 1200 can be disposed through at least one link module 1210 in a circumferential direction (which is generally oriented orthogonally relative to the longitudinal direction 1204). In some embodiments, the engagement aperture 1220 can be a through-hole that passes from a first side of the link module 1210 to a second side of the link module 1210. However, it is also contemplated that the engagement aperture 1220 can be configured as a slot or groove into which at least a portion of the interconnector module 1202 can be received.

[0120] The embodiment of the linkage sections 1200 illustrated in Figures 8-9 are depicted as including three engagement apertures 1220, with a single engagement aperture 1220 on a first end of the linkage section 1200 and two engagement apertures 1220 on a second end of the linkage section 1200. However, the linkage section 1200 can be configured to include two, four, or any number of engagement apertures 1220. Further, the number of engagement apertures 1220 can correspond to the configuration of the interconnector module 1202; however, other embodiments are contemplated wherein the number of engagement apertures 1220 for a given end of the linkage section does not correspond to the configuration of the interconnector module 1202.

[0121] The interconnector module 1202 can be configured to interconnect adjacent linkage sections 1200. The interconnector module 1202 can comprise a plurality

of interconnection members 1226 extending from an interconnector body 1228 thereof. As such, the interconnector module 1202 can extend from one link module 1210 toward the engagement aperture 1220 of another link module 1210. It is contemplated that the interconnection members 1226 and the interconnector body 1228 can be integrally formed from a continuous piece of material. The interconnector module 1202 can be a flexible element generally configured to circumferentially nest with respective adjacent linkage sections 1200. Further, it is contemplated that the interconnector body 1228 can be used to distribute forces throughout the structure of the stent in order to reduce localized stresses and forces.

[0122] Similar to the embodiments described above, the interconnector module 1202 can also be configured with the interconnection members 1226 of the interconnector module 1202 being offset from each other in the longitudinal direction 1204. Further, as illustrated in Figures 8-9, the interconnection member 1226 can comprise a ratcheting means 1232, which can comprise a plurality of teeth 1234 disposed along at least one side surface of the interconnector module 1202. Optionally, the teeth 1234 are disposed along both of the side surfaces of the interconnection member 1226.

[0123] Additionally, it is contemplated that the shape of the teeth 1234 can be configured to facilitate expansion of the stent using very minimal expansive force, while being configured to withstand substantial compressive forces to prevent collapse of the stent. In this regard, each of the teeth 1234 can be configured as a projection extending from the interconnection member 1226 that tapers towards its distal end either in the widthwise or lengthwise dimension. The teeth 1234 can also be configured as noted above, as a right triangle or an oblique triangle, when seen from a top view. Further, as illustrated in Figures 8-9, each of the teeth 1234 can be configured as an oblique projection shaped as a paddle that has a distal free end and a proximal fixed end that is coupled to the interconnection member 1226. The features and configuration of the paddle can be as similarly described above to prevent collapsing of the stent.

[0124] Referring again to Figure 9, the link modules 1210 can be configured with a central A-frame 1240 and opposing lateral wings 1242. As discussed above, the engagement apertures 1220 can be disposed in the link module 1210 in a generally circumferential direction. The engagement apertures 1220 can be disposed at an apex and bases of the A-frame 1240, as shown in Figure 9. Further, the lateral wings 1242 can comprise elongate connectors that extend from the respective bases of the A-frame 1240

to the apex thereof. The flexible sections 1212 can interconnect with the link modules 1210 along the length of the lateral wings 1242. It is contemplated that the lateral wings 1242 can allow flexibility of the stent construction and can tend to mitigate and/or reduce stresses in the stent resulting from distorting forces exerted on the stent. As a result, the unique configuration of the link module 1210 can tend to improve the structural stability of the stent and reduce localized stresses and forces.

Metal Stents and Methods of Manufacturing

[0125] Optional materials for making the stents in accordance with some embodiments of the inventions include cobalt chrome, 316 stainless steel, tantalum, titanium, tungsten, gold, platinum, iridium, rhodium and alloys thereof or pyrolytic carbon. In still other alternative embodiments, the stents may be formed of a corrodible material, for instance, a magnesium alloy. Although optional stent embodiments have been described as being conventional balloon expandable stents, those skilled in the art will appreciate that stent constructions according to the present inventions may also be formed from a variety of other materials to make a stent crush-recoverable. For example, in alternative embodiments, such as self expandable stents, shape memory alloys that allow for such as Nitinol and Elastinite® may be used in accordance with embodiments of the inventions.

[0126] Optionally, sheets are work-hardened prior to forming of the individual stent elements to increase strength. Methods of work hardening are well known in the art. Sheets are rolled under tension, annealed under heat and then re-worked. This may be continued until the desired modulus of hardness is obtained. Most stents in commercial use today employ 0% to 10% work hardened material in order to allow for "softer" material to deform to a larger diameter. In contrast, because expansion of the sliding and locking radial elements in accordance with embodiments of the inventions depends on sliding rather than material deformation, it is possible to use harder materials, optionally in the range of about 25-95% work hardened material to allow for thinner stent thickness. Optionally, the stent materials are 50-90% work hardened and in some embodiments, the materials can be 80-85% work hardened.

[0127] Optional methods of forming the individual elements from the metal sheets may be laser cutting, laser ablation, die-cutting, chemical etching, plasma etching and stamping and water jet cutting of either tube or flat sheet material or other methods

known in the art which are capable of producing high-resolution components. The method of manufacture, in some embodiments, depends on the material used to form the stent. Chemical etching provides high-resolution components at relatively low price, particularly in comparison to high cost of competitive product laser cutting. Some methods allow for different front and back etch artwork, which could result in chamfered edges, which may be desirable to help improve engagements of lockouts. Further one may use plasma etching or other methods known in the art which are capable of producing high-resolution and polished components. The current inventions is not limited to the means by which stent or stent elements can be fabricated.

[0128] Once the base geometry is achieved, the elements can be assembled numerous ways. Tack-welding, adhesives, mechanical attachment (snap-together and/or weave together), and other art-recognized methods of attachment, may be used to fasten the individual elements. Some methods allow for different front and back etch artwork, which could result in chamfered edges, which may be desirable to help improve engagements of lockouts. In one optional method of manufacture, the components of the stent may be heat set at various desired curvatures. For example, the stent may be set to have a diameter equal to that of the deflated balloon, as deployed, at a maximum diameter, or greater than the maximum diameter. In yet another example, elements can be electropolished and then assembled, or electropolished, coated, and then assembled, or assembled and then electropolished.

[0129] In another embodiment, in particular with shape memory alloys, the stent is heat set at beyond the maximum diameter then built mid diameter than placed over catheter and reverse ratcheted and locked into smaller diameter and onto catheter with positive catch hold down mechanism to achieve a small profile and excellent retention.

Polymeric Stents

[0130] While metal stents possess certain desirable characteristics, the useful lifespan of a stent is estimated to be in the range of about 6 to 9 months, the time at which in-stent restenosis stabilizes and healing plateaus. In contrast to a metal stent, a bioresorbable stent may not outlive its usefulness within the vessel. Moreover, a bioresorbable stent may be used to deliver a greater dose of a therapeutic agent, deliver multiple therapeutic agents at the same time or at various times of its life cycle, to treat

specific aspects or events of vascular disease. Additionally, a bioresorbable stent may also allow for repeat treatment of the same approximate region of the blood vessel. Accordingly, there remains an important unmet need to develop temporary (i.e., bioresorbable and/or radiopaque) stents, wherein the polymeric materials used to fabricate these stents have the desirable qualities of metal (e.g., sufficient radial strength and radiopacity, etc.), while circumventing or alleviating the many disadvantages or limitations associated with the use of permanent metal stents.

[0131] In one optional embodiment, the stent may be formed from biocompatible polymers that are bio-resorbable (e.g., bio-erodible or bio-degradable). Bio-resorbable materials can be selected from the group consisting of any hydrolytically degradable and/or enzymatically degradable biomaterial. Examples of suitable degradable polymers include, but are not limited to, polyhydroxybutyrate /polyhydroxyvalerate copolymers (PHV/PHB), polyesteramides, polylactic acid, hydroxy acids (i.e. lactide, glycolide, hydroxybutyrate), polyglycolic acid, lactone based polymers, polycaprolactone, poly(propylene fumarate-co-ethylene glycol) copolymer (aka fumarate anhydrides), polyamides, polyanhydride esters, polyanhydrides, polylactic acid/polyglycolic acid with a calcium phosphate glass, polyorthesters, silk-elastin polymers, polyphosphazenes, copolymers of polylactic acid and polyglycolic acid and polycaprolactone, aliphatic polyurethanes, polyhydroxy acids, polyether esters, polyesters, polydepsidpetides, polysaccharides, polyhydroxyalkanoates, and copolymers thereof.

[0132] In one mode, the degradable materials are selected from the group consisting of poly(glycolide-trimethylene carbonate), poly(alkylene oxalates), polyaspartimic acid, polyglutarunic acid polymer, poly-p-dioxanone, poly-.beta.-dioxanone, asymmetrically 3,6-substituted poly-1,4-dioxane-2,5-diones, polyalkyl-2-cyanoacrylates, polydepsipeptides (glycine-DL-lactide copolymer), polydihydropyranes, polyalkyl-2-cyanoacrylates, poly-.beta.-maleic acid (PMLA), polyalkanotes and poly-.beta.-alkanoic acids. There are many other degradable materials known in the art. (See e.g., Biomaterials Science: An Introduction to Materials in Medicine (29 July, 2004) Ratner, Hoffman, Schoen, and Lemons; and Atala, A., Mooney, D. Synthetic Biodegradable Polymer Scaffolds. 1997 Birkhauser, Boston; incorporated herein by reference).

[0133] Further still, in an optional embodiment, the stents may be formed of a polycarbonate material, such as, for example, tyrosine-derived polycarbonates, tyrosine-

derived polyarylates, iodinated and/or brominated tyrosine-derived polycarbonates, iodinated and/or brominated tyrosine-derived polyarylates. For additional information, see U.S. Patent Nos. 5,099,060, 5,198,507, 5,587,507, 5,658,995, 6,048,521, 6,120,491, 6,319,492, 6,475,477, 5,317,077, and 5,216,115, each of which is incorporated by reference herein. In another optional embodiment, the polymer is any of the biocompatible, bioabsorbable, radiopaque polymers disclosed in U.S. Patent Application Nos. 60/601,526; 60/586,796; and 10/952,202 the entire disclosures of which are incorporated herein by reference thereto.

[0134] Natural polymers (biopolymers) include any protein or peptide. Optional biopolymers may be selected from the group consisting of alginate, cellulose and ester, chitosan, collagen, dextran, elastin, fibrin, gelatin, hyaluronic acid, hydroxyapatite, spider silk, cotton, other polypeptides and proteins, and any combinations thereof.

[0135] In yet another modified embodiment, shape-shifting polymers may be used to fabricate stents constructed according to the present inventions. Suitable shape-shifting polymers may be selected from the group consisting of polyhydroxy acids, polyorthoesters, polyether esters, polyesters, polyamides, polyesteramides, polydepsidpetides, aliphatic polyurethanes, polysaccharides, polyhydroxyalkanoates, and copolymers thereof. For addition disclosure on bio-degradable shape-shifting polymers, see U.S. Patent No. 6,160,084, which is incorporated by reference herein. For additional disclosure on shape memory polymers, see U.S. Patent Nos. 6,388,043 and 6,720,402, each of which are incorporated by reference herein. Further the transition temperature may be set such that the stent is in a collapsed condition at a normal body temperature. However, with the application of heat during stent placement and delivery, such as via a hot balloon catheter or a hot liquid (e.g., saline) perfusion system, the stent expands to assume its final diameter in the body lumen. When a thermal memory material is used, it may provide a crush-recoverable structure.

[0136] Further still, stents may be formed from biocompatible polymers that are biostable (e.g., non-degrading and non-erodible). Examples of suitable non-degrading materials include, but are not limited to, polyurethane, Delrin, high density polyethylene, polypropylene, and poly(dimethyl siloxane).

[0137] In some embodiments, the layers may comprise or contain any example of thermoplastics, such as the following, among others: fluorinated ethylene-propylene, poly(2-hydroxyethlmethacrylate (aka pHEMA), poly(ethylene terephthalate) fiber (aka

Dacron®) or film (Mylar®), poly(methyl methacrylate (aka PMMA), Poly(tetraflouroethylene) (aka PTFE and ePTFE and Gore-Tex®), poly(vinylchloride), polyacrylates and polyacrylonitrile (PAN), polyamides (aka Nylon), polycarbonates and polycarbonate urethanes, polyethylene and poly(ethylene-co-vinyl acetate), polypropylene, polypropylene, polystyrene, polysulphone, polyurethane and polyetherurethane elastomers such as Pellethane® and Estane®, Silicone rubbers, Siloxane, polydimethylsiloxane (aka PDMS), Silastic®, Siliconized Polyurethane.

Methods of Manufacturing and Assembling Polymeric Stents

[0138] Where plastic and/or degradable materials are used, the elements may be made using laser ablation with a screen, stencil or mask; solvent casting; forming by stamping, embossing, compression molding, centripetal spin casting and molding; extrusion and cutting, three-dimensional rapid prototyping using solid free-form fabrication technology, stereolithography, selective laser sintering, or the like; etching techniques comprising plasma etching; textile manufacturing methods comprising felting, knitting, or weaving; molding techniques comprising fused deposition modeling, injection molding, room temperature vulcanized molding, or silicone rubber molding; casting techniques comprising casting with solvents, direct shell production casting, investment casting, pressure die casting, resin injection, resin processing electroforming, or injection molding or reaction injection molding. Certain optional embodiments with the present polymers may be shaped into stents via combinations of two or more thereof, and the like.

[0139] Such processes may further include two-dimensional methods of fabrication such as cutting extruded sheets of polymer, via laser cutting, etching, mechanical cutting, or other methods, and assembling the resulting cut portions into stents, or similar methods of three-dimensional fabrication of devices from solid forms. For additional information, see U.S. Patent Application No. 10/655,338, which is incorporated by reference herein.

[0140] Stents of the optional embodiment are manufactured with elements prepared in full stent lengths or in partial lengths of which two or more are then connected or attached. If using partial lengths, two or more may be connected or attached to comprise a full length stent. In this arrangement the parts are assembled to give rise to a central opening. The assembled full or partial length parts and/or modules may be

assembled by inter-weaving them in various states, from a collapsed state, to a partially expanded state, to an expanded state.

[0141] Further, elements may be connected or attached by solvent or thermal bonding, or by mechanical attachment. If bonding, optional methods of bonding comprise the use of ultrasonic radiofrequency or other thermal methods, and by solvents or adhesives or ultraviolet curing processes or photoreactive processes. The elements may be rolled by thermal forming, cold forming, solvent weakening forming and evaporation, or by preforming parts before linking.

[0142] Another method of manufacture allows for assembly of the stent components that have been cut out and assembled into flat series of radial elements. The linkage elements between longitudinally adjacent series of radial elements may be connected (e.g., by welding, inter-weaving frame elements, etc.), the flat sheets of material are rolled to form a tubular member. Coupling arms from floating coupling elements and end portions may be joined (e.g., by welding) to maintain the tubular shape. In embodiments that do not include coupling elements, the end portions of the top and bottom radial elements in a series may be joined. Alternatively, where sliding is desired throughout the entire circumference, a sliding and locking articulation can be made between the end portion of the top radial element and the rib(s)/rails of the bottom radial element (e.g., by tack-welding, heat-staking or snap-together). Similarly, a corresponding articulation can be made between the end portion of the bottom radial element and the rib(s)/rails of the top radial element.

[0143] Rolling of the flat series of module(s) to form a tubular member can be accomplished by any means known in the art, including rolling between two plates, which are each padded on the side in contact with the stent elements. One plate is held immobile and the other can move laterally with respect to the other. Thus, the stent elements sandwiched between the plates may be rolled about a mandrel by the movement of the plates relative to one another. Alternatively, 3-way spindle methods known in the art may also be used to roll the tubular member. Other rolling methods that may be used in accordance with the present inventions include those used for "jelly-roll" designs, as disclosed for example, in U.S. Pat. Nos. 5,421,955, 5,441,515, 5,618,299, 5,443,500, 5,649,977, 5,643,314 and 5,735,872; the disclosures of which are incorporated herein in their entireties by reference thereto.

[0144] The construction of the slide-and-lock stents in these fashions provides a great deal of benefit over the prior art. The construction of the locking mechanism is largely material-independent. This allows the structure of the stent to comprise high strength materials, not possible with designs that require deformation of the material to complete the locking mechanism. The incorporation of these materials will allow the thickness required of the material to decrease, while retaining the strength characteristics of thicker stents. In optional embodiments, the frequency of catches, stops or teeth present on selected circumferential elements prevents unnecessary recoil of the stent subsequent to expansion.

Radiopacity

[0145] Traditional methods for adding radiopacity to a medical product include the use of metal bands, inserts and/or markers, electrochemical deposition (i.e., electroplating), or coatings. The addition of radiopacifiers (i.e., radiopaque materials) to facilitate tracking and positioning of the stent could be accommodated by adding such an element in any fabrication method, by absorbing into or spraying onto the surface of part or all of the device. The degree of radiopacity contrast can be altered by element content.

[0146] For plastics and coatings, radiopacity may be imparted by use of monomers or polymers comprising iodine or other radiopaque elements, i.e., inherently radiopaque materials. Common radiopaque materials include barium sulfate, bismuth subcarbonate, and zirconium dioxide. Other radiopaque elements include: cadmium, tungsten, gold, tantalum, bismuth, platinum, iridium, and rhodium. In one optional embodiment, a halogen such as iodine and/or bromine may be employed for its radiopacity and antimicrobial properties.

Multi-Material Vascular Prosthesis

[0147] In still other alternative embodiments, various materials (e.g., metals, polymers, ceramics, and therapeutic agents) may be used to fabricate stent embodiments. The embodiments may comprise: 1) differentially layered materials (through the vertical or radial axis) to create a stack of materials (materials may be stacked in any configuration, e.g., parallel, staggered, etc.); 2) spatially localized materials which may vary along the long axis and/or thickness of the stent body; 3) materials that are mixed or fused to create a composite stent body; 4) embodiments whereby a material is laminated

(or coated) on the surface of the stent body (see Stent Surface Coatings with Functional Properties as well as see Therapeutic Agents Delivered by Stents); and, 5) stents comprised of 2 or more parts where at least one part is materially distinct from a second part, or any combination thereof.

[0148] The fashioning of a slide-and-lock multi-material stent can have between two or more materials. Thickness of each material may vary relative to other materials. This approach as needed or desired allows an overall structural member to be built with each material having one or more functions contributing towards enabling prosthesis function which includes, but is not limited to: 1) enabling mechanical properties for stent performance as defined by ultimate tensile strength, yield strength, Young's modulus, elongation at yield, elongation at break, and Poisson's ratio; 2) enabling the thickness of the substrate, geometrical shape (e.g., bifurcated, variable surface coverage); 3) enabling chemical properties of the material that bear relevance to the materials performance and physical state such as rate of degradation and resorption (which may impact therapeutic delivery), glass transition temperature, melting temperature, molecular weight; 4) enabling radiopacity or other forms of visibility and detection; 5) enabling radiation emission; 6) enabling delivery of a therapeutic agent (see Therapeutic Agents Delivered by Stents); and 7) enabling stent retention and/or other functional properties (see Stent Surface Coatings with Functional Properties).

[0149] In some embodiments, the materials may comprise load-bearing properties, elastomeric properties, mechanical strength that is specific to a direction or orientation e.g., parallel to another material and/or to the long axis of the stent, or perpendicular or uniform strength to another material and/or stent. The materials may comprise stiffeners, such as the following, boron or carbon fibers, pyrolytic carbon. Further, stents may be comprised of at least one re-enforcement such a fibers, nanoparticles or the like.

[0150] In another optional embodiment mode of the inventions, the stent is made, at least in part, from a polymeric material, which may be degradable. The motivation for using a degradable stent is that the mechanical support of a stent may only be necessary for several weeks. In some embodiments, bioresorbable materials with varying rates of resorption may be employed. For additional information, see U.S. Patent Application No. 10/952,202 and 60/601,526, which are incorporated by reference herein. Degradable polymeric stent materials may be particularly useful if it also controls

restenosis and thrombosis by delivering pharmacologic agents. Degradable materials are well suited for therapeutic delivery (see Therapeutic Agents Delivered by Stents).

[0151] In some embodiments, the materials may comprise or contain any class of degradable polymer as previously defined. Along with variation in the time of degradation and/or resorption the degradable polymer may have other qualities that are desirable. For example, in some embodiments the materials may comprise or contain any example of natural polymers (biopolymers) and/or those that degrade by hydrolytic and/or enzymatic action. In some embodiments, the material may comprise or contain any example of hydrogels that may or may not be thermally reversible hydrogels, or any example of a light or energy curable material, or magnetically stimulateable (responding) material. Each of these responses may provide for a specific functionality.

[0152] In some embodiments, the materials may comprise or be made from or with constituents which has some radiopaque material alternatively, a clinically visible material which is visible by x-ray, fluoroscopy, ultrasound, MRI, or Imatron Electron Beam Tomography (EBT).

[0153] In some embodiments, one or more of the materials may emit predetermined or prescribed levels of therapeutic radiation. In one embodiment, the material can be charged with beta radiation. In another embodiment, the material can be charged with Gamma radiation. In yet another embodiment, the material can be charged with a combination of both Beta and Gamma radiation. Stent radioisotopes that may be used include, but are not limited to, 103Pd and 32P (phosphorus-32) and two neutron-activated examples, 65Cu and 87Rb2O, (90)Sr, tungsten-188 (188).

[0154] In some embodiments, one or more of the materials may comprise or contain a therapeutic agent. The therapeutic agents may have unique, delivery kinetics, mode of action, dose, half-life, purpose, et cetera. In some embodiments, one or more of the materials comprise an agent which provides a mode and site of action for therapy for example by a mode of action in the extracellular space, cell membrane, cytoplasm, nucleus and/or other intracellular organelle. Additionally an agent that serves as a chemoattractant for specific cell types to influence tissue formation and cellular responses for example host-biomaterial interactions, including anti-cancer effects. In some embodiments, one or more of the materials deliver cells in any form or state of development or origin. These could for example be encapsulated in a degradable microsphere, or mixed directly with polymer, or hydrogel and serve as vehicle for

pharmaceutical delivery. Living cells could be used to continuously deliver pharmaceutical type molecules, for instance, cytokines and growth factors. Nonliving cells may serve as a limited release system. For additional concepts of therapeutic delivery, see the section entitled: Therapeutic Agents Delivered by Stents.

Therapeutic Agents Delivered by Stents

[0155] In another optional embodiment, the stent further comprises an amount of a therapeutic agent (as previously defined for a pharmaceutical agent and/or a biologic agent) sufficient to exert a selected therapeutic effect. In some optional embodiments of the stent (e.g., polymer stents and multi-material stents) the therapeutic agent is contained within the stent as the agent is blended with the polymer or admixed by other means known to those skilled in the art. In other optional embodiments of the stent, the therapeutic agent is delivered from a polymer coating on the stent surface. In some optional embodiments of the stent a therapeutic agent is localized in or around a specific structural aspect of the device.

[0156] In another optional embodiment, the therapeutic agent is delivered by means of a non-polymer coating. In other optional embodiments of the stent, the therapeutic agent is delivered from at least one region or one surface of the stent. The therapeutic can be chemically bonded to the polymer or carrier used for delivery of the therapeutic from at least one portion of the stent and/or the therapeutic can be chemically bonded to the polymer that comprises at least one portion of the stent body. In one optional embodiment, more than one therapeutic agent may be delivered.

[0157] The amount of the therapeutic agent can be sufficient to inhibit restenosis or thrombosis or to affect some other state of the stented tissue, for instance, heal a vulnerable plaque, and/or prevent rupture or stimulate endothelialization or limit other cell types from proliferating and from producing and depositing extracellular matrix molecules. The agent(s) may be selected from the group consisting of antiproliferative agents, anti-inflammatory, anti-matrix metalloproteinase, and lipid lowering, cholesterol modifying, anti-thrombotic and antiplatelet agents, in accordance with optional embodiments of the present inventions. Some of these optional anti-proliferative agents that improve vascular patency include without limitation paclitaxel, Rapamycin, ABT-578, everolimus, dexamethasone, nitric oxide modulating molecules for endothelial

function, tacrolimus, estradiol, mycophenolic acid, C6-ceramide, actinomycin-D and epothilones, and derivatives and analogs of each.

[0158] Some of these optional agents act as an antiplatelet agent, antithrombin agent, compounds to address other pathologic events and/or vascular diseases. Various therapeutic agents may be classified in terms of their sites of action in the host: agents that exert their actions extracellularly or at specific membrane receptor sites, those that act on the plasma membrane, within the cytoplasm, and/or the nucleus.

[0159] In addition to the aforementioned, therapeutic agents may include other pharmaceutical and/or biologic agents intended for purposes of treating body lumens other than arteries and/or veins). Therapeutic agents may be specific for treating nonvascular body lumens such as digestive lumens (e.g., gastrointestinal, duodenum and esophagus, biliary ducts), respiratory lumens (e.g., tracheal and bronchial), and urinary lumens (e.g., urethra). Additionally such embodiments may be useful in lumens of other body systems such as the reproductive, endocrine, hematopoietic and/or the integumentary, musculoskeletal/orthopedic and nervous systems (including auditory and ophthalmic applications); and finally, stent embodiments with therapeutic agents may be useful for expanding an obstructed lumen and for inducing an obstruction (e.g., as in the case of aneurysms).

[0160] Therapeutic release may occur by controlled release mechanisms, diffusion, interaction with another agent(s) delivered by intravenous injection, aerosolization, or orally. Release may also occur by application of a magnetic field, an electrical field, or use of ultrasound.

Stent Surface Coatings with Functional Properties

[0161] In addition to stents that may deliver a therapeutic agent, for instance delivery of a biological polymer on the stent such as a repellant phosphorylcholine, the stent may be coated with other bioresorbable polymers predetermined to promote biological responses in the body lumen desired for certain clinical effectiveness. Further the coating may be used to mask (temporarily or permanently) the surface properties of the polymer used to comprise the stent embodiment. The coating may be selected from the broad class of any biocompatible bioresorbable polymer which may include any one or combination of halogenated and/or non-halogenated which may or may not comprise any poly(alkylene glycol). These polymers may include compositional variations including

homopolymers and heteropolymers, stereoisomers and/or a blend of such polymers. These polymers may include for example, but are not limited to, polycarbonates, polyarylates, poly(ester amides), poly(amide carbonates), trimethylene carbonate, polycaprolactone, polydioxane, polyhydroxybutyrate, poly-hydroxyvalerate, polyglycolide, polylactides and stereoisomers and copolymers thereof, such as glycolide/lactide copolymers. In an optional embodiment, the stent is coated with a polymer that exhibits a negative charge that repels the negatively charged red blood cells' outer membranes thereby reducing the risk of clot formation. In another optional embodiment, the stent is coated with a polymer that exhibits an affinity for cells, (e.g., endothelial cells) to promote healing. In yet another optional embodiment, the stent is coated with a polymer that repels the attachment and/or proliferation of specific cells, for instance arterial fibroblasts and/or smooth muscle cells in order to lessen restenosis and/or inflammatory cells such as macrophages.

[0162] Described above are stent embodiments of the present inventions that may be modified with a coating to achieve functional properties that support biological responses. Such coatings or compositions of material with a therapeutic agent may be formed on stents or applied in the process of making a stent body via techniques such as dipping, spray coating, cross-linking combinations thereof, and the like. Such coatings or compositions of material may also serve purpose other than delivering a therapeutic, such as to enhance stent retention on a balloon when the coating is placed intraluminally on the stent body and/or placed over the entire device after the stent is mounted on the balloon system to keep the stent in a collapsed formation. Other purposes can be envisioned by those skilled in the art when using any polymer material.

[0163] In one aspect of the inventions, a stent would have a coating applied that has specific mechanical properties. The properties may include *inter alia* thickness, tensile strength, glass transition temperature, and surface finish. The coating is optionally applied prior to final crimping or application of the stent to the catheter. The stent may then be applied to the catheter and the system may have either heat or pressure or both applied in a compressive manner. In the process, the coating may form frangible bonds with both the catheter and the other stent surfaces. The bonds would enable a reliable method of creating stent retention and of holding the stent crossing profile over time. The bonds would break upon the balloon deployment pressures. The coating would be a lower Tg than the substrate to ensure no changes in the substrate.

Stent Deployment

[0164] First, a catheter is provided wherein an expandable member, in some embodiments an inflatable balloon, such as an angioplasty balloon, is provided along a distal end portion. One example of a balloon catheter for use with a stent is described in U.S. Patent No. 4,733,665 to Palmaz, which is incorporated by reference herein. A stent on a catheter is commonly collectively referred to as a stent system. Catheters include but are not limited to over-the-wire catheters, coaxial rapid-exchange designs and the Medtronic Zipper Technology that is a new delivery platform. Such catheters may include for instance those described in Bonzel U.S. Patent Nos. 4,762,129 and 5,232,445 and by Yock U.S. Patent Nos. 4,748,982; 5,496,346; 5,626,600; 5,040,548; 5,061,273; 5,350,395; 5,451,233 and 5,749,888. Additionally, catheters may include for instance those as described in U.S. Patent Nos. 4,762,129; 5,092,877; 5,108,416; 5,197,978; 5,232,445; 5,300,085; 5,445,646; 5,496,275; 5,545,135; 5,545,138; 5,549,556; 5,755,708; 5,769,868; 5,800,393; 5,836,965; 5,989,280; 6,019,785; 6,036,715; 5,242,399; 5,158,548; and 6,007,545. The disclosures of the above-cited patents are incorporated herein in their entirety by reference thereto.

[0165] Catheters may be specialized with highly compliant polymers and for various purposes such as to produce an ultrasound effect, electric field, magnetic field, light and/or temperature effect. Heating catheters may include for example those described in U.S. Patent No. 5,151,100, 5,230,349; 6,447,508; and 6,562,021 as well as WO9014046A1. Infrared light emitting catheters may include for example those described in U. S. Patent Nos. 5,910,816 and 5,423,321. The disclosures of the above-cited patents and patent publications are incorporated herein in their entirety by reference thereto.

[0166] An expandable member, such as an inflatable balloon, is optionally used to deploy the stent at the treatment site. As the balloon is expanded, the radial force of the balloon overcomes the initial resistance of the constraining mechanism, thereby allowing the stent to expand. As the balloon is inflated, the radial elements slide with respect to each other along the surface of the balloon until the stent has been expanded to a desired diameter.

[0167] The stent of embodiments of the inventions are adapted for deployment using conventional methods known in the art and employing percutaneous transluminal

catheter devices. This includes deployment in a body lumen by means of a balloon expandable design whereby expansion is driven by the balloon expanding. Alternatively, the stent may be mounted onto a catheter that holds the stent as it is delivered through the body lumen and then releases the stent and allows it to self-expand into contact with the body lumen. The restraining means may comprise a removable sheath and/or a mechanical aspect of the stent design.

[0168] Some embodiments of the inventions may be useful in coronary arteries, carotid arteries, vascular aneurysms (when covered with a sheath), and peripheral arteries and veins (e.g., renal, iliac, femoral, popliteal, subclavian, aorta, intercranial, etc.). Other nonvascular applications include gastrointestinal, duodenum, biliary ducts, esophagus, urethra, reproductive tracts, trachea, and respiratory (e.g., bronchial) ducts and sinuses. These applications may or may not require a sheath covering the stent.

[0169] It is desirable to have the stent radially expand in a uniform manner. Alternatively, the expanded diameter may be variable and determined by the internal diameter and anatomy of the body passageway to be treated. Accordingly, uniform and variable expansion of the stent that is controlled during deployment is not likely to cause a rupture of the body passageway. Furthermore, the stent will resist recoil because the locking means resist sliding of the mating elements. Thus, the expanded intraluminal stent will continue to exert radial pressure outward against the wall of the body passageway and will therefore, not migrate away from the desired location.

[0170] From the foregoing description, it will be appreciated that a novel approach for expanding a lumen has been disclosed. While the components, techniques and aspects of the inventions have been described with a certain degree of particularity, it is manifest that many changes may be made in the specific designs, constructions and methodology herein above described without departing from the spirit and scope of this disclosure.

[0171] While a number of optional embodiments of the inventions and variations thereof have been described in detail, other modifications and methods of using and medical applications for the same will be apparent to those of skill in the art. Accordingly, it should be understood that various applications, modifications, materials, and substitutions may be made of equivalents without departing from the spirit of the inventions or the scope of the claims.

[0172] Various modifications and applications of the inventions may occur to those who are skilled in the art, without departing from the true spirit or scope of the inventions. It should be understood that the inventions is not limited to the embodiments set forth herein for purposes of exemplification, but is to be defined only by a fair reading of the appended claims, including the full range of equivalency to which each element thereof is entitled.

References

[0173] Some of the references cited herein are listed below, the entirety of each one of which is hereby incorporated by reference herein:

- Charles R, Sandirasegarane L, Yun J, Bourbon N, Wilson R, Rothstein RP, et al. Ceramide-Coated Balloon Catheters Limit Neointimal Hyperplasia after Stretch Injury in Carotid Arteries. Circ Res 2000;87(4):282-288.
- Coroneos E, Martinez M, McKenna S, Kester M. Differential regulation of sphingomyelinase and ceramidase activities by growth factors and cytokines. Implications for cellular proliferation and differentiation. J Biol Chem 1995;270(40):23305-9.
- Coroneos E, Wang Y, Panuska JR, Templeton DJ, Kester M. Sphingolipid metabolites differentially regulate extracellular signal-regulated kinase and stress-activated protein kinase cascades. Biochem J 1996;316(Pt 1):13-7.
- Jacobs LS, Kester M. Sphingolipids as mediators of effects of platelet-derived growth factor in vascular smooth muscle cells. Am J Physiol 1993;265(3 Pt 1):C740-7.
- Tanguay JF, Zidar JP, Phillips HR, 3rd, Stack RS. Current status of biodegradable stents. Cardiol Clin 1994;12(4):699-713.
- Nikol S, Huehns TY, Hofling B. Molecular biology and post-angioplasty restenosis. Atherosclerosis 1996;123(1-2):17-31.
- Biomaterials Science: An Introduction to Materials in Medicine (29 July, 2004) Ratner, Hoffman, Schoen, and Lemons

WHAT IS CLAIMED IS:

1. An axially nested stent being expandable from an axially nested unexpanded state to an expanded state, the stent comprising a tubular member having longitudinal and circumferential axes, the tubular member comprising:

a plurality of elongate linkage sections being circumferentially disposed about the longitudinal axis, each linkage section comprising at least one engagement aperture disposed in the linkage section, the engagement aperture being disposed through the linkage section in a circumferential direction; and

at least one interconnector module extending intermediate the engagement apetures of at least two linkage sections, the interconnector module being generally aligned with the circumferential axis of the tubular member, the interconnector module being configured to allow one-way slidable movement of the linkage sections relative to the interconnector module during expansion of the stent from the axially nested unexpanded state to the expanded state.

2. The stent of Claim 1, wherein each linkage section comprises a plurality of link elements interconnected via flexible sections, the link elements each defining proximal and distal ends, the flexible sections extending intermediate the proximal end of a given link element and the distal end of another given link element to interconnect the plurality of link elements in an end-to-end manner, wherein the at least one engagement aperture is disposed in at least one link element of the linkage section, the engagement aperture being disposed through the link element in a circumferential direction.

3. The stent of Claim 1, wherein at least first, second, and third elongate linkage sections are circumferentially spaced apart from each other and connected via a plurality of interconnector modules, the interconnector modules connecting the first and second elongate linkage sections being longitudinally spaced apart from the interconnector modules connecting the second and third elongate linkage sections.

4. The stent of Claim 1, wherein the elongate linkage sections are formed separately from the at least one interconnector module.

5. The stent of Claim 1, wherein at least first, second, and third elongate linkage sections are circumferentially spaced apart from each other to form the tubular member, wherein the tubular member comprises respective interconnector modules being at least partially circumferentially interposed between respective circumferentially adjacent elongate linkage sections.

6. The stent of Claim 5, wherein the interconnector modules connecting the first and second elongate linkage sections and the interconnector modules connecting the second and third elongate linkage sections at least partially define an outer surface of the tubular member.

7. The stent of Claim 1, wherein in the expanded state, an end of the at least one interconnector module is at least partially received into a respective engagement aperture.

8. The stent of Claim 1, wherein in the expanded state, an end of the at least one interconnector module is substantially fixed relative to a respective engagement aperture.

9. The stent of Claim 1, wherein in the radially nested unexpanded state, the at least one interconnector module is circumferentially nested within the tubular member.

10. The stent of Claim 1, further comprising at least one interlink being circumferentially disposed about the longitudinal axis of the tubular member and being interposed between adjacent linkage sections, the interlink having an elongate interlink body being configured with an interconnector module extending from a first side of the interlink body.

11. The stent of Claim 10, wherein the interlink is configured with at least one interconnector module extending from a second side thereof.

12. The stent of Claim 1, wherein the interconnector module comprises a plurality of teeth disposed along at least one of top and bottom surfaces thereof to engage the engagement aperture of the link element for facilitating one-way expansion of the stent.

13. The stent of Claim 12, wherein the teeth comprise a flexible oblique projection extending from the top surface of the interconnector module.

14. The stent of Claim 13, wherein the teeth comprise paddles having a free end and a fixed end being coupled to the interconnector module, the paddles being operative to deflect during passage of the interconnector module through the engagement aperture and to return to an engaged position upon exiting the engagement aperture to facilitate one-way expansion of the stent.

15. The stent of Claim 1, wherein the interconnector module interconnects two adjacent linkage sections, and wherein a length of the interconnector module defines a maximum distance between the linkage sections.

16. The stent of Claim 1, wherein the interconnection member comprises a stop member for limiting expansion of the stent.

17. The stent of Claim 16, wherein the engagement aperture of the linkage section defines a first passing profile and the stop member defines a second passing profile being greater than the first passing profile.

18. The stent of Claim 1, wherein each linkage section further comprises:

a plurality of link modules defining an A-frame and opposing lateral wings; and

a flexible section extending intermediate the lateral wing of a given link module and the lateral wing of another given link module to interconnect the plurality of link modules in an end-to-end manner;

wherein the at least one engagement aperture is disposed in the A-frame of the link module of the linkage section, the engagement aperture being disposed through the link module in a circumferential direction; and

wherein the at least one interconnector module is circumferentially disposed about the longitudinal axis with a respective interconnector module being interposed between adjacent linkage sections, the interconnector module comprising a plurality of interconnection members extending intermediate the engagement apetures of the adjacent linkage sections, the interconnection members being generally aligned with the circumferential axis of the tubular member, the interconnection members being configured to allow one-way slidable movement of the linkage sections relative to the interconnection member during expansion of the stent from the axially nested unexpanded state to the expanded state.

19. The stent of Claim 18, wherein the interconnection member includes a plurality of teeth disposed along at least one side surface thereof to engage the engagement aperture of the link module for facilitating one-way expansion of the stent.

20. The stent of Claim 19, wherein the teeth comprise a flexible oblique projection extending from the both side surfaces of the interconnection member.

21. The stent of Claim 20, wherein the teeth comprise paddles having a free end and a fixed end being coupled to the interconnection member, the paddles being operative to deflect during passage of the interconnection member through the

engagement aperture and to return to an engaged position upon exiting the engagement aperture to facilitate one-way expansion of the stent.

22. The stent of Claim 18, wherein the interconnector modules comprise first and second sides, wherein the number of interconnection members extending from the first side is double the number of interconnection members extending from the second side.

23. The stent of Claim 18, wherein the link modules of a given linkage section are generally longitudinally aligned with the link modules of another given linkage section.

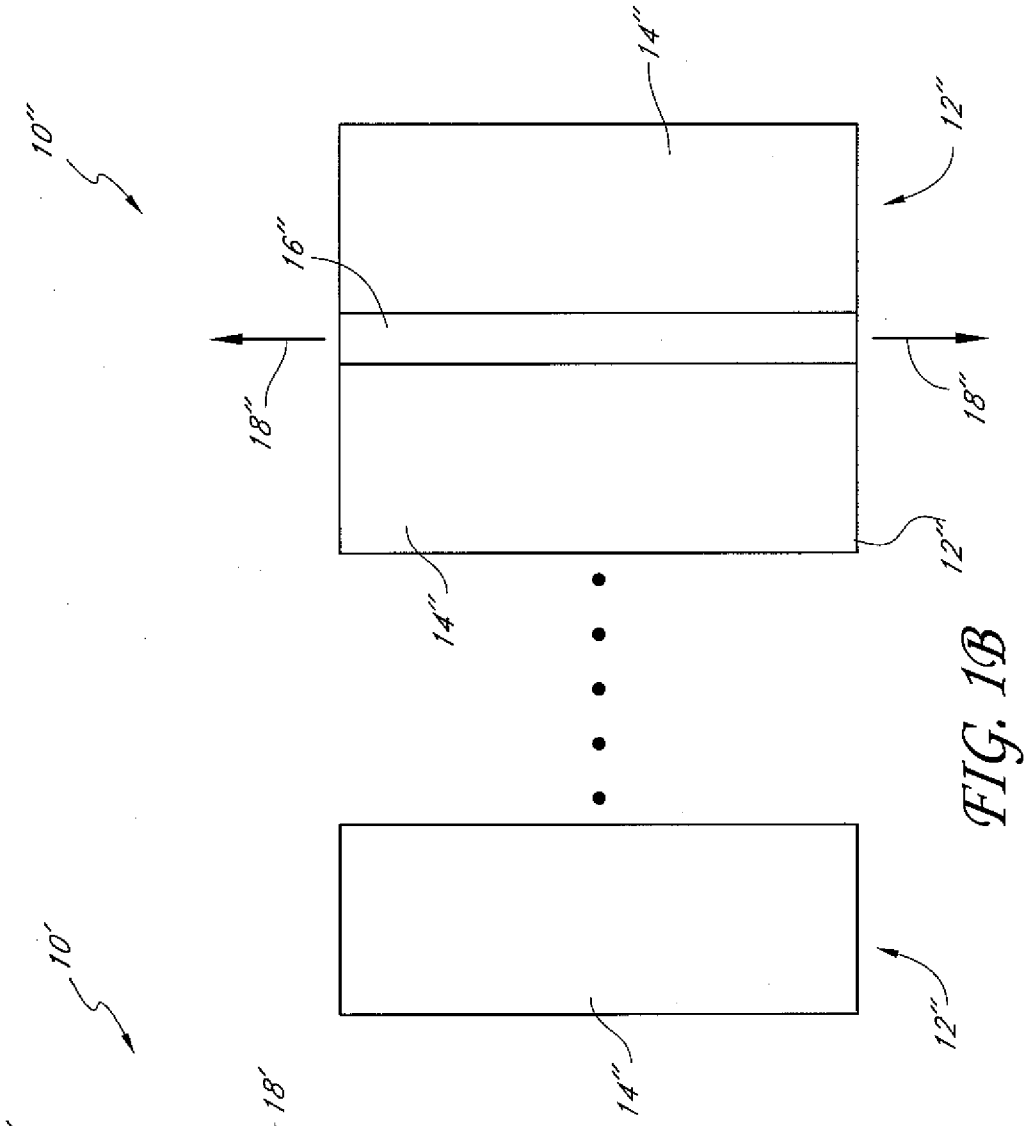

FIG. 1B

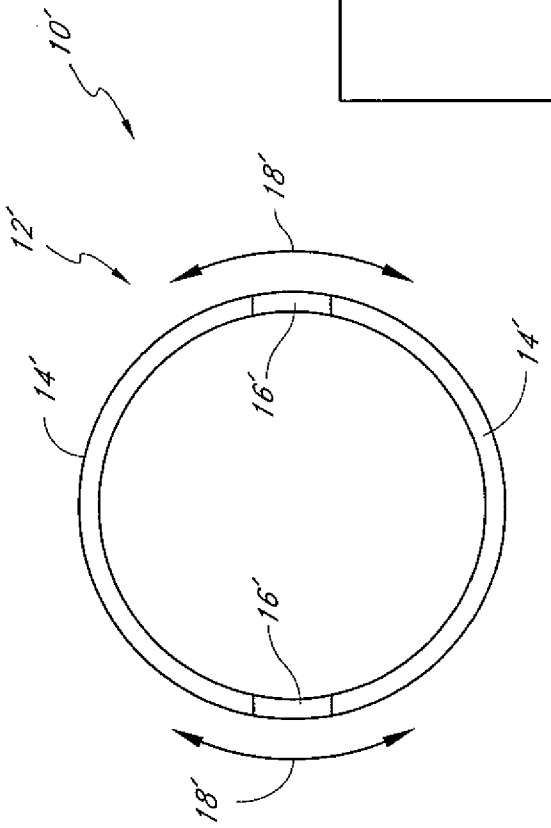

FIG. 1A

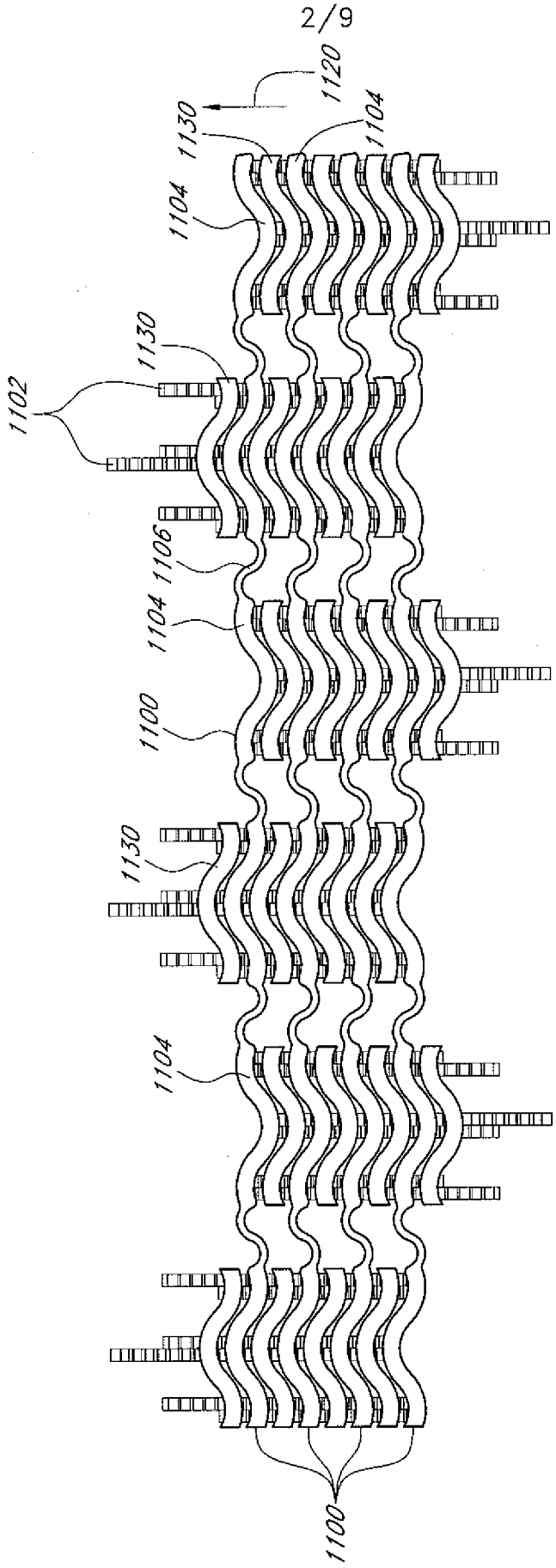
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FIG. 2

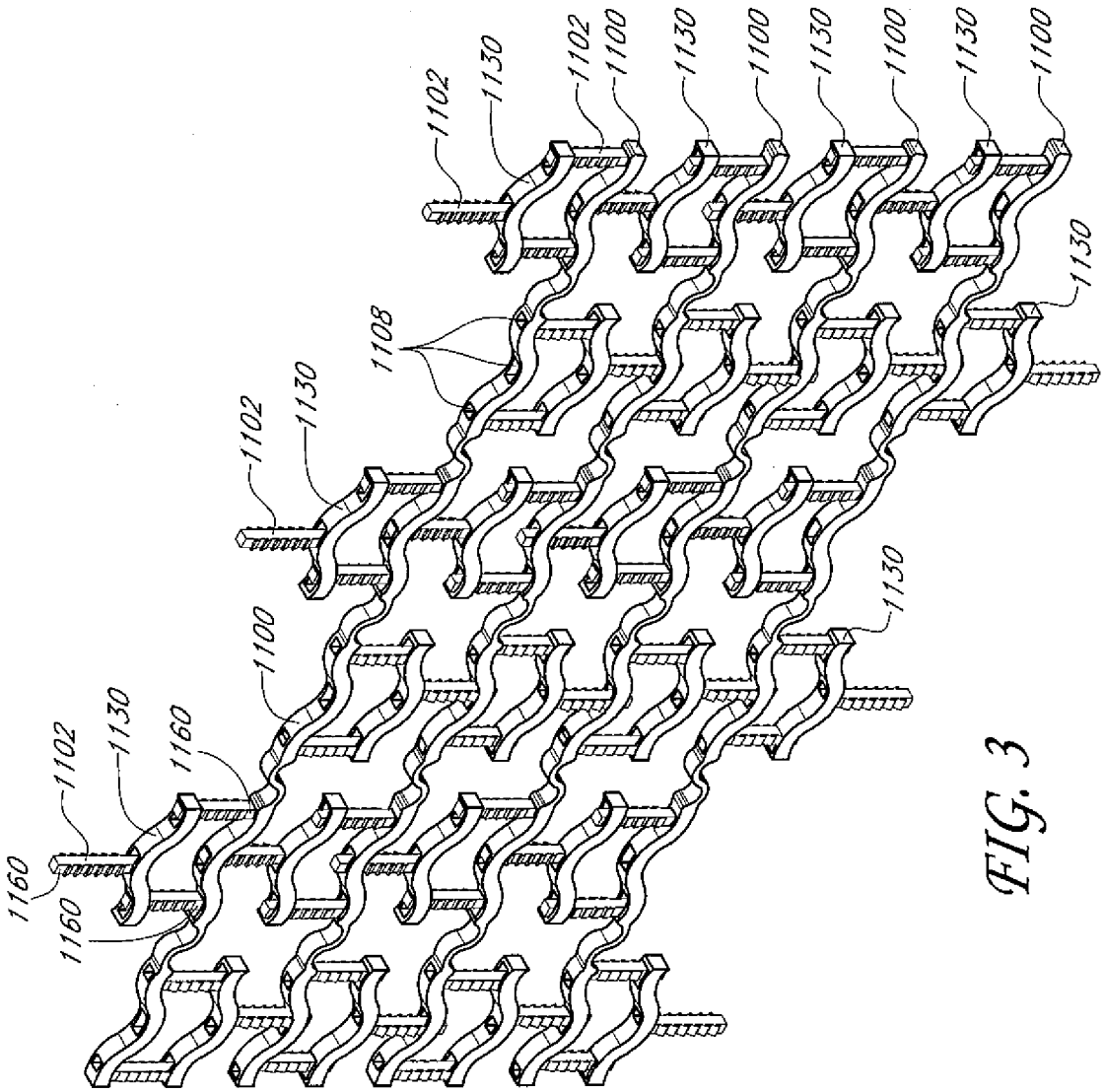
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FIG. 3

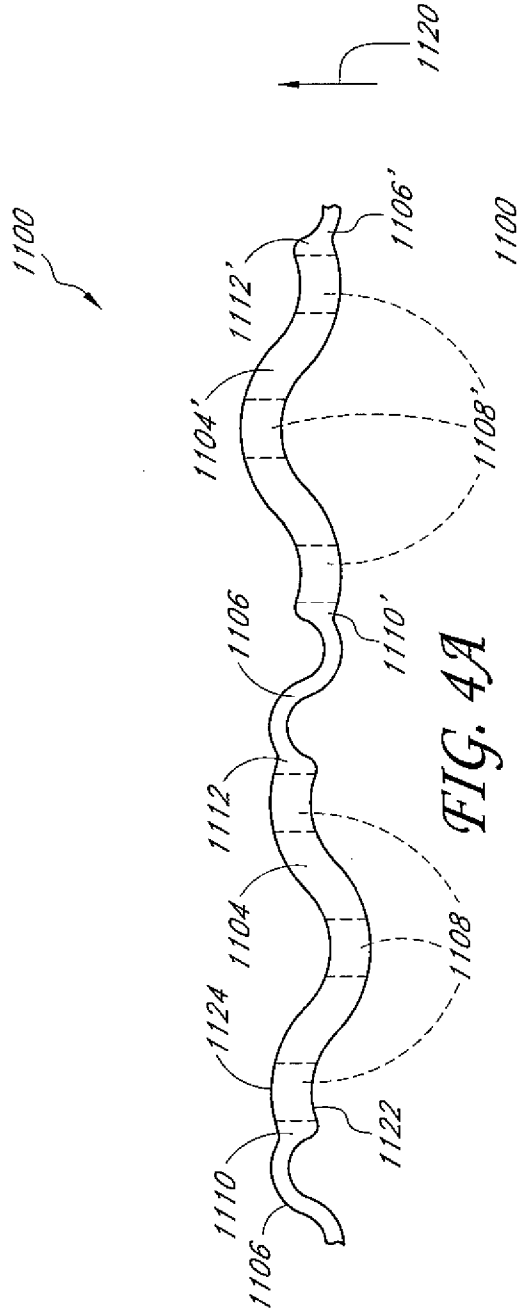
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FIG. 4A

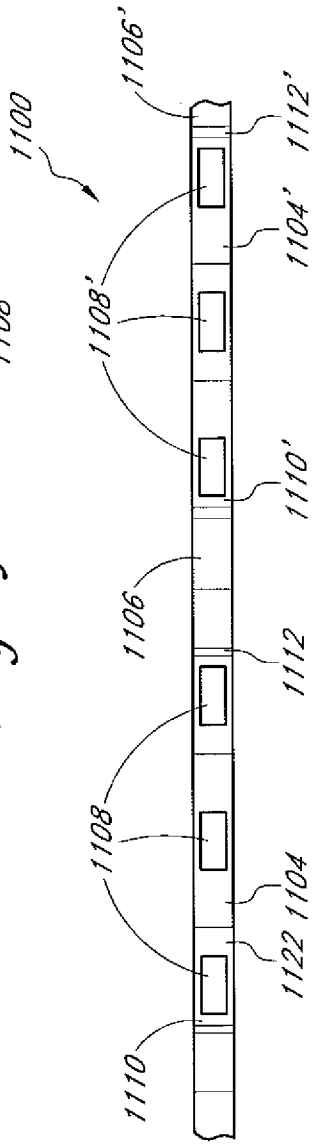
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FIG. 4B

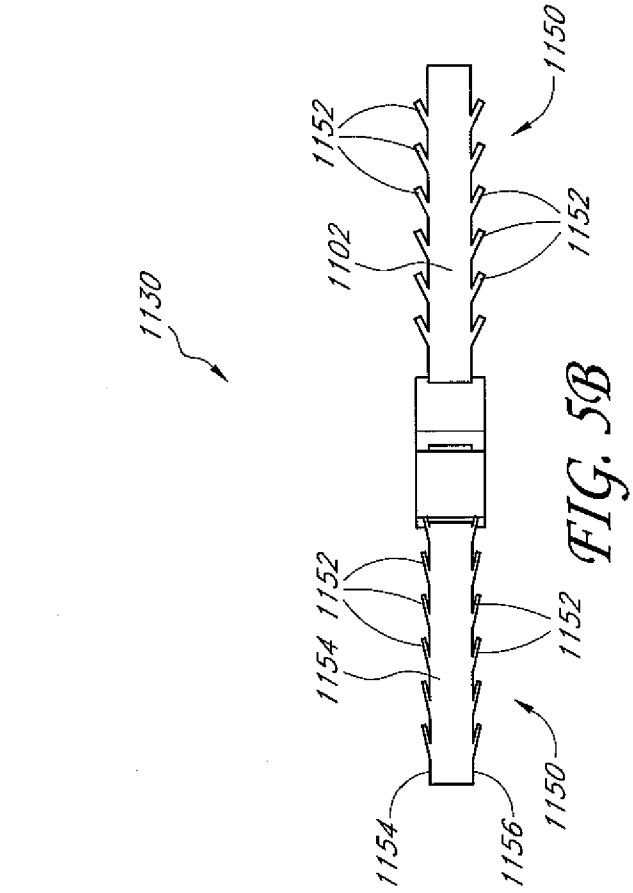
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FIG. 5B

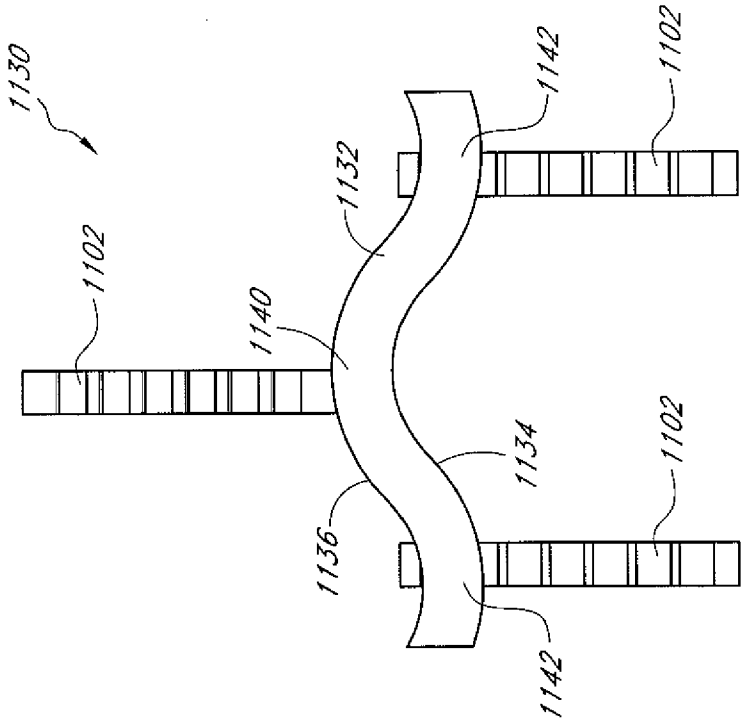
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FIG. 5A

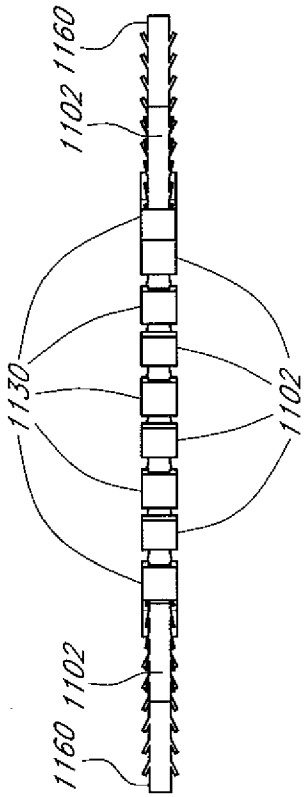
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FIG. 6A

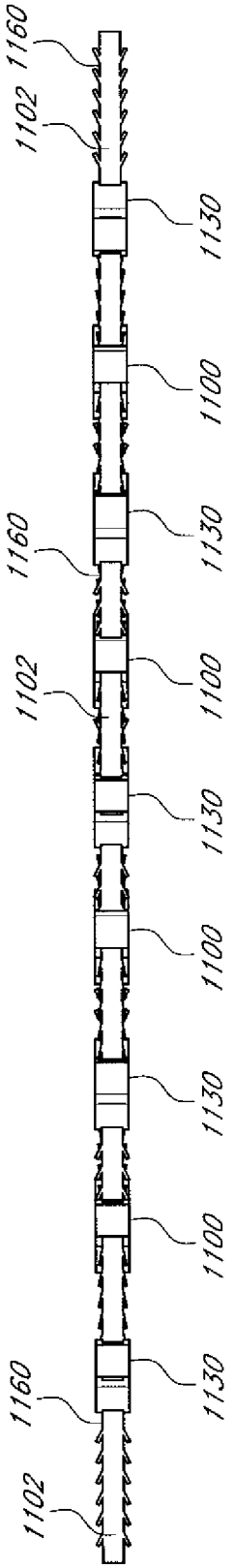
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FIG. 6B

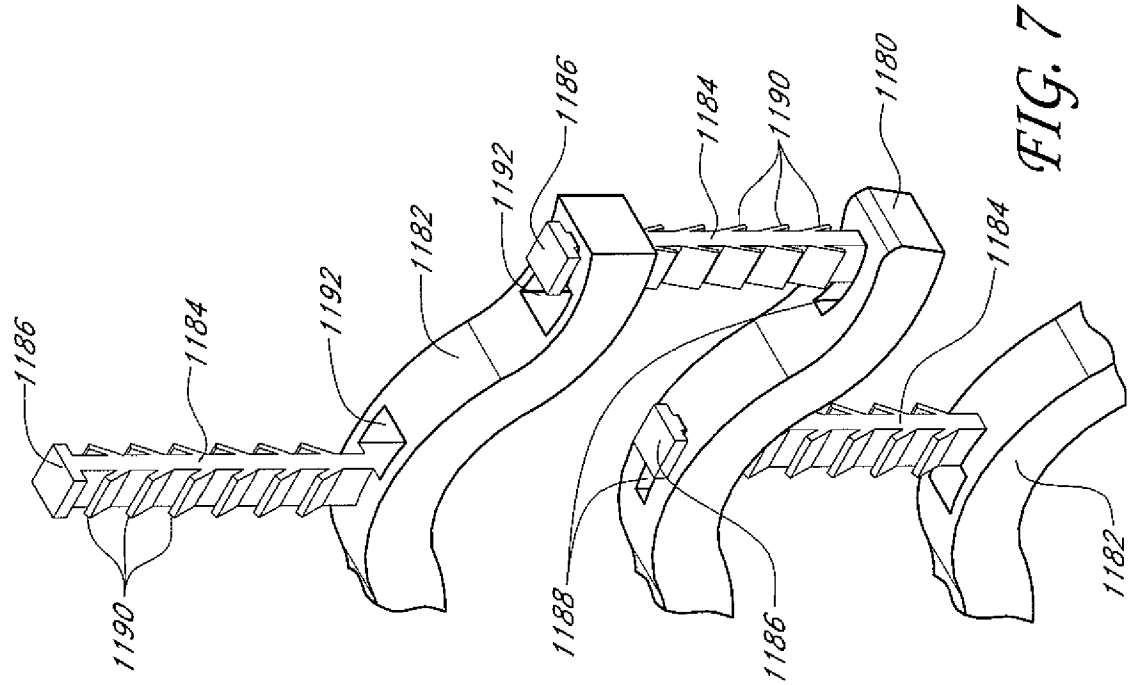
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FIG. 7

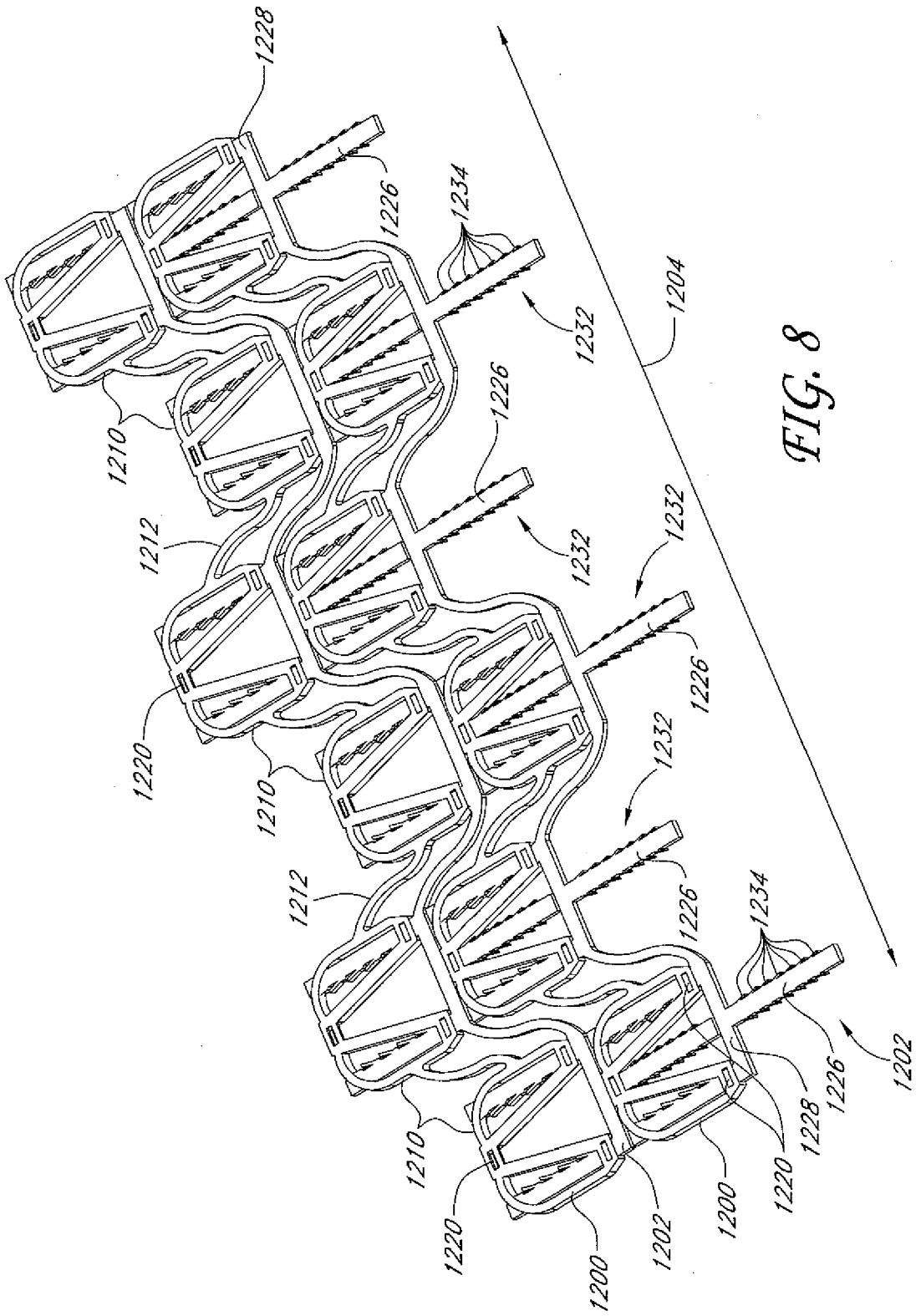
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FIG. 8

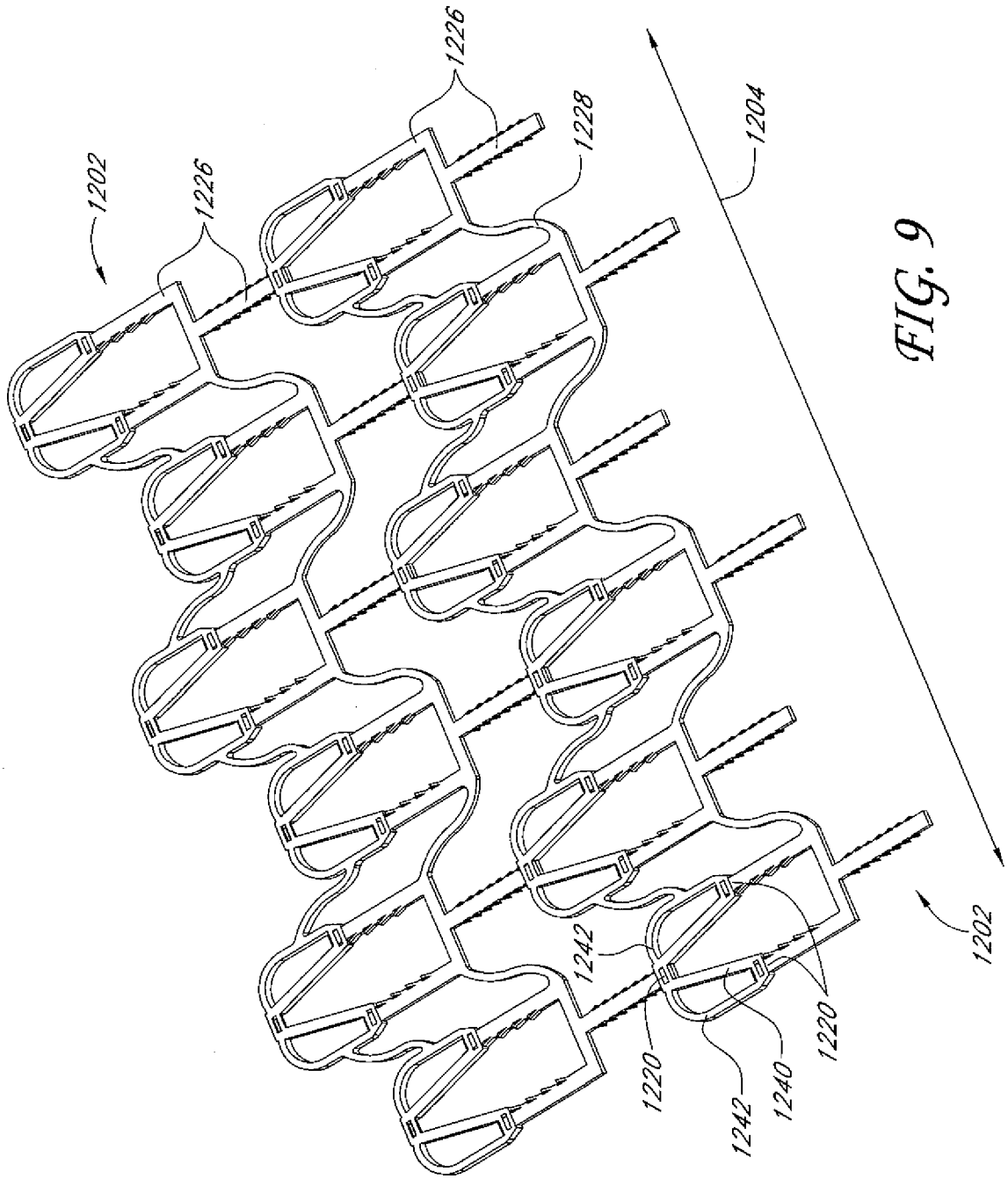

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 09/54087

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/06 (2009.01)
USPC - 623/1.15
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC8 : A61F 2/06 (2009.01)
USPC : 623/1.15

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC8 : A61F 2/82 or A61F 2/92 or A61F 2/94 (2009.01)
USPC : 623/1.16 or 623/1.17 or 623/1.18 or 623/1.2 or 623/1.11 or 623/1.12 or 623/1.21 or 623/1.3

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB,USPT,EPAB,JPAB), Google Scholar
frame or wing or rib, lock$ or oneway or unidirection$,circum$ or circul$ or around, link or linkage or element or interconnect$ or interlink$, longitud$ or length, slid$ or zip$, expan$ or nest$, artery or vein or vascular, stent or graft or endoluminal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,797,951 A (MUELLER) 25 August 1998 (25.08.1998) see especially col 1, ln 53 to col 2, ln 8, col 2, ln 65 to col 3, ln 44, col 4, ln 12-19, col 4, ln 41 to col 5, ln 3, figs 1, 2, 3, 9, 10	1-23
Y	US 2008/0195190 A1 (BLAND et al) 14 August 2008 (14.08.2008) see especially para [0042], [0043], [0049]-[0053], [0057], figs 5, 10-12, 15	1-23
Y	US 2007/0142901 A1 (STEINKE et al) 21 June 2007 (21.06.2007) see especially para [0048]-[0053], figs 4, 7	18-23
A	WO 2006/107608 A1 (CHO) 12 December 2006 (12.12.2006) see whole document	1-23
A	US 5,876,419 A (CARPENTER et al) 2 March 1999 (02.03.1999) see whole document	1-23

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 September 2009 (22.09.2009)	30 SEP 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)