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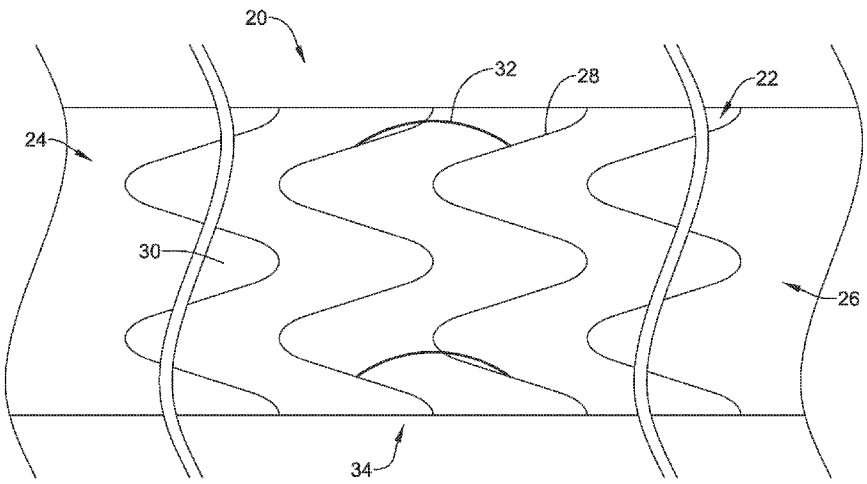

FIG. 2

(57) Abstract: Tracheal stents may include a plurality of wave form structures each extending radially about the support structure, a plurality of axial loop members extending axially between adjacent wave form structures and a polymeric covering disposed thereover. Tracheal stents may include an expandable metal structure and a plurality of spacer fins extending above an outer surface of the expandable metal structure. The plurality of spacer fins may be formed of a material different than that of the expandable metal structure.

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TRACHEAL STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority under 35 U.S.C. §119 to U.S. Provisional Application Serial No. 62/076,181, filed November 6, 2014, the entirety of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure pertains to medical devices, and methods for manufacturing medical devices. More particularly, the present disclosure pertains to endoprostheses such as tracheal stents.

BACKGROUND

[0003] An endoprosthesis may be configured to be positioned in a body lumen for a variety of medical applications. For example, an endoprosthesis may be used to treat a stenosis in a blood vessel, used to maintain a fluid opening or pathway in the vascular, urinary, biliary, tracheobronchial, esophageal or renal tracts, or to position a device such as an artificial valve or filter within a body lumen, in some instances. Bare or partially covered endoprostheses allow tissue ingrowth through the structure of the endoprosthesis to prevent migration of the endoprosthesis. However, if it is desired to remove the endoprosthesis at some later time, the ingrown tissue must be cut away, causing significant trauma to the body lumen. Fully covered stents, on the other hand, prevent tissue ingrowth to facilitate removal. However, fully covered endoprostheses are prone to migrate through the body lumen.

[0004] Accordingly, it is desirable to provide endoprostheses that exhibit anti-migration features, while reducing the trauma to the body lumen of the patient if removal of the endoprosthesis is desired.

BRIEF SUMMARY

[0005] The disclosure is directed to several alternative designs, materials and methods of manufacturing medical device structures and assemblies, and uses thereof.

[0006] In one example, a medical stent, such as a tracheal stent, extends from a first end to a second end and includes a support structure extending from the first end to the second end. The support structure includes a plurality of wave form structures each extending circumferentially about the support structure and a plurality of axial loop members extending axially between adjacent wave form structures and a polymeric covering disposed over the support structure. At least some of the plurality of axial loop members are configured to include an extended configuration in which the at least some of the plurality of axial loop members extend radially outward from an outer surface defined by the plurality of wave form structures.

[0007] Alternatively, or additionally, at least some of the wave form structures extend circumferentially about 360 degrees about the support structure and form closed rings.

[0008] Alternatively, or additionally, at least some of the wave form structures include a nickel-titanium alloy.

[0009] Alternatively, or additionally, at least some of the wave form structures are formed from nitinol wire.

[0010] Alternatively, or additionally, at least some of the wave structures are defined by a wire diameter that is in the range of about 0.2 millimeters (mm) to about 0.5 mm. Alternatively, or additionally, at least some of the wave form structures are defined by a wave frequency in the range of about 0.5 to about 4 waves per centimeter (cm) and a wave amplitude in the range of about 0.25 cm to about 1 cm.

[0011] Alternatively, or additionally, at least some of the plurality of axial loop members extend from a peak, a valley or a transition region of a wave form structure of the plurality of wave form structures to a peak, a valley or a transition region of an adjacent wave form structure of the plurality of wave form structures.

[0012] Alternatively, or additionally, the plurality of axial loop members provide the only direct connection between adjacent wave form structures of the plurality of wave form structures.

[0013] In another example, a support structure for an endoprosthesis has a first end, a second end and a lumen extending therebetween. The support structure includes a first wave form structure extending circumferentially about the support structure and defining a first closed ring, the first wave form structure formed of a first wire oscillating in a wave form having a first wave frequency and a first wave amplitude. The support structure includes a second wave form structure extending circumferentially about the support structure and defining a second closed ring, the second wave form structure formed of a second wire oscillating in a wave form having a second wave frequency and a second wave amplitude. An axial loop member extends from the first wave form structure to the second wave form structure and provides a connection between the first wave form structure and the second wave form structure and is configured to include an extended configuration in which the axial loop member extends radially outward from an outer surface defined by the first and second wave form structures.

[0014] Alternatively, or additionally, the first wave form structure and the second wave form structure are formed from nitinol wire.

[0015] Alternatively, or additionally, at least some of the wave structures are defined by a wire diameter that is in the range of about 0.2 mm to about 0.5 mm.

[0016] Alternatively, or additionally, at least some of the wave form structures are defined by a wave frequency in the range of about 0.5 to about 4 waves per cm and a wave amplitude in the range of about 0.25 cm to about 1 cm.

[0017] Alternatively, or additionally, in another example, the axial loop member extends from a peak, a valley or a transition region of the first wave form structure to a peak, a valley or a transition region of the second wave form structure.

[0018] In another example, a method of forming a support structure for an endoprosthesis having a first end, a second end and a lumen extending therebetween includes forming a first wave form structure from a first wire, the first wave form structure undulating side to side while extending circumferentially around to form a first closed ring.

A second wave form structure is formed from a second wire, the second wave form structure undulating side to side while extending circumferentially around to form a second closed ring. An axial loop member having a first end and a second end is secured, the first end secured to the first wave form structure and the second end secured to the second wave form structure.

[0019] Alternatively, or additionally, the first wave form structure is formed on a mandrel.

[0020] Alternatively, or additionally, the second wave form structure is formed on a mandrel.

[0021] Alternatively, or additionally, the method further includes forming a plurality of additional wave form structures from a plurality of wires, each of the plurality of additional wave form structures undulating side to side while extending circumferentially around to form a plurality of additional closed rings.

[0022] Alternatively, or additionally, the method further includes securing a plurality of axial loop members between adjacent wave form structures of the plurality of additional wave form structures.

[0023] Alternatively, or additionally, the first wire and the second wire include a nitinol wire.

[0024] Alternatively, or additionally, the first end of the axial loop member is secured to the first wave form structure via welding.

[0025] In another example, a medical stent, such as a tracheal stent, extending from a distal end to a proximal end includes an expandable metal structure extending from the distal end to the proximal end, the expandable metal structure convertible between a compressed configuration for delivery and an expanded configuration once deployed, the expandable metal structure including an inner surface defining a stent lumen and an outer

surface. A plurality of spacer fins extends above the outer surface of the expandable metal structure and are formed of a material different than that of the expandable metal structure.

[0026] Alternatively, or additionally, the plurality of spacer fins are formed of a biodegradable or bioabsorbable material.

[0027] Alternatively, or additionally, the plurality of spacer fins are formed from a filament that is interlaced within the expandable metal structure.

[0028] Alternatively, or additionally, the plurality of spacer fins are separately formed each having an end, and the ends of the plurality of spacer fins are encapsulated in a polymeric coating that is disposed over the expandable metal structure.

[0029] Alternatively, or additionally, the plurality of spacer fins include a cap secured to high spots formed within the expandable metal structure.

[0030] Alternatively, or additionally, at least some of the plurality of spacer fins are triangular in shape, with a base secured relative to the expandable metal structure and an apex extending above the base.

[0031] Alternatively, or additionally, the expandable metal structure comprises a laser cut expandable metal structure.

[0032] Alternatively, or additionally, the expandable metal structure includes a woven or braided expandable metal structure.

[0033] In another example, a medical stent, such as a tracheal stent, extending from a distal end to a proximal end includes an expandable metal structure extending from the distal end to the proximal end, the expandable metal structure convertible between a compressed configuration for delivery and an expanded configuration once deployed, the expandable metal structure including an inner surface defining a stent lumen and an outer surface. A biodegradable filament is interwoven through the expandable metal structure to

form a plurality of biodegradable spacer fins extending above the outer surface of the expandable metal structure.

[0034] Alternatively, or additionally, the expandable metal structure includes a laser cut expandable metal structure.

[0035] Alternatively, or additionally, the expandable metal structure includes a woven or braided expandable metal structure.

[0036] Alternatively, or additionally, the biodegradable filament includes square or round shaped protruding caps.

[0037] Alternatively, or additionally, the biodegradable filament has a diameter in the range of about 0.1 cm to about 1 cm.

[0038] Alternatively, or additionally, at least some of the plurality of spacer fins are triangular in shape.

[0039] In another example, a medical stent, such as a tracheal stent, extending from a distal end to a proximal end includes an expandable metal structure extending from the distal end to the proximal end, the expandable metal structure convertible between a compressed configuration for delivery and an expanded configuration once deployed, the expandable metal structure including an inner surface defining a stent lumen and an outer surface. A polymeric coating is disposed over the expandable metal structure and a plurality of biodegradable spacer fins are secured relative to the polymeric coating, the plurality of biodegradable spacer fins extending above the outer surface of the expandable metal structure.

[0040] Alternatively, or additionally, at least some of the plurality of spacer fins are triangular in shape, with a base secured relative to the expandable metal structure and an apex extending above the base.

[0041] Alternatively, or additionally, the plurality of biodegradable spacer fins are separately formed each having an end, and the ends of the plurality of biodegradable spacer fins are encapsulated in the polymeric coating.

[0042] Alternatively, or additionally, the plurality of biodegradable spacer fins are formed of a biodegradable material comprising poly-l-lactide acid (PLLA) and/or poly(lactide-co-Glycoside 8515) (PLGA 8515).

[0043] Alternatively, or additionally, the plurality of biodegradable spacer fins have an average height, relative to the outer surface of the expandable metal structure, ranging from about 0.1 cm to about 0.5 cm.

[0044] Alternatively, or additionally, the polymeric coating includes silicone.

[0045] The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The Figures, and Detailed Description, which follow, more particularly exemplify these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0046] The disclosure may be further understood in consideration of the following detailed description in connection with the accompanying drawings, in which:

[0047] Figure 1 is a schematic illustration of a patient, showing a trachea stent disposed within the patient's right main bronchus in accordance with an embodiment of the disclosure;

[0048] Figure 2 is an illustration of a trachea stent in accordance with an embodiment of the disclosure;

[0049] Figure 3 is a schematic illustration of a portion of the trachea stent of Figure 2 in accordance with an embodiment of the disclosure;

[0050] Figure 4 is a schematic illustration of a portion of the trachea stent of Figure 2 in accordance with an embodiment of the disclosure;

[0051] Figure 5 is a perspective illustration of a trachea stent in accordance with an embodiment of the disclosure;

[0052] Figure 6 is a schematic cross-sectional illustration of the trachea stent of Figure 5 in accordance with an embodiment of the disclosure;

[0053] Figure 7 is a schematic illustration of a portion of a trachea stent in accordance with an embodiment of the disclosure; and

[0054] Figure 8 is a schematic cross-sectional illustration of a portion of a trachea stent in accordance with an embodiment of the disclosure.

[0055] While the disclosure is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

[0056] For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

[0057] All numeric values are herein assumed to be modified by the term "about", whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (e.g., having the same function or result). In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

[0058] The recitation of numerical ranges by endpoints includes all numbers within that range (e.g. 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

[0059] As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

[0060] It is noted that references in the specification to "an embodiment", "some embodiments", "other embodiments", etc., indicate that the embodiment described may include one or more particular features, structures, and/or characteristics. However, such recitations do not necessarily mean that all embodiments include the particular features, structures, and/or characteristics. Additionally, when particular features, structures, and/or characteristics are described in connection with one embodiment, it should be understood that such features, structures, and/or characteristics may also be used connection with other embodiments whether or not explicitly described unless clearly stated to the contrary.

[0061] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The detailed description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure. The illustrative embodiments depicted are intended only as exemplary. Selected features of any illustrative embodiment may be incorporated into an additional embodiment. It will be appreciated that while the disclosure describes an airway or trachea stent, the features and elements described herein may be applied to any variety of endoprosthesis.

[0062] Figure 1 provides a schematic illustration of the torso of a patient 10. The patient 10 includes a trachea 12, a left main bronchus 14 and a right main bronchus 16 (relative to the patient's perspective). An endoprosthesis 18 may be seen in phantom, disposed within the right main bronchus 16. It will be appreciated that this placement is merely for illustrative purposes, as the endoprosthesis 18 may be deployed elsewhere in the trachea 12 or even down into the bronchia (not illustrated). It will also be appreciated that while the endoprosthesis 18 is described herein as an airway stent, the endoprosthesis 18

may be deployed in a variety of other bodily lumens, including but not limited to the vascular, urinary, biliary, tracheobronchial, esophageal or renal tracts. Although illustrated as a stent, the endoprosthesis 10 may be any of a number of devices that may be introduced endoscopically, subcutaneously, percutaneously or surgically to be positioned within an organ, tissue, or lumen, such as a heart, artery, vein, urethra, esophagus, trachea, bronchus, bile duct, or the like.

[0063] A difficulty in placing an endoprosthesis in the trachea 12 is that the patient 10 may have a tendency to try and cough out the endoprosthesis 18. The human respiratory system is designed, when encountering an obstacle or other foreign object, to try to move the obstacle out of the way. This may mean pushing the object farther down, to a position of relative safety. This may also mean trying to cough it out. The human body may try to forcibly eject the object. Accordingly, and in some embodiments, the endoprosthesis 18 may be configured to help hold the endoprosthesis 18 in place within the trachea 12.

[0064] Another difficulty in placing an endoprosthesis in the trachea 12 is that the presence of a foreign object such as an endoprosthesis triggers an inflammatory response that produces mucus. Mucus can become trapped between the body of an endoprosthesis and the wall of the trachea 12. Trapped mucus can stimulate or facilitate the growth of bacteria. Accordingly, and in some embodiments, the endoprosthesis 18 may be configured to provide air channels or voids by spacing at least a part of the endoprosthesis 18 away from the wall of the trachea 12.

[0065] Figure 2 provides an illustration of a trachea stent 20 that may be deployed as shown with respect to the endoprosthesis 18 of Figure 1. In Figure 2, the trachea stent 20 is shown on a mandrel 30. The trachea stent 20 may include a support structure 22 extending from a first end 24 to a second end 26. The support structure 22 may include one or more (a plurality are illustrated) wave form structures 28 that extend circumferentially about the support structure 22. In some embodiments, the wave form structures 28 extend about 360 degrees about the support structure 22 and thus each of the wave form structures 28 may form closed loops. In some embodiments, each wave form structure 28 is formed independently of any other wave form structure 28. The wave form structures 28 may be arranged axially adjacent one another along the length of the support

structure 22. In some embodiments, each wave form structure 28 may be formed on the mandrel 30, by forming a wire into the sinusoidal pattern shown, having peaks oriented toward the first end 24 of the support structure 22 and valleys oriented toward the second end 26 of the support structure 22.

[0066] The wave form structures 28 are joined together via connectors, such as one or more axial loop members 32. In some embodiments, the axial loop members 32 (two are illustrated in Figure 2) are the only physical connection between adjacent wave form structures 28. It will be appreciated that, while not illustrated, the trachea stent 20 may include a polymeric coating or covering to prevent tissue ingrowth into the interior of the trachea stent 20. The polymeric coating or covering, if present, may be disposed about an exterior of the support structure 22, for example. The axial loop members 32 are shown in an extended configuration in which they extend radially outward from an outer surface 34 that is defined by the wave form structures 28 and the polymeric coating or covering, if present. While not illustrated, it will be appreciated that the support structure 22 may have a compressed configuration for delivery in which the axial loop members 32 flatten against the outer surface 34.

[0067] The connectors or axial loop members 32 may be configured to engage a wall of a body lumen in the expanded state to inhibit migration of the endoprosthesis 18 subsequent to implanting the endoprosthesis 18 in the body lumen. For example, the connectors or axial loop members 32 may engage the tissue between cartilage rings within the tracheal anatomy to provide anti-migration support for the endoprosthesis 18.

[0068] A space or opening may be defined between the connectors or axial loop member 32 and the outer circumference of the wave form structures 28 and/or overlaying polymeric coating or covering as viewed along the central longitudinal axis of the support structure 22, as a result of the connectors or axial loop members 32 extending radially outward of or above the outer circumference of the wave form structures 28 and/or overlaying polymeric coating or covering. The space or opening may be unobstructed by any other structure of the endoprosthesis 18. Accordingly, tissue ingrowth through these spaces or openings subsequent to implanting the endoprosthesis 18 may further secure the endoprosthesis 18 in place in the anatomy and prevent migration of the endoprosthesis 18.

[0069] The support structure 22 may be formed of any suitable material. In some embodiments, the support structure 22 may be formed of a nickel-titanium alloy such as nitinol. In some embodiments, at least some of the wave form structures 28 may be formed of a nitinol or other wire having a wire diameter that is in the range of about 0.2 mm to about 0.5 mm. In some embodiments, at least some of the axial loop members 32 may be formed of a nitinol or other wire having a wire diameter that is in the range of about 0.25 mm to about 0.4 mm, which may be the same or different from the wire diameter used to form at least some of the wave form structures 28.

[0070] Figure 3 provides an illustration of a portion of a wave form structure 28. In some embodiments, at least some of the wave form structures 28 may be considered as undulating back and forth in a sinusoidal pattern. A sinusoidal pattern may be defined, at least in part, by a frequency and an amplitude. As illustrated, the wave form structure 28 may be considered as having a frequency that is in the range of about 0.5 to about 4 waves per cm. A wave may be defined as the distance or wavelength F between adjacent peaks. The wave form structure 28 may be considered as having an amplitude A, measured as the distance between peak and valley. In this, it will be appreciated that peaks and valleys are a matter of perspective. What appears as a peak from one side looks like a valley if viewing from the opposite side.

[0071] Figure 4 provides an illustration of two adjacent wave form structures 28. One of the wave form structures (i.e., the first wave form structure) is labeled as 28a and the adjacent wave form structure (i.e., the second wave form structure) is labeled as 28b. To avoid confusion, each wave form structure 28a, 28b are labeled as having peaks P and valleys V. It will be appreciated that in connecting the axial loop members 32 to adjacent wave form structures 28, there are a variety of different relative locations at which the axial loop members 32 may be connected. Each axial loop member 32 may be considered as having a first end 36 connected to the first wave form structure 28a and a second end 38 connected to the adjacent second wave form structure 28b.

[0072] In Figure 4, an axial loop member 32a is shown having its first end 36 secured to a peak P on the wave form structure 28a and its second end 38 secured to a peak P on

the wave form structure 28b. An axial loop member 32b is shown extending from an intermediate position I on the wave form structure 28a to an intermediate position I on the wave form structure 28b. An axial loop member 32c is shown extending from a valley V on the wave form structure 28a to a valley V on the wave form structure 28b. An axial loop member 32d is shown extending from a peak P on the wave form structure 28a to a valley V on the wave form structure 28b. It will be appreciated that these axial loop members 32a, 32b, 32c and 32d, are illustrative only, and are intended merely to illustrate the variety of available connection points. In alternative embodiments, the first end 36 of the axial loop member 32 may be secured at any desired location along the first wave form structure 28a while the second end 38 of the axial loop member 32 may be secured at any desired location along the second wave form structure 28b.

[0073] Figure 5 provides a perspective illustration of a trachea stent 40 having a first end 42 and a second end 44. The trachea stent 40 has an inner surface 46 defining a lumen 48 and an outer surface 50. In some embodiments, as illustrated, the outer surface 50 includes a plurality of spacer fins 52 that extend above the outer surface 50. In some embodiments, the spacer fins 52 are formed of a different material. In some embodiments, the spacer fins 52 are formed of a biodegradable or bioabsorbable material that will break down or dissolve over time once implanted. Accordingly, the spacer fins 52 may provide migration resistance upon implantation of the trachea stent 40 within a body lumen. Over time, the spacer fins 52, which are formed of a biodegradable or bioabsorbable material, will break down or dissolve once implanted. Thereafter, if it is desired to remove the trachea stent 40 at a later time, the degradation or absorption of the spacer fins 52 will reduce the trauma experienced by the patient in removing the trachea stent 40 from the body lumen.

[0074] Illustrative but non-limiting examples of suitable biodegradable or bioabsorbable materials include polymers, such as poly-L-lactide (PLLA), polyglycolide (PGA), polylactide (PLA), poly-D-lactide (PDLA), polycaprolactone, polydioxanone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), and combinations thereof.

[0075] In some embodiments, the spacer fins 52 could also provide drug elution. The terms "therapeutic agents," "drugs," "bioactive agents," "pharmaceuticals," "pharmaceutically active agents", and other related terms may be used interchangeably herein and include genetic therapeutic agents, non-genetic therapeutic agents, and cells. Therapeutic agents may be used singly or in combination. A wide range of therapeutic agent loadings can be used in conjunction with the devices of the present invention, with the pharmaceutically effective amount being readily determined by those of ordinary skill in the art and ultimately depending, for example, upon the condition to be treated, the nature of the therapeutic agent itself, the tissue into which the dosage form is introduced, and so forth.

[0076] Some specific beneficial agents include anti-thrombotic agents, anti-proliferative agents, anti-inflammatory agents, anti-migratory agents, agents affecting extracellular matrix production and organization, antineoplastic agents, anti-mitotic agents, anesthetic agents, anti-coagulants, vascular cell growth promoters, vascular cell growth inhibitors, cholesterol-lowering agents, vasodilating agents, and agents that interfere with endogenous vasoactive mechanisms.

[0077] More specific drugs or therapeutic agents include paclitaxel, sirolimus, everolimus, tacrolimus, Epo D, dexamethasone, estradiol, halofuginone, cilostazole, geldanamycin, ABT-578 (Abbott Laboratories), trapidil, liprostin, Actinomcin D, Resten-NG, Ap-17, abciximab, clopidogrel, Ridogrel, beta-blockers, bARKct inhibitors, phospholamban inhibitors, and Serca 2 gene/protein, resiquimod, imiquimod (as well as other imidazoquinoline immune response modifiers), human apolioproteins (e.g., AI, AII, AIII, AIV, AV, etc.), vascular endothelial growth factors (e.g., VEGF-2), as well as derivatives of the forgoing, among many others.

[0078] Numerous additional therapeutic agents useful for the practice of the present invention may be selected from those described in paragraphs [0040] to [0046] of commonly assigned U.S. Patent Application Pub. No. 2003/0236514, the entire disclosure of which is hereby incorporated by reference.

[0079] While the spacer fins 52 are illustrated as being generally aligned along an axial length of the trachea stent 40 (i.e., generally parallel to a central longitudinal axis of the trachea stent 40), it will be appreciated that in some embodiments, the spacer fins 52 could be aligned perpendicular or at an acute angle relative to an axial length of the trachea stent 40 (i.e., generally non-parallel to a central longitudinal axis of the trachea stent 40, such as perpendicular to or at an acute angle to the central longitudinal axis of the trachea stent 40), in order to limit migration in a particular direction, for example. Moreover, while the spacer fins 52 are shown as being generally triangular in shape, it will be appreciated that in some cases the spacer fins 52 may have other shapes, such as round or square.

[0080] Figure 6 provides a schematic cross-sectional view of the trachea stent 40, illustrating that the trachea stent 40 may, in some embodiments, include an expandable metal structure 54 and a polymeric coating or sleeve 56 disposed over the expandable metal structure 54. The expandable metal structure 54 is generically illustrated, as the expandable metal structure 54 may have any desired design and configuration. For example, in some embodiments, the expandable metal structure 54 may represent a laser cut structure that can be laser cut from a tube. In some embodiments, the expandable metal structure 54 may represent a wound metal structure. In some embodiments, the expandable metal structure 54 may represent a braided metal structure. In some embodiments, as shown in Figure 6, the spacer fins 52 may be secured relative to the trachea stent 40 by encapsulating the spacer fins 52 within the polymeric coating or sleeve 56. In some embodiments, the spacer fins 52 may have a base and an opposing apex positioned radially outward from the base, and the base of each of the spacer fins 52 may be encapsulated within the polymeric coating or sleeve 56 and the apex of each of the spacer fins is exposed from and extends radially outward from the polymeric coating or sleeve 56 such that the biodegradable material forming the spacer fins 52 are exposed after implantation.

[0081] In some embodiments, the spacer fins 52 may be formed by placing a biodegradable cap directly on a portion of the expandable metal structure 54. As schematically illustrated in Figure 7, an expandable metal structure 54a may include high spots 54b, such as an apex of a stent strut. A spacer fin 52a may be formed by securing a biodegradable cap 52b onto the high spot 54b or protruding portion of the expandable metal structure 54a. In some embodiments, while not illustrated, a polymeric covering or sleeve

could cover the expandable metal structure 54a prior to securing the biodegradable cap 52b onto the high spot 54b or protruding portion.

[0082] Another method for creating the spacer fins 52 is illustrated in Figure 8, which shows a schematic cross-sectional view of an expandable metal structure 54c. As discussed above with respect to the expandable metal structure 54, the expandable metal structure 54c may generically represent a laser cut structure, a wound structure or a braided metal structure. A filament 58 may be wrapped around the expandable metal structure 54c, in and out of apertures formed within the expandable metal structure 54c such that the filament 58 forms high spots 60 or radially outwardly protruding portions. The high spots 60 or protruding portions may form spacer fins. While a single filament 58 is shown, it will be appreciated that a plurality of filaments 58 may be wrapped around the expandable metal structure 54c. The filament 58 may be formed of any desired biodegradable or bioabsorbable material, as discussed above with respect to the spacer fins 52, and may have any desired diameter such as about 0.5 cm.

[0083] In some embodiments, as noted, the expandable metal structure 54, 54b and 54c may be cut from a metal tube using any desired technique, including but not limited to micro-machining, saw-cutting (e.g., using a diamond grit embedded semiconductor dicing blade), electron discharge machining, grinding, milling, casting, molding, chemically etching or treating, or other known methods, and the like. Some example embodiments of appropriate micromachining methods and other cutting methods, and structures for tubular members including slots and medical devices including tubular members are disclosed in U.S. Pat. Publication Nos. 2003/0069522 and 2004/0181174-A2; and U.S. Pat. Nos. 6,766,720; and 6,579,246, the entire disclosures of which are herein incorporated by reference. Some example embodiments of etching processes are described in U.S. Pat. No. 5,106,455, the entire disclosure of which is herein incorporated by reference.

[0084] In at least some embodiments, a laser cutting process may be used. The laser cutting process may include a suitable laser and/or laser cutting apparatus. For example, the laser cutting process may utilize a fiber laser. Utilizing processes like laser cutting may be desirable for a number of reasons. For example, laser cutting processes may allow for a number of different cutting patterns in a precisely controlled manner. Furthermore,

changes to the cutting pattern can be made without the need to replace the cutting instrument (e.g., blade).

[0085] The materials that can be used for the expandable metal structure 54, 54b, 54c may include those commonly associated with medical devices. For simplicity purposes, the following discussion makes reference to the expandable metal structure 54. However, this is not intended to limit the devices and methods described herein, as the discussion may be applied to other similar structures.

[0086] The expandable metal structure 54, 54b, 54c, may be made from a metal, metal alloy, polymer (some examples of which are disclosed below), a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable material. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

[0087] As alluded to herein, within the family of commercially available nickel-titanium or nitinol alloys, is a category designated "linear elastic" or “non-super-elastic” which, although may be similar in chemistry to conventional shape memory and super elastic varieties, may exhibit distinct and useful mechanical properties. Linear elastic and/or non-super-elastic nitinol may be distinguished from super elastic nitinol in that the linear elastic and/or non-super-elastic nitinol does not display a substantial "superelastic

plateau" or "flag region" in its stress/strain curve like super elastic nitinol does. Instead, in the linear elastic and/or non-super-elastic nitinol, as recoverable strain increases, the stress continues to increase in a substantially linear, or a somewhat, but not necessarily entirely linear relationship until plastic deformation begins or at least in a relationship that is more linear that the super elastic plateau and/or flag region that may be seen with super elastic nitinol. Thus, for the purposes of this disclosure linear elastic and/or non-super-elastic nitinol may also be termed "substantially" linear elastic and/or non-super-elastic nitinol.

[0088] In some cases, linear elastic and/or non-super-elastic nitinol may also be distinguishable from super elastic nitinol in that linear elastic and/or non-super-elastic nitinol may accept up to about 2-5% strain while remaining substantially elastic (e.g., before plastically deforming) whereas super elastic nitinol may accept up to about 8% strain before plastically deforming. Both of these materials can be distinguished from other linear elastic materials such as stainless steel (that can also can be distinguished based on its composition), which may accept only about 0.2 to 0.44 percent strain before plastically deforming.

[0089] In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy is an alloy that does not show any martensite/austenite phase changes that are detectable by differential scanning calorimetry (DSC) and dynamic metal thermal analysis (DMTA) analysis over a large temperature range. For example, in some embodiments, there may be no martensite/austenite phase changes detectable by DSC and DMTA analysis in the range of about –60 degrees Celsius (°C) to about 120 °C in the linear elastic and/or non-super-elastic nickel-titanium alloy. The mechanical bending properties of such material may therefore be generally inert to the effect of temperature over this very broad range of temperature. In some embodiments, the mechanical bending properties of the linear elastic and/or non-super-elastic nickel-titanium alloy at ambient or room temperature are substantially the same as the mechanical properties at body temperature, for example, in that they do not display a super-elastic plateau and/or flag region. In other words, across a broad temperature range, the linear elastic and/or non-super-elastic nickel-titanium alloy maintains its linear elastic and/or non-super-elastic characteristics and/or properties.

[0090] In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy may be in the range of about 50 to about 60 weight percent nickel, with the remainder being essentially titanium. In some embodiments, the composition is in the range of about 54 to about 57 weight percent nickel. One example of a suitable nickel-titanium alloy is FHP-NT alloy commercially available from Furukawa Techno Material Co. of Kanagawa, Japan. Some examples of nickel titanium alloys are disclosed in U.S. Patent Nos. 5,238,004 and 6,508,803, which are incorporated herein by reference. Other suitable materials may include ULTANIUM™ (available from Neo-Metrics) and GUM METAL™ (available from Toyota). In some other embodiments, a superelastic alloy, for example a superelastic nitinol can be used to achieve desired properties.

[0091] In at least some embodiments, portions or all of the trachea stents 20 and 40 described herein may also be doped with, made of, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like.

[0092] In some embodiments, a degree of Magnetic Resonance Imaging (MRI) compatibility is imparted into the trachea stents 20, 40. For example, the trachea stents 20, 40, or portions thereof, may be made of a material that does not substantially distort the image and create substantial artifacts (e.g., gaps in the image). Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. Trachea stents 20, 40, or portions thereof, may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nitinol, and the like, and others.

[0093] As noted, the trachea stents 20, 40 may include a sheath or covering thereover. Suitable polymeric material include but are not limited to polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP),

polyoxymethylene (POM, for example, DELRIN® available from DuPont), polyether block ester, polyurethane (for example, Polyurethane 85A), polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL® available from DSM Engineering Plastics), ether or ester based copolymers (for example, butylene/poly(alkylene ether) phthalate and/or other polyester elastomers such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), Marlex high-density polyethylene, Marlex low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide (PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly paraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID® available from EMS American Grilon), perfluoro(propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), poly(styrene-*b*-isobutylene-*b*-styrene) (for example, SIBS and/or SIBS 50A), polycarbonates, ionomers, biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like.

[0094] In some embodiments, the exterior surfaces of the expandable metal structures 22, 52 may be sandblasted, beadblasted, sodium bicarbonate-blasted, electropolished, etc. In these as well as in some other embodiments, a coating, for example a lubricious, a hydrophilic, a protective, or other type of coating may be applied thereover portions. Alternatively, the expandable metal structures 22, 52 may include a lubricious, hydrophilic, protective, or other type of coating. Hydrophobic coatings such as fluoropolymers provide a dry lubricity which improves guidewire handling and device exchanges. Lubricious coatings improve steerability and improve lesion crossing capability. Suitable lubricious polymers are well known in the art and may include silicone and the like, hydrophilic polymers such as high-density polyethylene (HDPE), polytetrafluoroethylene (PTFE), polyarylene oxides, polyvinylpyrrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof.

Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility. Some other examples of such coatings and materials and methods used to create such coatings can be found in U.S. Patent Nos. 6,139,510 and 5,772,609, which are incorporated herein by reference.

[0095] It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A medical stent extending from a first end to a second end, the medical stent comprising:

a support structure extending from the first end to the second end, the support structure including a plurality of wave form structures each extending circumferentially about the support structure and a plurality of axial loop members extending axially between adjacent wave form structures; and

a polymeric covering disposed over the support structure;

wherein at least some of the plurality of axial loop members are configured to include an extended configuration in which the at least some of the plurality of axial loop members extend radially outward from an outer surface defined by the plurality of wave form structures.

2. The medical stent of claim 1, wherein at least some of the plurality of wave form structures extend circumferentially about 360 degrees about the support structure and form closed rings.

3. The medical stent of any one of claims 1 or 2, wherein at least some of the plurality of wave form structures comprise a nickel-titanium alloy.

4. The medical stent of any one of claims 1 to 3, wherein at least some of the plurality of wave form structures comprise a nitinol wire.

5. The medical stent of any one of claims 1 to 4, wherein at least some of the plurality of wave structures are defined by a wire diameter that is in the range of about 0.2 to about 0.5 millimeters.

6. The medical stent of any one of claims 1 to 5, wherein at least some of the plurality of wave form structures are defined by a wave frequency in the range of about 0.5 to about 4 waves per centimeter and a wave amplitude in the range of about 0.25 to about 1 centimeters.

7. The medical stent of any one of claims 1 to 6, wherein at least some of the plurality of axial loop members extend from a peak, a valley or a transition region of a wave form structure of the plurality of wave form structures to a peak, a valley or a transition region of an adjacent wave form structure of the plurality of wave form structures.

8. A medical stent extending from a distal end to a proximal end, the medical stent comprising:

an expandable metal structure extending from the distal end to the proximal end, the expandable metal structure convertible between a compressed configuration for delivery and an expanded configuration once deployed, the expandable metal structure including an inner surface defining a stent lumen and an outer surface; and

a plurality of spacer fins extending above the outer surface of the expandable metal structure;

wherein the plurality of spacer fins are formed of a material different than that of the expandable metal structure.

9. The medical stent of claim 8, wherein the plurality of spacer fins are formed of a biodegradable or bioabsorbable material.

10. The medical stent of any one of claims 8 or 9, wherein the plurality of spacer fins are formed from a filament that is interlaced within the expandable metal structure.

11. The medical stent of any one of claims 8 or 9, wherein the plurality of spacer fins are separately formed each having an end, and the ends of the plurality of spacer fins are encapsulated in a polymeric coating that is disposed over the expandable metal structure.

12. The medical stent of any one of claims 8 or 9, wherein the plurality of spacer fins comprise a cap secured to high spots formed within the expandable metal structure.

13. The medical stent of any one of claims 8 to 12, wherein at least some of the plurality of spacer fins are triangular in shape, with a base secured relative to the expandable metal structure and an apex extending above the base.

14. The medical stent of any one of claims 8 to 13, wherein the expandable metal structure comprises a laser cut expandable metal structure.

15. The medical stent of any one of claims 8 to 13, wherein the expandable metal structure comprises a woven or braided expandable metal structure.

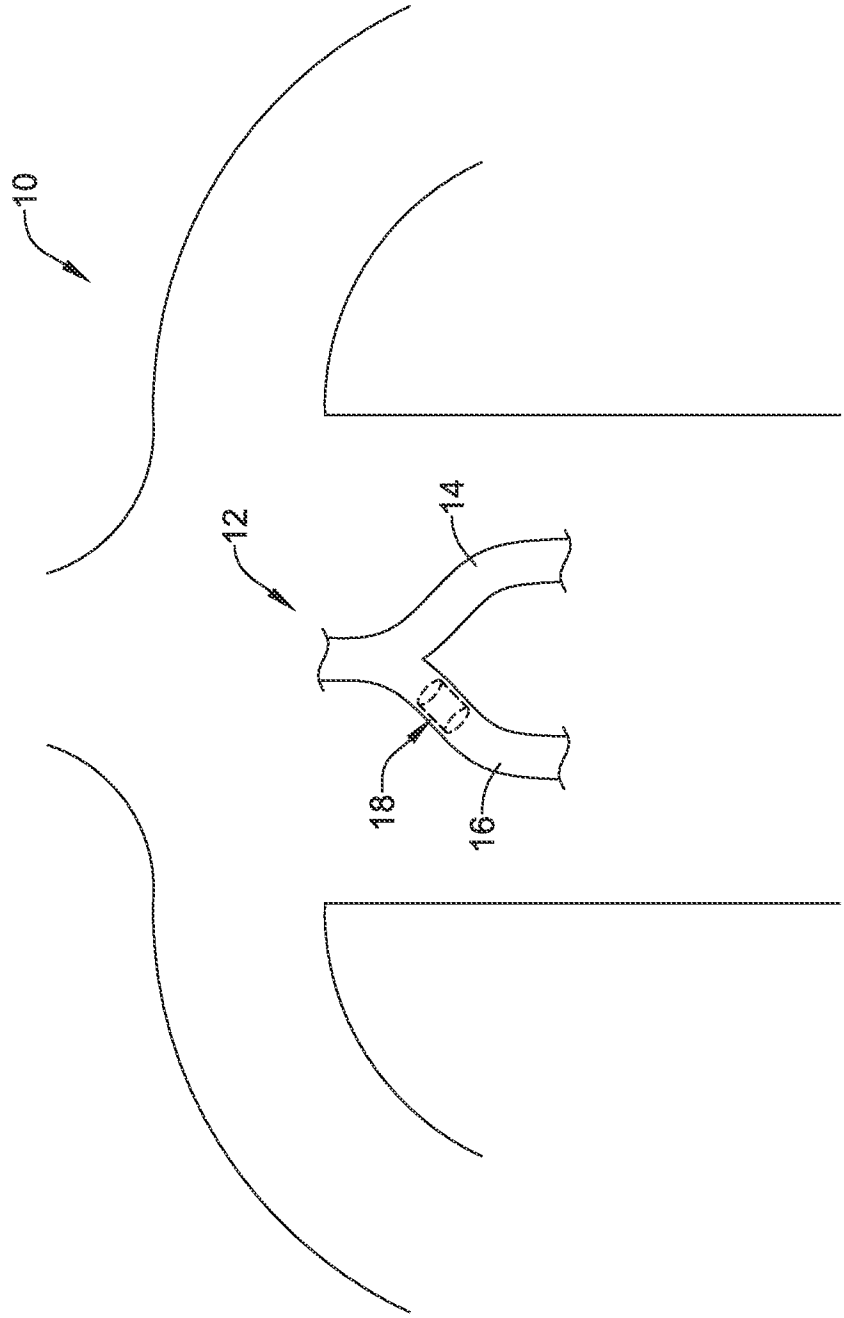

FIG. 1

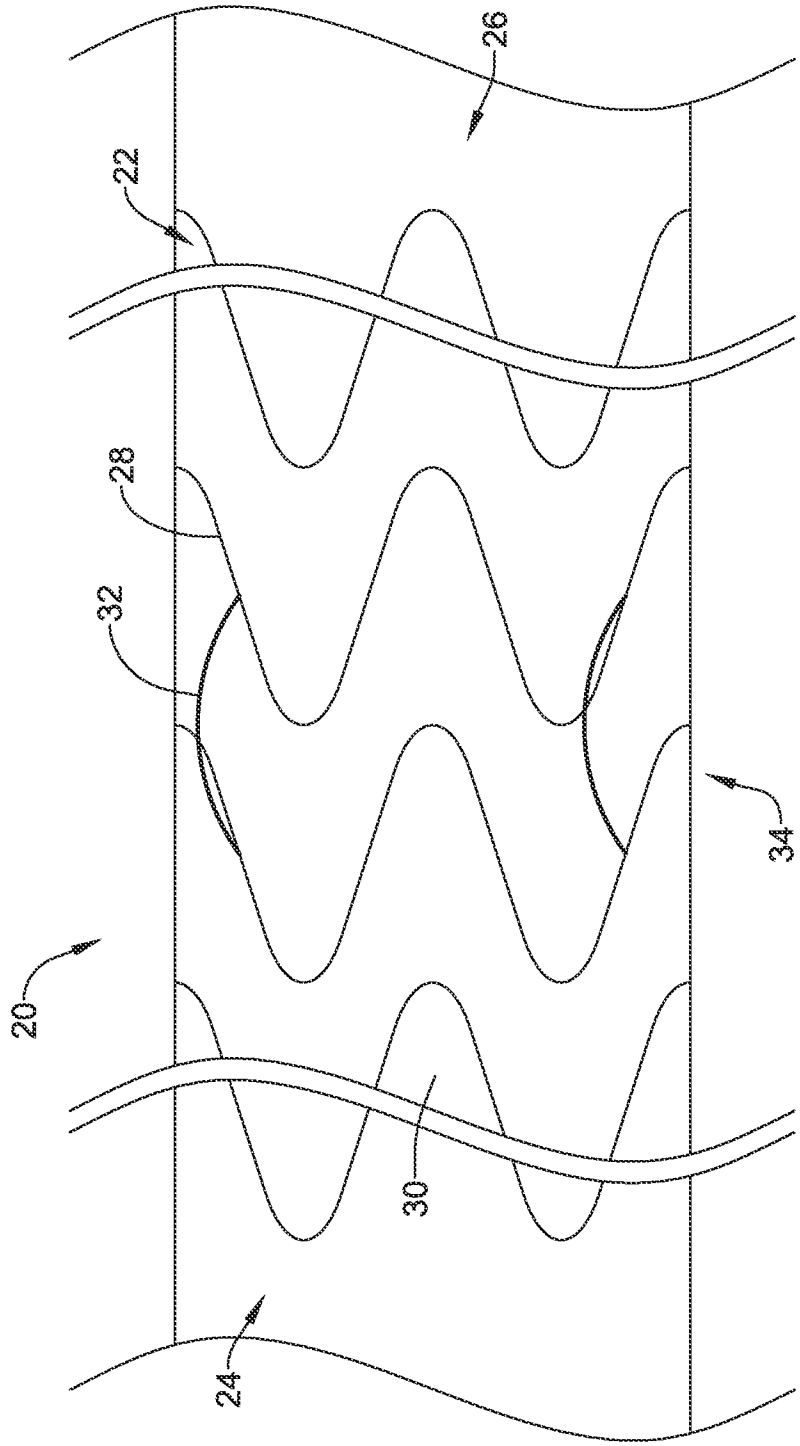

FIG. 2

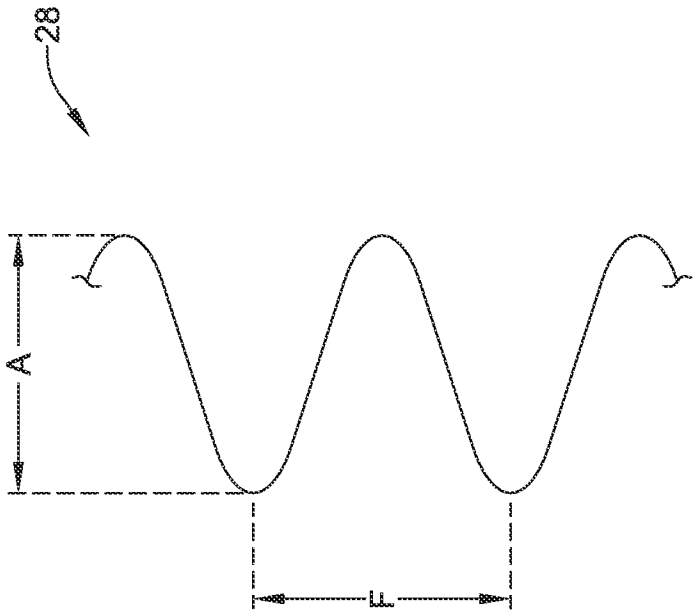

FIG. 3

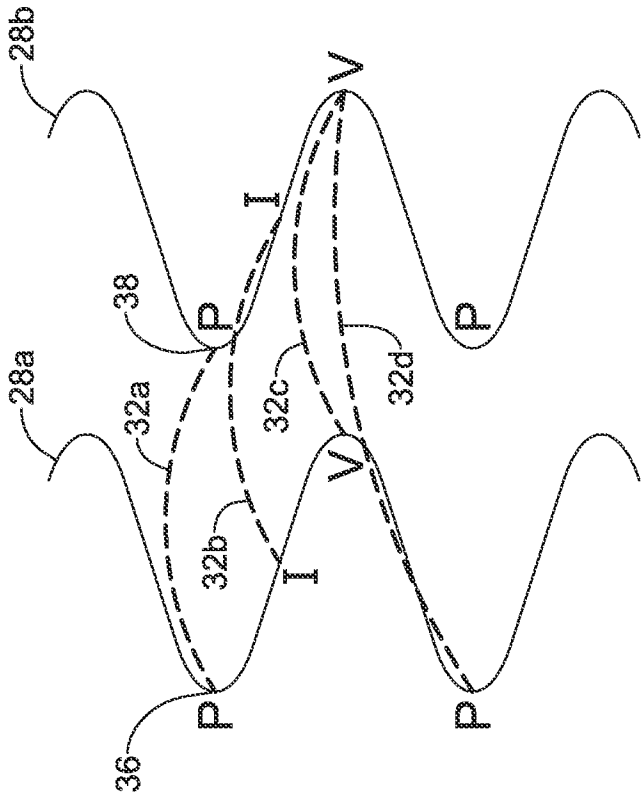

FIG. 4

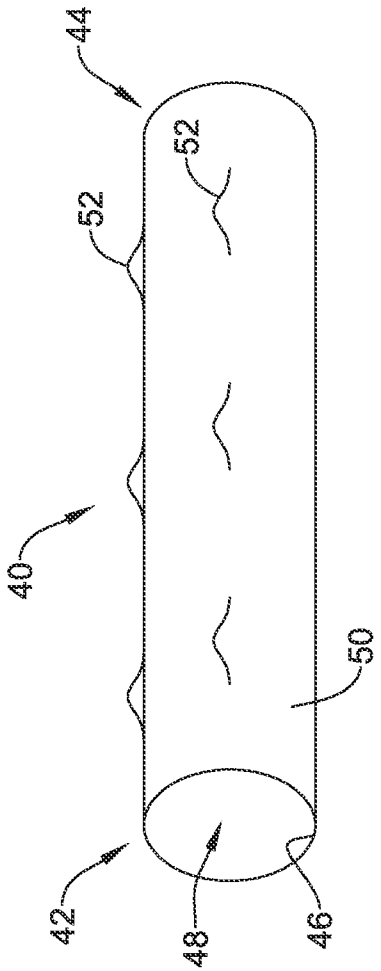

FIG. 5

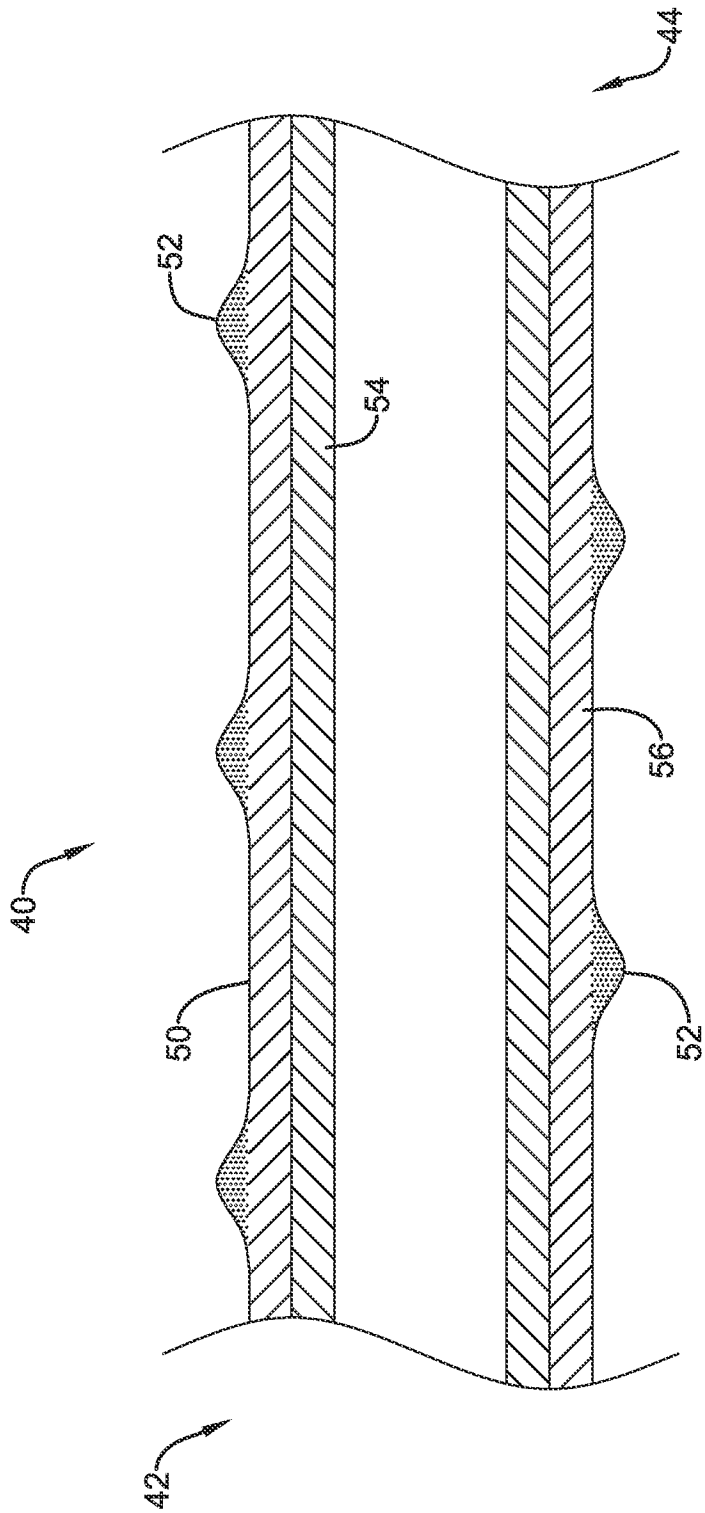

FIG. 6

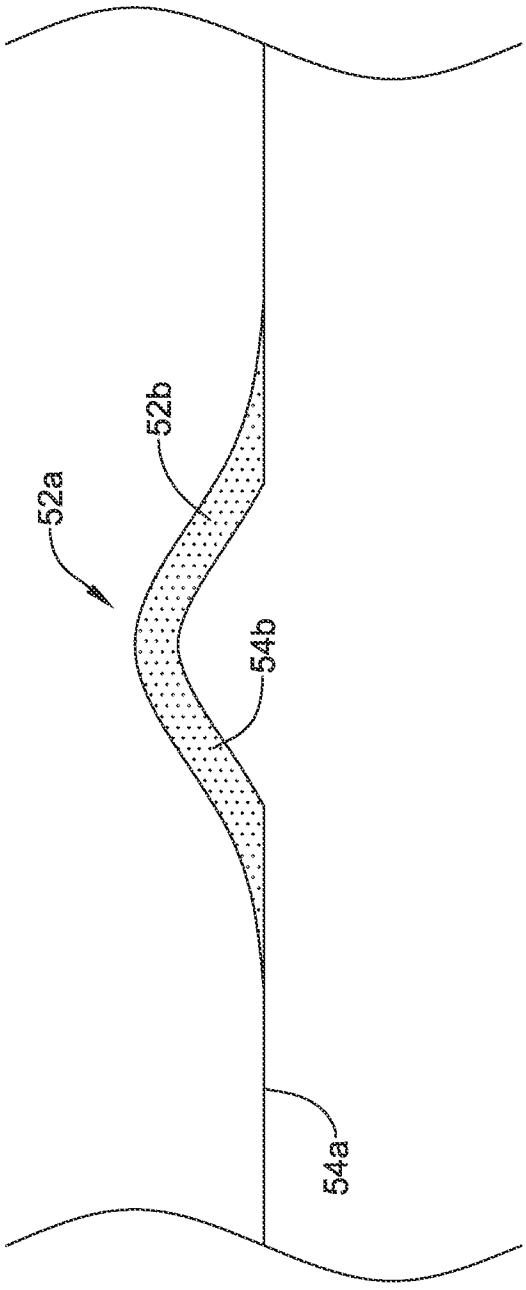

FIG. 7

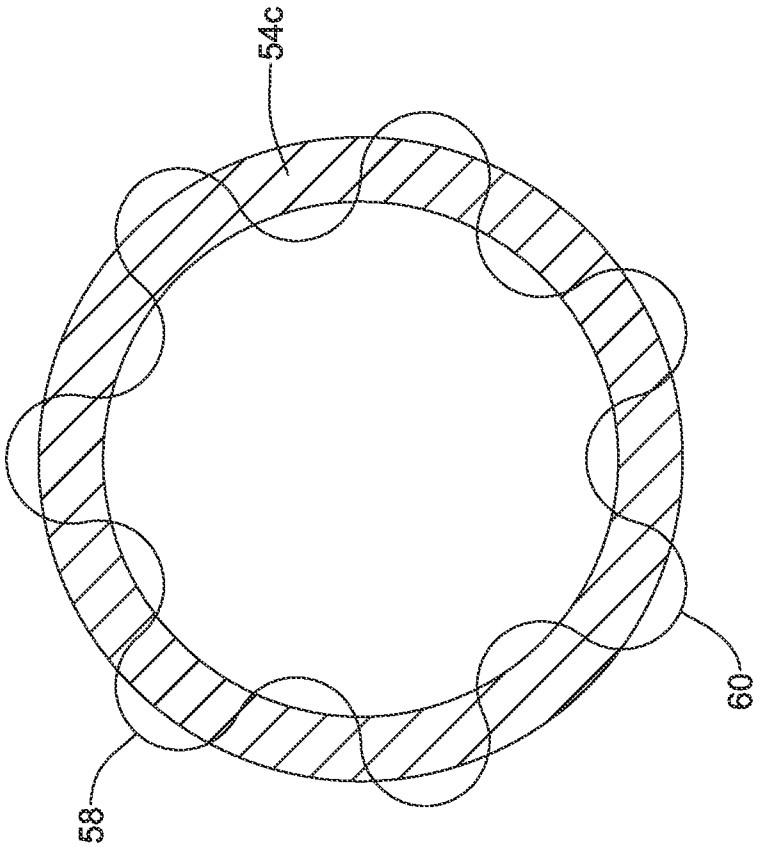

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/059023

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/04 A61F2/07 A61F2/915
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 2015/038790 A1 (BOSTON SCIENT SCIMED INC [US]) 19 March 2015 (2015-03-19) page 5, line 20 - page 12, line 11; figures 1, 2	1-7
X	US 2014/277562 A1 (SEDDON DANE T [US] ET AL) 18 September 2014 (2014-09-18) paragraph [0017] - paragraph [0039]	1-7
X	US 2009/248132 A1 (BLOOM ELIOT [US] ET AL) 1 October 2009 (2009-10-01) paragraph [0068] - paragraph [0100]; figures 1, 13, 19, 21, 22, 25, 26	1-7

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 January 2016	11/04/2016

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/059023

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 732 088 A2 (ADVANCED CARDIOVASCULAR SYSTEM [US]) 18 September 1996 (1996-09-18) page 10, line 42 - page 11, line 41; figures 6a, 7	1,2,5-7
X	WO 97/33532 A2 (MEDTRONIC INC [US]; COX BRIAN [US]; EVANS MICHAEL A [US]; WILL ALLAN [) 18 September 1997 (1997-09-18) page 25, line 8 - page 26, line 17; figures 7a, 7c, 7d	1-7

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/059023

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-7

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7

   Stent comprising annular wave form structure and axial loop members (connectors), wherein at least some of the connectors extend radially outward from the outer surface defined by the wave form structure. The stent also comprises a covering.

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2. claims: 8-15

   Stent comprising a metallic expandable structure and a plurality of spacer fins extending above the outer surface of the expandable metal structure, wherein the spacer fins are formed of a material different than that of the expandable structure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2015/059023

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