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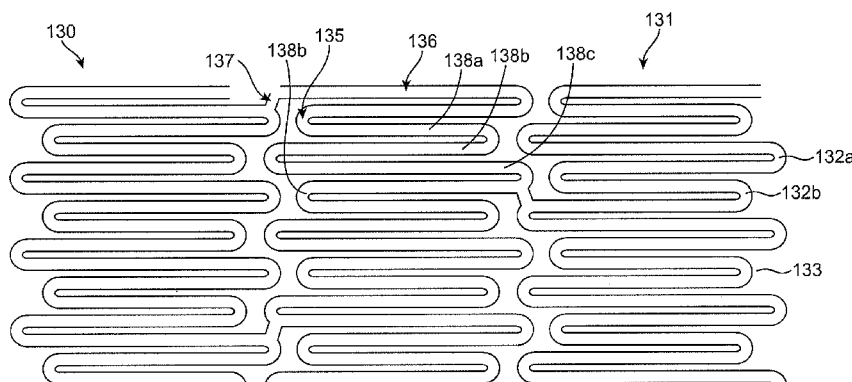


FIG. 13

(57) Abstract: A tubular prosthesis has a plurality of tubular rings that are radially expandable from a contracted configuration to an expanded configuration. Each ring comprises a plurality of axially oriented struts that are interconnected so as to form a circumferential series of at least one high peak and at least one low peak. The high and low peaks have apices that are oriented in the same axial direction. The apices of the high and low peaks are also oriented in the same direction and the apices of the high peaks are axially offset from the apices of the low peaks. A bridge member couples a pair of adjacent tubular rings together. The bridge member has a first end connected to a first low peak in a first tubular ring and a second end connected to either a high or low peak in an adjacent tubular ring.

APPARATUS HAVING VARIABLE STRUT LENGTH AND METHODS OF USE

BACKGROUND OF THE INVENTION

5 [0001] 1. Field of Invention. The invention generally relates to medical apparatus and methods, and more specifically to prosthetic devices such as stents for use in the coronary and peripheral arteries as well as in other vessels and body lumens.

[0002] Stenting is an important treatment for patients with vascular occlusive disease. A stent is often a hollow, tubular implant designed to provide scaffolding to the walls of a
10 diseased blood vessel or other body lumen in order to maintain patency of the vessel or lumen. Stents are usually placed at the site of a stenotic lesion within an artery after a primary treatment such as angioplasty. They are typically delivered to the arteries using long, flexible catheters inserted percutaneously through the patient's femoral artery.

[0003] Stents are typically either balloon expandable or self-expandable. Balloon
15 expandable stents are mounted over a balloon or other expansion element on a delivery catheter. When the balloon is inflated, the balloon expands and correspondingly expands and deforms the stent to a desired diameter. The balloon can then be deflated and removed, leaving the stent in place.

[0004] A self-expanding stent is simply released from the delivery catheter so that it
20 expands until it engages the vessel wall. Self-expanding stents are typically delivered to a treatment site while compressed or crimped within a constraining sheath. Retraction of the sheath removes the constraint and allows the stent to radially expand into engagement with the vessel wall.

[0005] Self-expanding stents may be made of materials having high elasticity or a shape
25 memory alloy such as Nitinol, a nickel-titanium (NiTi) alloy. Resilient, self-expanding stents are often used in the peripheral vascular system and regions of the body closer to the body's surface because their resilience helps minimize damage or crushing caused by body movement or externally applied forces.

[0006] Self-expanding stents may also have certain advantages over balloon expandable
30 stents in the treatment of arteries. Balloon expandable stents are often expanded to a constant

diameter and do not conform well with an artery having variations in diameter due to vessel tortuosity or taper. Because of the potential mismatch between stent diameter and vessel diameter, there is a possibility for gaps to form between the outer stent surface and the inner vessel wall, and this can lead to thrombosis formation. Self-expanding stents expand until
5 their outer surface is constrained by contact with the vessel wall and thus the use of a self-expanding stent may eliminate or reduce these gaps thereby reducing thrombosis formation.

[0007] Another trend in stenting is the use of longer stents for treatment of long diffuse lesions in the peripheral vessels. While this procedure is promising, some challenges still exist. For example, longer stents are often less flexible and therefore are harder to deliver
10 and deploy in torturous vessels, and they can fracture or kink. Therefore, there is a need for longer stents with improved flexibility.

[0008] The flexibility of stents may be improved through the variation of the stent geometry. Current stents are typically articulated tubes consisting of a series of axially adjacent, tubular rings interconnected with one another by one or more bridges. Each tubular
15 ring often consists of several repeating cells formed from axially oriented struts, each having the same length. The cells are often arranged to form a helical, zig-zag, diamond, rectangular, undulating, mesh, or other pattern. Using struts of the same length in a repeating cell pattern results in uniform stent compression and expansion thereby helping to ensure uniform loading of a stent with a delivery catheter as well as uniform scaffolding of the
20 treatment site after the stent has been deployed. The tubular rings are often rigid, providing mechanical support to the vessel but little or no axial flexibility. Thus, axial flexibility of the stent may be adjusted by using bridges to connect adjacent tubular rings. While it is desirable to keep the tubular rings close together in order to provide maximum scaffolding to the vessel, it is also desirable to have a longer gap between the tubular rings so that a longer
25 bridge may connect adjacent tubular rings for greater stent flexibility. Additionally, by bringing tubular rings closer together or interleaving segment ends, the overall stent column strength is increased along with the stent's ability to resist twisting. This allows the stent rings to be coupled together with fewer bridges, thereby also increasing stent flexibility. Stent column strength is important during retraction of a constraining sheath during stent
30 deployment. Friction between the sheath and the tubular rings may twist them relative to one another or buckle the stent forcing the segments together, thereby causing binding or potentially interfering with proper stent deployment. Thus, it is desirable to provide an improved stent that provides improved flexibility without substantially diminishing

scaffolding ability or column strength, as well as providing other structural advantages while avoiding some of the aforementioned challenges.

[0009] 2. Description of the Background Art. Prior patents and publications describing various stent geometries and stent delivery systems include U.S. Patent Nos. 5,421,955; 5,716,393; 6,022,374; 6,132,460; 6,264,688; 6,273,911; 6,334,871; 6,375,676; 6,464,720; 6,582,460; 6,918,928; U.S. Patent Publication No. 2003/0114919; International PCT Publication WO 2008/005111; and European Patent No. EP 1318765.

BRIEF SUMMARY OF THE INVENTION

[0010] The present invention provides prostheses and methods for use thereof. In a first aspect of the present invention, a tubular prosthesis comprises a plurality of tubular rings radially expandable from a contracted configuration to an expanded configuration. Each ring has a plurality of axially oriented struts interconnected so as to form a circumferential series of at least one high peak and at least one low peak. The high and low peaks have apices that are oriented in the same axial direction and the apices of the high peaks are also axially offset from the apices of the low peaks. A bridge member couples a pair of adjacent tubular rings together and the bridge member has a first end connected to a first low peak in a first tubular ring and a second end connected to either a high or low peak in an adjacent tubular ring.

[0011] In another aspect of the present invention, a tubular prosthesis comprises a plurality of tubular rings radially expandable from a contracted configuration to an expanded configuration. Each ring comprises a plurality of axially oriented struts interconnected so as to form a circumferential series of high peaks and low peaks, the high and low peaks having apices oriented in the same axial direction and the apices of the high peaks are axially offset from the apices of the low peaks. Adjacent tubular rings interleave with one another such that a high peak on a first tubular ring nests between two high peaks on an adjacent tubular ring. A bridge member couples a pair of adjacent tubular rings together and the bridge member has a first end connected to the first tubular ring and a second end connected to the adjacent tubular ring.

[0012] In yet another aspect of the present invention, a method for delivering a prosthesis to a treatment site in a body comprises advancing a delivery catheter to the treatment site. The delivery catheter has a tubular prosthesis disposed thereon and the tubular prosthesis comprises a plurality of tubular rings with each ring having a plurality of axially oriented

struts interconnected so as to form a circumferential series of at least one high peak and at least one low peak. The apex of the at least one high peak is axially offset from the apex of the at least one low peak. The method also includes selecting a first number of the tubular rings for deployment and radially expanding the first number of tubular rings into engagement with tissue at the treatment site. The delivery catheter may be repositioned to a second treatment site and then a second number of the tubular rings may be selected for deployment. The second number of rings is radially expanded so that they engage with tissue at the second treatment site without removing the delivery catheter from the body.

[0013] Advancing the delivery catheter may include intravascularly positioning the catheter in a blood vessel which may be an artery in a leg. Sometimes the plurality of tubular rings are self-expanding and radially expanding the first number comprises removing a constraint from the first number and/or the second number of tubular rings. The method may also include releasing a therapeutic agent carried by the tubular prosthesis at a controlled rate, such as an agent that inhibits restenosis. The first number may be greater than or equal to two and the second number may be different than the first number.

[0014] The apices of the high and low peaks in the first tubular ring may be circumferentially offset from the apices of the high and low peaks in the adjacent tubular ring. The apices of the low peaks in the first tubular ring may be circumferentially aligned with the apices of the high or low peaks in the adjacent tubular ring. The apices of the high and low peaks of the first tubular ring may point toward the apices of the high and low peaks of the adjacent tubular ring. The high and low peaks may be circumferentially alternative with one another in a tubular ring or they may be arranged circumferentially such that each high peak is disposed between two low peaks or one low peak and one high peak. Each high and low peak may be separated from an adjacent high or low peak by a valley, and the high peaks on the first tubular ring may be nested between valleys on the adjacent tubular ring. The circumferential width of each valley in the contracted configuration may be less than the circumferential width of each peak in the contracted configuration. The first low peak may be circumferentially offset from the high or the low peak in the adjacent tubular ring.

[0015] The plurality of axially oriented struts may comprise long struts and short struts with the short struts being shorter than the long struts and the plurality of axially oriented struts may be arranged circumferentially such that each short strut is disposed between one long strut and one short strut. Each high peak may comprise a long strut having a first length

and each low peak may comprise a short strut having a second length shorter than the first length. Each low peak may comprise two short struts and each high peak may comprise one long strut and one short strut with the short strut being shorter than the long strut.

[0016] Various embodiments of bridge members are disclosed including bridge members having a shape selected from the group consisting of z, u, and s-shaped as well as sigmoidal shaped. Sometimes the bridge member may have a surface defining one or more apertures therein and sometimes the apertures may extend entirely through the bridge member. The apertures may have an axis that is substantially parallel to an outer surface of the prosthesis and sometimes the apertures may form an elongate slot. The bridge member has a thickness in the radial direction and sometimes that thickness may vary across the bridge member. The bridge member may have a first thickness and the plurality of axially oriented struts may have a second thickness greater than or different than the first thickness. The first thickness may be less than the second thickness. Some bridge members may comprise a spring element, a strain relief region or a resilient elastomer. Sometimes the bridge member may be slidably engaged with the connector.

[0017] The bridge member may comprise a transverse portion and a first axially oriented portion with the transverse portion transverse to the first axially oriented portion and coupled thereto. The bridge member may also further comprise a second axially oriented portion with the transverse portion disposed between the first and second axially oriented portions. The bridge member may have an axial length between the first and second ends that is longer than the axial distance between high peaks on adjacent tubular rings, or the axial length may be longer than the axial distance between a high peak and a low peak on adjacent tubular rings. The first end may be connected to either a high or low peak in the first tubular ring and the second end may be connected to either a second high or low peak in the adjacent tubular ring. The first end of the bridge member may connect to either the apex of the peak or a portion of the peak offset from the peak's apex. The second end of the bridge member may also connect to a portion of a peak offset from the apex in the adjacent tubular ring.

[0018] The tubular prosthesis may have a first ring disposed between the adjacent tubular ring and a third tubular ring with the first tubular ring connected to the third tubular ring by a second bridge member. The bridge member may have a first orientation and the second bridge member may have a second orientation that is a mirror image thereof, or the bridge

member may have a first slope and the second bridge member may have a second slope that is opposite of the first.

[0019] The first end of the bridge member may connect to the first low peak at its apex. The second end of the bridge member may connect to the apex of either a high or low peak in the adjacent tubular ring. The bridge member may comprise a transverse portion that is transversely oriented to a longitudinal axis of the tubular prosthesis. The transverse portion may be disposed between a first peak on the first tubular ring and a second peak on the adjacent tubular ring thereby preventing the first peak from overlapping with the second peak when the tubular prosthesis is in compression. The transverse portion may have a length greater than a circumferential distance between the first and second peaks. The bridge member may also comprise an axial portion and a circumferential portion that is substantially transverse thereto. The bridge member may have a width that is substantially equivalent to a width of the axial struts. The bridge member may also comprise a first axially oriented region which includes the first end and a second axially oriented region which includes the second end.

[0020] The tubular prosthesis may be self-expanding and may have a length in the range from about 2 mm to about 200 mm. Sometimes, each of the plurality of tubular rings may have substantially the same axial length or they may be different. The prosthesis may comprise a third tubular ring adjacent the first tubular ring but that is not connected thereto. The prosthesis may further comprise a fourth tubular ring that is unconnected to but deployable with the first or third tubular ring. The prosthesis may carry a therapeutic agent that can be released from the prosthesis at a controlled rate and that agent may inhibit restenosis.

[0021] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] Fig. 1A is an unrolled view of an unexpanded stent.

[0023] Fig. 1B is an unrolled view of the stent of Fig. 1A in its expanded configuration.

[0024] Fig. 2A is an unrolled view of an unexpanded stent having variable strut lengths and sigmoidal shaped bridge members.

[0025] Fig. 2B is an unrolled view of the stent of Fig. 2A in its expanded configuration.

[0026] Fig. 3A is an unrolled view of an unexpanded stent having variable strut lengths and sigmoidal shaped bridge members with a transversely oriented portion.

5 [0027] Fig. 3B is an unrolled view of a stent similar to that shown in Fig. 3A but with less variability in strut lengths.

[0028] Figs. 4A-4C show enlarged views of a stent having slanted bridge members under various operating conditions.

[0029] Figs. 5A-5C show enlarged views of a stent having V-shaped bridge members under various operating conditions.

10 [0030] Fig. 6 shows a bridge member having strain relief regions.

[0031] Fig. 7A shows a bridge member having an arcuate surface.

[0032] Fig. 7B is a cross-sectional view of the bridge member of Fig. 7A.

[0033] Fig. 7C shows a bridge member having a tapered region.

[0034] Fig. 8 shows a spring-like bridge member.

15 [0035] Fig. 9 shows an elastomeric bridge member.

[0036] Fig. 10A shows a bridge member slidably engaged with struts of adjacent tubular rings.

[0037] Fig. 10B is a side-view of the strut in Fig. 10A.

[0038] Figs. 11A-11C show top and side views of a bridge member having an aperture.

20 [0039] Fig. 12 is a magnified view of a stent having helical bridge members.

[0040] Fig. 13 is an unrolled view of a stent having interleaving adjacent tubular rings.

[0041] Figs. 14A-14C illustrate an exemplary method of deploying a prosthesis.

DETAILED DESCRIPTION OF THE INVENTION

25 [0042] Figs. 1A and 1B show a commercially available stent 10 in an unrolled view, for ease of description. Figs. 1A and 1B show a portion of the stent 10 in its unexpanded and expanded configurations, respectively. Stent 10 may be balloon expandable or self-

expanding and is usually between 2 mm and 200 mm in length, although other lengths are possible. Most stents according to embodiments of the present invention will be self-expanding. Stent 10 may also be coated with a therapeutic agent, for example, an anti-restenosis agent such as, Paclitaxel, Rapamycin or derivatives thereof such as Biolimus A9.

5 Stent 10, like most stents, generally comprises a plurality of tubular rings 11 (shown in Figs. 1A-1B in an unrolled view) arranged axially adjacent one another. Each of the tubular rings 11 can be radially contracted and expanded. Each tubular ring 11 comprises a plurality of axially oriented struts 12. In the contracted configuration, struts 12 are parallel to the longitudinal axis of the stent 10. Generally, struts 12, and therefore each of the tubular rings
10 11, all share the same shape (usually rectangular) and dimensions to allow for uniform compression and expansion of the stent 10 as a whole. Circumferentially adjacent struts 12 are connected at a common longitudinal end by a U-shaped connector 13. Connectors 13 are placed on alternating pairs of struts 12 thereby forming an undulating pattern of peaks having apices circumferentially aligned with one another. In the expanded configuration, the U-
15 shaped connector 13 deflects outwardly so that the struts 12 form a undulating pattern of lower frequency when compared to the stent 10 in the collapsed configuration. Fig. 1B illustrates stent 10 in the expanded configuration. A bridge member 14 connects two axially adjacent tubular rings 11 together through adjacent connectors 13a, 13b. Bridge members 14 may be present for each connector 13, for every other connector 13, or in other alternating
20 patterns. The bridge member 14 limits the axial flexibility of stent 10. For example, the greater the number of bridge members 14, the less the axial flexibility of stent 10. On the other hand, a longer or thinner bridge member 14 increases stent 10 flexibility. As shown in Figs. 1A-B, bridge members 14 are generally straight and have alternating slopes between adjacent tubular rings 11 coupling staggered U-connectors 13 between adjacent tubular rings
25 11. Alternatively, bridge members 14 may all share the same slope or may all be parallel to the longitudinal axis of the stent. Besides being slanted as shown in Figs. 1A-1B, bridge members 14 may also have different shapes. For example, bridge members 14 may be S-shaped, V-shaped, U-shaped, Z-shaped, etc. and these alternative geometries are well documented in medical and patent literature. Like most stents, its component parts including
30 struts 12, connectors 13 and bridge members 14 are each integral parts of the stent and may be laser cut or EDM machined from tubing, or stent 10 may be photoetched from flat stock, with its ends rolled into a tube and welded together. While these commercially available designs are promising, stent flexibility still remains a challenge, especially when longer stents are required to treat long lesions or when stents are delivered in torturous vessels.

[0043] Figs. 2A and 2B show a portion of a stent 20 according to an exemplary embodiment of the present invention. Stent 20 has improved flexibility and is shown in Figs. 2A and 2B in its unexpanded state and its expanded state, respectively. Stent 20 is generally similar to the conventional stents described above with several exceptions noted below. Stent 20 is preferably a self-expanding stent fabricated from Nitinol although it may also be balloon expandable and fabricated from stainless steel, cobalt chromium alloy or other materials commonly used in balloon expandable stents. Stent 20 comprises tubular rings 22 which are connected together by bridge members 27. Each tubular ring 22 comprises several circumferentially adjacent struts 21. Although struts 21 are axially oriented and share the same rectangular shape, they are not of uniform length. Each of the tubular rings 22 comprises axially-oriented struts of alternating lengths. In the embodiments shown in Figs. 2A-B, tubular rings 22 comprises long struts 21a and short struts 21b. Within each tubular ring 22, a long strut 21a is followed by a short strut 21b, which is then followed by another short strut 21b, which is then followed by a long strut 21a, and so forth. The ends of struts 21 are connected together with a U-shaped connectors 26 thereby forming a series of high peaks 24 and low peaks 25. The apices of the high peaks 24 are axially offset from the apices of the low peaks 25 but the apices of both peaks face in the same direction. In the exemplary embodiment of Figs. 2A-2B, each low peak 25 is followed by two high peaks 24. Other strut arrangement patterns and strut lengths are also possible. Using struts of different, alternating lengths creates the high 24 and low peaks 25 which form a larger gap between adjacent rings 22 without significantly decreasing scaffolding ability of the stent 20. Scaffolding ability is maintained because the high peaks 24 still provide support in the gap region between adjacent tubular rings 22.

[0044] The larger gap created between low peaks 25 of stent 20 allow bridge members 27 to be axially longer than if all peaks were the same height as in a conventional stent, thereby creating a longer beam which can deflect more. This permits greater axial flexibility between adjacent tubular rings 22. As seen in Figs. 2A-2B, sigmoidally shaped bridge member 27 spans between axially adjacent peaks 25 and is axially oriented ends couple to the apex of U-shaped connector 26. Bridge members 27 may also span between one low peak 25 and one high peak 24 to create a bridge member having intermediate length and therefore intermediate flexibility, as compared to a bridge member between two high peaks 24. A greater variety of strut lengths and therefore a greater variety of peak "heights" can also be used. One of ordinary skill in the art will recognize that the bridge member 27 may also

couple with other portions of the tubular ring 22 including a region of peak 25 that is off-center from the apex 26 or laterally with strut 21. Additionally, any number of tubular rings 22 may be used in order to create a stent of varying length, although in this exemplary embodiment the overall stent length is preferably between about 2 mm and about 200 mm with individual tubular rings ranging from about 2 mm to about 5 mm long. Thus a stent may be composed of anywhere from 1 to 100 individual rings. Fig. 2B illustrates stent 20 in the expanded state.

[0045] Fig 3A shows another exemplary embodiment of the present invention. Stent 30 is similar to the embodiment shown in Figs. 2A-2B, with the major difference being the shape of its bridge member 32. In stent 30, each tubular ring 33 comprises long struts 34a and shorter struts 34b which are connected together with a U-shaped connector 36 thereby forming a plurality of high peaks 37 and low peaks 38. High peaks 37 are higher than the low peaks 38. Bridge member 32 is generally sigmoidally shaped and includes a transverse portion 35 generally perpendicular to the longitudinal axis of the stent 30. The bridge member 33 allows adjacent tubular rings 33 to flex relative to one another. The transverse portion 35 in bridge member 32 has a length greater than the circumferential distance between a peak on one tubular ring 33 and a peak on an adjacent tubular ring 33. Thus, the transverse portion 35 helps provide axial stability to the stent 30 during deployment. Often, stents are constrained by a protective outer sheath during delivery. As the outer sheath is retracted during stent delivery, friction between the sheath and the stent may cause adjacent ring sections of a stent to advance towards one another with ends potentially interleaving and overlapping, thereby causing binding between the stent and sheath during deployment. The transverse portion 35 extends circumferentially between adjacent tubular rings 33, therefore transverse portion 35 serves as a stop to prevent adjacent tubular rings 33 from overlapping with one another due to friction with a sheath during retraction and stent deployment. Therefore, using variable strut lengths allows a larger gap between adjacent tubular rings 33 to be created in order to accommodate the bridge member 32 having a transverse portion 35, resulting in a more axially stable stent 30.

[0046] Fig. 3B shows a stent similar to the embodiment of Fig. 3A with the major exception being that the height between high peaks 37a and low peaks 38a is less than the distance between high and low peaks 37, 38. Peak height is adjusted by varying the length of the axially oriented struts in stent 31. Stent 31 has long struts 34a and shorter struts 34c, yet in this embodiment strut 34c is longer than the short strut 34b in the previous embodiment.

Reducing the height between high and low peaks 37a, 37b allows a bridge member 32 to be utilized having a shorter axial length than the embodiment of Fig. 3A, therefore axial rigidity of stent 31 may be adjusted as desired.

[0047] As previously described, conventional stents have bridge members which connect adjacent tubular rings. Several embodiments of bridge members that may be used in the stent embodiments previously disclosed are described herein below. Figs. 4A-4C and Figs. 5A-5C show the bridge members commonly used in existing stents and which may also be used in any of the embodiments described herein. Figs. 4A, 4B and 4C show a sigmoidal bridge member 42 in a neutral, tensile and compressed configuration, respectively. Bridge member 42 spans between a connector 44a and a connector 44b. Connectors 44a, 44b link circumferentially adjacent struts 45 together. As shown in Figs. 4A-4C, the peaks of connectors 44a and 44b may not share the same longitudinal axis and thus they are offset from one another. Therefore, any bridge member between the connectors is slanted relative to the longitudinal axis of the stent. Figs. 5A-5C show bridge members 52 having a V-shape. Figs. 5A, 5B and 5C show the bridge members 52 in a neutral, tensile and compressed configuration, respectively. Bridge member 52 spans between peaks of connectors 55a and 55b which share the same longitudinal axis. These and other bridge member shapes, such as "S", "U", "Z", etc., are used in conventional stents and can be used in embodiments of the present invention.

[0048] An aspect of the present invention provides stent bridge members which increase the axial flexibility of the stent. Fig. 6 shows a bridge member 62 according to embodiments of the present invention. Bridge member 62 spans between axially adjacent peaks 63a and 63b and generally has two axially oriented sections coupled together with a transverse section 64 forming a stairway step shape. There are cut-away regions 66 (as marked by the dotted lines) located on the inside corners of the bridge member 62 as it transitions from being parallel to the longitudinal axis of the stent to being perpendicular. Cut-away regions 66 are strain relief regions which increase the flexibility of bridge member 62. Cut-away regions may alternatively be located on other regions of the bridge member 62.

[0049] Figs. 7A and 7B show another bridge member 72 according to embodiments of the present invention. Conventional stents have a uniform thickness throughout. Bridge member 72 has an arcuate surface thinner than the thickness of struts 74 and connectors 77. This is best seen in Fig. 7B which shows the cross section of bridge member 72 taken along line 7B-

7B between adjacent connectors 77a and 77b. The arcuate surface may be created by grinding material away from the original surface 72a of bridge member 72 using techniques such as laser ablation, sanding, water blasting, or the like. The bridge member 72 is thus thinner and has greater flexibility. As shown in Fig. 7B, the cross-section of bridge member 72 is concave on one side and convex on the opposite side. Alternatively, bridge member 72 may be curved on only one side. Other bridge member geometries may also be used. For example bridge member 72 may have a thicknesses less than that of the struts and connectors, or the overall width of the bridge member 72 can also be reduced as seen in Fig. 7C. In both cases, increased flexibility of the stent results from a thinner bridge member.

[0050] Fig. 8 shows another bridge member according to embodiments of the present invention. Bridge member 81 is spring-like and thus provides a high degree of flexibility in all directions. Unlike the bridge members previously described which are cut from the same material as the remainder of the stent, bridge member 81 may be laser cut and then formed separately over adjacent strut connectors 82a and 82b. Bridge member 81 may then be welded, bonded or otherwise attached to adjacent tubular stent rings thereby coupling them together.

[0051] Fig. 9 shows another bridge member according to embodiments of the present invention. In this embodiment, bridge member 92 comprises an elastomer which can be resiliently stretched in any direction, thus increasing the axial flexibility of the stent. For example, the elastomer may be rubber or a rubber-like material such as synthetic rubber and latex.

[0052] Figs. 10A-10B show another bridge member according to embodiments of the present invention. Bridge member 102 traverses between strut connectors 103a and 103b. Fig. 10B shows a cross section of a strut connector 103 taken along line 10B-10B. Strut connector 103 has a longitudinal aperture 104 in a plane generally parallel to the outer surface of the stent. Bridge member 102 traverses between strut connectors 103a and 103b and is received in apertures 104a and 104b, thus slidably coupling the two. Bridge member 102 also includes end portion 106a, 106b on each of its two longitudinal ends. Enlarged head regions 106a, 106b have a greater cross-sectional area than aperture 104a, 104b, restricting the axial movement of the connectors 103a and 103b relative to one another. Head regions 106a, 106b may be formed for example by folding the ends of the bridge member over itself or welding the enlarged region to the axial portion of bridge member 102.

[0053] Figs. 11A-11C show another bridge member according to embodiments of the present invention. Bridge member 112 has at least one aperture 115 through its width. The apertures 115 have an axis that is generally parallel to the outer surface of the stent. Fig. 11B is a side-view of Fig. 11A and shows three apertures while Fig. 11C is also a side-view of Fig. 11A and shows an alternative embodiment having an oval-shaped aperture. Other shapes and numbers of apertures may be used as well. Having at least one aperture through the width of the bridge member 112 increases the overall flexibility of the stent.

[0054] Fig. 12 shows a portion of a stent 120 having bridge members according to another embodiment of the present invention. Helical bridge member 122 comprises a bar having a section rotated approximately 90 degrees and a second section rotated another 90 degrees to form a helix with portions of the bar generally in two planes that are orthogonal to one another. Helical bridge member 122 may also be formed by a bar rotated multiple times. By rotating the bridge in such a manner, helical bridge member 122 has a greater degree of axial flexibility than a simple single plane bridge member without sacrificing the radial strength of the stent. The bridge member 122 may be formed separately from the remainder of the stent 120 and then welded or otherwise attached thereto in a secondary process, or individual bridge members 122 may be helically rotated in an integrally formed stent.

[0055] Fig. 13 shows yet another embodiment a stent having variable strut lengths in order to produce a more flexible stent. This embodiment is similar to previous embodiments with the major difference being that the gap created by high and low peaks is used to allow adjacent tubular rings to overlap or interleave with one another. Adjacent tubular rings are coupled together with a shorter bridge connector. Fig. 13 is a rolled out view of a stent 130 having interleaving peaks. Stent 130 comprises a plurality of tubular rings 131 each having low 132b and high peaks 132a. The tubular rings are in close, axial proximity with one another such that the peak of one of the tubular rings is nested between the recess 133 formed by two peaks of an adjacent tubular ring. In other words, the peaks interleave, providing better stability for the stent 130 in its compressed or crimped state. Because of the enhanced stability of the stent 130, fewer bridge members are required to couple adjacent tubular rings 131 together, thus the overall stent is more flexible even though shorter bridge members are used. As with the embodiments previously described, the peaks 132a, 132b are formed by U-shaped connectors 135 which connect circumferentially adjacent struts 136. A short, bridge member 137 is occasionally formed laterally between adjacent peaks. In other words, the bridge members 137 are attached to connectors on areas of the connector offset from the

apex of its peak. Overall length of stent 130 is similar to that disclosed for previous embodiments and thus stent 130 ranges in length from about 2 mm to about 200 mm.

[0056] The circumferentially adjacent struts 136 of stent 130 form a repeating sequence of four struts having three different lengths. The sequence comprises a short length strut 138a followed by a medium length strut 138b which is then followed by a long length strut 138c which is followed by another medium length strut 138b.

[0057] In preferred embodiments of Fig. 13, strut thickness is constant throughout each tubular ring and strut width is varied. The longest strut 138c has the largest strut width, the shortest strut 138a has the smallest strut width, and the intermediate length struts 138b have a width in between the width of the longest and shortest struts 138c and 138a. This configuration helps to ensure uniform strut expansion and thus uniform vessel scaffolding. In still other embodiments, variable strut thickness may be employed exclusively or in combination with variable strut width and variable strut length.

[0058] Figs. 14A-14C illustrate an exemplary method of deploying the stents disclosed herein. In Fig. 14A, a single stent 1506 is disposed over a catheter shaft 1504 in delivery system 1500. In other embodiments, multiple stents may be carried by the catheter shaft 1504. Delivery system 1500 is introduced and advanced in an artery V over a guidewire GW to lesion L using standard catheterization techniques well known in the art. Stent 1506 is a self-expanding prosthesis having multiple tubular rings coupled together and interleaving with one another as illustrated in Fig. 13. Outer sheath 1502 constrains stent 1506 and prevents it from expanding until it is properly positioned adjacent lesion L in vessel V. Once the physician has properly positioned stent 1506, outer sheath 1502 is retracted relative to pusher tube 1512 allowing stent 1506 to self-expand into its expanded configuration 1508 into lesion L. Fig. 14B shows expanded stent 1508 after the sheath 1502 has been retracted. In some embodiments, stent 1506 may also be coated, impregnated, infused or otherwise coupled with one or more drugs that inhibit restenosis, such as Rapamycin, Everolimus, Biolimus A9, Paclitaxel, derivatives, prodrugs, or derivatives of the aforementioned, or other suitable agents, preferably carried in a durable or bioerodable carrier of polymeric or other suitable material. Alternatively, the stent 1506 may be coated with other types of drugs or therapeutic materials such as antibiotics, thrombolytics, anti-thrombotics, anti-inflammatories, cytotoxic agents, anti-proliferative agents, vasodilators, gene therapy agents, radioactive agents, immunosuppressants, chemotherapeutics, endothelial cell attractors or

promoters and/or stem cells. Such materials may be coated over all or a portion of the surface of the stent or the stent may have a porous structure or include apertures, holes, channels, or other features in which such materials may be deposited.

[0059] Additionally, as previously mentioned, delivery catheter 1500 in this exemplary embodiment only carries a single stent 1506. However, in other embodiments, delivery catheter 1500 may carry multiple stents. For example, a delivery catheter 1500 may carry two stents 1506, 1510. After the first stent is deployed at a first lesion as seen in Fig. 14B, the delivery catheter 1500 may be repositioned to another lesion L as seen in Fig. 14C. Outer sheath 1502 may then be retracted again, allowing the second stent 1510 to self-expand into the second lesion, L. In addition to deploying multiple stents at multiple sites, multiple stents may also be deployed at a single treatment site, thereby customizing stent length. Additional disclosure relating to systems which may be for deployment of customized stent lengths, including any of the stents disclosed herein is disclosed in U.S. Patent Publication Nos. 2007/0027521 and 2006/0282150, the entire contents of which are incorporated herein by reference. Additionally, delivery systems which may be used with any of the stents disclosed herein and which may help to control stent delivery due to the tendency of the stent to jump away from the delivery catheter are disclosed in U.S. Patent Application No. 11/752,448 (Attorney Docket No. 021629-002711US), the entire contents of which are also incorporated herein by reference.

[0060] While the exemplary embodiments have been described in some details for clarity of understanding and by way of example, a variety of additional modifications, adaptations and changes may be clear to those of skill in the art. Hence, the scope of the present invention is limited solely by the appended claims.

WHAT IS CLAIMED IS:

- 1 1. A tubular prosthesis comprising:
2 a plurality of tubular rings radially expandable from a contracted configuration
3 to an expanded configuration, each ring comprising a plurality of axially oriented struts
4 interconnected so as to form a circumferential series of at least one high peak and at least one
5 low peak, the high and low peaks having apices oriented in the same axial direction, the
6 apices of the high peaks being axially offset from the apices of the low peaks; and
7 a bridge member coupling a pair of adjacent tubular rings together, the bridge
8 member having a first end connected to a first low peak in a first tubular ring and a second
9 end connected to either a high or low peak in an adjacent tubular ring.
- 1 2. The tubular prosthesis of claim 1, wherein the second end is connected
2 to a low peak in the adjacent tubular ring.
- 1 3. The tubular prosthesis of claim 1, wherein the apices of the high and
2 low peaks in the first tubular ring are circumferentially offset from the apices of the high and
3 low peaks in the adjacent tubular ring.
- 1 4. The tubular prosthesis of claim 1, wherein each high peak comprises a
2 long strut having a first length and each low peak comprises a short strut having a second
3 length shorter than the first length.
- 1 5. The tubular prosthesis of claim 1, wherein the plurality of axially
2 oriented struts comprise long struts and short struts, the short struts shorter than the long
3 struts and wherein the plurality of axially oriented struts are arranged circumferentially such
4 that each short strut is disposed between one long strut and one short strut.
- 1 6. The tubular prosthesis of claim 1, wherein the low and the high peaks
2 are arranged circumferentially such that each high peak is disposed between one low peak
3 and one high peak.
- 1 7. The tubular prosthesis of claim 1, wherein the apices of the high and
2 low peaks of the first tubular ring point toward the apices of the high and low peaks of the
3 adjacent tubular ring.

1 8. The tubular prosthesis of claim 1, wherein each high and low peak is
2 separated from an adjacent high or low peak by a valley, and wherein the high peaks on the
3 first tubular ring are nested between valleys on the adjacent tubular ring.

1 9. The tubular prosthesis of claim 1, wherein the first low peak is
2 circumferentially offset from the low peak in the adjacent tubular ring.

1 10. The tubular prosthesis of claim 1, wherein the first low peak is
2 circumferentially offset from the high peak in the adjacent tubular ring.

1 11. The tubular prosthesis of claim 1, wherein each low peak comprises
2 two short struts.

1 12. The tubular prosthesis of claim 1, wherein each high peak comprises
2 one long strut and one short strut, the short strut shorter than the long strut.

1 13. The tubular prosthesis of claim 1, wherein each high peak comprises
2 one long strut and one short strut, the long strut having a first width and the short strut having
3 a second width less than the first.

1 14. The tubular prosthesis of claim 1, wherein the bridge member is
2 sigmoidal shaped.

1 15. The tubular prosthesis of claim 1, wherein the bridge member has a
2 shape selected from the group consisting of z, u, and s-shaped.

1 16. The tubular prosthesis of claim 1, wherein the bridge member
2 comprises a surface defining one or more apertures therein.

1 17. The tubular prosthesis of claim 16, wherein the apertures extend
2 entirely through the bridge member.

1 18. The tubular prosthesis of claim 16, wherein the apertures have an axis
2 substantially parallel to an outer surface of the prosthesis.

1 19. The tubular prosthesis of claim 16, wherein at least one of the
2 apertures form an elongate slot.

1 20. The tubular prosthesis of claim 1, wherein the bridge member has a
2 thickness in the radial direction, the thickness varying across the bridge member.

1 21. The tubular prosthesis of claim 1, wherein the bridge member
2 comprises a spring element.

1 22. The tubular prosthesis of claim 1, wherein the bridge member
2 comprises a strain relief region.

1 23. The tubular prosthesis of claim 1, wherein the bridge member has a
2 first thickness and the plurality of axially oriented struts have a second thickness different
3 than the first thickness.

1 24. The tubular prosthesis of claim 23, wherein the first thickness is less
2 than the second thickness.

1 25. The tubular prosthesis of claim 1, wherein the bridge member
2 comprises a resilient elastomer.

1 26. The tubular prosthesis of claim 1, wherein the bridge member is
2 slidably engaged with the connector.

1 27. The tubular prosthesis of claim 1, wherein the bridge member
2 comprises a transverse portion and a first axially oriented portion, the transverse portion
3 transverse to the first axially oriented portion and coupled thereto.

1 28. The tubular prosthesis of claim 27, wherein the bridge member further
2 comprises a second axially oriented portion, the transverse portion disposed between the first
3 and second axially oriented portions.

1 29. The tubular prosthesis of claim 1, wherein the bridge member has an
2 axial length between the first and second ends longer than the axial distance between high
3 peaks on adjacent tubular rings.

1 30. The tubular prosthesis of claim 1, wherein the bridge member has an
2 axial length between the first and second ends longer than the axial distance between a high
3 peak and a low peak on adjacent tubular rings.

1 31. The tubular prosthesis of claim 1, wherein the first tubular ring is
2 disposed between the adjacent tubular ring and a third tubular ring, the first tubular ring being
3 connected to the third tubular ring by a second bridge member.

1 32. The tubular prosthesis of claim 31, wherein the bridge member has a
2 first orientation and the second bridge member has a second orientation, wherein the second
3 orientation is a mirror image of the first orientation.

1 33. The tubular prosthesis of claim 31, wherein the bridge member has a
2 first slope and the second bridge member has a second slope, the second slope being opposite
3 the first slope.

1 34. The tubular prosthesis of claim 1, wherein the first end of the bridge
2 member connects to the first low peak at the apex thereof.

1 35. The tubular prosthesis of claim 1, wherein the second end of the bridge
2 member connects to the apex of either the high or the low peak in the adjacent tubular ring.

1 36. The tubular prosthesis of claim 1, further comprising a therapeutic
2 agent carried by the prosthesis and adapted to being released therefrom at a controlled rate.

1 37. The tubular prosthesis of claim 36, wherein the therapeutic agent
2 inhibits restenosis.

1 38. The tubular prosthesis of claim 1, wherein the plurality of tubular rings
2 are self-expanding.

1 39. The tubular prosthesis of claim 1, wherein the tubular prosthesis has a
2 length in the range from about 2 mm to about 200 mm.

1 40. The tubular prosthesis of claim 1, wherein each of the plurality of
2 tubular rings has substantially the same axial length.

1 41. The tubular prosthesis of claim 1, further comprising a third tubular
2 ring adjacent the first tubular ring and unconnected thereto.

1 42. The tubular prosthesis of claim 41, further comprising a fourth tubular
2 ring unconnected to but deployable with the first or third tubular ring.

1 43. The tubular prosthesis of claim 1, wherein the bridge member
2 comprises a transverse portion transversely oriented to a longitudinal axis of the tubular
3 prosthesis, the transverse portion being disposed between a first peak on the first tubular ring
4 and a second peak on the adjacent tubular ring thereby preventing the first peak from
5 overlapping with the second peak when the tubular prosthesis is in compression.

1 44. The tubular prosthesis of claim 43, wherein the transverse portion has a
2 length greater than a circumferential distance between the first and second peaks.

1 45. The tubular prosthesis of claim 1, wherein the bridge member
2 comprises an axial portion and a circumferential portion substantially transverse thereto.

1 46. The tubular prosthesis of claim 1, wherein the bridge member has a
2 width substantially equivalent to a width of the axial struts.

1 47. The tubular prosthesis of claim 1, wherein the bridge member
2 comprises a first axially oriented region which includes the first end, and a second axially
3 oriented region which includes the second end.

1 48. A tubular prosthesis comprising:
2 a plurality of tubular rings radially expandable from a contracted configuration
3 to an expanded configuration, each ring comprising a plurality of axially oriented struts
4 interconnected so as to form a circumferential series of high peaks and low peaks, the high
5 and low peaks having apices oriented in the same axial direction, the apices of the high peaks
6 being axially offset from the apices of the low peaks,

7 wherein adjacent tubular rings interleave with one another such that a high
8 peak on a first tubular ring nests between two high peaks on an adjacent tubular ring; and
9 a bridge member coupling a pair of adjacent tubular rings together, the bridge
10 member having a first end connected to the first tubular ring and a second end connected to
11 the adjacent tubular ring.

1 49. The tubular prosthesis of claim 48, wherein each high and low peak is
2 separated from an adjacent high or low peak by a valley, and wherein the circumferential
3 width of each valley in the contracted configuration is less than the circumferential width of
4 each peak in the contracted configuration.

1 50. The tubular prosthesis of claim 48, wherein the first end is connected
2 to a high peak in the first tubular ring and the second end is connected to either a second high
3 peak or a low peak in the adjacent tubular ring.

1 51. The tubular prosthesis of claim 48, wherein the high and low peaks
2 circumferentially alternate with one another in the first tubular ring.

1 52. The tubular prosthesis of claim 50, wherein the second end is
2 connected to a second high peak in the adjacent tubular ring.

1 53. The tubular prosthesis of claim 48, wherein the apices of the high and
2 low peaks in the first tubular ring are circumferentially offset from the apices of the high and
3 low peaks in the adjacent tubular ring.

1 54. The tubular prosthesis of claim 48, wherein each high peak comprises
2 a long strut having a first length and each low peak comprises a short strut having a second
3 length shorter than the first length.

1 55. The tubular prosthesis of claim 48, wherein the plurality of axially
2 oriented struts comprise long struts and short struts, the short struts shorter than the long
3 struts and wherein the plurality of axially oriented struts are arranged circumferentially such
4 that each short strut is disposed between one long strut and one short strut.

1 56. The tubular prosthesis of claim 55, wherein the long struts have a first
2 width and the short struts have a second width less than the first width.

1 57. The tubular prosthesis of claim 48, wherein the low and the high peaks
2 are arranged circumferentially such that each high peak is disposed between two low peaks.

1 58. The tubular prosthesis of claim 48, wherein the apices of the high and
2 low peaks of the first tubular ring point toward the apices of the high and low peaks of the
3 adjacent tubular ring.

1 59. The tubular prosthesis of claim 48, wherein each high and low peak is
2 separated from an adjacent high or low peak by a valley, and wherein the high peaks on the
3 first tubular ring are nested between valleys on the adjacent tubular ring.

1 60. The tubular prosthesis of claim 48, wherein the apices of the low peaks
2 in the first tubular ring are circumferentially aligned with the apices of the high peaks in the
3 adjacent tubular ring.

1 61. The tubular prosthesis of claim 48, wherein the apices of the high
2 peaks in the first tubular ring are circumferentially aligned with the apices of the low peaks in
3 the adjacent tubular ring.

1 62. The tubular prosthesis of claim 48, wherein the first tubular ring is
2 disposed between the adjacent tubular ring and a third tubular ring, the first tubular ring being
3 connected to the third tubular ring with a second bridge member.

1 63. The tubular prosthesis of claim 62, wherein the bridge member has a
2 first orientation and the second bridge member has a second orientation, wherein the second
3 orientation is a mirror image of the first orientation.

1 64. The tubular prosthesis of claim 62, wherein the bridge member has a
2 first slope and the second bridge member has a second slope, the second slope being opposite
3 the first slope.

1 65. The tubular prosthesis of claim 48, wherein the first end of the bridge
2 member connects to a portion of a first peak offset from the apex thereof in the first tubular
3 ring.

1 66. The tubular prosthesis of claim 48, wherein the second end of the
2 bridge member connects to a portion of a peak offset from the apex thereof in the adjacent
3 tubular ring.

1 67. The tubular prosthesis of claim 48, further comprising a therapeutic
2 agent carried by the prosthesis and adapted to being released therefrom at a controlled rate.

1 68. The tubular prosthesis of claim 67, wherein the therapeutic agent
2 inhibits restenosis.

1 69. The tubular prosthesis of claim 48, wherein the plurality of tubular
2 rings are self-expanding.

1 70. The tubular prosthesis of claim 48, wherein the tubular prosthesis has a
2 length in the range from about 2 mm to about 200 mm.

1 71. The tubular prosthesis of claim 48, wherein each of the plurality of
2 tubular rings has substantially the same axial length.

1 72. The tubular prosthesis of claim 48, further comprising a third tubular
2 ring adjacent the first tubular ring and unconnected thereto.

1 73. The tubular prosthesis of claim 72, further comprising a fourth tubular
2 ring unconnected to but deployable with the first or third tubular ring.

1 74. A method for delivering a prosthesis to a treatment site in a body, the
2 method comprising:

3 advancing a delivery catheter to the treatment site, the delivery catheter having
4 a tubular prosthesis disposed thereon, the tubular prosthesis comprising a plurality of tubular
5 rings with each ring having a plurality of axially oriented struts interconnected so as to form a
6 circumferential series of at least one high peak and at least one low peak, wherein the apex of
7 the one at least one high peak is axially offset from the apex of the at least one low peak;

8 selecting a first number of the tubular rings for deployment;

9 radially expanding the first number of tubular rings into engagement with
10 tissue at the treatment site;

11 repositioning the delivery catheter to a second treatment site;

12 selecting a second number of the tubular rings for deployment; and

13 radially expanding the second number of tubular rings into engagement with
14 tissue at the second treatment site without removing the delivery catheter from the body.

1 75. The method of claim 74, wherein advancing the delivery catheter
2 comprises intravascularly positioning the catheter in a blood vessel.

1 76. The method of claim 74, wherein the plurality of tubular rings are self-
2 expanding and radially expanding the first number comprises removing a constraint from the
3 first number of tubular rings.

- 1 77. The method of claim 74, wherein the plurality of tubular rings are self-
2 expanding and radially expanding the second number comprises removing a constraint from
3 the second number of tubular rings.
- 1 78. The method of claim 74, further comprising releasing a therapeutic
2 agent carried by the tubular prosthesis at a controlled rate.
- 1 79. The method of claim 78, wherein the therapeutic agent inhibits
2 restenosis.
- 1 80. The method of claim 74, wherein the first number is greater than or
2 equal to two.
- 1 81. The method of claim 74, wherein the second number is different than
2 the first number.
- 1 82. The method of claim 74, wherein the treatment site is in an artery.
- 1 83. The method of claim 74, wherein the treatment site is in a leg.
- 1 84. The method of claim 74, wherein the at least one peak and at least one
2 valley of a first tubular ring interleave with the at least one peak and the at least one valley of
3 an adjacent tubular ring.

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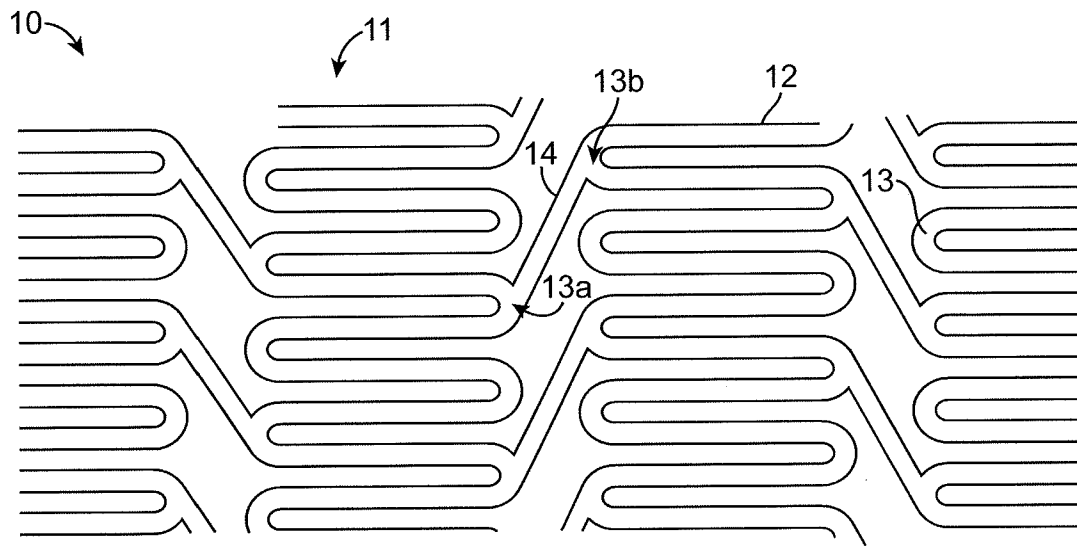


FIG. 1A

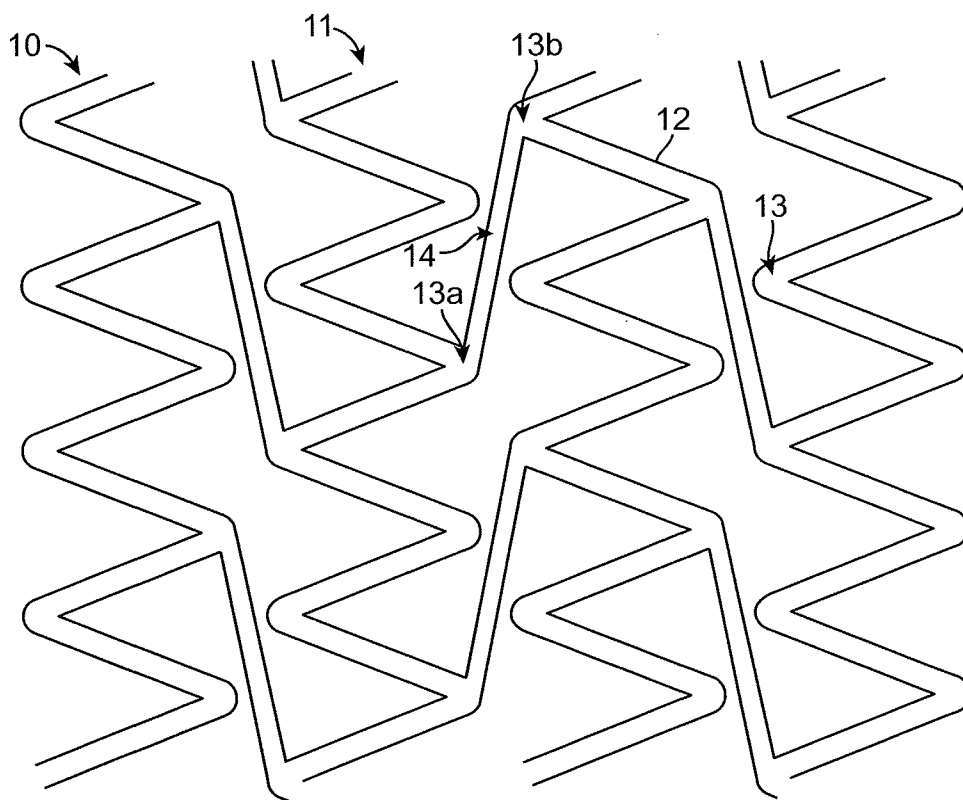


FIG. 1B

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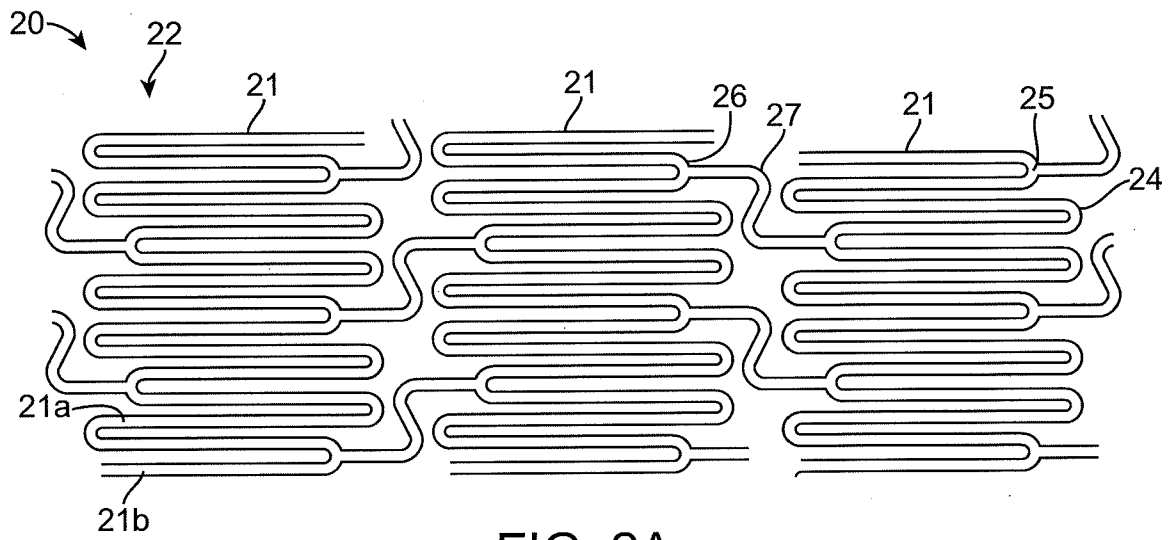


FIG. 2A

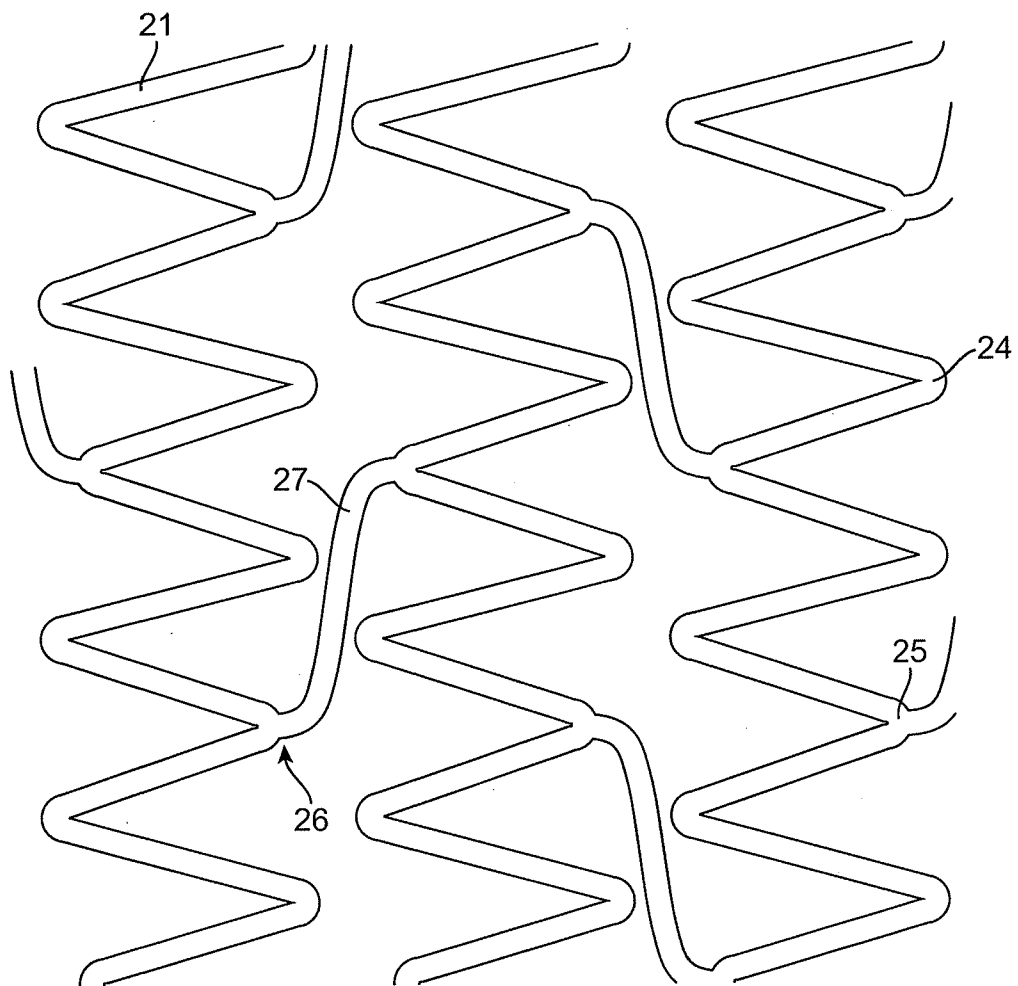


FIG. 2B

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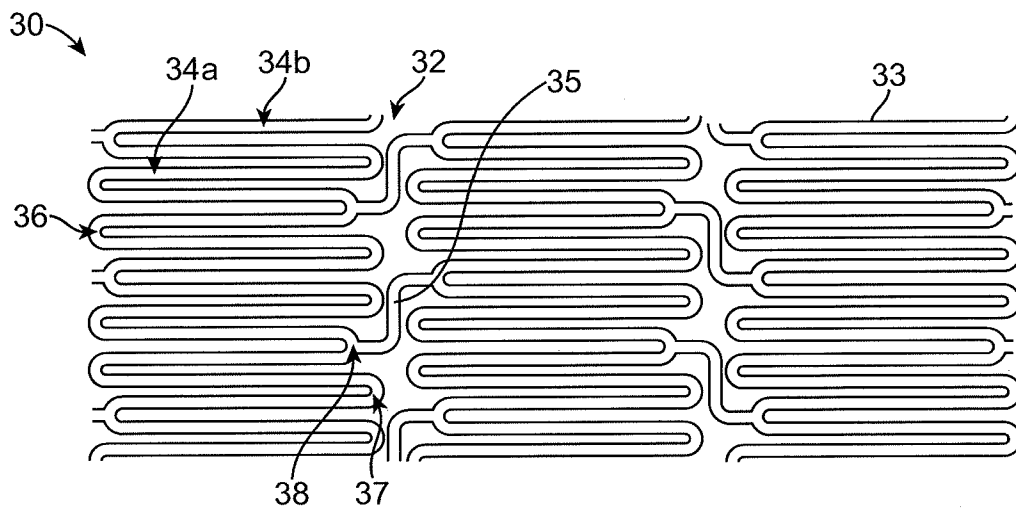


FIG. 3A

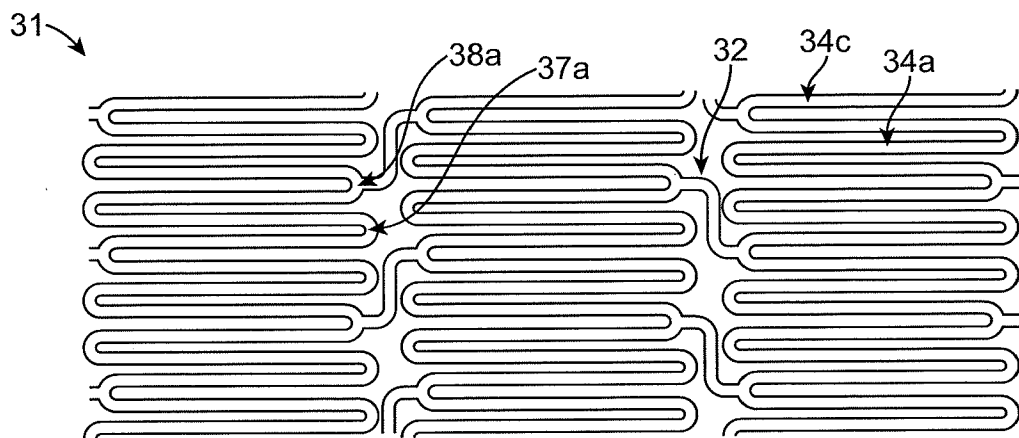


FIG. 3B

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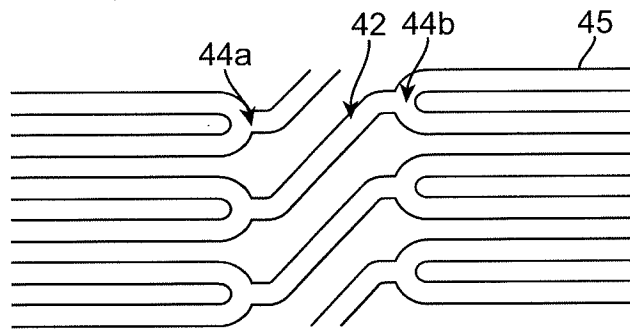


FIG. 4A

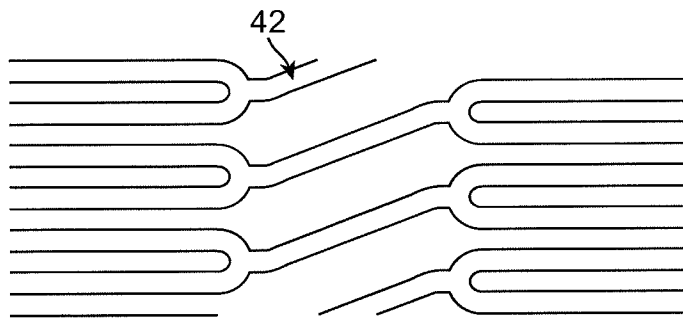


FIG. 4B

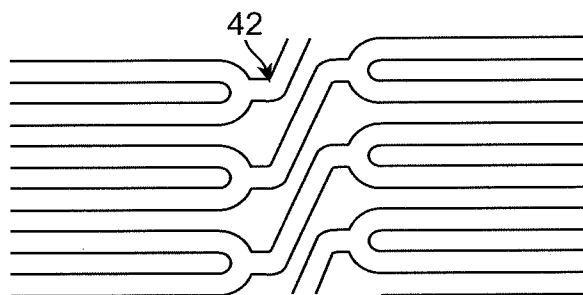


FIG. 4C

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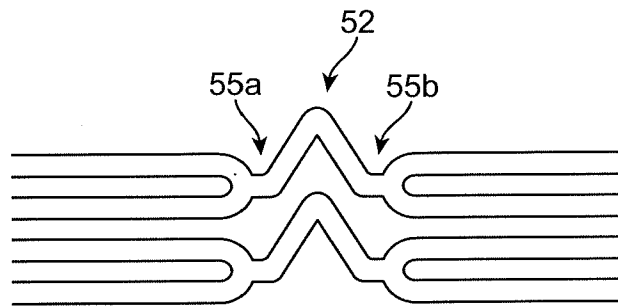


FIG. 5A

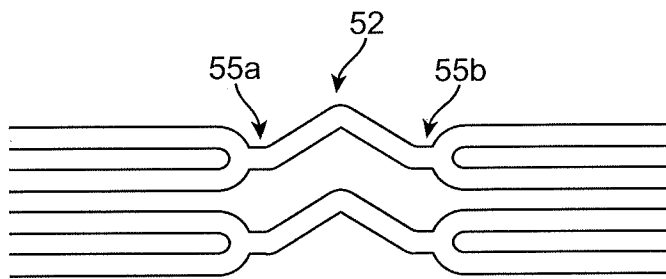


FIG. 5B

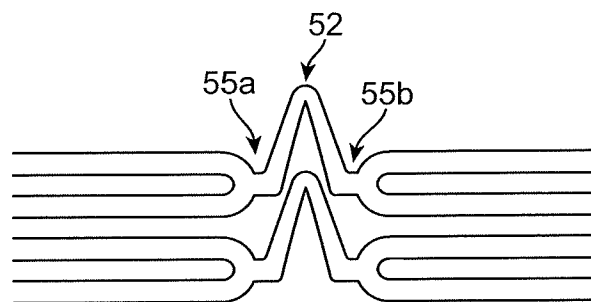


FIG. 5C

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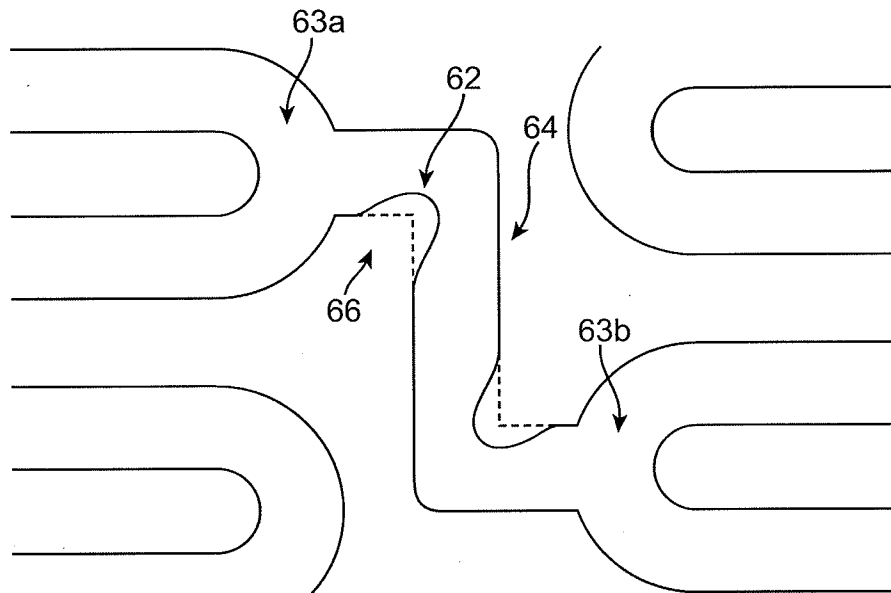


FIG. 6

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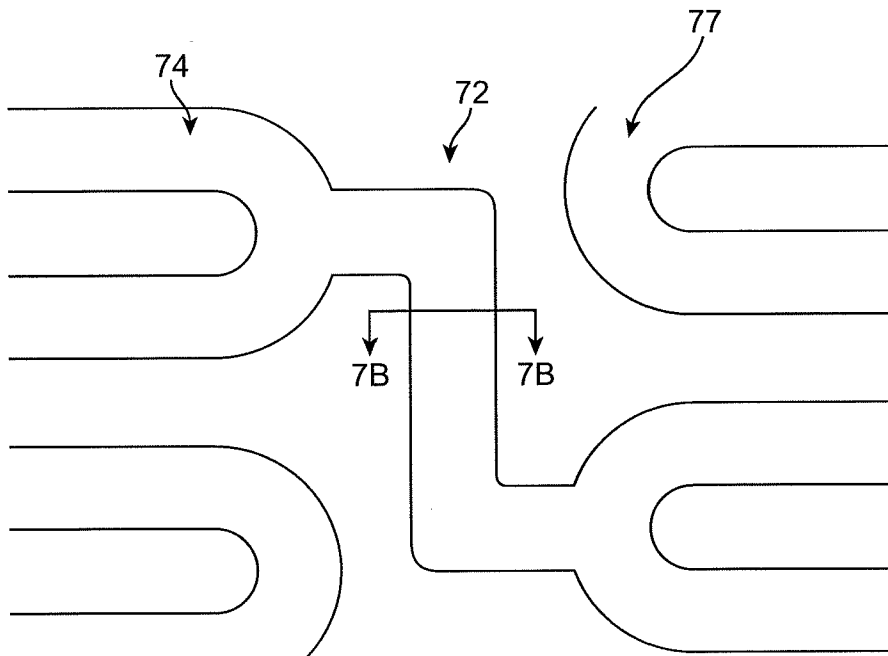


FIG. 7A

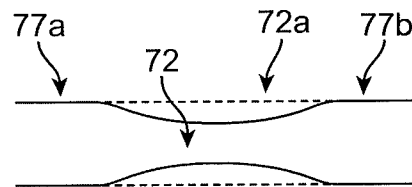


FIG. 7B

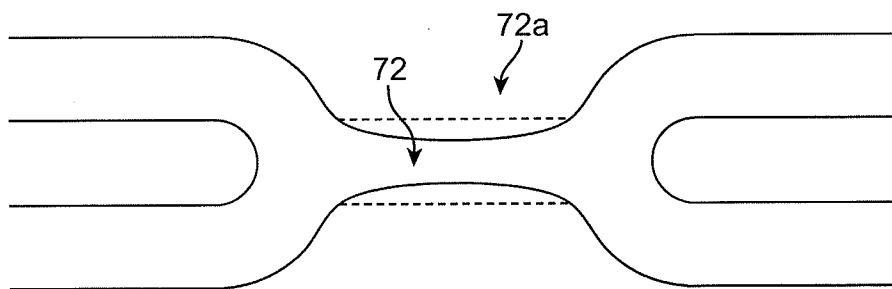


FIG. 7C

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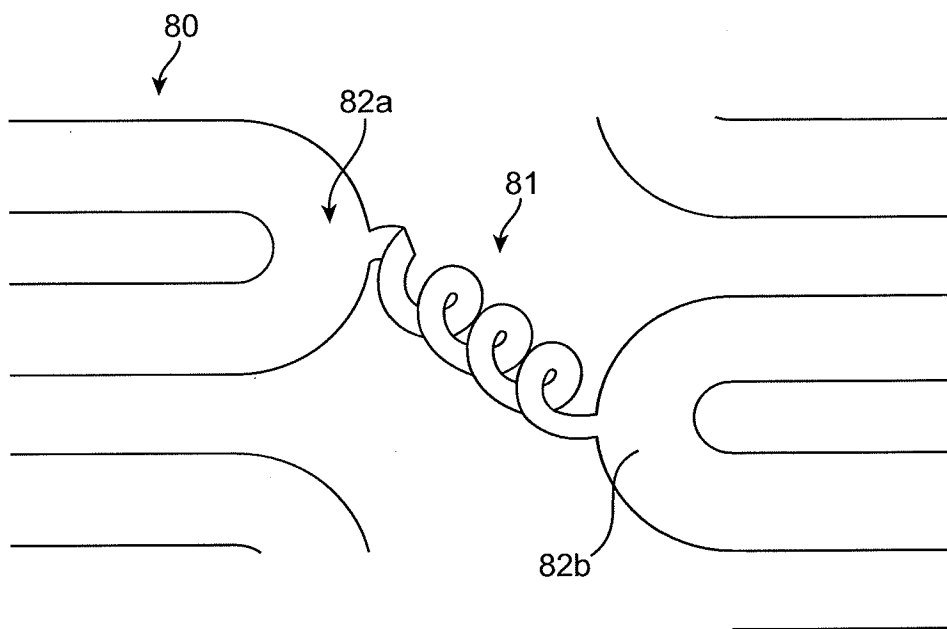


FIG. 8

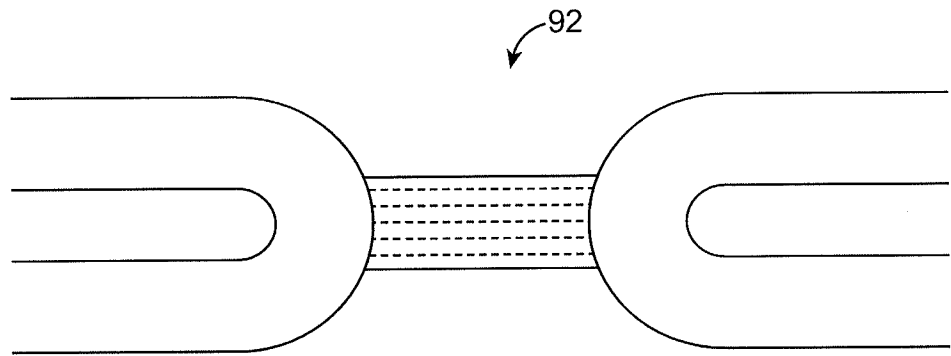


FIG. 9

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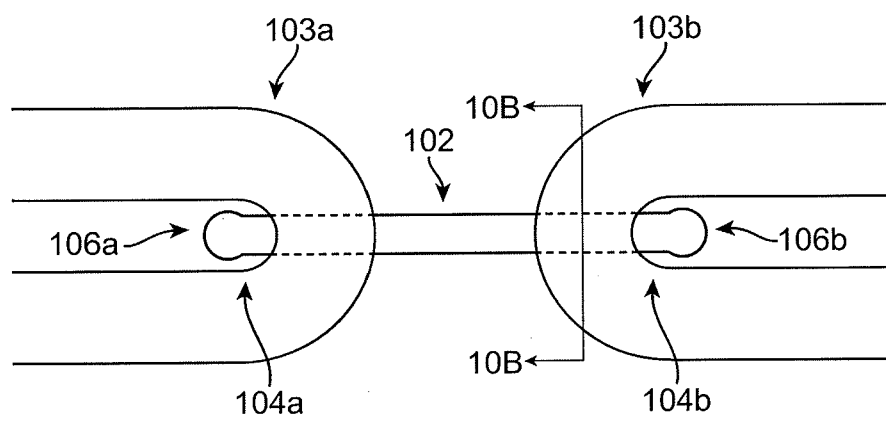


FIG. 10A

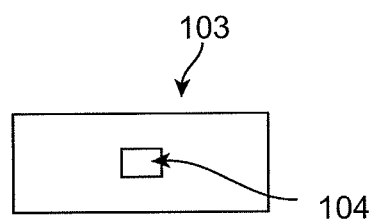


FIG. 10B

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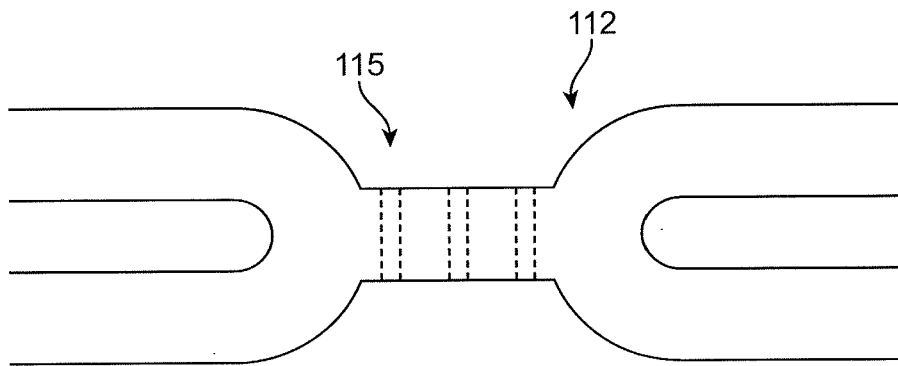


FIG. 11A

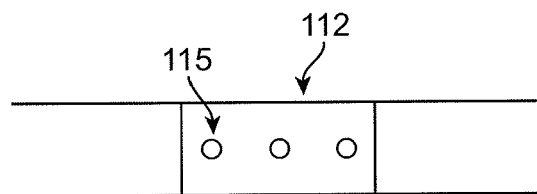


FIG. 11B

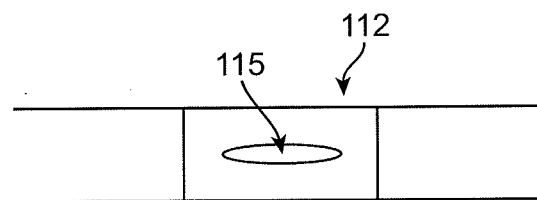


FIG. 11C

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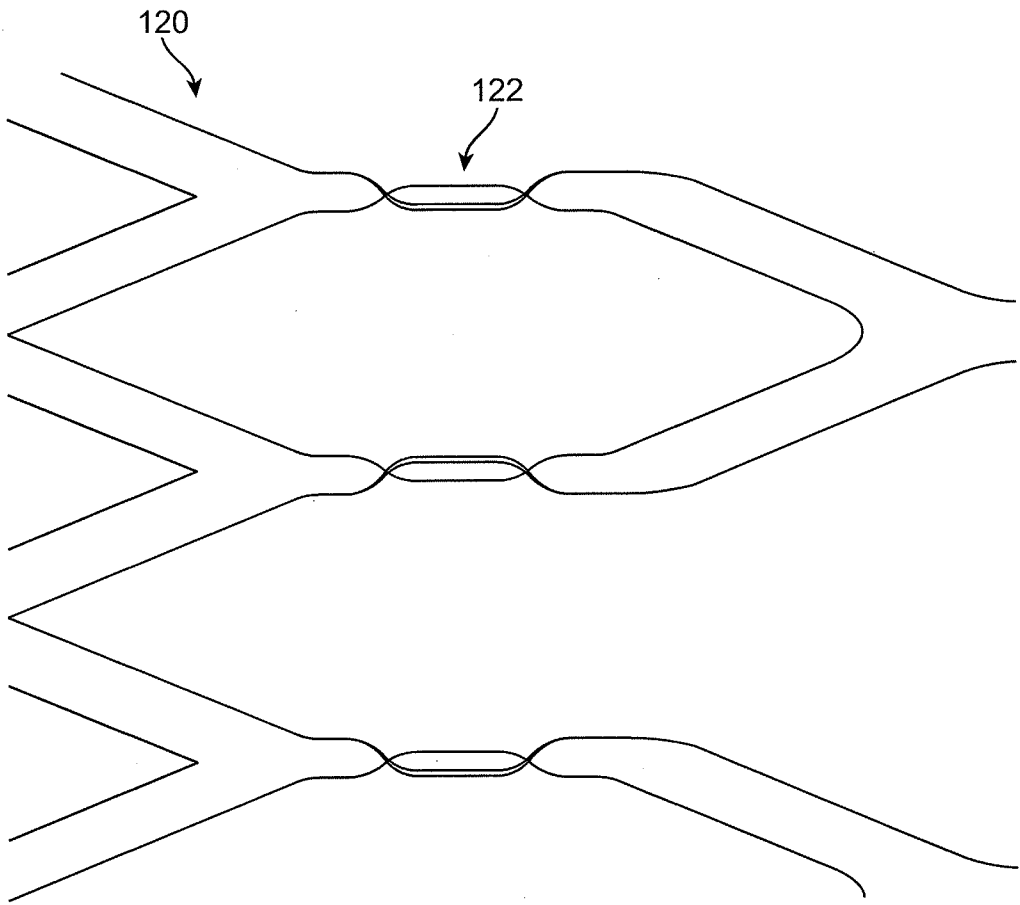


FIG. 12

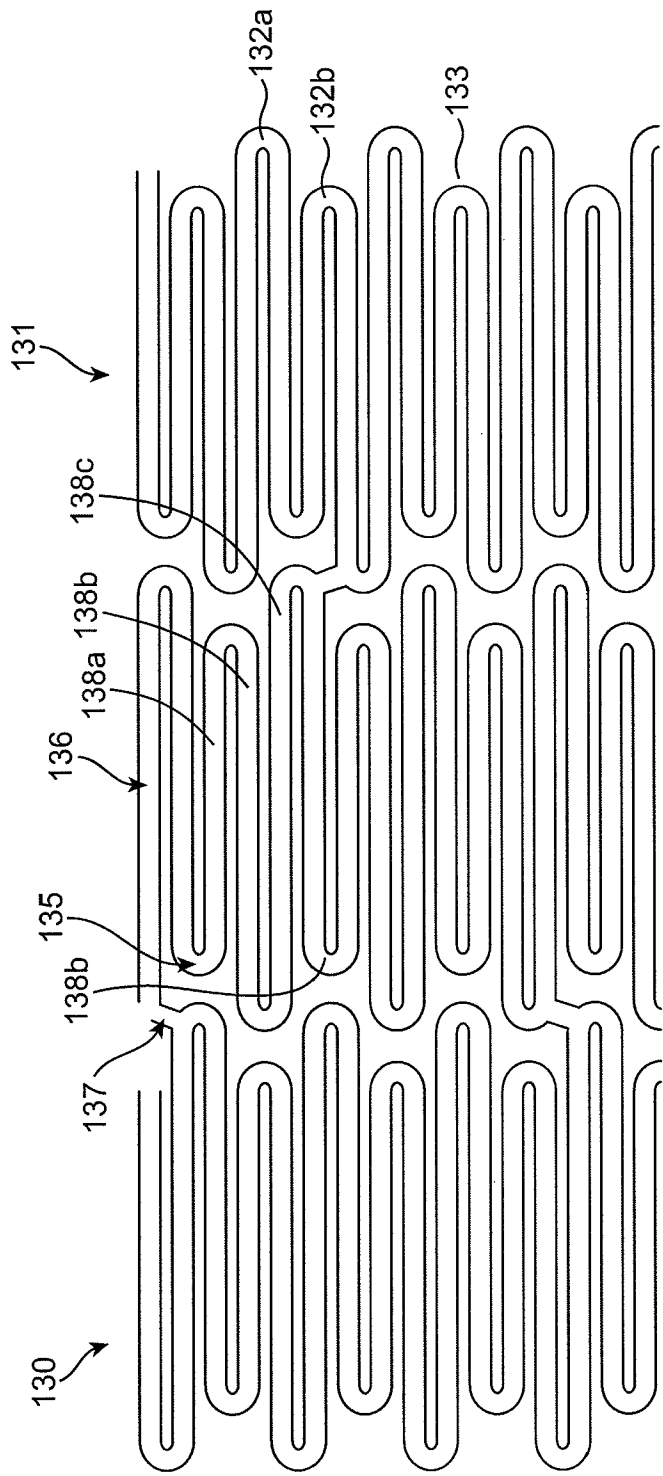


FIG. 13

