



(12) **DEMANDE DE BREVET CANADIEN**
CANADIAN PATENT APPLICATION

(13) **A1**

(86) Date de dépôt PCT/PCT Filing Date: 2017/03/28

(87) Date publication PCT/PCT Publication Date: 2017/10/05

(85) Entrée phase nationale/National Entry: 2018/09/17

(86) N° demande PCT/PCT Application No.: US 2017/024614

(87) N° publication PCT/PCT Publication No.: 2017/172823

(30) Priorité/Priority: 2016/03/31 (US62/316,128)

(51) Cl.Int./Int.Cl. *A61F 2/915* (2013.01),
A61F 2/93 (2013.01)

(71) Demandeur/Applicant:
VESPER MEDICAL, INC., US

(72) Inventeurs/Inventors:
LONGO, MICHAEL A., US;
KORKUCH, CHRISTOPHER N., US;
HARRISON, WILLIAM JAMES, US;
SANDER, THEA ROSE, US

(74) Agent: MBM INTELLECTUAL PROPERTY LAW LLP

(54) Titre : IMPLANTS INTRAVASCULAIRES

(54) Title: INTRAVASCULAR IMPLANTS

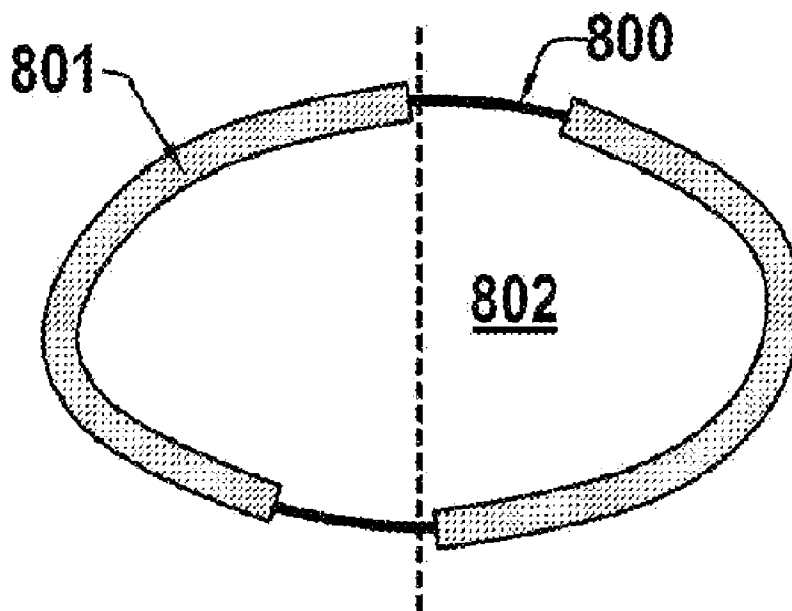


FIG. 5B

(57) Abrégé/Abstract:

A radially expandable, tubular stent, includes a first section having a first crush resistance force and a second section have a second crush resistance force, wherein the first crush resistance force is less than the second crush resistance force. The first section is connected to the second section to form a tube, connection of the first and second sections extending in an axial direction of the tube.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(10) International Publication Number
WO 2017/172823 A1

(43) International Publication Date
5 October 2017 (05.10.2017)

- (51) International Patent Classification:
A61F 2/915 (2013.01) *A61F 2/93* (2013.01)
- (21) International Application Number:
PCT/US2017/024614
- (22) International Filing Date:
28 March 2017 (28.03.2017)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
62/316,128 31 March 2016 (31.03.2016) US
- (71) Applicant: **VESPER MEDICAL, INC.** [US/US]; 1285 Drummers Lane, Suite 200, Wayne, Pennsylvania 19087 (US).
- (72) Inventors: **LONGO, Michael A.**; 131 Shea Lane, Glenmoore, Pennsylvania 19343 (US). **KORKUCH, Christopher N.**; 318 Elmhurst Dr., Chester Springs, Pennsylvania 19425 (US). **HARRISON, William James**; 612 Windy Way, Signal Mtn, Tennessee 37377 (US). **SANDER, Thea Rose**; 110 W North Lane, APT C3, Conshohocken, Pennsylvania 19428 (US).
- (74) Agents: **RUDICH, Rebecca G.** et al.; Meunier Carlin & Curfman LLC, 999 Peachtree Street NE, Suite 1300, Atlanta, Georgia 30309 (US).

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

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

Declarations under Rule 4.17:

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

[Continued on next page]

(54) Title: INTRAVASCULAR IMPLANTS

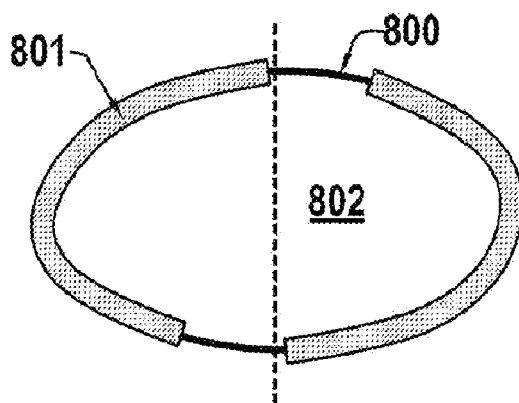


FIG. 5B

(57) Abstract: A radially expandable, tubular stent, includes a first section having a first crush resistance force and a second section have a second crush resistance force, wherein the first crush resistance force is less than the second crush resistance force. The first section is connected to the second section to form a tube, connection of the first and second sections extending in an axial direction of the tube.

WO 2017/172823 A1



Published:

— *with international search report (Art. 21(3))*

INTRAVASCULAR IMPLANTS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a non-provisional application of, and claims the priority benefit of, Provisional Application Serial Number 62/316,128, filed March 31, 2016, which is hereby incorporated by this reference in its entirety for all purposes as if fully set forth herein.

BACKGROUND

Field of the Invention

[0002] Disclosed herein are stents for implantation within the body and methods for delivery and/or deployment. Certain embodiments disclosed herein may be used in procedures to treat May-Thurner syndrome and/or deep venous thrombosis and the resulting post-thrombotic syndrome.

Description of the Related Art

[0003] May-Thurner syndrome, also known as iliac vein compression syndrome, is a condition in which compression of the common venous outflow tract of the left lower extremity may cause various adverse effects, including, but not limited to, discomfort, swelling, pain, and/or deep venous thrombosis (DVT) (commonly known as blood clots). May-Thurner syndrome occurs when the left common iliac vein is compressed by the overlying right common iliac artery, leading to stasis of blood, which may cause the formation of blood clots in some individuals. Other, less common, variations of May-Thurner syndrome have been described, such as compression of the right common iliac vein by the right common iliac artery.

[0004] While May-Thurner syndrome is thought to represent between two to five percent of lower-extremity venous disorders, it frequently goes unrecognized. Nevertheless, it is generally accepted that May-Thurner syndrome is about three times more common in women than it is in men and typically manifests itself between the age of twenty and forty. Patients exhibiting both hypercoagulability and left lower extremity thrombosis may be suffering from May-Thurner syndrome. To confirm that diagnosis, it may be necessary to rule out other causes for hypercoagulable state, for example by evaluating levels of antithrombin, protein C, protein S, factor V Leiden, and prothrombin G20210A.

[0005] By contrast to the right common iliac vein, which ascends almost vertically parallel to the inferior vena cava, the left common iliac vein takes a more transverse course. Along this course, it lies under the right common iliac artery, which may compress it against the lumbar spine. Iliac vein compression is a frequent anatomic variant – it is thought that as much as 50% luminal compression of the left iliac vein occurs in a quarter of healthy individuals. However, compression of the left common iliac vein becomes clinically significant only if such compression causes appreciable hemodynamic changes in venous flow or venous pressure, or if it leads to acute or chronic deep venous thrombosis, which will be discussed in more detail below. In addition to the other problems associated with compression, the vein may also develop intraluminal fibrous spurs from the effects of the chronic pulsatile compressive force from the overlying artery.

[0006] The narrowed, turbulent channel associated with May-Thurner syndrome may predispose the afflicted patient to thrombosis. And, the compromised blood flow often causes collateral blood vessels to form - most often horizontal transpelvis collaterals, connecting both internal iliac veins to create additional outflow possibilities through the right common iliac vein. Sometimes vertical collaterals are formed, most often paralumbar, which can cause neurological symptoms, like tingling and numbness.

[0007] Current best practices for the treatment and/or management of May-Thurner syndrome is proportional to the severity of the clinical presentation. Leg swelling and pain is best evaluated by vascular specialists, such as vascular surgeons, interventional cardiologists, and interventional radiologists, who both diagnose and treat arterial and venous diseases to ensure that the cause of the extremity pain is evaluated. Diagnosis of May-Thurner syndrome is generally confirmed one or more imaging modalities that may include magnetic resonance venography, and venogram, which, because the collapsed/flattened left common iliac may not be visible or noticed using conventional venography, are usually confirmed with intravascular ultrasound. To prevent prolonged swelling or pain as downstream consequences of the left common iliac hemostasis, blood flow out of the leg should be improved/increased. Early-stage or uncomplicated cases may be managed simply with compression stockings. Late-stage or severe May-Thurner syndrome may require thrombolysis if there is a recent onset of thrombosis, followed by angioplasty and stenting of the iliac vein after confirming the diagnosis with a venogram or an intravascular ultrasound. A stent may be used to support the area from further compression following angioplasty. However, currently available stenting

options suffer from several complications – including severe foreshortening, lack of flexibility (which can force the vessel to straighten excessively), vessel wear and eventual perforation, increased load on and deformation of the stent causing early fatigue failure, and/or impendence of flow in the overlying left iliac artery potentially causing peripheral arterial disease. The compressed, narrowed outflow channel present in May-Thurner syndrome may cause stasis of the blood, which is an important contributing factor to deep vein thrombosis.

[0008] Some patients suffering from May-Thurner syndrome may exhibit thrombosis while others may not. Nevertheless, those patients that do not experience thrombotic symptoms may still experience thrombosis at any time. If a patient has extensive thrombosis, pharmacologic and/or mechanical (i.e., pharmacomechanical) thrombectomy may be necessary. The hemostasis caused by May-Thurner syndrome has been positively linked to an increased incidence of deep vein thrombosis (“DVT”).

[0009] Deep vein thrombosis, or deep venous thrombosis, is the formation of a blood clot (thrombus) within a deep vein, predominantly in the legs. The right and left common iliac are common locations for deep vein thrombosis, but other locations of occurrence are common. Non-specific symptoms associated with the condition may include pain, swelling, redness, warmth, and engorged superficial veins. Pulmonary embolism, a potentially life-threatening complication of deep vein thrombosis, is caused by the detachment of a partial or complete thrombus that travels to the lungs. Post-thrombotic syndrome, another long-term complication associated with deep venous thrombosis, is a medical condition caused by a reduction in the return of venous blood to the heart and can include the symptoms of chronic leg pain, swelling, redness, and ulcers or sores.

[0010] Deep vein thrombosis formation typically begins inside the valves of the calf veins, where the blood is relatively oxygen deprived, which activates certain biochemical pathways. Several medical conditions increase the risk for deep vein thrombosis, including cancer, trauma, and antiphospholipid syndrome. Other risk factors include older age, surgery, immobilization (e.g., as experienced with bed rest, orthopedic casts, and sitting on long flights), combined oral contraceptives, pregnancy, the postnatal period, and genetic factors. Those genetic factors include deficiencies with antithrombin, protein C, and protein S, the mutation of Factor V Leiden, and the property of having a non-O blood type. The rate of new cases of deep vein thrombosis increases dramatically from childhood to old age; in adulthood, about 1 in 1000 adults develops the condition annually.

[0011] Common symptoms of deep vein thrombosis include pain or tenderness, swelling, warmth, redness or discoloration, and distention of surface veins, although about half of those with the condition have no symptoms. Signs and symptoms alone are not sufficiently sensitive or specific to make a diagnosis, but when considered in conjunction with known risk factors can help determine the likelihood of deep vein thrombosis. Deep vein thrombosis is frequently ruled out as a diagnosis after patient evaluation: the suspected symptoms are more often due to other, unrelated causes, such as cellulitis, Baker's cyst, musculoskeletal injury, or lymphedema. Other differential diagnoses include hematoma, tumors, venous or arterial aneurysms, and connective tissue disorders.

[0012] Anticoagulation, which prevents further coagulation but does not act directly on existing clots, is the standard treatment for deep vein thrombosis. Other, potentially adjunct, therapies/treatments may include compression stockings, selective movement and/or stretching, inferior vena cava filters, thrombolysis, and thrombectomy.

BRIEF SUMMARY OF THE INVENTION

[0013] Accordingly, the present invention is directed to an intravascular stent that obviates one or more of the problems due to limitations and disadvantages of the related art.

[0014] An advantage of the present invention is to provide a radially expandable, tubular stent, including a first section having a first crush resistance force and a second section have a second crush resistance force, wherein the first crush resistance force is less than the second crush resistance force; and the first section connected to the second section to form a tube, connection of the first and second sections extending in an axial direction of the tube.

[0015] In another aspect of the present invention, further embodiment of a a radially expandable, tubular stent, includes a plurality of circumferentially adjacent closed cells defining at least two axially repeating rings; and a plurality of linkage struts connecting respective ones of the circumferentially adjacent closed cells, wherein the plurality of linkage struts is fewer than the plurality of linkage struts such that fewer than the plurality of circumferentially adjacent closed cells in adjacent rings are connected by a linkage strut.

[0016] Further embodiments, features, and advantages of the intravascular stent, as well as the structure and operation of the various embodiments of the intravascular stent, are described in detail below with reference to the accompanying drawings.

[0017] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and are not restrictive of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] The accompanying figures, which are incorporated herein and form part of the specification, illustrate an intravascular stent. Together with the description, the figures further serve to explain the principles of the intravascular stent described herein and thereby enable a person skilled in the pertinent art to make and use the intravascular stent.

[0019] Figure 1 shows an inferior-posterior view of the L5 lumbar and the bifurcations of the abdominal aorta and inferior vena cava.

[0020] Figure 2 shows a schematic of the standard overlap of the right common iliac artery over the left common iliac vein.

[0021] Figure 3 shows a cross-sectional schematic of the arterio-venous system shown in Figure 2 taken along the gray dotted line.

[0022] Figures 4A-4C show an embodiment of an elliptical stent in three different states: Figure 4A shows the stent uncompressed and unconstrained; Figure 4B shows the stent highly compressed for delivery; and Figure 4C shows the stent deployed within a blood vessel.

[0023] Figure 5A is an embodiment of an elliptical stent having bilaterally symmetrical weaker sections and bilaterally symmetrical stronger sections.

[0024] Figure 5B is an embodiment of an elliptical stent having bilaterally asymmetrical weaker sections and bilaterally asymmetrical stronger sections.

[0025] Figures 6A-6B show an embodiment of the struts of the weaker sections of the stents of Figures 5A-5B.

[0026] Figures 7A-7B show an embodiment of the struts of the stronger sections of the stents of Figures 5A-5B.

[0027] Figure 8A shows the stent of Figure 5B in comparison to a maximum reference vessel diameter.

[0028] Figures 8B-8C show the stronger struts and the weaker struts of the stent of Figure 8A when the stent is at the maximum reference vessel diameter.

[0029] Figure 9A shows the stent of Figure 5B in comparison to a minimum reference vessel diameter.

[0030] Figures 9B-9C show the stronger struts and the weaker struts of the stent of Figure 8A when the stent is at the minimum reference vessel diameter.

[0031] Figure 10A shows the stent of Figure 5B held within the lumen of a delivery device.

[0032] Figures 10B-10C show the stronger struts and the weaker struts of the stent of Figure 8A when the stent held within the lumen of a delivery device.

[0033] Figures 11A-11E are various views of an embodiment of an elliptical stent having stronger sections and weaker sections.

[0034] Figure 12 shows the anatomical cross section of Figure 3 with a circular stent deployed in the left common iliac vein.

[0035] Figure 13 shows the anatomical cross section of Figures 3 with an elliptical stent deployed in the left common iliac vein.

[0036] Figure 14 is a hybrid stent having a first section, a second section, and a third transitional section.

[0037] Figures 14A-14C show various views of an embodiment of a stent having both high radial force and flexibility along its length.

[0038] Figure 15 shows a “Z” strut of the stent shown in Figures 14A-14C in various positions.

[0039] Figure 16 shows the individual components, including cells and flexible bridge members of an embodiment of a stent.

[0040] Figure 17 shows a cell geometry having a high radial force.

[0041] Figure 18 illustrates a network of flexible constructs formed of cells and flexible bridge members.

[0042] Figures 19A and 19B show various flexible bridge member geometries.

[0043] Figures 20A-20H show various views of an implant having an expanded implantation size that may be selectively adjustable across a range of diameters.

[0044] Figures 21A-21D show various views of an embodiment of a stent configured to minimize foreshortening while retaining flexibility.

[0045] Figures 22A-22E show various views of an intravascular stent having a plurality of anchor members.

[0046] Figures 23A-23F show various potential configurations of anchors that may be used with the intravascular stent of Figures 22A-22E.

DETAILED DESCRIPTION

[0047] May-Thurner syndrome, or iliac vein compression syndrome, occurs in the peripheral venous system when the iliac artery compresses the iliac vein against the spine as shown in Figure 1. Figure 1 illustrates a vertebra, the right and left common iliac arteries near the bifurcation of the abdominal aorta, and the right and left common iliac arteries near the bifurcation of the inferior vena cava. The bifurcations generally occur near the L5 lumbar vertebra. Thus, it can be seen that Figure 1 shows an inferior-posterior view of the L5 lumbar and the bifurcations of the abdominal aorta and inferior vena cava.

[0048] As shown, the strong right common iliac artery has compressed the iliac vein causing it to become narrowed. This is one possible, if not a classic, manifestation of May-Thurner syndrome. Over time, such narrowing may cause vascular scarring which can result in intraluminal changes that could precipitate iliofemoral venous outflow obstruction and/or deep vein thrombosis. As discussed above, venous insufficiency (i.e., a condition in which the flow of blood through the veins is impaired) can ultimately lead to various deleterious pathologies including, but not limited to, pain, swelling, edema, skin changes, and ulcerations. Venous insufficiency is typically brought on by venous hypertension that develops as a result of persistent venous obstruction and incompetent (or subcompetent) venous valves. Current treatments for venous outflow obstruction include anticoagulation, thrombolysis, balloon angioplasty and stenting.

[0049] Figure 2 illustrates the standard overlap of the right common iliac artery over the left common iliac vein. The arteries shown include the abdominal aorta 1500 branching into the left common iliac artery 1501 and the right common iliac artery 1502. The veins shown include the inferior vena cava 1503 branching into the left common iliac vein 1504 and right common iliac vein 1505. It will be understood that the rough diagram illustrated in Figure 2 represents the view looking down on a patient laying face-up (i.e., an anterior-poster view of the patient at the location of the bifurcation of the abdominal aorta 1500 and the inferior vena cava 1503). The overlap of the right common iliac artery 1502, which is relatively strong and muscular, over the left common iliac vein 1504 can cause May-Thurner syndrome by pressing down on the vein 1504, crushing it against the spine, restricting flow, and, eventually, causing thrombosis and potentially partially or completely clotting off of the

left common iliac vein 1054 and everything upstream of it (i.e., the venous system in the left leg, among others).

[0050] Figure 3 illustrates a cross-section of the arterio-venous system shown in Figure 2 taken along the gray dotted line. Shown in schematic are the right common iliac artery 1600, the left common iliac vein 1601, and a vertebra 1602 of the spine (possibly the L5 lumbar vertebra of the lumbar spine). As can be seen, the right common iliac artery 1600 is substantially cylindrical, due to its strong, muscular construction (among other potential factors). That strong, muscular artery has pressed down on the left common iliac vein 1601, until it has almost completely lost patency, i.e., it is nearly completely pinched off. It will be understood that May-Thurner syndrome may indeed involve such severe pinching/crushing of the underlying left common iliac vein 1601 against the vertebra 1602 of the lumbar spine. However, it will also be understood that May-Thurner syndrome may involve much less pinching/crushing of the underlying left common iliac vein 1601 against the vertebra 1602. Indeed, embodiments disclosed herein are appropriate for the treatment of various degrees of May-Thurner syndrome, including full crushing/pinching of the left common iliac vein 1602 by the right common iliac artery 1600. Other embodiments disclosed herein are appropriate for the treatment of various degrees of May-Thurner syndrome, including, but not limited to a crush/pinch of the underlying left common iliac vein 1601 of between about 10-95%, about 15-90%, about 20-85%, about 25-80%, about 30-75%, about 35-70%, about 40-65%, about 45-60%, and about 50-55%, or any other crush/pinch that could merit treatment using one or more of the devices disclosed herein.

[0051] In some embodiments, a self-expanding elliptical stent is provided, including elliptical stents having a high crush resistance, but a low radial force on the vessel wall. Therefore, some embodiments of stents discussed herein, including elliptical stents, may be useful in the treatment of May-Thurner syndrome. Figures 4A-4C illustrate an embodiment of an elliptical stent in various states: Figure 4A shows the stent uncompressed and unconstrained (e.g., sitting on a table); Figure 4B shows the stent comparatively highly compressed for delivery within a patient and constrained by a delivery device (e.g., a catheter-base delivery device); finally, Figure 4C shows the stent compressed and constrained by and within the left common iliac vein of a patient.

[0052] More specifically, Figure 4A shows one embodiment of an elliptical stent in a first state (e.g., an uncompressed, unconstrained state) having an unconstrained cross-

section with a first cross-sectional diameter 100 (or diameter across a minor axis of an ellipse) in a first direction and a second cross-sectional diameter 101 (or diameter across a major axis of an ellipse) in a second direction (perpendicular to the first direction). As can be seen, when uncompressed, the first cross-sectional diameter 100 may be less than the perpendicular, second cross-sectional diameter thereby defining a substantially elliptical cross-section.

[0053] Figure 4B illustrates the elliptical stent of Figure 4A in a second state (e.g., a highly compressed state) having a crimped cross-sectional with a first cross-sectional diameter 120 in the first direction and a second cross-sectional diameter 121 in the perpendicular, second direction. As can be seen, when compressed for delivery, the elliptical stent may have a first cross-sectional diameter that is substantially equal to its perpendicular, second cross-sectional diameter – that is to say that when in the second, highly compressed, or delivery, state, the elliptical stent may have a cross sectional profile that is substantially circular.

[0054] Figure 4C illustrates the elliptical stent of Figures 4A-4B in a third state (e.g., an implanted or deployed state) and deployed or placed within a blood vessel (e.g., a left common iliac vein). As shown in Figure 4C, the stent may be placed within a vessel 132 and thereby be constrained or restricted by the intraluminal wall of the vessel 132. As will be easily understood, when deployed, the stent pushes outward to hold open the vessel 132 to maintain patency. Figure 4C shows that after deployment, at least some embodiments of the elliptical stents disclosed herein main maintain their elliptical cross-section to hold open the vessel 132 in an elliptical cross-sectional shape, rather than in a standard circular cross-sectional shape – that is to say that after deployment, the first cross-sectional diameter 130 (or diameter across a minor axis of an ellipse) in the first direction is less than the second cross-sectional diameter 131 (or diameter across a major axis of an ellipse) in the perpendicular second direction.

[0055] In some embodiments, the first cross-sectional diameter 100 when in the unconstrained first state is greater than the first cross-sectional diameter 130 when in the deployed third state, which is greater than the first cross-sectional diameter 120 when in the highly compressed second state. Stated more simply, the elliptical stent has a larger cross-sectional diameter when uncompressed than when deployed in the lumen of a vessel. This is natural as the stent must be under some compression when deployed to be of any use holding the vessel open. And, the stent has a smaller cross-sectional diameter when compressed into a delivery device than when uncompressed (e.g., on a table) or deployed in a vessel lumen. The

stent must be able to traverse tortuous blood vessel systems to arrive at its deployment location – and it must be smaller than the lumens through which it must pass, so as to not scrape and damage the vessel walls.

[0056] As just discussed, some of the stents disclosed herein have an elliptical cross section (i.e., a first diameter across a minor axis smaller than a second, perpendicular diameter across a major axis). In some embodiments of the elliptical (or other) stents disclosed herein, the stent generates a first radial force in the first cross-sectional direction (e.g., Figure 4A 100) that is substantially equal to a second radial force in the second cross-section direction (e.g., Figure 4A 101). In other embodiments of the elliptical (or other) stents disclosed herein, the stent is advantageously capable of generating a first radial force in the first cross-sectional direction (e.g., Figure 4A 100) and a different, lesser second radial force in the perpendicular second cross-sectional direction (e.g., Figure 4A 101). In still other embodiments of the elliptical (or other) stents disclosed herein, the stent generates a first radial force in the first cross-sectional direction (e.g., Figure 4A 100) and a different, greater second radial force in the perpendicular second cross-sectional direction (e.g., Figure 4A 101).

[0057] Some embodiments of the stents disclosed herein may have one or more strong sections in the wall of the stent and one or more weak sections in the wall of the stent. By selectively positioning these strong and weak sections, the stent may be tailored to have selective crush-resistance. Various examples, which are not intended to be exhaustive, of such selective crush-resistance are discussed below.

[0058] Figure 5A illustrates an embodiment of an elliptical stent having bilaterally symmetrical weaker sections of the stent wall (e.g., struts or other structures) and bilaterally symmetrical stronger sections of the stent wall (e.g., struts or other structures). The stent may have an elliptical cross-sectional shape (although it should be understood that it may have other cross-sectional shapes, when uncompressed, highly compressed, or deployed) in its uncompressed state that is symmetrical across its center axis 702 (e.g., Figure 4A 100) that is substantially perpendicular to the stent's longitudinal axis (which is generally the same as the longitudinal axis of the blood vessel into which the stent is deployed, when deployed). As shown in Figure 5A, the stent has two stronger sections 701 (e.g., reinforced sections, load bearing sections, etc.) that are separated by two weaker sections 700 (e.g., connection portions). The strong sections 701 are shown as being symmetric across the center axis 701 of the ellipse such that the stronger sections 701 are positioned in the more convex portions of the ellipse.

Such a configuration of strong sections 701 and weak sections 700 may create a higher resistance to crush force in the vertical cross-sectional direction than the horizontal cross-sectional direction. And, the weak sections 700 may create a point where the stent is more susceptible to collapse along the center axis 701 than the points working away from the axis.

[0059] Figure 5B illustrates an embodiment of an elliptical stent having bilaterally asymmetrical weaker sections of the stent wall (e.g., struts or other structures) and bilaterally asymmetrical stronger sections of the stent wall (e.g., struts or other structures). The stent may have an elliptical cross-sectional shape (although it should be understood that it may have other cross-sectional shapes, when uncompressed, highly compressed, or deployed) in its uncompressed state that is symmetrical across its center axis 802 (e.g., the same as Figure 4A 100) that is substantially perpendicular to the stent's longitudinal axis (which is generally the same as the longitudinal axis of the blood vessel into which the stent is deployed, when deployed). Similar to the stent shown in Figure 5A, the stent shown in Figure 5B has two stronger sections 801 (e.g., reinforced sections, load bearing sections, etc.) that are separated by two weaker sections 800 (e.g., connection portions). However, unlike the stent shown in Figure 5A, the stent shown in Figure 5B is not symmetric around the center axis 802 of the ellipse. This configuration of stronger sections 801 and weaker sections 800 may create a higher resistance to crush force in the vertical cross-sectional direction than in the horizontal cross-sectional direction while minimizing the vertical weakness of the weaker sections 800.

[0060] Figures 6A-6B illustrate an embodiment of the struts of the weaker sections 700, 800 of the stents shown in Figures 5A-5B. The struts of the weaker sections may comprise a first strut that has a first strut state 900 of Figure 6A and a second strut state 901 of Figure 6B. The shape change of the stent cross-section is discussed further below and references the changes in strut state to enable/facilitate changes in stent shape. The first strut state 900 of Figure 6A is partially collapsed. By contrast, the second strut state 901 of Figure 6B is fully collapsed. The strut may collapse through an increase in loading. The base of the strut comes into contact 902 when fully collapsed – such contact at the base of the strut may prevent further collapse upon additionally increased loading. The deformation from partially collapsed to fully collapsed may be reversible deformation. The weak sections discussed above (i.e., weaker sections 700, 800) are created through a series of at least one first strut(s).

[0061] Figures 7A-7B illustrate an embodiment of the struts of the stronger sections 701, 801 of the stents shown in Figures 5A-5B. The struts of the stronger sections may

comprise a first strut that has a first strut state 1000 of Figure 7A and a second strut state 1001 of Figure 7B. The first strut state 1000 of Figure 7A is partially collapsed. By contrast, the second strut state 1001 of Figure 7B is more collapsed. The strut may collapse through an increase in loading, just like the weaker struts of Figures 6A-6B – however, collapse of the stronger sections (e.g., shown in Figures 7A-7B) requires more force than the collapse of the weaker sections (e.g., shown in Figures 6A-6B). The shape change of the stent cross-section is discussed further below and references the changes in strut state to enable/facilitate changes in stent shape. The first strut state 1000 of Figure 7A is shown substantially unconstrained with little to no collapse. By contrast, the second strut state 1001 of Figure 7B is shown partially collapsed, but not completely collapsed. The strut may collapse through an increase in loading. The deformation from partially collapsed to fully collapsed may be reversible deformation. The strong section discussed above (i.e., stronger sections 701, 801) are created through a series of at least one second strut(s).

[0062] The discussion surrounding Figures 6A-6B and Figures 7A-7B involves, among other things, creating weaker struts and stronger struts merely using less material and more material, respectively. While that simple solution can prove quite effective, it will be understood that many other ways of creating weaker sections and stronger section exist. For example, strut density (i.e., number of struts in a given space) may be increased for the stronger sections while strut density may be decreased for the weaker sections. Alternatively, strut angles (or lack thereof) and prismatic configuration may be used to increase or decrease section strength. Any method or way of creating a stent having sections of varying strength may be used.

[0063] Figure 8A illustrates a cross-section of the stent of Figure 5B in comparison to a maximum reference vessel diameter 1100. The diameter of the reference vessel 1101 creates a generally deformable circumference which contains and must compress (at least to some extent) the stent. In this case, the circumference of the stent is just less than the circumference of the maximum vessel diameter. As can be seen, the stent 1100 has stronger sections (shown in Figure 8C) that remain relatively uncompressed and weaker sections (shown in Figure 8B) that remain relatively uncompressed. That is to say (with reference to the descriptions of Figures 6A-6B and 7A-7B, both the stronger struts and the weaker struts are in their first strut state when the stent 1100 is in this maximum vessel diameter configuration. The maximum (circular) diameter of a blood vessel which can be treated using the devices (e.g.,

stents, vascular devices, vascular endoprotheses) disclosed herein is about 10-23mm, about 12-22mm, about 14-21mm, about 16-20mm, about 17-19mm, and about 18mm.

[0064] Figure 9A illustrates a cross-section of the stent 1200 of Figure 5B in comparison to a minimum reference vessel diameter 1201. The diameter of the reference vessel 1201 creates a generally deformable circumference which contains and must compress (to some extent) the stent. Again, the circumference of the stent is just less than the circumference of the maximum vessel diameter. However, it can be easily seen that the stent 1200 of Figure 9A is more compressed than the stent 1100 of Figure 8A. The change in circumference of the stent from the maximum reference vessel to the minimum reference vessel is achieved substantially through the transition of the weaker struts from the first strut state to the second strut state of the first, weaker struts (though it should be understood that some deformation of the stronger struts may be possible). Indeed, Due to the stronger structure of the stronger struts (second strut), the stronger struts stay mostly in their first strut state, although some minor collapse may occur. As can be seen, the stent 1100 has stronger sections (shown in Figure 9C) that remain relatively uncompressed and weaker sections (shown in Figure 9B) that compress almost completely. That is to say (with reference to the descriptions of Figures 6A-6B and 7A-7B, the stronger struts remain substantially in their first strut state and the weaker struts collapse substantially to their second strut state when the stent 1100 is in this minimum vessel diameter configuration. The result achieved using this dual-strength or multi-strength (as more than one strength region may be used) is the sizing at a maximum and minimum reference diameter with minimal radial force (e.g., resistance of the weak section). The higher radial force of the stronger section is present to resist crush of the vessel, but does not impart high radial force onto the vessel. Therefore, the stent at its minimum vessel sizing may be significantly circular. The minimum (circular) diameter of a blood vessel which can be treated using the devices (e.g., stents, vascular devices, vascular endoprotheses) disclosed herein is about 7-20mm, about 8-18mm, about 9-16mm, about 10-14mm, about 11-13mm and about 12mm.

[0065] Figure 10A illustrates the stent 1300 of Figure 5B held within and compressed by a delivery device, e.g., the wall of a delivery catheter 1301. The transition from the minimum vessel diameter to the crimped diameter (e.g., highly compressed diameter, delivery diameter, etc.) is achieved through the transition of the stronger struts from the first strut state to the second strut state. The weaker struts compress first and therefore can merely stay in the second strut state. Figures 10B and 10C illustrate the weaker struts and the stronger

struts, respectively, compressed down to their second strut state. The outer diameter of a delivery catheter in which stents, vascular devices, and vascular endoprostheses as disclosed herein may be delivered can be in the range of about 7-12Fr, about 8-11Fr, about 9-10Fr, or any other diameter that can both hold the device and fit through the target vasculature.

[0066] Figures 11A-11E illustrate various views of an embodiment of an elliptical stent having stronger sections and weaker sections, as discussed above. Figure 11A simply illustrates a top/front view of an embodiment of an elliptical stent, showing an elliptical shape. Figure 11B illustrates a three-quarter view of an embodiment of an elliptical stent. Figure 11C shows that the weak section may comprise only a single first strut 401 whereas the stronger section may comprise a series of second struts 400. The single first strut 401 may be stronger than each second strut of the series of second struts. Alternatively, the single first strut 401 may be weaker than each second strut of the series of second struts. But, regardless of their individual strength, in this embodiment, the weaker section has less resistance to deformation than does the stronger section. Figure 11D illustrates a flat pattern view (not necessarily in scale) of an embodiment of an elliptical stent. The stronger section is made up of several second struts 500 and the weaker section is made up of a single first struts 501 in a vertically repeating pattern. As shown, the stronger section and the weaker sections do not need to each contain the same number of repeating struts. In at least some embodiments, the weak sections are configured so as to not make contact with each other when in an unconstrained state and in a fully compressed state. Figure 11E illustrates a side view of view of an embodiment of an elliptical stent. Figure 11F illustrates an embodiment of an elliptical stent similar to that shown in Figure 11D, except that it includes an angled distal end. This angled distal end may be configured to match the vessel geometry where the left common iliac vein and the right common iliac vein merge into the inferior vena cava. In such a configuration, the end of the stent having the angled termination may be deployed so as to reside at the merger of the two iliac veins (i.e., the bifurcation of the inferior vena cava) while the length of the stent extends distally or downward into the left common iliac vein. This may advantageously serve to provide additional support to the vein(s) at the vena caval bifurcation. Of course, the stent may have any angle necessary to match a given patient's anatomy. But, the angle will generally be in the range of about 5-45°, about 10-40°, about 15-35°, about 20-30°, or about 25°, or any other angle necessary to fit a patient's vasculature.

[0067] Figure 12 illustrates the same anatomical cross section shown in Figure 3 with the addition of a circular stent 1703 deployed in the left common iliac vein 1701. To achieve full fill (e.g., full apposition of the exterior surface of the stent against the intraluminal wall) of the vein, the circular stent must exert significant force, denoted by arrows 1704, on the right common iliac artery 1700. Levels of force high enough to achieve clinically meaningful fill of the vein (e.g., substantially full or meaningful apposition of the exterior surface of the stent against the intraluminal wall) may result in several adverse effects, including, but not limited to, vessel wear and eventual perforation, increased load on and deformation of the stent causing early fatigue failure, and/or impedance of blood flow in the right common iliac artery 1700, which may result in peripheral arterial disease. Note, the vertebra 1702 of the spine does not displace and is assumed substantially rigid with little-to-no give.

[0068] Figure 13 illustrates the same anatomical cross section shown in Figures 3 with the addition of an elliptical stent 1703 deployed in the left common iliac vein. It should be noted that the elliptical stent 1703 of Figure 13 has the same circumference as the circular stent 1704 of Figure 12. Use of elliptical stents 1703 may advantageously allow in the creation of patency in the left common iliac vein 1701 without much of the added load caused by the increased height of a circular stent 1703. Using an elliptical stent may advantageously allow a comparatively low vertical load. To achieve the same low vertical load using a circular stent, a significantly smaller stent would be used. And, such a smaller stent would have a dramatically lower cross-sectional area than the elliptical stent. Reduced load minimizes the likelihood of the complication referenced above with respect to circular stents for the treatment of May-Thurner syndrome (e.g., in the description of Figure 12), while still providing a similar cross-sectional area to maintain flow and prevent clotting off of the vein. In some embodiments, specific orientation of the pre-loaded or crimped elliptical implant in a delivery catheter is mitigated as certain implant designs disclosed herein may allow for some level of self-alignment. The elliptical stent can be capable of self-orientation in a compressed vein: the high radial force vs. low radial force of the elliptical design could cause the implant to rotate/orient itself such that the higher radial force/crush resistance section (long axis) is perpendicular to the compression force. Due to the constraints on the left common iliac vein 1701 from the right common iliac artery 1700 and the L5 lumbar vertebra 1702, the elliptical stent can be deployed at an angle up to but not including 90 degrees from horizontal and self-align back to horizontal.

[0069] In some embodiments, a hybrid stent including at least a first section comprising an elliptical stent portion and at least a second section comprising another, different stent portion, is provided. Figure 14 illustrates a schematic view of a hybrid stent having a first section 2200 a second section 2202 and a third transitional section 2201, which transitions from the first section to the second section. In some embodiments, the first section 2200 of the hybrid stent is an elliptical stent such as disclosed elsewhere herein. In some embodiments, the second section 2202 comprises a portion of a stent having high radial force circular stent with flexible axial length. In other embodiments, the second section 2202 may comprises any other type of stent, including those disclosed herein. In some embodiments, the third section 2201 gently or gradually transitions from the stent of the first section 2200 to the stent of the second section 2202 so as to conform best to the patient's vasculature. Such hybrid stents may advantageously prove useful in the simultaneous treatment of May-Thurner syndrome and an accompanying deep venous thrombosis, such as deep venous thrombosis in the iliac and common femoral vein.

[0070] In some embodiments, vascular endoprotheses for the treatment of deep venous thrombosis, including in the iliac and common femoral veins, are provided, including vascular endoprotheses (e.g., stents) having high radial force and flexibility along their length. Figures 14A-14C illustrate various view of an embodiment of a stent (e.g., a circular stent) having both high radial force and flexibility along its length. Figure 14A illustrates the stent from its front or top (i.e., perpendicular to the stent's longitudinal axis) while Figure 14C illustrates the stent from a three-quarter's perspective or an isometric view. Figure 14B illustrates the flat pattern of the stent. The pattern consists of large "Z" cell patterns 1900 and small "Z" cell patterns 1901. The staggered "Z" cell pattern allows for a high radial force along with maintained flexibility along the length of the stent. The "Z" patterns repeat along the length of the stent (e.g., vertical) but alternates in orientation along the diameter (e.g., horizontal) of the stent. The "Z" cell pattern is defined by large "Z" struts 1902, small "Z" struts 1903, and crossing link struts 1904.

[0071] Figure 15 illustrates a single "Z" strut of the stent shown in Figures 14A-14C in various positions. The middle "Z" strut is shown in the "Z" strut's relaxed or unconstrained position 2102. The most compressed "Z" strut is shown in the "Z" strut's compressed state 2100. And, the most spread out "Z" strut is shown in the "Z" strut's stretched state 2101. In some embodiments, the "Z" structure of the struts can advantageously allow

each segment of the stent to independently articulate under loads, such as in bending. When the stent is bending, the top of the “Z” joint is in tension (e.g., absorbed by stretched state 2101) and the bottom of the arch is in compression (e.g., absorbed by compressed state 2011).

[0072] Currently available venous implants often lack the appropriate radial force necessary to resist compression and recoil of scarred, diseased veins while providing sufficient flexibility to account for the tortuosity and physiology of the peripheral venous system. In some embodiments, a venous implant for treating ilio-femoral venous outflow obstruction, vein compression, and venous insufficiency disease and methods for deploying such an implant are provided. The implant may provide a high radial force along with flexibility along its length and may be manufactured from self-expanding Nitinol. The implant may have sufficient radial force to resist compression/recoil of the diseased vein while providing flexibility and fatigue resistance. Additionally, the implant includes sufficient radial force to resist compression/recoil of scarred, diseased vein, while providing flexibility to resist kinking and good fatigue resistance. In some embodiments, the vascular implant is self-expanding.

[0073] In some embodiments, an implant comprises a cylindrical, self-expanding stent (e.g., made of a shape-memory material, such as Nitinol) with individual circumferential stent frame/cell geometries joined by flexible bridge members. Repetition of such individual stent cells and flexible bridge members may make up the final diameter and total length of the stent. Figure 16 illustrates an exemplary “equation” for the creation of such a stent. As can be seen on the left side of the “equation,” a first single cell may be joined to a second single cell using two (or more) bridge members thereby forming a flexible construct. Multiple, if not many of these flexible constructs may be joined together to form a network. Alternatively, the flexible constructs may all be cut from a single tube. Figure 18 illustrates a network of flexible constructs formed of cells and flexible bridge members. Figure 17 illustrates a strut configuration that can give the resultant stent a high radial force. Flexible bridge members can be placed to join individual stent frame/cell geometries in alternate configurations resulting in different flexibility characteristics of the final stent. In some embodiments, the bridge members join the individual stent frame/cell geometry in a straight line continuous repeating pattern, as shown in Figure 18. In other embodiments, the bridge members can be placed at varying intervals or in a helical or multi-helical configurations. Figures 19A and 19B illustrate additional flexible bridge member geometries – Figure 19A is the same as Figure 19B except that it is shown flat while Figure 19B is shown as it would appear in a stent.

[0074] In some embodiments an implant is provided that has an expanded implantation size that may be selectively adjustable across a range of diameters. Figures 20A-20H illustrate various views of an implant manufactured from a super-elastic and/or shape memory tube (e.g., Nitinol) and laser cut with a series of engaging fingers or teeth. Figure 20A illustrates the implant flat and laid out, with interlocking fingers at opposite ends of the implant. Figure 20B illustrates a three-quarters view of the implant in its tubular conformation with at least some of the interlocking fingers being engaged. Figure 20C illustrates a side view of the implant (perpendicular to the implant's longitudinal axis) showing a close-up of the interlocking fingers. Figure 20D illustrates a front or top view of the implant. Figure 20E illustrates the implant prior to expansion, finger interlocking, and deployment (in this figure no fingers are interlocked). Figure 20F illustrates a top or front view of the implant showing the diameter prior to expansion/deployment (diameter D1). Figure 20G illustrates the implant after expansion, finger interlocking, and deployment (in this figure at least some fingers are interlocked). Figure 20H illustrates a top or front view of the implant showing the diameter after expansion/deployment (diameter D2). As can be seen, the diameter of the implant after deployment/expansion/interlocking of fingers (i.e., D2) is larger than the diameter of the implant before deployment/expansion/interlocking of fingers (i.e., D1).

[0075] To deploy the implant, the implant may be radially compressed/crimped to a smaller diameter for loading onto/into a delivery catheter. The implant may be crimped over a balloon on the inner core of the delivery system which may be later inflated to expand the coiled implant to the desired diameter. The engagement fingers are pre-configured at specific locations to allow discrete incremental expansion of the stent. In some embodiments, the implant can be expanded in 0.5mm increments. In some embodiments more than one implant may be joined together. For example, the ultimate length of the implant can be controlled by joining any desired number of individual adaptive diameter cells via flexible or rigid bridge members.

[0076] Implants such as those described above may be advantageously provide an adaptive diameter and/or flexibility to conform the dynamic movement of peripheral veins in leg/pelvis thereby facilitating treatment of both iliac vein compression syndrome and ilio-femoral venous outflow obstructions.

[0077] It may be desirable to have a stent that will conform to the existing path of a vein instead of a straightening out of the vessel by the stent. It may also be desirable to have

a high radial stiffness of the stent to resist collapse of the stent under crushing load and to maximize the resultant diameter of the treated vessel at the location of the stent deployment. With most stent constructions there is a direct relationship between radial stiffness and axial stiffness.

[0078] Common commercially available balloon expandable stents experience a dramatic change in length as a balloon is used to expand the stent within the vessel. Common commercially available self-expanding stents experience a change in length less dramatic, but still substantial, which increases with increasing stent length. Change in length between the configuration within the delivery system and when deployed in the vessel causes difficulty in placing/landing the stent precisely at the target location. When the stent is deployed in its crimped configuration and expanded, the shortening in length causes the stent target deployment location to have to offset from the target dwell location. The magnitude of this effect is not controllable or easily anticipated as it is dependent on the luminal cross-section along the length of the target dwell location (which is frequently and unexpectedly influenced by residual stenosis, irregular shape due to external objects, and/or forces, etc.). For target lesions leading up to the junction of the left and right iliac into the IVC, this causes difficulty in placing the stent to dwell completely within the iliac along its total length up to the junction to the inferior vena cava without crossing into the inferior vena cava.

[0079] In some embodiments a venous stent with high radial force, no impactful foreshortening along multiple lengths, and high flexibility/vessel conformity is provided. Minimization of foreshortening allows the stent advantageously accurate and predictable deployment. And, high flexibility maximizes the fatigue life of the stent under bending. Of course, it will be understood that the stent may find applications in the arterial system as well.

[0080] Figures 21A-21D illustrate various views of an embodiment of a stent configured to minimize foreshortening while retaining flexibility. The stent 100, which may be self-expanding, consists of a series of circumferentially adjacent closed cells 200 that define at least two axially repeating rings 301. Each axially repeating ring 301 has an inner diameter 101, an outer diameter 103, and a length 203. Each ring is connected by pairs of linkage struts 202 with the total length of the repeating rings 102 and linkage struts 202 defining the length of the stent. In some embodiments, the closed cells 200 may be defined by an enclosed perimeter.

[0081] The linkage struts 202 attach to the rings 301 at or near the attachment of each adjacent closed cell 202 in the ring 301. In this way, the linkage struts 202 are connected

to portions of the rings 301 that never change axially upon compression or expansion of the ring – this advantageously improves the foreshortening properties of this stent. In some embodiments, the linkage struts 202 are configured in pairs to mirror each other on opposite sides of the stent 303 when the flat laser-cut pattern (shown in Figure 21B) is cut into a tube as in Figures 21A & 21C. In some embodiments, adjacent linkage struts 202 are positioned with at least one axially indexed cell rotation around the axis creating a spiral orientation of linkage struts 202 connecting the rings 301.

[0082] The stent has a first unconstrained/uncompressed configuration, shown in Figure 21A, that is defined by a first diameter 101 and a first length 102. The stent also has a second crimped configuration, shown in Figure 21D, that is defined by a second diameter 401 (that is less than the first diameter 101) and a second length 402. Because the linkage struts 202 are attached only at points on the rings 301 that do not move axially, the first length 102 and the second length 402 are substantially the same. There is only very little change in length only from the 1st half and trailing cell. In some embodiments, the length of the struts prevents contact of the cells in axially adjacent rings from making contact in the first unconstrained/uncompressed configuration and the second crimped configuration. In some embodiments, the spacing between the joining of the cells in the unconstrained state at the first end 104 and second end 105 substantially equals the spacing between the joining of the cells in the crimped state at the first end 404 and the second end 405. In some embodiments, there is a radiopaque marker at the joining location of the cells at the first end 104, 404 and second end 105, 405.

[0083] Some embodiments disclosed herein, such as those shown in Figures 21A-21D, decouple the relationship between radial stiffness and axial stiffness through their configuration of individual one cell long rings fixed together at the joining of the cells of each ring through the linkage struts. This allows for maintenance of controlled spacing by the linkage strut between the joined rings along a pathway but gives them the freedom to orient with the axis of one ring being different than the axis of the adjacent rings. The individual rings, with a relatively low axial flexibility, orient themselves largely straight along their individual length with the bending happening substantially along the linkage struts which are characterized by a much higher axial flexibility. Therefore, radial force can be controlled by the width of the cell struts and kept independent of the axial flexibility that is controlled by the width of the linkage struts. Additionally, the axially rotated indexing position of each adjacent

pair of linkage struts, creating a spiral orientation of linkage struts, ensures that the stent has substantially similar axial flexibility regardless of angular orientation around its axis.

[0084] With each cell connected at the attachment of the struts, there is no change in position of one cell to the adjacent cells when the stent is fully crimped and when it's fully unconstrained. Therefore, the only foreshortening of the stent would come from half of the leading cell and half of the trailing cell. Also, the foreshortening of the presented invention is the same regardless of stent overall length given equally configured cells (increasing length by adding more rings). When the presented invention is deployed into the iliac-inferior vena cava (as discussed above), the location of the stent within the delivery system will equal the location of the stent when deployed from the delivery system into the vessel. The positioning and deployment of the stent will be the same regardless of the stent length. Therefore, a marker located at the connection of the cells/attachment of the struts can give excellent visualization and indication of the position of the stent when in the delivery system and when deployed in the vessel.

[0085] Currently available implants are typically loaded and retained onto a delivery system in a crimped configuration and then navigated and deployed in the desired anatomical location where they expand to the implanted configuration. The final implanted configuration can be achieved through mechanical expansion/actuation (e.g., balloon-expandable) or self-expansion (e.g., Nitinol). Self-expanding implants are manufactured from super elastic or shape memory alloy materials. Accurate and precise deployment of a self-expanding implant can be challenging due to a number of inherent design attributes associated with self-expanding implants. The implant may jump/advance from the distal end of the delivery system during deployment due to the stored elastic energy of the material. Additionally, the implant may foreshorten during deployment due to the change in the implant diameter from the crimped configuration to the expanded configuration. Finally, physiological and anatomical configurations, such a placement at or near bifurcations of body lumens, can affect accurate placement of implants. Once the implant is placed within the body lumen there is potential for uneven expansion or lack of circumferential implant apposition to the body lumen which can result in movement, migration or in certain severe cases implant embolization.

[0086] In some embodiments, a self-expanding implant designed with sufficient radial force to resist constant compression of the body lumen while providing optimal fatigue resistance, accurate placement, and in-vivo anchoring to prevent is provided. Additionally,

various methods for deployment and implantation for treating iliac vein compression syndrome and venous insufficiency disease are provided.

[0087] In some embodiments, the implant comprises a purposely designed venous implant intended to focally treat iliac vein compression (May-Thurner Syndrome). The implant may be relatively short in length (~40mm) and may be manufactured from self-expanding Nitinol with integrated anchor features to aid in accurate placement and to mitigate migration following implantation. The implant and delivery system are designed for precise deployment and placement at the bifurcation of the inferior vena cava into the right and left common iliac veins.

[0088] Figures 22A-22E illustrate various views of an intravascular stent having a plurality of anchor members. Figure 22A illustrates the stent in a substantially cylindrical configuration. Figure 22B illustrates the stent in a flat, laser cut pattern. Figures 22C and 22D illustrate the stent in a substantially uncompressed state. Figure 22E illustrates the stent implanted within the left common iliac vein at the bifurcation of the inferior vena cava.

[0089] In one embodiment, the stent comprises a cylindrical self-expanding Nitinol structure with anchor features integrated into the stent frame cell pattern that are heat set into an angled configuration, thus resulting in anchor features circumferentially protruding outward from the base diameter of the stent when deployed. When the stent implant is crimped and loaded into a delivery catheter the anchors are constrained by the outer sheath of the delivery catheter thus allowing them to be flush with the base diameter of the stent.

[0090] As can be seen in Figure 22B, the first set of anchor features may be set back a distance DIM 'A' from the distal end of the stent, thus allowing the stent to be partially deployed from the delivery system allowing the operator to finely reposition the entire delivery system as necessary such to align the distal end of the implant at the target deployment location. Once the distal end of the partially deployed stent is in the appropriate deployment location, the remainder of the stent can be deployed and the anchor features will engage the vessel wall upon deployment from the delivery catheter.

[0091] The anchor features may aid in accurate and precise deployment at the target implantation location of the stent. For example, engagement of the anchor features in the vessel wall may mitigate jumping of the implant from the delivery system and missing the target implantation location due to the expansion energy from self-expanding implants. Moreover, distal to proximal engagement of the anchor features in the vessel wall during

deployment may serve to mitigate foreshortening of the implant in the distal-to-proximal direction. As the distal end of the implant is first anchored against the vessel wall the implant can only foreshorten in the proximal-to-distal direction during deployment as the distal end of the implant is fixed/anchored against the vessel wall. And, following implantation of the stent, the anchor features may help mitigate migration of the implant.

[0092] Figures 23A-23F show various potential configurations of anchors that may be used with the intravascular stent of Figures 22A-22E.

[0093] In another embodiment, shown clearly in Figures 22C and 22D, the implant with anchor features consists of a cylindrical self-expanding Nitinol stent with distal flared section. The distal flared section is controlled by radius 'r'. The flared distal end of the stent may be used for placement of the stent at a bifurcation of two vessels as shown in Figure 22E.

[0094] The pre-loaded stent configuration on the delivery system allows the distal flared section of the stent to be partially deployed from the delivery system allowing the operator to position the flared section of the stent at the bifurcation of two vessels. The delivery catheter is advanced distal to the vessel bifurcation to be treated, in this case the left common iliac vein. Using the radiopaque markers on the implant, the operator can seat the partially deployed flare section of the stent at the bifurcation junction. Once the distal flared end of the partially deployed stent is in the appropriate deployment location and seated at the bifurcation junction the remainder of the stent can be deployed and the anchor features can engage the vessel wall upon deployment from the delivery catheter.

[0095] The implant shown in Figures 22A-23F may advantageously facilitate accurate and precise deployment of the stent implant, prevent migration of the stent implant following deployment, and mitigate protuberance of the stent implant into the inferior vena cava (causing hemodynamic insufficiencies) when treating iliac vein compression syndrome (May-Thurner syndrome).

[0096] Although this invention has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In addition, while a number of variations of the invention have been shown and described in detail, other modifications, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that

various combinations or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the invention. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed invention. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

[0097] Similarly, this method of disclosure, is not to be interpreted as reflecting an intention that any claim require more features than are expressly recited in that claim. Rather, as the following claims reflect, inventive aspects lie in a combination of fewer than all features of any single foregoing disclosed embodiment. Thus, the claims following the Detailed Description are hereby expressly incorporated into this Detailed Description, with each claim standing on its own as a separate embodiment.

[0098] While various embodiments of the present invention have been described above, it should be understood that they have been presented by way of example only, and not limitation. It will be apparent to persons skilled in the relevant art that various changes in form and detail can be made therein without departing from the spirit and scope of the present invention. Thus, the breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents.

WHAT IS CLAIMED IS:

1. A radially expandable, tubular stent, comprising:
 - a first section having a first crush resistance force and a second section have a second crush resistance force, wherein the first crush resistance force is less than the second crush resistance force; and
 - the first section connected to the second section to form a tube, connection of the first and second sections extending in an axial direction of the tube.
2. The radially expandable, tubular stent of claim 1, wherein the first section has less resistance to deformation than the second section.
3. The radially expandable, tubular stent of claim 1, the stent comprising two first sections and two second sections connected to form the tube.
4. The radially expandable tubular stent of claim 3, wherein the first sections are between the second sections such that second sections are separated from each other by a first section and the first sections are separated from each other by a second section.
5. The radially expandable, tubular stent of claim 4, wherein the first sections are symmetrical about a first axis and the second sections are symmetrical about a second axis, the first and second axes being axes of a cross section of the tube substantially perpendicular to the axial direction of the tube.
6. The radially expandable, tubular stent of claim 5, wherein a length of the first axis is greater than a length of the second axis.
7. The radially expandable, tubular stent of claim 4, wherein the first sections are bilaterally asymmetrical about a first axis and the second sections are bilaterally asymmetrical about a second axis, the first and second axes being axes of a cross section of the tube substantially perpendicular to the axial length of the tube.

8. The radially expandable, tubular stent of claim 0, wherein a length of the first axis is greater than a length of the second axis.
9. The radially expandable, tubular stent of claim 1, wherein the first section comprises at least one weak strut, each weak strut having a partially collapsed state and a collapsed state, and wherein each second section comprises a plurality of strong struts, each strong strut having a partially collapsed state and a collapsed state, wherein a force required to collapse each strong strut is greater than a force to collapse each weak strut.
10. The radially, expandable, tubular stent of claim 9, wherein the at least one weak strut does not make contact with another weak strut when the weak struts are in an unconstrained state.
11. The radially, expandable, tubular stent of claim 9, wherein the at least one weak strut do not make contact with another weak strut when the weak struts are in a fully compressed state.
12. The radially expandable, tubular stent of claim 9, comprising more strong struts than weak struts.
13. The radially expandable, tubular stent of claim 1, wherein the first section comprises at least one weak strut, each weak strut having a partially collapsed state and a collapsed state, and wherein each second section comprises a plurality of strong struts, each strong strut having a partially collapsed state and a collapsed state, and wherein an individual strut crush resistance force of each weak strut is greater than an individual strut crush resistance force of each strong strut.
14. The radially expandable, tubular stent of claim 1, further comprising and angled distal end.
15. The radially expandable, tubular stent of claim 1, wherein the angle of the distal end is generally in the range of 5°-45°.

16. The radially expandable, tubular stent of claim 1, wherein the angle of the distal end is generally in the range of 10°-40°.
17. The radially expandable, tubular stent of claim 1, wherein the angle of the distal end is generally in the range of 15°-35°.
18. The radially expandable, tubular stent of claim 1, wherein the angle of the distal end is generally in the range of 20°-25°.
19. The radially expandable, tubular stent of claim 1, wherein the angle of the distal end is about 25°.
20. The radially expandable, tubular stent of claim 1, wherein the angle of the distal end is an angle necessary to fit a patient's vasculature.
21. A radially expandable, tubular stent, comprising:
a plurality of circumferentially adjacent closed cells defining at least two axially repeating rings; and
a plurality of linkage struts connecting respective ones of the circumferentially adjacent closed cells, wherein the plurality of linkage struts is fewer than the plurality of linkage struts such that fewer than the plurality of circumferentially adjacent closed cells in adjacent rings are connected by a linkage strut.
22. The radially expandable, tubular stent, of claim 21, wherein the linkage struts are configured in pairs on opposite sides of a respective ring.
23. The radially expandable tubular stent of claim 21, wherein adjacent ones of the linkage struts are positioned with at least one axially indexed cell rotation around an axis of a respective ring, thereby creating a spiral orientation of the linkage struts.

24. The radially expandable tubular stent of claim 21, wherein the linkage struts are configured to provide predetermined flexibility along the length of the stent.
25. The radially expandable tubular stent of claim 24, wherein the flexibility varies along the length of the stent.
26. An implant, comprising
- a self-expanding stent having varying flexibility along its length, comprising:
 - a first plurality of individual stent cells; and
 - a plurality of flexible bridge members
 - wherein at least one first cell of the stent cells is joined to a second cell of the stent cells by at least one of the flexible bridge members, thereby forming a flexible construct; and
 - wherein a second plurality of the individual stent cells are not joined to any other stent cells by one of the flexible bridge members, the second plurality of the individual stent cells fewer than the first plurality of individual stent cells.
27. The implant of claim 26, wherein a total length of the stent comprises the lengths of the individual stent cells and the lengths of the flexible bridge members

1/20

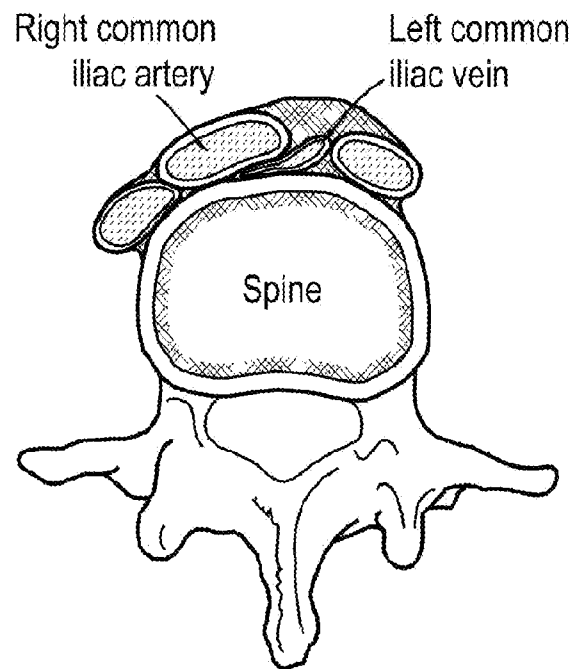


FIG. 1

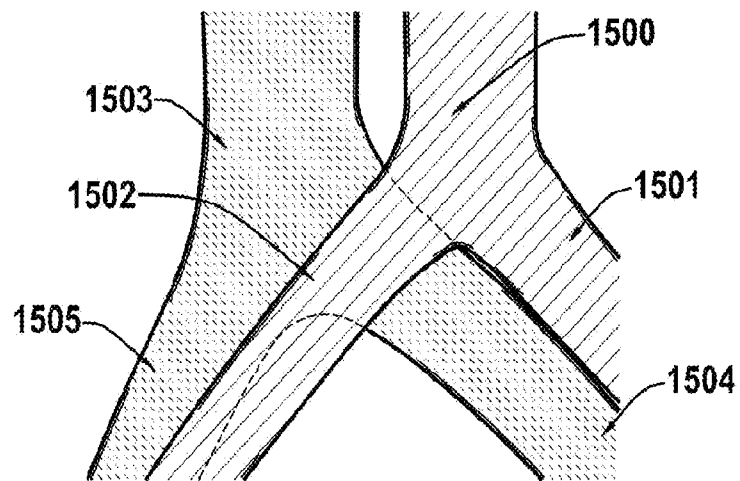


FIG. 2

2/20

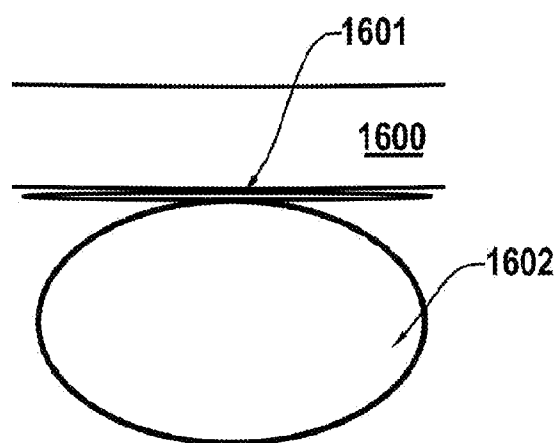


FIG. 3

3/20

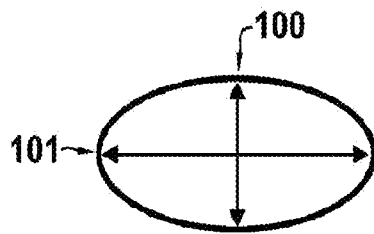


FIG. 4A

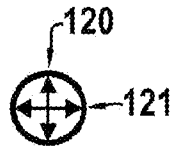


FIG. 4B

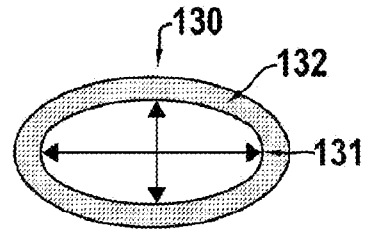


FIG. 4C

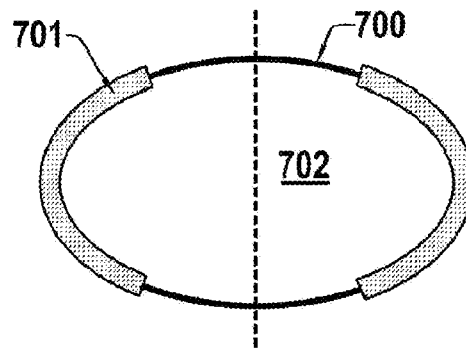


FIG. 5A

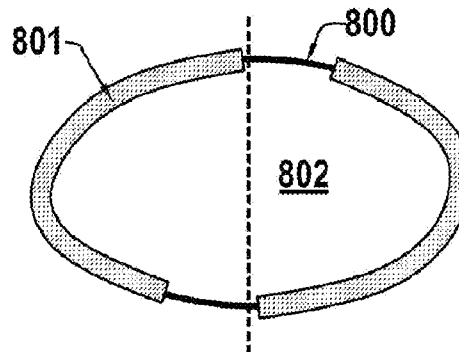


FIG. 5B

4/20

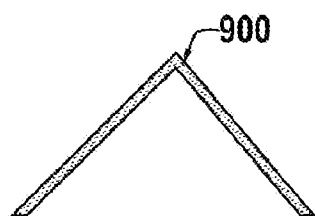


FIG. 6A

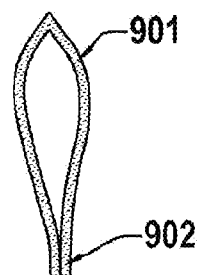


FIG. 6B

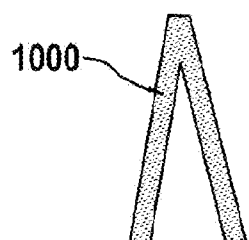


FIG. 7A

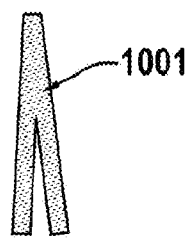


FIG. 7B

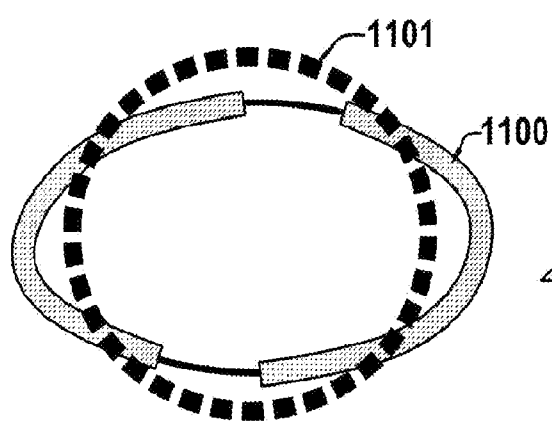


FIG. 8A



FIG. 8B



FIG. 8C

5/20

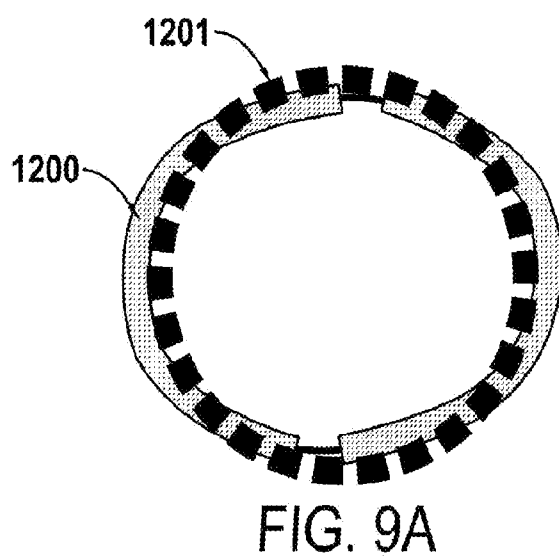


FIG. 9B



FIG. 9C

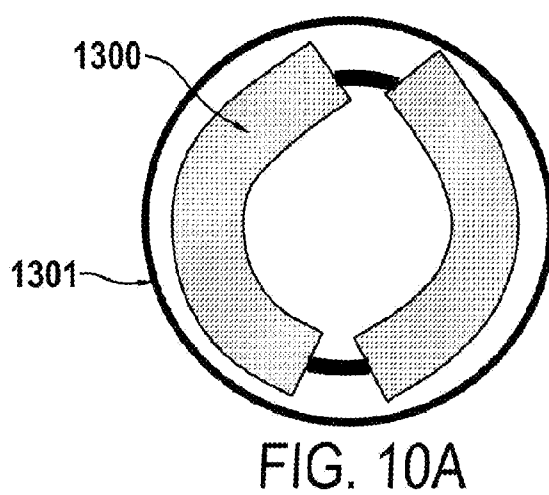


FIG. 10B

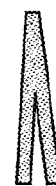


FIG. 10C

6/20

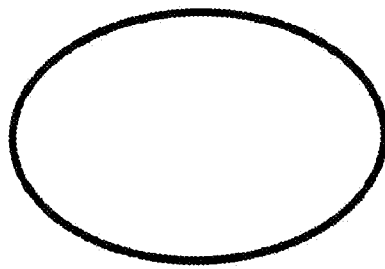


FIG. 11A

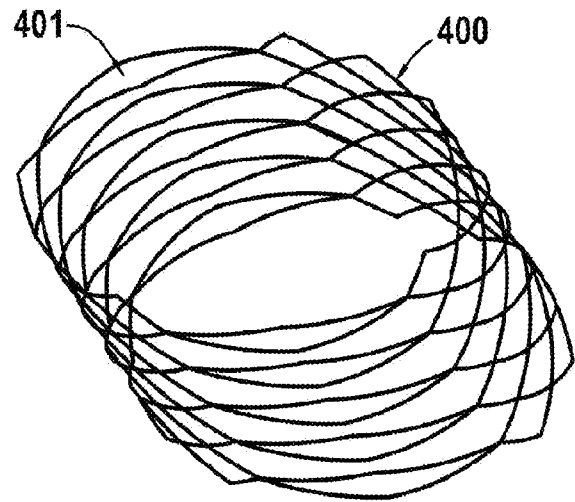


FIG. 11B

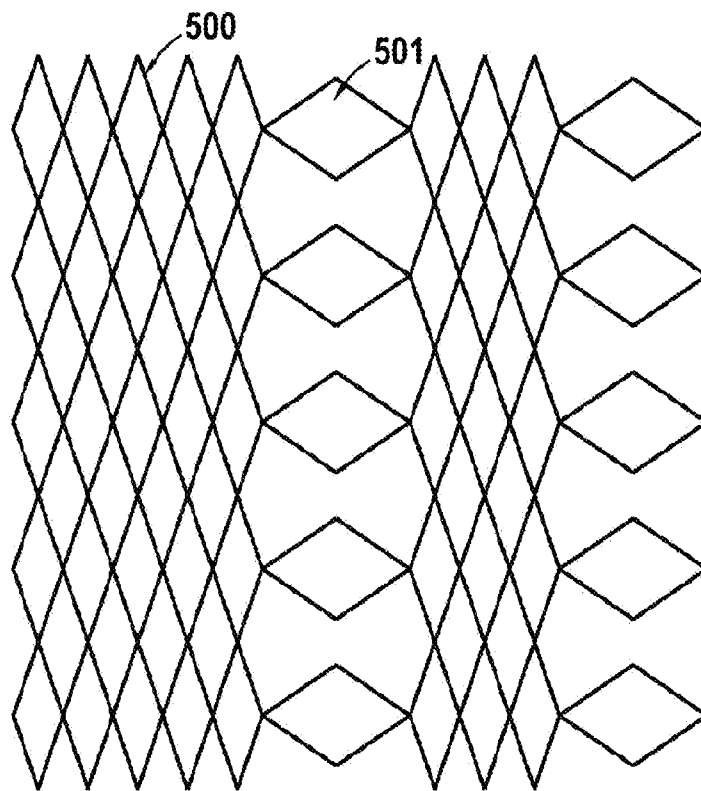


FIG. 11C

7/20

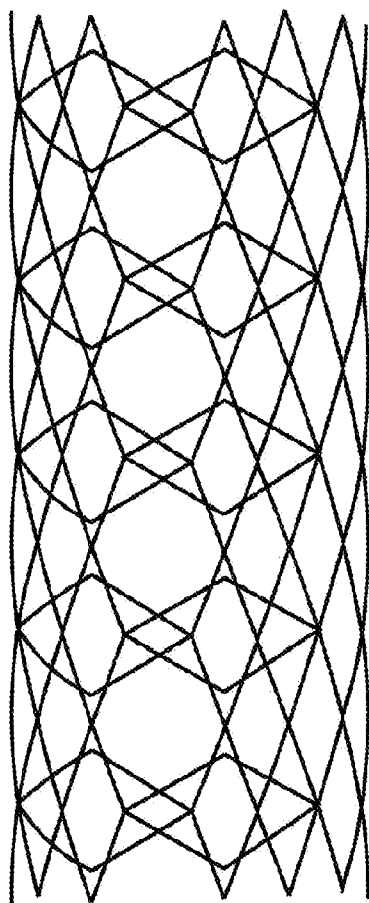


FIG. 11D

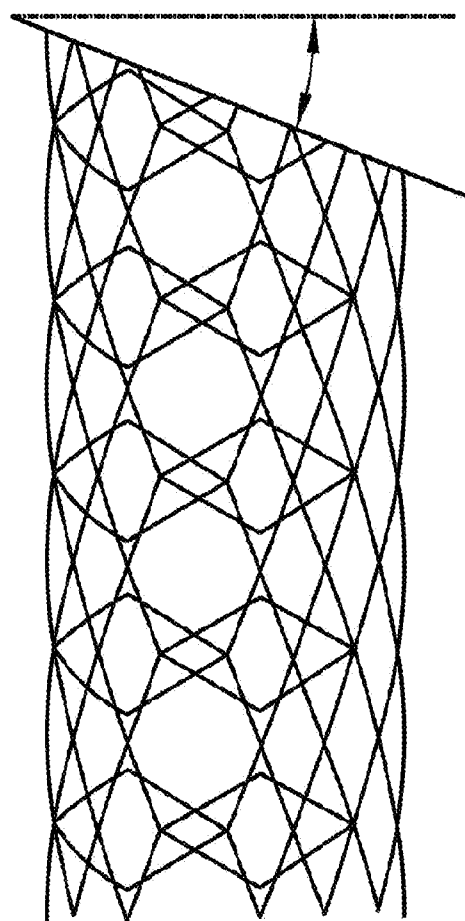


FIG. 11E

8/20

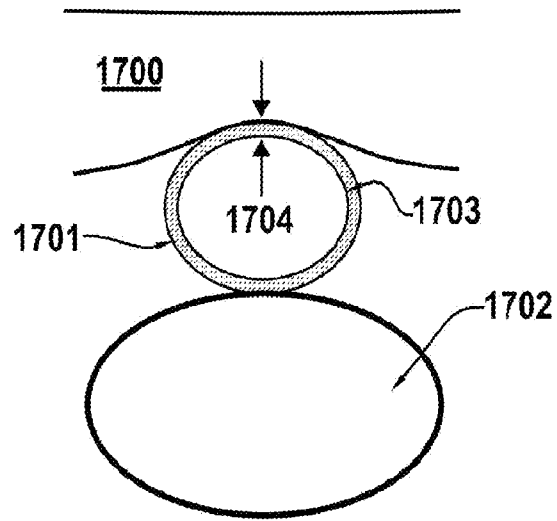


FIG. 12

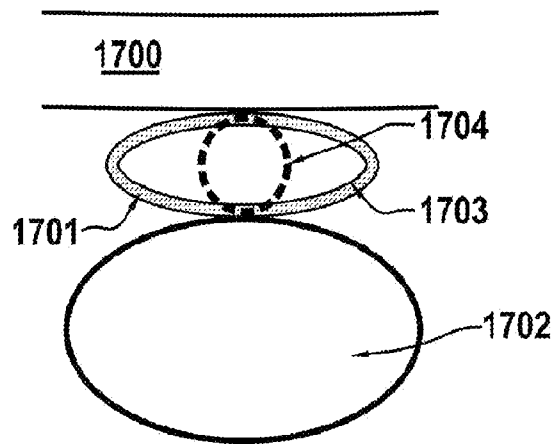


FIG. 13

9/20

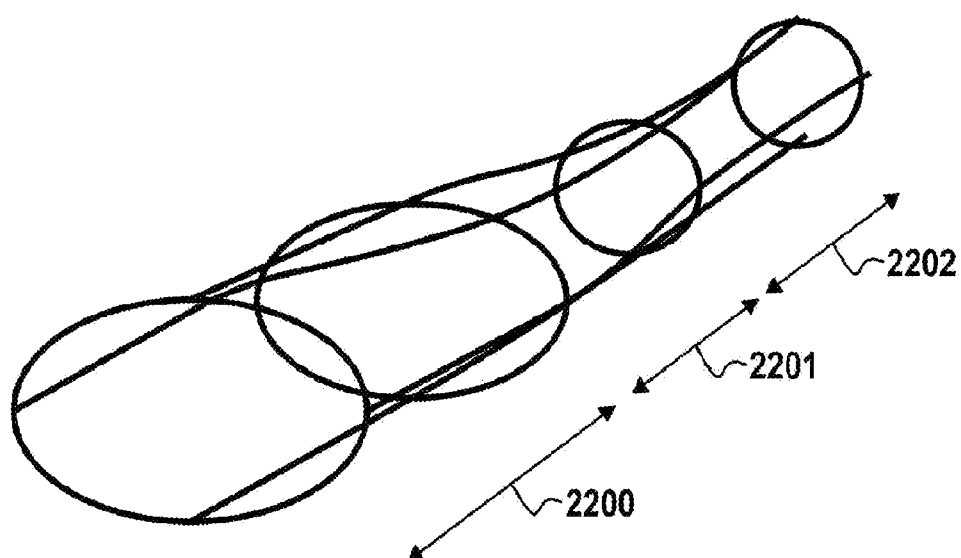


FIG. 14

10/20

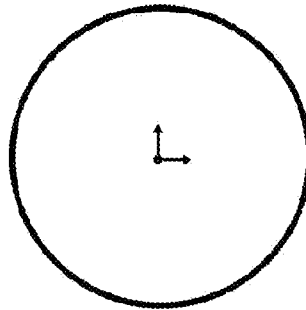


FIG. 14A

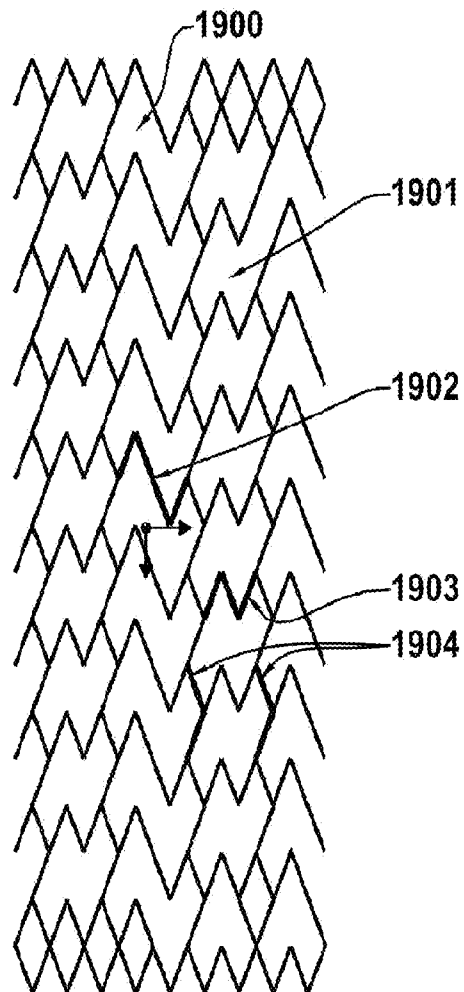


FIG. 14B

11/20

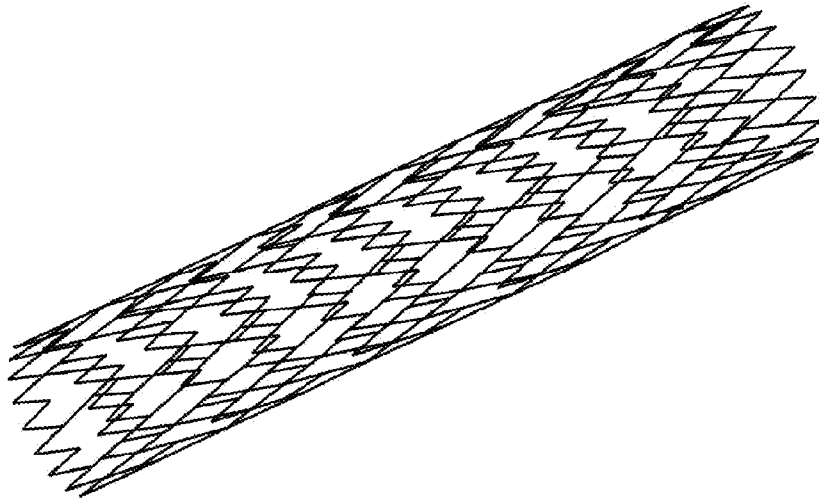


FIG. 14C

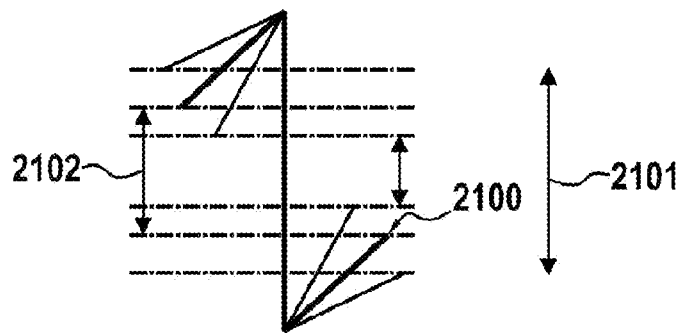


FIG. 15

12/20

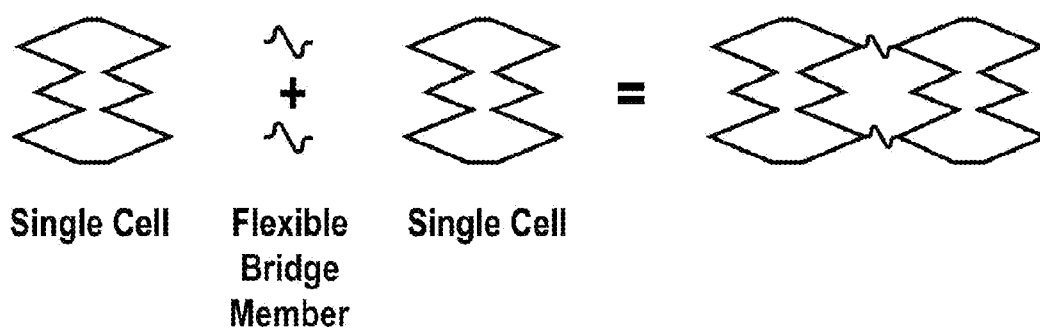


FIG. 16

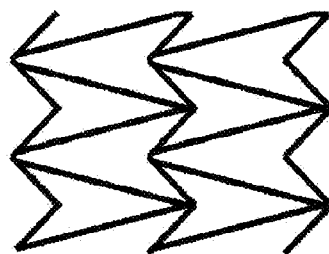


FIG. 17

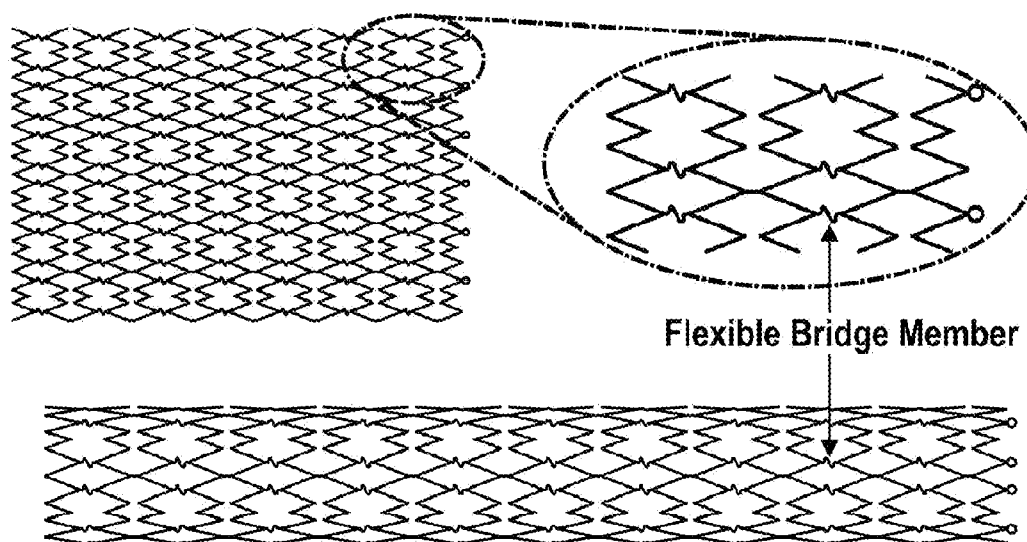


FIG. 18

13/20

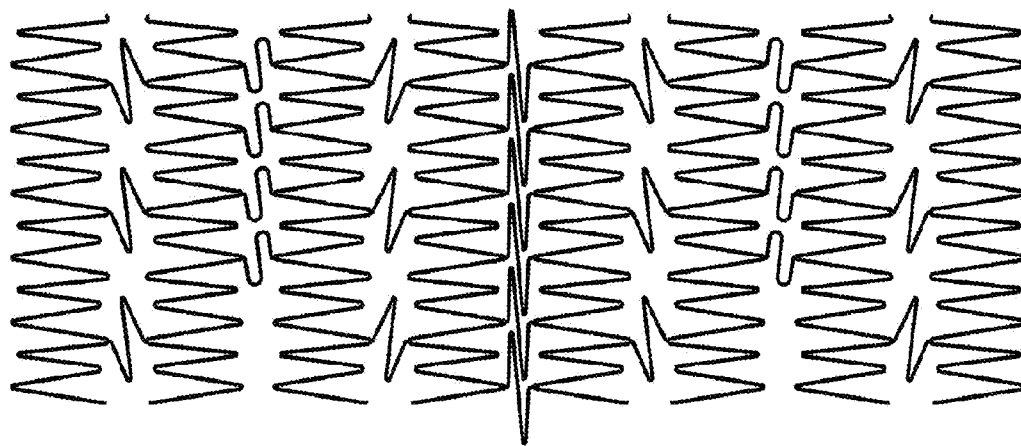


FIG. 19A

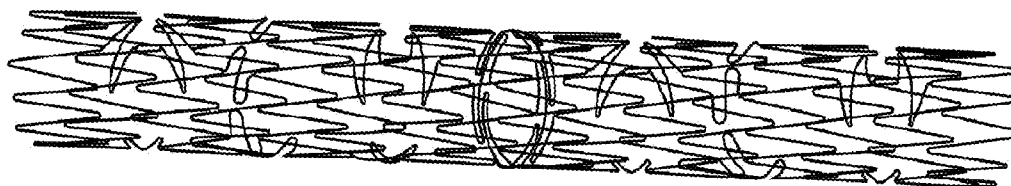


FIG. 19B

14/20

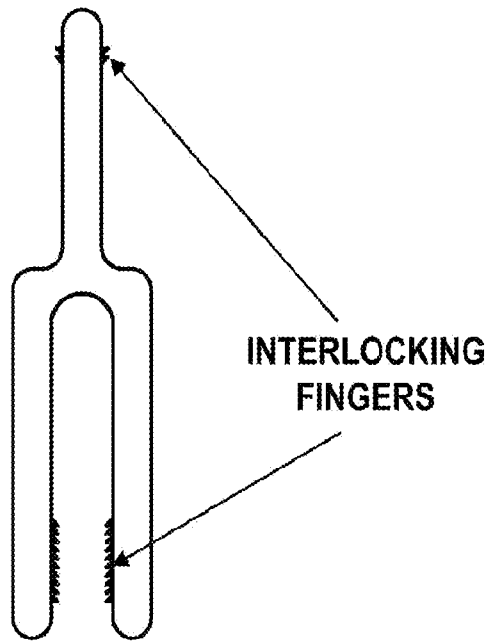
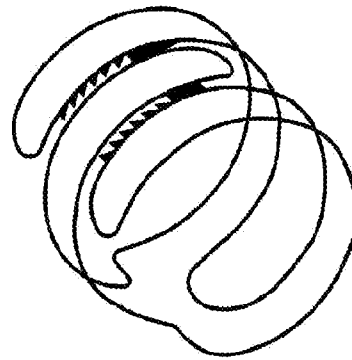
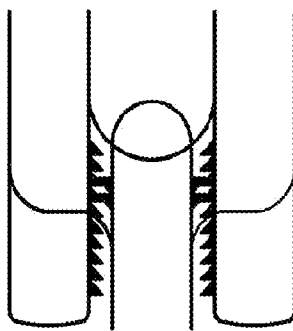


FIG. 20A



TUBE VIEW

FIG. 20B



FRONT AND SIDE VIEW

FIG. 20C

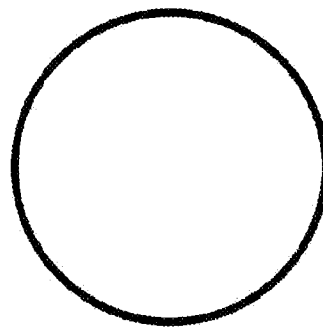
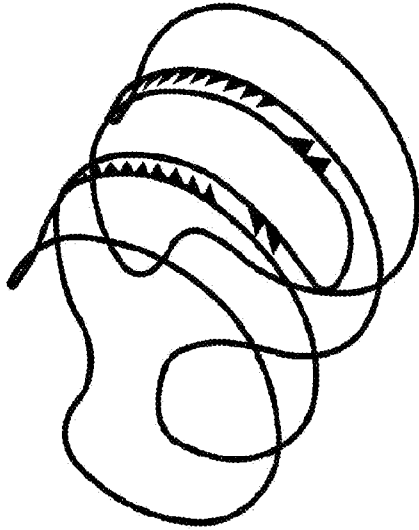


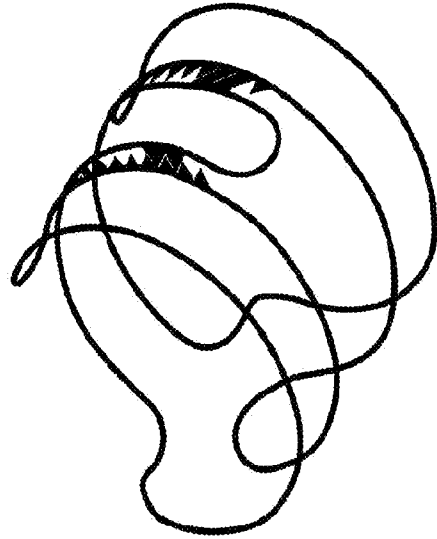
FIG. 20D

15/20



Diameter 1
(no finger engagement)

FIG. 20E



Diameter 2

FIG. 20G

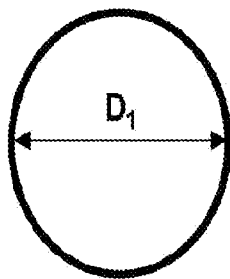


FIG. 20F

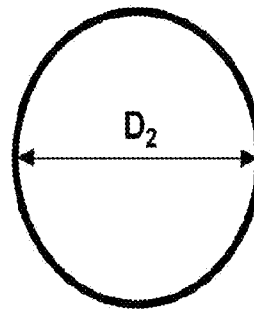


FIG. 20H

16/20

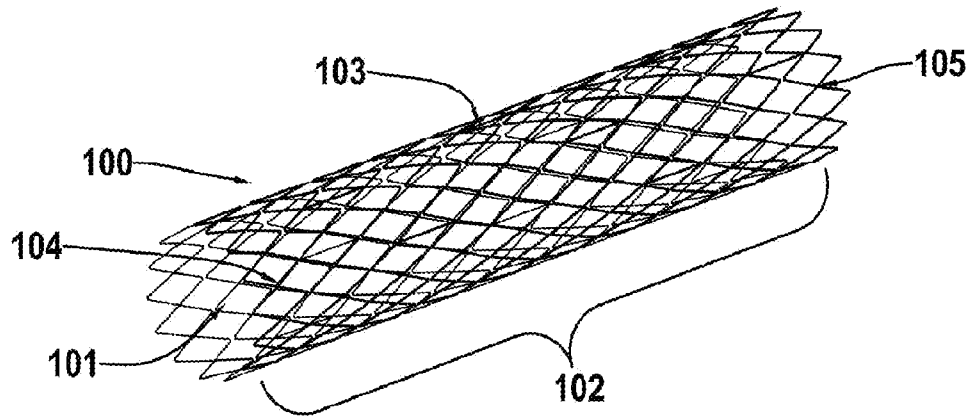


FIG. 21A

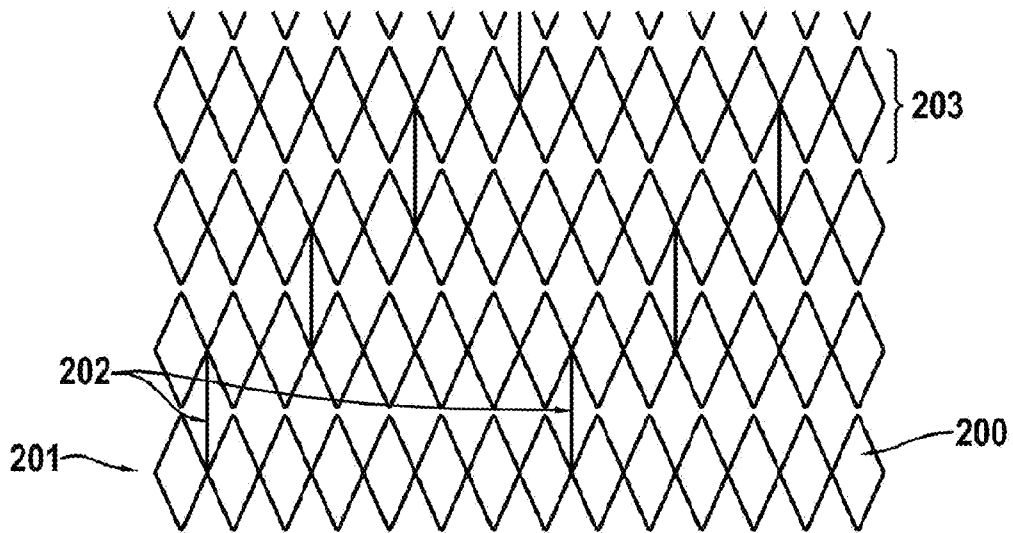


FIG. 21B

17/20

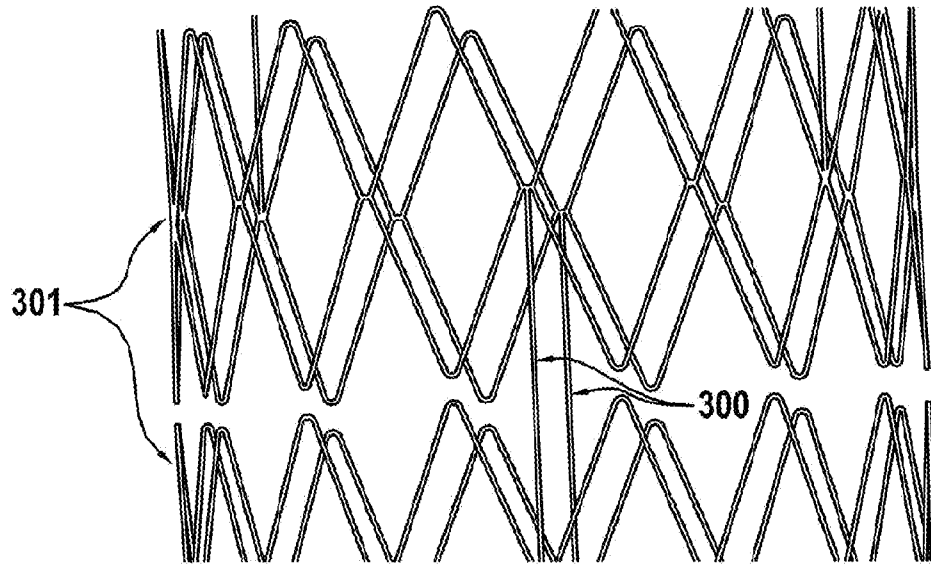


FIG. 21C

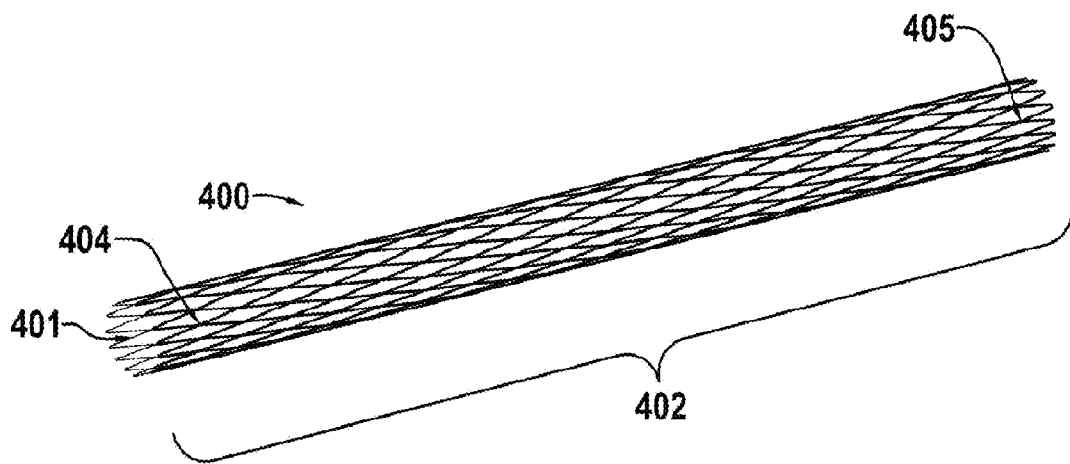


FIG. 21D

18/20

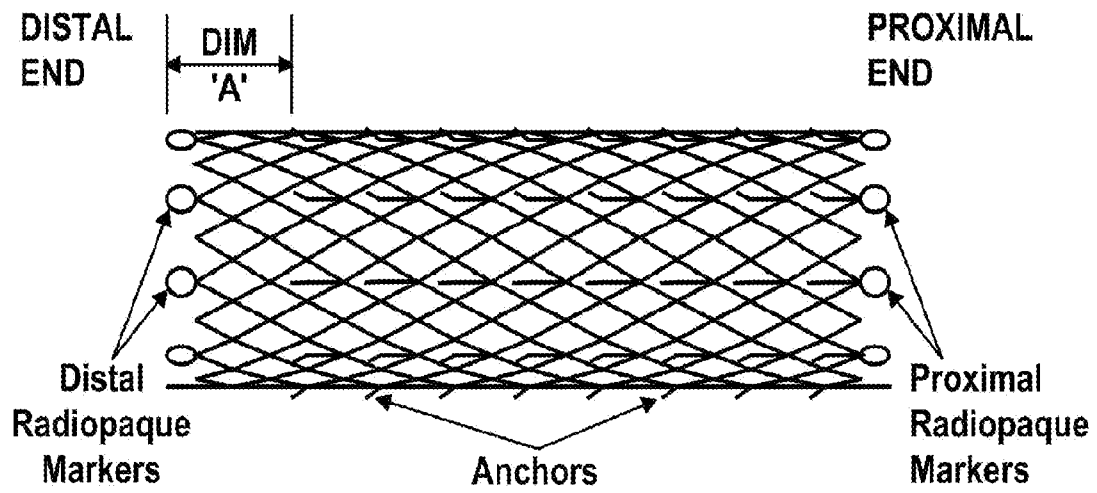


FIG. 22A

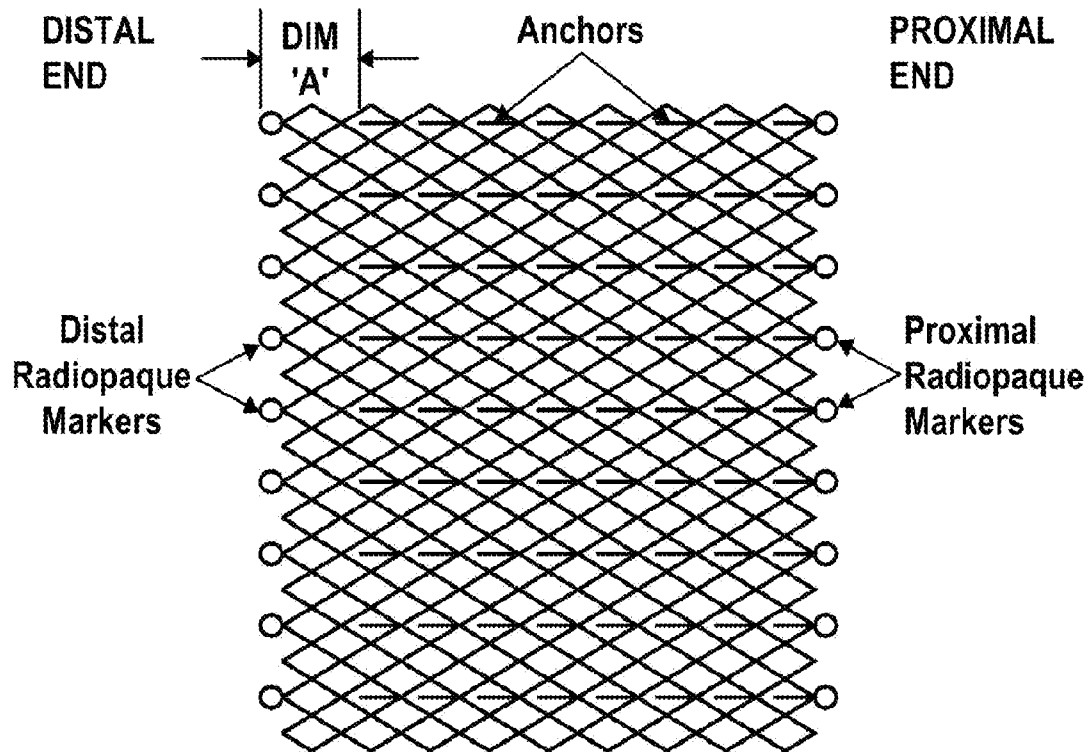


FIG. 22B

19/20

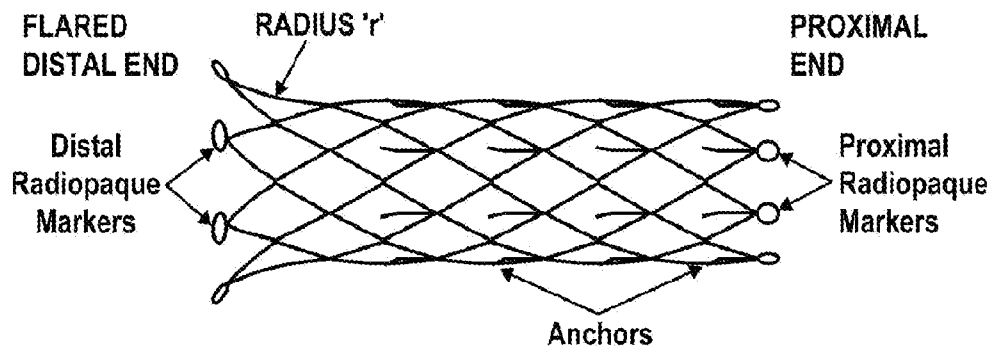


FIG. 22C

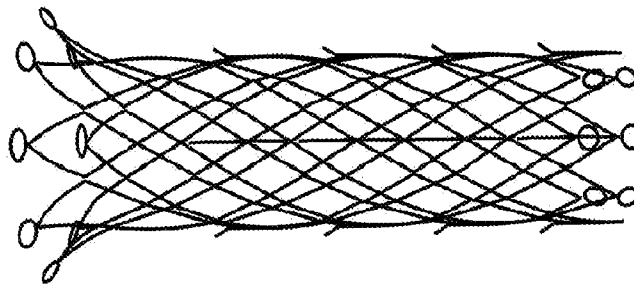


FIG. 22D

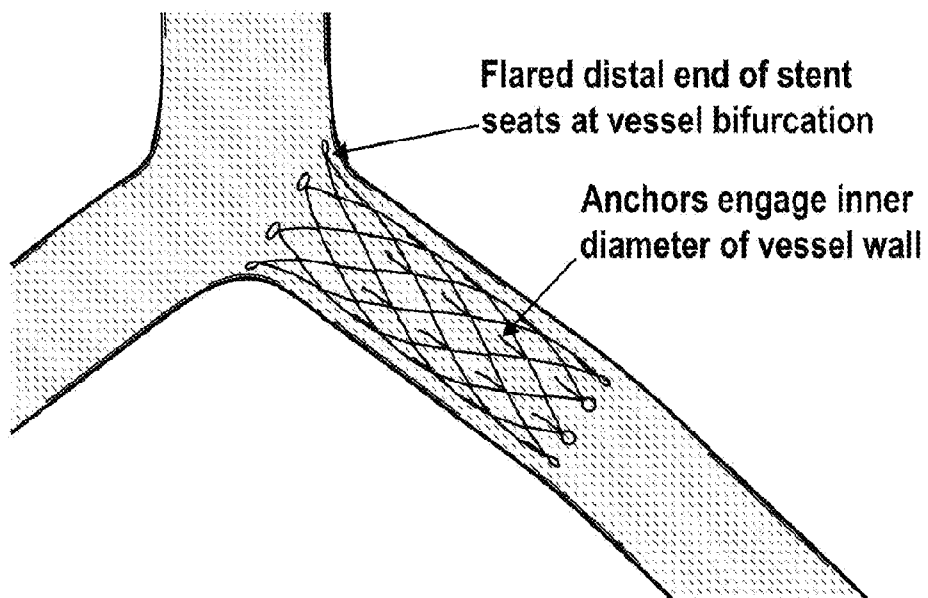
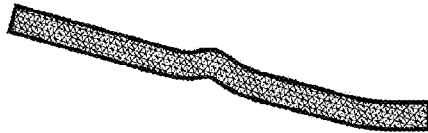
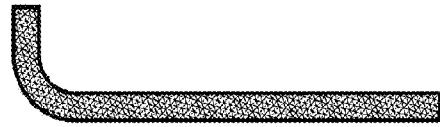


FIG. 22E

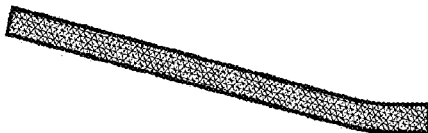
20/20



CONFIG 1
FIG. 23A



CONFIG 4
FIG. 23D



CONFIG 2
FIG. 23B



CONFIG 5
FIG. 23E



CONFIG 3
FIG. 23C



CONFIG 6
FIG. 23F

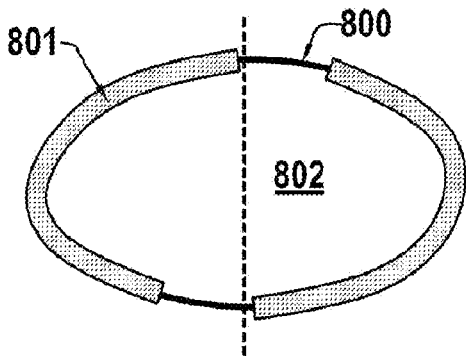


FIG. 5B