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[Continued on next page]

(54) Title: TAPERED STENT AND FLEXIBLE PROSTHESIS

(57) Abstract: A stent (51) has parallel first and second longitudinal regions (53, 54) with struts (55) and circumferentially connecting the first region and the second region. The first region (53) has a longitudinal length that is greater than the second region (54) longitudinal length and the struts (55) have varying longitudinal lengths that gradually decrease from the first region to the second region. A flexible prosthesis (50) comprises at least two alternating tapered stents.

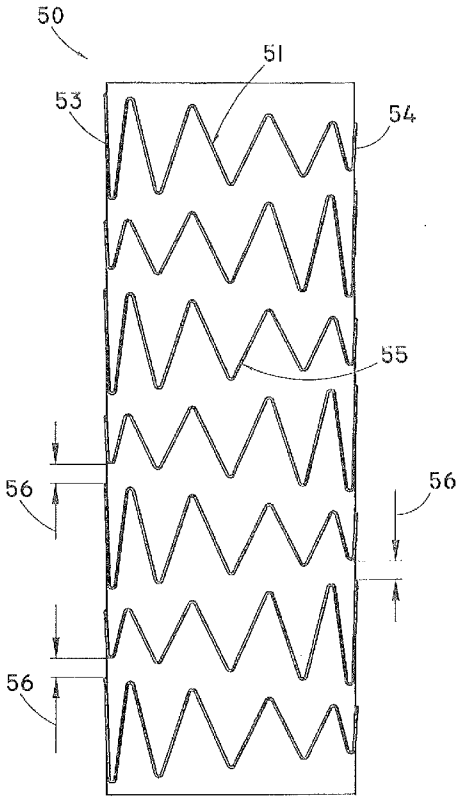

FIG. 5

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TAPERED STENT AND FLEXIBLE PROSTHESIS

Description

Background

Aneurysms occur in blood vessels in locations where, due to age, disease or genetic predisposition, insufficient blood vessel strength or resiliency may cause the blood vessel wall to weaken and/or lose its shape as blood flows through it, resulting in a ballooning or stretching of the blood vessel at the limited strength/resiliency location, thus forming an aneurysmal sac. Left untreated, the blood vessel wall may continue to expand to the point where the remaining strength of the blood vessel wall is insufficient and the blood vessel will fail at the aneurysm location, often with fatal result.

To prevent rupture, various implantable prostheses may be introduced into the blood vessel. Minimally invasive methods for implantation of these prostheses have been developed to deliver these prostheses within the lumen of a body vessel. These prostheses are advantageously inserted intravascularly, such as from an implantation catheter. For example, to prevent rupture of an aneurysm, a tubular stent graft may be introduced into the blood vessel and deployed and secured in a location within the blood vessel such that the stent graft spans the aneurysmal sac. The outer surface of the stent graft, at its opposed ends, abuts and seals against the interior wall of the blood vessel at a location where the blood vessel wall has not suffered a loss of strength or resiliency. U.S. Patent Nos. 6,423,084 and 7,060,091 disclose stents having varying outward radial force along their length to provide greater force in vessel regions requiring greater force and less force in regions requiring less. The stent graft channels the blood flow through the hollow interior of the stent graft, thereby reducing, if not eliminating, any stress on the blood vessel wall at the aneurysmal sac location.

One particular example of an aneurysm is a thoracic aortic aneurysm. The tortuous and hardened anatomy of a thoracic aortic aneurysm presents several challenges when implanting a prosthesis. Many current prostheses may

be limited in their ability to conform to the radial and tortuous curvature, possibly resulting in poor sealing at the proximal and/or distal portion of the prosthesis. Some prostheses designs incorporate features designed to improve the radial curvature and conformability of the prosthesis when used in a directionally constrained fashion. For example, U.S. Patent Application No. 2002/0052644 discloses a prosthesis having a support structure including sliding links to permit flexibility. While the directional constraint may provide improved conformance, the same directional constraint makes the prosthesis more difficult to properly deploy in the thoracic aorta with a possibly increased risk of nonconformance should the directional features not line up with the appropriate radius (inner and outer).

Summary

In a first aspect, a stent for implantation in a body vessel is provided. The stent comprises a substantially annular element including a first longitudinal region and a second longitudinal region. The second longitudinal region is substantially parallel to and spaced radially apart from the first region. The first region has a longitudinal length that is greater than the second region longitudinal length. A plurality of struts is disposed intermediate the first region and the second region and circumferentially connects the first region and the second region. The struts comprise varying longitudinal lengths that gradually decrease from the first region to the second region. In one example, the stent may be a Z-stent. The stent may be an asymmetric tube having a continuously decreasing axially length from the first region to the second region.

In another aspect, the stent comprises substantially annular element comprising quadrants. The first and third quadrants are diametrically opposed to one another. The second and fourth quadrants are diametrically opposed to one another. The first quadrant may have a longitudinal length about equal to the third quadrant longitudinal length. The second quadrant has a longitudinal length about equal to the fourth quadrant longitudinal length. The first and third quadrant longitudinal lengths are greater than the second and fourth quadrant

longitudinal lengths. In one example, a plurality of struts comprising varying longitudinal lengths may circumferentially connect the first, second, third, and fourth quadrants.

In a further aspect, an intraluminal prosthesis comprises a graft having a proximal end, a distal end, and a body defining a lumen extending between the proximal end and the distal end. The body comprises at least a first tapered stent and a second tapered stent. The first and second tapered stents each have the general form of an annulus and each have a first region aligned along the circumference of the stent with a second region radially displaced from the first region. The first regions each have a longitudinal length greater than the longitudinal length of the second regions. A plurality of struts is disposed intermediate the first region and the second region and circumferentially connects the first region and the second region. The struts comprise varying longitudinal lengths that gradually decrease from the first region to the second region. In one example, the first region of the first stent is aligned with the second region of the second stent. The stents may be of any configuration. In one example, the stents are Z-stents. The stent may be an asymmetric tube having a continuously decreasing axial length from the first region to the second region.

Other systems, methods, features and advantages will be, or will become, apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, methods, features and advantages be included within this description, be within the scope of the disclosure, and be protected by the following claims.

Brief Description of the Drawings

The stent and stent-graft may be better understood with reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the disclosure. Moreover, in the figures, like referenced numerals designate corresponding parts throughout the different views.

FIG. 1A is a perspective view of one example of a tapered stent.

FIG. 1B is a perspective view of another example of a tapered stent.

FIG. 2A is a perspective view of a further example of a tapered stent.

FIG. 2B are perspective views of yet another example of a tapered stent.

FIG. 3 is a perspective view of an example of a tapered stent made from wire having a tapering diameter.

FIG. 4 depicts the tapered stent illustrated in **FIG. 3** viewed along the radial plane.

FIG. 5 is a perspective view of one example of a stent-graft incorporating tapered stents.

FIG. 6 is a schematic illustration of the stent-graft shown in **Fig. 5**.

FIGS. 7A and **7B** schematically depict the radial curvature possible for a stent-graft segment comprising alternating tapered stents.

FIG. 8A schematically depicts the radial curvature possible for a 3-tapered stent-graft segment comprising alternating tapered stents.

FIG. 8B schematically depicts the radial curvature possible for a 5-tapered stent-graft segment comprising alternating tapered stents.

FIGS. 9A – 9B schematically depict a radial curvature for a 3-tapered stent-graft segment comprising alternating tapered stents, assuming no stent overlap.

FIGS. 10A – 10B schematically depict a radial curvature for a 3-stent conventional stent-graft segment, assuming no stent overlap.

FIGS. 11A – 11B schematically depict a radial curvature for another 3-stent conventional stent-graft segment, assuming no stent overlap.

FIGS. 12A – 12B schematically depict a radial curvature for yet another 3-stent conventional stent-graft segment, assuming no stent overlap.

FIGS. 13A – 13B schematically depict a radial curvature for a 3-tapered stent-graft segment comprising alternating tapered stents, assuming stent overlap.

FIGS. 14A – 14B schematically depict a radial curvature for a 3-stent conventional stent-graft segment, assuming stent overlap.

FIGS. 15A – 15B schematically depict a radial curvature for another 3-stent conventional stent-graft segment, assuming stent overlap.

FIGS. 16A – 16B schematically depict a radial curvature for yet another 3-stent conventional stent-graft segment, assuming stent overlap.

FIG. 16C depicts the instability of the stent-graft segment shown in **FIGS. 16A – 16B**.

Detailed Description

The present disclosure provides for a tapered stent and flexible stent-graft for bridging a defect in a body vessel. Exemplary aspects are described below in reference to the stent-grafts application in connection with endovascular treatment of aneurysms and dissections, particularly thoracic aortic aneurysms. However, it is likewise applicable to any suitable endovascular treatment or procedure including, without limitation, endovascular treatment of abdominal aortic aneurysms and dissections.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention pertains. In case of conflict, the present document, including definitions, will control. Preferred methods and materials are described below, although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present disclosure. All publications, patent applications, patents and other references mentioned herein are incorporated by reference in their entirety. The materials, methods, and examples disclosed herein are illustrative only and not intended to be limiting.

Definitions

"Implantable" refers to an ability of a prosthetic implant to be positioned, for any duration of time, at a location within a body, such as within a body vessel. Furthermore, the terms "implantation" and "implanted" refer to the positioning, for

any duration of time, of a prosthetic implant at a location within a body, such as within a body vessel.

"Body vessel" means any body passage lumen that conducts fluid, including but not limited to blood vessels such as those of the human vasculature system, esophageal, intestinal, billiary, urethral and ureteral passages.

"Graft" means a member that acts as an artificial vessel. A graft by itself or with the addition of other elements can be an endoluminal prosthesis.

"Stent" means any device or structure that adds rigidity, expansion force, and/or support to a prosthesis.

"Stent graft" refers to a prosthesis comprising a stent and a graft associated therewith that forms a lumen through at least a portion of its length.

The terms "about" or "substantially" used with reference to a quantity includes variations in the recited quantity that are equivalent to the quantity recited, such as an amount that is insubstantially different from a recited quantity for an intended purpose or function.

"Proximal" means that position or portion of a component which is closest to the patient's heart.

"Distal" means that position of portion of a component which is furthest from the patient's heart.

"Biocompatible" refers to a material that is substantially non-toxic in the in vivo environment of its intended use, and that is not substantially rejected by the patient's physiological system (i.e., is non-antigenic). This can be gauged by the ability of a material to pass the biocompatibility tests set forth in International Standards Organization (ISO) Standard No. 10993 and/or the U.S. Pharmacopeia (USP) 23 and/or the U.S. Food and Drug Administration (FDA) blue book memorandum No. G95-1, entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing." Typically, these tests measure a material's toxicity, infectivity, pyrogenicity, irritation potential, reactivity, hemolytic activity, carcinogenicity and/or immunogenicity. A biocompatible structure or material, when introduced into a

majority of patients, will not cause a significantly adverse, long-lived or escalating biological reaction or response, and is distinguished from a mild, transient inflammation which typically accompanies surgery or implantation of foreign objects into a living organism.

"Extracellular matrix" (ECM) is a collagen-rich substance that is found in between cells in animal tissue and serves as a structural element in tissues. It is generally a complex mixture of polysaccharides and proteins secreted by cells. The extracellular matrix can be isolated and treated in a variety of ways. Following isolation and treatment, it is referred to as an "extracellular matrix material," or ECMM. ECMMs may be isolated from submucosa (including small intestine submucosa), stomach submucosa, urinary bladder submucosa, tissue mucosa, dura mater, liver basement membrane, pericardium or other tissues.

"Submucosa" refers to a layer of collagen-containing connective tissue occurring under the mucosa in most parts of the alimentary, respiratory, urinary, and genital tracts of animals. A specific example of an ECMM is small intestinal submucosa (SIS), such as is described in U.S. Patent No. 6,206,931, which is incorporated herein by reference.

"Axially embraces radially and diametrically extending axes.

Tapered stent

FIGS. 1A and **1B** depict exemplary tapered stents having a taper from one side **2** of the stent to the axially opposing side **3** of the stent. In **FIG. 1A**, the tapered stent **1** comprises a tapered 4-point Z-stent configuration having an offset taper. The stent comprises struts 5 of varying lengths. The strut **5** length of the stent **1** varies to form a trapezoidal side profile with a long stent length side (L_L) **2** and a short stent length side (L_S) **3**. As shown, the offset taper, as defined herein, is one which originates at the long stent length side **2** and tapers non-symmetrically with the short length side **3** off center with an imaginary centerline **4** drawn perpendicular to and through the midpoint of the long stent length side **2**. Although **FIG. 1A** shows a 4-point Z-stent, the stent may have greater or few points, and need not be a Z-stent.

FIG. 1B depicts a tapered 4-point Z-stent **11** having a mid-line taper. The mid-line taper, as defined herein, is one that originates at the long length side **12** and tapers symmetrically with both the short length side **13** and the long length side **12** centered about an imaginary centerline **14** drawn through each midpoint. The side profile of a mid-line tapered Z-stent would form that of an isosceles trapezoid. Although **FIG. 1B** shows a 4-point Z-stent, the stent may have greater or few points, and need not be a Z-stent.

Tapered stents are not limited to single taper stents, and may have any suitable tapering configuration. For example, **FIG. 2A** depicts a tapered 7-point Z-stent **20** comprising a dual mid-line taper with the long stent length at the mid-line and the short stent length at the sides. The stent **20** has a first long length side **21**, a second long length side **22**, a first short length side **23**, and a second short length side **24**. The dual mid-line taper originates at the first and second long length sides **21** and **22** and tapers symmetrically with both the both the first and second short length sides **23** and **24** and the first and second long length sides **21** and **22** centered about an imaginary centerline **25** drawn through each midpoint. Viewed from the long length side the stent **20** has a biconvex side profile.

FIG. 2B depicts a tapered 7-point Z-stent **26** comprising a dual mid-line taper with the short stent length at the mid-line and the long stent length at the sides. The stent **26** has a first long length side **27**, a second long length side **28**, a first short length side **29**, and a second short length side **30**. The dual mid-line taper originates at the first and second short length sides **29** and **30** and tapers symmetrically with both the both the first and second long length sides **27** and **28** and the first and second short length sides **29** and **30** centered about an imaginary centerline **31** drawn through each midpoint. Viewed from the short length side the stent **26** has a biconcave side profile.

The ratio of the long length side to the short length side (L_L:L_S) may be any suitable ratio, and the tapered stent need only be able to provide the functionality described herein. The optimal ratio will depend on several factors,

including the type of taper and intended use. For example, a specific L_L:L_S may be selected to enhance and maintain stability of a tapered stent. A high L_L:L_S may adversely affect a tapered stent's stability when expanded and deployed in a body vessel. In one example, to enhance stability in a stent having an offset taper, L_L:L_S is between about 1:1 to about 2:1; preferably between about 1.2:1 and about 1.8:1; more preferably between about 1.4:1 and most preferably about 1.6:1. In a particularly preferred example, L_L:L_S for a stent having an offset taper is no greater than 2:1.

In another example, to enhance the stability of a stent having a midline taper, L_L:L_S is between about 1:1 to about 10:1; preferably between about 1.5:1 and about 5:1 more preferably; between about 2:1 and most preferably about 2.5:1. In a particularly preferred example, L_L:L_S for a stent having a midline taper is no greater than 10:1.

In the expanded configuration, the stents may have a radial force sufficient to maintain the prosthesis at a desired treatment location within a body vessel. Due to the varying stent strut length, a constant strut diameter may result in nonequivalent radial force about the tapered stent circumference. Tapering the strut diameter along the length of the tapered stent may balance the substantially radial force about a tapered stent's circumference. For example, the mechanical properties of the strut diameter and strut length may be used to substantially balance the radial force about a tapered stent circumference in the deployed configuration.

FIG. 3 depicts one example of a tapering stent having struts with a tapering diameter. The mid-line taper stent **32** is made from wire having a tapering diameter. The tapering wire diameter provides for a larger diameter (D_S) **33** for the shorter strut lengths **35** and gradually decreases to a smaller diameter (D_L) **34** for the longer strut lengths **36**. Further depicted in the developed view of **FIG. 4**, the short strut length diameter **33** is greater than the long strut length diameter **34** (D_S>D_L), thereby providing equivalent radial force about the tapered stent circumference **37**.

The tapered aspect of the strut diameter may correlate with the change in strut length. For example, the rate of change in strut diameter per change in strut length ($\Delta D/\Delta L$) may provide equivalent radial force about the stent circumference. In one example, such as the tapered stent of **FIG. 4**, $\Delta D/\Delta L$ may be linear, thereby producing a constant radial force about the circumference of the stent despite changes in the strut length.

Tapered strut diameter may be manufactured by, for example, modifying the extrusion, or drawing, process through variable extrusion/draw speed or variable extrusion/drawing orifice diameter. In one example, an adjustable drawing die may be set to increase and decrease the die diameter at a constant rate, thereby modifying the strut diameter by a given ΔD over a given change in length ΔL. For example, an iris configuration may be utilized to create the adjustable diameter drawing die.

In general, stents for use in connection with the present invention, such as stents **1**, **11**, or otherwise, typically comprise a plurality of apertures or open spaces between metallic filaments (including fibers and wires), segments or regions. Typical structures include: an open-mesh network comprising one or more knitted, woven or braided metallic filaments; an interconnected network of articulable segments; a coiled or helical structure comprising one or more metallic filaments; and, a patterned tubular metallic sheet (*e.g.*, a laser cut tube).

The stents may be self-expanding or balloon-expandable, and may be deployed according to conventional methodology, such as by an inflatable balloon catheter, by a self-deployment mechanism (after release from a catheter), or by other appropriate means. The stents may be bifurcated, configured for any body vessel including coronary arteries and peripheral arteries (*e.g.*, renal, superficial femoral, carotid, and the like), a urethral stent, a biliary stent, a tracheal stent, a gastrointestinal stent, or an esophageal stent, for example.

The stents may be made of one or more suitable biocompatible materials such as stainless steel, nitinol, MP35N, gold, tantalum, platinum or platinum

irdium, niobium, tungsten, iconel, ceramic, nickel, titanium, stainless steel/titanium composite, cobalt, chromium, cobalt/chromium alloys, magnesium, aluminum, or other biocompatible metals and/or composites or alloys such as carbon or carbon fiber, cellulose acetate, cellulose nitrate, silicone, cross-linked polyvinyl alcohol (PVA) hydrogel, cross-linked PVA hydrogel foam, polyurethane, polyamide, styrene isobutylene-styrene block copolymer (Kraton), polyethylene teraphthalate, polyester, polyorthoester, polyanhydride, polyether sulfone, polycarbonate, polypropylene, high molecular weight polyethylene, polytetrafluoroethylene, or other biocompatible polymeric material, or mixture of copolymers thereof; polyesters such as, polylactic acid, polyglycolic acid or copolymers thereof, a polyanhydride, polycaprolactone, polyhydroxybutyrate valerate or other biodegradable polymer, or mixtures or copolymers thereof; extracellular matrix components, proteins, collagen, fibrin or other therapeutic agent, or mixtures thereof. Desirably, the stents comprise stainless steel or nitinol.

The annular elements may have a non-circular cross-section, i.e. when viewed from the top of Figures 1 to 3. In this case, references to the circumference are to be interpreted as references to the periphery.

The wire forming the struts may have a non-circular cross-section. In this case, references to the diameter are to be interpreted as references to the transverse dimension.

Flexible stent-graft

FIG. 5 depicts an exemplary stent-graft having improved flexibility and conformance to tortuous anatomy, such as the thoracic aorta. The stent-graft **50** includes tapered stents **51** positioned in an alternating fashion over the length of the graft **50**. The tapered stents **51** create a trapezoid **52** (shown in **FIG. 6**) when viewed from a side profile with one side consisting of a long strut length L_L **53** and the other side consisting of a short strut length L_S **54** with intermediate struts **55** varying in length according to taper. Alternating short and long strut lengths **54** and **53** provides enhanced flexibility in bending the stent-graft **50** into a radius

while providing sufficient stent contact area. Further, the alternating tapered stent configuration provides flexibility that is not directionally constrained or dependent.

In one example, the tapered stents **51** are of similar configuration, permitting equal graft gap spacing **56** at all points between two adjacent stents. Equal graft gap spacing **56**, combined with the alternating taper, may provide additional stent-graft flexibility.

It is possible to calculate the radial curvature possible for a stent-graft segment comprising alternative tapered stents. For example, the angles Θ and α may define the achievable radial curvature of a stent-graft segment when an opposing tapered stent **70** is rotated until making contact with the imaginary trapezoidal boundary line of an adjacent tapered stent **71**. Note that the analysis below does not account for possible overlap of adjacent tapered stents, which may result in even greater angles of stent-graft segment radial curvature.

As depicted in **FIG. 7A**, where the graft gap spacing **72** is less than or equal to the long length side **73** minus the short length side **74** (*e.g.*, Graft Gap Spacing $\leq [L_L - L_S]$):

$$\text{If } X \leq \left(\frac{L_L - L_S}{2}\right)$$

$$\Theta = \tan^{-1}\left[\frac{\left(\text{GraftGap} - \left(\frac{L_L - L_S}{2}\right)\right)}{\text{StentDiameter}}\right]$$

$$\alpha = \tan^{-1}\left[\frac{\left(\frac{L_L - L_S}{2}\right)}{\text{StentDiameter}}\right]$$

As depicted in **FIG. 7B**, where the graft gap spacing **75** is greater than the long length side **76** minus the short length side **77** (*e.g.*, Graft Gap Spacing $> [L_L - L_S]$):

$$\text{If } X > \left(\frac{L_L - L_S}{2}\right)$$

$$\Theta = \sin^{-1}\left[\frac{\left(\text{GraftGap} - \left(\frac{L_L - L_S}{2}\right)\right)}{\sqrt{\left(\frac{L_L - L_S}{2}\right)^2 + (\text{StentDiameter})^2}}\right]$$

$$\alpha = \tan^{-1}\left[\frac{\left(\frac{L_L - L_S}{2}\right)}{\text{StentDiameter}}\right]$$

The total radial curvature for a stent-graft segment including tapered stents may be calculated using the angles Θ and α. As noted above, the analysis does not account for possible overlap of adjacent tapered stents, which may result in even greater angles of stent-graft segment radial curvature. For example, the total radial curvature ß for a 3-tapered stent-graft segment **80** (shown in **FIG. 8A**):

$$ß = 2(\theta + 2\alpha)$$

The total radial curvature ß for a 5-tapered stent-graft segment **81** (shown in **FIG. 8B**):

$$ß = 2(2\theta + 3\alpha)$$

Improved tapered stent-graft flexibility is depicted in **FIGS. 9A – 9B** compared to stent-grafts with conventional non-tapered stents depicted in **FIGS. 10A – 12B**. In the examples depicted in **FIGS. 9A – 12B**, a radial curvature is provided for each stent-graft segment. The radial curvature is intended to be illustrative only and not limit the present disclosure. The curvature is dependent on a number of variables, including the long length side L_L, the short length side L_S, and the graft gap for each segment. The radial curvature provided for each Figure does not limit the wide range of curvatures possible for stent-graft segments.

FIGS. 9A – 9B depict the radial curvature for a 3-tapered stent-graft segment **90** having a segment length **91** and alternating stent long length side **92** and short length side **93**. The radial curvature achievable **94** is approximately 68 degrees, assuming no stent overlap.

A stent-graft **100** with conventional non-tapered stents is shown in **FIGS. 10A – 10B**. The stent-graft segment **100** has a segment length **101** equal to the segment length **91** of the stent-graft segment **90** with tapered stents of **FIG. 9A**, and a stent length **102** equal to the long length side **92** of **FIG. 9A**. The conventional stent-graft segment **100** only has an achievable radial curvature **103** of about 23 degrees assuming no stent overlap, a decrease of about 45 degrees compared to the stent-graft segement **90** of **FIG. 9B**.

An additional stent-graft **110** with conventional non-tapered stents is shown in **FIGS. 11A – 11B**. The stent-graft segment **110** has a segment length **111** equal to the segment length **91** of the stent-graft segment **90** with tapered stents of **FIG. 9A**, and a graft gap between stents **112** equal to graft gap **95** of **FIG. 9A**. The conventional stent-graft segment **110** only has an achievable radial curvature **113** of about 46 degrees assuming no stent overlap, a decrease of about 22 degrees compared to the stent-graft segment **90** of **FIG. 9B**.

A further stent-graft **120** with conventional non-tapered stent is shown in **FIGS. 12A – 12B**. The conventional stent-graft segment **120** has a segment length **121** equal to the segment length **91** of the stent-graft segment **90** of **FIG. 9A**, and a stent length **122** equal to the short length side **93** of **FIG. 9A**. The conventional stent-graft segment **120** has an achievable radial curvature **123** of about 94 degrees assuming no stent overlap, an increase of about 26 degrees compared to the stent-graft segment **90** of **FIG. 9B**. However, the conventional stent configuration may exhibit instability due to the short stent lengths **122** and long graft gap **124** necessary to cover the same segment length **121** as the segment length **91** of the stent-graft segment **90** depicted in **FIG. 9A**. This results in instability of the stent-graft segment **120**, described in further detail below (see **FIG. 16C**).

FIGS. 13A – 16B depict the achievable radial curvature for stent-graft segments having stent overlap. When the stent configurations are allowed to overlap, the enhanced flexing and bending capabilities of the alternating tapered stent-graft configuration are more apparent, as well as improved stability compared to stent graft segments with conventional non-tapered stents.

FIGS. 13A – 13B depict the radial curvature for a 3-tapered stent-graft segment **130** having a segment length **131** and alternating stent long length side **132** and short length side **133**. The radial curvature achievable **134** with stent overlap is approximately 113 degrees.

A stent-graft **140** with conventional non-tapered stents is shown in **FIGS. 14A – 14B**. The conventional stent-graft segment **140** has a segment length **141** equal to the segment length **131** of the tapered stent-graft segment **130** of **FIG. 13A**, and a stent length **142** equal to the long length side **132** of **FIG. 13A**. The stent-graft segment **140** only has an achievable radial curvature **143** of about 45 degrees with stent overlap, a decrease of about 68 degrees compared to the tapered stent-graft segment **130** of **FIG. 13B**.

An additional stent-graft **150** with conventional non-tapered stents is shown in **FIGS. 15A – 15B**. The conventional stent-graft segment **150** has a segment length **151** equal to the segment length **131** of the stent-graft segment **130** with tapered stents of **FIG. 13A**, and a graft gap between stents **152** equal to graft gap **135** of **FIG. 13A**. The stent-graft segment **150** with conventional non-tapered stents only has an achievable radial curvature **153** of about 81 degrees with stent overlap, a decrease of about 32 degrees compared to the stent-graft segment **130** of **FIG. 13B**.

A further stent-graft **160** with conventional non-tapered stents is shown in **FIGS. 16A – 16B**. The conventional stent-graft segment **160** has a segment length **161** equal to the segment length **131** of the stent-graft segment **130** with tapered stents of **FIG. 13A**, and a stent length **162** equal to the short length side **133** of **FIG. 13A**. The stent-graft segment **160** with conventional non-tapered stents has an achievable radial curvature **163** of about 116 degrees with stent

overlap, an increase of only about 3 degrees compared to the stent-graft segment **130** of **FIG. 13B**. However, the conventional stent configuration **160** exhibits instability due to the short stent lengths **162** and long graft gap **164** necessary to cover the same segment length **161** as the segment length **131** of the stent-graft segment **130** depicted in **FIG. 13A**. This results in instability of the stent-graft segment **160**, as depicted in **FIG. 16C**.

Graft Material

The graft may include any biocompatible material which is suitable for facilitating repair to the injured or diseased body vessel. The graft material may be synthetic, naturally-derived material, and/or manufactured.

For example, graft material may include a film, a coating, a sheet of biocompatible fabrics, non-woven materials or porous materials. Examples of biocompatible polymers from which a graft can be formed include polyesters, such as poly(ethylene terephthalate), polylactide, polyglycolide and copolymers thereof; fluorinated polymers, such as polytetrafluoroethylene (PTFE), expanded PTFE and poly(vinylidene fluoride); polysiloxanes, including polydimethyl siloxane; and polyurethanes, including polyetherurethanes, polyurethane ureas, polyetherurethane ureas, polyurethanes containing carbonate linkages and polyurethanes containing siloxane segments. In addition, materials that are not inherently biocompatible may be subjected to surface modifications in order to render the materials biocompatible. Examples of surface modifications include polymerization of biocompatible polymers from the material surface, coating of the surface with a crosslinked biocompatible polymer, and chemical modification with biocompatible functional groups. Thus, any polymer that may be formed into a porous sheet can be used to make a flexible covering, provided the final porous material is biocompatible. Polymers that can be formed into a porous sheet include polyolefins, polyacrylonitrile, nylons, polyaramids and polysulfones, in addition to polyesters, fluorinated polymers, polysiloxanes and polyurethanes as listed above.

In one aspect, the graft material may comprise a biocompatible polyurethane, for example THORALON (THORATEC, Pleasanton, CA). As described in U.S. Patent Application Publication No. 2002/0065552 A1 , incorporated herein by reference, THORALON is a polyetherurethane urea blended with a siloxane-containing surface modifying additive. THORALON has been used in certain vascular applications and is characterized by thromboresistance, high tensile strength, low water absorption, low critical surface tension and good flex life. A variety of other biocompatible polyurethanes/polycarbamates and urea linkages (hereinafter "-C(O)N or CON type polymers") may also be employed. Biocompatible CON type polymers modified with cationic, anionic and aliphatic side chains may also be used. See, for example, U.S. Pat. No. 5,017,664, which is incorporated herein by reference in its entirety. Other biocompatible CON type polymers include: segmented polyurethanes, such as BIOSPAN; polycarbonate urethanes, such as BIONATE; polyetherurethanes, such as ELASTHANE; (all available from POLYMER TECHNOLOGY GROUP, Berkeley, CA); siloxane-polyurethanes, such as ELAST-EON 2 and ELAST-EON 3 (AORTECH BIOMATERIALS, Victoria, Australia); polytetramethyleneoxide (PTMO) and polydimethylsiloxane (PDMS) polyether-based aromatic siloxane-polyurethanes, such as PURSIL-10, -20, and -40 TSPU; PTMO and PDMS polyether-based aliphatic siloxane-polyurethanes, such as PURSIL AL-5 and AL-10 TSPU; aliphatic, hydroxy-terminated polycarbonate and PDMS polycarbonate-based siloxane-polyurethanes, such as CARBOSIL-10, -20, and -40 TSPU (all available from POLYMER TECHNOLOGY GROUP). Examples of siloxane-polyurethanes are disclosed in U.S. Pat. Application Publication No. 2002/0187288 A1, which is incorporated herein by reference in its entirety.

In addition, any of these biocompatible CON type polymers may be end-capped with surface active end groups, such as, for example, polydimethylsiloxane, fluoropolymers, polyolefin, polyethylene oxide, or other

suitable groups. See, for example the surface active end groups disclosed in U.S. Pat. No. 5,589,563, which is incorporated herein by reference in its entirety.

Examples of biocompatible polyesters include DACRON® (DUPONT, Wilmington, DE) and TWILLWEAVE® MICREL (VASCUTEK, Renfrewshire, Scotland).

Another potential biocompatible graft material is ECMM, such as a purified collagen-based matrix derived from submucosa tissue. Upon implantation into a host, ECMM may undergo remodeling and induce the growth of endogenous tissues. When implanted, ECMM may be able to serve as a matrix for, promote and/or induce the growth of endogenous tissue and undergo a process of bioremodeling. Common events related to this bioremodeling process may include: widespread and rapid neovascularization, proliferation of granulation mesenchymal cells, biodegradation/resorption of implanted purified intestinal submucosa material, and lack of immune rejection.

Studies have shown that warm-blooded vertebrate submucosa may be capable of inducing host tissue proliferation, bioremodeling and regeneration of tissue structures following implantation in a number of in vivo microenvironments including lower urinary tract, body wall, tendon, ligament, bone, cardiovascular tissues and the central nervous system. Upon implantation, cellular infiltration and a rapid neovascularization may be observed and the submucosa material may be bioremodeled into host replacement tissue with site-specific structural and functional properties. This may occur as a result of one or more of the components of submucosa including, for example, glycosaminoglycans, glycoproteins, proteoglycans, and/or growth factors, including Transforming Growth Factor-[alpha], Transforming Growth Factor-[beta], and/or Fibroblast Growth Factor 2 (basic).

ECMM is preferably obtained from human or other mammalian sources, including animals raised for meat production, e.g., pigs, cattle and sheep or other warm-blooded vertebrates. More specifically, ECMM is preferably made from a submucosa isolated from the alimentary, respiratory, urinary or genital tracts,

renal capsule or other appropriate sources. In general, purified submucosa is prepared from these tissue sources by determinating the purified submucosa from both the smooth muscle layers and the mucosal layers. The preparation of intestinal submucosa is described in U.S. Patent No. 4,902,508, and the preparation of tela submucosa is described in U.S. Patent Application Serial No. 08/916,490, both of which are incorporated herein by reference. The preparation of submucosa is also described in U.S. Patent No. 5,733,337 and in 17 Nature Biotechnology 1083 (Nov. 1999); and WIPO Publication WO 98/221 58, dated 28 May 1998, which is the published application of PCT/US97/14855.

Purified tela submucosa, a preferred type of ECMM, has been previously described in U.S. Patent Nos. 6,206,931, 6,358,284 and 6,666,892 as a bio-compatible, non-thrombogenic material that enhances the repair of damaged or diseased host tissues. U.S. Patent Nos. 6,206,931, 6,358,284 and 6,666,892 are incorporated herein by reference. Purified submucosa extracted from the small intestine ("small intestine submucosa" or "SIS") is a more preferred type of ECMM for use in this invention. Another type of ECMM, isolated from liver basement membrane, is described in U.S. Patent No. 6,379,710, which is incorporated herein by reference. ECMM may also be isolated from pericardium, as described in U.S. Patent No. 4,502,159, which is also incorporated herein by reference.

In a further example, the grafts may comprise a porous biocompatible polymer in which a collagenous biomaterial has been dispersed, as is disclosed in U.S. Provisional Application Serial No. 60/558,794 filed March 31, 2004 and U.S. Provisional Application Serial No. 60/558,667 filed March 31, 2004, which are hereby incorporated herein by reference.

The grafts may be made of a single material, or may be a blend, weave, laminate or composite of two or more materials. The graft material may also include other additives, such as plasticizers, compatibilizers, surface modifiers, biological materials such as peptides and enzymes, and therapeutic agents such as drugs or other medicaments.

In addition to xenogenic biomaterials, such as SIS, autologous tissue can be harvested as well. Additionally Elastin or Elastin Like Polypetides (ELPs) and the like offer potential as a material to fabricate the flexible covering or discrete shaping members to form a device with exceptional biocompatibility. Another alternative is use of allographs such as harvested native valve tissue. Such tissue is commercially available in a cryopreserved state.

In one example, to achieve enhanced collapsibility, the material from which the graft is produced may be selected based on the material's ability to achieve an enhanced collapsibility.

Delivery of Stent Graft

Stent grafts can be configured for delivery to a body vessel. For example, a prosthesis comprising tapered stents according to the present disclosure can be compressed to a delivery configuration within a retaining sheath that is part of a delivery system, such as a catheter-based system. Upon delivery, the prosthesis can be expanded, for example, by inflating a balloon from inside the stents. The delivery configuration can be maintained prior to deployment of the prosthesis by any suitable means, including a sheath, a suture, a tube or other restraining material around all or part of the compressed prosthesis, or other methods.

Prostheses can be deployed in a body vessel by means appropriate to their design. Prostheses of the present disclosure can be adapted for deployment using conventional methods known in the art and employing percutaneous transluminal catheter devices. The prostheses are designed for deployment by any of a variety of in situ expansion means.

In one example, a prosthesis comprising self-expanding tapered stents of the present disclosure may be mounted onto a catheter that holds the prosthesis as it is delivered through the body lumen and then releases the prosthesis and allows it to self-expand into contact with the body lumen. This deployment is effected after the prosthesis has been introduced percutaneously, transported transluminally and positioned at a desired location by means of the catheter. The

self-expanding prosthesis may be deployed according to well-known deployment techniques for self-expanding medical devices. For example, the prosthesis may be positioned at the distal end of a catheter with a removable sheath or sleeve placed over the prosthetic valve to hold the prosthesis in a contracted state with a relatively small diameter. The prosthesis may then be implanted at the point of treatment by advancing the catheter over a guide wire to the location of the lesion and then withdrawing the sleeve from over the prosthesis. The stent graft will automatically expand and exert pressure on the wall of the blood vessel at the site of treatment. The catheter, sleeve, and guide wire are removed from the patient.

In some examples, a bioabsorbable suture or sheath can be used to maintain a self-expanding stent graft in a compressed configuration both prior to and after deployment. As the bioabsorbable sheath or suture is degraded by the body after deployment, the prosthesis can expand within the body vessel. In some examples, a portion of the prosthesis can be restrained with a bioabsorbable material and another portion allowed to expand immediately upon implantation. For example, a self-expanding stent graft can be partially restrained by a bioabsorbable material upon deployment and later expand as the bioabsorbable material is absorbed.

In another example, a stent graft may be first positioned to surround a portion of an inflatable balloon catheter. The prosthesis, with the balloon catheter inside is configured at a first, collapsed diameter. The prosthesis and the inflatable balloon are percutaneously introduced into a body vessel, following a previously positioned guide wire. For example, in rapid exchange, a rapid exchange prosthesis delivery balloon catheter allows exchange from a balloon angioplasty catheter to a prosthesis delivery catheter without the need to replace the angioplasty catheter guide wire with an exchange-length wire guide before exchanging the catheters. The prosthesis may be tracked by a fluoroscope, until the balloon portion and associated prosthesis are positioned within the body passageway at the point where the prosthesis is to be placed. Thereafter, the

balloon is inflated and the prosthesis is expanded by the balloon portion from the collapsed diameter to a second expanded diameter. After the prosthesis has been expanded to the desired final expanded diameter, the balloon is deflated, reduced yarn density regions are perforated, and the catheter may be withdrawn, leaving the prosthesis in place. The prosthesis may be covered by a removable sheath during delivery to protect both the prosthesis and the vessels.

While various aspects and examples have been described, it will be apparent to those of ordinary skill in the art that many more examples and implementations are possible within the scope of the disclosure. Accordingly, the disclosure is not to be restricted except in light of the attached claims and their equivalents.

Claims

1. A stent for implantation in a body vessel, the stent comprising:

an annular element comprising a first longitudinal region and a second longitudinal region, the second region being substantially parallel to the first region;

the first region having a longitudinal length greater than the second region longitudinal length;

a plurality of struts disposed intermediate the first region and the second region and peripherally connecting the first region and the second region;

the struts comprising varying longitudinal lengths that gradually decrease from the first region to the second region.

2. The stent of claim 1, where the first region has a radial centerline and the strut longitudinal lengths decrease symmetrically about the radial centerline such that the second region longitudinal midpoint is aligned with the radial centerline.

3. The stent of claim 1 or 2, where the ratio of the first region longitudinal length to the second region longitudinal length is between about 1:1 to about 10:1.

4. The stent of claim 1, where the first region has a radial centerline and the strut longitudinal lengths decrease non-symmetrically about the radial centerline such that the second region is longitudinally offset from the first region.

5. The stent of claim 4, where the ratio of the first region longitudinal length to the second region longitudinal length is between about 1:1 to about 2:1.

6. The stent of any preceding claim , the first region and second region each comprising a material transverse dimension , where the first region material transverse dimension is less than the second region material transverse dimension.

7. The stent of claim 6, the struts comprising a material transverse dimension that decreases from the second region material transverse dimension to the first

region material transverse dimension such that the annular element has a substantially uniform radial force about the element periphery.

8. The stent of claim 7, where the rate of change in strut material transverse dimension per change in strut longitudinal length is substantially linear.

9. The stent of any preceding claim , where the annular element is moveable between a first radially compressed configuration and a second radially compressed configuration sized for vessel implantation.

10. The stent of claim 9, where the expanded configuration comprises a Z-shaped zigzag pattern.

11. The stent of any preceding claim, where the circumferential element comprises a material selected from the group consisting of stainless steel, nitinol, tantalum, a nonmagnetic nickel-cobalt-chromium-molybdenum alloy, platinum, titanium, a suitable biocompatible alloy, a suitable biocompatible material, and a combination thereof.

12. The stent of claim 11, wherein the circumferential element material is nitinol or stainless steel.

13. A stent for implantation in a body vessel and comprising a plurality of struts, the stent comprising:

an annular element comprising a first peripheral region, a second peripheral region, a third peripheral region, and a fourth peripheral region, the first peripheral region being substantially parallel to the third peripheral region and the second peripheral region being substantially parallel to the fourth peripheral region;

where the first peripheral region has a longitudinal length about equal to the length of the third peripheral region and the second peripheral region has a longitudinal length about equal to the length of the fourth peripheral region; ;

where the lengths of the first peripheral region and the third peripheral region are greater than the lengths of the second peripheral region and the fourth peripheral region

wherein the struts peripherally interconnecting the peripheral regions have varying lengths.

14. The stent of claim 13, the first, second, third, and fourth peripheral regions each having a respective material transverse dimension, the transverse dimensions in the first and third peripheral regions being substantially equal, the transverse dimensions in the second and third peripheral regions being substantially equal, and the transverse dimensions in the first and third peripheral regions being less than the transverse dimensions in the second and fourth peripheral regions.

15. An intraluminal prosthesis comprising:

a graft comprising a proximal end, a distal end, and a body defining a lumen extending between the proximal end and the distal end;

the body comprising at least a first tapered stent and a second tapered stent;

the first and second tapered stents each comprising a first longitudinal region and a second longitudinal region, the second region being substantially parallel to the first region, the first region having a longitudinal length greater than the second region longitudinal length, a plurality of struts disposed intermediate the first region and the second region and peripherally connecting the first region and the second region, the struts having varying longitudinal lengths that gradually decrease from the first region to the second region;

where the first stent first region is longitudinally aligned with the second stent second region.

16. The prosthesis of claim 15, where the first stent first region has a radial centerline and the first stent strut longitudinal lengths decrease symmetrically about the first stent radial centerline such that first stent second region longitudinal midpoint is aligned with the first stent radial centerline; and

where the second stent first region has a radial centerline and the second stent strut longitudinal lengths decrease symmetrically about the second stent

radial centerline such that second stent second region longitudinal midpoint is aligned with the second stent radial centerline.

17. The prosthesis of claim 15 or 16, the body further comprising a third tapered stent comprising a first longitudinal region and a second longitudinal region, the second region being substantially parallel to and spaced axially apart from the first region, the first region having a longitudinal length greater than the second region longitudinal length, a plurality of struts disposed intermediate the first region and the second region and peripherally connecting the first region and the second region, the struts having varying longitudinal lengths that gradually decrease from the first region to the second region;

where the first stent first region is longitudinally aligned with the second stent second region and the third stent first region;

where the first stent second region is longitudinally aligned with the second stent first region and the third stent second region.

18. The prosthesis of claim 17, where the longitudinal distance along the body between the first stent and second stent is substantially equal to the longitudinal distance along the body between the second stent and third stent.

19. The prosthesis of any of claims 15 to 18, where the prosthesis is moveable between a first radially compressed configuration and a second radially compressed configuration sized for vessel implantation.

20. The prosthesis of any of claims 15 to 19, where in the expanded configuration the first stent and second stent each comprise a Z-shaped zigzag pattern.

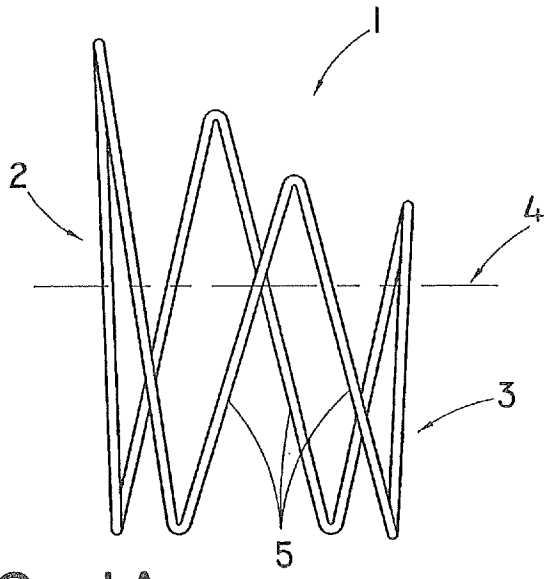

FIG. IA

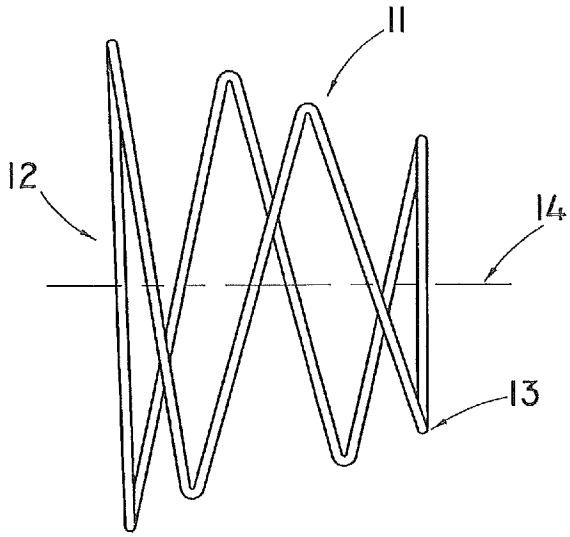

FIG. IB

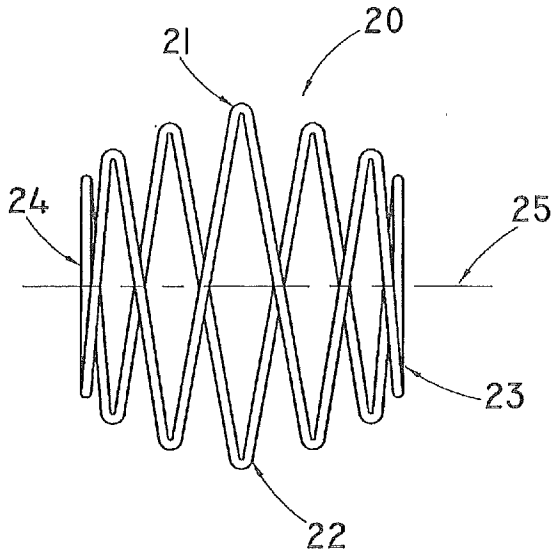

FIG. 2A

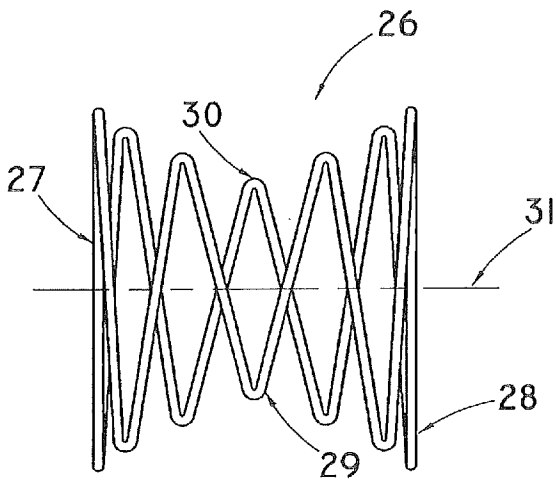

FIG. 2B

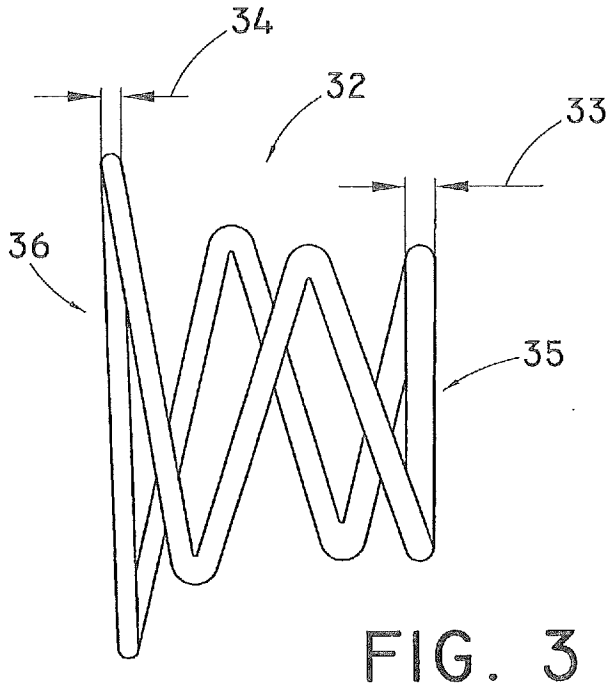

FIG. 3

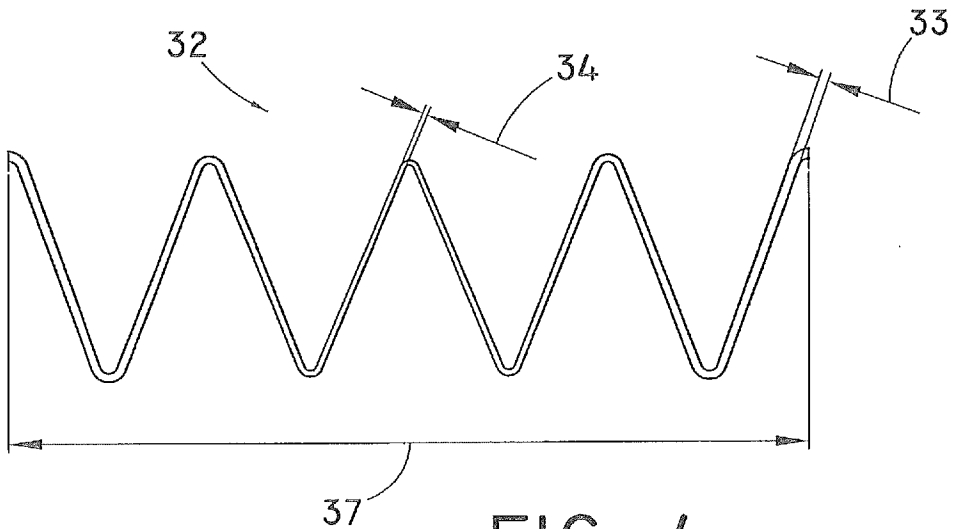

FIG. 4

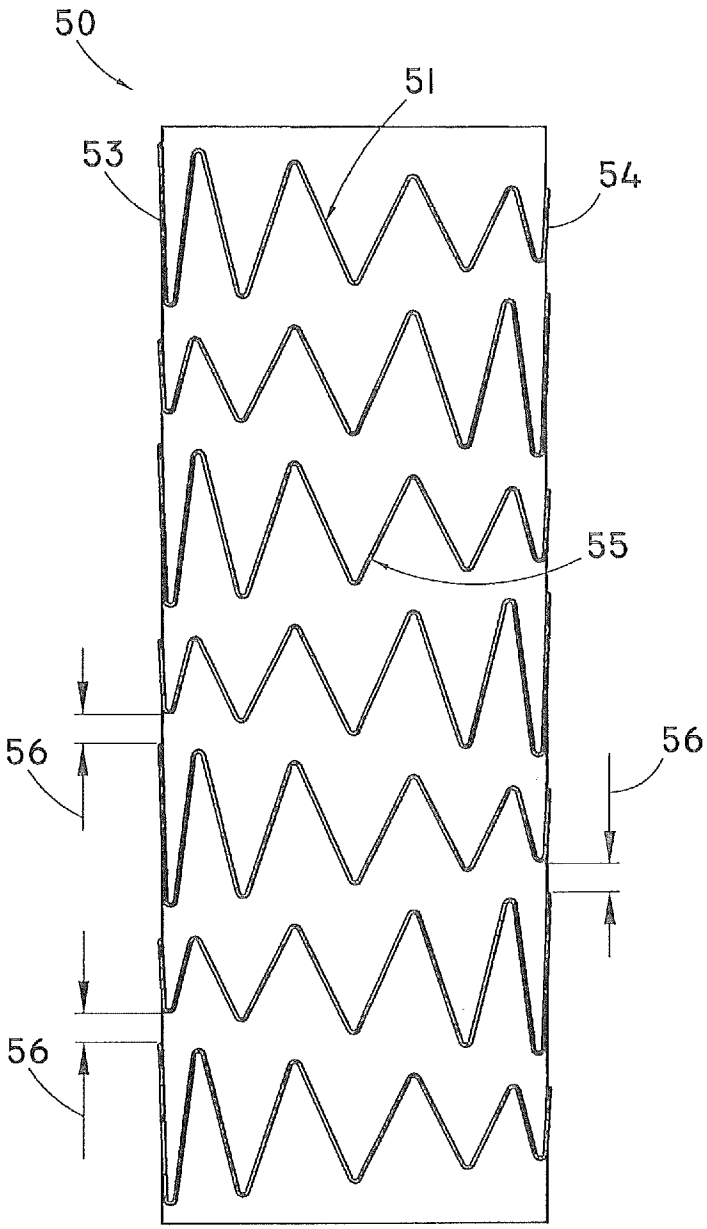

FIG. 5

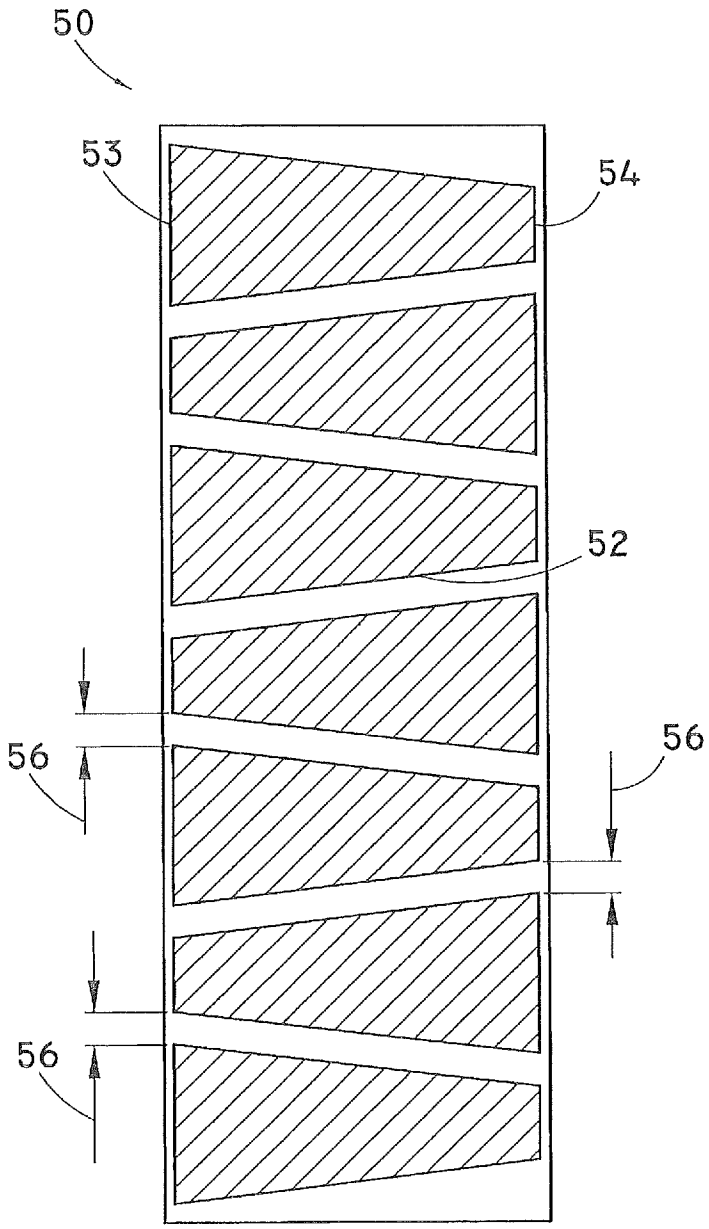

FIG. 6

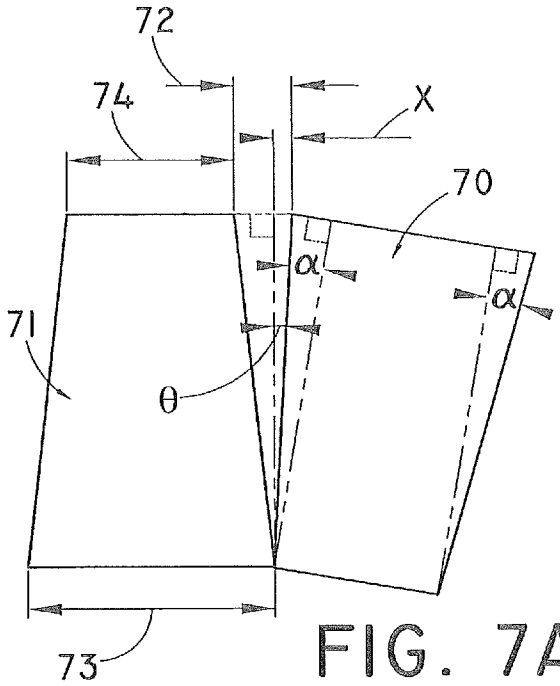

FIG. 7A

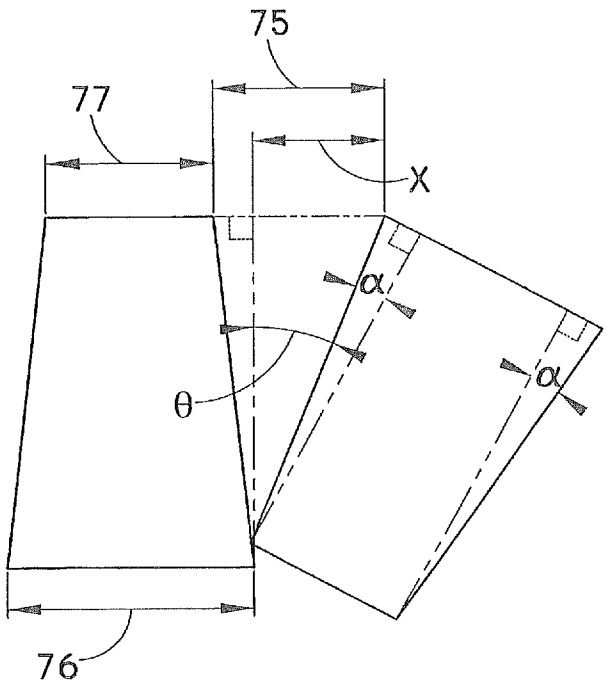

FIG. 7B

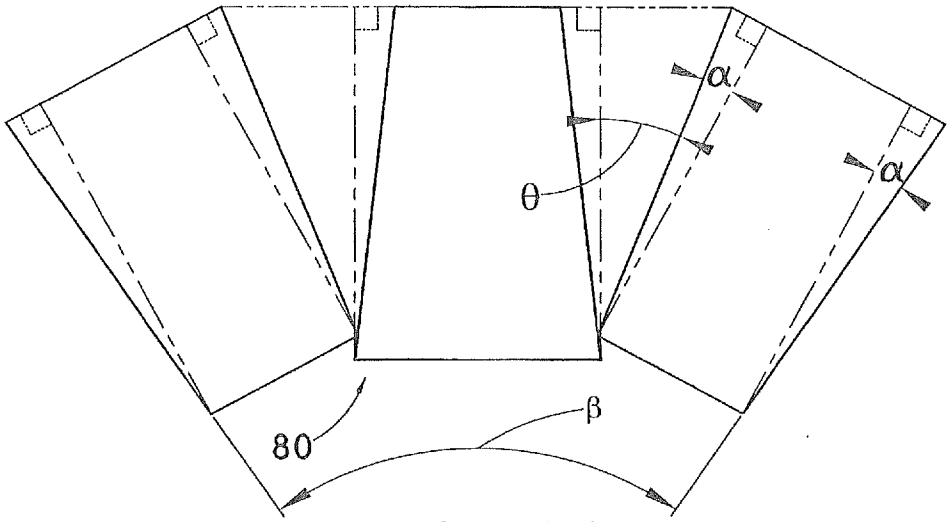

FIG. 8A

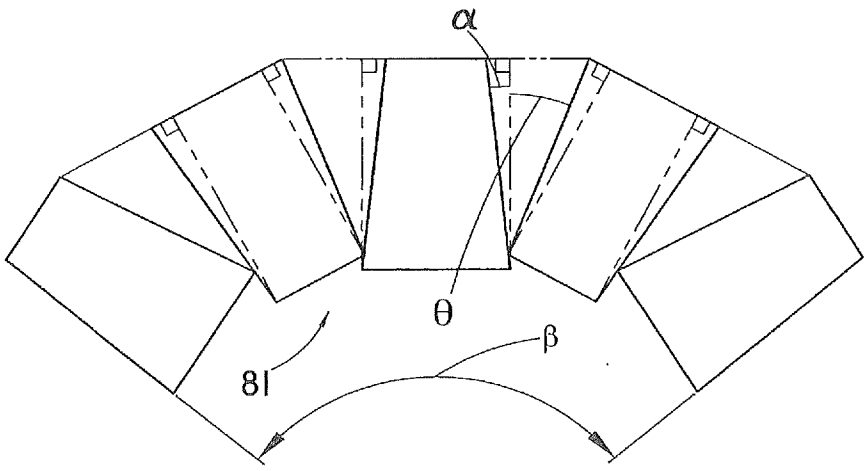

FIG. 8B

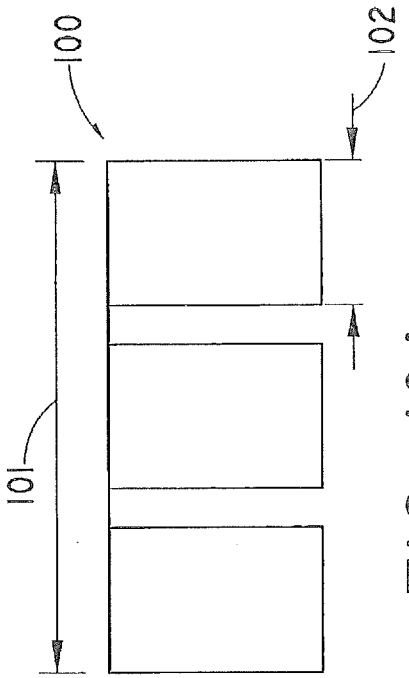

FIG. 10A

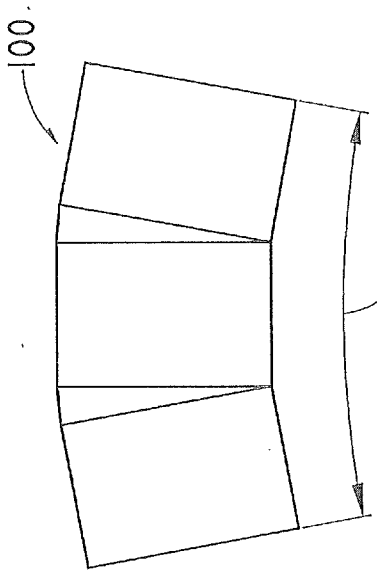

FIG. 10B

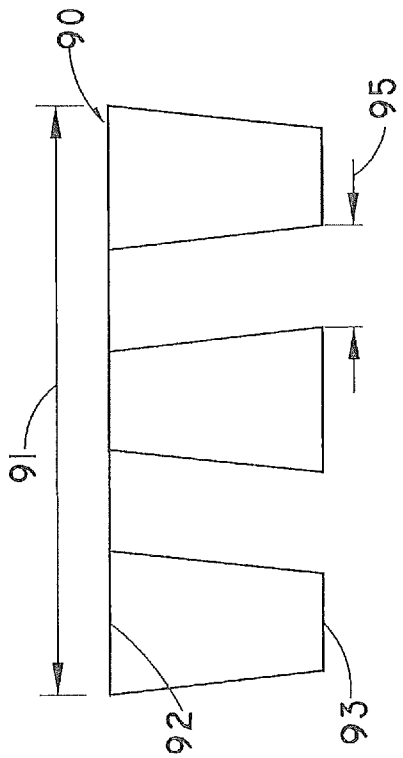

FIG. 9A

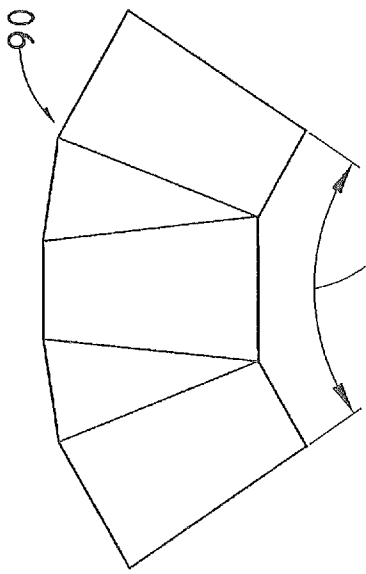

FIG. 9B

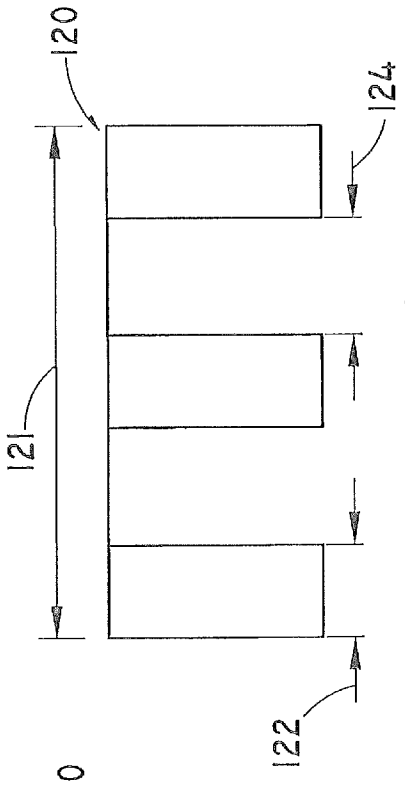

FIG. 12A

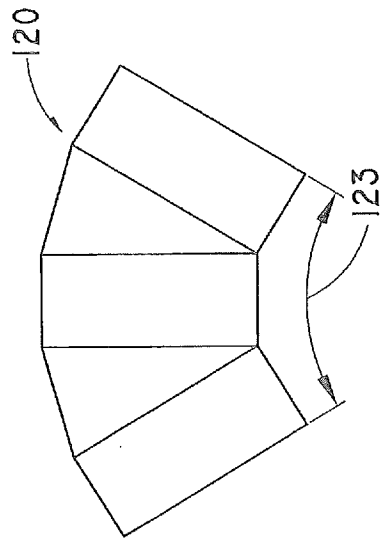

FIG. 12B

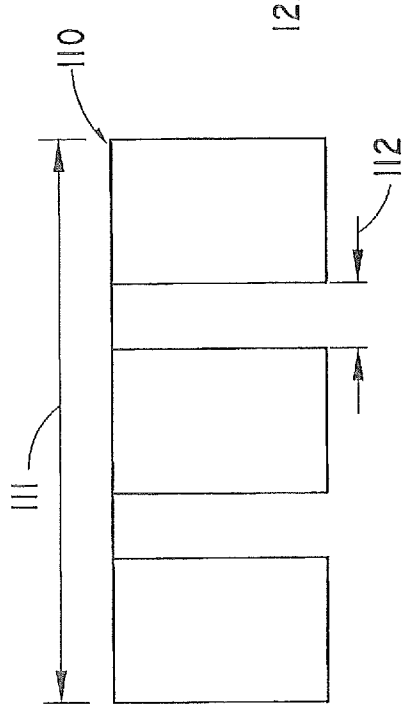

FIG. 11A

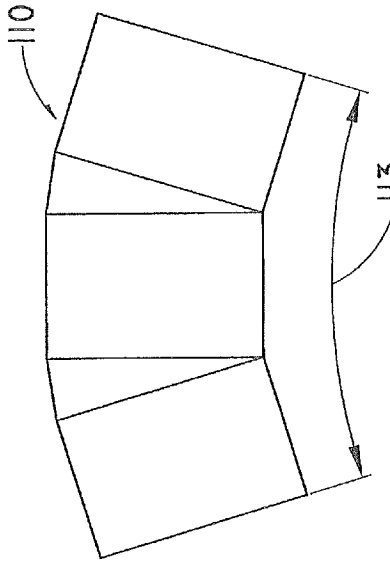

FIG. 11B

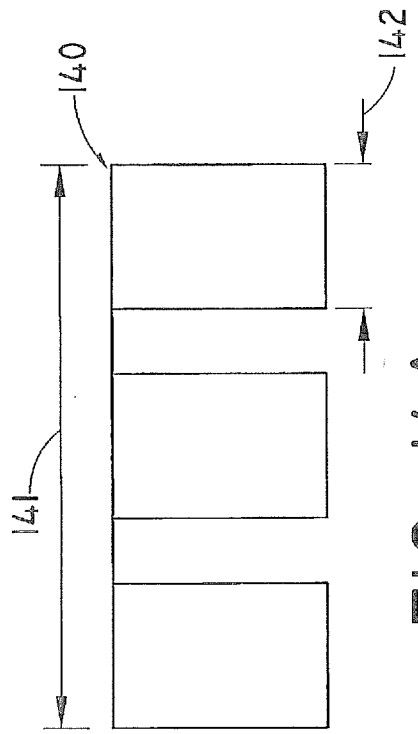

FIG. 14A

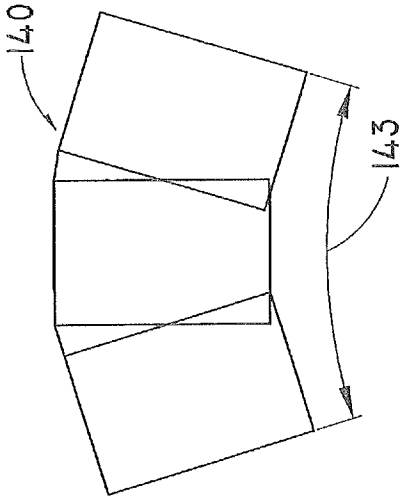

FIG. 14B

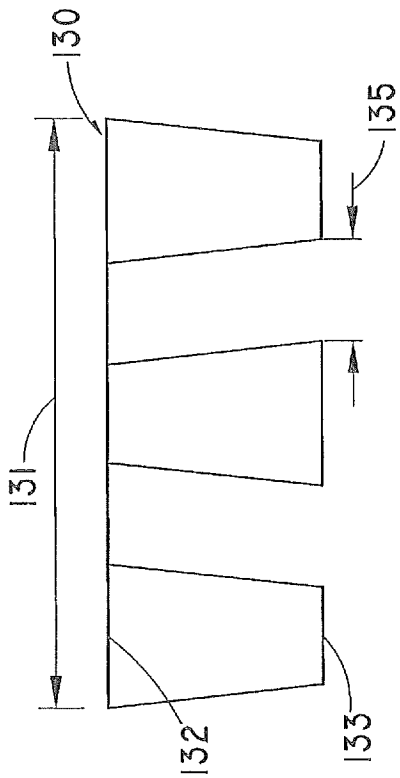

FIG. 13A

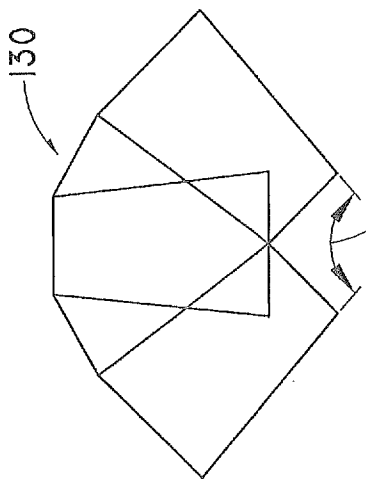

FIG. 13B

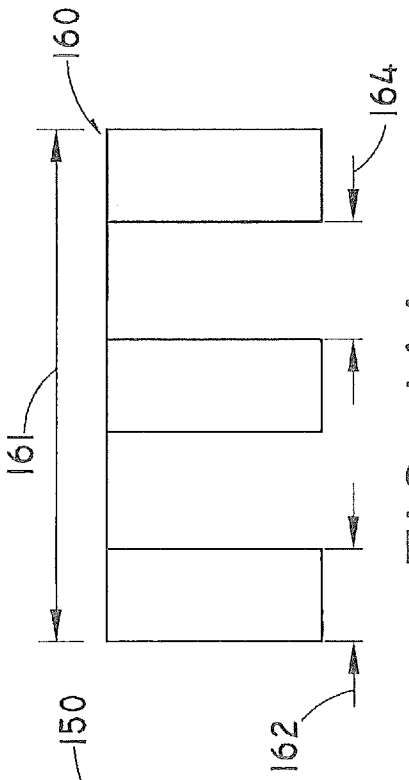

FIG. 16A

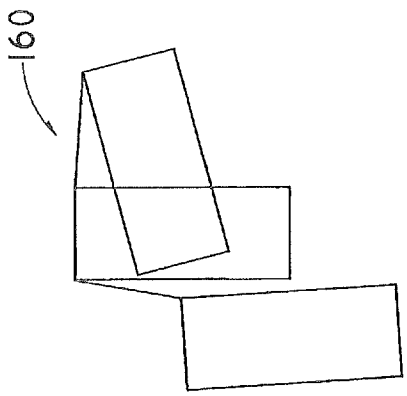

FIG. 16C

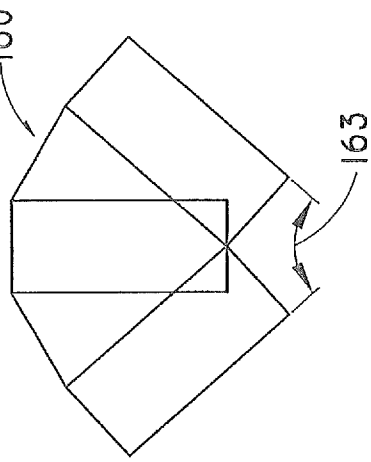

FIG. 16B

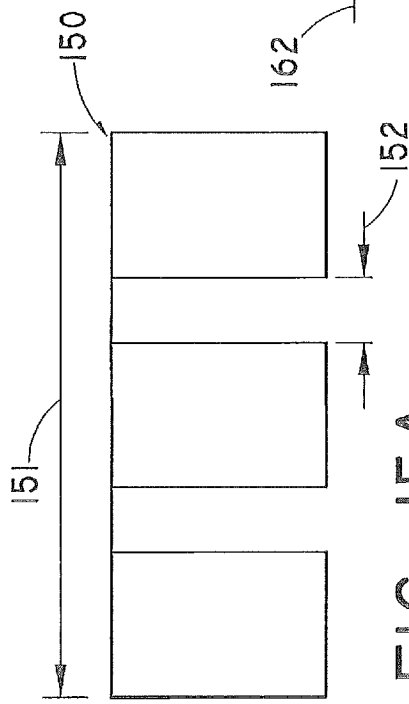

FIG. 15A

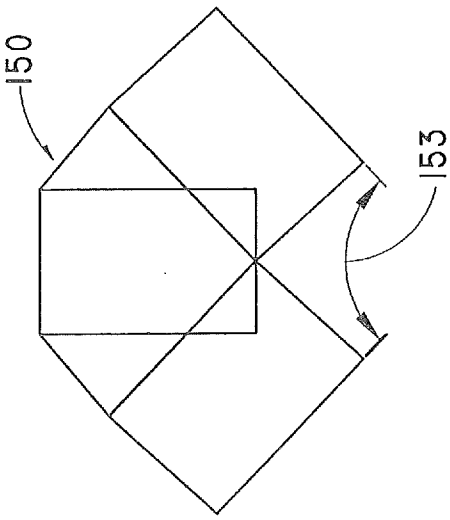

FIG. 15B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/068033

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/06 A61F2/86
ADD. A61F2/00 A61F2/82 A61F2/90

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 2008/051543 A2 (COOK INCORPORTED [US]; COOK WILLIAM A AUSTRALIA [AU]; MELSHEIMER JEFFR) 2 May 2008 (2008-05-02) the whole document -----	1-5, 9-13, 15-20 6-8,14
X	WO 2006/125382 A1 (MICROPORT MEDICAL SHANGHAI CO [CN]; LUO QIYI [CN]; NIE HONGLIN [CN]; Z) 30 November 2006 (2006-11-30) page 6, line 8 - page 7, line 29 page 14, line 1 - page 15, line 18; figures 2,3 page 16, line 4 - page 18, line 13; figures 7,8 ----- -/--	1-5, 9-13, 15-20

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

[X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 February 2010	18/02/2010

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/068033

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	US 6 899 729 B1 (COX DANIEL L [US] ET AL) 31 May 2005 (2005-05-31) column 3, line 66 - column 4, line 30 column 9, line 15 - column 9, line 20; figures 5A,5B	6-8,14
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International application No
PCT/US2009/068033

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