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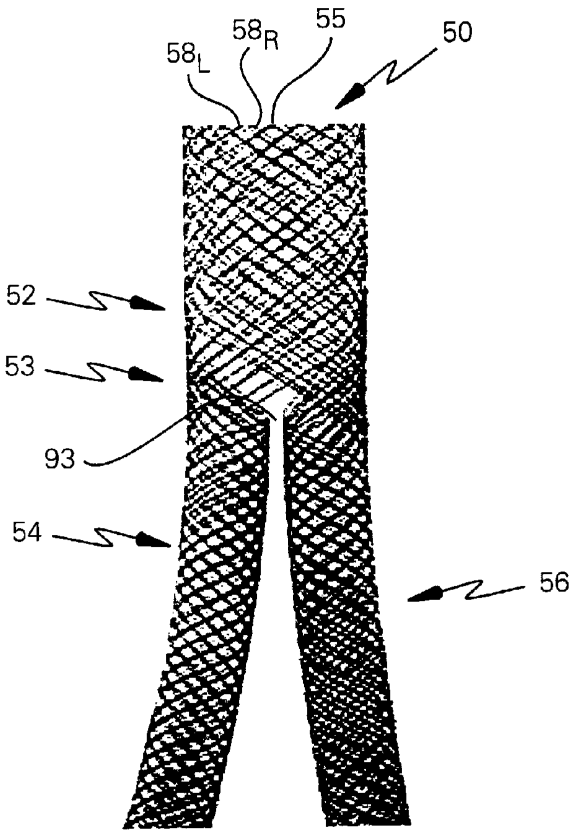
(54) Title: BRAIDED, BRANCHED, IMPLANTABLE DEVICE AND PROCESSES FOR MANUFACTURE THEREOF



(57) Abstract: A braided, branching implantable device, such as a stent, a graft, or a composite stent-graft, for deployment in a lumen, the device comprising a body that branches into a plurality of legs. At least a first leg portion of each leg comprises a discrete plurality of continuous strands braided together and at least a first body portion of the body comprises at least one of said continuous strands from each discrete plurality of continuous strands braided together. Processes for fabricating the device and a method for using the device are also claimed. One fabrication process comprises braiding a first plurality of continuous strands to individually form at least a portion of a first leg; braiding at least a second plurality of continuous strands to individually form at least a portion of a second leg; and braiding at least one strand from each of the first plurality of continuous strands and the second plurality of continuous strands together to form at least a portion of the body. This process may be performed using circular braiding equipment. Another process comprises the steps of creating a plurality of flat-braided strips having longitudinal edges; attaching at least one portion of one longitudinal edge of one strip to a corresponding portion of an opposite longitudinal edge of another strip; and continuing to attach selected portions of the longitudinal edges of the plurality of strips to one another until the braided, branched, implantable, tubular device is formed.

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BRAIDED, BRANCHED, IMPLANTABLE DEVICE AND PROCESSES FOR MANUFACTURE THEREOF

TECHNICAL FIELD

This invention relates generally to endoluminal stents, grafts, and/or prostheses and, more specifically, to braided implantable devices adapted for deployment in branched lumina and processes for their manufacture.

BACKGROUND OF THE INVENTION

A stent is an elongated device used to support an intraluminal wall. In the case of a stenosis, a stent provides an unobstructed conduit for blood in the area of the stenosis. Such a stent may also have a prosthetic graft layer of fabric or covering lining the inside or outside thereof, such a covered stent being commonly referred to in the art as an intraluminal prosthesis, an endoluminal or endovascular graft (EVG), or a stent-graft.

A prosthesis may be used, for example, to treat a vascular aneurysm by removing the pressure on a weakened part of an artery so as to reduce the risk of rupture. Typically, a prosthesis is implanted in a blood vessel at the site of a stenosis or aneurysm endoluminally, i.e. by so-called "minimally invasive techniques" in which the prosthesis, restrained in a radially compressed configuration by a sheath or catheter, is delivered by a deployment system or "introducer" to the site where it is required. The introducer may enter the body through the patient's skin, or by a "cut down" technique in which the entry blood vessel is exposed by minor surgical means. When the introducer has been threaded into the body lumen to the prosthesis deployment location, the introducer is manipulated to cause the prosthesis to be ejected from the surrounding sheath or catheter in which it is restrained (or alternatively the surrounding sheath or catheter is retracted from the prosthesis), whereupon the prosthesis expands to a predetermined diameter at the deployment location, and the introducer is withdrawn. Stent expansion may be effected by spring elasticity, balloon expansion, or by the self-expansion of a thermally or stress-induced return of a memory material to a pre-conditioned expanded configuration.

Various types of stent architectures are known in the art, including many designs comprising a filament or number of filaments, such as a wire or wires, wound or braided into a particular configuration. Included among these wire stent configurations are braided stents, such as is described in U.S. Patent No. 4,655,771 to Hans I. Wallsten and incorporated herein by reference, the '771 Wallsten patent being only one example of many variations of braided stents known in the art and thus not intended as a limitation of the invention described herein later. Braided stents tend to be very flexible, having the ability to be placed in tortuous anatomy and still maintain patency. The flexibility of braided stents make them particularly well-suited for treating aneurysms in the aorta, where the lumen of the vessel often becomes contorted and irregular both before and after placement of the stent.

Braided grafts are also known in the art. U.S. Patents Nos. 5,718,159, 5,758,562, and 6,019,786 to Thompson and 5,957,974 to Thompson et al. (hereinafter "the Thompson patents") and incorporated herein by reference, describe braided graft structures, composite braided stent/graft structures having wire stent filaments interwoven with fabric graft yarns, and processes for their manufacture. In addition to the circular braiding processes described in the Thompson patents, other braiding technologies are known in the art, although not typically associated with the fabrication of implantable medical devices. For example, U.S. Patent No. 4,881,444, to Konrad Krauland, U.S. Patent No. 4,885,973 to Raymond Spain, and U.S. Patent No. 4,621,560 to Brown et al. generally describe 3-dimensional braiding equipment and processes, also referred to as Cartesian braiding or jacquard braiding. Such braiding technology is typically used to make fiber-reinforced structural members, where, for example, fibrous structures are braided and then coated with a resin that hardens, providing a structure wherein the fibers provide tensile strength and the hardened resin provides compressive strength.

Among the many applications for stent-grafts is for deployment in bifurcated lumen, such as for repair of abdominal aortic aneurysms (AAA). Various stent-graft configurations are known in the art for bifurcated applications, including single-piece and modular designs, graft designs fully supported by stents, and graft designs only partially supported by stents. Referring now to Figs. 1A and 1B, there are shown the components of a modular, non-braided, bifurcated, stent 10 for use with a fully-supported graft as is fully described in U.S. 5,609,627 to Goicoechea *et al* and adapted for implantation within the aorta of a human. By "fully-supported" it is meant that the graft is adapted to have stent structure underlying the graft throughout the entire length of the graft, as opposed to having extensive lengths of unsupported graft between anchoring stent portions, as will be described herein later.

As shown in Fig. 1A, stent 10 comprises a main body 12 which bifurcates into a first frustoconical leg transition 14 with a dependent first leg 16, and a second frustoconical leg transition 18. Second leg 20 is a modular component comprising a frustoconical part 22 adapted to interlock within second leg transition 18, and a depending portion 24. Frustoconical part 22 may have barbs 23 to help firmly connect second leg 20 to leg transition 18. As shown in Fig. 2, such a bifurcated stent 10 is typically implanted within the vasculature such that the main body 12 and leg transitions 14 and 18 are positioned within the aorta main portion 26 and with the dependent first leg 16 and depending portion 24 of second leg 20 each positioned within respective iliac arteries 28 and 30. Modular designs are also available wherein both legs are modular components. All of the bifurcated stents described herein, regardless of underlying structure, generally resemble the configuration shown in Fig. 2 when fully implanted.

As shown in Figs. 1A and 1B and as fully described in the '627 patent, the structure of stent 10 is a continuous wire zig-zag structure comprising a series of struts 32 joined at apices 34 and wound into hoops 36, with abutting hoops joined together in some manner, such as with sutures, at abutting apices. One potential disadvantage of zig-zag stent architecture is that the apices of the zig-zag structure can rub against the graft, causing wear in the graft.

Modular, fully-supported, bifurcated stent-graft designs using braided architecture are also known. Such designs typically comprise a tubular stent and/or graft that is crimped or pinched together in the middle or at one end to form a septum and two smaller lumina. These two lumina can then be used as sockets for the iliac sections. The braided stents have the advantage of being very adaptable to tortuous anatomy as compared to other stent architectures. The formation of the crimp, however, can cause metal cold-work and embrittlement in the stent wires and can result in bulkiness in the bifurcation region, requiring a relatively larger deployment profile than other designs.

To overcome the potential disadvantages of modular designs, it is also known to provide one-piece or "unitary" stent designs. Such known designs may be fully supported or only partially supported, such as by having anchoring stent portions only located at the end sections adjacent each opening of the graft. One piece stent designs having a zig-zag stent architecture still have the same disadvantage of potential graft wear due to rubbing of the apices. One-piece graft designs that are only partially supported have the potential disadvantage that the differences in radial strength and flexibility between the unsupported and supported regions make the stent-grafts susceptible to kinking when navigating through tortuous lumina.

SUMMARY OF THE INVENTION

The invention comprises a branching implantable device for deployment in a lumen. The device comprises a body that branches into a plurality of legs, wherein at least a first leg portion of each leg comprises a discrete plurality of continuous strands braided together and at least a first body portion of the body comprises at least one of said continuous strands from each discrete plurality of continuous strands braided together. The device may comprise a stent, a graft comprising a plurality of fabric yarns, or a composite stent-graft comprising a plurality of fabric yarns interbraided with a plurality of structural stent filaments.

The invention also comprises a method for treating a diseased branched lumen, the branched lumen comprising a main section that branches into a plurality of branches. The method comprises the step of deploying within the branched lumen a branching implantable device comprising a body that branches into a plurality of legs. At least a first leg portion of each leg comprises a discrete plurality of continuous strands braided together. At least a first body portion of the body comprises at least one of said continuous strands from each discrete plurality of continuous strands braided together. The deployment step comprises deploying the body in the main section and deploying each leg within one of the branches.

The invention further comprises a process for constructing a braided, branched implantable device having a body and a plurality of legs, each leg comprising a discrete plurality of strands. The process comprises the steps of braiding a first plurality of continuous strands to individually form at least a portion of a first leg; braiding at least a second plurality of continuous strands to individually form at least a portion of a second leg; and braiding at least one strand from each of the first plurality of continuous strands and the second plurality of continuous strands together to form at least a portion of the body. The legs may be formed sequentially before the body, or vice versa. The steps may be performed using circular braiding equipment, in which case the first leg may be formed sequentially before the second leg. The steps may also be performed using cartesian braiding equipment, in which case the legs may be formed simultaneously.

The invention also comprises a process for constructing a braided, branched, implantable, tubular device having a body and a plurality of legs, where the process comprises the step of first creating a plurality of flat-braided strips having longitudinal edges. The, at least one portion of one longitudinal edge of one strip is attached to a corresponding portion of an opposite longitudinal edge of another strip. This step is repeated to attach selected portions of the longitudinal edges of the plurality of strips to one another until the braided, branched, implantable, tubular device is formed.

BRIEF DESCRIPTION OF DRAWINGS

The invention is best understood from the following detailed description when read in connection with the accompanying drawing. It is emphasized that, according to common practice, some of the features of the drawing are not to scale. On the contrary, the dimensions of some of the features are arbitrarily expanded or reduced for clarity. Included in the drawing are the following figures:

Fig. 1A is a front view of one stent component of an exemplary bifurcated intraluminal stent known in the art.

Fig. 1B is a front view of a mating stent component adapted to be connected to the bifurcated stent component of Fig. 1A.

Fig. 2 is a front view of the stent components shown in Fig. 1A and Fig. 1B in an assembled configuration implanted in the aortic region of a human, as is known in the art.

Fig. 3 is a front view of a portion of an exemplary embodiment of an implantable device having an open crotch according to the present invention.

Fig. 4A is a front view of an exemplary assembled modular mandrel in accordance with this invention.

Fig. 4B is a right side view of the assembled modular mandrel of Fig. 4A, showing hidden components (not shown in Fig. 4A) with dashed lines.

Fig. 4C is a bottom view of the trunk mandrel portion of the mandrel of Fig. 4A.

Fig. 5A is a front view of the notch gears of a braiding machine, loaded with the first set of bobbins to form the first leg section of the braided implantable device about the first leg mandrel.

Fig. 5B is a front view of the notch gears in the braiding machine of Fig. 5A, with the first set of bobbins regrouped to the right side after forming the first leg section.

Fig. 5C is a front view of the notch gears in the braiding machine of Fig. 5A, with the second set of bobbins regrouped to the left side after forming the second leg section of the implantable device about the second leg mandrel.

Fig. 5D is a front view of the notch gears in the braiding machine of Fig. 5C, shown fully loaded with both the first set and second set of bobbins and both leg mandrels.

Fig. 5E is a front view of the notch gears in the braiding machine of Fig. 5D forming the braided trunk portion of the implantable device about the trunk mandrel that is connected to both leg mandrels.

Fig. 5F is a front view of the notch gears in the braiding machine of Fig. 5A in an alternative embodiment wherein the second set of bobbins is not regrouped to the left side prior to adding back in the first set of bobbins.

Fig. 6 is a side view of the notch gears in the braiding machine of Fig. 5A showing the conical configuration of the filaments being braided about the mandrel.

Fig. 7 is a front view of a portion of the notch gears in the braiding machine of Fig. 5A and a front view of a rack for holding bobbins removed from the machine.

Fig. 8 is a front view of a portion of an exemplary embodiment of an implantable device having a closed crotch and open hips according to the present invention.

Fig. 9 is a front view illustration of an exemplary embodiment of an implantable device having legs in a 1:1 single filament braiding ratio and the body in a 1:1 paired filament braiding ratio according to the present invention.

Fig. 10A is a front view illustration of a portion of an exemplary embodiment of an implantable device having a closed crotch and closed hips according to the present invention.

Fig. 10B is a front view of an enlarged portion of the device of Fig. 10A, showing interlocked filaments from each leg providing closure for the crotch.

Fig. 11A is a front view illustration of a portion of another exemplary implantable device having a closed crotch and closed hips according to the present invention.

Fig. 11B is a front view of an enlarged portion of the exemplary device of Fig. 11A, showing a staple providing closure for the crotch.

Fig. 12 depicts an end portion of an exemplary stent embodiment having an atraumatic end winding, the stent having been cut longitudinally and flattened.

Fig. 13A depicts an end portion of an exemplary stent embodiment having continuous apices at the end of the stent as is known in the art, the stent having been cut longitudinally and flattened.

Fig. 13B depicts an end portion of an exemplary stent embodiment having ends that terminate freely at the end of the stent as is known in the art, the stent having been cut longitudinally and flattened.

Fig. 13C depicts an end portion of an exemplary stent embodiment having ends that terminate in a twisted configuration at the end of the stent as is known in the art, the stent having been cut longitudinally and flattened.

Fig. 13D depicts an end portion of an exemplary stent embodiment having ends that terminate in a non-braided configuration with continuous apices at the end of the stent, the stent having been cut longitudinally and flattened.

Fig. 14A depicts an exemplary side view of a male quick connect component that facilitates removal and replacement of the bobbin carrier in performing the method according to the present invention.

Fig. 14B depicts an exemplary plan view of a female quick connect component that facilitates removal and replacement of the bobbin carrier in performing the method according to the present invention.

Fig. 15A depicts a portion of an exemplary stent embodiment having a 1:1 single filament braiding ratio as is known in the art, the stent having been cut longitudinally and flattened.

Fig. 15B depicts a portion of an exemplary stent embodiment having a 2:2 single filament braiding ratio as is known in the art, the stent having been cut longitudinally and flattened.

Fig. 15C depicts a portion of an exemplary stent embodiment having a 1:1 paired filament braiding ratio as is known in the art, the stent having been cut longitudinally and flattened.

Fig. 16 is a front view of the notch gears of a braiding machine, loaded with a set of wire bobbins in 1:1-in-train configuration that produces a 1:1 paired filament braiding ratio, as is known in the art.

Fig. 17 is a cross-sectional view of an exemplary stent comprising tapered filaments.

Figs. 18A-D depict steps in an exemplary method for moving bobbins to a rack after braiding the right and left legs on a 24-carrier braider.

Figs. 19A-C depict steps in an exemplary method for moving bobbins from left and right semicircular racks onto a 48-carrier braider.

Fig. 20A-C depicts the steps of joining a plurality of braided flat strips together to make an exemplary bifurcated graft of the present invention.

Fig. 21 depicts an exemplary bifurcated graft of the present invention wherein an open crotch area is sealed with a patch, viewed looking toward the graft body from between the graft legs.

Fig. 22 is a longitudinal section illustration of an exemplary bifurcated graft of the present invention depicting a membrane between the stent and graft.

DETAILED DESCRIPTION OF INVENTION

The invention will next be illustrated with reference to the figures wherein similar numbers indicate the same elements in all figures. Such figures are intended to be illustrative rather than limiting and are included herewith to facilitate the explanation of the apparatus of the present invention.

Referring now to Fig. 3, there is shown a bifurcated, braided implantable device 50 according to the present invention. As shown in Fig. 3, implantable device 50 is a stent comprising a trunk section 52, a first iliac leg 54 and a second iliac leg 56. Stent 50 as shown in Fig. 3 is a unitary stent. That is, iliac legs 54 and 56 are continuous with trunk section 52, unlike modular stent designs in which two or more stent segments are assembled together to form the various parts of the stent (e.g., the trunk section and the two legs). As used herein, the term "unitary" means a device having portions of each of its various parts made as a single unit. Thus, a unitary device contemplates a device whose entire length of all of its parts are made as a single unit, without the need to attach additional segments upon deployment. In addition, a unitary device may be used in conjunction with additional segments, if it is desired to attach such segments to either the legs or the trunk section upon deployment.

It should be noted herein that unitary stent 50 as shown in Fig. 3 is merely one exemplary embodiment, and that this invention is applicable to "modular", braided stents and stent-grafts as well. As used herein, the term "modular" means a device having at least two discrete portions adapted for assembly in situ. As is well-known in the art, one type of exemplary modular bifurcated device may include a trunk section that bifurcates into a single leg on one side adapted to extend into one iliac, and a socket on the other side, with the other leg being a modular piece adapted to be inserted into the socket, similar to the configuration shown in Figs. 1A and 1B. Another type of modular bifurcated device may comprise only a trunk section with a bifurcated region that terminates is two short sockets into which two discrete leg members are adapted to be inserted. Although not depicted herein, such general configurations are well-known in the art, and when fully assembled, resemble the unitary configurations depicted in Figs. 3 and 8, except that there is an overlap region where each leg member is inserted into each socket as is well-known in the art. The term "leg" as used herein with respect to a device having a body portion and leg portions may refer to a full, integral leg adapted to, for example, extending into an iliac artery, or may refer to a socket portion of a leg adapted to receive a modular leg element. Thus, although the invention as illustrated and described herein primarily references full leg structures, each of the methods and structures described herein is equally applicable to partial leg structures such as sockets for receiving modular leg elements.

Bifurcated region 53 as shown in Fig. 3, rather than being a crimped or pinched region, is formed by the weave of the strands 58R and 58L. As can be seen in Fig. 3, a typical braided device comprises a first set of strands 58L wound in a first helical direction (to the left as shown in Fig. 3) and a second set of strands 58R wound in a second, opposite helical direction (to the right as shown in Fig. 3), forming a plurality of overlaps 55. As used herein, the term "strand" is a generic term referring either to an elongated wire filament (typically metal) or an elongated fibrous yarn, with each strand representing one of the elements which are braided with other strands to form the device of the present invention. Strands 58L and 58R may be wire filaments, such as nitinol or stainless steel, or may comprise polymer or any type of filaments known in the art. For fabricating a braided graft, the strands may comprise yarns made from one or more materials from the group including but not limited to polyethyleneterepthalate (PET), polyetheretherketone (PEEK), polysulfone, polytetrafluroethylene (PTFE), expanded polytetrafluroethylene (ePTFE), fluorinated ethylene propylene (FEP), polycarbonate urethane, a polyolefin (such as polypropylene, polyethylene, or high density polyethylene (HDPE)), silicone, and polyurethane. The yarns may comprise monofilaments or multifilament yarns, either with round or non-round cross-section, and multifilament yarns may comprise twisted or untwisted filaments. It should be pointed out that the term "filament" is essentially synonymous with "strand" in the context of wires. With respect to fabrics, however, the term "filament" represents a single component of a multifilament yarn or the sole component of a monofilament yarn.

As used herein, a "braided" device refers to a device formed of at least two continuous strands which are interwoven in a pattern, thus forming overlaps 55, as shown in Fig. 3. At each overlap, one strand is positioned radially outward relative to the other strand. Following each strand along its helical path through a series of consecutive overlaps, that strand may, for example be in the radial inward position in one overlap and in the radial outward position in a next overlap, or may in the inward position for two overlaps and in the outward position for the next two, and so on. As mentioned above, exemplary braided stents are disclosed in U.S. Patent No. 4,655,771 to Hans I. Wallsten. A typical braided stent is formed on a mandrel by a braiding or plaiting machine, such as a standard braiding machine known in the art and manufactured by Rotek of Ormond Beach, Florida. Any such braiding or plaiting machine may be used, however, and the use of terminology specific to components of the machine manufactured by Rotek is not intended as a limitation to the use of that machine design. To the extent that the terminology used herein is specific to the components of any one or several machines, it should be understood such components specifically referred to herein generally have corresponding functionally equivalent components with respect to other machines. Thus, the scope of the method described and claimed herein for braiding the device of present invention is not intended to be limited to the specific machine embodiment described herein, but extends to functionally equivalent machines also. In particular, Cartesian or jacquard braiding machines and methods, such as are described in U.S. Patent Nos. 4,885,973, 4,881,444, and 4,621,560, incorporated herein by reference, may also be used to manufacture implantable devices in accordance with this invention.

Braiding machines can be used for manufacturing the device of the present invention about an exemplary modular mandrel as shown in Figs. 4A-C. Modular mandrel 60 as shown from the front in Fig. 4A and from the side in Fig. 4B, comprises a large diameter trunk section 62 and two, smaller diameter leg sections 64_L and 64_R. Leg sections 64 may comprise a male connector 66, as shown in Fig. 4B, which mates with a female receptacle 67 in trunk section 62 as shown in Figs. 4B and 4C. Hidden lines are not shown in Fig. 4A. Conversely, the female receptacle may be on leg sections 64_L and 64_R and the male connector on trunk section 62. Connector 66 and receptacle 68 may be threaded, may comprise slip fittings, or may otherwise enable leg sections 64_L and 64_R to be releasably connected trunk section 62. Tapered recess 69 serves to model the device gradually to the different diameters of an aorta and iliac arteries.

Referring now to Figs. 5A-F, braiding machine 70 is shown schematically as typically comprising a number of notch gears 72 arranged in a circle. Machine 70 shown in Figs. 5A-F has twenty such notch gears 72, each notch gear adapted to rotate in the opposite direction as its neighboring notch gears, as illustrated by arrows A and B. This counter-rotation passes bobbin carriers 71, and the bobbins 74 mounted thereon, in a sinusoidal fashion from gear to gear, thus causing the bobbins to revolve about a longitudinal axis on which the circle is centered. The configuration of the notch gears, bobbin carriers, and bobbins to achieve this movement are well-known in the art, and an example of such a configuration is found in the braiding machine manufactured by Rotek.

Each bobbin comprises strand 75 wound thereon. The bobbin carrier and bobbin typically interface in a way that helps keep the strand unraveling from the bobbin under proper tension, as is known in the art. Although the motion of the bobbins is described herein, it should be understood that the bobbins 74 are moved by virtue of being mounted on bobbin carriers 71. Thus, although empty bobbin carriers 71 are shown in Fig. 5A, for example, each bobbin 74 also is mounted upon a bobbin carrier, creating a "loaded" bobbin carrier. To reduce clutter in Figs. 5A-5F, the underlying bobbin carrier is not shown for carriers loaded with bobbins 74. Bobbins 74L, shown in Fig. 5A with strand 75 unraveling from the left-hand side of the bobbin as viewed facing the bobbin from outside of the circle of notch gears 72, travel sinusoidally around the circle of notch gears 72 in a counter-clockwise direction as viewed in Fig. 5A. Conversely, bobbins 74R with strand 75 unraveling from the right-hand side of the bobbin as viewed facing the bobbin from outside of the circle of notch gears 72, travel in a clockwise direction. Similarly, bobbin carriers 71L travel counter-clockwise and carriers 71R travel clockwise.

The mandrel around which braided device 50 is formed, such as leg mandrel 64R as shown in Fig. 5A, is moved in a controlled manner substantially along a longitudinal axis about which the circle of notch gears 72 is centered and about which the bobbin carriers 71 revolve. Thus, during processing, wires 75 extend from braiding machine 70 to mandrel 64 in a conical configuration, as shown in Fig. 6. As can be seen from Fig. 6, as two bobbins cross one another, their respective strands form an overlap such that the strand from the bobbin on the outer radius 76 is disposed radially outward (with respect to the axis of the stent being assembled) relative to the strand from the bobbin on the inner radius 78. The space contained within the cone formed by the strands extending between the bobbins and the mandrel and including the space occupied by the mandrel is referred to herein as the "braiding zone" 90. Although the angles α_1 and α_2 of the strand to the mandrel may be varied as desired, α_1 and α_2 preferably each comprise an angle of approximately 55° when the braiding angle of a braided stent β is approximately 110°. This angle may vary dependent upon the exact radial position of the bobbin relative to the mandrel and whether the strand is on the inside radial position or outside radial position on an overlap. Note, for example, that when bobbin 74L is positioned radially outwardly with respect to bobbin 74R on gear 72, angle α_1 is slightly larger than angle α_2. As used herein, the phrase "substantially along the longitudinal axis" as used with respect to the alignment of the moving mandrel means that the mandrel does not have to be perfectly centered in the braiding zone, but merely needs to be aligned close enough to the longitudinal axis that the angles of the strands between the mandrel and the bobbins allows the braiding operation to create a functional braid without tangling the strands.

Mandrel leg sections 64_L and 64_R may therefore each comprise a puller interface 68 for attaching a "puller" adapted to pull the mandrel away from the circle of notch gears 72 at a controlled rate as the braid is formed. For example, puller interface 68 may be a drilled and tapped hole 68 in mandrel 64R as shown in Fig. 4B, and the puller may be a metal rod that has a threaded end or slip fitting adapted to be threaded or otherwise locked into the hole. The puller rod may be retracted away from the circle, for example, by a set of counter-rotating caterpillar tracks which hold the rod therebetween and move the rod in a controlled manner. Other types of pullers, methods of attachment of the puller to the mandrel, and means for moving the puller are also acceptable, and the invention is in no way limited to the exemplary configuration provided herein. In alternative machine designs, a "pusher" may be provided at the opposite end rather than a puller. Any means for axially moving the mandrel through braiding zone 90 is acceptable.

The circle of notch gears 72 can be considered to have an outer radius 76 (on which bobbins 74R are positioned in Fig. 5A) and an inner radius 78 (on which bobbins 74L are positioned in Fig. 5A). In the half-full configuration shown in Fig. 5A, each bobbin 74L crosses over one bobbin 74R while on outer radius 76 before returning to inner radius 78 and crossing under another bobbin 74R. The braid created by such a weave can be said to have a 1:1 single strand braiding ratio (because each single strand crosses under another single strand, then over one, then under one, and so on). The 1:1 single strand braiding ratio is illustrated in Fig. 15A. During the cross-over step where a bobbin on outer radius 76 crosses over a bobbin on inner radius 78, the difference between angle α_1 and α_2 is sufficient to assure that the strands clear one another without tangling.

To form a braid around a mandrel, strands 75 extending from bobbins 74 can be secured to the end of the mandrel in almost any manner, such as by taping them or tying them, and do not even have to be kept in any particular orientation. For example, all the strands may all be taped or tied to a single point on one side of the mandrel. Once the braiding machine starts, it will stabilize into the proper braid configuration after only a few circumferential hoops of overlaps 55 (shown in Fig. 3) are formed. The portion between the proper configuration and the end can either be cut away as scrap or unbraided and then manipulated to form a non-braided end winding, as is discussed herein later. In the alternative, to minimize scrap, the ends of strands 75 may be wound around pins (not shown) or otherwise secured to the mandrel in a spaced circumferential configuration similar to the configuration of bobbins 74 in braiding machine 70.

In one method for creating the braided bifurcated structure of the present invention using a circular braiding machine, the braiding machine is first loaded as shown in Fig. 5A with a first portion 73 of a predetermined number of bobbins 74. The predetermined number of bobbins may comprise the maximum capacity of the machine and first portion 73 may, for example, comprise half of the bobbin capacity of the machine. The braiding operation is then performed as described above to form a first leg section of the braided stent around a first leg mandrel, for example leg mandrel 64R (either 64L or 64R may be the first leg mandrel, in which case the other is the second leg mandrel). After braiding the first leg section about mandrel first leg section 64R, bobbins 74 of first portion 73 can be regrouped to one side (the right side as shown in Fig. 5B) of the circle of notch gears 72.

The method for moving the bobbins may be by any of a number of ways. For example, certain bobbin carriers may comprise closed eyelets through which the wire is threaded, in which case the entire bobbin carrier may be removed. Other bobbin carriers, such as those manufactured, for example, by the Wardwell Braiding Machine Company of Central Falls, RI, comprise open, curled guides resembling a "pigtail" such that the bobbins may be simply unlocked and lifted off of their respective bobbin carriers and the strand readily removed from the guide. It should be understood that as referred to herein, removing or replacing "the bobbins" on and off of the machine may comprise removing or replacing the bobbins only or the bobbins as still attached to the bobbin carriers. Where the entire bobbin carrier is removed, the bobbin carrier may be removed by simply removing any fasteners holding it in place, or to facilitate quicker removal and replacement, a quick-connect fitting can be used. The quick-connect fitting may comprise any number of means well-known in the art for providing an interlocking engagement of one element with another, such as a magnetic connection, a twist-and-lock connection, a spring-loaded ball in channel connection, a lever-controlled cam connection, or any connection known in the art. The configuration shown in Figs. 14A and 14B is provided merely to show one example of such a quick-connection device. Any quick connection device may be used, however, and the invention is by no means limited to the use of the configuration shown in Figs. 14A and 14B.

Exemplary quick disconnect comprises a male component 140 (shown in Fig. 14A) attached to bobbin carrier base 142 and a female component 141 (shown in Fig. 14B), typically attached to the bobbin carrier footplate (not shown) that rides along the notch gears (not shown) of the braiding machine (not shown). Male component 140 comprises a cylindrical post 144 and a cylindrical pin 145 inserted perpendicular to and through the post. A helical spring 146 extends about post 144 from pin 145 to bobbin carrier base 142. The bobbin carrier (not shown) typically attaches to male component 140 on the surface (not shown) of bobbin carrier base 142 opposite post 144. Female component 141 comprises a base 148 having therein a cavity 147 having an X-shaped entryway 149 adapted to accept the post and the pin in one of two orientations. To connect male component 140 to female component 141, post 144 and pin 145 are inserted in cavity 149 and spring 146 is compressed while the male component is turned 1/8 of a full revolution such that the pin is positioned in accordance with indent 150 shown in dashed outline in Fig. 14B. Thus, the spring 146 biases pin 145 against indent 150 in the cavity wall such that the post and pin cannot rotate unless the spring is compressed further. The X-shape of the entryway 149 allows male component 140 to either be inserted and turned to the right or inserted and turned to the left, depending upon which side of the X the pin is inserted into. To disconnect the components, then, male component 140 may merely be manipulated to compress spring 146 and then turned 1/8 of a revolution either to the left or the right so that the pin can exit the cavity through the X-shaped entryway. In an exemplary construction, base 148 of female component 141 may comprise a block of metal machined to create cavity 149 and indent 150 and then attached to the bobbin carrier footplate, such as with screws 151.

The bobbin regrouping process can be essentially understood by comparing Figs. 5A and 5B. Prior to bobbin regrouping, the bobbins are configured as shown in Fig. 5A, with pairs of bobbins I, II, III, and IV positioned relative to one another as shown. To regroup the bobbins, pair III remains in place, and the remaining bobbins are moved such that there are no empty bobbin carriers between pairs of loaded bobbin carriers in the loaded portion of the circle of notch gears 72, as shown in Fig. 5B. Thus, pairs I, II, and IV move from the positions shown in Fig. 5A to the positions shown in Fig. 5B.

During the bobbin regrouping steps, it is desirable to preserve the clockwise or counter-clockwise rotation of each bobbin 74. Bobbin carriers 71L can be said to form a first set of bobbin carriers that traverse the circle of notch gears 72 in the counter-clockwise direction, whereas bobbin carriers 71R form a second set of bobbin carriers that traverse the circle in the clockwise direction. Thus, it may be desirable for bobbin 74L that rests on a bobbin carrier 71L before regrouping, to also reside on a bobbin carrier 71L after regrouping. Where the entire bobbin carrier is removed, it is desirable for the bobbin carrier to be replaced in a position where it travels in the same direction as it traveled prior to removal. For example, when braiding with a 1:1 single strand braiding ratio in the legs and a 2:2 single strand braiding ratio (described herein later) in the trunk, bobbin 74 (or bobbin/bobbin carrier combination) on inner radius 78 may need to be switched with the bobbin (or bobbin/bobbin carrier combination) on outer radius 76 for every alternating pair of bobbins. So, for pairs of bobbins I, II, III, and IV shown in Fig. 5A, where pair III stays in position and the remaining bobbins are regrouped together, pair III and pair I remain with bobbin 74L on outer radius 76 and bobbin 74R on inner radius 78, whereas pair II and pair IV switch bobbin 74L to inner radius 78 and bobbin 74R to outer radius 76. The counter rotation of the notch gears means that each notch gear 72 having a clockwise-rotating bobbin 74R on outer radius 76 has neighboring notch gears on either side with the clockwise-rotating bobbin on inner radius 78.

In an alternate embodiment, bobbin carriers 71L (and therefore bobbins 74L) may travel clockwise instead of counter-clockwise, with carriers 71R and bobbins 74R travelling counter-clockwise. It may be preferable, however, for the tangent of the wire to the bobbin to be on the same side of the bobbin as on the mandrel so that the wire is wound on the same helical direction on the mandrel as it was on the bobbin. For example, as shown in Fig. 5A, the wire originating from bobbin 74R is tangent to the right side of both the bobbin and mandrel 64R, and likewise the wire originating from bobbin 74L is tangent to the left side of both the bobbin and mandrel.

After regrouping of the bobbins is complete, first portion 73 of the predetermined number of bobbins 74 is removed and put aside, along with the completed leg braid still on leg mandrel 64R. Referring now to Fig. 7, to facilitate removing (and later replacing) first portion 73 of bobbins 74, the bobbins (or bobbin carriers) may be stored on a rack 80 so that the bobbins maintain the correct orientation and do not get tangled while they are set aside. The rack may take any form, from a configuration that mimics the configuration of the circle of notch gears 72 to a linear configuration wherein each place for holding a bobbin is easily identified with a corresponding position in the circle. For example, as shown in Fig. 7, the rack may comprise a 10-row by 2-column array, columns C_{76} and C_{78} corresponding to outer radius 76 and inner radius 78 of machine 70, respectively, and rows R_i -R_x corresponding to pairs of bobbins i - x on machine 70. Thus, the bobbin on outer radius 76 of pair i is placed on row R_i, column C_{76} of rack 80, the bobbin on inner radius 78 of pair x is placed on row R_x, column C_{78}, and so on.

A second leg is then braided about leg mandrel 64L with a second portion 77 of the predetermined number of bobbins 74 in the same manner as the first leg, except this time, after the leg has been braided, the second portion 77 is regrouped to the opposite side (the left side as shown in Fig. 5C) of the circle of notch gears 72. The first portion 73 of bobbins has a first discrete plurality of continuous strands associated with it while the second portion 77 has a second discrete plurality of continuous strands associated with it. Thus, each leg 54 and 56 is individually braided and comprises a discrete plurality of continuous strands, such that each leg consists of strands that are separate entities relative to the strands of the other leg. After second portion 77 has been regrouped, first portion 73 is returned to the machine, and leg mandrel 64R and the braid thereon are positioned alongside the second leg mandrel 64L as shown in Fig. 5D. The two mandrels are then attached to trunk section mandrel 62 as shown in Fig. 5E. With first portion 73 returned to braiding machine 70, each bobbin carrier on the machine now has a bobbin mounted thereon. The braiding operation continues, now with all forty bobbins traversing the circle of notch gears 72 to create a braid around trunk section mandrel 62.

Although not shown, some of the strands may be curtailed at the interface between the legs and the trunk portion, such that the trunk portion might consist of less than all of the strands from the two portions 73 and 77. Conversely, the trunk portion may comprise more than all the strands from the two portions 73 and 77. It is only necessary that at least one continuous strand from each discrete plurality of continuous strands extend into the trunk portion, although it is preferred that at least half of each do so, and most preferred that all of them do so. Furthermore, portions 73 and 77 as illustrated herein each comprise half of the total number of bobbins. It may be desirable in certain applications, however, for one leg to have more strands in it than the other, such as if one leg has a greater diameter than the other. In such a case, portions 73 and 77 may be unequal.

A variation on the above method may eliminate the step of regrouping the bobbins to one side of the circle of notch gears 72 before removing first portion 73 of the predetermined number of bobbins 74. In such case, first portion 73 is merely removed from the circle without regrouping, such as in the position shown in Fig. 5A, and stored. After braiding the second leg, second portion 77 of the predetermined number of bobbins 74 is then left in a spaced configuration similar to that shown in Fig. 5F, and the first portion 73 is merely inserted to fill the gaps between the second portion 77. Trunk section mandrel 62 is then attached to leg mandrels 64L and 64R and the winding continues as described above. This method produces a device such as is shown in Fig. 8.

By either method described above for braiding about trunk section mandrel 62, the strands are braided in a 2:2 single strand braiding ratio with the machine at full capacity as shown in Fig. 5E. A 2:2 single strand braiding ratio is illustrated in Fig. 15B wherein, for example, following consecutive overlaps of single strand 152 wound in a first helical direction, the strand travels over two oppositely-wound strands 153 and 154 at overlaps 155 and 156, respectively, and then travels under two strands 157 and 158 at overlaps 159 and 160, respectively, and so on. This is true of each strand in the braid. Fig. 15A illustrates a 1:1 single strand braiding ratio, wherein following consecutive overlaps of strand 161 wound in a first helical direction, the single strand travels over one oppositely-wound strand 162 at overlap 163 and then travels under strand 164 at overlap 165, and so on.

Rather than braiding a first leg, removing the bobbins, then braiding a second leg, bringing back in the removed bobbins, and then braiding the trunk section all on the same machine, a plurality of machines may be used. For example, a first machine may be used only for braiding leg sections. After each leg section is braided on the first machine, the bobbins may then be removed such as onto a rack as described above, and ported to a second machine. The second machine may be used for combining together two or more pre-braided leg sections.

The stent may be manufactured using braiding machines having a different number of notch gears or using a different percentage of the capacity when winding, thus allowing preparation of stents having a 1:1 single strand braiding ratio throughout as described below, a 1:1 paired strand braiding ratio as shown in Fig. 15C and described below, or other configurations as desired. The exact braiding configuration, however, is not intended as a limitation upon this invention. Furthermore, the illustrations in Figs. 15A-C are intended only to depict the general braiding configurations of the strands in relation to one another, and do not necessarily represent the actual number of strands or the precise look of an actual device.

Using braiding machines having a different number of notch gears for different steps in the manufacturing process allows customization of the braid pattern in different regions of the stent. For example, referring now to Figs. 18A-D and 19A-C, a 24-carrier braiding machine 180 having twelve notch gears 72 is used to braid left leg 64L in a 1:1 braiding ratio as shown in Fig. 18A, ending with the bobbins configured in bobbin pairs 184i-vi as shown. For the left leg, these bobbin pairs 184i-vi are then transferred to a semicircular rack 182L in the positions shown. Bobbins 74L on outer radius 76 of braiding machine 180 shown in Fig. 18A are placed on the outer radius R_{76} of rack 182L shown in Fig. 18B and bobbins 74R on inner radius 78 are placed on inner radius R_{78} of the rack. Braiding machine 180 may be separated from bobbin pairs 184i-vi and then used to braid a right leg 64R as shown in Fig. 18D. Alternatively, a second 24-carrier braiding machine may be used to braid right leg 64R. In yet another alternative embodiment, a second braiding machine adapted to accommodate greater or less than 24 carriers may be used, and the number of bobbins loaded on the machine may be less than or greater than the number used to form left leg 64L. Thereafter, bobbin pairs 186i-vi are transferred to semicircular rack 182R as shown in Fig. 18C, in the same manner as bobbin pairs 184i-vi were transferred to rack 182L. It should be noted that rack 182R may merely be an identical rack or even the same rack as rack 182L, merely oriented differently before being loaded with bobbins. Rack 182R has an orientation relative to rack 182L rotated 180°, as shown in Figs. 18B and 18C.

It should also be noted that braiding machines 180 and 190 are adapted to accommodate more than the number of bobbin carriers actually shown loaded on the machines in Figs. 18A-19C, and, in fact are loaded at half of their full capacity to achieve a 1:1 braiding ratio throughout the stent. The method of using different braiding machines may incorporate a first machine to make a first leg, a second machine to make the second leg, and a third machine to make the body. Each machine may have a different full capacity of bobbins and each may have a different capacity as actually loaded to make the respective stent elements. Furthermore, the first machine may be identical to the second machine, but may merely be loaded at a different capacity to produce a leg with a different number of strands than the leg formed on the second machine. Where the first leg comprises a first number of strands, the second leg comprises a second number of strands, and the body comprises a third number of strands, the third number can be less than, greater than, or equal to the first number plus the second number.

Semicircular racks 182L and 182R are then brought together as shown in Fig. 19A to form a full circle surrounding 48-carrier braiding machine 190, which has twenty-four notch gears 72. The bobbin pairs 184i-vi and 186i-vi are then transferred to braiding machine 190 as shown in Fig. 19B. In an alternative embodiment, the bobbin pairs 184i-vi on rack 182L can be unloaded onto braiding machine 190 prior to creating leg 64R, and then the same rack 182L can be inverted to form rack 182R and used to transfer bobbin pairs 186i-vi to braiding machine 190. Trunk mandrel 62 is then attached to leg mandrels 64L and 64R and braiding of the trunk in a 1:1 ratio is commenced.

Although the method of using multiple machines having different numbers of carriers is one method for creating a device having a 1:1 braiding ratio throughout, the multi-machine method can be used to customize the braid pattern in any number of ways. For example, a multi-machine method may be used to provide a stent having a 2:2 ratio throughout, or a 2:2 ratio in the legs and a 1:1 configuration in the trunk, or any other suitable configuration.

A 1:1 paired strand braiding ratio can be achieved by positioning the bobbin carriers on the notch gears in such a way that the bobbins traveling in the same helical direction travel in pairs such that no bobbin traveling in the opposite direction crosses in-between the pairs. This particular bobbin carrier configuration for achieving a 1:1 paired strand braiding ratio may also be referred to as "1:1-in-train" configuration, referring to how the bobbin pair travel together as if linked in a train. Such a positioning is shown in Fig. 16, where bobbins 74L proceed about the circle counterclockwise and bobbins 74R proceed clockwise.

Referring now to Fig. 9, this method may be used, for example, to produce a stent 92 having a body section 52 with a 1:1 paired strand braiding ratio. The 1:1 paired strand braiding ratio is also shown in Fig. 15C. As shown in Fig. 15C, following a pair of strands 166 and 167 wound in a first helical direction through consecutive overlaps, the pair travels together over a pair of oppositely-wound strands 168 and 169 at overlap 170 and then travels under another pair of oppositely-wound strands 171 and 172 at overlap 173.

In an alternative embodiment for achieving a 1:1 paired strand braiding ratio, each bobbin carrier 71 may be adapted to hold two bobbins. The body of the stent may be braided with the bobbins grouped two bobbins to a single carrier, whereas the legs are braided with the bobbins distributed with only a single bobbin per each occupied carrier. This configuration for braiding the body appears similar to Fig. 5A or 5F from above, except that each bobbin as shown represents two bobbins 74 stacked one on top of another. The stacked configuration can be derived essentially by first grouping the bobbins as shown in Fig. 5D and then consolidating, for example, bobbin $74L_{ix}$ on top of $74L_x$ and bobbin $74R_{ix}$ on top of $74R_x$ and so on around the circle, so that the resulting configuration resembles the configuration in Fig. 5F but with two bobbins stacked one on top of the other. The result is that each carrier in each set of carriers having a common direction of rotation having two bobbins thereon is surrounded on both sides by empty carriers, such as for example, carrier 74L having empty carriers 71L on either side as shown in Fig. 5F. Similarly, each pair of loaded carriers having two bobbins apiece has an empty carrier therebetween, such as for example, carriers 74R having empty carrier 71R therebetween as shown in Fig. 5F.

The braided bifurcated device may also be constructed by processes that are essentially the reverse of those described above. By such processes, the braiding begins about trunk section mandrel 62 with the full capacity of bobbins as shown in Fig. 5E, and then one portion of the bobbins 74 are removed from the machine and set aside while one leg of the stent is braided about a leg mandrel using the remaining portion of the bobbins. For example, first portion 73 may be removed while second portion 77 forms a braid about mandrel 64L as shown in Fig. 5C. After the trunk section and one leg of the device have been created with one portion of the bobbins, that portion is removed and the other portion is returned to the machine so that the other leg can be braided about the other leg mandrel. Thus, second portion 77 may be removed and first portion 73 replaced in the machine to form a braid about mandrel 64R as shown in Fig. 5B.

Similar to the process wherein the legs are braided first, the full set of bobbins can be split to make the legs such that all the bobbins on one portion are used for one leg and all the bobbins on the other portion are used for the other leg, such as is shown in Figs. 5B and 5C, or the bobbins used to braid one side and the bobbins used to braid the other side may comprise alternating pairs prior to being split, such as is shown in Figs. 5A and 5F. Because one leg must be braided first and then the other leg must be braided in a position parallel to that leg, leg mandrel 64 must be removed and the first-created leg bent back out of the path of braiding zone 90 during creation of the second-created leg. Similarly, during creation of the first-created leg, the set of bobbins 74 and wires 75 connected thereto for creation of the second-created leg and extending from the trunk section of the stent must be pulled into a position that does not interfere with the braiding of the first-created leg.

Referring to Figs. 18A-D and 19A-C, the multi-machine method may also be practiced in reverse with the trunk being wound first and then each individual leg. In such case, after winding the trunk, bobbin pairs 184i-vi are transferred from machine 190 to rack 182L and bobbin pairs 186i-vi are transferred from machine 180 to rack 184L. Then, before winding each leg, the respective bobbin pairs are transferred from the respective rack to carrier 180.

Depending on the method of grouping the bobbins when converting from braiding the legs to braiding the body, or vice versa, crotch region 93 of the device may be open or closed. The method wherein the bobbins are grouped such that the bobbins from one leg are grouped on one side of the machine and the bobbins from the other leg are grouped on the other side of the machine as shown in Fig. 5D, produces a device with an open crotch 93 such as is shown in Fig. 3. A braided stent having an open crotch that is later covered with graft material thus has an unsupported bifurcation septum. That is, the graft may not have underlying stent structure in the area where the graft bifurcates into the two legs. This may provide certain advantages, such as elimination of any graft-stent wear in that particular region, which is a region that may be subjected to more movement than other portions of the stent, and thus likely to provide more such wear in other designs.

The method wherein the bobbins from each leg are alternated with the bobbins from the other leg as described with respect to Fig. 5F, produces a device having a closed, woven crotch 93 and open hips 95, such as are shown in Fig. 8. To provide a closed crotch for the design shown in Fig. 3, one or more strands from the adjacent legs may be crossed in crotch region 93 as illustrated in the enlarged view in Fig. 10B. Other configurations for closing crotch 93 with crossing strands may be provided, such as by switching bobbins from one carrier to another as desired to produce different degrees of interwinding. Referring now to Figs. 11A and 11B, it may be desirable to group certain of the braided strands 58 together, in particular strands from opposite legs in crotch region 93, using staples or sutures 96 to provide additional structure.

For a braided graft 2100 having an open crotch 2110 between legs 2102 and 2104 and body 2106, the open crotch area may be subsequently sealed with a graft patch 2120, as shown in Fig. 21. One or more such patches may be attached with sutures, adhesives, or by any means known in the art, and may be attached to any open portion created by the braiding process, including an open hip 95, as shown in Fig. 8. A polymer coating, such as applied by a spraying or dipping step, may also be used to close any open areas of a graft, including the interstices between graft yarns as a way to reduce permeability. In yet another embodiment, a graft membrane 2200 may be provided inside stent 2210, between stent 2210 and braided graft 2220 (as shown in the longitudinal section drawing of Fig. 22), or over the braided graft, to reduce permeability. As the graft itself may be positioned inside or outside the stent, the membrane may thus be positioned on an inner surface of the graft or stent, an outer surface of the stent or graft, or on a combination thereof, such as between the inner surface of the graft and the outer surface of the stent where the graft is outside the stent, or between the inner surface of the stent and the outer surface of the graft where the graft is inside the stent. More than one membrane may be used. In another embodiment, the graft itself may also comprise merely a polymer coating applied to the braided stent filaments, as is known in the art.

To provide increased radial strength at the ends of the braided stent of this invention or to counteract a known end-effect of braided stent architecture wherein the ends tend to have lesser radial strength than the intermediate portion of the stent, the ends may be flared as is well known in the art, or the ends may comprise a non-braided stent architecture such as is shown in Fig. 12. The structure and method for making a hexagonal non-braided architecture 97 with an overlapping zig-zag end winding 98 shown in Fig. 12 is disclosed fully in pending U.S. Patent Application Serial Number 09/442,165 by the common inventors Chouinard and Haverkost of this invention, filed on November 17, 1999, assigned to the common assignee, and incorporated herein by reference. Consistent with the disclosure in the '165 Application, a stent according to the present invention having a braided transition region between the body and the legs may have a non-braided architecture in any portion of the stent other than in the transition region. For example, in one embodiment every region except the transition region may have a non-braided architecture. Other embodiments may include non-braided architecture in any region of the stent where additional radial strength is desired, such as between two braided regions. Yet another embodiment may have a non-braided architecture at every end on both the distal (furthest from the position outside the lumen from which the stent is introduced) and proximal (nearest to the position outside the lumen from which the stent is introduced) ends of the stent, or on only selected ends of the stent, such as only on the upstream end or ends. The end architecture is not limited to the architecture shown and described above, but may comprise any number of configurations known in the art. If desired, a separate stent having greater radial strength may be deployed to overlap one or more of the ends, as is also known in the art.

Another method for developing a greater radial strength in one section of the device relative to another comprises using tapered filaments to form the device. For example, the filaments can taper from a first, relatively smaller diameter or cross-sectional area used for braiding leg sections 54 and 56, for example, to a second, relatively larger diameter or cross-sectional area used for braiding body 52. Thus, body 52 may have a greater radial strength than otherwise provided by a single filament diameter throughout. The taper may also be reversed to provide greater radial strength in the legs, if desired. This tapering may also be applied to non-bifurcated, braided stent, graft, and composite stent-graft designs. The use of a continuous wire having regions of different cross-sectional area for providing variable stiffness in different regions of a stent is generally discussed in U.S. Application Serial Number 09/442,192 to Zarbatany et al., incorporated herein by reference.

In a braided device having tapered filaments, all of the plurality of continuous filaments may be tapered, or only a fraction of the filaments may be tapered. In a non-bifurcated device, one end portion of the braided device may comprise the larger cross-section ends of all the tapered filaments and the other end portion of the stent may comprise the smaller cross-section ends of all the tapered filaments. As used herein in connection with the braided device, the "end portion" may comprise only a short portion, such as a single row of overlaps that includes the end of the device, or may include a larger portion, such as one half or more of the device that includes the end. One example of such a non-bifurcated device comprising tapered filaments is shown in Fig. 17. Device 175 comprises a distal end portion 176 and a proximal end portion 177. The distal end portion has a larger filament diameter D1 and the proximal end portion has a smaller filament diameter D2. In certain applications, it may be desirable for the larger diameter portion of the filament to comprise a larger diameter filament than the filament diameter in the smaller diameter portion. Thus, as shown, each filament may have a diameter d1 in the larger diameter portion of the device and a smaller diameter d2 in the smaller diameter portion of the device. Furthermore, both the device and the filament may gradually taper, such that intermediate diameters D3 and d3 are present in the region between diameters D1 and D2. In other embodiments, the diameter of the filament may taper less gradually, such that the change in filament diameter along the device is more in the nature of a step-change. In one exemplary embodiment, for example, D1 may equal about 24 mm and D2 may equal about 12 mm, with d1 equal to about 0.355 mm and d2 equal to about 0.255 mm. Any variety of dimensions may be used. In some applications D1 may equal D2, with only d1 and d2 being varied along the length of the device.

The tapered-filament device may comprise any combination of end windings or braiding ratios discussed herein or known in the art. The tapered-filament device may be configured in any way desired for placement in a lumen, such as tapering from one end to the other as shown in Fig. 17, or with a smaller diameter in the middle than in the ends, or vice versa, or merely a single diameter throughout. All of the filaments in the braided device may be tapered, or only some fraction of the filaments. The filament may have multiple tapers, such as from a larger diameter at one end, to a smaller diameter in the middle, to a larger diameter at the other end, or vice versa. The smaller diameter section of the filament may be positioned such that is coincides with a tortuous portion of a lumen requiring greater flexibility than other regions of the device. Although described herein with reference to a larger or smaller diameter, the filament may have a non-round cross-section, in which case the filament may taper from a relatively larger cross-sectional area to a relatively smaller cross-sectional area.

The end architecture as shown in Fig. 12 can be described as "atraumatic" in the sense that there are no loose wire ends that may puncture or irritate (cause trauma to) the lumen wall after implantation. Other methods of providing atraumatic ends may also be used as are known in the art. In particular, the device may comprise, rather than, for example, ten strands wound onto ten bobbins, five continuous strands each having a first end wound onto a first bobbin and a second end wound onto a second bobbin, thus still having ten bobbins in all. The strands can be positioned on the braiding machine with the midpoint of the strand making a loop around, for example, a radially protruding pin secured in the mandrel, and the first and second bobbins positioned on bobbin carriers in positions consistent with the helical angle of the device and the distance of the mandrel from the bobbin carriers. Thus, the first and second bobbins may be positioned at opposite ends of a radius of the circle of notch gears, or at opposite ends of some chord through the circle, depending on the exact configuration of the machine and desired helical angle of the braided device. An exemplary process for providing a device with such ends is described in publication WO 99/25271 to Burlakov et al. and is incorporated herein by reference.

Thus, using the method described above, one end of the device has continuous-strand apices 99 such as are shown in Fig. 13A. The strands on the opposite ends may be freely terminating ends 100, such as are shown in Fig. 13B; twisted together ends 101, such as are shown in Fig. 13C and in publication WO 99/25271; or atraumatically disposed ends in a non-braided architecture, such as for example in positions 102 and 103 as shown in Fig. 12 and further discussed in U.S. Patent Application Serial Number 09/442,165. These are only examples, however, as the free ends may terminate in any way known in the art. For a braided graft or any braided device with polymer strands, any free ends are typically secured by cutting the strands and melting them together to prevent fraying. In a preferable embodiment, a laser, such as a CO_2 laser, is used to simultaneously cut and melt the fibers cleanly while the graft is mounted on a mandrel. Other methods may also be used.

Although one end of a device may have some combination of continuous-strand apices 99 and otherwise-terminated free ends 100, 101, or 102 and 103, a preferred stent embodiment comprises one end of stent having only continuous-strand apices 99. It should also be understood that because the braiding process proceeds from one end of the device to the other, typically either the body end comprises continuous-strand apices 99 and the leg ends comprise otherwise-terminated free ends 100, 101, or 102 and 103, or the leg ends comprise all continuous-strand apices and the body end comprises all otherwise-terminated free ends. All or only some of the leg ends may comprise continuous-strand apices.

The above method for providing continuous-strand apices at one end may also be combined with the use of tapered filaments as described herein. For example, a filament having multiple tapers with a relatively smaller diameter in a middle region of the wire and a relatively larger diameter in the opposite end regions, may be wound onto two bobbins. The relatively smaller diameter filament may be, for example, wound about a protruding pin at the midpoint of the filament, and the each leg region braided as described herein. The trunk region may then be braided as described herein, with the taper in the filament diameter located such that the trunk has a relatively larger diameter filament than each of the legs. The filament may comprise only the first diameter at the opposite ends and the second diameter in the middle, with a gradual taper between regions, or the filament may comprise a third diameter intermediate the end and middle diameters for use in the bifurcated region.

The use of continuous-strand apices at one end may be further combined with the configurations described in U.S. Patent Application Serial Number 09/442,165, wherein one or more regions of the device may comprise a non-braided configuration. Thus, for example, the midpoint of a strand, such as a tapered filament, may be positioned at a non-braided end of a device, creating continuous apices 104 such as are shown in Fig. 13D. The non-braided architecture may be created, for example, by winding the strand about pins on a mandrel as is well known in the art, and then once the non-braided section has been formed, braiding the remainder of the stent about the mandrel as described herein. The parallel strand sections 105 in the non-braided portion may be optionally welded or otherwise joined together prior to braiding the remainder of the stent.

The above combinations may also be used with a non-bifurcated, braided device. For example, a braided, non-bifurcated device may comprise tapered filaments wherein the ends of the device comprise larger cross-sectional area regions of the tapered filaments and the middle of the device comprises the smaller cross-sectional area regions of the tapered filaments. Conversely, the smaller cross-sectional area regions may be on the ends and the larger cross-sectional area in the middle. As the larger cross-sectional area filament tends to provide greater stiffness or greater radial strength or both, the larger cross-sectional filament may be used in any region of the device desired to have increased stiffness and radial strength relative to the rest of the device, or may be used in certain regions to counteract influences which otherwise would result in lesser stiffness or lesser radial strength in such regions. Atraumatic end windings, such as the continuous-strand apices described herein and with reference to Publication WO 99/25271 and the various configurations as described herein with reference to U.S. Patent Application Serial Number 09/442,165, may also be used in conjunction with tapered filaments in such braided, non-bifurcated devices. Such end windings may also be used in non-bifurcated devices without tapered filaments.

To deploy the device of this invention, the device is typically compressed into a radially compressed state into an introducer as is well-known in the art. The device is then introduced to the lumen into which it is to be deployed, navigated through the lumen to a deployment location, typically a diseased artery such as the aorta, and then expanded to a radially expanded state in the deployment location as is known in the art. The deployment of a unitary device of the present invention is thus deployed by a method similar to that used for any unitary bifurcated device known in the art, and the deployment of a modular device according to the present invention is thus deployed by a method similar to that used for any modular bifurcated device known in the art.

Although bifurcated designs have been shown and described herein, the method of the present invention may be used for creating a device that branches into any number of multiple lumen, so long as there are a sufficient number of bobbins available in the braiding machine to provide an adequate number of strands for braiding the branch sections. To the extent that existing braiding machines may not have a sufficient number of bobbins, machines with a greater number of bobbins may be designed without departing from the scope of this invention.

Furthermore, although illustrated and discussed primarily with respect to stents herein, the invention pertains to any type of bifurcated implantable device, including grafts. Grafts made in accordance with this invention essentially resemble the stents depicted in the figures referred to herein, but typically with more strands so that there is little or no interstitial space between the braided strands. Although braided grafts traditionally require more strands than do stents, the methods described herein with respect to circular braiding machines may be applied to grafts as well as stents. As described herein earlier, grafts typically comprise fabric yarns instead of wire filaments. The yarns used in this invention can vary over a wide range of linear density, depending on the devices used to fabricate the grafts and the application of the graft. In particular the linear density should not be too low so as too become difficult to braid but should not be so high so that the profile of the formed graft is too great. In general, it is desirable to maintain a profile (or diameter) of the compressed graft as low as possible to facilitate the deployment of the graft in the body. The range of linear density may vary, using some braiding machines, over a range between 10 to 500 denier, preferably between about 40 to 225 denier. Also, the thickness of the graft itself may vary over a wide range depending on the application and the desired profile. Typical thicknesses of the graft are between about 0.003 to about 0.015 inches, although not limited to such range. As such designs preferably comprise a large number of yarns (typically anywhere from about 75 to about 600, depending on yarn thickness, and preferably greater than about 200 yarns for thicknesses in a range of about 0.003 to about 0.015 inches), however, the methods described herein requiring manual handling of multiple bobbins and carriers may be undesirably complex. In particular, one bifurcated braided graft may comprise 120 yarns for each leg portion and 240 yarns for the body portion. Therefore, other braiding methods and apparatus, such as cartesian or jacquard braiding methods and machines, may be preferred, particularly for braiding grafts or composite stent-grafts that typically have a substantial number of yarns. Such methods may also be advantageous for braiding stents, particularly because they may allow the same design flexibility provided by using different circular braiding machines to make the legs versus the body, but without any of the complexity or extra steps required to move bobbins or bobbin carriers on and off the braiding equipment.

Cartesian braiding methods and machines are known in the art for making tubular structures and such cartesian braiding methods and machines can be used in making a braided stent of the present invention. Cartesian braiding machines have the advantage of being able to move yarn carriers anywhere along an x-y plane, and may be controlled by computer software to maneuver the plurality of carriers as desired. This flexibility in maneuvering provides the ability to transition from the braiding of a single trunk section to the braiding of two leg sections without having to remove and replace particular yarn carriers on the machine. It also allows the two legs to be fabricated simultaneously, as opposed to the circular braiding method wherein the legs are fabricated sequentially. Furthermore, cartesian braiding apparatus allows easier interweaving of the yarns in the transition section between the trunk and leg sections, to minimize or eliminate any open crotch or open hip section.

Yet another braiding method known in the art is flat braiding. As shown in Fig. 20A, four flat braided strips 2000, 2001, 2002, and 2003 each having longitudinal sides A and B and upper and lower halves U and L. These braided strips may be created by any flat braiding method known in the art. The braiding may be performed in such a way as to leave loops 2005 on one or more of the longitudinal edges of the strips. As shown in Fig. 20B, upper halves U of strip 2000 side B and strip 2001 side A may be joined together, as may the upper halves U of strip 2002 side B and strip 2003 side A. Then, as shown in Fig. 20C, the entire side B of strip 2001 may be joined to the entire side A of strip 2002. Finally, lower half L of strip 2002 side B may be joined to lower half L of strip 2001 side A and lower half L of strip 2003 side A may be joined to lower half L of strip 2000 side B, and the entire side B of strip 2003 joined to the entire side A of strip 2000 to form a bifurcated tubular structure, not shown. The above steps of joining the various portions of one strip to the other may be performed in any logical order desired.

The longitudinal sides of the flat braided strips may be joined by any means known in the art, such as by threading graft yarns through the loops to stitch them together, or, for example, by positioning strip 2000 on one side of the flat braider and strip 2002 on the other side during the fabrication of strip 2001 so that upper side A of strip 2001 can be woven directly into upper side B of strip 2000 and the entire side B of strip 2001 can be woven directly into the entire side A of strip 2002. Alternatively, the strips may be made simultaneously with the appropriate sides or portions of sides being interwoven during fabrication of the strips. Likewise, the other strips and sides may be so positioned so that the flat braiding step may be used to create the desired tubular structure. In an alternative embodiment, the strips may be joined along the desired sides by suturing, adhesive bonding, or any method known in the art.

Finally, in accordance with the methods described in the aforementioned Thompson patents, the bifurcated implantable device of this invention may comprise a composite stent-graft having structural stent filaments interbraided with fabric graft yarns. For example, for every one nitinol wire filament, one may use between 5 and 30, preferably between 10 and 20 fabric yarns to obtain and interwoven stent-graft having increased rigidity over a braided graft. In an alternate embodiment, similar to embodiments described in the '974 Thompson patent, the bifurcated braided graft and bifurcated braided stent of the present invention may be separate elements that are joined together, such as with a polymer adhesive or with sutures. Preferably the resulting graft has a permeability of less than or equal to 1500 ml/cm^2 per minute. Also preferably, the braid angle β of the graft (shown in Fig. 20A) is approximately 110°.

Although illustrated and described above with reference to certain specific embodiments, the present invention is nevertheless not intended to be limited to the details shown. Rather, various modifications may be made in the details within the scope and range of equivalents of the claims and without departing from the spirit of the invention.

What is claimed:

1. A branching implantable device for deployment in a lumen, the device comprising a body that branches into a plurality of legs, wherein at least a first leg portion of each leg comprises a discrete plurality of continuous strands braided together and at least a first body portion of the body comprises at least one of said continuous strands from each discrete plurality of continuous strands braided together.

2. The device of claim 1 wherein the device is a graft and said strands are fabric yarns.

3. The device of claim 1 wherein the device is a composite stent-graft and the strands comprise a plurality of fabric yarns interbraided with a plurality of structural stent filaments.

4. The device of claim 2 wherein the fabric yarns comprise a material selected from the group consisting of: polyethyleneterepthalate (PET), polyetheretherketone (PEEK), polysulfone, polytetrafluroethylene (PTFE), expanded polytetrafluroethylene (ePTFE), fluorinated ethylene propylene (FEP), polycarbonate urethane, a polyolefin, silicone, polyurethane, and a combination thereof.

5. The device of claim 2 wherein the fabric yarn is a polyolefin selected from the group consisting of polypropylene, polyethylene, high density polyethylene (HDPE), and a combination thereof.

6. The device of claim 2 comprising a number of yarns in a range of about 70 to about 600 yarns.

7. The device of claim 2 wherein the fabric yarns have a linear density of between about 10 to 500 denier.

8. The device of claim 7 wherein the fabric yarns have a linear density of between about 40 to 225 denier.

9. The device of claim 2 wherein the graft has a thickness in a range of about 0.003 to about 0.015 inches.

10. The device of claim 2 wherein the graft has a permeability of less than or equal to 1500 ml/cm^2 per minute.

11. The device of claim 2 wherein the graft has a braiding angle of approximately 110°.

12. The device of claim 2 wherein the braided graft has both a closed crotch section and a closed hip section.

13. The device of claim 2 wherein the braided graft has an open crotch section or an open hip section and further comprises a patch to seal the open section.

14. The device of claim 2 wherein the braided graft is coated with a polymer to reduce permeability.

15. The device of claim 2 further comprising a stent over or under which the graft is positioned to create a stent-graft combination, the stent-graft combination further comprising at least one graft membrane positioned on an inner surface of the graft or stent, an outer surface of the stent or graft, or a combination thereof.

16. The device of claim 1 comprising a stent-graft combination comprising:

a stent comprising a stent body that branches into a plurality of stent legs wherein at least a first stent leg portion of each stent leg comprises a discrete plurality of continuous stent filaments braided together and at least a first stent body portion of the stent body comprises at least one of said continuous stent filaments from each discrete plurality of continuous stent filaments braided together; and

a graft comprising a graft body that branches into a plurality of graft legs wherein at least a first graft leg portion of each graft leg comprises a discrete plurality of continuous graft yarns braided together and at least a first graft body portion of the graft body comprises at least one of said continuous graft yarns from each discrete plurality of continuous graft yarns braided together;

wherein the stent and graft are discrete components that are joined together to form the stent-graft combination.

17. The device of claim 16 wherein the stent and graft are joined together with an adhesive.

18. The device of claim 16 wherein the stent and graft are joined together with a plurality of sutures.

19. A method for treating a diseased branched lumen, the branched lumen comprising a main section that branches into a plurality of branches, the method comprising the step of deploying within the branched lumen a branching implantable device comprising a body that branches into a plurality of legs, wherein at least a first leg portion of each leg comprises a discrete plurality of continuous strands braided together and at least a first body portion of the body comprises at least one of said continuous strands from each discrete plurality of continuous strands braided together, the deployment step comprising deploying the body in the main section and deploying each leg within one of the branches.

20. A process for constructing a braided, branched implantable device having a body and a plurality of legs, each leg comprising a discrete plurality of strands, the process comprising the steps of:

(a) braiding a first plurality of continuous strands to individually form at least a portion of a first leg;

(b) braiding at least a second plurality of continuous strands to individually form at least a portion of a second leg;

(b) braiding at least one strand from each of the first plurality of continuous strands and the second plurality of continuous strands together to form at least a portion of the body.

21. The process of claim 20 comprising performing steps (a) and (b) sequentially before step (c).

22. The process of claim 20 comprising performing step (c) sequentially before steps (a) and (b).

23. The process of claim 20 comprising performing steps (a)-(c) using circular braiding equipment.

24. The process of claim 23 comprising performing step (a) and step (b) sequentially.

25. The process of claim 20 comprising performing steps (a)-(c) using cartesian braiding equipment.

26. The process of claim 25 comprising performing step (a) and step (b) simultaneously.

27. The process of claim 20 comprising performing steps (a)-(c) to create a graft comprising a plurality of fabric yarns.

28. The process of claim 27 comprising performing each of steps (a)-(c) using a number of yarns in a range of about 70 to about 600.

29. The process of claim 27 wherein said yarns have a linear density in a range of about 10 to 500 denier.

30. The process of claim 29 wherein said yarns have a linear density in a range of about 40 to 225 denier.

31. The process of claim 20 comprising interweaving a plurality of fabric yarns with a plurality of structural stent filaments to create a unitary braided, branched stent-graft combination.

32. A process for constructing a braided, branched, implantable, tubular device having a body and a plurality of legs, the process comprising the steps of:

(a) creating a plurality of flat-braided strips having longitudinal edges;

(b) attaching at least one portion of one longitudinal edge of one strip to a corresponding portion of an opposite longitudinal edge of another strip;

(c) repeating step (b) by attaching selected portions of the longitudinal edges of the plurality of strips to one another until the braided, branched, implantable, tubular device is formed.

33. The device of claim 3 wherein the structural stent filaments are interbraided with the fabric yarns in a ratio between 1:5 and 1:30.

34. The device of claim 3 wherein the structural stent filaments are interbraided with the fabric yarns in a ratio between 1:10 and 1:20.

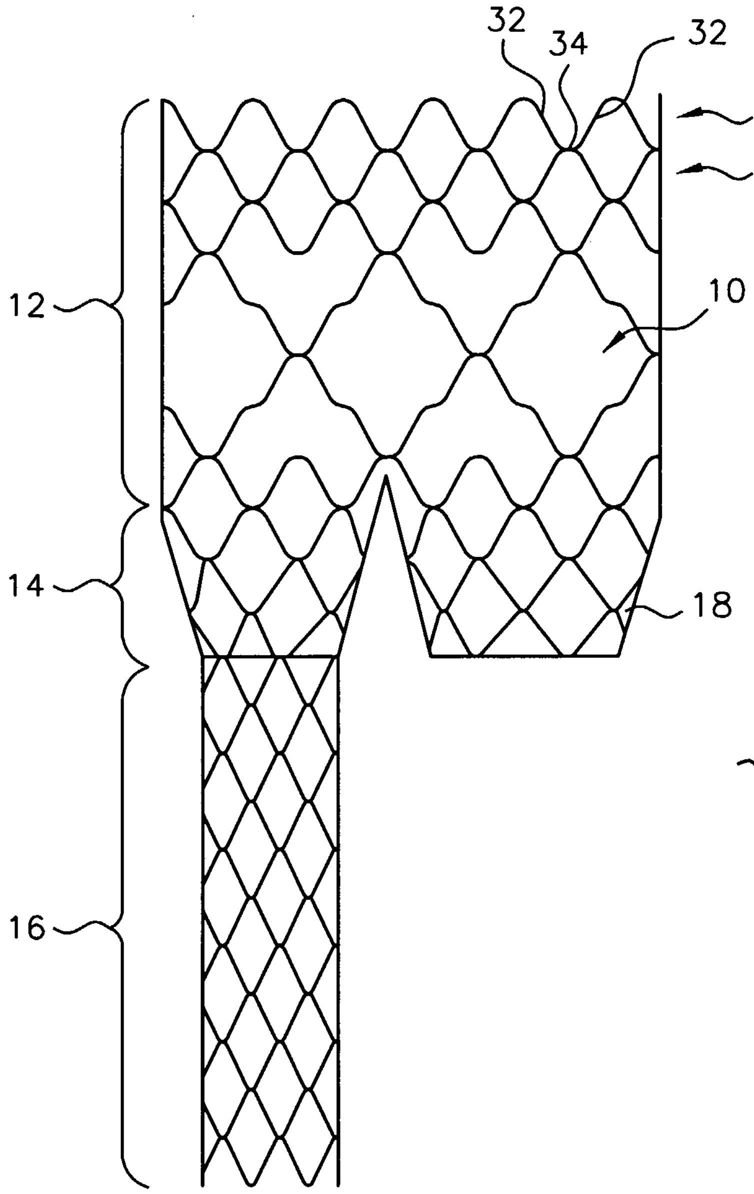


FIG. 1A
(Prior Art)

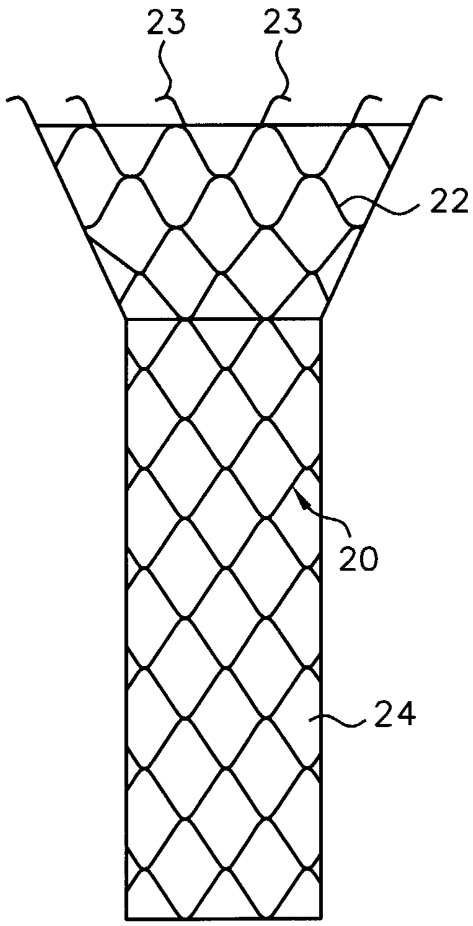


FIG. 1B
(Prior Art)

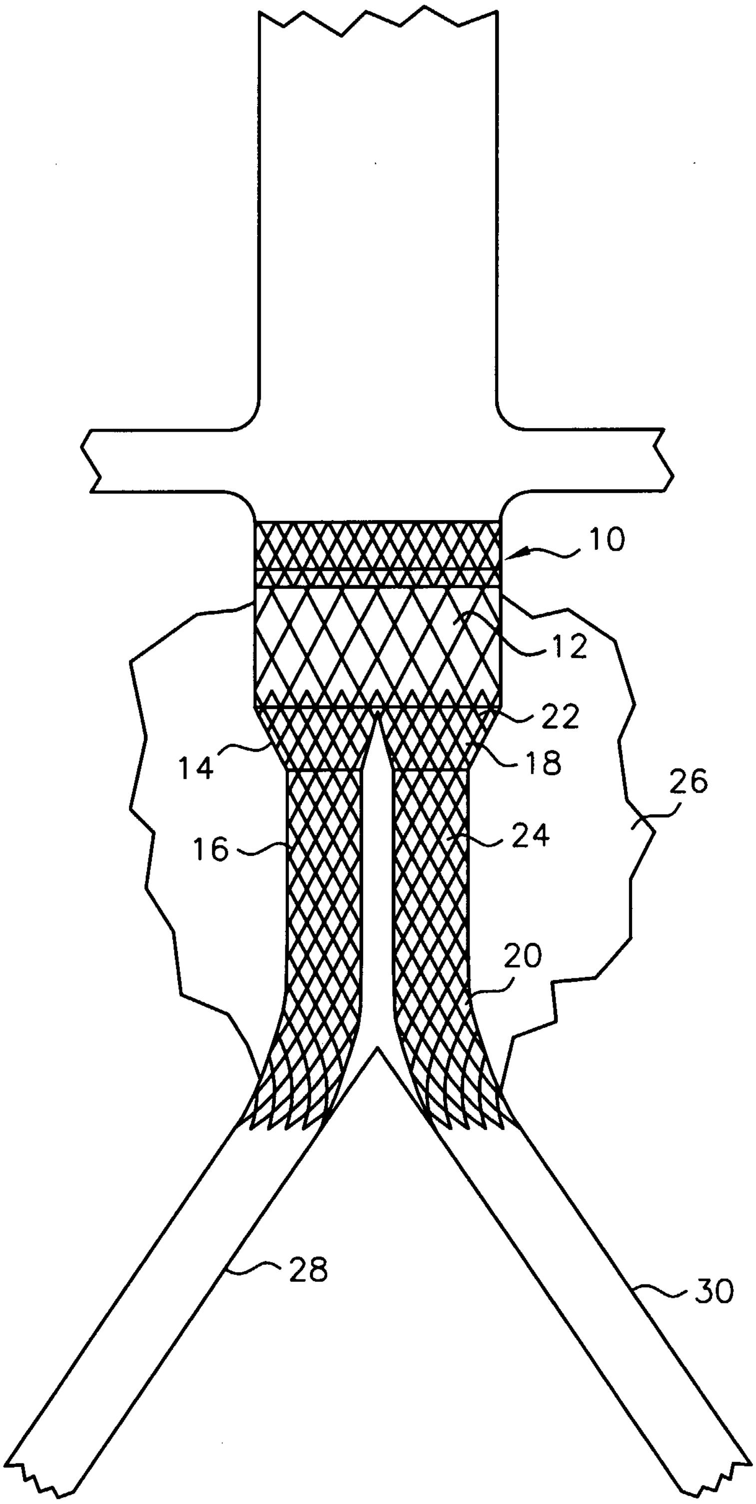


FIG. 2
(Prior Art)

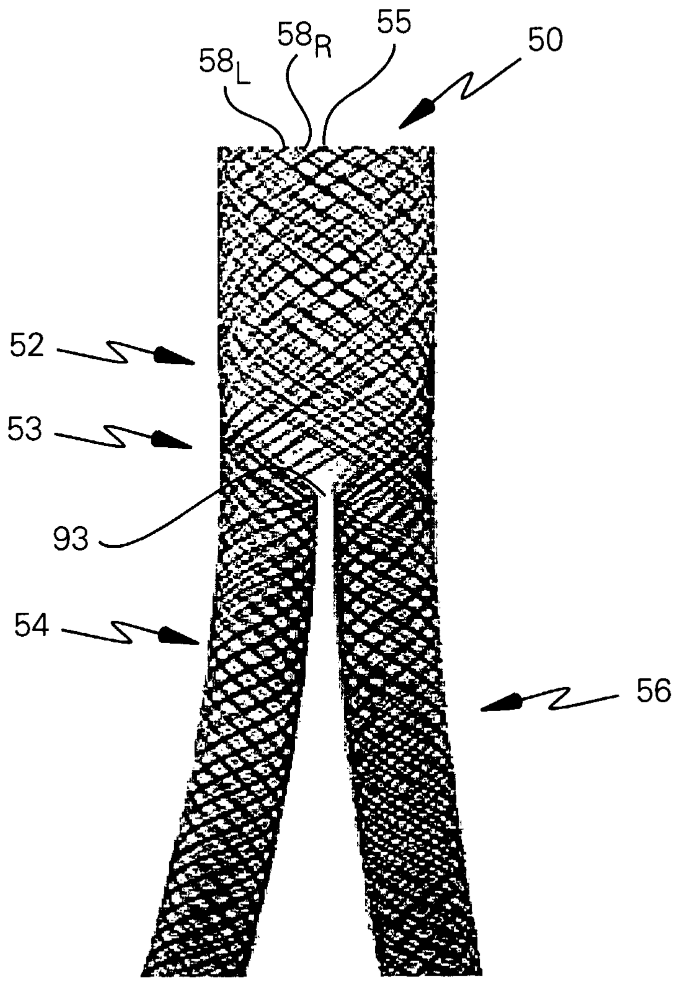


FIG. 3

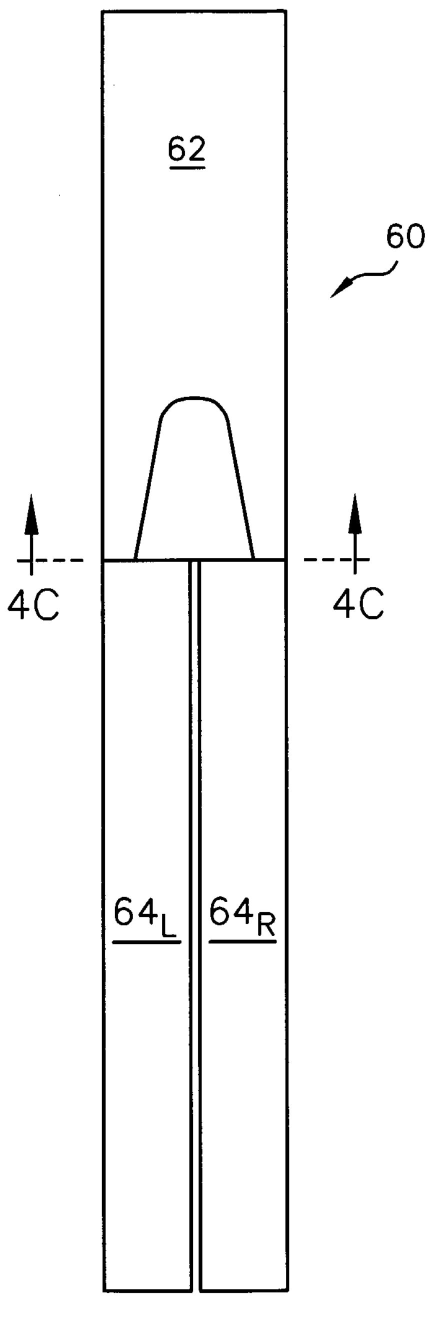


FIG. 4A

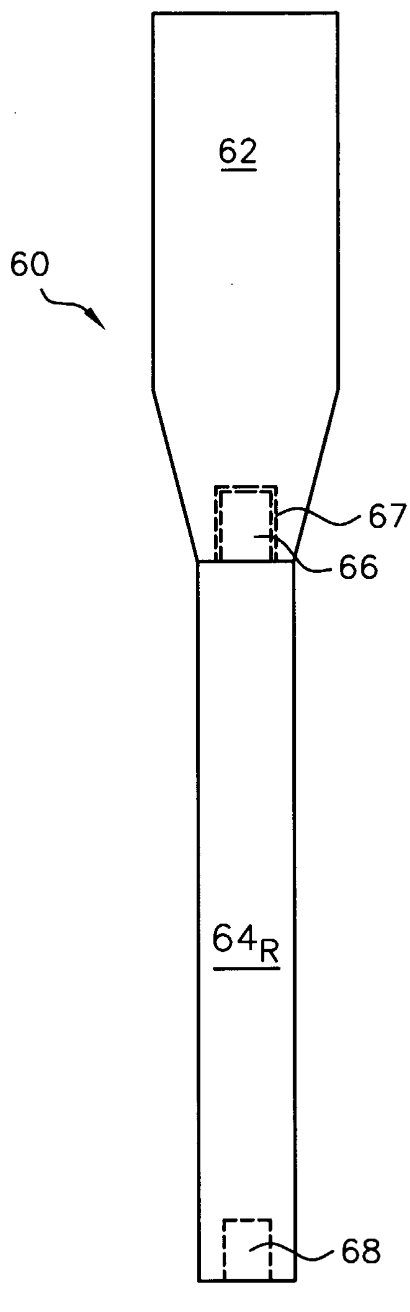


FIG. 4B

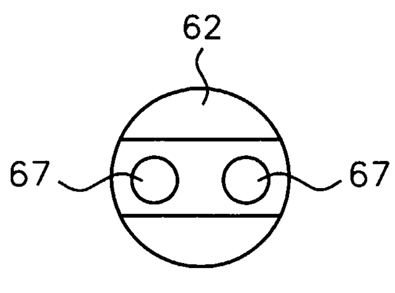


FIG. 4C

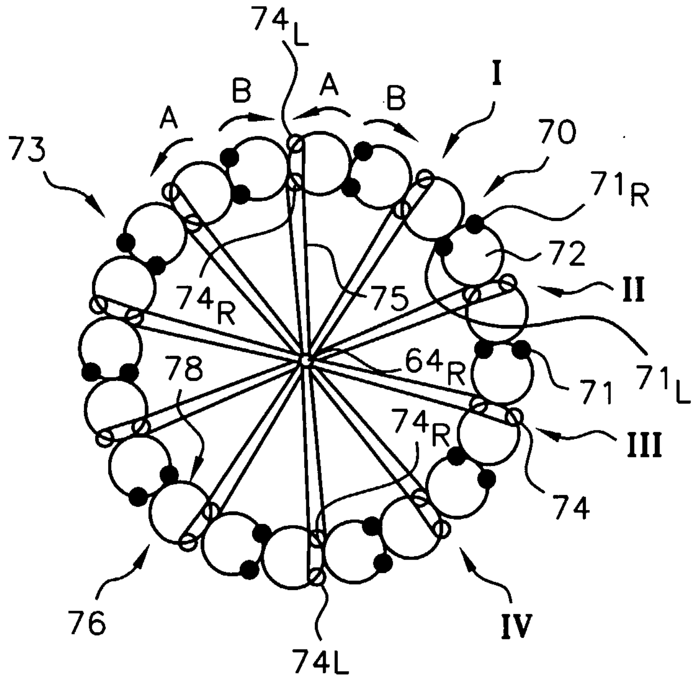


FIG. 5A

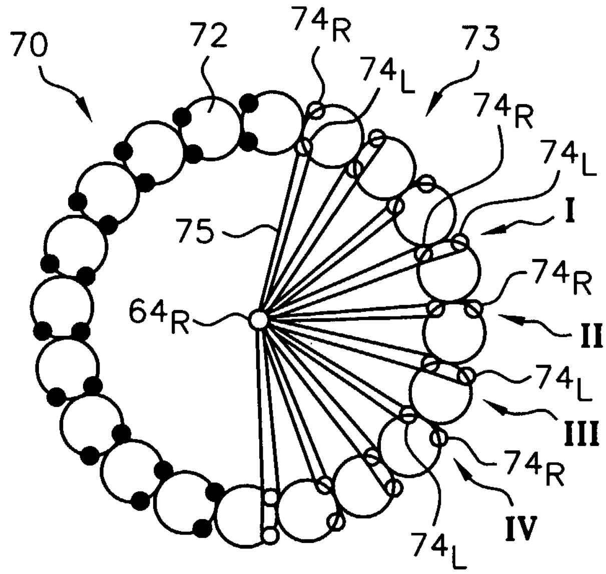


FIG. 5B

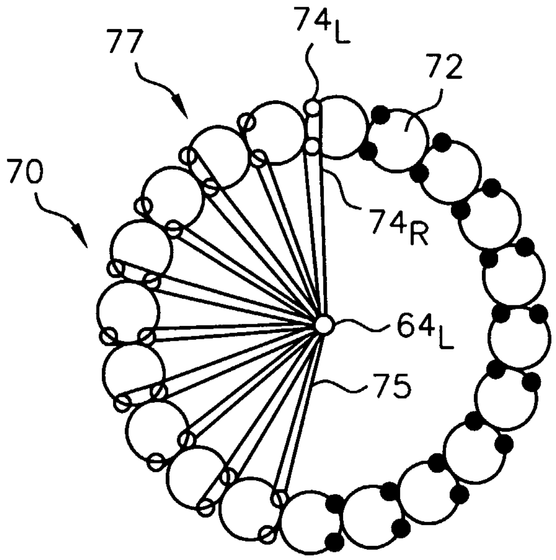


FIG. 5C

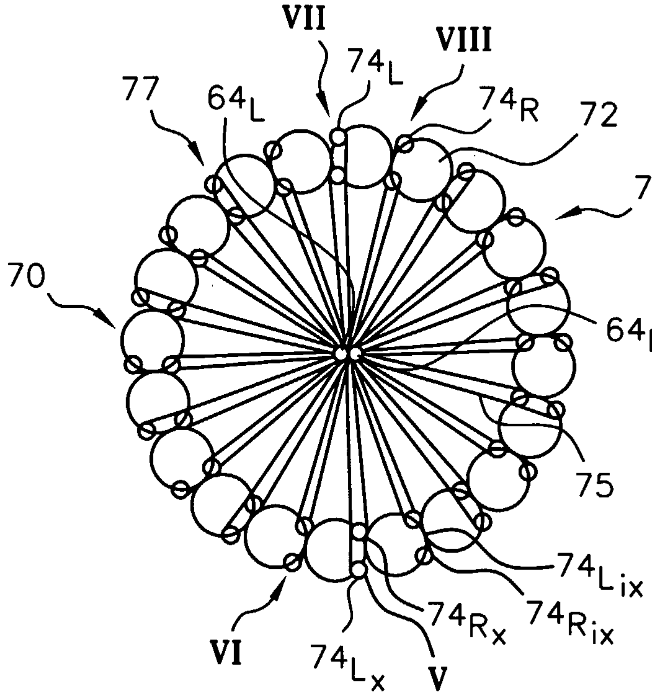


FIG. 5D

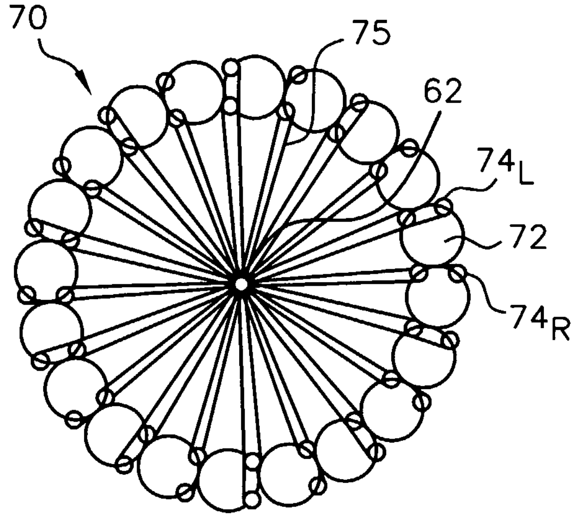


FIG. 5E

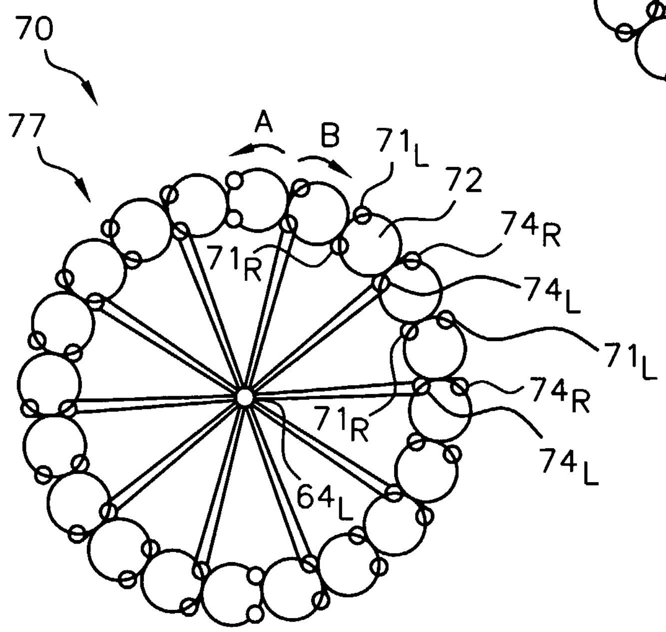


FIG. 5F

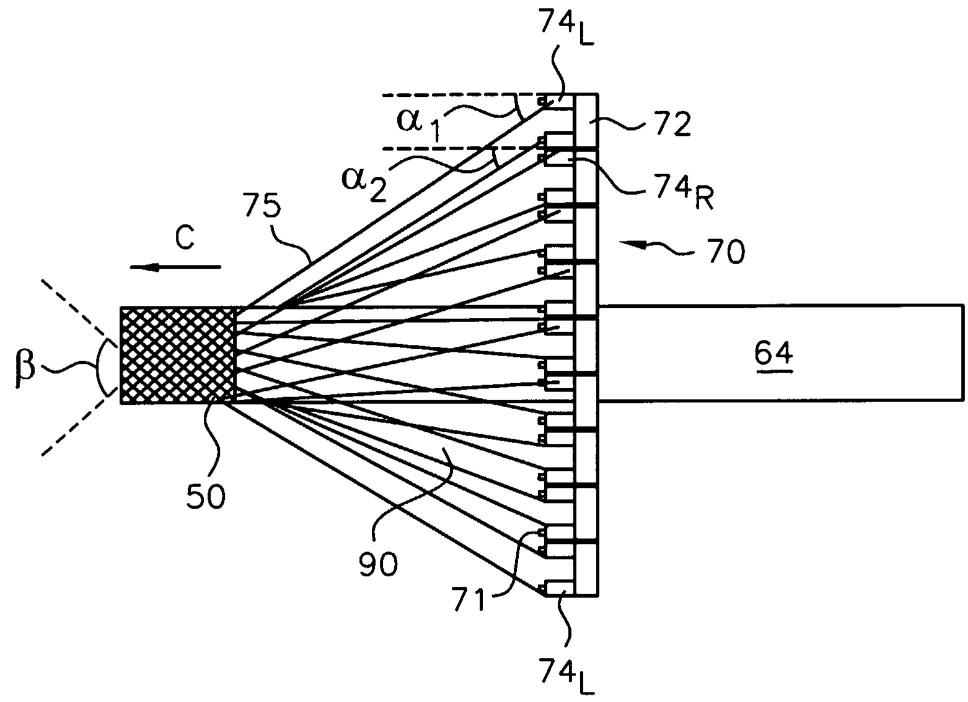
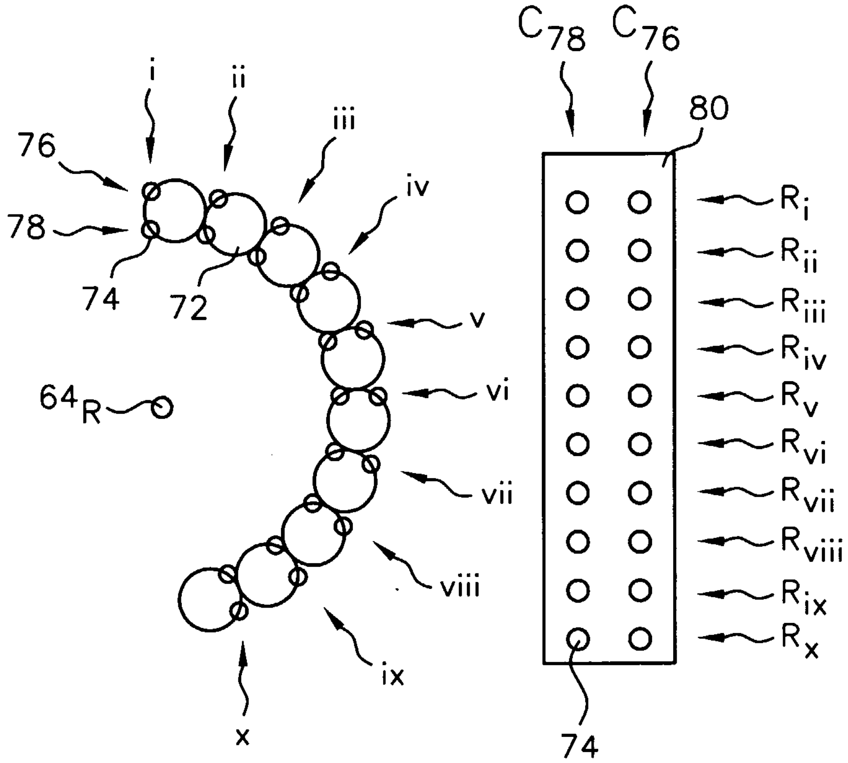

74L
α1
72
α2
74R
75
C
70
64
β
50
90
71
74L

FIG. 6


C78
C76
80
i
ii
iii
iv
76
78
74
72
v
vi
vii
viii
ix
x
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Riv
Rv
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Rvii
Rviii
Rix
Rx
74

FIG. 7

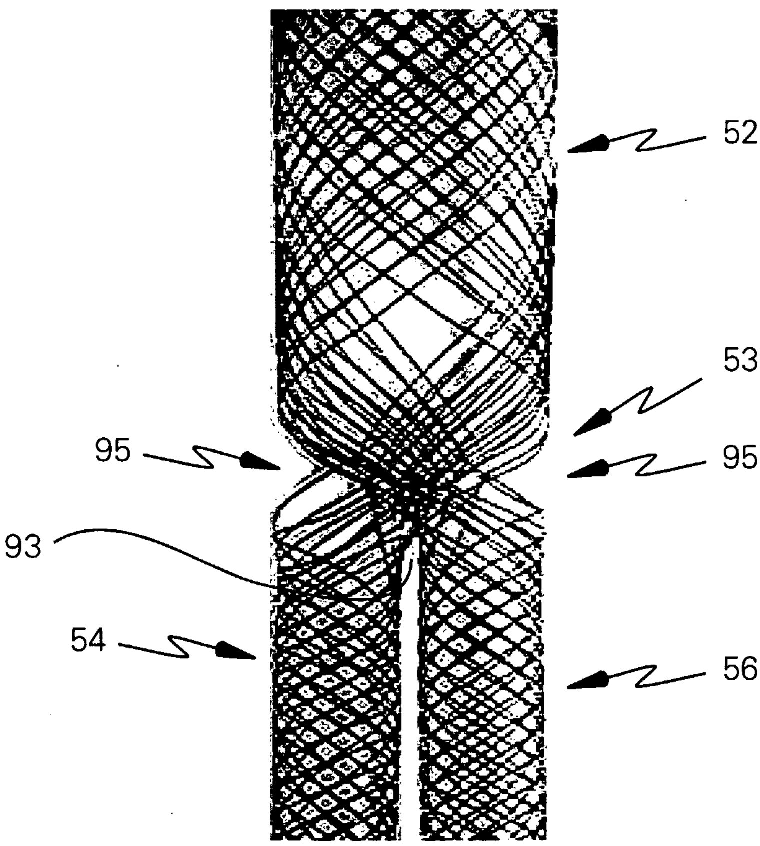

FIG. 8

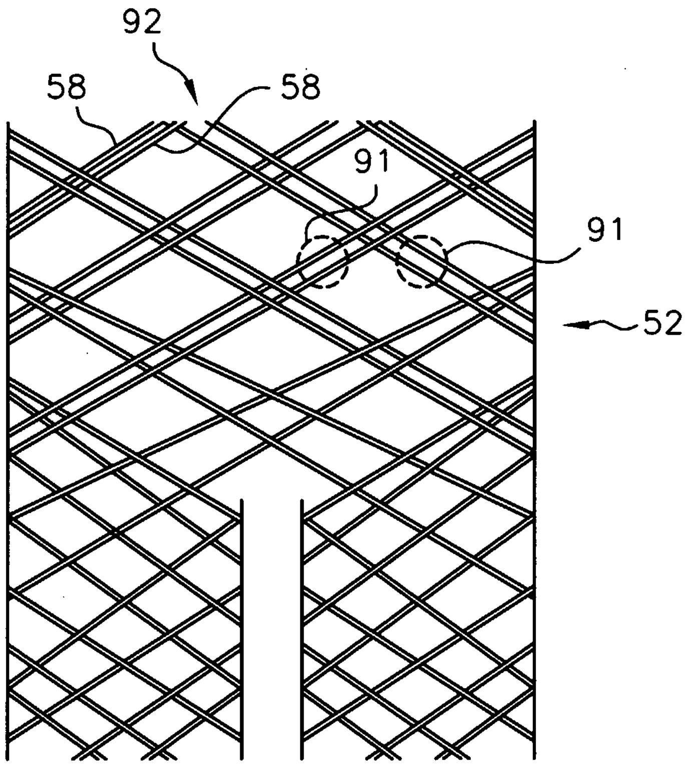

FIG. 9

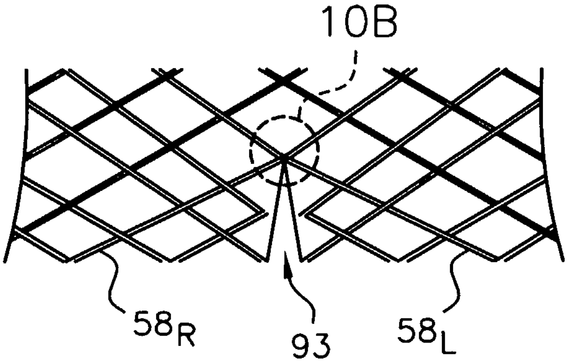

FIG. 10A

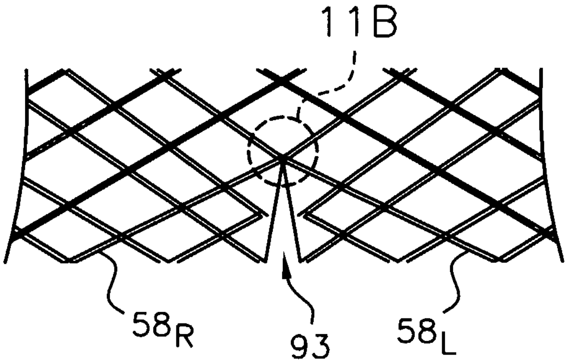

FIG. 11A

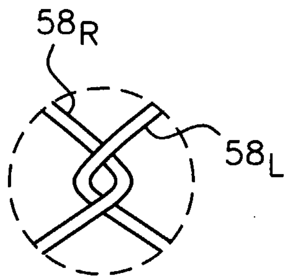

FIG. 10B

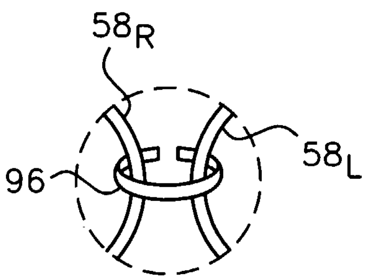

FIG. 11B

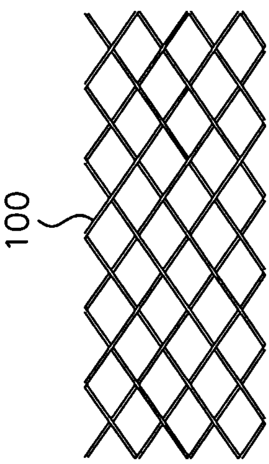

FIG. 13B
(Prior Art)

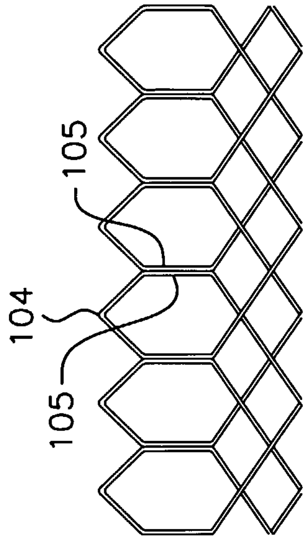

FIG. 13D
(Prior Art)

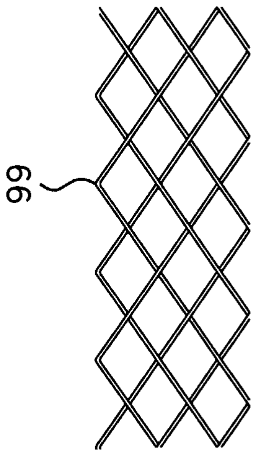

FIG. 13A
(Prior Art)

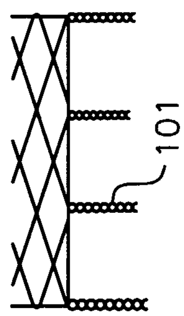

FIG. 13C
(Prior Art)

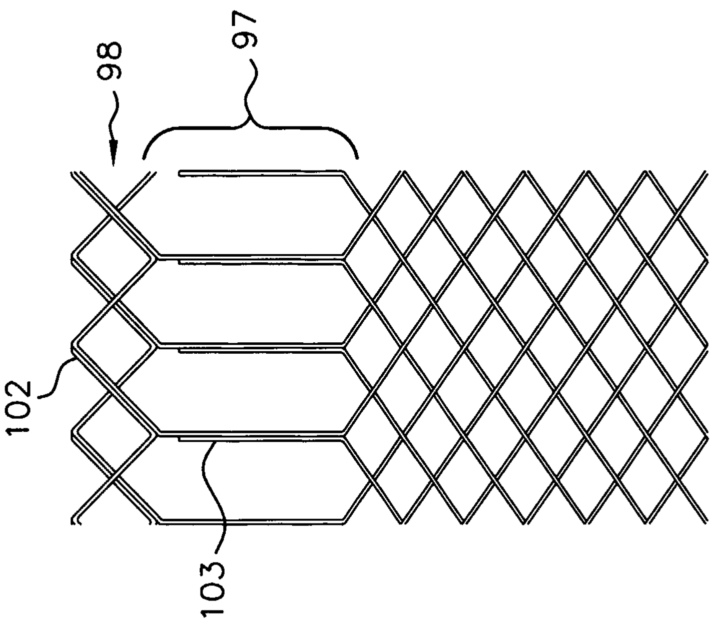

FIG. 12

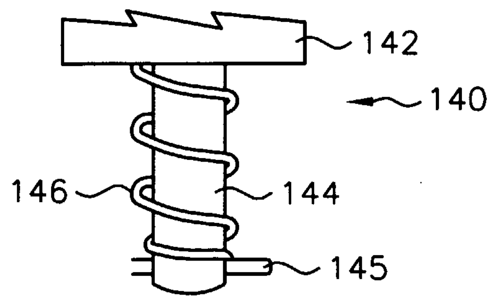

FIG. 14A

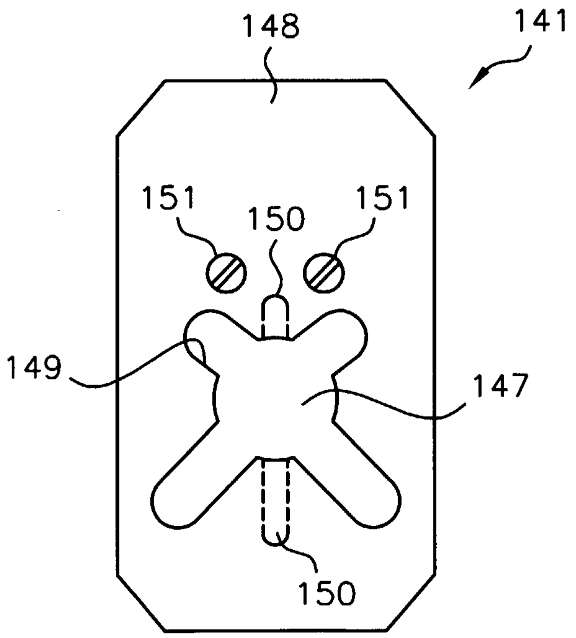

FIG. 14B

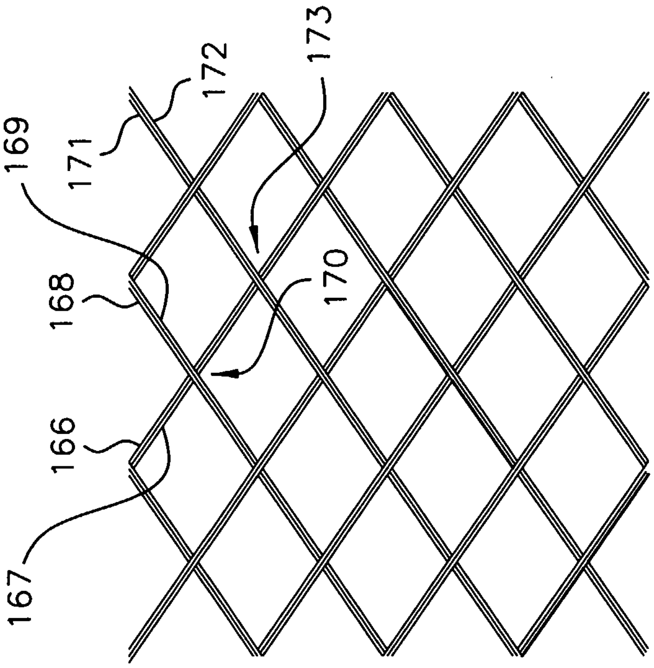

FIG. 15C
(Prior Art)

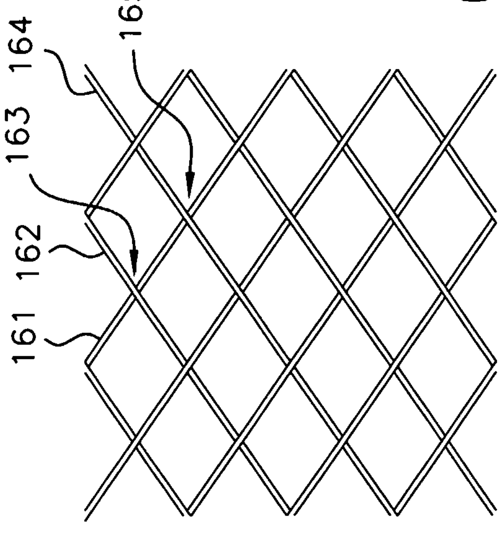

FIG. 15A
(Prior Art)

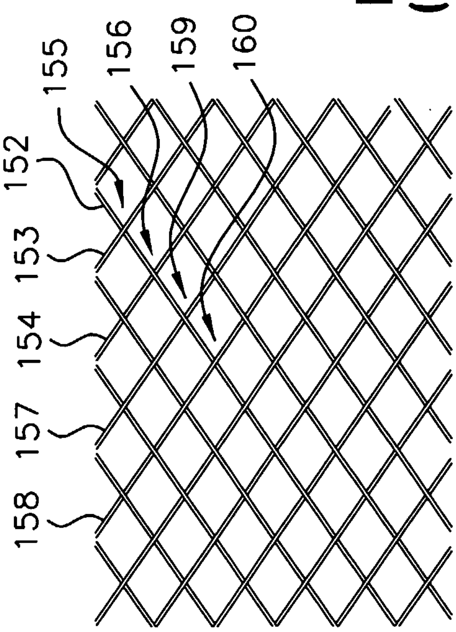

FIG. 15B
(Prior Art)

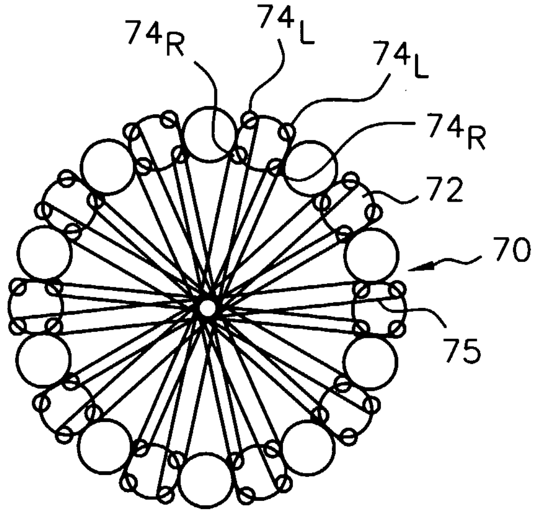

FIG. 16
(Prior Art)

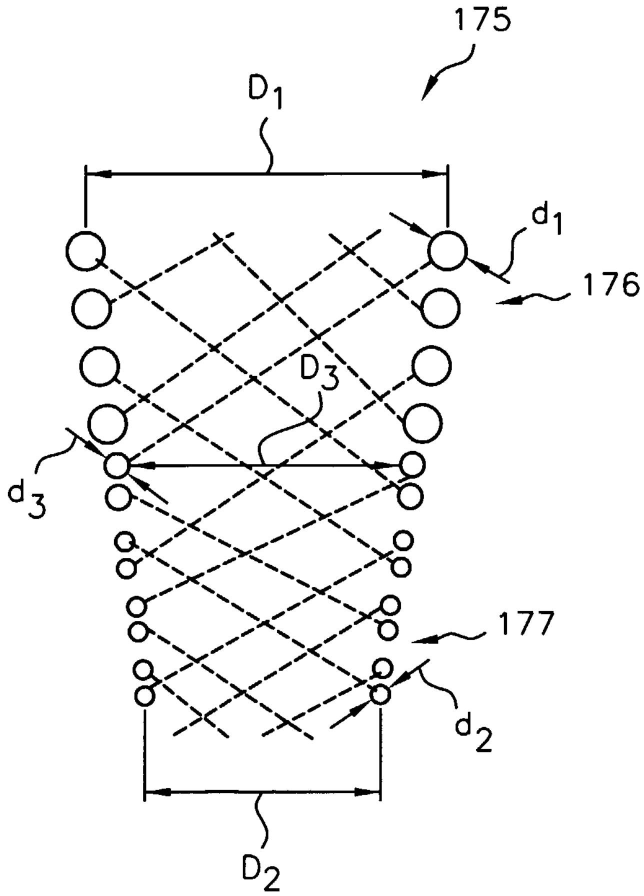

FIG. 17

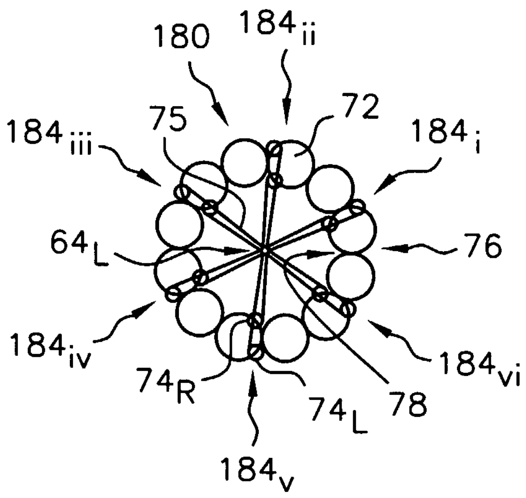

FIG. 18A

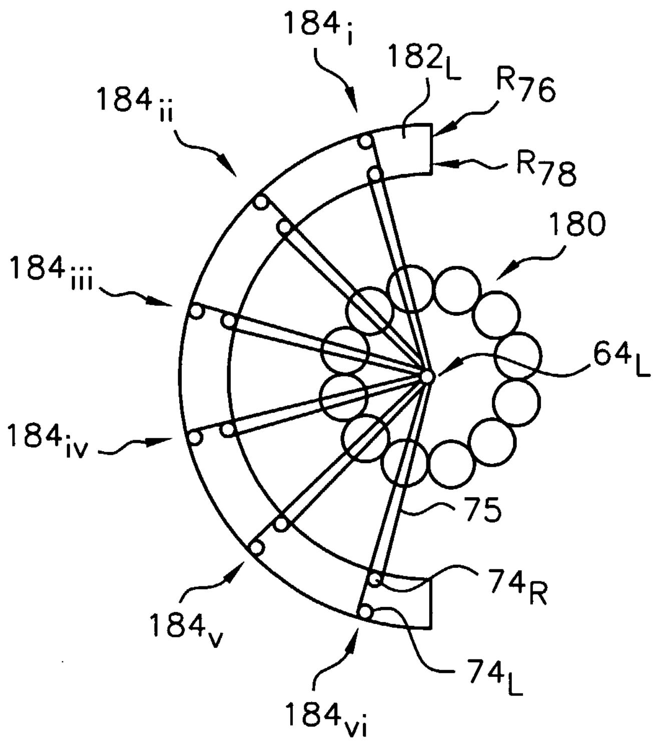

FIG. 18B

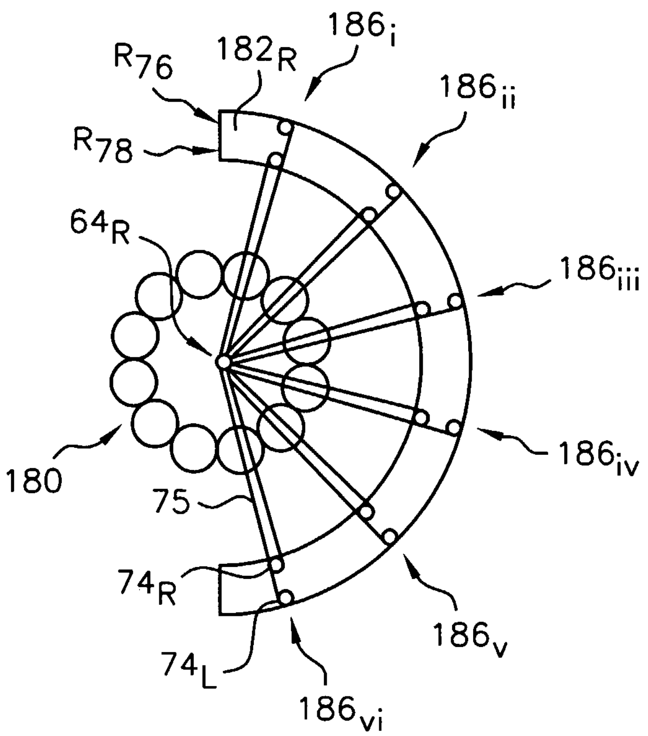

FIG. 18C

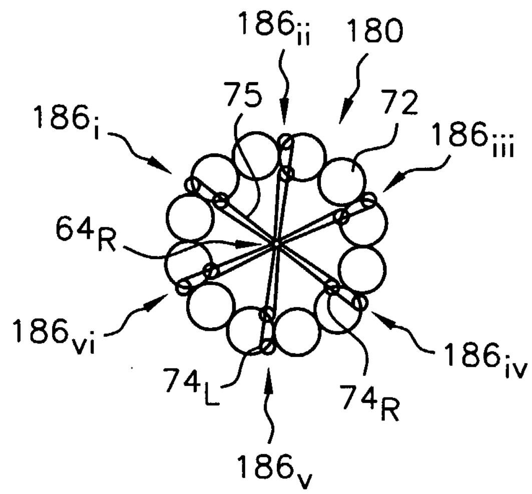

FIG. 18D

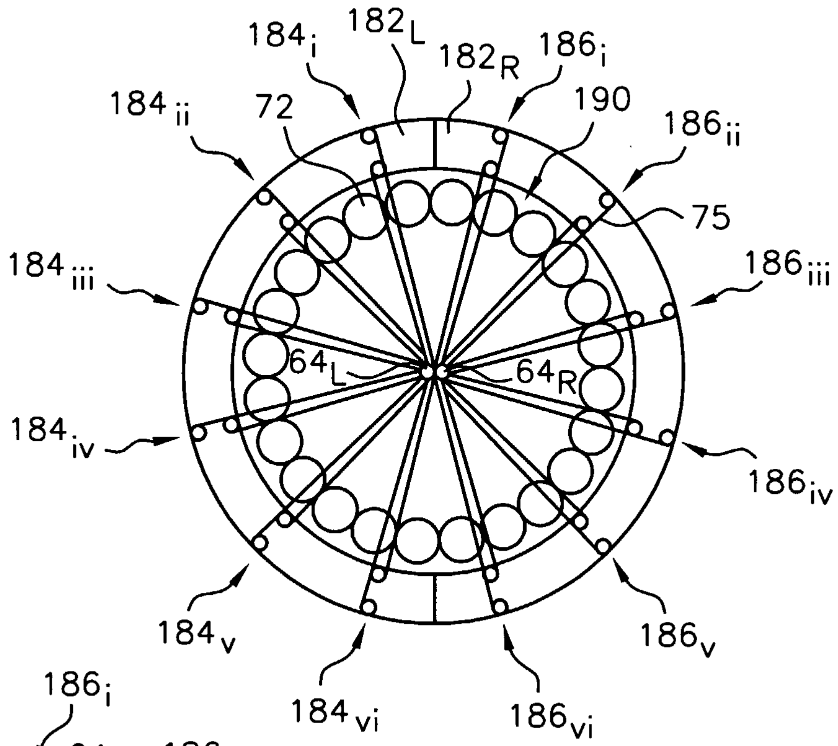

FIG. 19A

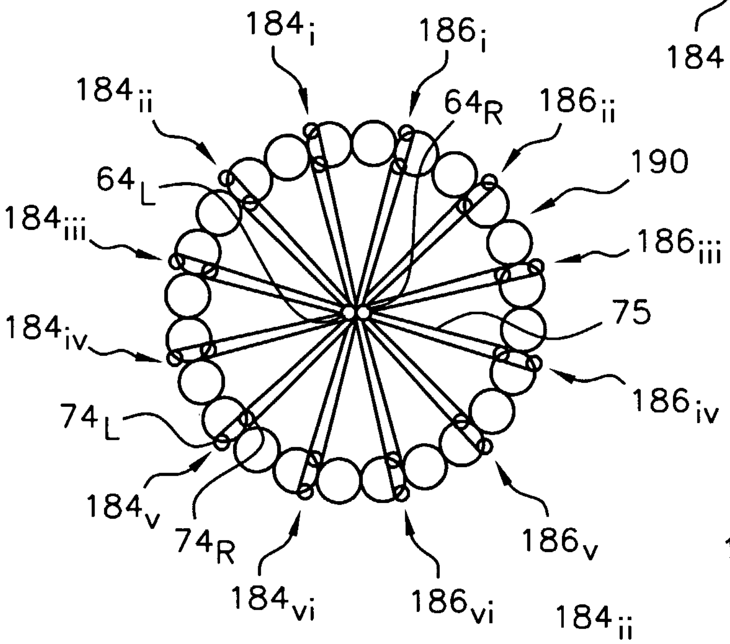

FIG. 19B

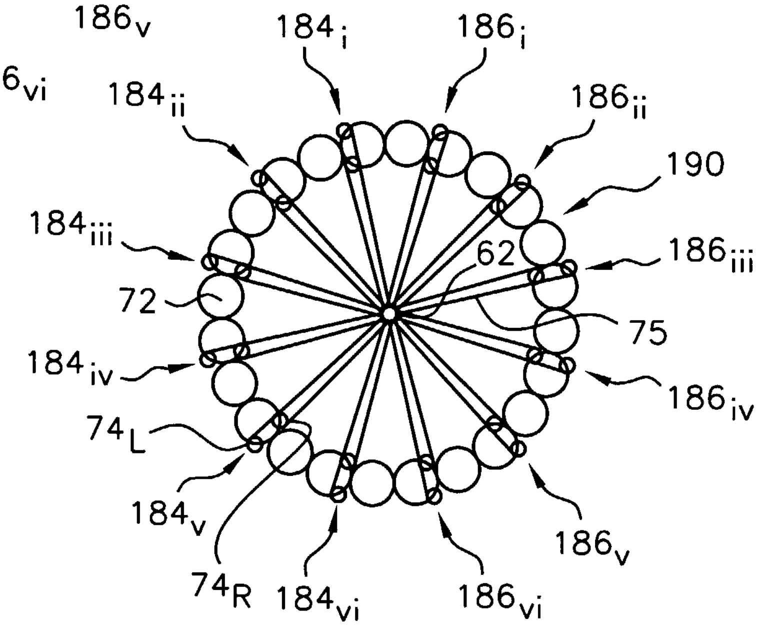

FIG. 19C

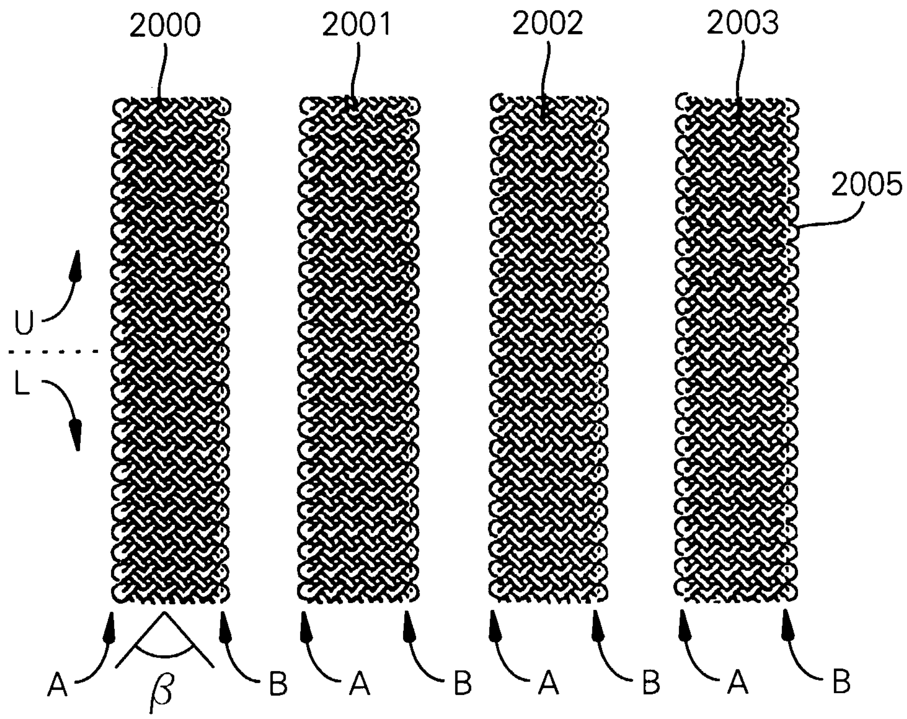

FIG. 20A

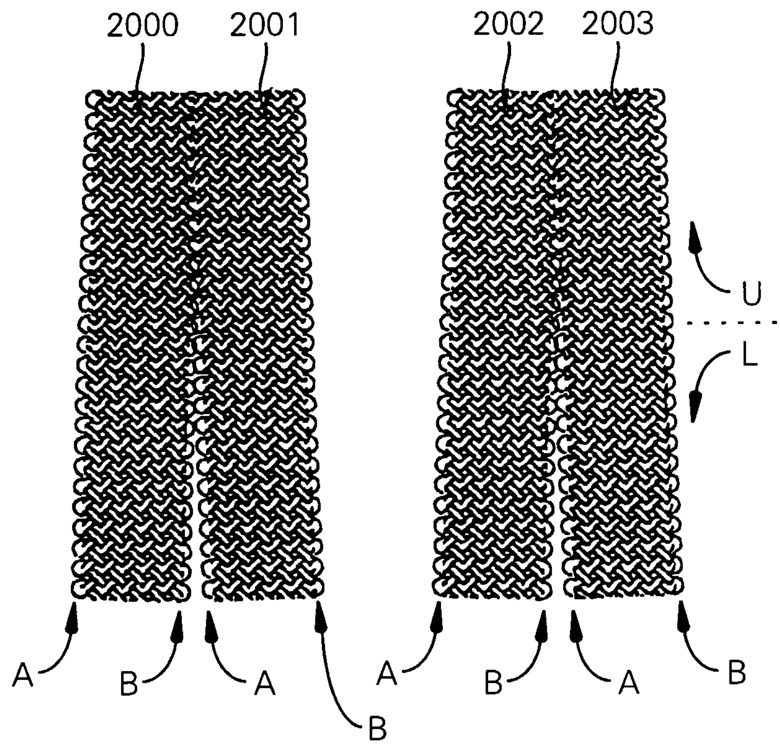

FIG. 20B

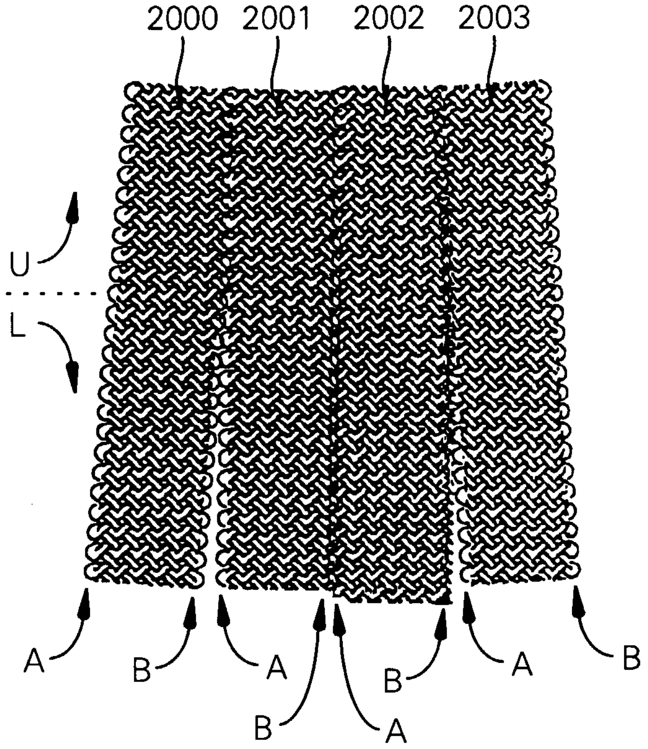

FIG. 20C

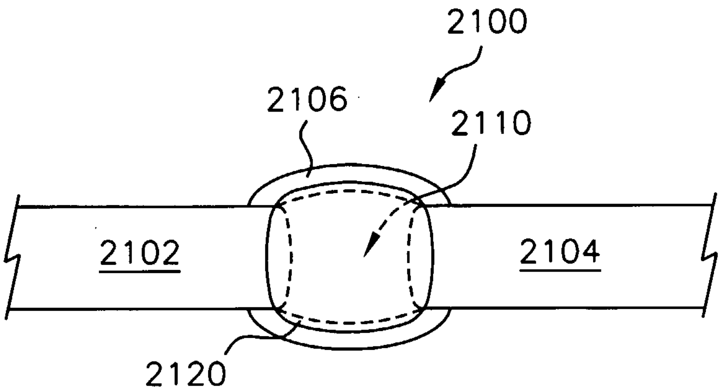
2100
2106
2110
2102
2104
2120

FIG. 21

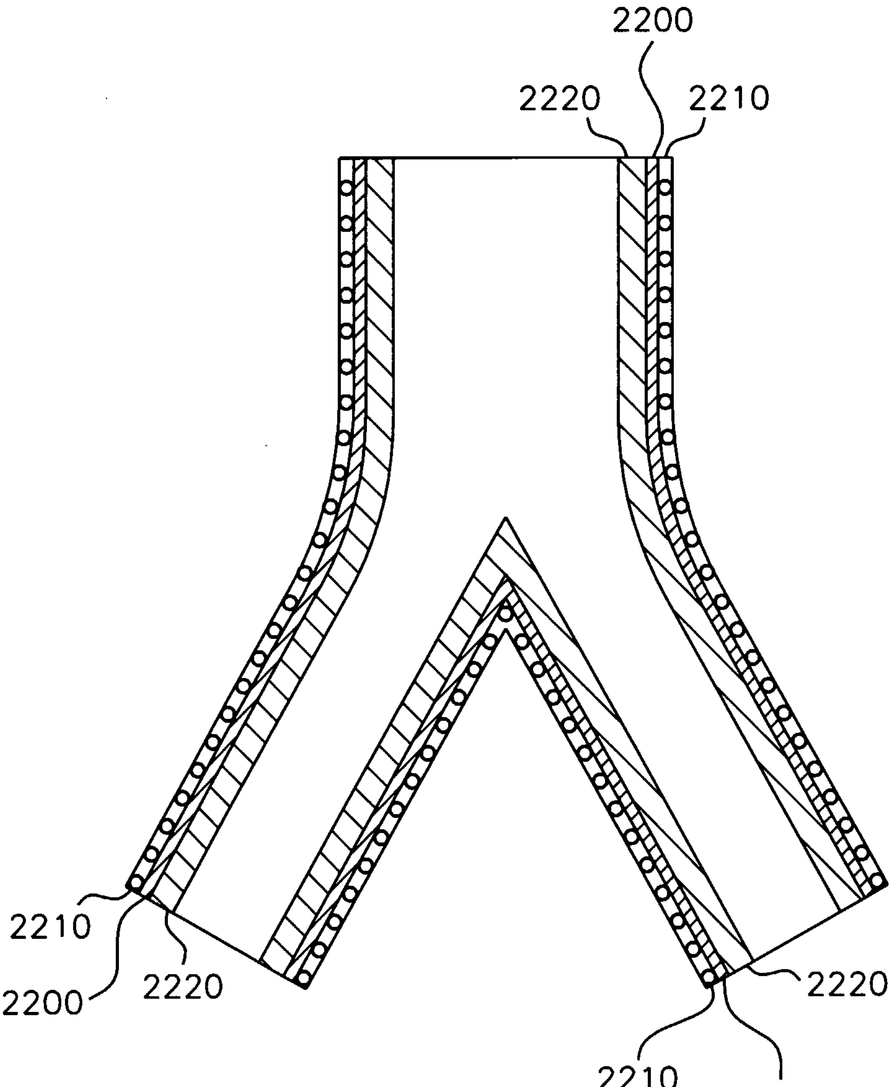
2200
2220
2210
2210
2200
2220
2220
2210
2200

FIG. 22