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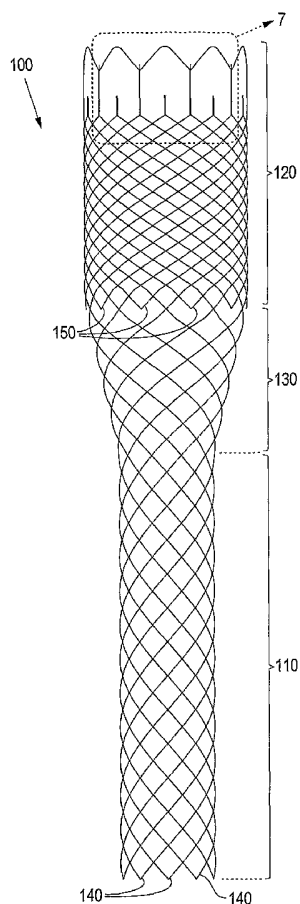
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(54) Title: BRAIDED STENT AND METHOD FOR ITS MANUFACTURE TECHNICAL FIELD



(57) Abstract: A stent and method for making the stent are provided. The stent comprises regions of differing numbers of braided filaments to provide a stent with different dimensions and/or properties in different regions along the stent length. A preferred stent (100) comprises a first (11) and second plurality (12) of braided filaments each braided together. The second plurality of braided filaments is braided into the first plurality of braided filaments to form a region of different properties than the first. A preferred embodiment is a stent (100) having a narrower diameter along a more flexible region (110) and a broader diameter along a more rigid region (120). Also included is a method of constructing a braided stent in accordance with the above. The method comprises the steps of braiding a first plurality of filaments to form the flexible portion, combining a second plurality of filaments to the first plurality of filaments, and then braiding the second plurality of filaments with the first plurality of filaments to form the more rigid region from the combination of the first and second plurality of filaments, wherein the second plurality of filaments are braided only in the rigid region.



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BRAIDED STENT AND METHOD FOR ITS MANUFACTURE

TECHNICAL FIELD

This invention relates generally to stents and stent-grafts, and more specifically, to braided stents and stent-grafts having segments of
5 different strength and rigidity along the length, and/or different diameters of varying or constant strength and rigidity along the length.

BACKGROUND OF THE INVENTION

A stent is an elongated device used to support a luminal wall. A stent, along with a graft cover or liner, together provide an unobstructed
10 conduit for fluid flow in the area of a stenosis. Such a stent-graft would typically have a tubular graft layer covering, or lining, the inside or outside of the stent (or both), thus providing a fluid conduit to bypass a stenosis or otherwise diseased body passageway.

Various types of stent architectures are known in the art, including
15 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 Wallsten patent is only one example of the many variations of braided stents
20 known in the art and thus is not intended to be 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 use in intraluminal delivery where the lumen of the vessel becomes contorted and
25 irregular both before and after placement of the stent.

The most common use of stents and stent-grafts is in the vascular system, in which stents and stent-grafts having a first small diameter compressed configuration may be introduced into a body lumen at a point remote from a site in that lumen in need of repair and then transported
30 through that lumen, typically through a catheter, to that site. Once the site in need of repair is reached, the stent or stent-graft is either expanded or allowed to expand to a second, expanded configuration to provide an open passageway through that site.

Many of these braided stents have the problem, however, of either being too rigid such that intraluminal delivery and placement becomes difficult, or too flexible (at the cost of reducing radial strength) such that radial expansion forces exhibited at the site of treatment are insufficient to
5 adequately maintain an open passageway through the site. Moreover, by increasing the radial strength of a stent, one typically reduces flexibility, because the stent is more rigid. Likewise, by increasing flexibility, radial strength is often sacrificed.

Thus, there is still a need to provide a fully-supported stent-graft
10 that is flexible enough for navigation through tortuous lumina but rigid enough to properly anchor the device and maintain patency through the device at the site of treatment.

SUMMARY OF THE INVENTION

The present invention provides a stent having segments of
15 different strength and rigidity, or other differential properties, along its length, and/or different diameters of varying or constant properties along its length. In one embodiment of the invention, the diameter along the length of the stent is constant, but the rigidity of the stent changes along the longitudinal axis. In another embodiment, the rigidity of the stent stays the same along the
20 longitudinal length, but the diameter changes. In still yet another embodiment, both rigidity and diameter change along the length of the stent. This variance in diameter and/or radial strength or rigidity is achieved through the use of different numbers of filaments braided into the stent at different locations. Generally, where more rigidity, or the same rigidity with a larger
25 diameter, is desired, more filaments are added.

More specifically, and in a preferred embodiment, the stent of the present invention has a first plurality of braided filaments in one region, and an additional plurality of filaments added to the first plurality of filaments which are together braided to form a second region. The second plurality of filaments
30 are present only in the second region. A preferred embodiment comprises a stent having a narrow region and a broader region with the broader region comprising more filaments than the narrow region such that increased radial strength is exhibited in the broader region. A more preferred stent of the

present invention has a first plurality of filaments extending throughout the narrow region and the broader region, and a second plurality of filaments extending along only the broader region. The second plurality of filaments is preferably braided into the first plurality of filaments. In a still yet more
5 preferred embodiment, the stent further comprises a transition region between the narrow region and the broader region. The transition region is comprised of the first plurality of filaments whose braiding increases in diameter from the narrow region to the broader region.

Also included in the invention is a method of braiding a stent
10 having a region of relatively greater flexibility and a region of relatively higher radial strength. The method includes the steps of first braiding a first plurality of filaments to form the more flexible region, and then adding a second plurality of filaments to the first plurality and together braiding the combination to form the more rigid region of the stent. The method preferably includes the
15 steps of first braiding a first plurality of filaments to form a narrow region, then combining a second plurality of filaments to the first portion, and braiding the second plurality of filaments with the first plurality of filaments to form a broader region from the combination of the first and second plurality of filaments. The method preferably includes braiding the stent around a mandrel
20 having a mandrel body comprised of a first portion and a second portion, wherein the first step comprises braiding the first plurality of filaments about the first mandrel portion, and the last step comprises braiding the second plurality of filaments combined with the first plurality of filaments about the second mandrel portion. The second plurality of filaments are present only in
25 the more rigid region. The second mandrel portion preferably has a larger diameter than the first mandrel portion.

An optional, but preferred feature of the invention, is the provision of atraumatic termination to the braided stent structure, both at the stent ends and at the mid-stent locations where one plurality of braided filaments ends.

30 BRIEF DESCRIPTION OF DRAWINGS

The invention is best understood from the following detailed description when read in connection with the accompanying drawings. It is emphasized that, according to common practice, some of the features of the

drawings 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 side view of a stent according to the present invention
5 having a constant radius;

Fig. 1B is a side view of a stent according to the present invention
having a narrow region and a broader region;

Fig. 2 is a close-up, partial view of an area of the stent of Figs. 1A
or 1B between the flexible region and the rigid region;

10 Fig. 3 is a side view of a mandrel used in accordance with the
present invention to make the stent shown in Fig. 1B;

Fig. 4 is a front view of part of a braiding machine used to braid
the narrow region of the stent shown in Fig. 1B;

15 Fig. 5 is a front view of part of a braiding machine used to braid
the broader region of the stent shown in Fig. 1B;

Fig. 6 is a side view of part of a braiding machine used to braid
the stent shown in Fig. 1B; and

Fig. 7 is a close-up, partial view of an atraumatic end of a stent in
accordance with the present invention.

20 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.

25 Referring to Fig. 1A, there is shown a braided stent 10 according
to the present invention. For purposes of this invention, a braided stent is one
formed by at least two sets of parallel continuous filaments, the two sets
traversing the circumference of the stent in lengthwise but angularly
intersecting directions. The two sets of filaments are interlaced or interwoven
30 to form a tubular, supportive structure. The stent shown in Fig. 1A comprises a
relatively flexible region 11 and a relatively rigid region 12 (having greater
radial strength than flexible region 11). Rigid region 12 comprises more
filaments than flexible region 11 and therefore exhibits greater radial strength.

In one embodiment (and as shown in Fig. 1A), the number of filaments in rigid region 12 is twice that of flexible region 11. A stent as shown in Fig. 1A can be braided on a mandrel (not shown) using the method described in detail below.

Referring now to Fig. 1B, there is shown a braided stent 100 according to the present invention. As shown in Fig. 1B, the stent comprises a narrow (or smaller diameter) region 110 defining a first lumen comprised of a first plurality of filaments, and a broader (or larger diameter) region 120 defining a larger lumen than said first lumen. Broader region 120 is comprised of the plurality of filaments from narrow region 110, plus a second plurality of filaments braided into the first plurality of filaments. Narrow region 110 has greater flexibility than broader region 120, and, likewise, broader region 120 exhibits greater radial strength than narrow region 110.

Fig. 1B also shows transition region 130. Transition region is formed between narrow region 110 and broader region 120 and is comprised of the filaments which make up narrow region 110. Transition region 130 is formed during braiding on a mandrel of changing diameter, as described in more detail below.

The stents shown in Figs. 1A and 1B are unitary stents. That is, the stent is one piece, unlike modular stent designs in which two or more stent segments are assembled together to form the various parts of the overall device (e.g., a trunk section and two legs). Thus, a unitary stent contemplates a stent whose entire length is made as a single unit, without the need to attach additional stent segments upon deployment. The stent as shown in Fig. 1B, for example, although unitary, exhibits different radial strengths along its longitudinal axis. This is because of the introduction of additional filaments in broader region 120.

It should be noted here that unitary stents 10 and 100 as shown in Figs. 1A and 1B, respectively, are merely exemplary embodiments, and that this invention is applicable to "modular" braided stents as well. As used herein, the term "modular" means a stent having at least two discrete portions adapted for assembly *in situ*. As is well-known in the art, one type of exemplary modular stent may include a modular bifurcated stent comprising a trunk section with a bifurcated region that terminates in 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. Thus, although the invention as illustrated and described herein primarily references a non-bifurcated structure, each of the methods and structures described
5 herein is equally applicable to pieces of structures such as trunk components for receiving modular leg elements, which may themselves be made in accordance with the present invention.

Braiding of the filaments which form the stent of the present invention may be performed on a braiding machine having a predetermined plurality of bobbin carriers adapted to revolve in a pattern about a longitudinal
10 axis. A first set of bobbin carriers may be adapted to revolve in a first circumferential direction and a second set of bobbin carriers may be adapted to revolve in a second circumferential direction, each bobbin carrier adapted to carry at least one bobbin. Each bobbin is adapted to provide one or more
15 filaments for braiding the stent.

In such a case, braiding of the narrow, or flexible, region comprises using filaments from a first portion of the predetermined plurality of bobbins to braid the narrow portion about the first, narrow portion of the detachable mandrel leg positioned substantially along the longitudinal axis in a
20 braiding zone. The braiding zone is defined as a conical zone defined by the filaments extending from the bobbins to the stent on the mandrel. The preferred number of filaments used to braid the narrow region is 12, although any suitable number may be used to achieve the desired balance between compressibility and radial strength of this region. The filaments used with the
25 present invention may be any known to those skilled in the art, and preferably may be wire, such as nitinol or stainless steel, or may comprise a polymer.

In braiding the broader, or more rigid, region, the process comprises adding filaments from a second portion of the predetermined plurality of bobbins to increase the number of filaments used to braid the
30 broader region about the second portion of the detachable mandrel leg positioned in the braiding zone. The additional filaments added are used in conjunction with the filaments already in place from braiding the narrow region of the stent. In other words, this second step comprises using filaments from

both portions of the predetermined plurality of bobbins to braid the body about the second, larger diameter, mandrel body positioned in the braiding zone. The second plurality of filaments are only used in the broader region, and nowhere else in the stent.

5 Fig. 2 shows a flattened, partial view of the lower part of broader region 120 shown in Fig. 1. This part of the stent according to the present invention is discussed in more detail below. At each overlap, one filament is positioned radially outward relative to the other filament. Following each filament along its helical path through a series of consecutive overlaps, that
10 filament 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
15 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
20 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 stent of the present invention is not intended to
25 be limited to the specific machine embodiment described herein, but extends to functionally equivalent machines as well.

Braiding machines can be used for manufacturing the stent of the present invention about an exemplary modular mandrel as shown in Fig. 3. In Fig. 3, mandrel 300 comprises lower region 310 and upper region 320, with
30 transition region 330 disposed therebetween. These regions correspond with the narrow region, broader region, and transition region, respectively, as shown in Fig. 1B. Pins 340 are also shown. Pins 340 are used to anchor

filaments during braiding, an aspect known to those skilled in the art and discussed in more detail below.

Referring now to Figs. 4 and 5, braiding machine 70 is shown schematically as typically comprising a number of notch gears 72 arranged in a circle. Machine 70 shown in Figs. 4 and 5 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 filament 75 wound thereon. The bobbin carrier and bobbin typically interface in a way that helps keep the wire 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. 4 (as darkened circles having no filament extending therefrom), each bobbin 74 also is mounted upon a bobbin carrier, creating a "loaded" bobbin carrier. To reduce clutter in Figs. 4 and 5, the underlying bobbin carrier is not shown for carriers loaded with bobbins 74.

During braiding, the mandrel around which braided stent 100 is formed, such as mandrel 300 as shown in Fig. 3, 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. Fig. 6 illustrates, from the side, such a configuration. Thus, during braiding, wires 75 extend from braiding machine 70 to mandrel 300 in a conical configuration, as shown in Fig. 6.

As can be seen from Fig. 6, as two bobbins cross one another, their respective filaments form an overlap such that the filament 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 filament from the bobbin on the inner radius 78. The space contained within the cone formed by the wires extending between the bobbins and the mandrel and including the space occupied by the mandrel is referred to herein as the "braiding zone" 90.

5 Although the angles α_1 and α_2 of the wire 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 wire is on the inside radial position or outside radial
10 position on an overlap. 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 filaments between the mandrel and the bobbins allows the
15 braiding operation to create a functional braid without tangling the filaments.

To form a braid around a mandrel, wires 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 specifically do not have to be kept in any particular orientation. For example, all the wires may all be taped or
20 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 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
25 below. In the alternative, to minimize scrap, the ends of wires 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 a preferred embodiment, each filament has each of its two
30 halves wound around a separate bobbin so that the filament is wound on to two bobbins, each half of the filament on a separate bobbin. In such a case, a first end of the filament is wound on a first respective bobbin and a second end of the filament is wound on a second respective bobbin, with the filament

midpoint exposed between the two bobbins. From this pair of bobbins, the midpoint of the filament is withdrawn and positioned on the mandrel to form an apex at a point where each filament is added to the stent. It is not required that the exact midpoint be exposed between the two bobbins, only that the
5 filament is wound generally equivalently on to each bobbin such that enough of the filament exists on each bobbin to allow braiding of the stent.

For example, if a stent is desired such as that shown in Fig. 1B, six pairs of bobbins are prepared and disposed on a braiding machine as described in more detail below. Each apex 140, for a total of 6 apices, is
10 formed by attaching the approximate midpoint of each filament to the mandrel. With 12 bobbins thus disposed to provide 12 wires to braid (one "wire" extending in opposing directions from each of six apices 140), narrow region 110 is braided. In such a case, although actually six filaments are used, the narrow region is effectively braided with 12 wires because each filament bends
15 at apex 140. Then, once narrow region 110 and transition region 130 are braided, an additional six pairs of bobbins are added, with six apices 150 formed at the beginning of broader region 120. Thus, broader region 120, as shown, is effectively braided of 24 wires. The apices described above are preferably formed by winding each filament about a respective pin on the
20 mandrel as is well known in the art. Each such pin is the point where an apex is formed.

In such a case as just described, the first and second bobbins should be positioned on bobbin carriers in positions consistent with the helical angle of the stent and the distance of the mandrel from the bobbin carriers.
25 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 stent. An exemplary process for providing a stent with such ends is described in publication WO 99/25271 to Burlakov et al. and is
30 incorporated herein by reference.

In one method for creating the braided stent of the present invention, the braiding machine is first loaded as shown in Fig. 4 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. In such a case, a different machine, with at least twice the number of bobbin carriers, would have to be used for braiding the broader region. Alternatively, the first portion 73 may comprise half of the bobbin capacity of the machine.

5 This latter embodiment is that which is shown in Fig. 4, in which 10 of the 20 available bobbin carriers are loaded and ready for braiding.

The braiding operation is then performed as described above to form the narrow region of the braided stent around lower region 310 of mandrel 300. After braiding the narrow region about the lower region of the
10 mandrel, and the transition region of the stent about the transition region of the mandrel, the stent is ready to have the additional filaments added so that the additional filaments can join the existing filaments and together form broader region 120 around upper region 320 of the mandrel.

Where the bobbins used to braid narrow region 110 must be
15 moved from the braiding machine as described in more detail below, the existing filaments which are going to be used to finish braiding the stent must be secured to prevent backlashing or loosening of that part of the stent already braided. This can be done either by tying each off on a pin on the mandrel, or simply tying or clamping all of the filaments against the mandrel at a point
20 where the additional filaments are going to be added to form the broader region of the stent.

As noted above, the method for adding filaments in preparation of braiding the broader region may include moving the bobbins used in the braiding of the narrow region. This movement may be accomplished by any of
25 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
30 be simply unlocked and lifted off of their respective bobbin carriers and the filament 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
5 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 filament addition process can be essentially understood by
10 comparing Figs. 4 and 5. Prior to filament addition, the bobbins are configured as shown in Fig. 5, with pairs of bobbins positioned relative to one another shown with empty bobbin holders between each pair. To prepare to braid the broader region of the stent in one embodiment, additional bobbin pairs are added between each bobbin pair used to braid the narrow region.

15 Alternatively, if the bobbin machine used to braid the narrow region of the stent has no additional bobbin holders (a situation not shown in Fig. 4), the system of bobbin pairs and mandrel used to braid the narrow region and transition region can be moved to a machine which has at least twice the number of bobbin carriers. During the bobbin movement step in such
20 a case, it is desirable to preserve the clockwise or counter-clockwise rotation of each bobbin 74. Bobbin carriers 71 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 71 form a second set of bobbin carriers that traverse the circle in the clockwise direction. Furthermore, where the entire
25 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.

Important in the filament addition step is that the bobbins be arranged, either by movement to a different machine, or addition of extra bobbins, so that the desired overlap between filaments be obtained. For
30 example, and as shown in Fig. 2, the general pattern is under/over/under/over through the length of the filament. Certain regions, however, such as for filament 210 in transition region 130, will have the filament, such as filament 210, disposed under to consecutive parallel filaments 211 and 212. The

preferred arrangement of the braiding can vary, and is generally known by those skilled in the art. So long as a desired pattern is known, the bobbins can be arranged when the filaments are added for the broader region so as to achieve that desired pattern.

5 With regard again to Figs. 4 and 5, the counter rotation of the notch gears means that each notch gear 72 having a clockwise-rotating bobbin 74 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 71 (and therefore bobbins 74) may travel clockwise instead of
10 counter-clockwise, with carriers 71 and bobbins 74 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. 4, the wire originating from bobbin 74 is tangent
15 to the right side of both the bobbin and mandrel 300, and likewise the wire originating from bobbin 74 is tangent to the left side of both the bobbin and mandrel.

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
20 architecture where 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. 7. The structure and method for making a hexagonal non-braided architecture 700 with an overlapping end winding 710 shown in Fig. 7
25 can be accomplished through known winding and welding techniques. In the embodiment shown in Fig. 7, each filament end 710 is welded to an adjacent piece of filament near its end 710. Apices 720 are formed to make the end of the stent "atraumatic." Shorter filament segments terminating below apices 720 may be otherwise-terminated, such as by clipping them at otherwise-
30 terminated free ends 730. The end architecture as shown in Fig. 7 can be described as "atraumatic" in the sense that there are no loose or sharp wire ends that may puncture or irritate (or otherwise cause trauma to) the lumen wall after implantation. Other methods of providing atraumatic ends may also

be used as are known in the art. The end architecture is not limited to the architecture shown and described above, but may comprise any number of configurations known in the art.

Atraumatic ends of the braided stent structure may also be
5 provided by making adjacent filament pairs of filaments from each of the
angularly disposed sets of parallel filaments, continuous with one another.
Such atraumatic ends may be located at an end of the stent, as seen at 140 in
Fig. 1B, or at the mid-stent end of a stent region as seen at 150 in Fig. 1B,
where an additional plurality of braided filaments are continuous with one
10 another.

Moreover, using the method described above, one end of the stent
has atraumatic, continuous-wire apices 140 such as are shown in Fig. 1B at the
end of the narrow region 110. The filaments on the opposite end are
preferably also atraumatically disposed ends in a non-braided architecture,
15 such as for example apices 720 shown in Fig. 7. These are only examples,
however, as the free ends may terminate in any way known in the art.
Although one end of a stent may have some combination of continuous-wire
apices 720 and otherwise-terminated free ends 730, the preferred embodiment
comprises one end of the stent having only continuous-wire apices 720.

20 To deploy the stent of this invention, the stent is typically
compressed into a radially compressed state into an introducer as is well-
known in the art. The stent 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
25 state in the deployment location as is known in the art. The deployment of a
unitary stent of the present invention is thus accomplished by a method similar
to that used for any stent known in the art. Expansion is also achieved through
known methods (e.g. the stent is expandable between the radially compressed
configuration and the radially expanded configuration by one of: balloon
30 expansion, self-expansion via spring elasticity, or self-expansion via a
thermally or stress-induced return of a pre-conditioned memory material).

Although non-bifurcated stent designs have been shown and
described herein, the method of the present invention may be used for creating

stent segments which are combined to form bifurcated systems or any number of multiple lumen systems.

The stent of the present invention can also be used with any biocompatible graft connected thereto as one of: an outer covering, an inner
5 liner, or a combination thereof. These grafts are known to those skilled in the art. As used herein, the term, "stent" is intended to generally refer to a wire support frame alone, or a wire support frame in conjunction with a graft material connected thereto as one of: an outer covering, an inner liner, or a combination thereof. This later stent is sometimes referred to as a "stent-
10 graft" or "prosthesis comprised of a stent and graft."

While described above with reference to embodiments having only two regions of differential properties, stents or stent-grafts with three or more regions of differential properties are also envisioned and may also be made by duplicating the teaching above for introducing and terminating a separate
15 plurality of filaments at a mid-stent location.

Note too that the differential properties provided by varying the number of filaments in a braided stent structure are not limited to dimensional or rigidity/flexibility/strength characteristics, but may also include other properties, such as magnetizability, imagability, space density (the proportion
20 of stent circumference occupied or not occupied by filaments), etc.

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
25 departing from the spirit of the invention.

What is claimed:

- 1 1. A tubular stent comprising at least one lengthwise region,
2 differing from a second region of the stent with respect to one or both of
3 diameter and mechanical properties, said stent comprising:
4 a first plurality of braided filaments extending throughout
5 said stent, said plurality comprising two sets of parallel filaments
6 angularly disposed with respect to one another, defining the
7 circumference of the stent and running in a lengthwise direction
8 thereof; and
9 a second plurality of braided filaments extending along only
10 a second lengthwise region, said second plurality of filaments
11 braided into said first plurality of braided filaments only along said
12 second lengthwise region.
- 1 2. The stent of claim 1 wherein said one lengthwise region has
2 a diameter which is less than the diameter of said second region.
- 1 3. The stent of claim 2 further comprising a transition region
2 between said one lengthwise region and said second region, said transition
3 region comprised of the first plurality of filaments.
- 1 4. The stent of claim 1 combined with a biocompatible tubular
2 graft, said graft comprising one of: an outer covering, an inner liner, or a
3 combination thereof, for at least a portion of said stent.
- 1 5. The stent of claim 1 wherein the filaments comprise wire.
- 1 6. The stent of claim 5 wherein said wire is either nitinol or
2 stainless steel.
- 1 7. The stent of claim 1 wherein the stent extends between two
2 ends and each end comprises an atraumatic termination structure.
- 1 8. The stent of claim 1 wherein the stent has a radially
2 compressed configuration for introduction into the lumen and a radially
3 expanded configuration for deployment within the lumen.
- 1 9. The stent of claim 8 wherein the stent is expandable
2 between the radially compressed configuration and the radially expanded
3 configuration by one of: balloon expansion, self-expansion via spring elasticity,

4 or self-expansion via a thermally or stress-induced return of a pre-conditioned
5 memory material.

1 10. A stent comprising a narrow region and a broader region,
2 said stent comprising:

3 a first plurality of braided filaments extending along the
4 entire stent; and

5 a second plurality of braided filaments extending along only
6 said broader region, wherein said second plurality of filaments are
7 braided into said first plurality of filaments.

1 11. The stent of claim 10 further comprising a transition region
2 between said narrow region and said broader region, said transition region
3 comprised of said first plurality of braided filaments and increasing in diameter
4 from said narrow region to said broader region.

1 12. The stent of claim 10 combined with a biocompatible tubular
2 graft, said graft comprising one of: an outer covering, an inner liner, or a
3 combination thereof, for at least a portion of said stent.

1 13. The stent of claim 10 wherein the filaments comprise wire.

1 14. The stent of claim 13 wherein said wire is either nitinol or
2 stainless steel.

1 15. The stent of claim 10 wherein the stent extends between a
2 narrow end and a broader end, and each filament at the broader end
3 terminates in an atraumatic termination structure.

1 16. The stent of claim 10 wherein the stent extends between a
2 narrow end and a broader end, and each filament at both said ends terminates
3 in an atraumatic termination structure.

1 17. The stent of claim 10 wherein the stent has a radially
2 compressed configuration for introduction into the lumen and a radially
3 expanded configuration for deployment within the lumen.

1 18. The stent of claim 17 wherein the stent is expandable
2 between the radially compressed configuration and the radially expanded
3 configuration by one of: balloon expansion, self-expansion via spring elasticity,
4 or self-expansion via a thermally or stress-induced return of a pre-conditioned
5 memory material.

1 19. A method of constructing a braided stent having first and
2 second lengthwise regions of differing properties, said method comprising the
3 steps of:

4 (a) braiding a first plurality of filaments to form one lengthwise
5 region; and

6 (b) braiding together the second plurality of filaments with the first
7 plurality of filaments to form the second lengthwise portion;

8 wherein the second plurality of filaments are braided only in the second
9 portion.

1 20. The method of claim 19 comprising performing the braiding
2 on a braiding machine having a predetermined plurality of bobbins adapted to
3 revolve about a longitudinal axis, a first set of bobbins adapted to revolve in a
4 first circumferential direction and a second set of bobbins adapted to revolve in
5 a second circumferential direction, each bobbin mounted upon a bobbin carrier
6 adapted to carry at least one bobbin, each bobbin adapted to provide one or
7 more filaments for braiding into the stent;

8 step (a) comprising using filaments from a first portion of the
9 predetermined plurality of bobbins to braid the one lengthwise region about the
10 first mandrel portion positioned substantially along the longitudinal axis in a
11 braiding zone, the braiding zone being a conical zone defined by the filaments
12 extending from the bobbins to the stent on the mandrel, and

13 step (b) comprising using filaments from both portions of the
14 predetermined plurality of bobbins to braid the second lengthwise portion about
15 the second mandrel portion positioned in the braiding zone.

1 21. The method of claim 20 further comprising the steps of:

2 (A) first performing step (a);

3 (B) then removing the first portion of the predetermined
4 plurality of bobbins from the braiding machine and removing the mandrel from
5 the braiding zone;

6 (C) then performing step (b);

7 (D) then returning the first portion of the predetermined
8 plurality of bobbins to the braiding machine, attaching the mandrel to the
9 mandrel body, and positioning the mandrel in the braiding zone; and

10 (E) then performing step (c).

1 22. The method of claim 21, further comprising the steps of:
2 prior to step (a), winding each filament between two bobbins such
3 that a first end of each filament is wound on a first respective bobbin and a
4 second end of each filament is wound on a second respective bobbin, and
5 positioning a point of each filament on the mandrel to form an
6 apex at a location where each said filament is added to the stent.

1 23. A method of constructing a braided stent having a narrow
2 region and a broader region which has a greater diameter than the narrow
3 region, said method comprising the steps of:

4 (a) braiding a first plurality of filaments to form the narrow region;

5 (b) combining a second plurality of filaments to the narrow region
6 formed in step (a); and

7 (c) braiding the second plurality of filaments with the first plurality of
8 filaments to form the broader region from the combination of the first and
9 second plurality of filaments;

10 wherein the second plurality of filaments are braided only in the broader
11 region.

1 24. The process of claim 23 comprising braiding the stent
2 around a mandrel having a mandrel body comprised of a first portion and a
3 second portion, wherein step (a) comprises braiding the first plurality of
4 filaments about the first mandrel portion, and step (c) comprises braiding the
5 second plurality of filaments combined with said first plurality of filaments
6 about the second mandrel portion.

1 25. The method of claim 23 comprising performing the braiding
2 on a braiding machine having a predetermined plurality of bobbins adapted to
3 revolve about a longitudinal axis, a first set of bobbins adapted to revolve in a
4 first circumferential direction and a second set of bobbins adapted to revolve in
5 a second circumferential direction, each bobbin mounted upon a bobbin carrier
6 adapted to carry at least one bobbin, each bobbin adapted to provide one or
7 more filaments for braiding into the stent,

8 step (a) comprising using filaments from a first portion of the
9 predetermined plurality of bobbins to braid the narrow region about the first

10 mandrel portion positioned substantially along the longitudinal axis in a
11 braiding zone, the braiding zone being a conical zone defined by the filaments
12 extending from the bobbins to the stent on the mandrel, and
13 step (b) comprising using filaments from both portions of the
14 predetermined plurality of bobbins to braid the broader region about the
15 second mandrel portion positioned in the braiding zone.

1 26. The process of claim 23 further comprising the steps of:
2 (A) first performing step (a);
3 (B) then removing the first portion of the predetermined
4 plurality of bobbins from the braiding machine and removing the mandrel from
5 the braiding zone;
6 (C) then performing step (b);
7 (D) then returning the first portion of the predetermined
8 plurality of bobbins to the braiding machine, attaching the mandrel to the
9 mandrel body, and positioning the mandrel in the braiding zone; and
10 (E) then performing step (c).

1 27. The process of claim 23, further comprising the steps of:
2 prior to step (a), winding each filament between two bobbins such
3 that a first end of each filament is wound on a first respective bobbin and a
4 second end of each filament is wound on a second respective bobbin, and
5 positioning a point of each filament on the mandrel to form an
6 apex at a location where each said filament is added to the stent.

1 / 4

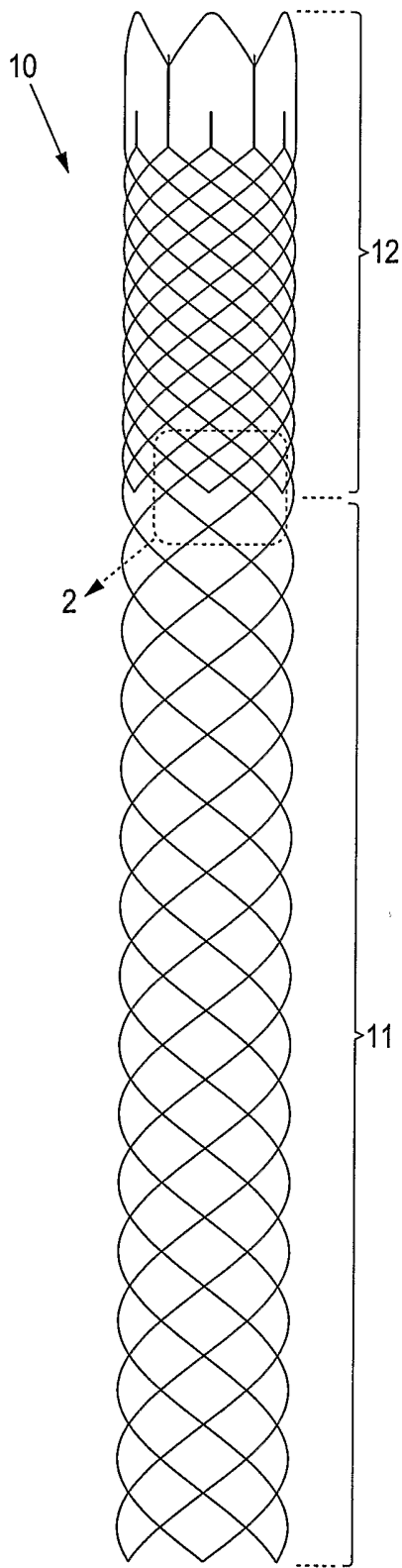


FIG. 1A

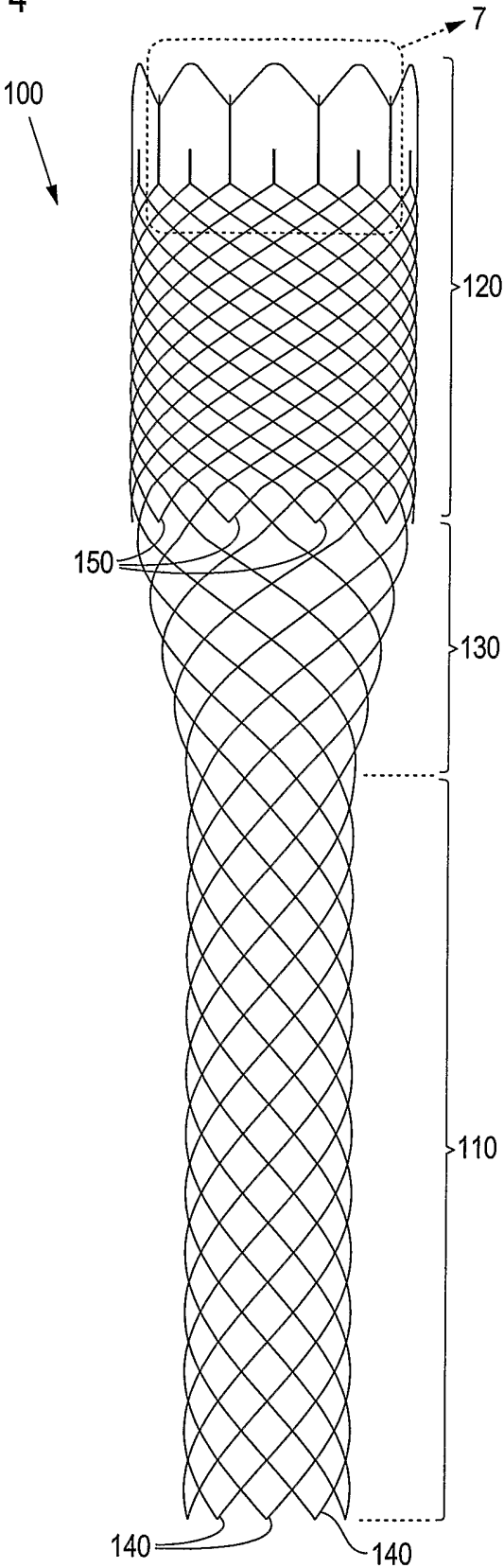


FIG. 1B

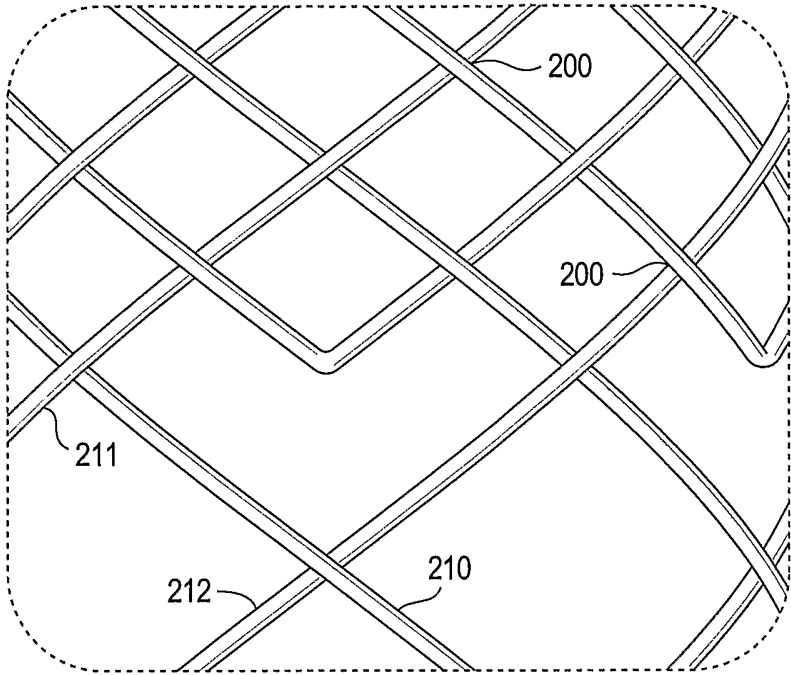


FIG. 2

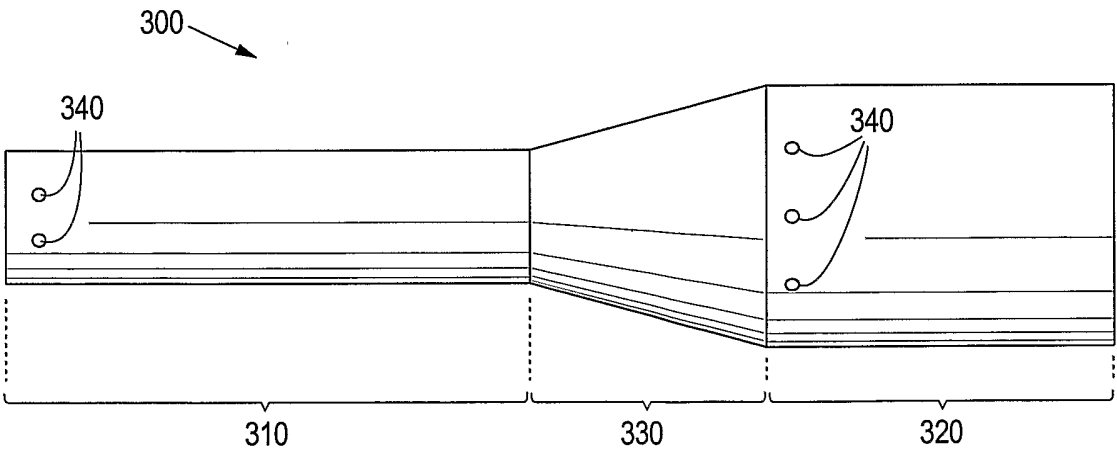


FIG. 3

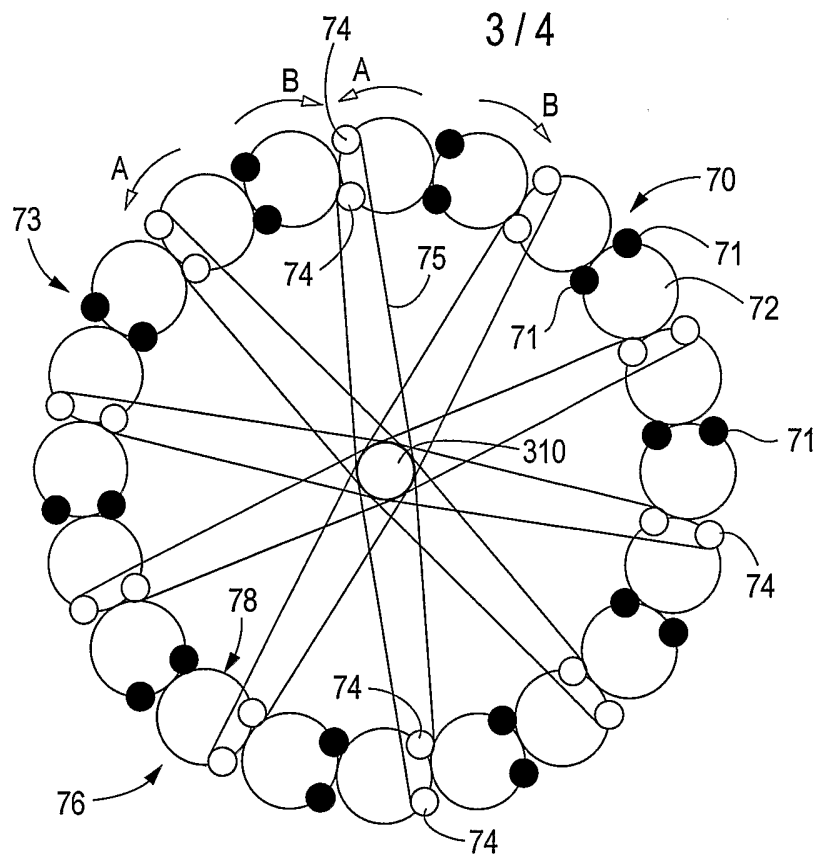


FIG. 4

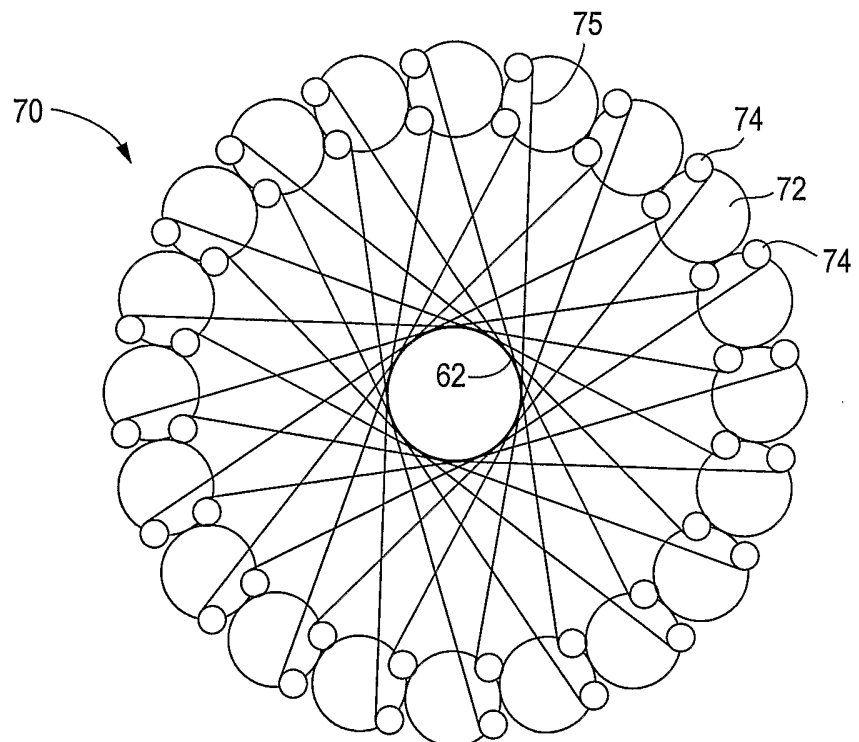
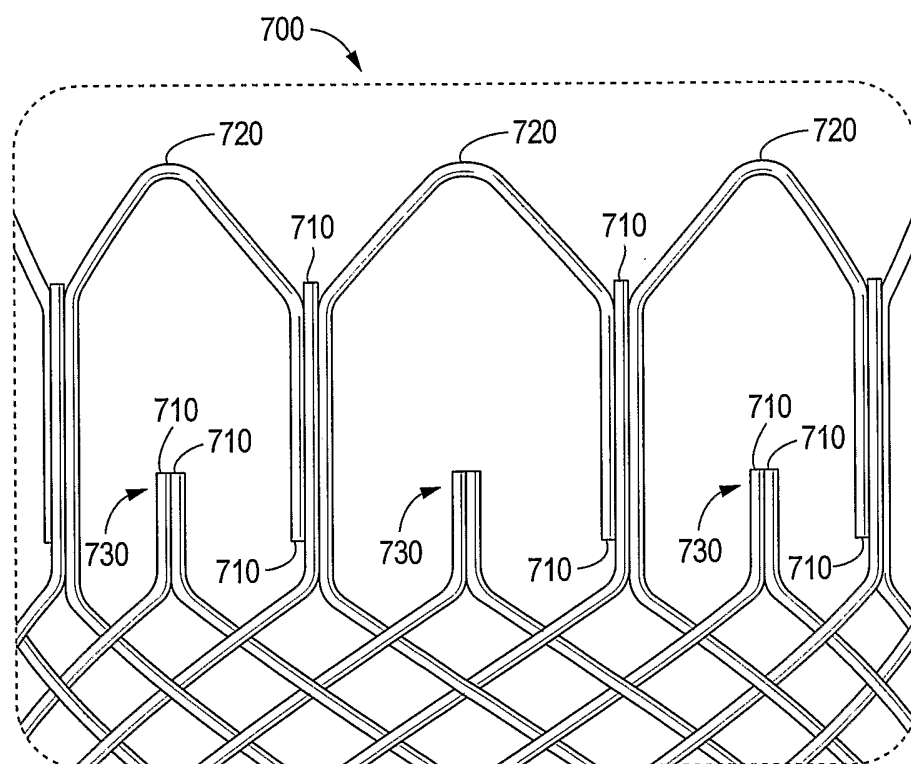
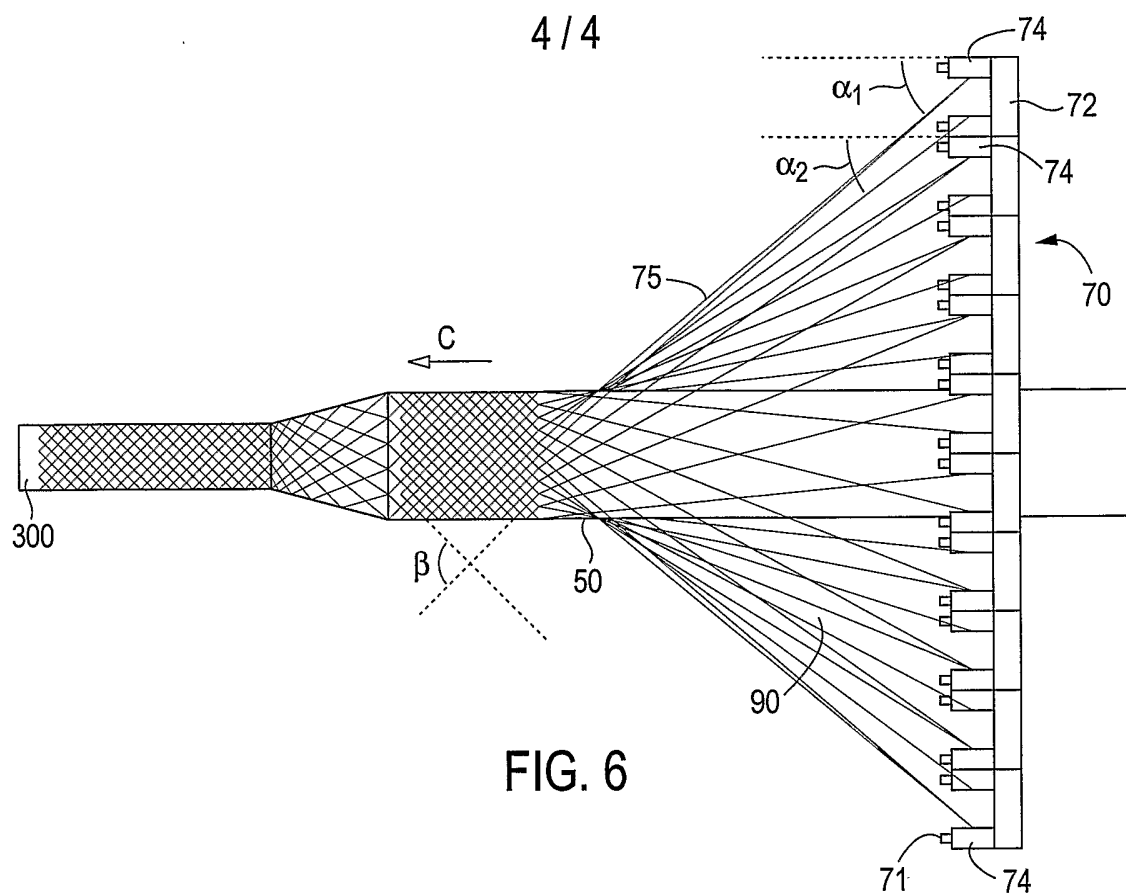


FIG. 5



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/33409

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/06

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y		2,3, 20-22
A	page 6, line 21 - line 26 page 10, line 10 -page 16 figures 1,5	10,23
Y	WO 96 25124 A (CORVITA CORP) 22 August 1996 (1996-08-22) figure 5 page 13, paragraph 2	2
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

17 March 2004

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INTERNATIONAL SEARCH REPORT

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Information on patent family members

International Application No

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