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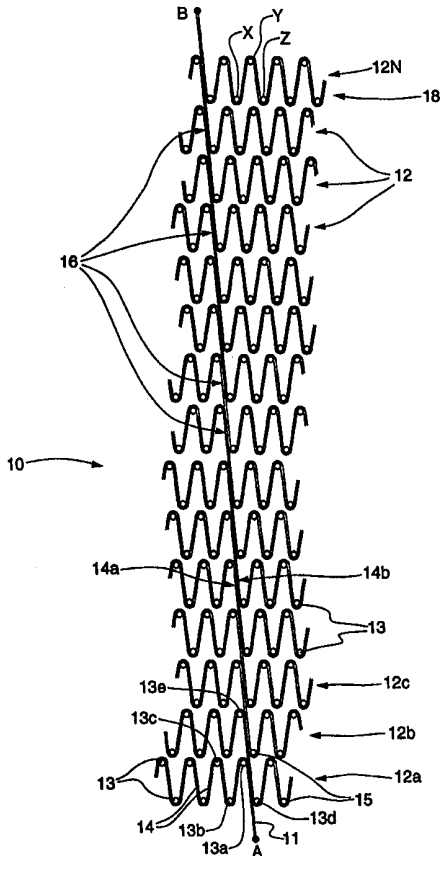
(57) Abstract

This invention is an intra–luminal stent (10) made of a zigzag or sinusoidal member defining a successive series of struts (14) connected by apex sections (15), and formed into a series of axially displaced hoop members (12c) wherein at least one of the hoop members has at least one strut (14) connected to a strut (14) of an adjacent hoop. The connected struts (14) may be connected by spot welding, continuous welding, or suturing, for example, or by a bridging member (26) connected to each strut (14), and may be spaced along the length of the stent in a pattern to form a connective spine (16). The number of zigs of the zigzag member in each hoop member (12c) may be varied, as can the zig length (L1). A plurality of connective spines (16) may also be included.



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INTRALUMINAL STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This invention claims priority based on U.S. Provisional Application Serial Number 60/076,946, filed March 5, 1998, which is hereby incorporated by reference.

FIELD OF INVENTION

This invention relates generally to intraluminal prostheses, and more particularly to intraluminal stents comprised of zig-zag or sinusoidal wire hoops.

BACKGROUND OF THE INVENTION

A common method of treating vessel diseases such as stenoses, strictures, thrombosis, or aneurysms involves placing a stent into the affected vessel. Among other advantages, stents prevent vessels from collapsing, reinforce vessel walls, increase cross sectional area (and thereby volumetric flow), and restore or maintain healthy blood flow. Many stents have been developed, and the prior art includes a wide variety of types and methods for their manufacture.

SUMMARY OF THE INVENTION

The present invention is a generally cylindrical intraluminal stent including a plurality of circumferential wire hoops disposed in succession along the axis of the stent. Each of the hoops has zig-zag or sinusoidal members defined by a successive series of struts connected by apex sections alternately pointing in opposite axial directions. The struts may be substantially straight sections connected to essentially sharp apex sections in a jagged zig-zag configuration, or the apex sections may be more rounded so that together with the struts there is formed a sinusoidal configuration. The lengths of these struts may be uniform throughout the stent or may vary alternately or continuously. Likewise, the angles or radii of curvature and configurations of the apices may be uniform or may vary. To provide mechanical integrity, selected portions of the hoops may be secured against relative axial movement, such as by spot welding overlying straight sections either in an individual hoop or in adjacent hoops. Such connections may also be made with bridging members aligned with straight sections in adjacent hoops.

These connections (with or without intervening bridging members) may be disposed in one or more linear or helical paths along the length of the stent, thus acting as stabilizing spines. Alternatively, these connections may be disposed in other preselected patterns, such as alternating around the circumference of the stent, to impart stability at these preselected locations.

BRIEF DESCRIPTION OF THE DRAWINGS

The figures provided are for illustrative purposes, and are not drawn to scale. The expanded relative dimensions allow a better understanding of the present invention. One skilled in the art will readily determine actual dimensions based on information supplied in this specification.

FIG. 1 is a diagrammatic view of an exemplary embodiment of a stent according to this invention, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened; also shown are mandrel pins used in forming the stent.

FIG. 2 is a diagrammatic view of another exemplary embodiment of a stent according to this invention having multiple spines and axial and circumferential offsets between facing apex sections, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened; also shown are mandrel pins used in forming the stent.

FIG. 3 is a partial diagrammatic view of another exemplary embodiment of a stent according to this invention having a plurality of longitudinal sections, the middle section having a different number of spines, a different number of zigs, and a different zig length than the end sections, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened.

FIG. 4 is a diagrammatic view of another exemplary embodiment of a stent according to this invention having end portions with different zig characteristics relative to a center portion, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened; also shown are mandrel pins used in forming the stent.

FIG. 5 is a diagrammatic view of another exemplary embodiment of a stent according to this invention having connecting members that include separate bridging

members, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened; also shown are mandrel pins and weld holes used in forming the stent.

FIGS. 6A is a diagrammatic view of an exemplary embodiment of a stent according to this invention having interdigitated zigs, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened.

FIGS. 6B - 6D are diagrammatic views of enlarged portions of the stent of FIG. 6A, showing an exemplary end weld, and exemplary middle weld, and an exemplary radiopaque marker, respectively.

FIG. 6E is a diagrammatic view of an exemplary embodiment of stent 6A, where the stent is shown in its normal tubular configuration.

FIG. 6F is a diagrammatic view of an exemplary embodiment of a stent according to this invention having interdigitated zigs and a plurality of longitudinal sections of different zig configurations, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened

FIG. 7 is a partial side view of an exemplary embodiment of a stent according to this invention having alternating zig lengths, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened.

FIG. 8 is a partial diagrammatic view of another exemplary embodiment of a stent according to this invention having straight-edged apex sections, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened.

FIG. 9 is a partial diagrammatic view of another exemplary embodiment of a stent according to this invention having connecting members formed by elongated struts, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened; also shown are mandrel pins used in forming the stent.

FIG. 10 is a partial diagrammatic view of the stent shown in FIG. 6A mounted on a mandrel during fabrication of the stent.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 illustrates an exemplary stent **10** according to the present invention. Stent **10** is generally cylindrical and adapted to be inserted into a lumen. Stent **10** has been cut longitudinally and laid flat for purposes of illustration. Stent **10** is formed by winding a continuous filament such as a wire **11** into a zig-zag or sinusoidal configuration and into a plurality of circumferential hoop members **12a**, **12b**, **12c** disposed in succession along the axis of stent **10**. Wire **11** is preferably nitinol wire, which provides a stent that auto-expands by shape memory, but it may be made of any suitable material, including stainless steel and thermoplastic polymers. Thus, the stent may be capable of deployment by shape memory auto-expansion, thermal auto-expansion or balloon expansion, as are well-known in the art. The width of the wire affects the radial force exerted by stent **10**. Increasing the diameter of wire **11** increases the radial force.

For convenience, the configuration of the wire is referred to throughout having a "zig-zag" shape with zigs or zig lengths. As so used herein, however, the term "zig-zag" encompasses not only a jagged zig-zag shape where the apex sections are relatively sharp and the struts are substantially straight, but also a sinusoidal shape where the apex sections are rounded and, together with the struts, form a shape resembling a sine wave having an amplitude (zig length) and a period or wavelength (zig width). Similarly, although the apex sections may be referred to as defining a zig angle, the angle may be more rounded such that lesser and greater angles may be more envisioned as smaller and larger radii of curvature, respectively. Of course, the actual wire configuration may have a shape intermediate the jagged zig-zag and rounded sine wave shapes, or may be even more rounded than a sine wave, and the apex sections may in fact have a truncated, straight edge rather than a rounded shape or sharp angle, as described herein later.

To form stent **10**, wire **11** is wound around pins **13** on a mandrel (not shown). The mandrel is typically cylindrical (although other shapes may be used as necessary to form stents of varying shapes) and of a diameter determined by the diameter of the vessel into which stent **10** is to be inserted. Typically, the mandrel diameter, and hence the intended diameter of stent **10**, is slightly larger (for example, by one millimeter)

than the diameter of the vessel. The length of stent **10** is also determined by the particular application.

Stent **10** is formed by winding wire **11** around pins **13** beginning at point **A** in FIG. 1. Wire **11** is extended to and around pins **13a**, **13b**, **13c** and so forth. In this manner, zig-zag members are formed and defined by a successive series of substantially straight sections (struts) **14** connected by apex sections **15** alternately pointing in opposite axial directions. The winding continues in this manner around the mandrel until a first hoop member **12a** is completed by winding wire **11** once around the circumference of the mandrel. Hoop member **12a** as shown in FIG. 1 has a circumference lying in a plane substantially perpendicular to the axis of the mandrel (and hence of stent **10**). Once a first hoop member **12a** is formed, wire **11** is extended from pin **13d** to and around pin **13e**. Winding then continues as before to form a second hoop member **12b** adjacent to first hoop member **12a**. By forming hoop members in this manner, adjacent hoops **12a** and **12b** are connected by the portion of wire **11** extending between first hoop member **12a** and second hoop member **12b**. At the completion of the second hoop member **12b**, wire **11** is again extended to the third hoop member **12c**, which is wound as before, and so forth until the desired number N of hoop members **12** are formed along the length of stent **10**. Thus, as shown in FIG. 1, the winding extends in a series of hoops between hoops **12a** and hoop **12N**, with the wire beginning at point **A** and ending at point **B**. After completion of winding, wire **11** is typically cut so that the wire terminates short of points **A** and **B**, generally terminating within the first hoop **12a** and last hoop **12N**, respectively, as described with reference to FIG. 6C herein later.

Stent **10** is removed from the mandrel and pins **13a**, **13b**, **13c**, etc., prior to use. In the illustrated embodiment, each hoop member **12** has one pair of aligned, adjacent struts **14a** and **14b**. According to one embodiment of the present invention, aligned, adjacent struts **14a** and **14b** of the same hoop are welded together. Such welding may be spot welding along the length of aligned, adjacent struts **14a** and **14b**, or it may be a continuous weld. In either case, a welded, connective spine **16** is formed along the perimeter of stent **10**. Connective spine **16** typically winds around the circumference of stent **10** in an offset helical fashion (the embodiment shown flat in FIG. 1 being

cylindrical or tubular in actual use). Connective spine **16** provides strength and stability to stent **10** while preserving the flexibility of stent **10**. During insertion of stent **10** into a vessel (described below), connective spine **16** renders stent **10** easier to push through a catheter. As an alternative to welding, connective spine **16** may be formed by connecting aligned, adjacent struts **14a** and **14b** according to any other suitable attachment means, including without limitation, tying, suturing, gluing, and stapling, with the glue or sutures being absorbable or non-absorbable, and including the use of polymer-containing connections.

When stent **10** comprises thermally expandable nitinol, stent **10** is annealed before removal from the mandrel and pins **13a**, **13b**, **13c**, etc., at an annealing temperature for about one hour and then allowed to cool. This annealing temperature is desirably on the order of about 500°C, although any temperature sufficient to effect annealment of stent **10** will suffice. During annealing, it may be necessary to secure the nitinol wire to the mandrel by wrapping bailing wire, a thicker gauge and different material than the nitinol, around the stent on the mandrel. Such annealing of nitinol wire imparts a memory to the nitinol, such that stent **10** will "remember" its annealed shape and return to it after subsequent reconfiguration. This is a known property of nitinol, which has two distinct temperature-dependent phases, martensite and austenite. Below a certain temperature (the martensite transition temperature), nitinol is martensitic; above a certain temperature (the austenite transition temperature), it is austenitic. It is in the austenitic phase that nitinol remembers its annealed configuration.

After annealing, stent **10** is removed from the mandrel on which it is wound to compress stent 10 into a configuration for introduction to a body passageway. Then, it is cooled to below its martensitic transition temperature. In this phase, nitinol is malleable and has virtually no resiliency. Thus, it can be easily compressed. Stent **10** can be easily returned to its annealed shape by heating it to a temperature above its austenite transition temperature. Above this temperature, the stent resumes its annealed configuration.

In its annealed configuration, stent **10** has a first diameter. This is a relatively large diameter that is the intended final diameter of stent **10**. In order to be

inserted into a body vessel, stent **10** must be compressed such that it may be inserted into a catheter. As indicated above, with a nitinol stent, this is accomplished by cooling stent **10** to below its martensite transition temperature at which temperature stent **10** is malleable and less resilient. Stent **10** can then be easily compressed into a second, relatively small diameter for insertion into the catheter. Once inside the catheter, stent **10** may be advanced to the desired location within a body vessel according to methods known in the art and discharged from the catheter at that location. U.S. Patents Nos. 5,405,377 and 5,609,627, the disclosures of which are incorporated herein by reference, contain additional details regarding the formation, use, and insertion of nitinol stents. Those patents are incorporated herein by reference for their teaching on those subjects. When stainless steel, thermoplastic polymers, or other materials are used for wire **11**, formation, use and insertion of stent **10** may be accomplished according to methods known to those skilled in the art.

Connective spine **16** lends strength, including hoop strength, to stent **10** during and after implantation to better resist compressive forces within the vessel in which stent **10** is implanted. Connective spine **16** also allows flexibility, however, such that stent **10** may be easily compressed and expanded during the insertion process.

Particular features of the stent according to this embodiment of the invention are illustrated in FIG. 2. As shown in FIG. 2, facing apex sections **15** of respective adjacent hoops of stent **10A** are offset circumferentially from one another by a distance **D1**, as opposed to abutting one another. The offset allows stent **10A** to be compressed to a smaller diameter (profile) for insertion into the catheter because the apex sections do not contact one another and hinder such compression. Increasing the axial distance **D2** between apex sections **15** (the "zig gap") also prevents interference between these sections during compression. The particular amount of offset and zig gap can be optimized according to particular stent sizes and the desired flexibility and compressed diameter as will be understood by those skilled in the art.

FIG. 2 also illustrates an embodiment of this invention having multiple, in this case two, connective spines **16**. To form two connective spines **16**, two separate wires **11** and **11A** are used to form stent **10A**. As shown in FIG. 3, first wire **11** is

formed in a zig-zag shape extending from point **A** to points **B, C, D, E, F, G, H, I, J, K, L, M, N, O, P** (etc.) sequentially. A second wire **11A** is used to form the remainder of the stent by extending, in sequence from point **E** to points **Q, R, S, A, T, U, V, W, X, Y, Z** (etc.). In this manner, each hoop contains two pairs of aligned, adjacent struts **14a** and **14b**. Aligned, adjacent struts **14a** and **14b** are then welded (or otherwise connected) to form connective spines **16**. In general, the number of wires **11, 11A,** etc. used to form stent **10A** directly corresponds to the number of connective spines **16** that are desired. The strength and rigidity of stent **10A** increase with the addition of connective spines **16**.

In the above configuration, the mandrel peg at each lettered point may be considered to be one of a set of pegs corresponding to the wire to wound about the set. Thus, pegs at points **A, B, C**, etc. above are a part of one set, and pegs **E, Q, R**, etc. above are part of a second set. Each set, however, contains at least one common peg (for example, **F** in the first set and **W** in the second set) where both wires follow a common path between the common pegs of the circumferentially adjoining sets. The wires that form the common path (adjacent struts **14a** and **14b**) are connected as described above.

FIG. 3 illustrates another alternative embodiment of this invention wherein the zig length L_1 is varied within stent **10B**. Zig length L_1 is the distance between apex sections **15'** and **15"** measured in a direction parallel to the stent axis (vertical, in FIG. 3). As previously indicated, the zig length may similarly be described as the amplitude of a sinusoidally shaped zig-zag. In this embodiment, the zig length at end sections **22** of stent **10B** may be relatively short (relatively small amplitude), while the zigs in middle section **20** of stent **10B** are relatively long (having greater amplitude). This may provide greater radial force at the ends of stent **10B** to assist in anchoring the stent in place in the vessel into which it is inserted by asserting a greater force against the walls of the vessel. This may also prevent blood from leaking between stent **10B** (when the stent is used in combination with a graft, as will be understood by those skilled in the art) and the vessel wall.

As illustrated in FIG. 3, there may also be a transition section **21** in which there is a transition zig length, between the short zig length at the stent ends **22** and the long zig length in the stent middle **20**, to provide a gradual transition from the short to the

long zigs. Typical short zig lengths are between two and three millimeters. Typical long zig lengths are between three-and-a-half and five millimeters. The actual zig lengths may be optimized for particular applications as will be understood to those skilled in the art based on the disclosure herein.

Another aspect of this invention involves the variation of the number of zigs in each hoop member. Referring back to FIG. 1, a "zig" is considered to be the part of wire **11** extending from, for example, point **X** to point **Y** to point **Z**. **X-Y-Z** in FIG. 1 is considered to represent one zig. Thus, each similarly-oriented apex section (i.e. each apex section pointing in the same direction) defines a zig. As previously indicated, the number of zigs in a hoop may be similarly described as the number of periods of a sinusoidally shaped zig-zag. In FIG. 1, each hoop member has five zigs. Using fewer zigs allows stent **10** to be compressed to a smaller insertion diameter (that is, fewer zigs decreases the profile of stent **10**). Increasing the number of zigs provides more support for any graft covering used in conjunction with the stent, however, preventing the possibility of in-folding of such graft layer.

FIG. 4 illustrates an alternative embodiment, not drawn to scale, wherein the center portion **20** of stent **10** has four zigs per hoop member **12**, a first zig length, and one connective spine **16;** and the end portions **22** have six zigs per hoop member **12**, a second zig length, and two connective spines **16**. The second spines on both ends overlap two hoop members **12** of the center portion as a transition. The number of connective spines **16** can thus be varied within a stent to provide a more rigid portion at the ends and a more flexible portion in the middle. The stent illustrated in FIG. 8 may have, for example, a wire diameter of 0.007 inches, a 6.4 mm OD, a 6 mm ID, and a length of 100 mm. Other wire diameters slightly larger than 0.007 inches such as 0.008 or 0.009 inches, for example, will suffice.

As shown in FIG. 9, another method of making connecting members may comprise axially opposed apex sections **15** of adjacent hoops **12** being axially spaced from one another with one or both of the first and second struts **14'** of the connecting member elongated relative to the remainder of the struts **14** in the adjacent hoops. Such elongated

struts **14'** may thus lie adjacent one another for at least some axial distance to permit connection therebetween.

FIG. 5 illustrates a stent constructed according to another exemplary embodiment of the present invention. Stent **30** is generally cylindrical and adapted to be inserted into a lumen. Stent **30** has been cut longitudinally and laid flat for purposes of illustration. Stent **30** is formed by winding a continuous filament such as a wire **24** into a zig-zag configuration and into a plurality of circumferential hoop members **33, 25a . . . 25N,** and **37** disposed in succession along the axis of stent **30**. Wire **24** is extended to and around pins **23a, 23b, 23c** and so forth. In this manner, zig-zag members are formed and defined by a successive series of substantially straight sections **34** connected by apex sections **35** alternately pointing in opposite axial directions. The winding continues in this manner around the mandrel until a first hoop member **33** is completed by winding wire **24** once around the circumference of the mandrel. Winding then continues as before to form a second hoop member **25a** adjacent to first hoop member **33** and a third hoop member **25b** adjacent to second hoop member **25a**. Unlike hoop members **12** of stent **10** as shown in FIG. 1, hoops **25a . . . 25N** are disposed at an angle to a plane perpendicular to the stent longitudinal axis; wire **24** then gradually spirals about the axis of stent **30** to form a coil. End hoops **33** and **37**, however, are disposed perpendicular to the stent axis. The helical configuration may be effected by each apex section in the helix having one connected strut longer than the other.

As further illustrated in FIG. 5, adjacent hoops are connected by a separate bridging member **26** adjacent portions of respective straight sections **34** and **34A** of axially opposed apex sections of adjacent hoops. As illustrated in FIG. 5, bridging member **26** is preferably linear and aligned with aligned struts **34** and **34A** of proximate sections of adjacent hoops 25_i and 25_{i+1}, although non-linear and non-aligned bridging members are also contemplated in accordance with the present invention, as may be appreciated by those skilled in the art. Separate bridging member **26** may be the same material as or a different material than wire **24** used to form hoops **33, 25a-N,** and **37** of stent **30,** depending on the desired flexibility and compressed stent diameter. In one embodiment, separate bridging member **26** and wire **24** are made of the same material, for example,

nitinol. Separate bridging member **26** and wire **24** may have approximately the same or different cross sectional dimensions (i.e. the same or a different wire gauge), depending on the desired implementation.

An exemplary separate bridging member **26** is preferably formed by extending a wire segment between a pair of pins **28** extending from the mandrel proximate straight sections **34** and **34A** of adjacent hoops 25_i and 25_{i+1}. These pins **28** and **29** are in addition to pins **23a**, **23b**, **etc.** used to form zig-zag members of the respective hoops of stent **30**. Wire-segment bridging member **26** is extended between pins **28** and both ends are at least partially wrapped around the pins, preferably with enough tension to remove unwanted slack from the wire, although various amounts of slack may be maintained, depending on the desired rigidity, flexibility, and compressed diameter of stent **30**.

To effect welds during manufacture of a stent of the present invention, and as shown in FIG. 5, ball weld cutting holes **29** may be formed in the mandrel providing access to the mandrel interior, the holes desirably positioned such that sections to be welded, such as aligned, adjacent struts **34** and **34A**, lie approximately above the ball weld cutting holes. In this way, a laser may be focused into ball weld cutting holes **29** to: (i) remove excess wire extending past ball weld cutting holes **29** and around the pins, and (ii) weld the remaining wire segment between the aligned, adjacent struts of adjacent hoops as, for example, bridging member **26** between struts **34** and **34A.** The connection between bridging member **26** and struts **34** and **34A** may, instead of a weld, may be accomplished according to any other suitable attachment means, including without limitation, tying, suturing, gluing, and stapling, with the glue or sutures being absorbable or non-absorbable, and including the use of polymer-containing connections.

As further illustrated in FIG. 5, a stent **30** constructed in accordance with the present invention may further include the plurality of separate bridging members **26a-26N** disposed in succession along the length of the stent. Each successive separate bridging member 26_i connects a successive pair of adjacent hoops along the axis of stent **30** to form a spine along the length of stent **30**. The spine may be a continuous spine of helically-aligned bridging members, similar to the spine illustrated in Fig. 1, or may be constructed of a single bridging member connecting a plurality of hoops along the length

of the stent. Alternatively, as shown in FIG. 5, each successive connecting member **26**$_i$ may be circumferentially offset from a preceding connecting member with respect to the axis of stent **30** to define a helical spine of disjointed connecting members, or a "floating" spine. Hoop members **33**, **37** disposed at each end of stent **30** may have the apex sections that point outwardly from the stent disposed in common planes perpendicular to the axis of stent **30**, such as apex sections **35'** of hoop **34** along plane **I**, as shown in FIG. 5.

To make this transition from hoops other than perpendicular end hoops **33** and **37** to the end hoops, the successive lengths of struts in the end hoops may be reduced along the circumference of the hoops. Additionally, or in the alternative, the successive amount of interdigitation (overlap) between apex sections of adjacent hoops may increase along the circumference of end hoops **33** and **37** approaching the end of wire **24**.

FIGS. 6A-6E illustrate stent **40**, another exemplary embodiment of the present invention. In stent **40**, adjacent hoops **42a . . . 42N** are interdigitated with respect to one another. That is, oppositely directed apex sections **44A** and **44B** in respective adjacent hoops **42b** and **42c**, for example, overlap one another axially, or expressed another way, they intersect a common plane angularly disposed with respect to the axis of stent **40**. Hoop members **42a ... 42N** also preferably have zigs substantially in phase circumferentially about stent **40**. Stent **40** comprises a continuous series of similarly-oriented apex sections **44A** arranged in a helix in which each hoop **42*i*** comprises one 360-degree wrap of the helix. Each apex section in the helix comprises two struts attached thereto, in this embodiment with one strut being longer than the other to effect the helical progression. Such a hoop configuration is also seen in U.S. Patent No. 5,575,816 to Rudnick *et al.*, which is incorporated herein by reference and which illustrates a variety of other interdigitated stent configurations.

In a pair of adjacent hoops, such as hoops **42b** and **42c**, one strut **45** of hoop member **42b** is aligned with and overlaps strut **45** of hoop member **42c**, and is connected to form a connecting member **48a-N**, preferably by spot welding, although other connection mechanisms are contemplated as will be understood by those skilled in the art. Interdigitated stent **40** in its normal tubular form is illustrated in FIG. 6E.

Referring now to FIG. 10, there is shown a helical stent **110**, corresponding to the layout shown in FIG 6A, on a tubular mandrel **114**. Helical stent **110** or a helical segment thereof, as shown in FIG. 10, may be constructed by winding N filaments **111**, where N is a whole number of at least 1, around N respective sets of pegs **112a-N** on a tubular mandrel **114**. As shown in FIG. 11, N = 1. Each of the N sets includes at least three axially offset pegs, such as pegs **112a**, **112b**, and **112c**, defining a zig-zag configuration at a preselected axial location on mandrel **114**, with circumferentially successive pairs of pegs (pegs **112c** and **112d**, for example) being axially offset in a preselected direction from the pair which precedes it (pegs **112a** and **112b**) so as to form a helical zig-zag pattern repeatedly traversing the mandrel along the length of stent **110**. Each traversal of a preselected angular portion of mandrel **114** by pegs **112a-N** includes at least one common peg (**112r**, for example) approximately 360° helically offset from an adjacent peg (**112k**). The peg adjacent the common peg may be part of the same set of pegs (for instance, where N is equal to 1) or a part of a circumferentially adjoining set of pegs (where N is greater than 1). Common peg **112r** provides at least one circumferential location in each traversal of a preselected angular portion, where a portion of the filament in each traversal of a preselected angular portion contacts a portion of a filament in an adjacent traversal. This contact may be with the same filament (for instance, where N is equal to 1 as shown in FIG. 11) or with an different filament (where N is greater than 1). A connection **48** is formed along the contacting adjacent filaments or portions thereof, forming a circumferential stent or segment thereof comprised of a helical succession of zig-zags. Thus, the wire configuration may form a helix as shown in FIGS. 6A, 6E, and 11, or a double- or other multiple-helix (not shown). As shown in FIG. 6A, a single filament (N = 1) repeatedly traverses the mandrel (not shown) along a single set of pegs, wherein in each angular traversal of 450° there is a common peg **13'** approximately (in this case slightly greater than) 360° offset from an adjacent peg **13'** (the pegs immediately adjacent each connecting member **48a-N**).

Stent **40** as shown in FIGS. 6A comprises a plurality of connecting members **48a-N** disposed in succession along the stent axis between pairs of adjacent

hoops. Each set of connecting members **48a-N** connects a successive pair of adjacent hoops along the axis of stent **40** to form a spine along the length of the stent. As with the successive connecting members **26** of FIG. 5, each pair of successive connecting members 48_i is circumferentially offset from a preceding connecting member 48_{i-1} with respect to the axis of stent **40**.

As shown in FIG. 6A, each apex section **44B** includes an apex angle α and a zig width **W** measured between adjacent, apex sections **44A** opposite apex section **44B**. As shown in FIG. 6A, the included angle (zig angle) and zig width of apex sections **44B** are essentially uniform throughout stent **40**, except for the apex sections **44B'** and **44B"** that include the struts **45** that form connecting members **48a-N.** Apex sections **44B'** and **44B"** have a non-uniform zig angle and resulting zig width as compared to apex sections **44B**. As shown in FIG. 6A, the zig including apex section **44B'** has a greater included angle and has a greater zig width than the uniform angle and width included by apex sections **44B**; apex section **44B"** has a lesser included angle and smaller zig width than the uniform angle and width. As shown in FIG. 6A, stent **40** comprises a helical configuration having 4 zigs per 360-degree wrap, each such wrap comprising a hoop. Apex section **44B'** is spaced 5 zigs from each preceding **44B'**; apex section **44B"** is similarly spaced 5 zigs from each preceding **44B"**. Thus, for a stent with N zigs, the non-uniform zigs are spaced every N+1 zigs to achieve the helical pattern of connections **48a-N** as shown in Fig. 6A. In other words, for the 4-zig stent of 6A, connecting members **48a-N** are uniformly distributed in a helical spacing approximately every 450° along the length of the stent to form a helical spine. Other helical or non-helical spine configurations may be achieved by spacing the non-uniform zigs differently.

FIGS. 6B and 6C illustrate exemplary spot weld configurations within stent **40**. For adjacent, aligned struts **48b** - 48_{N-1}, the portion of each strut adjacent one another may be of a first length having a weld **54** of length L_1, as shown in FIG. 6B. For adjacent, aligned struts **48a** and **48N** on the end hoops, however, the portions of each strut adjacent one another may be longer, and thus may include a weld **56** of length L_2, as shown in FIG. 6B. To avoid sharp edges protruding from the stent, end strut **58** may be cut, as shown in FIG. 6C, so that it terminates a distance **D** from weld **56** in a position

that lies short of plane **II** on which apex section **46** lies. For instance, the end of end strut **58** may be cut so that it terminates a distance above plane **II** equivalent to the radius **R** of apex section **46**. As shown in FIG. 6A, end strut **58** has not yet been cut, but may be cut using ball weld cutting hole **29**, similar to those described with reference to FIG. 5.

FIG. 6D illustrates an exemplary radiopaque marker **59** that may be used with the present invention. Marker **59** may comprise a radiopaque substance, such as a platinum wire, wrapped about a strut on an end hoops. This substance thus defines a surface having a different radiopacity than the area surrounding it. This same effect may be achieved by marking a particular location of the stent with an area of lower radiopacity. One or more markers **59** may be disposed on one or both of the end hoops. Marker **59** generally may be tightly wound with no underlying strut visible to the unaided eye, and may extend 1 - 2 wraps past the start of the radius where the strut bends to form the apex section. Marker **59** is typically configured without sharp edges at the ends.

FIG. 6F is a diagrammatic view of an exemplary embodiment of stent **60**, opened along a line parallel to the stent axis and flattened, having interdigitated zigs, similar to stent **40** of FIG. 6A-E, but additionally having a plurality of longitudinal sections, similar to stent **10C** as shown in FIG. 4. Middle section **62** has a longer zig length than end sections **64**, and transition sections **63** intermediate the middle section and each end section have a zig length that is between the length of the middle and the end section zigs.

FIG. 7 illustrates still another stent **70** constructed in accordance with the present invention. Stent **70** has been cut longitudinally and laid flat for purposes of illustration. Stent **70** is formed by winding a wire around pins extending from a mandrel somewhat similar to the manner described with reference to FIG. 1, although the pins are configured such that zig-zag sections of respective hoops **76a**, **76b**, **76c**, **76d** are of varying height and varying width. In the embodiment illustrated in FIG. 7, the width of the zig length alternates between distance **XX** and **WW** along each hoop circumferentially about stent **70**. The zig length similarly alternates between length **YY** and **ZZ** moving along each hoop circumferentially about stent **70**. Length **ZZ** is approximately half of length **YY** in FIG. 7, although other length variations are contemplated. Adjacent hoops,

such as hoops **76a** and **76b**, are phase-shifted by approximately and 180 degrees and inverted with respect to one another. Accordingly, apex sections **65** and **66** of hoop member **76a** pass through a plane perpendicular to the axis of stent **60** determined by the positions of oppositely directed alternate apex sections **67** and **68** in adjacent hoop **76b**. The configuration of FIG. 7 may be incorporated into transition segments of other stents constructed according to the present invention.

A series of separate bridging members **72a**, **72b**, and **72c** connects adjacent hoops **76a** and **76b**, as shown in Fig. 7. Another series of separate connecting members **74a** and **74b** connects adjacent hoops **62b** and **62c**. Bridging members **72a**, **72b**, and **72c** are angled relative to the tubular axis of stent **70** in opposite orientations than bridging members **74a** and **74b**, to counter rotating effects in stents in which bridging members between successive pairs of adjacent hoops are oriented in the same direction. The number of bridging members may vary, depending on the desired implementation, as may the orientations of bridging members **72a**, **72b**, **72c**, **74a** and **74b**.

Stent **80** of FIG. 8 is formed by winding a first wire **81** around pins (not shown) on a mandrel. The geometry of the pins may be substantially circular to produce rounded apex sections, as in FIG. 1, or have straight edges such as to produce apex sections having straight edges as in FIG. 8. In this manner, zig-zag members are formed and defined by a successive series of struts **84** connected by apex sections **85** alternately pointing in opposite axial directions. The winding continues in this manner around about half the circumference of stent **80**. A second wire **86** is introduced and wound around the remaining circumference of stent **80** to complete a first hoop member **82a**. Where wires **81** and **86** overlie one another, they may be spot or linearly welded, thus to produce a pair of helical spines lending integrity to stent **80**.

Any of the variations described herein may be combined with any other variation described herein or known in the art, where practical, to develop a stent architecture according to the present invention. Such variations may be uniformly utilized throughout the length of the stent, or as shown in Fig. 6F, the stent may comprise a plurality of longitudinal sections, each of which may differ from another segment with respect to, for example without limitation: the size of one or more of the apex section

angles, the apex section axial length, the number of apex sections per hoop, the number of connective spines, the spacing or offset between facing apex sections, the type of connecting member, and the uniformity of adjacent zigs. Moreover, the "struts" of each apex section and the connections therebetween may be straight, as in a jagged zig-zag configuration, or curved somewhat, such as when the overall stent section is more sinusoidal.

Although this invention has been described with reference to particular embodiments, it is not intended that this invention be limited thereto. Rather, the scope of the appended claims should be construed to cover all forms and variants of the invention as may be made by those skilled in the art without departing from the spirit and scope thereof.

What is Claimed is:

1. A tubular stent having a tubular axis, said stent comprising a plurality of circumferential hoops linearly disposed in succession along said axis, each of said hoops comprising zig-zag or sinusoidal members defined by a successive series of struts connected by apex sections alternately pointing in opposite axial directions, at least one pair of adjacent hoops being connected to one another by a connecting member, said connecting member connecting a first strut, which is part of one of said connected adjacent hoops, to a second strut, which is part of the other of said adjacent hoops, said first and second struts being aligned with one another.

2. The stent according to claim 1 wherein each connecting member is a connector selected from the group consisting of: a spot weld, a continuous weld, an absorbable suture, a non-absorbable suture, a staple, absorbable glue, non-absorbable glue, and a polymer-containing connection.

3. The stent according to claim 1 wherein axially opposed apex sections of adjacent hoops are axially spaced from one another and said connecting member is a bridge member aligned with and connected to said first and second struts.

4. The stent according to claim 3 wherein each bridge member is connected to each of said first and second struts by a connector selected from the group consisting of: a spot weld, a continuous weld, an absorbable suture, a non-absorbable suture, a staple, absorbable glue, non-absorbable glue, and a polymer-containing connection.

5. The stent according to claim 3 wherein said bridging member and said struts connected thereto are comprised of the same material of construction and are of the same cross sectional dimensions.

6. The stent according to claim 1 wherein axially opposed apex sections of adjacent hoops are axially spaced from one another and one or both of said first and second struts are elongated, relative to the remainder of the struts in said adjacent

hoops, and lie adjacent one another for at least some axial distance to permit connection therebetween.

7. The stent of claim 1, wherein the stent comprises a continuous series of similarly-oriented apex sections that point in a first direction, said similarly-oriented apex sections arranged in a helix in which each hoop comprises one 360-degree wrap of said helix.

8. The stent according to claim 7 wherein each apex section in said helix comprises two struts attached thereto, one strut being longer than the other.

9. The stent according to claim 8 wherein at least some of said axially opposed apex sections of adjacent hoops overlap one another axially.

10. The stent according to claim 9 wherein the included angle and axial length of said apex sections are generally uniform, except for selected apex sections including said first and second struts.

11. The stent according to claim 9 wherein the included angle and axial length of said apex sections are generally uniform, except for selected apex sections including said first and second struts and end apex sections comprising one or both end hoops of said stent.

12. The stent according to claim 11 wherein said end apex sections define a plane perpendicular to said tubular axis at the end of said stent.

13. The stent according to claim 9 wherein the included angle and axial length of said apex sections are generally uniform, except for those apex sections including said first and second struts, and those non-uniform apex sections include, respectively, included angles more and less than those of said uniform apex sections.

14. The stent according to claim 9, wherein the selected apex sections are spaced every N+1 zigs.

15. The stent according to claim 8 further comprising an end hoop disposed at each end of said stent in which apex sections that point outwardly from said stent lie in a common plane perpendicular to the axis of the stent.

16. The stent according to claim 15 wherein the apex sections of said end hoop have a progressively shorter zig length or amplitude leading to an end strut.

17. The stent according to claim 15 wherein the struts between apex sections of said end hoop progressively further overlap struts of an adjacent hoop leading to an end strut.

18. The stent according to claim 15 wherein the end hoops each comprise an end strut that is aligned adjacent to and connected to a another strut of said end hoop.

19. The stent according to claim 18 wherein said end strut is connected to said another strut with a weld having a first weld length and said connecting members in said hoops that are not end hoops comprise a weld having a second weld length that is less than said first weld length.

20. The stent according to claim 19 wherein the end strut terminates short of said common plane perpendicular to the axis of the stent on which lie said end hoop apex sections that point outwardly from said stent.

21. The stent according to claim 1 wherein the connecting members of adjacent pairs of hoops are arranged in a pattern to form a connective spine along the length of the stent.

22. The stent according to claim 21 wherein each pair of adjacent hoops includes a plurality of paired struts in axially opposed apex sections, each of said strut pairs being connected to one another to form a plurality of connective spines along the length of said stent.

23. The stent according to claim 21 or 22 wherein the connected struts forming said connective spines are aligned with one another helically along the length of said stent.

24. The stent according to claim 21 or 22 wherein the connected struts forming said connective spines are not aligned with one another along the length of said stent.

25. The stent according to claim 1 wherein said stent comprises at least one continuous filament wound into said zig-zag members, said filament comprising a material selected from the group consisting of: nitinol wire, stainless steel wire, and thermoplastic polymer.

26. The stent according to claim 25 wherein said stent comprises a single continuous filament.

27. The stent according to claim 25 wherein said stent comprises a plurality of continuous filaments.

28. The stent according to claim 1 wherein facing apex sections of adjacent hoops abut one another.

29. The stent according to claim 1 wherein facing apex sections of adjacent hoops are circumferentially offset from one another.

30. The stent according to claim 1 comprising four to six similarly-oriented apex sections in each hoop.

31. The stent according to claim 1 in which all of said hoops have a similar number of similarly-oriented apex sections.

32. The stent according to claim 1 further comprising at least two longitudinal segments, the hoops in at least one of said segments differing from those in another of said segments with respect one or more of apex section included angles, zig length, and number of apex sections per hoop.

33. The stent according to claim 1 wherein the stent has a length and comprises a constant number of continuous filaments and connective spines along its length.

34. The stent according to claim 1 further comprising at least two longitudinal segments, at least one of said segments having a different number of continuous filaments and connective spines than a second of said segments.

35. The stent according to claim 1 further comprising at least two longitudinal segments, each hoop a first of said segments having a first zig length and

each hoop in a second of said segments having a second zig length that is different from said first zig length.

36. The stent according to claim 35 further comprising a transition segment between said first and second segments, each hoop in said transition segment having a third zig length intermediate said first and second zig lengths.

37. The stent according to claim 35 further comprising a transition segment between said one and said second segments, said transition segment having a plurality of zig lengths that provide a gradual transition between said first and second zig lengths.

38. The stent of claim 1 wherein each apex section pointing in a first direction and two struts attached thereto comprise a zig, the zig length and zig width of each adjacent zig being uniform in each hoop.

39. The stent of claim 1 wherein each zig of each hoop has a different zig length, a different zig width, or a combination thereof, with respect to each adjacent zig.

40. The stent of claim 39 wherein one or more selected zigs of each hoop are connected to a zig of an adjacent hoop with a bridging member.

41. The stent of claim 40 wherein the bridging members between selected zigs of a first and second hoop are angled with respect to the stent tubular axis in a first direction and bridging members between selected zigs of said second and a third hoop are angled with respect to the stent tubular axis in a second direction opposite said first direction.

42. The stent according to claim 1 having an diameter of 3-40 millimeters.

43. The stent according to claim 1 further comprising a graft layer enclosing at least a portion of the interior space defined by said stent.

44. The stent according to claim 1 wherein the apex sections have a geometry selected from the group consisting of: rounded or straight-edged.

45. The stent according to claim 1 further comprising at least one selected surface area, said selected surface area having a different radiopacity than the surface area surrounding said selected surface area.

46. The stent according to claim 1 wherein the zig-zag members have a sinusoidal configuration.

47. A tubular stent having a tubular axis, said stent comprising a plurality of zig-zag members arranged in a helix, said zig-zag members defined by a successive series of struts connected by apex sections alternately pointing in first and second axial directions, the apex sections that point in the first direction axially overlapping the apex sections that point in the second direction on axially adjacent traversals of said helix, wherein at least one strut of an apex section that points in the first direction on one traversal of said helix is aligned with and welded to another strut of an apex section that points in the second direction on an adjacent traversal of said helix, said welded one and another strut comprising a connecting member.

48. The stent of claim 47 further comprising a plurality of connecting members uniformly distributed along the stent according to a predetermined helical spacing.

49. The stent of claim 48 wherein the predetermined helical spacing is once approximately every 450 degrees.

50. A method of making a stent comprising,

a) winding a first wire in a predetermined pattern about pins disposed on the surface of a mandrel conforming generally to the intended stent outer shape:

i) transversely about the zig-zag pins into a series of zig-zag members defined by a successive series of substantially straight sections connected by apex sections alternately pointing in opposite axial directions,

ii) circumferentially about the mandrel to form at least two circumferential hoops of zig-zag members disposed axially in succession along the length of said stent,

b) winding a second wire having end portions between a pair of weld segment pins disposed between proximate sections of said adjacent hoops, respectively,

c) welding the end portions of the second wire to proximate sections of said adjacent hoops to define a weld segment connecting said adjacent hoops.

51. The method of claim 50 wherein step c) includes directing a laser through a hole formed in the mandrel to weld the end portions of the second wire to the first wire, to shorten the end portions of the second wire, or a combination thereof.

52. A method of making a stent comprising,

first, winding a filamentary material in a predetermined pattern around pins on a mandrel, said preselected pattern including segments wherein a first portion of said filament lies adjacent a second portion of said filament at an area on said mandrel surface which includes an access hole to the interior of said mandrel, and,

second, using said access hole to connect said first and second portions of said filament.

53. The method of claim 52 wherein said filamentary material is a wire and said access hole is used to connect said first and second filamentary portions by a weldment thereof.

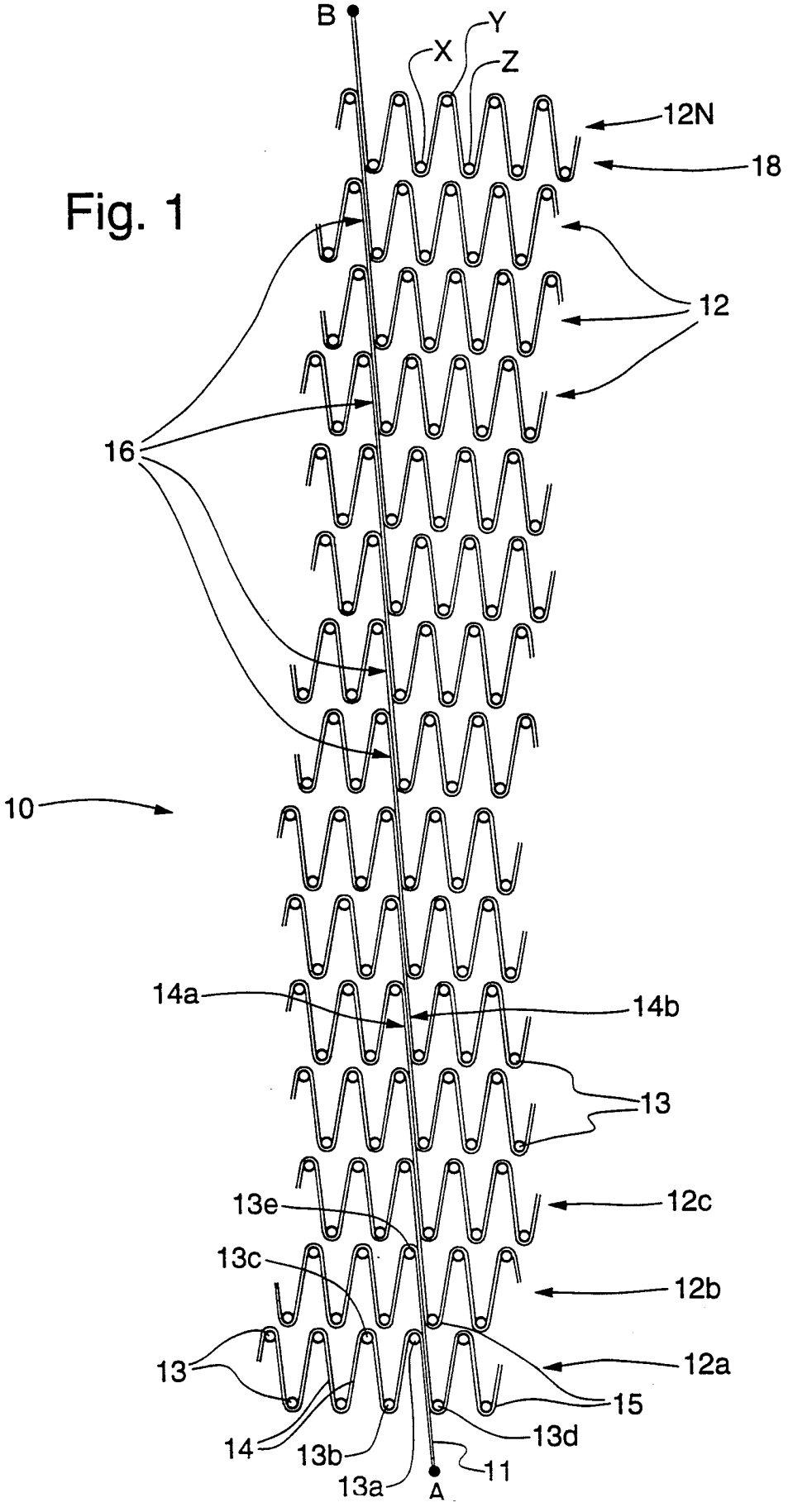
54. A method of making a stent segment comprising (1) winding N filaments, where N is a whole number of at least 2, around N respective sets of pegs on a tubular mandrel, each of said N sets including at least three axially offset pegs defining a zig-zag configuration at a preselected axial location on said mandrel, each of said sets including at least one common peg adjacent a circumferentially adjoining set, each of said filaments following a common path for a full distance between the common pegs of said circumferentially adjoining sets, and (2) forming a connection between said filaments along said common paths, and thus forming a circumferential stent segment comprising a succession of zig-zags.

55. A method of making a stent segment comprising (1) winding N filaments, where N is a whole number of at least 1, around N respective sets of pegs on a tubular mandrel, each of said N sets including at least three axially offset pegs defining a

zig-zag configuration at a preselected axial location on said mandrel, circumferentially successive pairs of pegs being axially offset in a preselected direction from the pair which precedes it so as to form a helical zig-zag pattern along the length of the stent, wherein in at least one circumferential location in each traversal of a preselected angular portion of the mandrel by said pegs there is a common peg approximately 360° offset from an adjacent peg of the same or a circumferentially adjoining set, adjacent which each filament contacts a portion of the same filament or an adjacent filament, and (2) forming a connection between said contacting adjacent filament portions, and thus forming a circumferential stent segment comprised of a helical succession of zig-zags.

56. A method of making a stent comprising making a succession of stent segment, as recited in either of claims 54 or 55.

Fig. 1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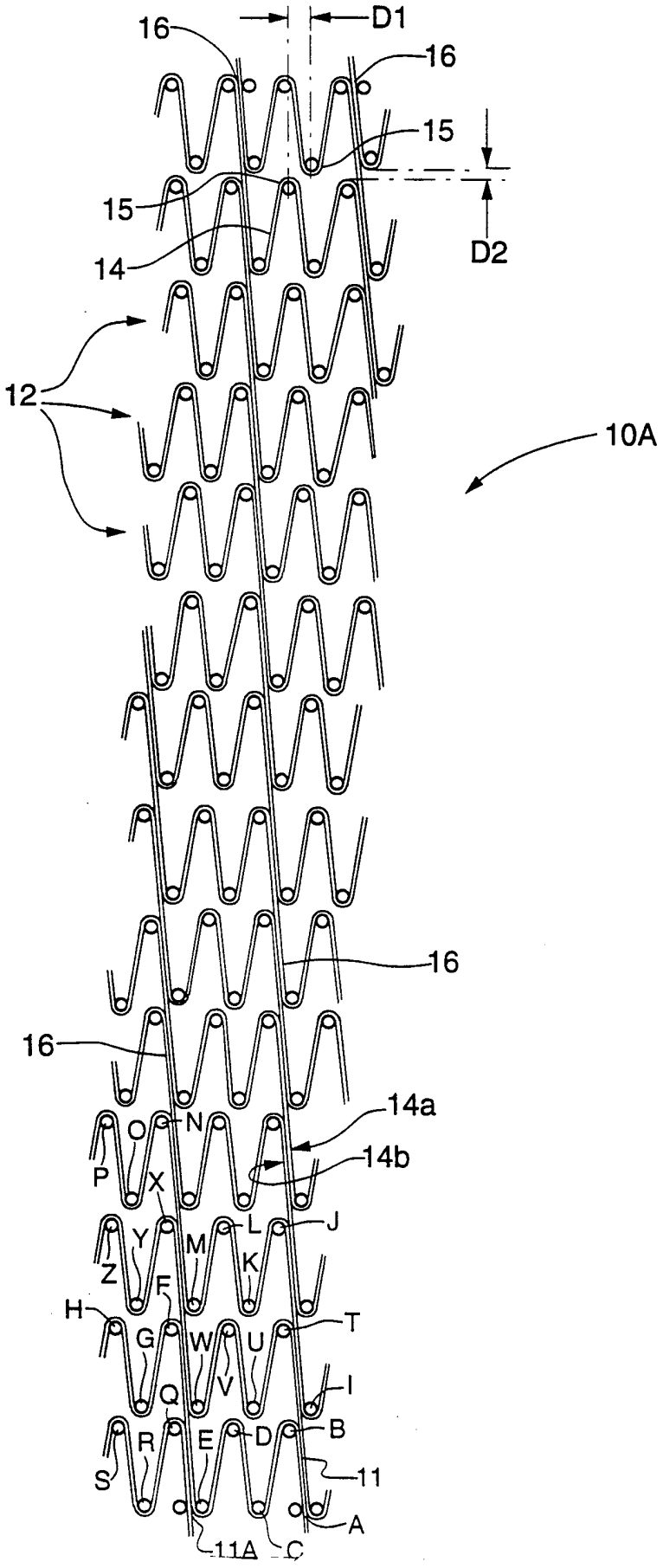
15
13d
14
13b
11
13a
A

Fig. 2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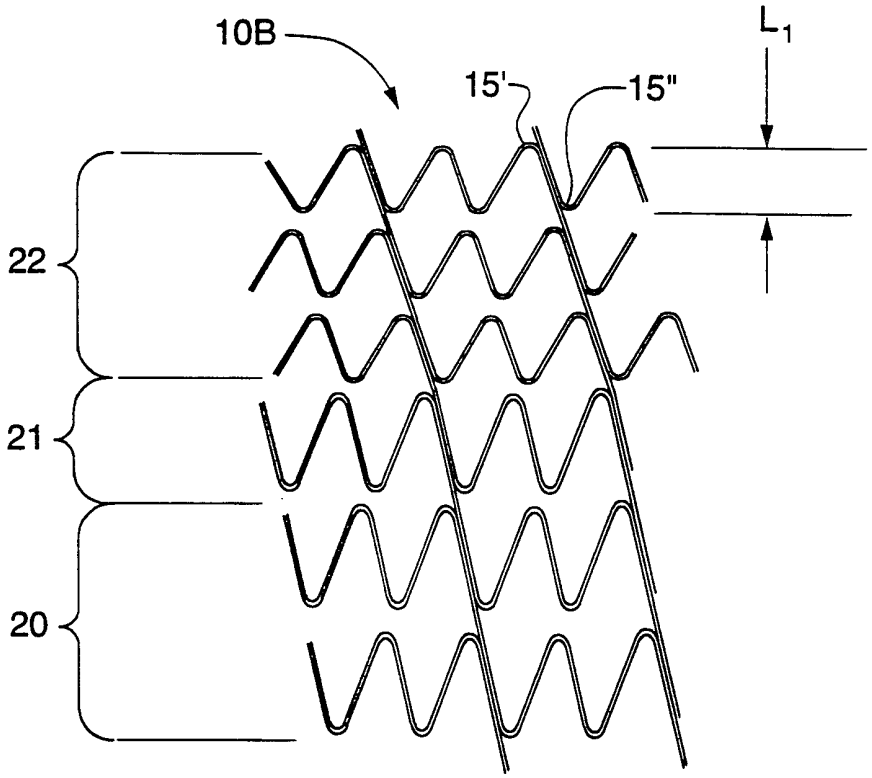


Fig. 3

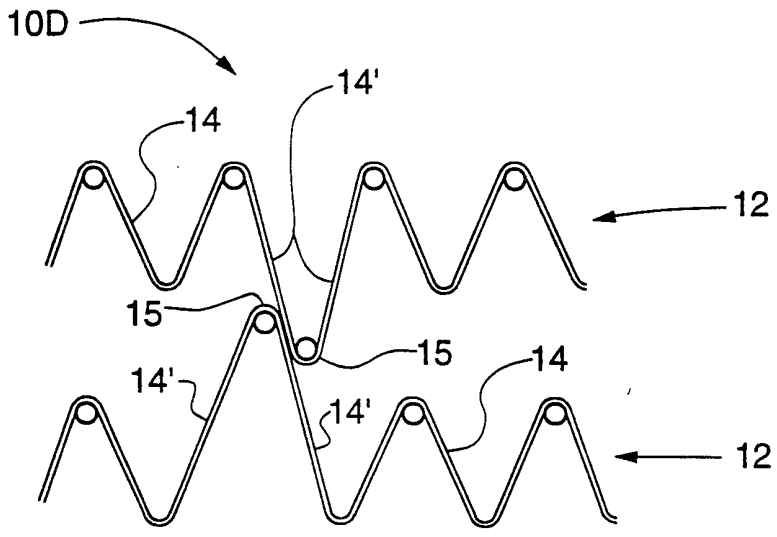


Fig. 9

Fig. 4

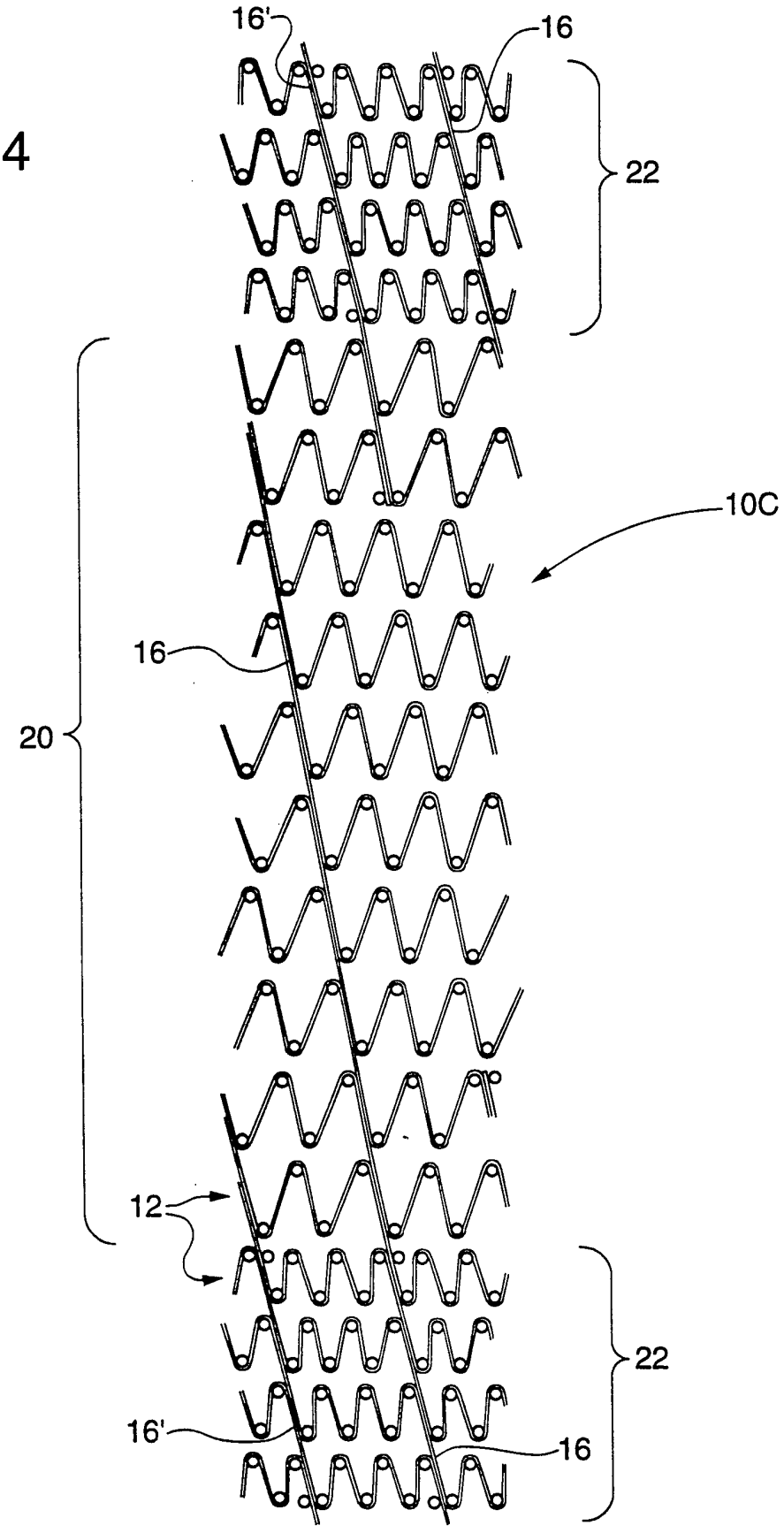
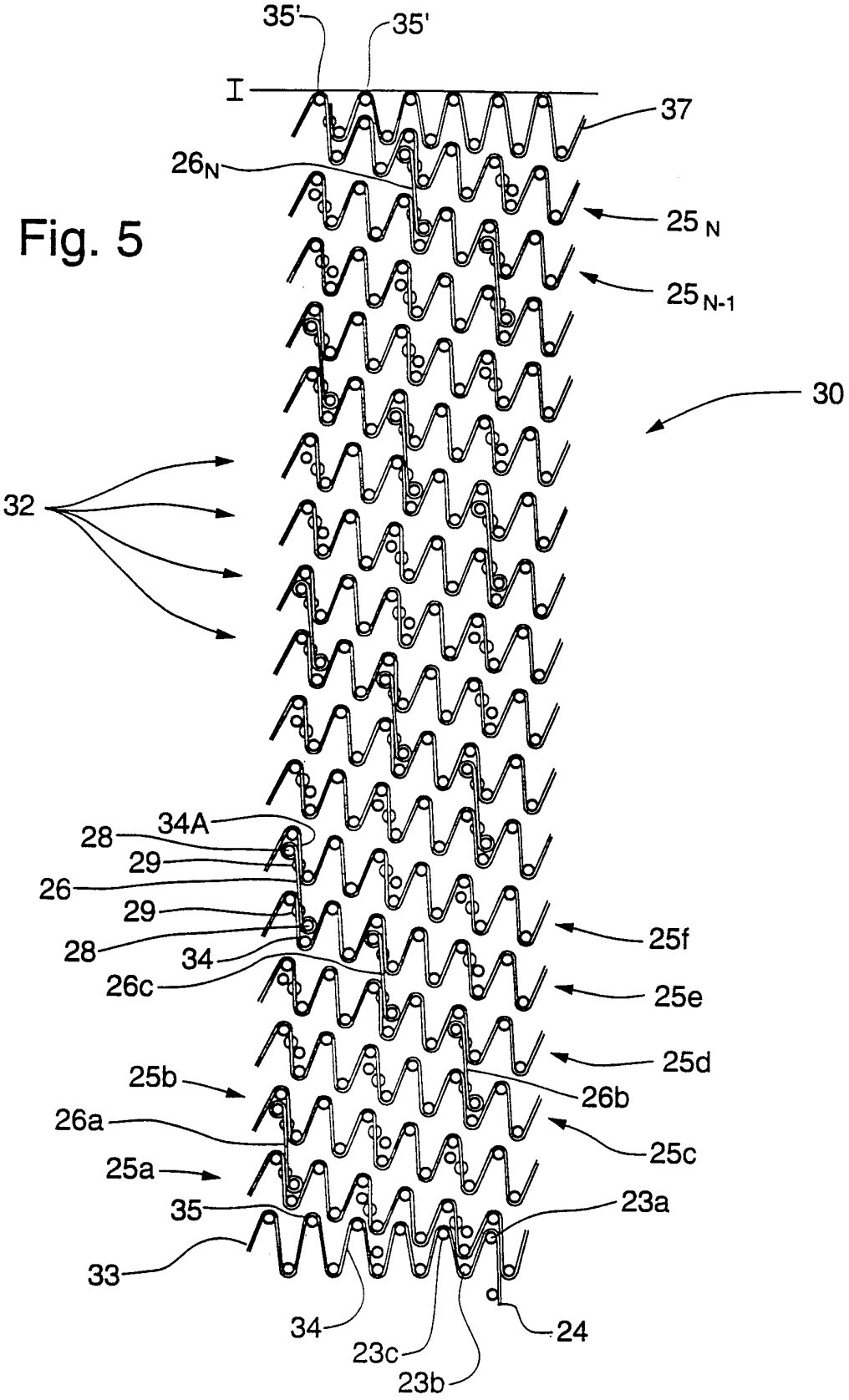


Fig. 5


35'
35'
I
37
26N
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25 N-1
30
32
34A
28
29
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29
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34
26c
25f
25e
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25c
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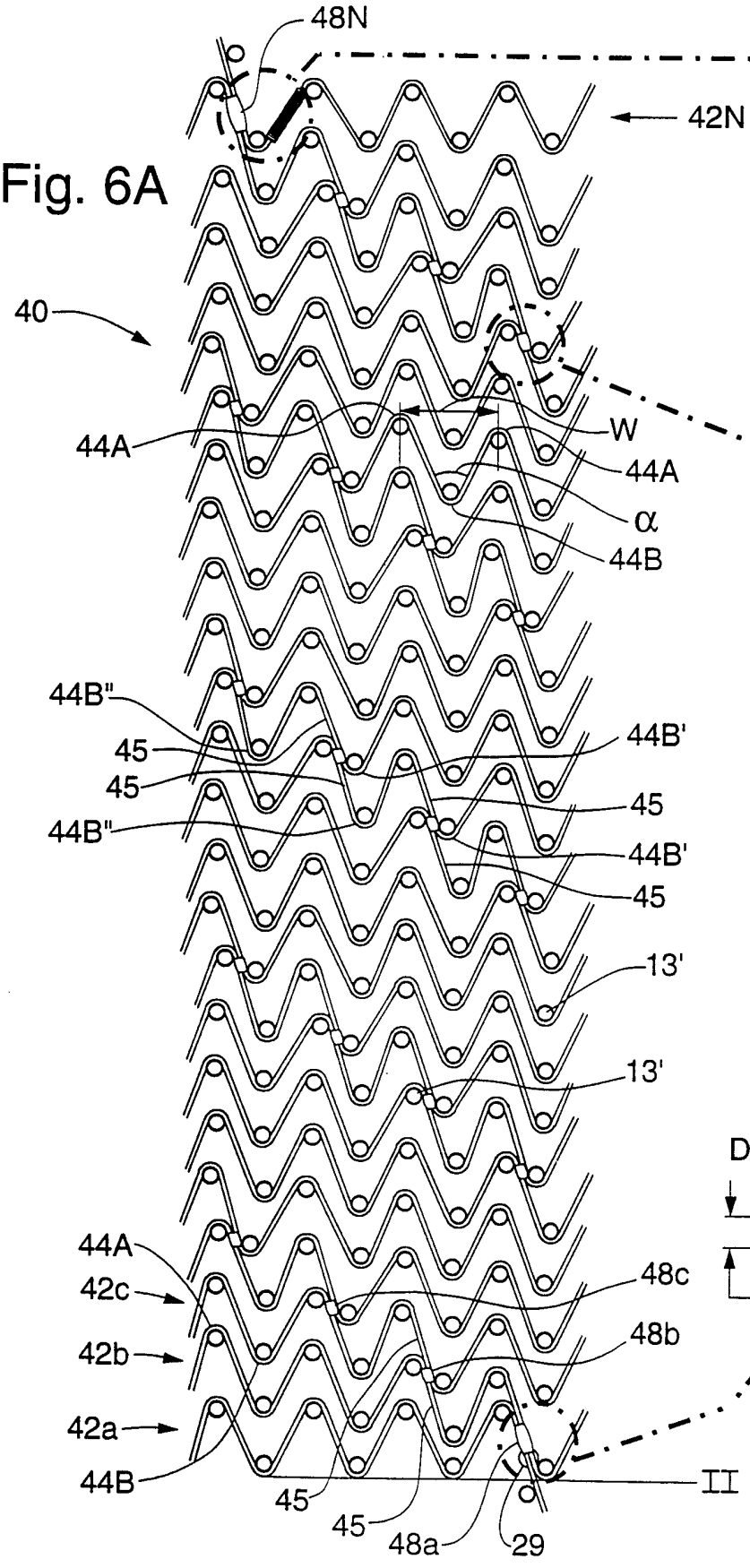
34
24
23c
23b

Fig. 6A



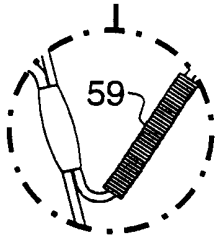


Fig. 6D

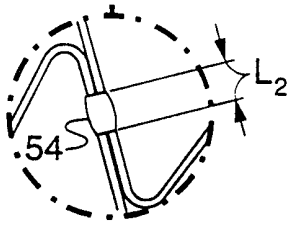


Fig. 6B

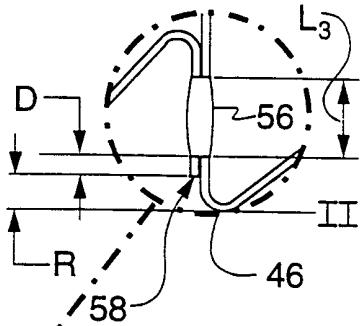


Fig. 6C

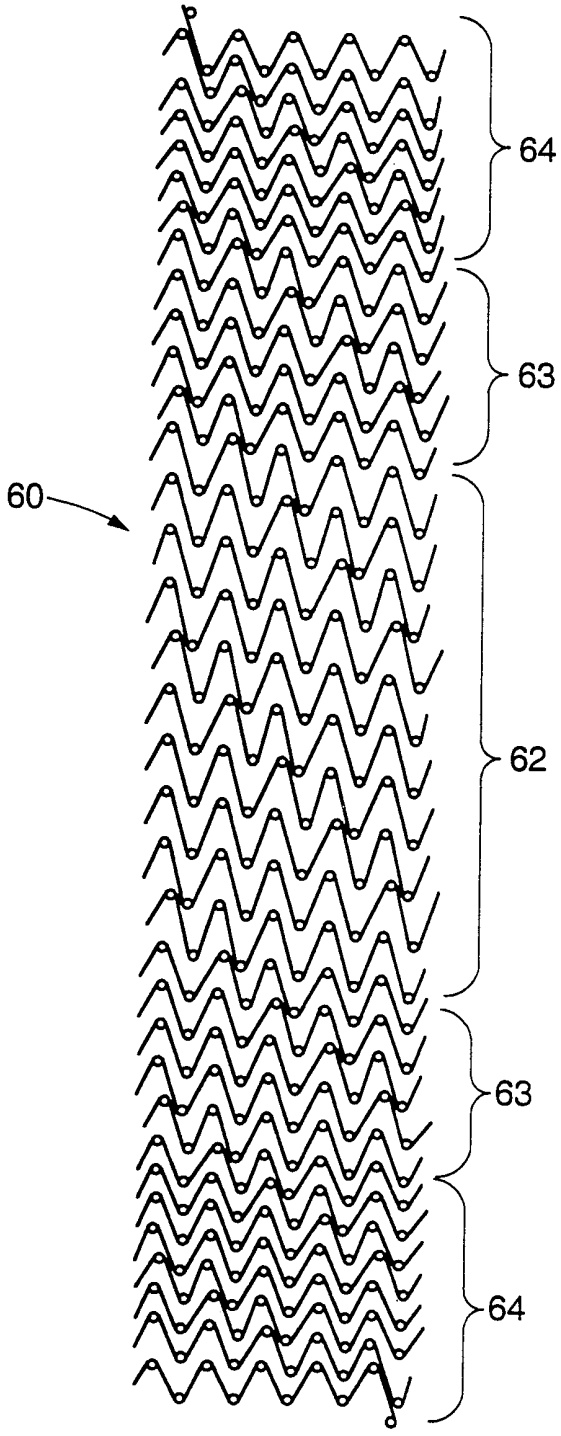


Fig. 6F

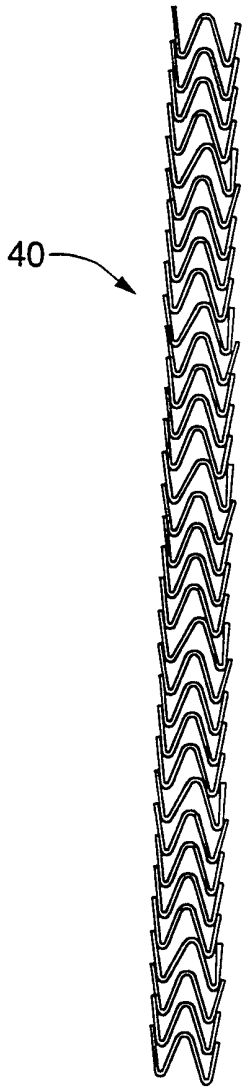


Fig. 6E

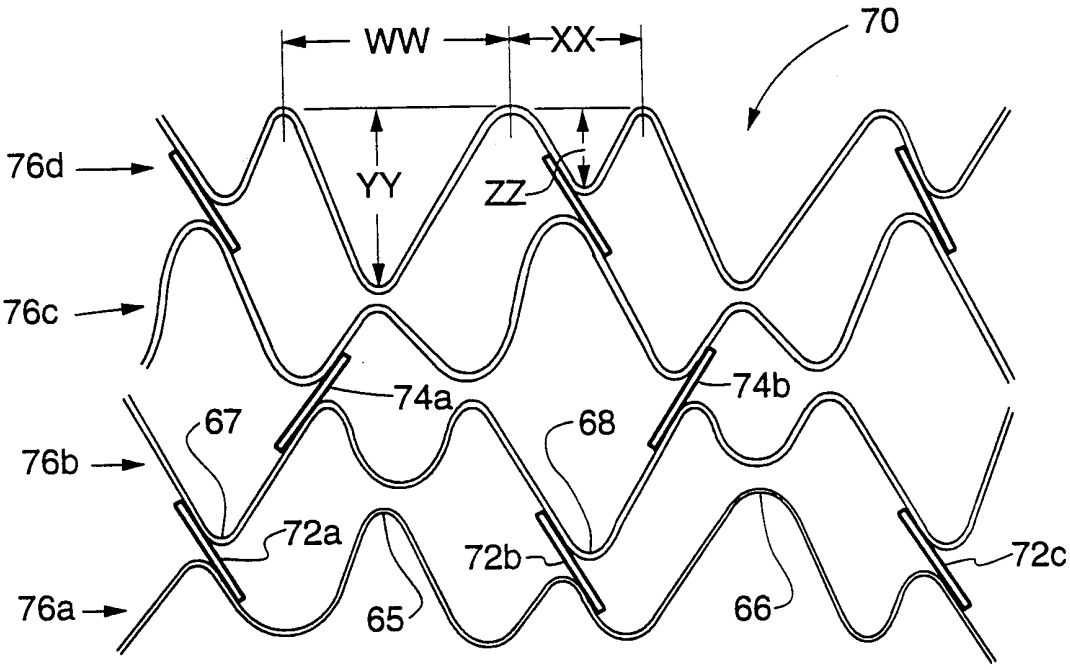

WW
XX
70
YY
ZZ
76d
76c
74a
74b
67
68
76b
72a
72b
72c
76a
65
66

Fig. 7

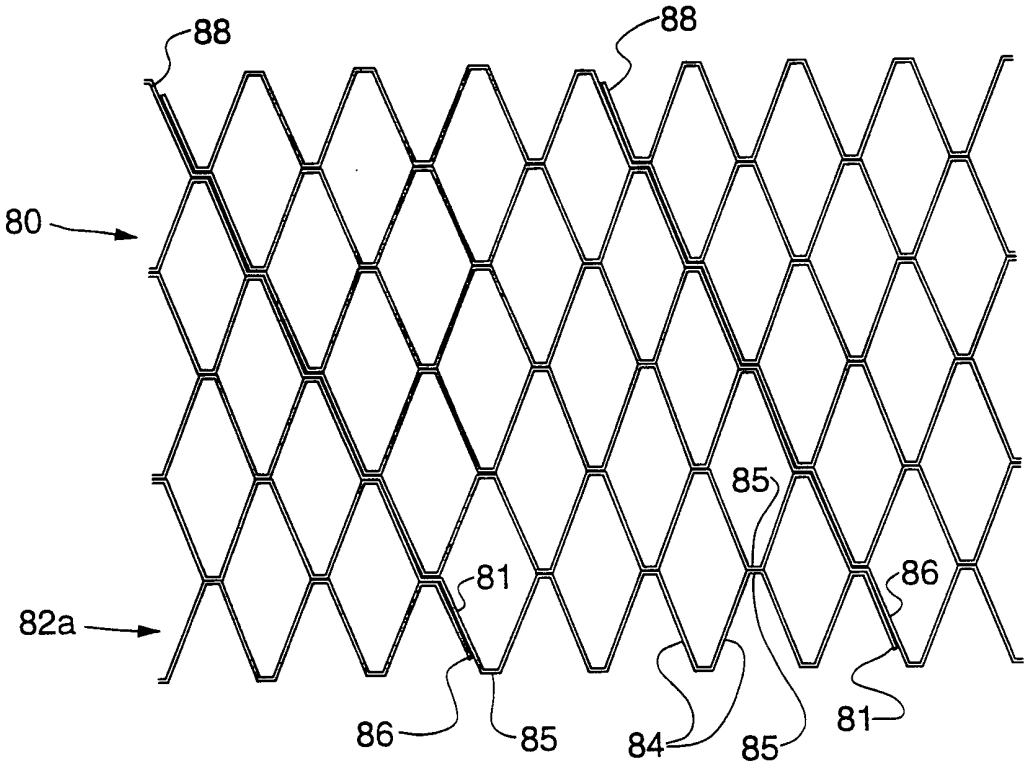

88
88
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Fig. 8

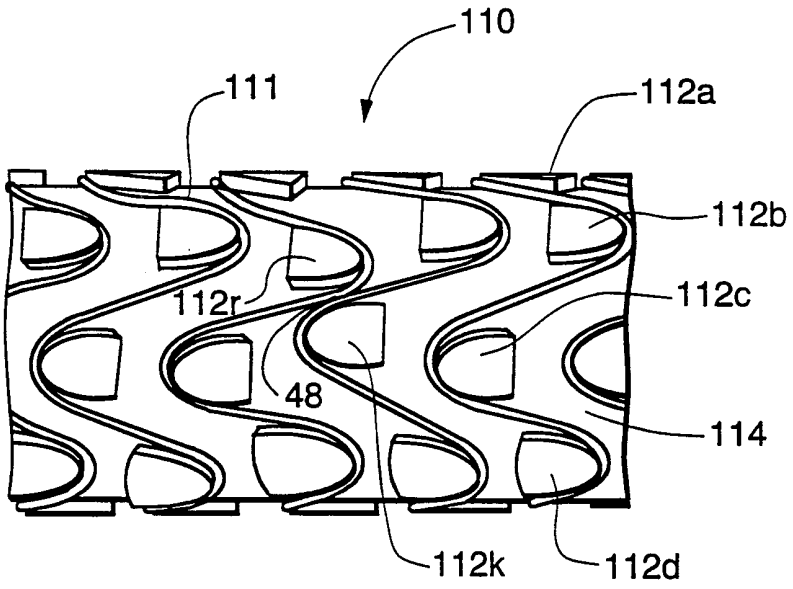

Fig. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/04694

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/04, 06; A61M 29/00
US CL :606/195, 198; 632/1, 12

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)

U.S. : 632/1, 12; 606/195, 198

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US 5,800,515 A [NADAL et al.] 01 September 1998, col. 3 lines 39-54, col. 3 lines 55-65, col. 4 lines 68-67, Figs. 1-3 and 6, and col. 6 lines 38-40.	1-6, 8-11, 13, 14, 16-,18, 20-22, 24, 25, 27, 28, 30, 31, 33, 34, 38, 42, 44, 46-48
Y	US 5,716,396 A [WILLIAMS, JR.] 10 February 1998, col. 4 lines 35-44, and Figs. 1-3.	7, 23, 26
Y, P	US 5,800,519 A [SANDOCK] 01 September 1998, col 4 lines 60-67, and Figs. 2-2b.	12
Y, P	US 5,800,508 A [GOICOECHEA et al.] 01 September 1998, col. 10 lines 49-69, and Fig. 2A.	29, 32, 35, 50, 54-56

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 05 JUNE 1999	Date of mailing of the international search report 29 JUN 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer HIEU PHAN Telephone No. (703) 308-8969

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/04694

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,549,663 A [COTTONE, JR.] 27 August 1996, col. 6 lines 40-50.	43