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United States Patent [19] Jang

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[45] **Date of Patent:** ***Jul. 13, 1999**

- [54] **INTRAVASCULAR STENT**
- [76] Inventor: **G. David Jang**, 30725 Eastburn La., Redlands, Calif. 92374
- [*] Notice: This patent is subject to a terminal disclaimer.
- [21] Appl. No.: **08/845,657**
- [22] Filed: **Apr. 25, 1997**

4303181 A1	8/1994	Germany	A61M 29/00
29608037 U1	8/1996	Germany	A61M 29/00
WO96/03029	2/1996	WIPO	A61F 2/02
WO96/26689	9/1996	WIPO	A61F 2/06
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Primary Examiner—David H. Willse
Assistant Examiner—Tram A. Nguyen
Attorney, Agent, or Firm—Wilson Sonsini Goodrich & Rosati

Related U.S. Application Data

- [63] Continuation-in-part of application No. 08/824,142, Mar. 25, 1997, application No. 08/824,866, Mar. 25, 1997, and application No. 08/824,865, Mar. 25, 1997
- [60] Provisional application No. 60/017,484, Apr. 26, 1996.
- [51] **Int. Cl.⁶** **A61F 2/06**
- [52] **U.S. Cl.** **623/1; 623/12**
- [58] **Field of Search** 623/1, 11, 12; 606/108, 191, 194, 195, 198

[57] ABSTRACT

A stent in a non-expanded state has a first expansion strut pair consisting of a first expansion strut positioned adjacent to a second expansion strut and a joining strut which couples the first and second expansion struts at a distal end of the first expansion strut pair. A plurality of the first expansion strut pair form a first expansion column. A second expansion strut pair consists of a first expansion strut positioned adjacent to a second expansion strut and a joining strut couples the first and second expansion struts at a proximal end of the second expansion strut pair. A plurality of the second expansion strut pair form a second expansion column. A first connecting strut includes a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section. The first connecting strut proximal section is coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section is coupled to the proximal end of the second expansion strut pair of the second expansion column. A plurality of the first connecting struts form a first connecting strut column that couples the first expansion column to the second expansion column. A length of the first connecting strut proximal section is equal to a length of the first connecting strut distal section, and a length of the first connecting strut intermediate section is greater than the length of the first connecting strut proximal and distal sections.

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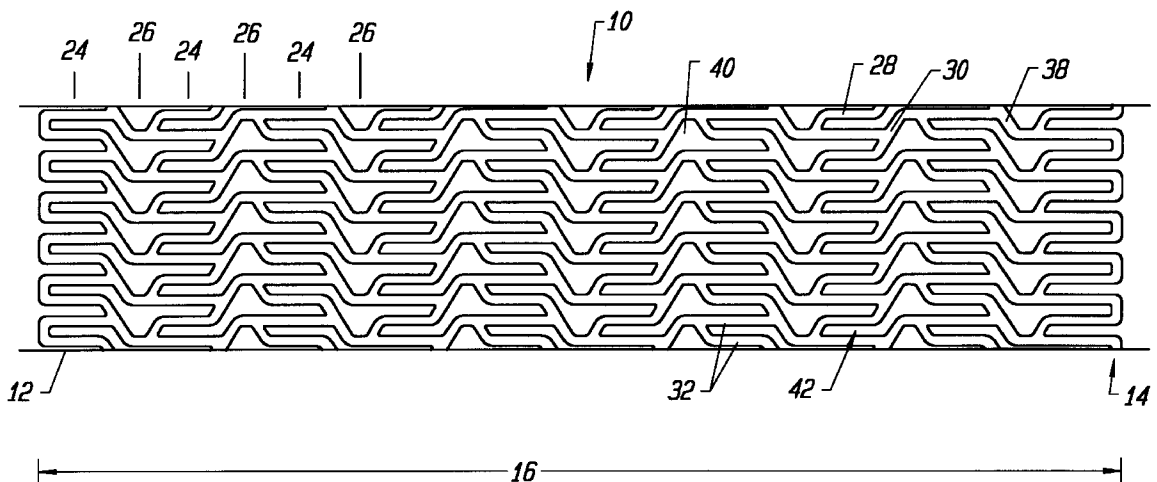
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85 Claims, 27 Drawing Sheets



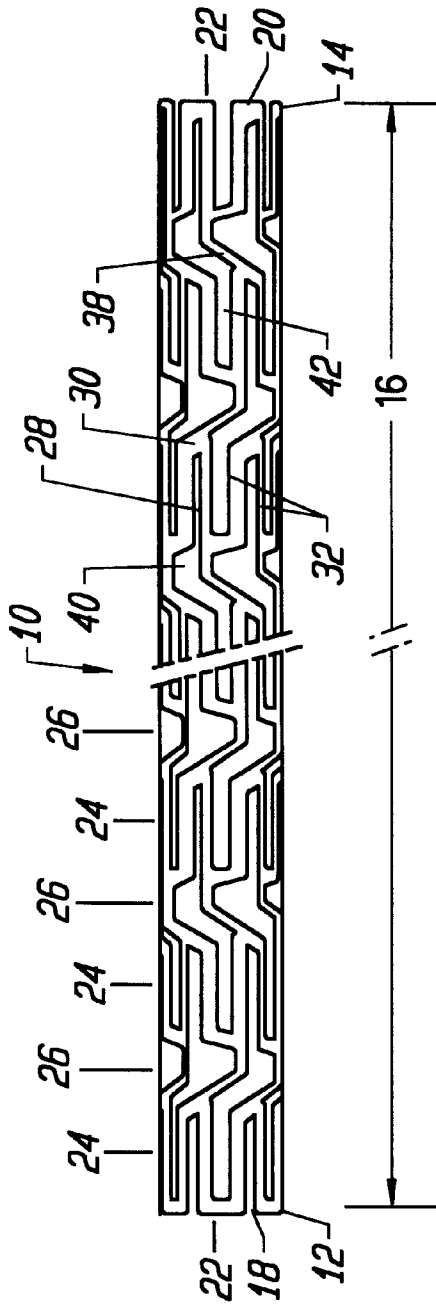


FIG. 1A

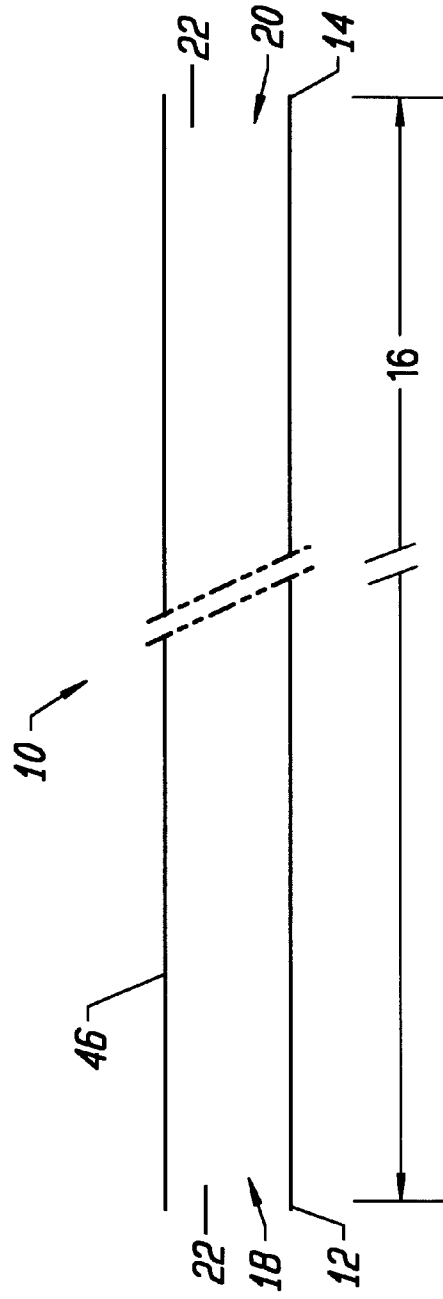


FIG. 1B

FIG. 1C

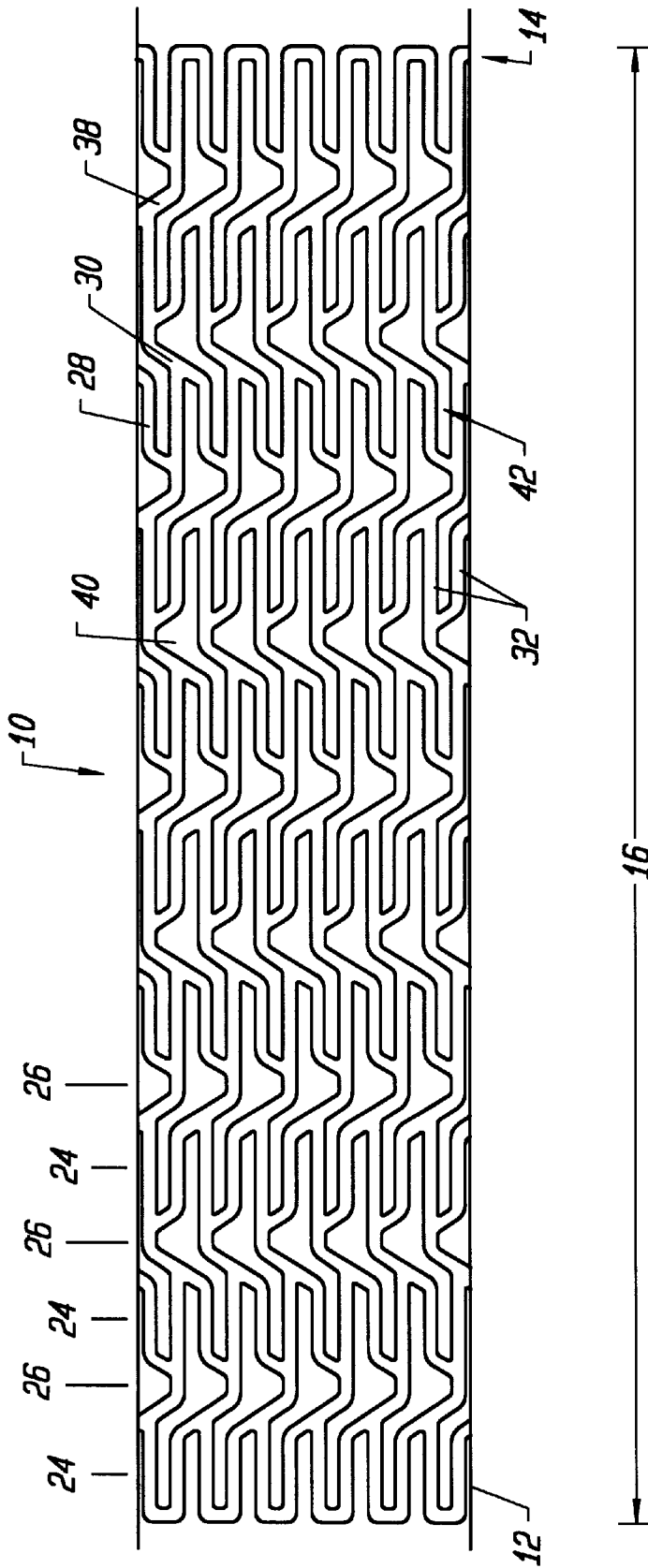


FIG. 2A

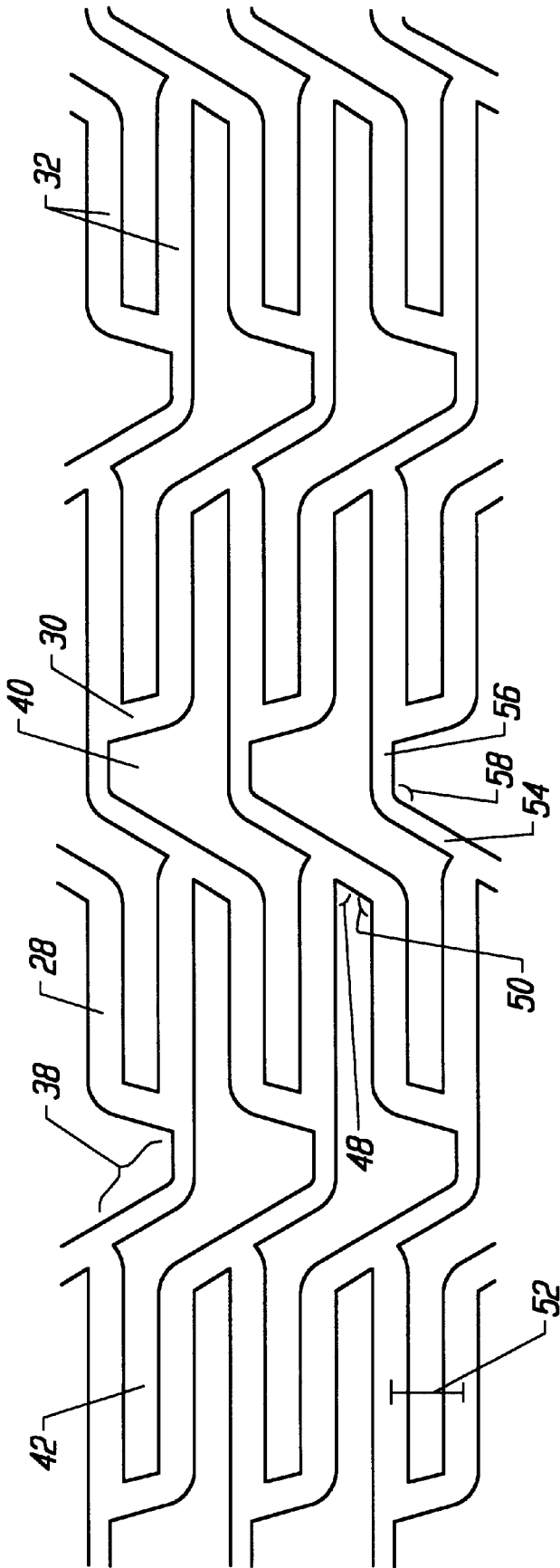


FIG. 2B

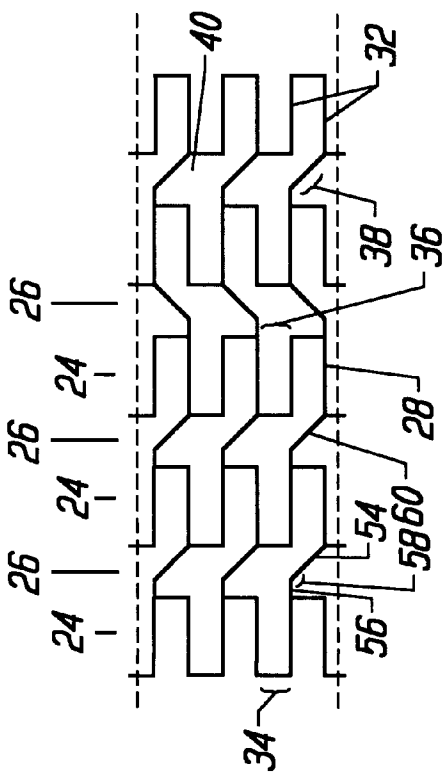


FIG. 3A

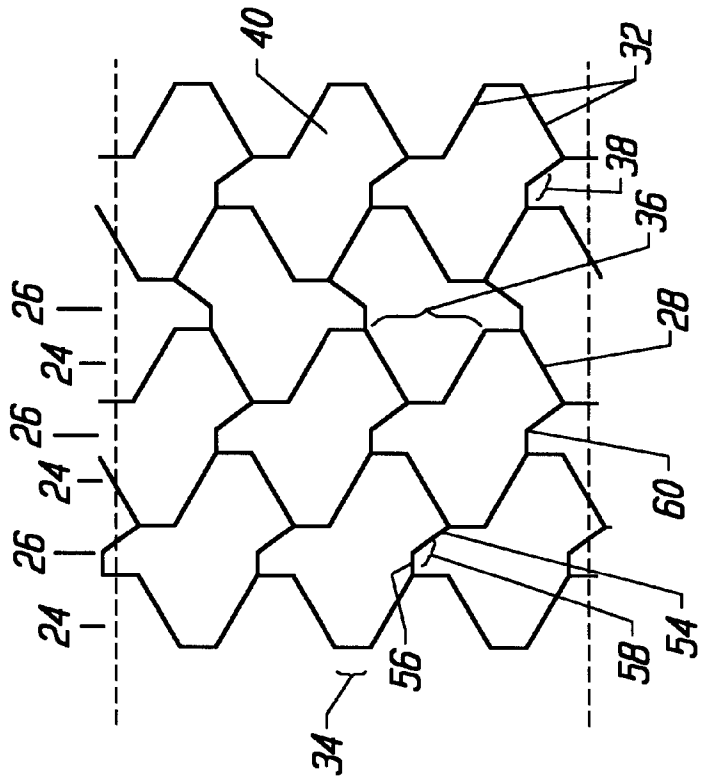


FIG. 3B

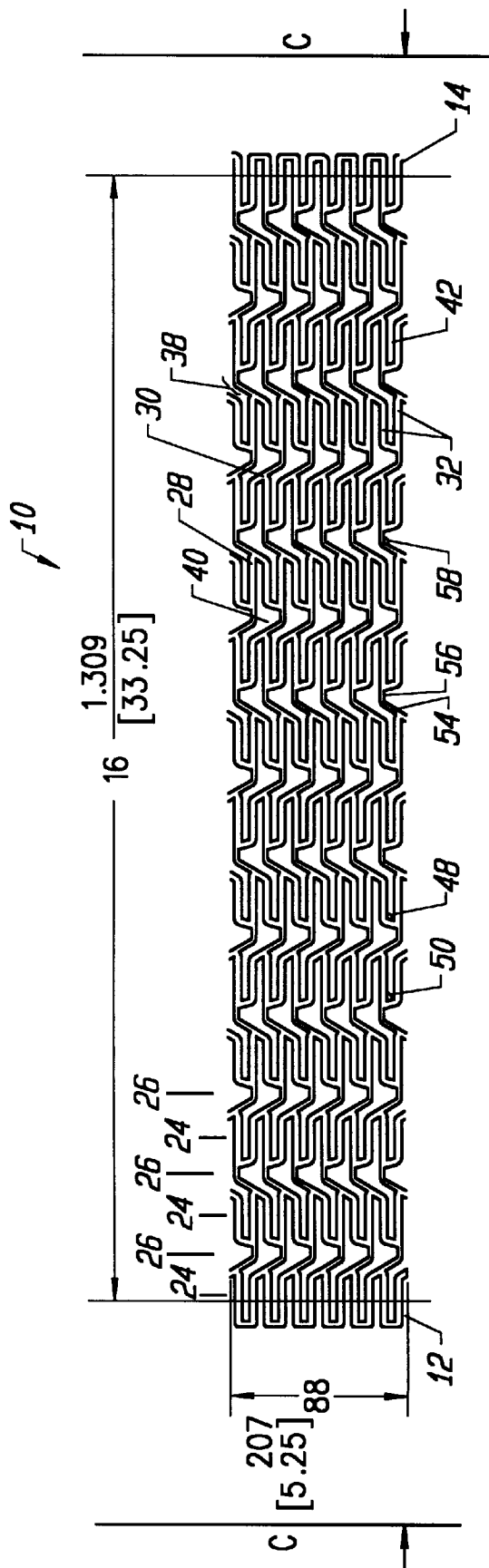


FIG. 4A

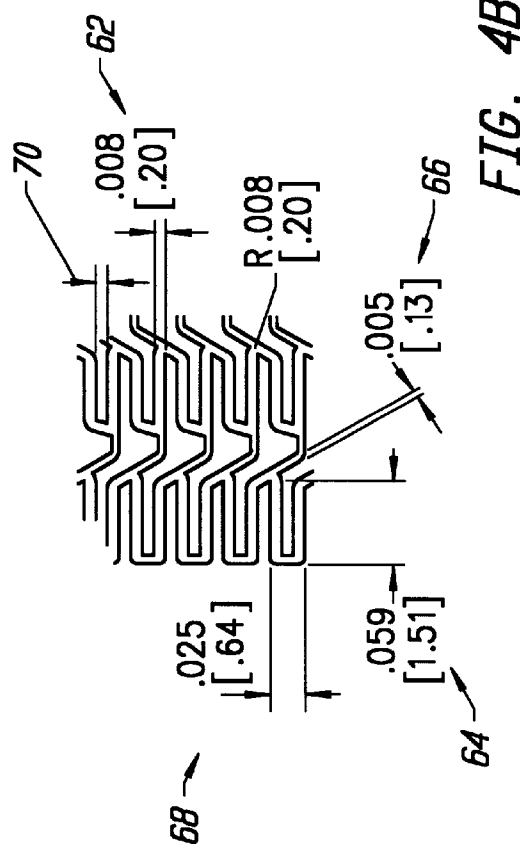
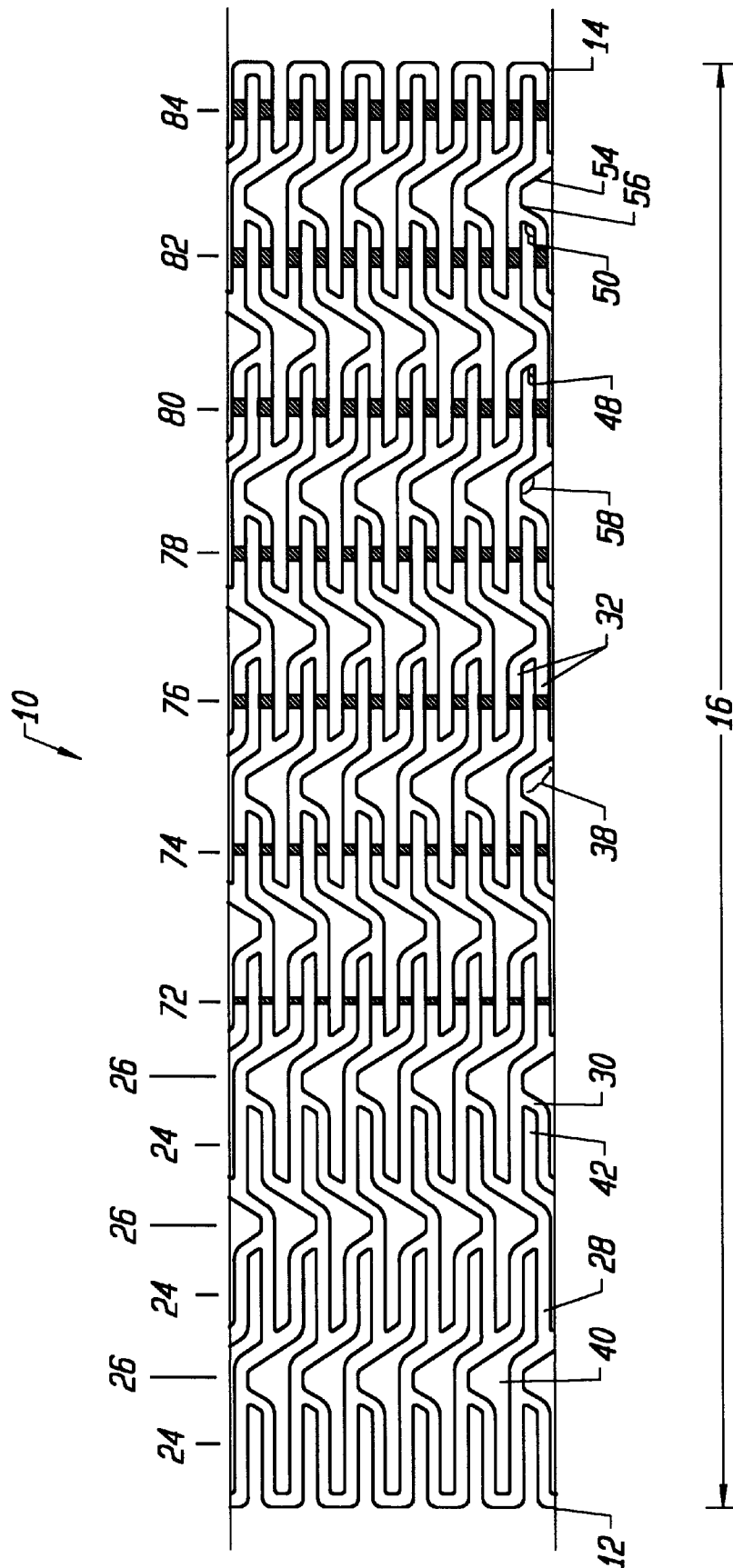


FIG. 4B



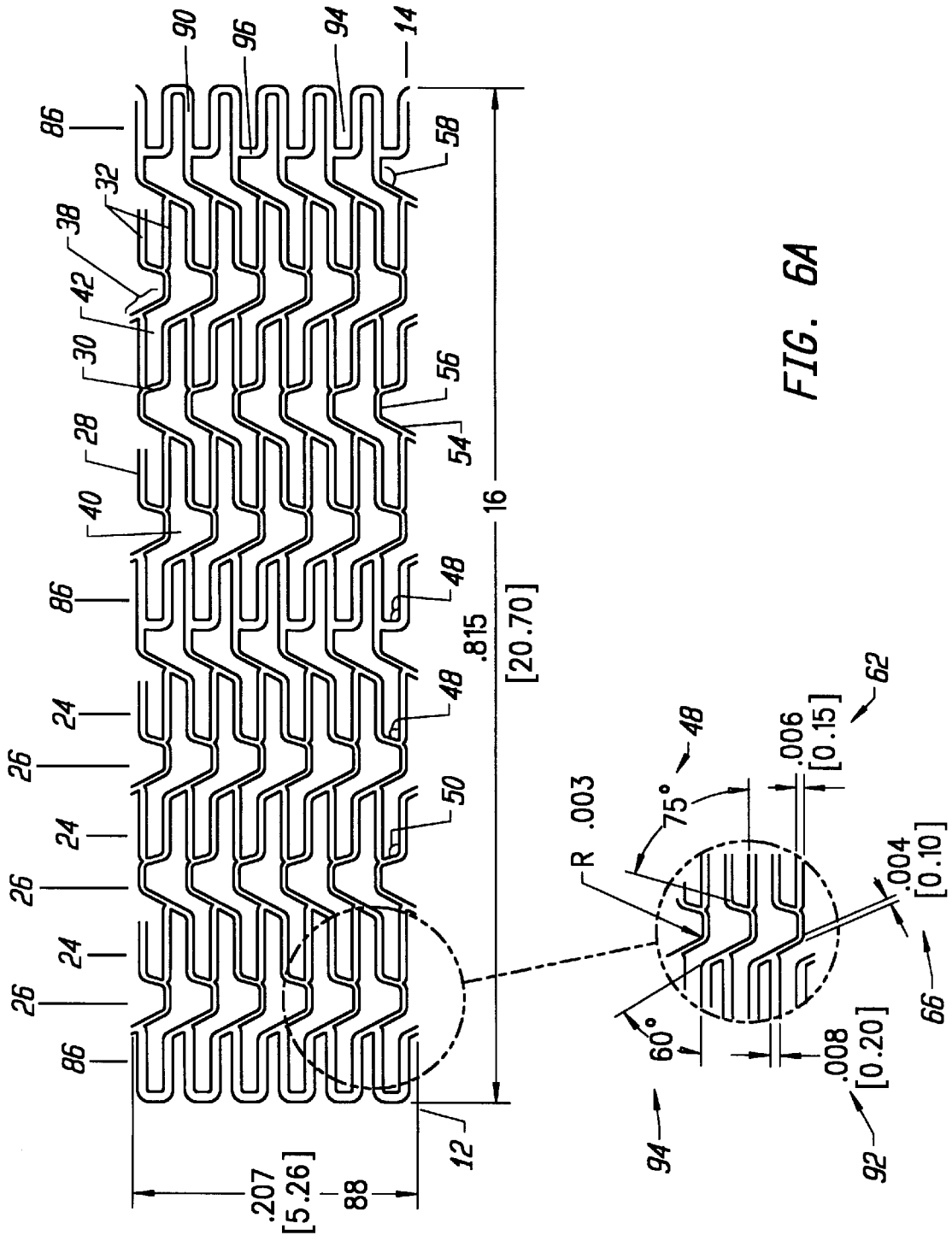


FIG. 6A

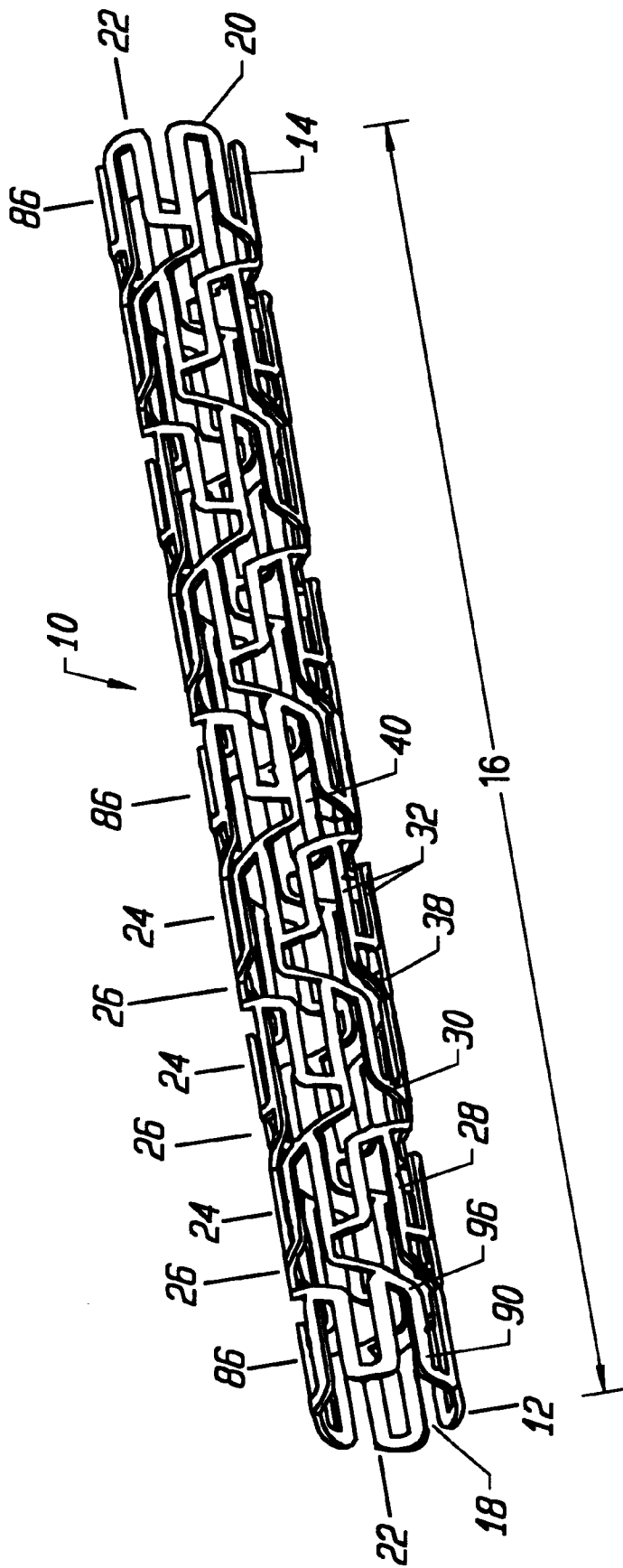


FIG. 6B

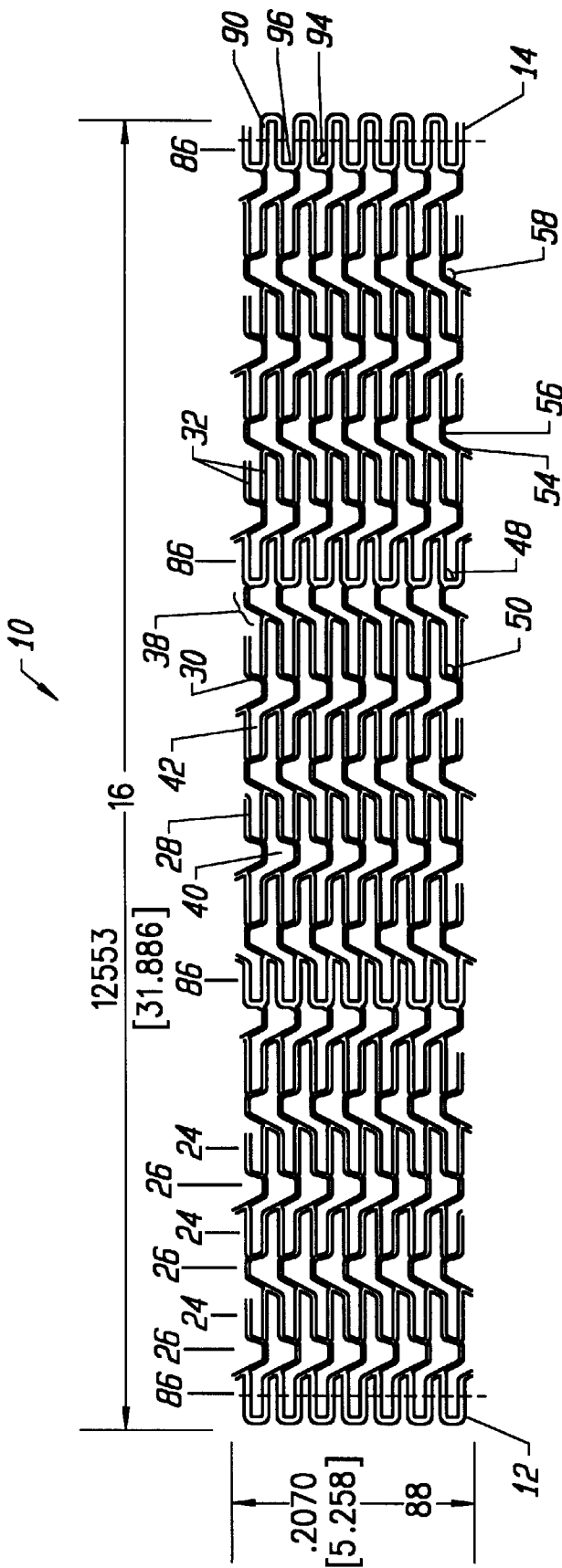


FIG. 7A

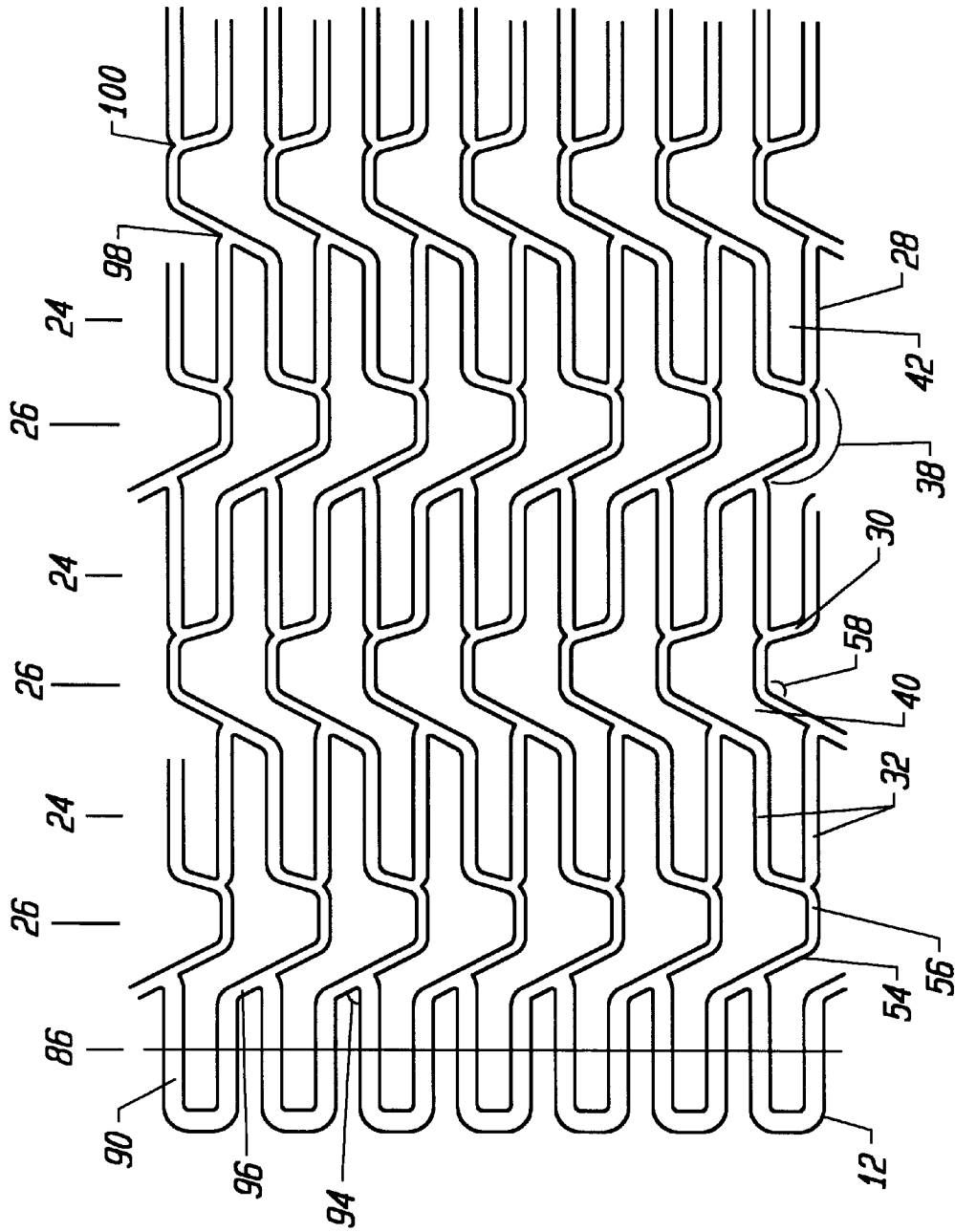


FIG. 7B

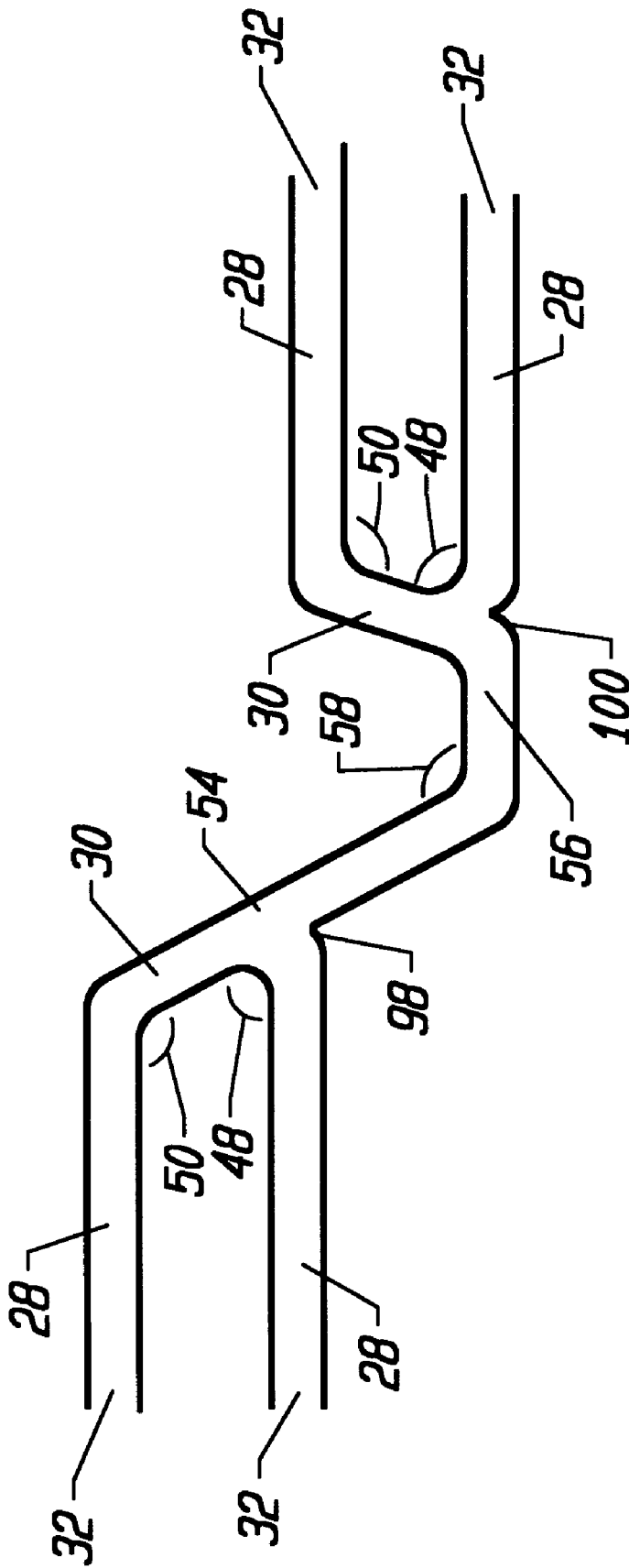


FIG. 7C

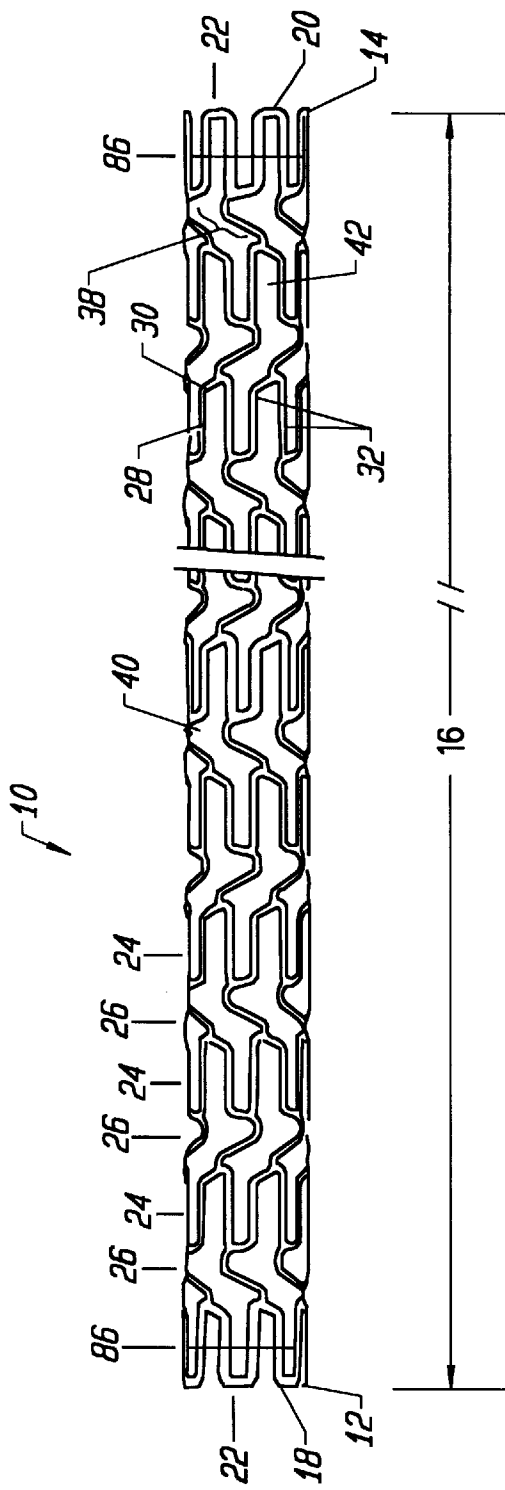


FIG. 8A

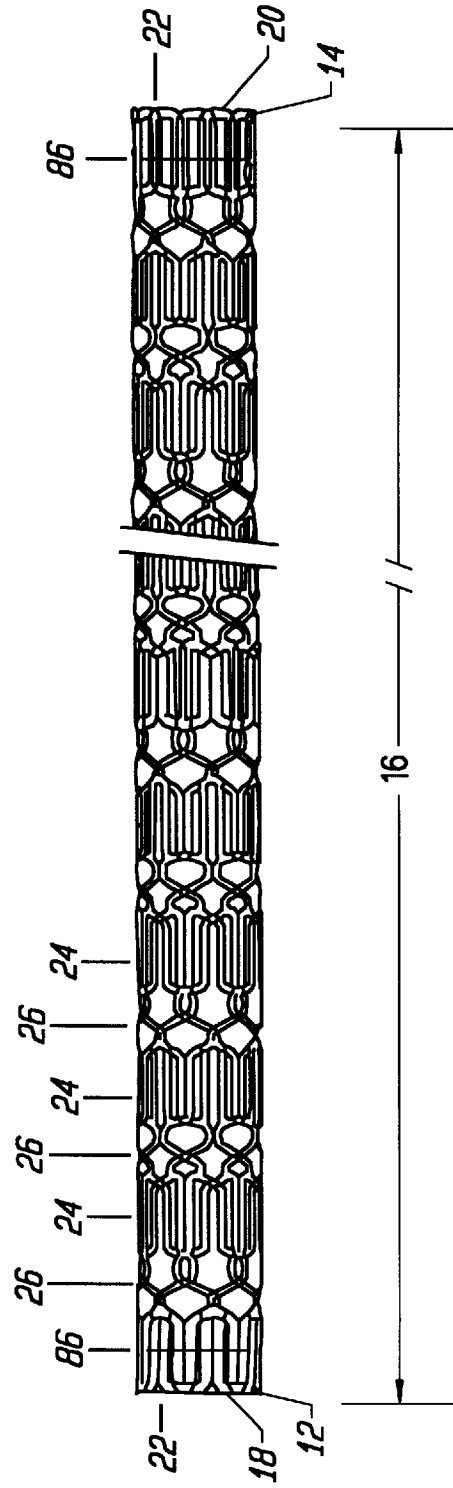


FIG. 8B

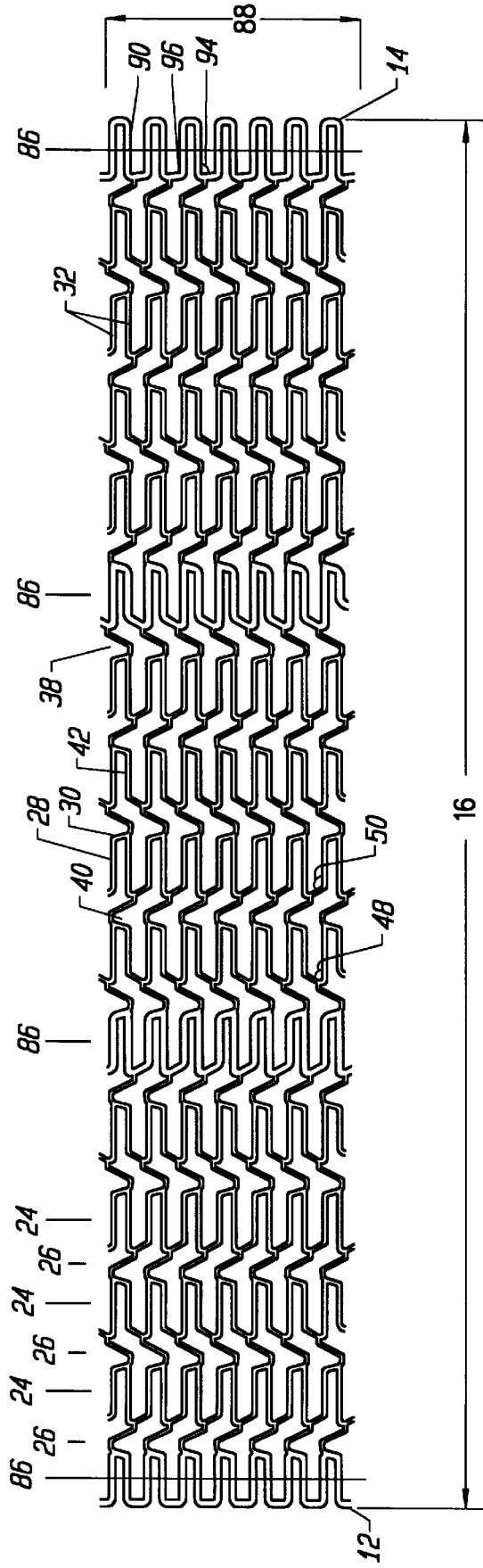


FIG. 8C

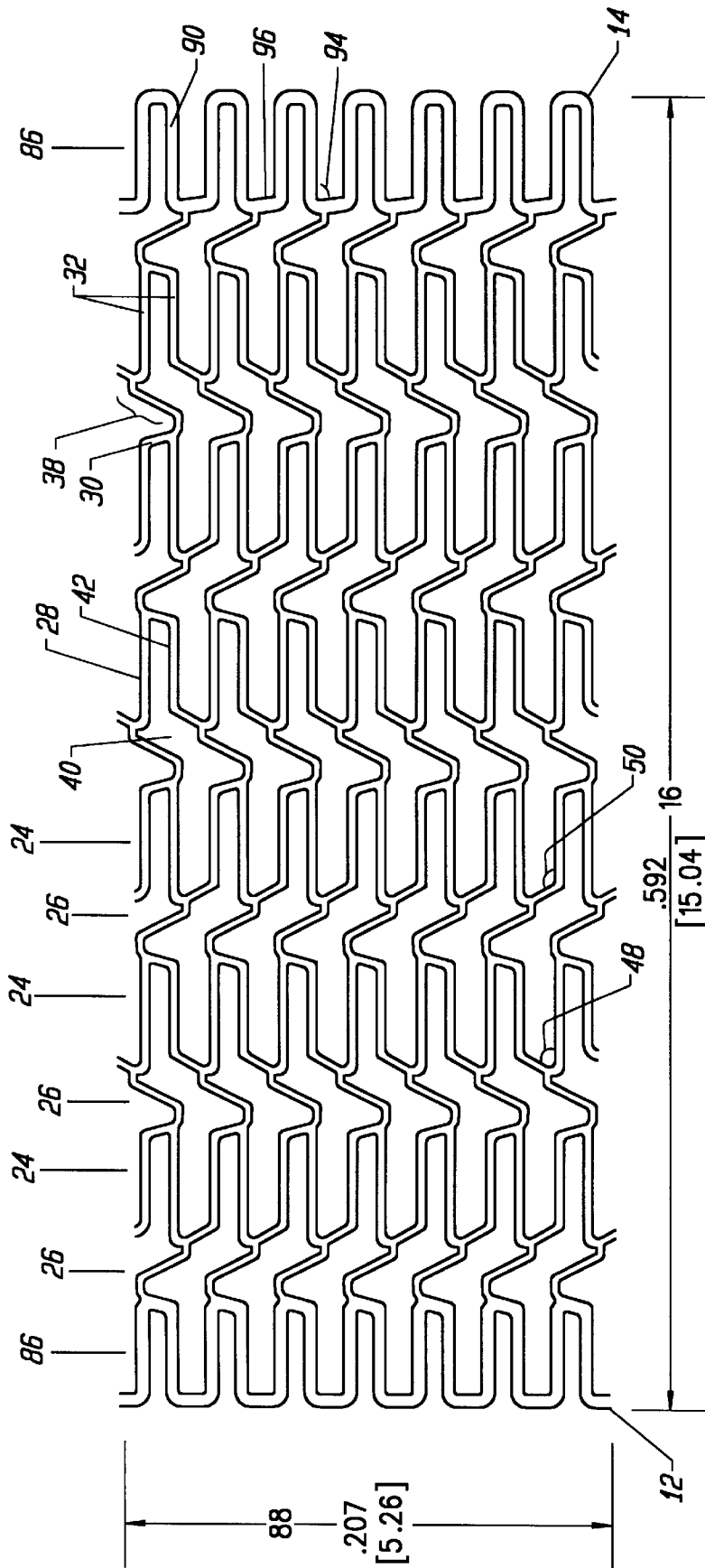
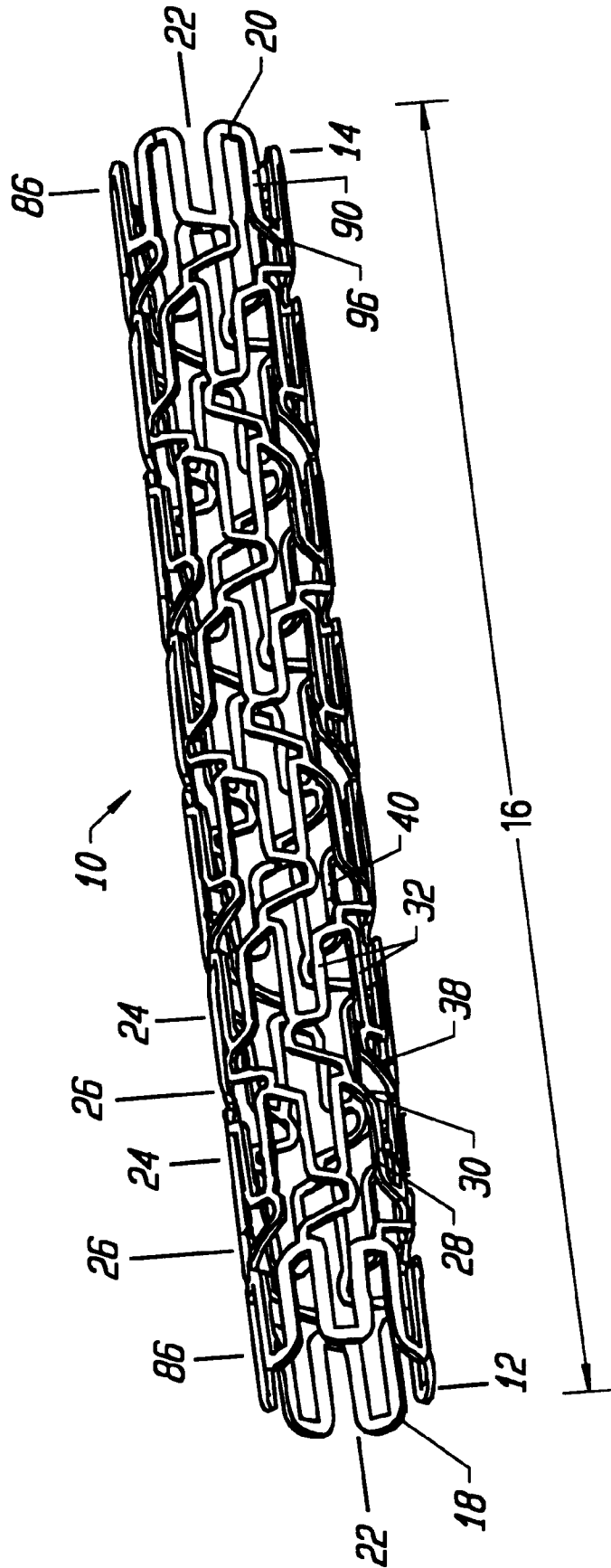


FIG. 8D

FIG. 8E



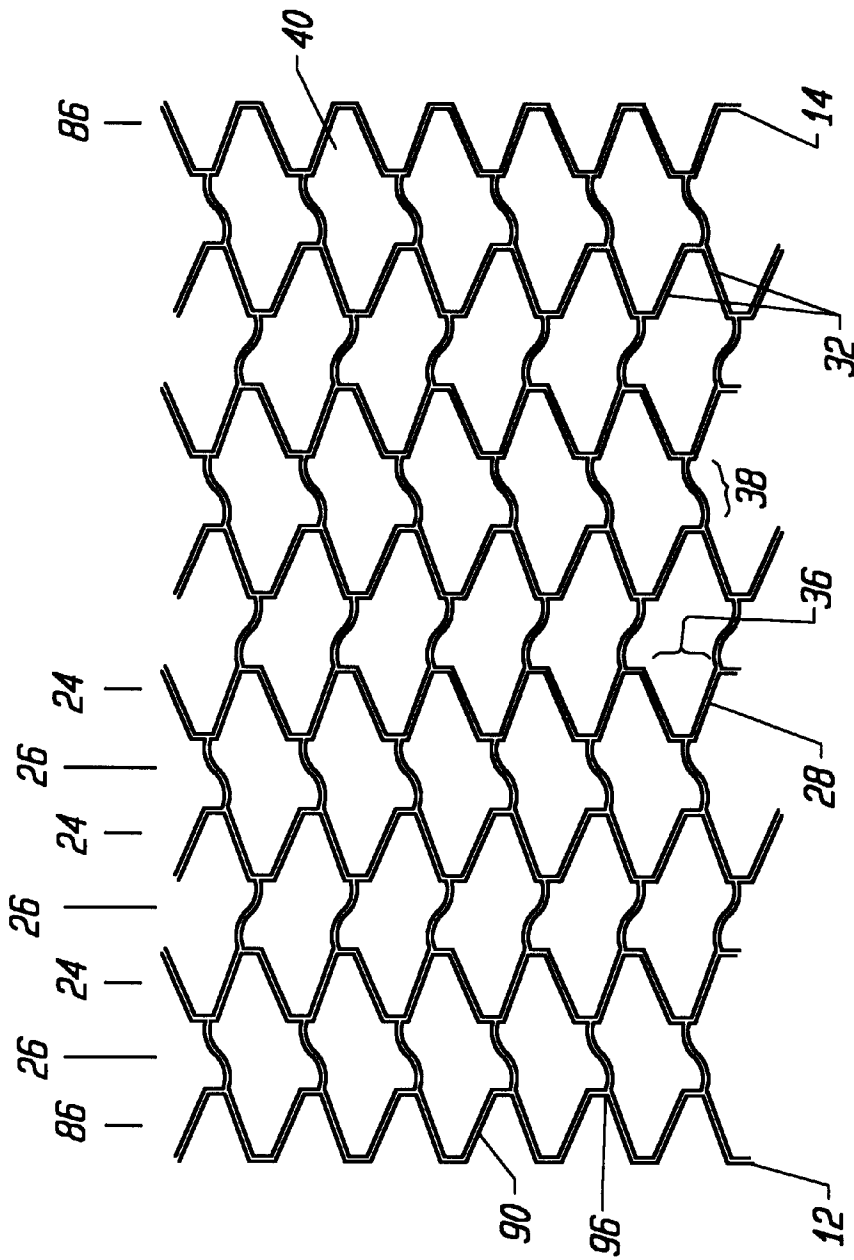


FIG. 8F

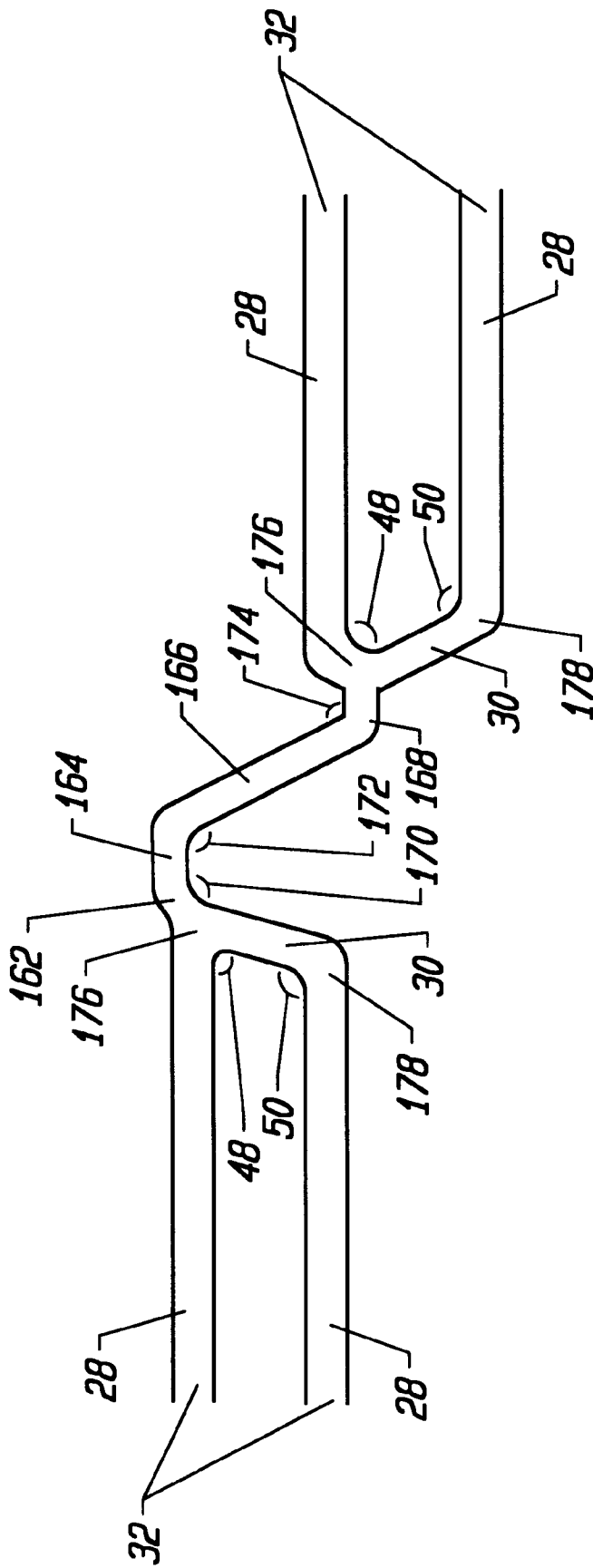


FIG. 8G

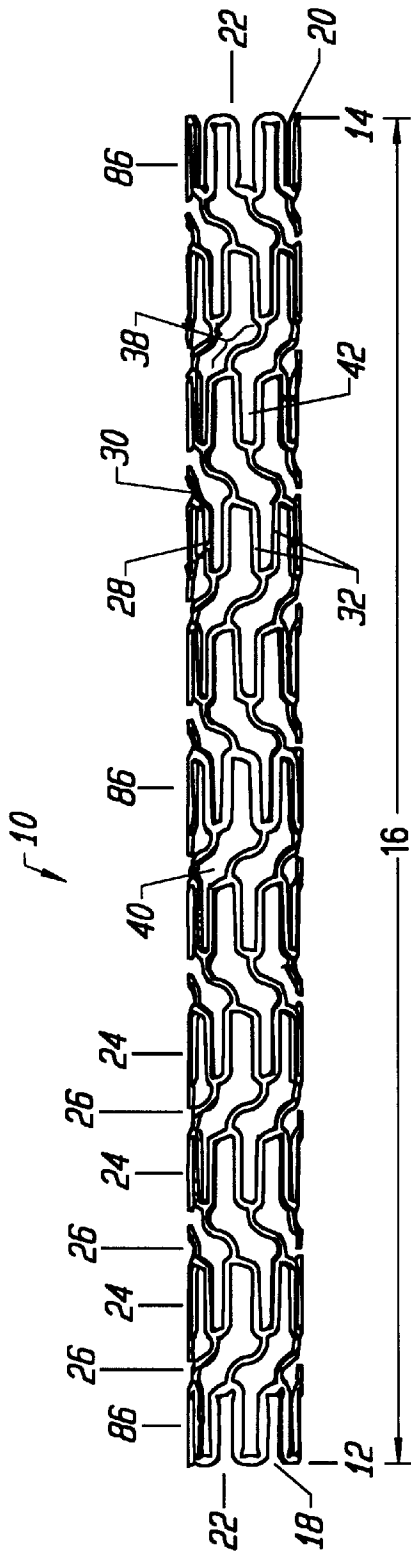


FIG. 9A

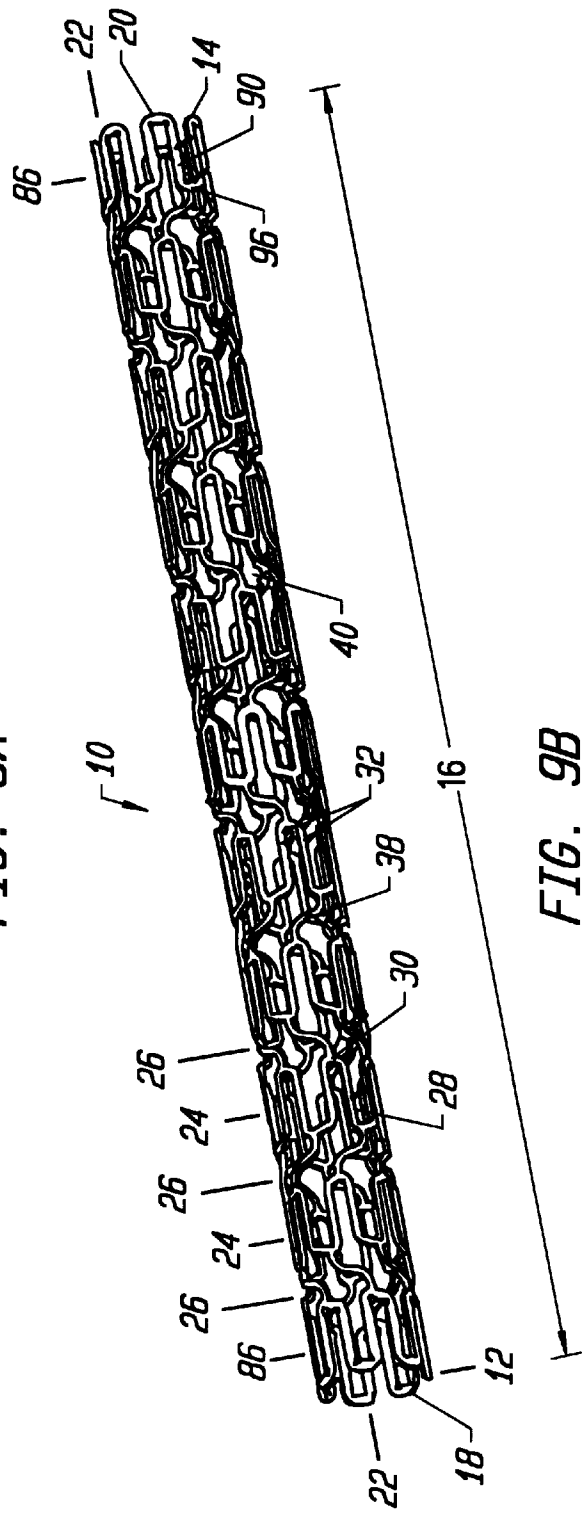


FIG. 9B

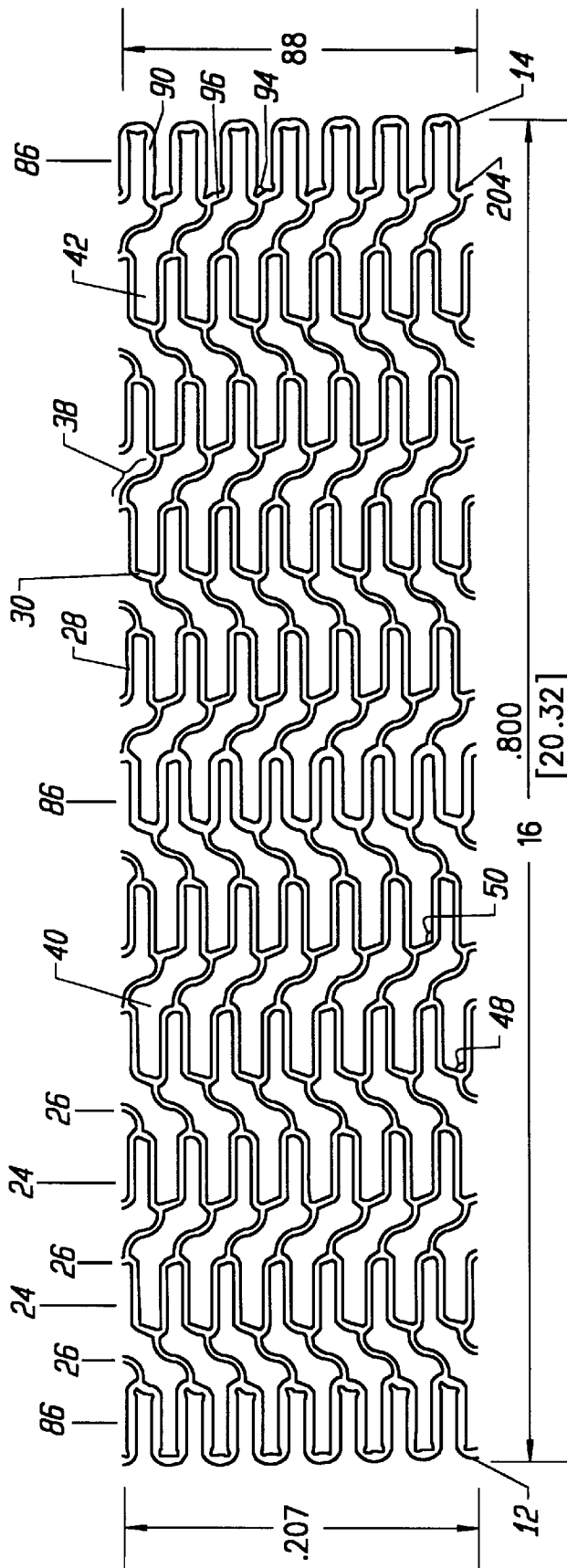


FIG. 9C

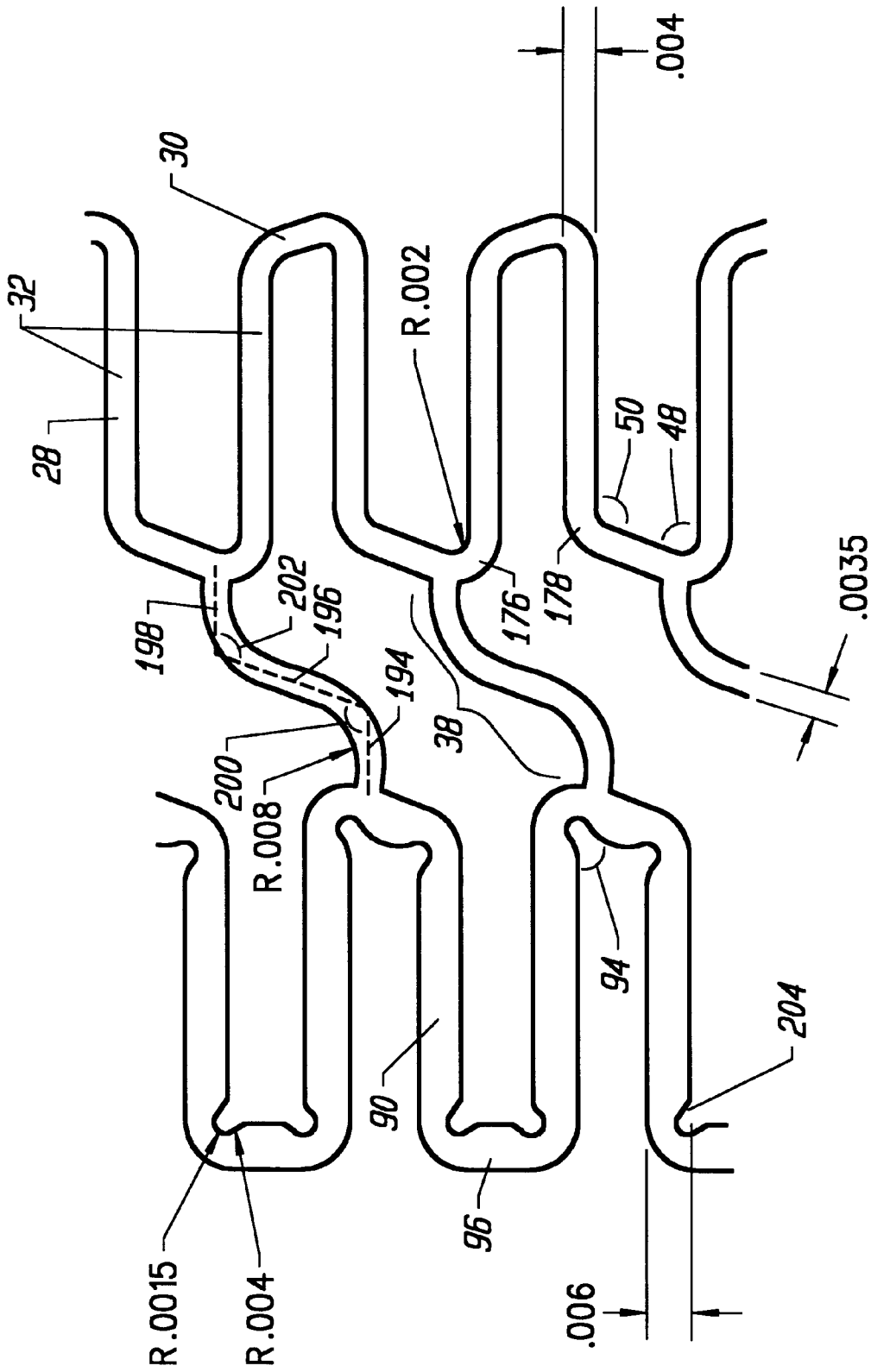


FIG. 9D

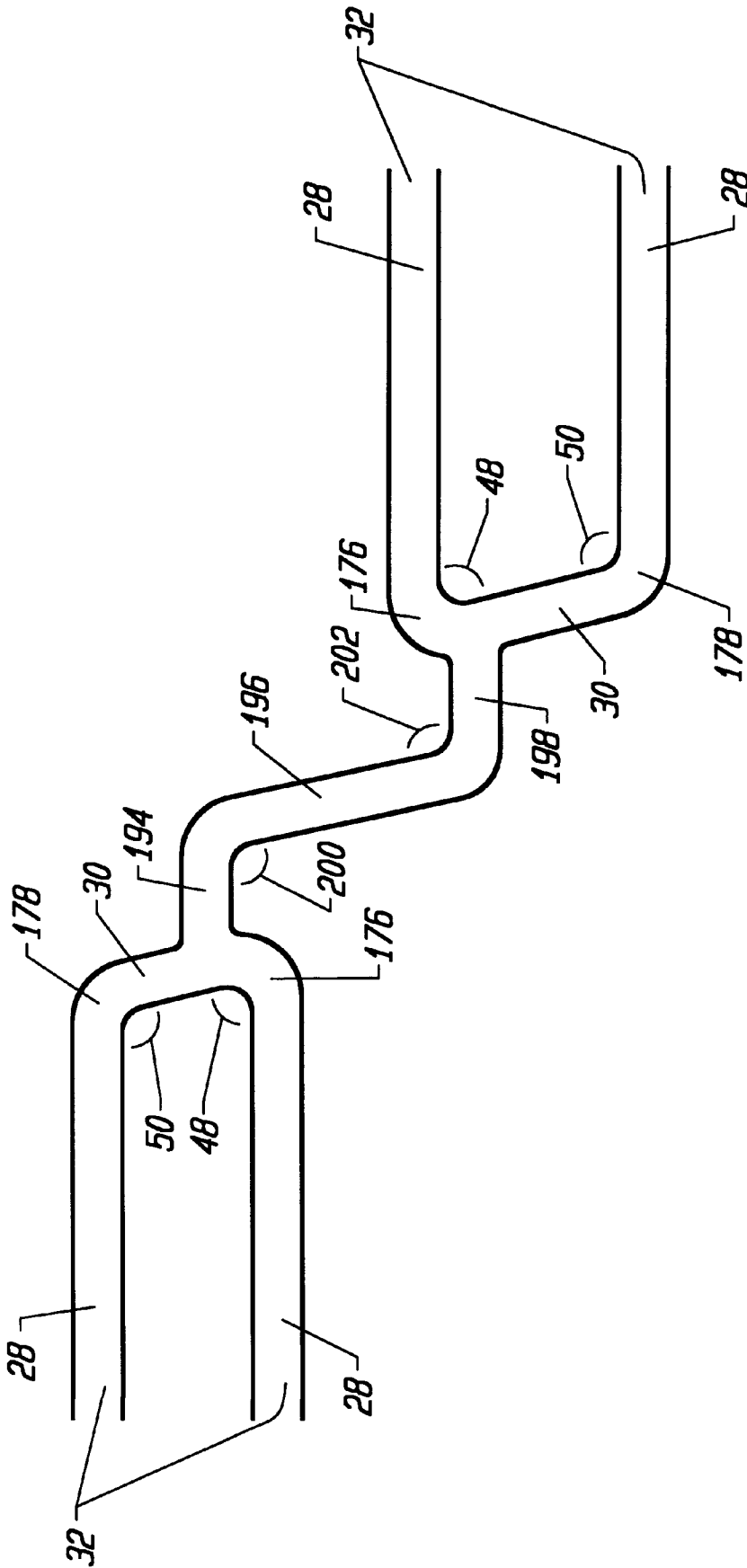


FIG. 9E

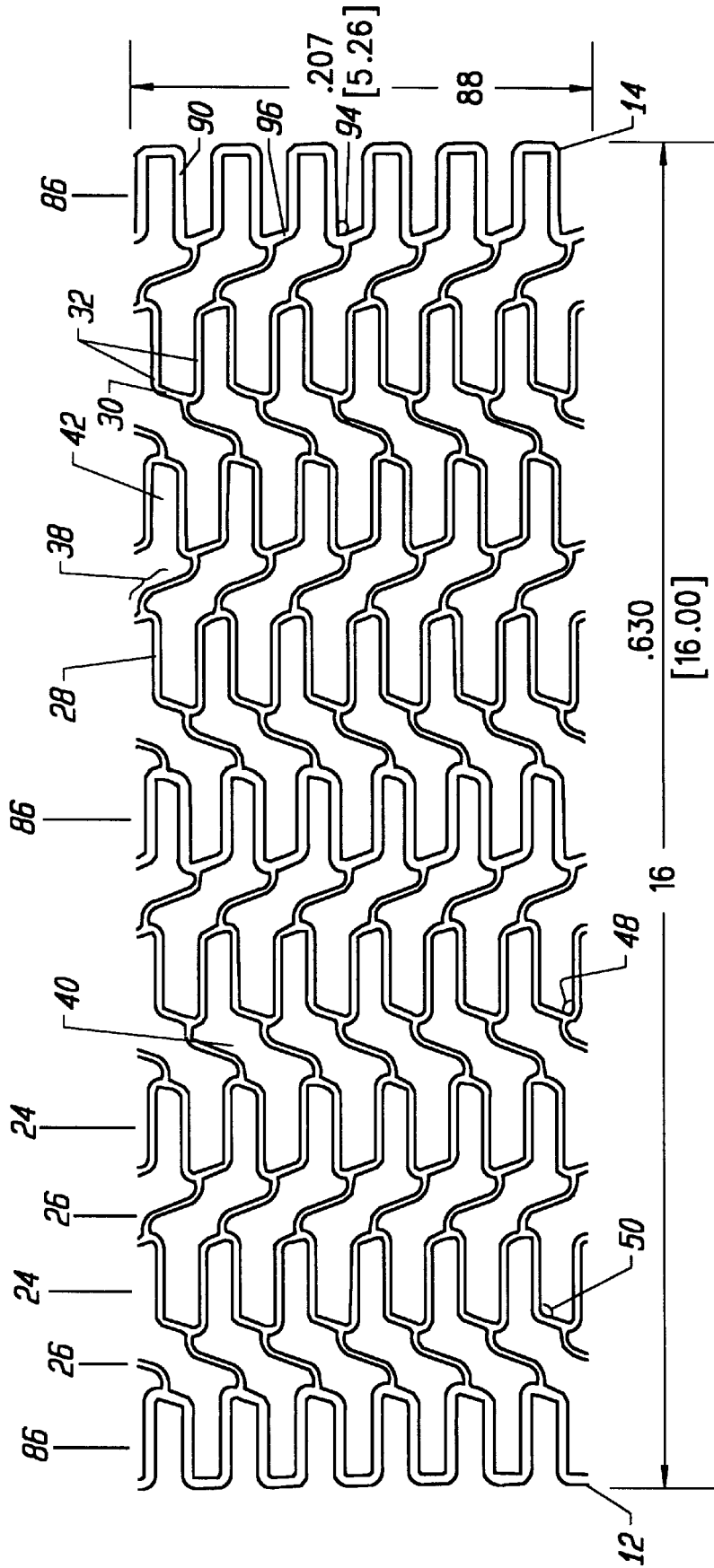


FIG. 9F

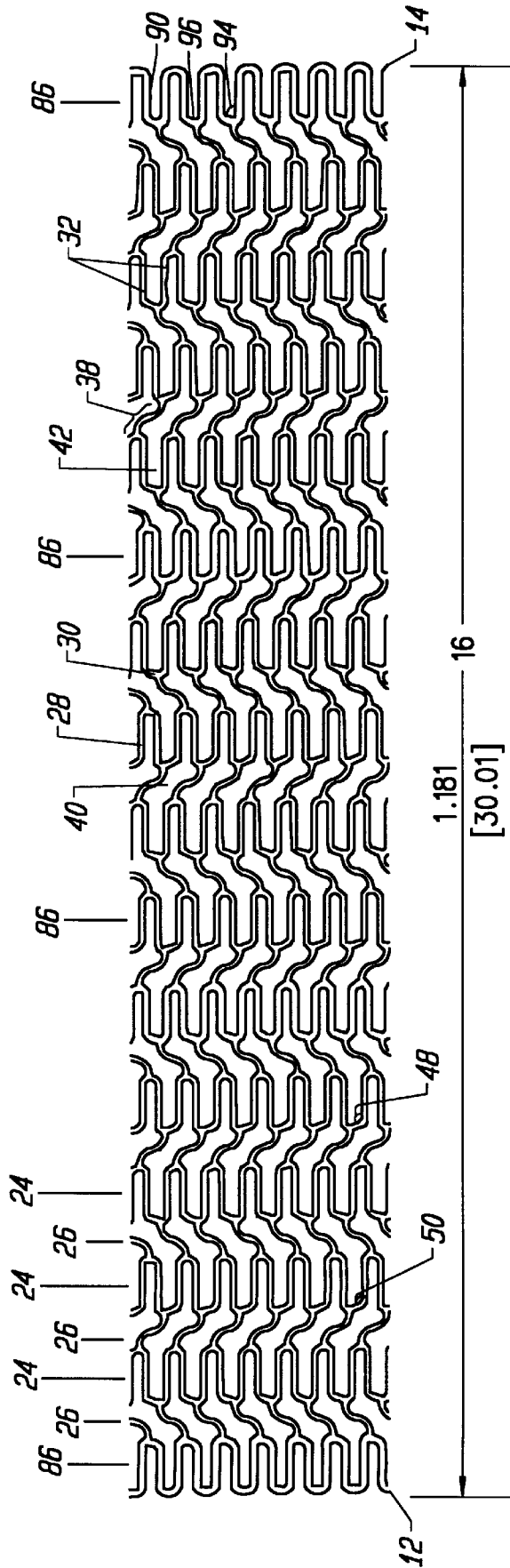


FIG. 96

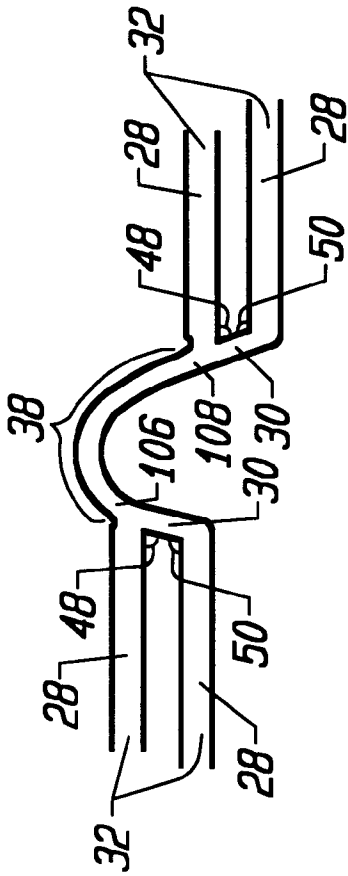


FIG. 10A

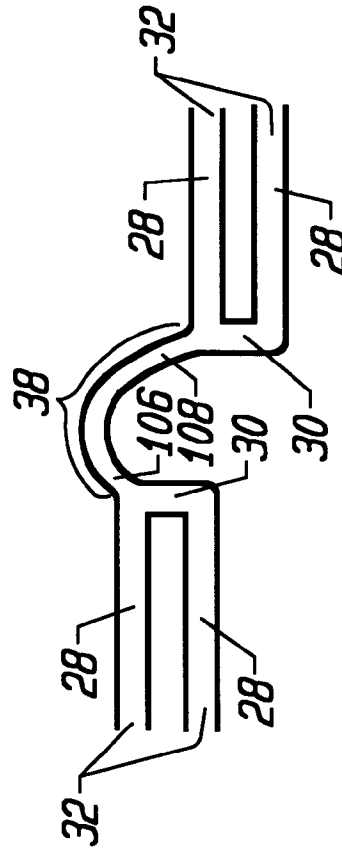


FIG. 10B

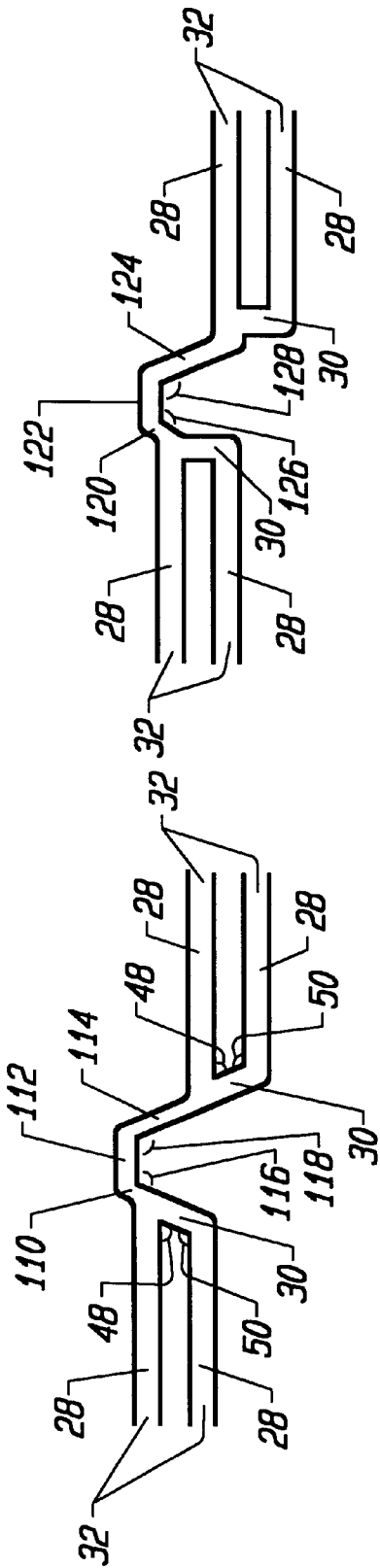


FIG. 10C

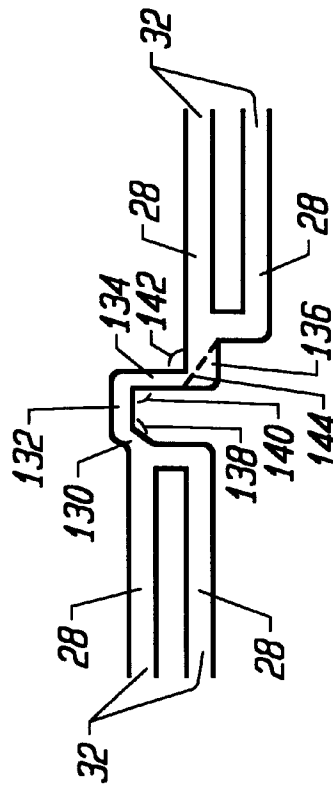


FIG. 10E

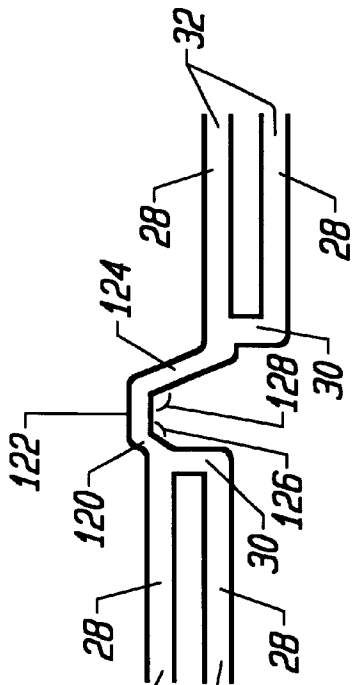


FIG. 10D

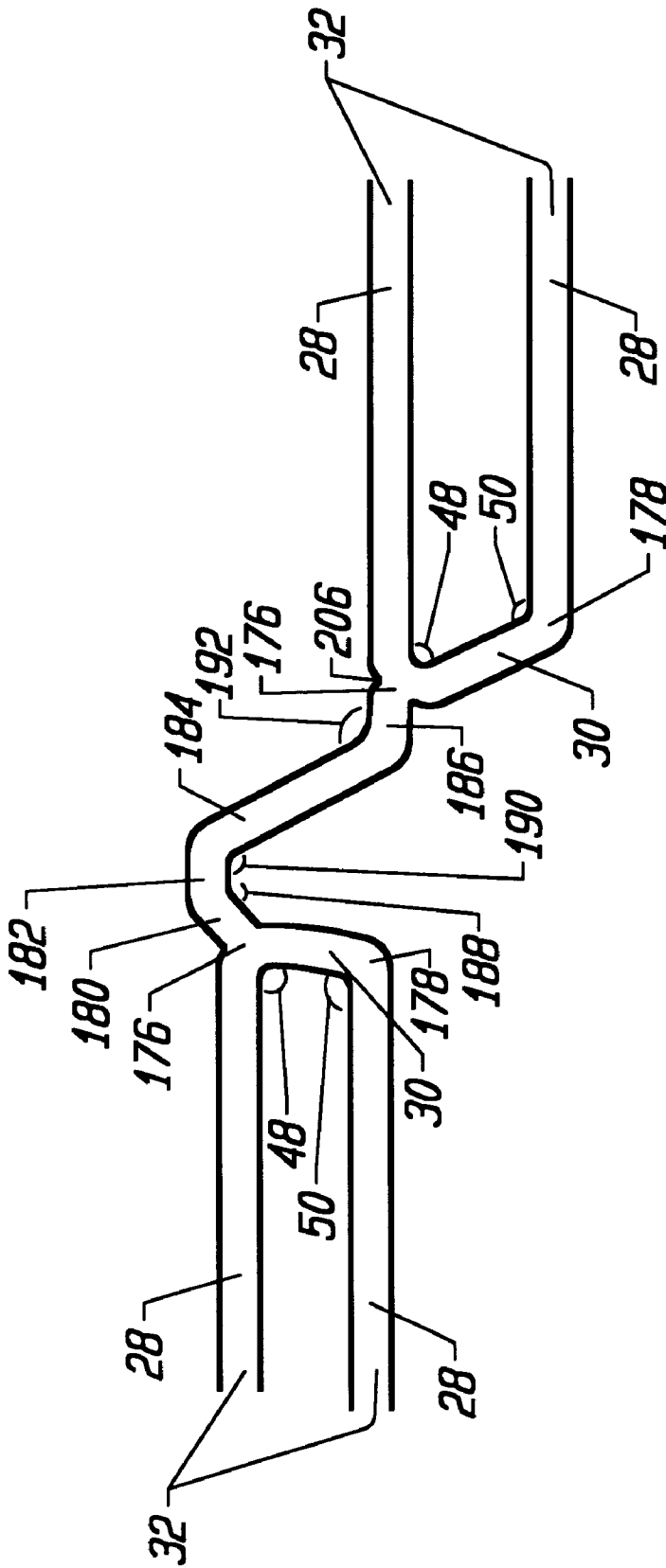


FIG. 10F

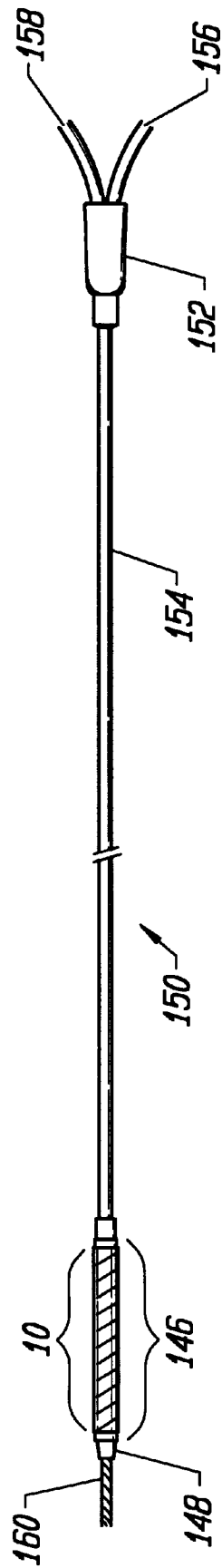


FIG. 11

INTRAVASCULAR STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of Provisional Patent Application No. 60/017,484 filed Apr. 26, 1996, the disclosure of which is incorporated by reference. This application is a continuation in part of U.S. patent application Ser. No. 08/824,142, filed Mar. 25, 1997, entitled "Intravascular Stent", and a continuation in part of U.S. Pat. application Ser. No. 08/824,866, filed Mar. 25, 1997, entitled "Intravascular Stent", and a continuation in part of U.S. patent application Ser. No. 08/824,865, filed Mar. 25, 1997, entitled "Intravascular Stent" and is related to U.S. patent application Ser. No. 08/845,734, filed Apr. 25, 1997, entitled "Intravascular Stent" each having same named inventor G. David Jang and being incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to intravascular stents, and more particularly to an intravascular stent which provides easy introduction through tortuous sections of vessels.

2. Description of the Related Art

Angioplasty, either coronary or general vascular, has advanced to become the most effective means for revascularization of stenosed vessels. In the early 1980's, angioplasty first became available for clinical practice in the coronary artery, and has since proven an effective alternative to conventional bypass graft surgery. Balloon catheter dependent angioplasty has consistently proven to be the most reliable and practical interventional procedure. Other ancillary technologies such as laser based treatment, or directional or rotational atherectomy, have proven to be either of limited effectiveness or dependent on balloon angioplasty for completion of the intended procedure. Restenosis following balloon-based angioplasty is the most serious drawback and is especially prevalent in the coronary artery system.

Many regimens have been designed to combat restenosis, with limited success, including laser based treatment and directional or rotational atherectomy. Intravascular stenting, however, noticeably reduces the restenosis rate following angioplasty procedures. The procedure for intravascular stent placement typically involves pre-dilation of the target vessel using balloon angioplasty, followed by deployment of the stent, and expansion of the stent such that the dilated vessel walls are supported from the inside.

The intravascular stent functions as scaffolding for the lumen of a vessel. The scaffolding of the vessel walls by the stent serve to: (a) prevent elastic recoil of the dilated vessel wall, (b) eliminate residual stenosis of the vessel; a common occurrence in balloon angioplasty procedures, (c) maintain the diameter of the stented vessel segment slightly larger than the native unobstructed vessel segments proximal and distal the stented segment and (d) as indicated by the latest clinical data, lower the restenosis rate. Following an angioplasty procedure, the restenosis rate of stented vessels has proven significantly lower than for unstented or otherwise treated vessels; treatments include drug therapy and other methods mentioned previously.

Another benefit of vessel stenting is the potential reduction of emergency bypass surgery arising from angioplasty procedures. Stenting has proven to be effective in some cases for treating impending closure of a vessel during

angioplasty. Stenting can also control and stabilize an unstable local intimal tear of a vessel caused by normal conduct during an angioplasty procedure. In some cases, an incomplete or less than optimal dilatation of a vessel lesion with balloon angioplasty can successfully be opened up with a stent implant.

Early in its development, the practice of stenting, especially in coronary arteries, had serious anticoagulation problems. However, anticoagulation techniques have since been developed and are becoming simpler and more effective. Better and easier to use regimens are continuously being introduced, including simple outpatient anticoagulation treatments, resulting in reduced hospital stays for stent patients.

An example of a conventional stent patent is U.S. Pat. No. 5,102,417 (hereafter the Palmaz Patent). The stent described in the Palmaz Patent consists of a series of elongated tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members. The tubular members are connected by at least one flexible connector member.

The unexpanded tubular members of the Palmaz Patent are overly rigid so that practical application is limited to short lengths. Even with implementation of the multilink design with flexible connector members connecting a series of tubular members, longer stents can not navigate tortuous blood vessels. Furthermore, the rigidity of the unexpanded stent increases the risk of damaging vessels during insertion. Foreshortening of the stent during insertion complicates accurate placement of the stent and reduces the area that can be covered by the expanded stent. There is, further, no method of programming the stent diameter along its longitudinal axis to achieve a tapered expanded stent, and no method of reinforcement of stent ends or other regions is provided for.

Another example of a conventional stent patent is WO 96/03092, the Brun patent. The stent described in the Brun patent is formed of a tube having a patterned shape, which has first and second meander patterns. The even and odd first meander patterns are 180 degrees out of phase, with the odd patterns occurring between every two even patterns. The second meander patterns run perpendicular to the first meander patterns, along the axis of the tube.

Adjacent first meander patterns are connected by second meander patterns to form a generally uniform distributed pattern. The symmetrical arrangement with first and second meander patterns having sharp right angled bends allows for catching and snagging on the vessel wall during delivery. Furthermore, the large convolutions in the second meander pattern are not fully straightened out during expansion reducing rigidity and structural strength of the expanded stent. There is, further, no method of programming the stent diameter along its longitudinal axis to achieve a tapering stent design, and no method of reinforcement of stent ends or other regions is provided for.

These and other conventional stent designs suffer in varying degrees from a variety of drawbacks including: (a) inability to negotiate bends in vessels due to columnar rigidity of the unexpanded stent; (b) lack of structural strength, axio-laterally, of the unexpanded stent; (c) significant foreshortening of the stent during expansion; (d) limited stent length; (e) constant expanded stent diameter; (f) poor crimping characteristics; and (g) rough surface modulation of the unexpanded stent.

There is a need for a stent with sufficient longitudinal flexibility in the unexpanded state to allow for navigation

through tortuous vessels. There is a further need for a stent that is structurally strong in the unexpanded state such that risk of damage or distortion during delivery is minimal. A further need exists for a stent that maintains substantially the same longitudinal length during expansion to allow greater coverage at the target site and simplify proper placement of the stent. Yet a further need exists for a stent design with sufficient longitudinal flexibility that long stents of up to 100 mm can be safely delivered through tortuous vessels. There is a need for a stent that is configured to expand to variable diameters along its length, such that a taper can be achieved in the expanded stent to match the natural taper of the target vessel. A need exists for a stent which, (i) can be crimped tightly on the expansion balloon while maintaining a low profile and flexibility, (ii) has a smooth surface modulation when crimped over a delivery balloon, to prevent catching and snagging of the stent on the vessel wall during delivery or (iii) with reinforcement rings on the ends or middle or both to keep the ends of the stent securely positioned against the vessel walls of the target blood vessel.

SUMMARY OF THE INVENTION

Accordingly an object of the present invention is to provide a scaffold for an interior lumen of a vessel.

Another object of the invention is to provide a stent which prevents recoil of the vessel following angioplasty.

A further object of the invention is to provide a stent that maintains a larger vessel lumen compared to the results obtained only with balloon angioplasty.

Yet another object of the invention is to provide a stent that reduces foreshortening of a stent length when expanded.

Another object of the invention is to provide a stent with increased flexibility when delivered to a selected site in a vessel.

A further object of the invention is to provide a stent with a low profile when crimped over a delivery balloon of a stent assembly.

Yet a further object of the invention is to provide a stent with reduced tuliping of a stent frame.

Another object of the invention is to provide a chain mesh stent that reduces vessel "hang up" in a tortuous vessel or a vessel with curvature.

A further object of the invention is to provide a chain mesh stent that increases radial and axio-lateral strength of the expanded stent.

These and other objects of the invention are achieved in a stent in a non-expanded state. A first expansion strut pair includes a first expansion strut positioned adjacent to a second expansion strut and adjoining strut couples the first and second expansion struts at a distal end of the first expansion strut pair. A plurality of the first expansion strut pair form a first expansion column.

A second expansion strut pair includes a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the second expansion strut pair couples the first and second expansion struts at a proximal end of the second expansion strut pair. A plurality of the second expansion strut pair form a second expansion column.

A first connecting strut includes a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section. The first connecting strut proximal section is coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section being coupled to the proximal end of the second expansion strut pair of the

second expansion column. A plurality of the first connecting struts forms a first connecting strut column that couples the first expansion column to the second expansion column. A length of the first connecting strut proximal section is equal to a length of the first connecting strut distal section, and a length of the first connecting strut intermediate section is greater than the length of the first connecting strut proximal and distal sections.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a side elevation view of the pre-expansion mode of an embodiment of the stent of the present invention;

FIG. 1B is a cross sectional view of an embodiment of the stent of the present invention;

FIG. 1C is a longitudinal cross sectional view of an embodiment of the stent of the present invention;

FIG. 2A is a scale drawing of the strut pattern of an embodiment of the stent of the present invention;

FIG. 2B is an expanded view of a section of the pattern of FIG. 2A;

FIG. 3A is a schematic illustration of a pre-expansion mode of an embodiment of the stent of the present invention;

FIG. 3B is a schematic illustration of the post-expansion mode of an embodiment of the stent of the present invention;

FIG. 4A is a scale drawing including dimensions of an embodiment of the stent of the present invention;

FIG. 4B is an enlarged section of the scale drawing of FIG. 4A;

FIG. 5 is a scale drawing of an embodiment of the stent of the present invention with a tapered diameter in its post-expansion mode;

FIG. 6A is a scale drawing of an embodiment of the stent of the present invention with reinforcement expansion columns;

FIG. 6B is a perspective view of the embodiment of FIG. 6A;

FIG. 7A is a scale drawing of an embodiment of the stent of the present invention including relief notches at strut joints to increase flexibility of the joints;

FIG. 7B is an enlarged region of the embodiment of FIG. 7A;

FIG. 7C is an enlarged view of a single connecting strut joining two expansion strut pairs in accordance with the embodiment of FIG. 7A;

FIG. 8A is a side elevation view of an embodiment of the stent of the present invention;

FIG. 8B is a side elevation view of an embodiment of the stent of the present invention, shown as if the stent struts and space there between were transparent;

FIG. 8C is a scale drawing of an embodiment of the stent of the present invention;

FIG. 8D is a variation of the embodiment of the stent of FIG. 8C;

FIG. 8E is a perspective view of the embodiment of FIG. 8D;

FIG. 8F is a drawing illustrating the post-expansion mode of the stent of the embodiment of FIG. 8D of the present invention;

FIG. 8G is an enlarged view of a single connecting strut joining two expansion strut pairs in accordance with an embodiment of the present invention;

FIG. 9A is a side elevation view of an embodiment of the stent of the present invention;

FIG. 9B is a perspective view of the embodiment of FIG. 9A;

FIG. 9C is a scale drawing of the embodiment of FIG. 9A;

FIG. 9D is an enlarged region of the drawing of FIG. 9C;

FIG. 9E is a scale drawing of an embodiment of the stent

of the present invention;

FIG. 9G is an enlarged view of a single connecting strut joining two expansion strut pairs in accordance with an embodiment of the present invention;

FIG. 10A is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10B is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10C is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10D is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10E is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10F is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention; and

FIG. 11 is a delivery balloon catheter, illustrating a method of deliver of a stent in accord with the present invention.

DETAILED DESCRIPTION

A first embodiment of the present invention is shown in FIGS. 1A, 1B, 1C, 2A and 2B. Referring to FIG. 1A, an elongate hollow tubular stent 10 in an unexpanded state is shown. A proximal end 12 and a distal end 14 define a longitudinal length 16 of stent 10. The longitudinal length 16 of the stent 10 can be as long as 100 mm or longer. A proximal opening 18 and a distal opening 20 connect to an inner lumen 22 of stent 10. Stent 10 can be a single piece, without any seams or welding joints or may include multiple pieces.

Stent 10 is constructed of two to fifty or more expansion columns or rings 24 connected together by interspersed connecting strut columns 26. The first column on the proximal end 12 and the last column on the distal end 14 of stent 10 are expansion columns 24.

Expansion columns 24 are formed from a series of expansion struts 28, and joining struts 30. Expansion struts 28 are thin elongate members arranged so that they extend at least in part in the direction of the longitudinal axis of stent 10. When an outward external force is applied to stent 10 from the inside by an expansion balloon or other means, expansion struts 28 are reoriented such that they extend in a more circumferential direction, i.e. along the surface of cylindrical stent 10 and perpendicular to its longitudinal axis. Reorientation of expansion struts 28 causes stent 10 to have an expanded circumference and diameter. In FIG. 1A, expansion struts 28 of unexpanded stent 10 are seen to extend substantially parallel to the longitudinal axis of stent 10.

Expansion struts 28 are joined together by joining struts 30 to form a plurality of expansion strut pairs 32. Expansion

strut pairs have a closed end 34 and an open end 36. Additional joining struts 30 join together expansion struts 28 of adjacent expansion strut pairs 32, such that expansion struts 28 are joined alternately at their proximal and distal ends to adjacent expansion struts 28 to form expansion columns 24. Each expansion column 24 contains a plurality, typically eight to twenty, twenty to sixty, or larger of expansion struts 28. Expansion columns are preferably continuous unbroken ring structures extending around the circumference of the stent 10; however, broken structures in which individual struts or pieces of struts are removed from an otherwise continuous expansion column 24 can also be used.

Connecting struts 38 connect adjacent expansion columns 24 forming a series of interspersed connecting strut columns 26 each extending around the circumference of stent 10. Each connecting strut 38 joins a pair of expansion struts 28 in an expansion column 24 to an adjacent pair of expansion struts 28 in an adjacent expansion column 24. For stent 10 of FIG. 1A, the ratio of expansion struts 28 in an expansion column 24 to connecting struts 38 in a connecting strut column 26 is two to one; however, this ratio in general can be x to 1 where x is greater or less than two. Furthermore, since the stent 10 of FIG. 1A begins with an expansion column 24 on the proximal end 12 and ends with an expansion column 24 on the distal end 14, if there are n expansion columns 24 with m expansion struts 28 per column, there will be $m-1$ connecting strut columns 26, and $n(m-1)/2$ connecting struts 38.

The reduced number of connecting struts 38 in each connecting strut column 26, as compared to expansion struts 28 in each expansion column 24, allows stent 10 to be longitudinally flexibility. Longitudinal flexibility can be further increased by using a narrow width connecting strut, providing additional flexibility and suppleness to the stent as it is navigated around turns in a natural blood vessel.

At least a portion of the open spaces between struts in stent 10 form asymmetrical cell spaces 40. A cell space or geometric cell is an empty region on the surface of stent 10, completely surrounded by one or a combination of stent struts, including expansion struts 28, connecting struts 38, or joining struts 30. Asymmetrical cell spaces 40 are cell spaces which have no geometrical symmetry i.e. no rotation, reflection, combination rotation and reflection or other symmetry. Asymmetrical cell spaces 40 have an asymmetrical geometric configuration.

Asymmetrical cell spaces 40 in FIG. 1A are surrounded by a first expansion strut pair 32 in a first expansion column 24, a first connecting strut 38, a second expansion strut pair 32 in an adjacent expansion column 24, a first joining strut 30, a second connecting strut 38, and a second joining strut 30. Furthermore, expansion strut pairs 32 of asymmetrical cell space 40 may be circumferentially offset i.e. have longitudinal axes that are not collinear and have their open ends 36 facing each other. The space between two expansion struts of an expansion strut pair 32 is known as a loop slot 42.

FIG. 1B shows inner lumen 22, radius 44 and stent wall 46 of stent 10. Stent wall 46 consists of stent struts including expansion struts 28, connecting struts 38 and joining struts 30.

FIG. 1C shows, proximal end 12, distal end 14, longitudinal length 16, inner lumen 22, and stent wall 46 of stent 10. Inner lumen 22 is surrounded by stent wall 46 which forms the cylindrical surface of stent 10.

Referring now to FIGS. 2A and 2B, joining struts 30 of stent 10 are seen to extend at an angle to the expansion struts

28, forming a narrow angle 48 with one expansion strut 28 in an expansion strut pair 32 and a wide angle 50 with the other expansion strut 28 of an expansion strut pair 32. Narrow angle 48 is less than ninety degrees, while wide angle 50 is greater than ninety degrees. Joining struts 30 extend both longitudinally along the longitudinal axis of stent 10 and circumferentially, along the surface of the stent 10 perpendicular to its longitudinal axis.

Expansion strut spacing 52 between adjacent expansion struts 28 in a given expansion column 24 are uniform in stent 10 of FIGS. 2A and 2B; however, non-uniform spacings can also be used. Expansion strut spacings 52 can be varied, for example, spacings 52 between adjacent expansion struts 28 in an expansion column 24 can alternate between a narrow and a wide spacings. Additionally, spacings 52 in a single expansion column 24 can differ from other spacings 52 in other columns 24.

It is noted that varying expansion strut spacings 52 which form the loop slots 42 results in variable loop slot widths. Furthermore, the longitudinal axis of the loop slots 42 need not be collinear or even parallel with the longitudinal axis of loop slots 42 of an adjacent expansion column 24. FIGS. 2A and 2B show an arrangement of expansion struts 28 such that collinear, parallel adjacent loop slots 42 are formed, but non-collinear and non-parallel loop slots 42 can also be used.

Additionally the shape of loop slots 42 need not be the same among loop slots of a single or multiple expansion columns 24. The shape of loop slots 42 can be altered by changing the orientation or physical dimensions of the expansion struts 28 and/or joining struts 30 which connect expansion struts 28 of expansion strut pairs 32 defining the boundaries of loop slots 42.

Connecting struts 38 couple adjacent expansion columns 24, by connecting the distal end of an expansion strut pair in one expansion column 24 to the proximal end of an adjacent expansion strut pair 32 in a second expansion column 24. Connecting struts 38 of FIGS. 2A and 2B are formed from two linear sections, a first linear section 54 being joined at its distal end to a second linear section 56 at its proximal end to form a first slant angle 58.

The first linear section 54 of a connecting strut 38 is joined to expansion strut 28 at the point where joining strut 30 makes narrow angle 48 with expansion strut 28. First linear section 54 extends substantially collinear to joining strut 30 continuing the line of joining strut 30 into the space between expansion columns 24. The distal end of the first linear section 54 is joined to the proximal end of the second linear section 56 forming slant angle 58. Second linear section 56 extends substantially parallel to expansion struts 28 connecting at its distal end to joining strut 30 in an adjacent expansion column 24. The distal end of second linear section 56 attaches to expansion strut 28 at the point where joining strut 30 makes narrow angle 48 with expansion strut 28. Further, joining strut 30 can have a second slant angle with a width that can be the same or different from the width of the first slant angle.

FIGS. 2A and 2B show connecting struts 38 and joining struts 30 slanted relative to the longitudinal axis of stent 10, with the circumferential direction of the slanted struts alternating from column to adjacent column. Circumferential direction refers to the handedness with which the slanted struts wind about the surface of the stent 10. The circumferential direction of the slant of connecting strut first linear sections 54 in a connecting strut column 26 is opposite the circumferential direction of the slant of connecting strut first

linear sections 54 in an adjacent connecting strut column 26. Similarly, the circumferential direction of the slant of joining struts 30 in an expansion column 24 is opposite the circumferential direction of the slant of joining struts 30 in an adjacent expansion column 24. Alternating circumferential slant directions of connecting struts 38 and joining struts 30 prevents axial warping of stent 10 during deliver and expansion. Other non-alternating slant direction patterns can also be used for connecting struts 38 or joining struts 30 or both.

FIG. 3A and 3B show a schematic illustration of a stent design according to the present invention in an unexpanded and expanded state respectively. The design is depicted as a flat projection, as if stent 10 were cut lengthwise parallel to its longitudinal axis and flattened out. The connecting struts 38 consist of first and second linear sections 54 and 56 forming slant angle 58 at pivot point 60. An asymmetrical cell space 40 is formed by expansion strut pairs 32, connecting struts 38 and joining struts 30. Multiple interlocking asymmetrical cell spaces 40 make up the design pattern.

As the stent is expanded, see FIG. 3B, the expansion strut pairs 32 spread apart at their open ends 36, shortening the length of expansion struts 28 along the longitudinal axis of the cylindrical stent. The longitudinal shortening of expansion struts 28 during expansion is countered by the longitudinal lengthening of connecting struts 38. The widening of slant angle 58 during expansion straightens connecting struts 38 and lengthens the distance between the coupled expansion strut pairs 32. The widening of the slant angle of connecting struts 38 substantially compensates for the longitudinal shortening of expansion struts 28. Thus, the stent has substantially constant unexpanded and expanded longitudinal lengths.

When the stent is expanded, each expansion column 24 becomes circumferentially stretched, enlarging the space between struts. The interlinking of expansion columns 24 by connecting struts 38 that have been straightened through the expansion process gives the stent 10 a high radial support strength. The entire stent 10 when expanded is unitized into a continuous chain mesh of stretched expansion columns 24 and connecting strut columns 26 forming an asymmetrical interlocking cell geometry which resists collapse both axially and radially. When the stent is expanded it has increased rigidity and fatigue tolerance.

In addition, efficient bending and straightening of connecting struts 38 at pivot points 60 allows increased longitudinal flexibility of the stent. For the stent to bend longitudinally, at least some of connecting struts 38 are forced to bend in their tangent plane. The tangent plane of a specific connecting strut 38 refers to the plane substantially tangent to the cylindrical surface of the stent at that connecting strut 38. The width of connecting struts 38 can be twice as wide as a thickness. Preferably, a one-to-one ratio is preferred. However, pivot points 60 in connecting struts 38 provide connecting struts 38 a flexible joint about which to more easily bend increasing longitudinal flexibility of the stent.

Referring to FIGS. 4A and 4B, a variation of the first embodiment of stent 10 of the present invention is shown. In this variation, stent 10 has a length 16 of 33.25 mm and an uncrimped and unexpanded circumference 88 of 5.26 mm. Fifteen expansion columns 24 are interspersed with connecting strut columns 26. Each expansion column 24 consists of twelve expansion struts 28 joined alternately at their proximal and distal ends by joining struts 30 forming six expansion strut pairs 32. Expansion struts 28 are aligned parallel to the longitudinal axis of cylindrical stent 10.

Joining struts **30** form a narrow angle **48** and a wide angle **50** with the respective expansion struts **28** of expansion strut pairs **32**. Adjacent expansion columns **24** employ alternating circumferential slant directions of joining struts **30**.

In this variation of the first embodiment, expansion strut width **62** is 0.20 mm, expansion strut length **64** is 1.51 mm, and connecting strut width **66** is 0.13 mm. Distance **68** from the outer edge of a first expansion strut **28** to the outer edge of a second adjacent expansion strut **28** in the same expansion column **24** is 0.64 mm, leaving a loop slot width **70** of 0.24 mm.

In this variation of the first embodiment, connecting struts **38** consist of a slanted first linear section **54** joined to a second linear section **56** at a slant angle **58**. First linear section **54** is slightly longer than second linear section **56** and is attached at its proximal end to an expansion strut **28** in an expansion column **24**. The attachment of the proximal end of first linear section **54** to expansion strut **28** is at the point where joining strut **30** makes narrow angle **48** with expansion strut **28**. First linear section **54** extends substantially collinear to joining strut **30** attaching at its distal end to the proximal end of second linear section **56** to form slant angle **58**. Second linear section **56** extends substantially collinear to expansion struts **28**, attaching at its distal end to an expansion strut **28** in an adjacent expansion column **24**. The attachment occurs at the point where expansion strut **28** forms narrow angle **48** with joining strut **30**. Joining struts **30** and connecting strut first linear sections **54** slant in alternating circumferential directions from column to adjacent column.

The joining of connecting struts **38** and expansion struts **28** at the point where narrow angle **48** is formed aids smooth delivery of stent **10** by streamlining the surface of the unexpanded stent and minimizing possible catching points. Bare delivery of stent **10** to the target lesion in a vessel will thus result in minimal snagging or catching as it is navigated through turns and curvatures in the vessel. Stent **10** behaves like a flexible, tubular sled as it is moved forward or backward in the vessel on the delivery catheter, sliding through tortuous vessels and over irregular bumps caused by atherosclerotic plaques inside the vessel lumen.

When fully expanded Stent **10** of FIGS. **4A** and **4B** has an internal diameter of up to 5.0 mm, while maintaining an acceptable radial strength and fatigue tolerance. The crimped stent outer diameter can be as small as 1.0 mm or less depending on the condition of the underlying delivery balloon profile; A small crimped outer diameter is especially important if stent delivery is to be attempted without predilation of the target site. When the stent is optimally crimped over the delivery balloon, the surface of the crimped stent is smooth allowing for no snagging of the stent struts during either forward or backward movement through a vessel.

FIG. **5** shows a second embodiment of the present invention in which the stent **10** in its expanded form has a gradual taper from proximal end **12** to distal end **14**. The shaded segments **72**, **74**, **76**, **78**, **80**, **82** and **84** of expansion struts **28** represent regions of expansion struts **28** to be removed. Removal of the shaded segments **72**, **74**, **76**, **78**, **80**, **82** and **84** provides stent **10** with a gradual taper when expanded with distal end **14** having a smaller expanded diameter than proximal end **12**. The degree of shortening of the expanded diameter of the stent **10** at a given expansion column **24** will be proportional to the length of the removed segment **72**, **74**, **76**, **78**, **80**, **82**, or **84** at that expansion column **24**. In the expanded stent **10** the shortened expansion struts **28** will

have a shortened component along the circumference of the stent resulting in a shortened circumference and diameter. The tapered diameter portion can be positioned anywhere along the length of stent **10**, and the tapering can be made more or less gradual by removing appropriately larger or smaller portions of the expansion struts **28** in a given expansion column **24**.

Tapering is especially important in long stents, longer than 12 mm, since tapering of blood vessels is more pronounced over longer lengths. A long stent with a uniform stent diameter can only be matched to the target vessel diameter over a short region. If the proximal vessel size is matched with the stent diameter, the expanded distal end of the stent will be too large for the natural vessel and may cause an intimal dissection of the distal vessel by stent expansion. On the other hand, if the distal vessel size is matched with the stent diameter, the proximal end of the expanded stent will be too small to set inside the vessel lumen. It is therefore desirable to have a stent with a tapered expanded diameter.

Another way to achieve a tapered expanded stent is to change the stiffness of the stent struts, expansion struts, connecting struts or joining struts such that the stiffness of the struts varies along the length of the stent. The stiffness of the struts can be changed by altering length, width or thickness, adding additional stiffening material, using a chemical or mechanical means to alter the physical properties of the stent material, or applying one or a series of elastic elements about the stent.

Along with the use of a tapered diameter stent, a matching tapered balloon catheter would ideally be made for delivery and deployment of the tapered diameter stent. The method of using a tapered matching balloon catheter with a tapered diameter stent is within the scope of the present invention.

Using a tapered balloon to expand a non-tapered stent will also achieve a tapered expanded stent; however, since no metal is removed from the stent, the stent is tapered as a result of incomplete expansion. The stent will therefore have increased metal fraction at the tapered end resulting in increased risk of acute thrombosis. Metal fraction is the proportion of the surface of the expanded stent covered by the stent strut material. Shortening the expansion struts as shown in FIG. **5** allows for a tapered expanded stent with substantially constant metal fraction along its length.

A third embodiment of the present invention shown in FIGS. **6A** and **6B** has multiple reinforcement expansion columns **86** placed along the length of the stent **10**. The reinforcement columns **86** are placed along the stent length to provide additional localized radial strength and rigidity to stent **10**. Additional strength and rigidity are especially important at the ends of the stent to prevent deformation of the stent both during delivery and after placement. During delivery the stent ends can catch on the vessel wall possibly deforming the unexpanded stent and altering its expansion characteristics. After the stent has been placed it is important that the stent ends are rigid so that they set firmly against the vessel wall; otherwise, during a subsequent catheter procedure, the catheter or guidewire can catch on the stent ends pulling the stent away from the vessel wall and possibly damaging and/or blocking the vessel.

The specific variation of the third embodiment of stent **10** depicted in FIGS. **6A** and **6B** has a length **16** of 20.70 mm and an uncrimped and unexpanded circumference **88** of 5.26 mm. The stent **10** consists of six expansion columns **24** and three reinforcement expansion columns **86**, each consisting respectively of twelve expansion struts **28** or reinforcement

expansion struts **90**. The reinforcement expansion columns **86** are positioned one at either end, and one along the length of the stent **10**.

The expansion strut width **62** is 0.15 mm, reinforcement expansion strut width **92** is 0.20 mm, and the connecting strut width **66** is 0.10 mm. The narrow angle **48** formed by joining strut **30** and expansion strut **28** is 75 degrees, and the narrow angle **94** formed by reinforcement joining strut **96** and reinforcement expansion strut **90** is 60 degrees.

Other arrangements of reinforcement expansion columns **86**, such as providing reinforcement expansion columns **86** only on the ends of the stent, only on one end, or at multiple locations throughout the length of the stent can also be used and fall within the scope of the present invention. A taper can also be programmed into the reinforced stent **10** by shortening expansion struts **28** and reinforcement expansion struts **90** in appropriate expansion columns **24** and **86**.

A fourth embodiment of the present invention, shown in the FIGS. **7A**, **7B** and **7C**, is similar to the third embodiment but has the added feature of relief notches **98** and **100**. A relief notch is a notch where metal has been removed from a strut, usually at a joint where multiple struts are connected. Relief notches increase flexibility of a strut or joint by creating a thinned, narrow region along the strut or joint. Relief notch **98** is formed at the joint formed between first linear section **54** of connecting strut **38** and expansion strut **28**. Relief notch **100** is formed at the joint between second linear section **56** of connecting strut **38** and expansion strut **28**. The positioning of the relief notches gives added flexibility to the unexpanded stent and prevents warping at the joints when the stent is expanded. This results in a smooth surface modulation to the expanded stent frame. Relief notches can be placed at other joints and can be included in any of the previously mentioned embodiments.

FIGS. **8A** and **8B** show a side elevation view of a variation of the fifth embodiment of the stent of the present invention. In this embodiment a four piece slanted connecting strut **38** is used to couple the corner of an expansion strut pair **32** in one expansion column **24** to the joining strut **30** of a circumferentially offset expansion strut pair **32** in an adjacent expansion column **24**. The expansion struts **28**, joining struts **30**, expansion columns **24**, reinforcement expansion struts **90**, reinforcement joining struts **96**, and reinforcement expansion columns **86** are substantially similar to the fourth embodiment of FIG. **6A**. Connecting struts **38** in connecting strut columns **26**, however, have an altered geometry and connectivity, described in more detail below.

FIG. **8A** shows only the stent struts on the front half of the stent surface. The stent struts on the rear half of the stent surface are not shown. The stent appears as it would if the stent struts and space there between were opaque. FIG. **8B** shows all stent struts from both the front and rear halves. The stent appears as it would if the stent struts and the space there between were transparent.

A first variation of a fifth embodiment of the present invention, shown in FIG. **8C** consists of a stent **10** with twelve expansion columns **24**, four reinforcement expansion columns **86**, and fifteen connecting strut columns **26**. In this variation, the stent **10** has a length **16** of 31.96 mm, and an unexpanded circumference **88** of 5.26 mm.

Connecting struts **38** shown in an enlarged view in FIG. **8G** are made up of four linear sections, a proximal end section **162**, first and second intermediate sections **164** and **166** respectively and a distal end section **168** forming three slant angles **170**, **172** and **174**. The proximal end of proximal section **162** is attached to a corner **176** of an expansion strut

pair **32** of an expansion column **24**. Corner **176** is formed where joining strut **30** makes narrow angle **48** with expansion strut **28**. A second corner **178** of expansion strut **32** is formed where joining strut **30** makes wide angle **50** with expansion strut **28**. Corners **176** and **178** can have an angular shape formed by joining linear expansion struts **28** and joining struts **30**, or preferably corners **176** and **178** are rounded to remove sharp edges and provide increased flexibility. Additionally rounded corners provide stent **10** with greater expandability and reduce stress in the stent strut material at the corners in the expanded stent.

Proximal end section **162** of connecting strut **38** extends from corner **176** and is attached at its distal end to first intermediate section **164** forming slant angle **170**. First intermediate section **164** extends from proximal end section **162** such that first intermediate section **164** is parallel to expansion struts **28** and is connected at its distal end to the proximal end of second intermediate section **166** forming slant angle **172**.

Second intermediate section **166** extends in a slanted orientation relative to the longitudinal axis of stent **10**, extending both longitudinally along and circumferentially about stent **10**. Preferably, second intermediate section **166** is parallel to joining strut **30** of the circumferentially offset expansion strut pair **32** in adjacent expansion column **24**.

Second intermediate section **166** attaches at its distal end to the proximal end of distal end section **168** forming slant angle **174**. Distal end section **168** extends from second intermediate section **166** attaching at its distal end to joining strut **30** of circumferentially offset expansion strut pair **32** of adjacent expansion column **24**. The attachment is at a point intermediate corners **176** and **178**, where joining strut **30** forms narrow angle **48** and wide angle **50** respectively with expansion struts **28**.

The connection point of distal end section **168** to joining strut **30** is closer to corner **176** than corner **178**. Preferably the connection point is one to two or more expansion strut widths from corner **176**. Offsetting the connection point of distal end section **168** to joining strut **30** from corner **176** to a point intermediate corner **176** and corner **178** reduces warping of the expanded stent **10**, resulting in a smooth surface modulation and reduced risk of thrombosis. Additionally, this design provides a longer total straightened length of connecting strut **38**, which further reduces foreshortening of stent **10** during expansion.

A second variation of a fifth embodiment of the present invention, shown in an unexpanded form in FIGS. **8D**, **8E** and in an expanded form in FIG. **8F** consists of a stent **10** with six expansion columns **24**, two reinforcement expansion columns **86**, and seven connecting strut columns **26**. In this variation, the stent **10** has a length **16** of 15.04 mm, and an unexpanded circumference **88** of 5.26 mm. The stent design **10** is substantially similar to the design of the first variation of the fifth embodiment of FIG. **8C** with a reduced number of expansion columns, reinforcement expansion columns, and connecting strut columns.

FIG. **8F** illustrates a portion of the expanded stent **10** of the second variation of the fifth embodiment. After expansion of stent **10** by balloon or other means, the expansion struts **28** are spread apart circumferentially, increasing the separation at the open end **36** of expansion strut pairs **32** resulting in an increase in the circumference of the stent **10**. The spreading of the expansion struts **28** causes a longitudinal shortening of the expansion columns **24**, which is compensated by a straightening of the connecting struts **38**. During the expansion process, the slant angles **170**, **172** and

174 widen straightening the connection struts 38, and causing an increase in the separation distance between adjacent expansion columns 24. The asymmetrical interlocking cell geometry of the expanded stent is illustrated in FIG. 8F.

FIGS. 9A, 9B, 9C, 9D, 9E, 9F and 9G illustrate a sixth embodiment of the stent of the present invention. In this embodiment a three piece slanted connecting strut 38 is used to couple the joining strut 30 of an expansion strut pair 32 in one expansion column 24 to the joining strut 30 of a circumferentially offset expansion strut pair 32 in an adjacent expansion column 24. The joints between segments of connecting strut 38 are curved forming a smooth rounded shape. The expansion struts 28, joining struts 30, expansion columns 24, reinforcement expansion struts 90, reinforcement joining struts 96, and reinforcement expansion columns 86 are substantially similar to the fourth embodiment of FIG. 8A. Connecting struts 38 in connecting strut columns 26, however, have an altered geometry and connectivity, described in more detail below.

A first variation of a sixth embodiment of the present invention, shown in FIG. 9A, 9B and 9C consists of a stent 10 with eight expansion columns 24, three reinforcement expansion columns 86, and ten connecting strut columns 26. In this variation, the stent 10 has a length 16 of 20.32 mm.

Relief notches 204 are utilized at the joints between reinforcement expansion struts 90 and reinforcement joining struts 96 in the reinforcement expansion columns 86 at the stent proximal end 12 and distal end 14. Relief notches 204 reduce the width of the joints between reinforcement expansion struts 90 and reinforcement joining struts 96, which reduces stress in the metal at the joints during and after expansion of the stent. Relief notches 204 are particularly important at the stent ends since the stent ends are especially susceptible to warping during and after expansion. Preferably relief notches 204 reduce the joint widths, such that the joint widths are substantially the same as the thickness of stent wall 46 (see FIGS. 1B and 1C).

Connecting struts 38 shown in an enlarged view in FIG. 9D are made up of three linear sections, a proximal end section 194, an intermediate section 196 and a distal end section 198 forming two slant angles 200, 202. The connecting struts 38 have wide radii of curvature at the joints between connecting strut sections 194, 196 and 198. The shape of connecting strut 38 is thus curved or wavy rather than jagged and angular. The slant angles 200 and 202 are defined by linearly extrapolating proximal end section 194, intermediate section 196 and distal end section 198, as shown by the dotted lines in FIG. 9D.

FIG. 9E shows a variation of the connecting strut design of the sixth embodiment of the present invention. The connecting strut 38 of FIG. 9E has smaller radii of curvature at the joints between proximal end section 194, intermediate section 196 and distal end section 198. Connecting strut 38 of FIG. 9E is thus more jagged and angular than that of FIG. 9D.

Referring to the connecting struts 38 of FIG. 9D and 9E, the proximal end of proximal section 194 is attached to joining strut 30 of expansion strut pair 32 intermediate corners 176 and 178. Proximal end section 194 of connecting strut 38 extends from joining strut 30 and is attached at its distal end to intermediate section 196 forming slant angle 200. Intermediate section 196 extends from proximal end section 194 in a slanted orientation relative to the longitudinal axis of stent 10, extending both longitudinally along and circumferentially about stent 10. Intermediate section 196 is preferably parallel to joining struts 30 of coupled expansion strut pairs 32.

Intermediate section 196 is connected at its distal end to the proximal end of distal end section 198 forming slant angle 202. Distal end section 198 extends from second intermediate section 196 attaching at its distal end to joining strut 30 of circumferentially offset expansion strut pair 32 of adjacent expansion column 24. The attachment is at a point intermediate corners 176 and 178, where joining strut 30 forms narrow angle 48 and wide angle 50 respectively with expansion struts 28.

The connection point of proximal end section 194 and distal end section 198 to joining struts 30 is closer to corner 176 than corner 178. Preferably the connection point is one to two or more expansion strut widths from corner 176. Offsetting the connection point of distal end section 198 to joining strut 30 from corner 176 to a point intermediate corner 176 and corner 178 reduces warping of the expanded stent 10, resulting in a smooth surface modulation and reduced risk of thrombosis. Additionally, this design provides a longer total straightened length of connecting strut 38, which further reduces foreshortening of stent 10 during expansion.

The connecting strut 38 of the sixth embodiment has one hundred and eighty degree rotational symmetry about its center. The symmetry of the connecting strut 38 does not, however, result in a symmetrical cell space as the width of loop slots 42 connected in each cell space are different. Adjacent loop slots 42 in each expansion column have alternating narrow and wide widths, preserving the asymmetry of the cell spaces. Introduction of one or many symmetrical cell spaces can be achieved in this design e.g. by providing uniform loop slot width to loop slots in adjacent expansion columns 24 contained in the same cell space. Additionally completely non-uniform cell space patterns utilizing symmetric or asymmetric cell spaces can be achieved e.g. by providing non-uniform variations in the widths of loop slots 42.

A second variation of a sixth embodiment of the present invention, shown in an unexpanded form in FIGS. 9F consists of a stent 10 with six expansion columns 24, three reinforcement expansion columns 86, and eight connecting strut columns 26. In this variation, the stent 10 has a length 16 of 16.00 mm, and an unexpanded circumference 88 of 5.26 mm. The stent design 10 is substantially similar to the design of the first variation of the sixth embodiment of FIGS. 9A, 9B and 9C with a reduced number of expansion columns 24 and connecting strut columns 26.

A third variation of a sixth embodiment of the present invention, shown in an unexpanded form in FIGS. 9F consists of a stent 10 with twelve expansion columns 24, four reinforcement expansion columns 86, and fifteen connecting strut columns 26. In this variation, the stent 10 has a length 16 of 30.01 mm, and an unexpanded circumference 88 of 5.26 mm. The stent design 10 is substantially similar to the design of the first variation of the sixth embodiment of FIGS. 9A, 9B and 9C with an increased number of expansion columns 24 reinforcement expansion columns 86 and connecting strut columns 26.

FIGS. 10A, 10B, 10C, 10D, 10E and 10F illustrate some examples of alternate connecting strut designs which can be used in any of the previously discussed embodiments. FIG. 10A shows a rounded loop connecting strut 38 which joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by adjoining strut 30. Joining struts 30 are slanted such as to form a narrow angle 48 and a wide angle 50 with the expansion struts 28 they

connect. The rounded loop connecting strut **38** connects expansion struts **28** at the point where narrow angle **48** is formed between expansion struts **28** and joining struts **30**. The slopes of the rounded connecting strut **38** at its proximal end **102** and distal end **104** substantially match the slopes of the joining struts **30** connecting the pairs of expansion struts **28**. The rounded loop connecting strut **38** thus blends smoothly into the joining struts **30**. Additionally the rounded loop connecting strut **38** has a first radius of curvature **106** and a second radius of curvature **108**.

In the design of FIG. **10B** a rounded loop connecting strut **38** joins two circumferentially offset expansion strut pairs **32** in adjacent expansion columns. Expansion struts **28** in each expansion strut pair **32** are joined by a joining strut **30**. Joining struts **30** are at right angles to the expansion struts **28** they connect. The rounded loop connecting strut **38** connects to expansion struts **28** at the same point as joining struts **30**. The rounded connecting strut **38** has a first radius of curvature **106** and a second radius of curvature **108** such that it connects circumferentially offset expansion strut pairs **32**.

In the design of FIG. **10C** connecting strut **38** joins two circumferentially offset expansion strut pairs **32** in adjacent expansion columns. Expansion struts **28** in each expansion strut pair **32** are joined by adjoining strut **30**. Joining struts **30** are slanted such as to form a narrow angle **48** and a wide angle **50** with the expansion struts **28** they connect. The connecting strut **38** connects expansion struts **28** at the point where narrow angle **48** is formed between expansion strut **28** and joining strut **30**.

The connecting strut **38** is made up of three linear sections **110**, **112**, and **114** forming two slant angles **116** and **118**. The proximal end of section **110** is attached to expansion strut **28** at the point where joining strut **30** forms narrow angle **48** with expansion strut **28**. Section **110** extends substantially collinear to joining strut **30** and is attached at its distal end to intermediate section **112** forming slant angle **116**. Intermediate section **112** extends at an angle to section **110** such that intermediate section **112** is substantially parallel to expansion struts **28** and is connected at its distal end to the proximal end of distal section **114** forming slant angle **118**. Distal section **114** extends at an angle such that it is substantially collinear to joining strut **30** of the adjacent expansion strut pair **32**. Distal section **114** attaches at its distal end to expansion strut **28** of the adjacent expansion strut pair **32**, at the point where joining strut **30** forms narrow angle **48** with expansion strut **28**.

In the design of FIGS. **10D** and **10E** a connecting strut **38** joins two circumferentially offset expansion strut pairs **32** in adjacent expansion columns. Expansion struts **28** in each expansion strut pair **32** are joined by a joining strut **30**. Joining struts **30** are at right angles to the expansion struts **28** they connect. The connecting strut **38** connects to expansion struts **28** at the same point as joining struts **30**.

The connecting struts **38** of FIGS. **10D** and **10E** are made up of multiple connecting strut sections connected end to end to form a jagged connecting strut **38** with multiple slant angles, coupling expansion strut pair **32** to adjacent expansion strut pair **32**. The connecting strut of FIG. **10D** is made up of three connecting strut sections, a proximal section **120**, an intermediate section **122** and a distal section **124** defining two slant angles **126** and **128**, while the connecting strut of FIG. **10E** consists of four connecting strut sections, a proximal section **130**, intermediate sections **132** and **134**, and a distal section **136** defining three slant angles **138**, **140** and **142**. In addition, connecting strut section **134** can be

modified by replacing connecting strut section **136** by the dotted connecting strut section **144** to give another possible geometry of connecting struts **38**.

In the design of FIGS. **10F** connecting strut **38** joins two circumferentially offset expansion strut pairs **32** in adjacent expansion columns. Expansion struts **28** in each expansion strut pair **32** are joined by a joining strut **30**. Joining struts **30** are slanted such as to form a narrow angle **48** and a wide angle **50** with the expansion struts **28** they connect.

Connecting strut **38** is made up of four linear sections, a proximal end section **180**, first and second intermediate sections **182** and **184** respectively and a distal end section **186** forming three slant angles **188**, **190** and **192**. The proximal end of section **180** is attached to corner **176** at the point where joining strut **30** forms narrow angle **48** with expansion strut **28**. Proximal end section **180** extends at an angle to joining strut **30** and is attached at its distal end to first intermediate section **182** forming slant angle **188**. First intermediate section **182** extends at an angle to proximal end section **180** such that first intermediate section **182** is substantially parallel to expansion struts **28** and is connected at its distal end to the proximal end of second intermediate section **184** forming slant angle **190**. Second intermediate section **184** is substantially longer than the first intermediate section **182**. Second intermediate section **184** extends at an angle such that it is substantially collinear to joining strut **30** of the adjacent expansion strut pair **32**. Second intermediate section **184** attaches at its distal end to the proximal end of distal end section **186** forming slant angle **192**. Distal end section **186** extends in a slightly sloping orientation relative to expansion struts **28**, attaching to corner **176** of expansion strut pair **32** where joining strut **30** forms narrow angle **48** with expansion strut **28**. Relief notches **206** are formed at the joint between distal end segment **186** of connecting strut **38** and corner **176** of expansion strut pair **32** to increase flexibility of the unexpanded stent and prevent warping when the stent is expanded.

One skilled in the art will recognize that there are many possible arrangements of connecting struts and joining struts consistent with the present invention; the above examples are not intended to be an exhaustive list. In particular, it is noted that (a) connecting strut sections need not be linear but may contain one or many radii of curvature, (b) connecting strut sections may each have a different longitudinal axis, (c) the joint between connecting strut sections need not be jagged or sharp, but rather can be smooth containing one or multiple radii of curvature, and (d) relief notches may be present at any of the strut joints.

The stent of the present invention is ideally suited for application in coronary vessels although versatility in the stent design allows for applications in non-coronary vessels, the aorta, and nonvascular tubular body organs.

Typical coronary vascular stents have expanded diameters that range from 2.5 to 5.0 mm. However, a stent with high radial strength and fatigue tolerance that expands to a 5.0 mm diameter may have unacceptably high stent metal fraction when used in smaller diameter vessels. If the stent metal fraction is high, the chances of acute thrombosis and restenosis potential will increase. Even with the same metal fraction a smaller caliber vessel is more likely than a larger one to have a high rate of thrombosis. It is, therefore, preferred to have at least two different categories of stents for coronary application, for example, small vessels stents for use in vessels with diameters from 2.5 mm to 3.0 mm, and large vessel stents for use in vessels with diameters from 3.0 mm to 5.0 mm. Thus, both small vessels and large

vessels when treated with the appropriate sized stent will contain stents of similar idealized metal fraction.

The stent of the present invention can be made using a CAM-driven laser cutting system to cut the stent pattern from a stainless steel tube. The rough-cut stent is preferably electro-polished to remove surface imperfections and sharp edges. Other methods of fabricating the stent can also be used such as EDM, photo-electric etching technology, or other methods. Any suitable material can be used for the stent including other metals and polymers so long as they provide the essential structural strength, flexibility, biocompatibility and expandability.

The stent is typically at least partially plated with a radiopaque metal, such as gold, platinum, tantalum or other suitable metal. It is preferred to plate only both ends of the stent by localized plating; however, the entire stent or other regions can also be plated. When plating both ends, one to three or more expansion columns on each end of the stent are plated to mark the ends of the stent so they can be identified under fluoroscopy during the stenting procedure. By plating the stent only at the ends, interference of the radiopaque plating material with performance characteristics or surface modulation of the stent frame is minimized. Additionally the amount of plating material required is reduced, lowering the material cost of the stent.

After plating, the stent is cleaned, typically with detergent, saline and ultrasonic means that are well-known in the art. The stents are then inspected for quality control, assembled with the delivery balloon catheter, and properly packaged, labeled, and sterilized.

Stent **10** can be marketed as stand alone or as a pre-mounted delivery balloon catheter assembly as shown in FIG. **11**. Referring to FIG. **11**, the stent **10** is crimped over a folded balloon **146** at the distal end **148** of a delivery balloon catheter assembly **150**. The assembly **150** includes a proximal end adapter **152**, a catheter shaft **154**, a balloon channel **156**, a guidewire channel **158**, a balloon **146**, and a guidewire **160**. Balloon **146** can be tapered, curved, or both tapered and curved from a proximal end to a distal end in the expanded state. Additionally stent **10** can be non-tapered or tapered in the expanded state.

Typically the guidewire **160** is inserted into the vein or artery and advanced to the target site. The catheter shaft **154** is then forwarded over the guidewire **160** to position the stent **10** and balloon **146** into position at the target site. Once in position the balloon **146** is inflated through the balloon channel **156** to expand the stent **10** from a crimped to an expanded state. In the expanded state, the stent **10** provides the desired scaffolding support to the vessel. Once the stent **10** has been expanded, the balloon **146** is deflated and the catheter shaft **154**, balloon **146**, and guidewire **160** are withdrawn from the patient.

The stent of the present invention can be made as short as less than 10 mm in length or as long as 100 mm or more. If long stents are to be used, however, matching length or preferably slightly longer delivery catheter balloons will typically be needed to expand the stents into their deployed positions. Long stents, depending on the target vessel, may require curved long balloons, tapered long balloons or curved and tapered long balloons for deployment. Curved and/or tapered balloons which match the natural curve and taper of a blood vessel reduce stress on the blood vessel during and after stent deployment. This is especially important in many coronary applications which involve stenting in curved and tapered coronary vessels. The use of such curved and/or tapered balloons is within the scope of the present invention.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

1. A stent in a non-expanded state, comprising:

a first expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the first expansion strut pair that couples the first and second expansion struts at a distal end of the first expansion strut pair, a plurality of the first expansion strut pair forming a first expansion column;

a second expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the second expansion strut pair that couples the first and second expansion struts of the second expansion strut pair at a proximal end of the second expansion strut pair, a plurality of the second expansion strut pair forming a second expansion column;

a first connecting strut including a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section, the first connecting strut proximal section being coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section being coupled to the proximal end of the second expansion strut pair of the second expansion column, a plurality of the first connecting strut forming a first connecting strut column that couples the first expansion column to the second expansion column, the first connecting strut intermediate section being non-parallel to the first connecting strut proximal and distal sections, wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.

2. The stent of claim **1**, wherein a spacing distance between the first expansion strut pair and an adjacent first expansion strut pair in the first expansion column are the same.

3. The stent of claim **1**, wherein a spacing distance between the second expansion strut pair and an adjacent second expansion strut pair in the second expansion column are different.

4. The stent of claim **1**, wherein a spacing distance between the first expansion strut pair and an adjacent first expansion strut pair in the first expansion column, and a spacing distance between the second expansion strut pair and an adjacent second expansion strut pair in the second expansion column are the same.

5. The stent of claim **1**, wherein a spacing distance between the first expansion strut pair and an adjacent first expansion strut pair in the first expansion column, and a spacing distance between the second expansion strut pair and an adjacent second expansion strut pair in the second expansion column are different.

6. The stent of claim **1**, wherein a first radius of curvature is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section.

7. The stent of claim **1**, wherein a second radius of curvature is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section.

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8. The stent of claim 1, wherein a first radius of curvature is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section and a second radius of curvature is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section. 5

9. The stent of claim 1, wherein a first slant angle is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section.

10. The stent of claim 1, wherein a second slant angle is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section.

11. The stent of claim 1, wherein a first slant angle is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section and a second slant angle is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section. 15

12. The stent of claim 1, wherein the stent further includes a radiopaque marker. 20

13. The stent of claim 1, wherein the stent includes an electroplated material for radiopaque observation under fluoroscopy.

14. The stent of claim 1, wherein a proximal end and a distal end of the stent are at least partially radiopaque electroplated. 25

15. The stent of claim 1, wherein a ratio of a number of expansion struts in an expansion strut column to a number of connecting struts in a connecting strut column is 2 to 1.

16. The stent of claim 1, wherein the stent includes m first and second expansion columns, n expansion struts per column and $n(m-1)/2$ connecting struts. 30

17. The stent of claim 1, wherein the first and second expansion columns are each unbroken, continuous structures. 35

18. The stent of claim 1, further comprising:

a reinforcement expansion column made of a plurality of reinforcement expansion struts, wherein each reinforcement expansion strut has a width that is greater than a width of an expansion strut in the first or second expansion columns. 40

19. The stent of claim 18, wherein the reinforcement expansion column includes a plurality of relief notches.

20. The stent of claim 1, wherein the stent has a proximal end with a first reinforcement expansion column and a distal end with a second reinforcement expansion column. 45

21. The stent of claim 20, wherein the first and second reinforcement expansion columns each include a plurality of relief notches.

22. The stent of claim 20, further comprising: 50

a third reinforcement expansion column intermediate the stent proximal end and the stent distal end.

23. A stent in a non-expanded state, comprising:

a first expansion column formed of a plurality of first expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion 55
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strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut;

a second expansion column formed of a plurality of second expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut; and

a first connecting strut column formed of a plurality of first connecting struts, each connecting strut of the first connecting strut column including a connecting strut proximal section, a connecting strut distal section and a connecting strut intermediate section, a first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the first expansion 60
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39. The stent of claim 38, wherein the first column loop slots are parallel to the second column loop slots.

40. The stent of claim 38, wherein the first column loop slots are not parallel to the second column loop slots.

41. The stent of claim 38, wherein the first column loop slots are longitudinally offset from the second column loop slots.

42. The stent of claim 38, wherein the first column loop slots are non-collinear to the second column loop slots.

43. The stent of claim 38, wherein the first column loop slots are collinear with the second column loop slots.

44. The stent of claim 38, wherein a width of first column loop slots is the same as a width of second column loop slots.

45. The stent of claim 38, wherein a width of the first column loop slots is different than a width of the second column loop slots.

46. The stent of claim 38, wherein a shape of the first column loop slots is different than a shape of the second column loop slots.

47. The stent of claim 38, wherein a shape of the first column loop slots is the same as a shape of the second column loop slots.

48. The stent of claim 38, wherein a shape of a first column loop slot of the first expansion column is different from a shape of an adjacent first column loop slot of the first expansion column.

49. The stent of claim 38, wherein a shape of a first column loop slot of the first expansion column is the same as a shape of an adjacent first column loop slot of the first expansion column.

50. The stent of claim 38, wherein a width of a first column loop slot of the first expansion column is different from a width of an adjacent first column loop slot of the first expansion column.

51. The stent of claim 38, wherein a width of a first column loop slot of the first expansion column is the same as a width of an adjacent first column loop slot of the first expansion column.

52. The stent of claim 23, wherein each connecting strut proximal section has a substantially linear geometry.

53. The stent of claim 52, wherein each connecting strut distal section has a substantially linear geometry.

54. The stent of claim 53, wherein each connecting strut intermediate section has a substantially linear geometry.

55. The stent of claim 23, wherein a ratio of a number of expansion struts in an expansion strut column to a number of connecting struts in a connecting strut column is 2 to 1.

56. The stent of claim 23, wherein the stent includes m first and second expansion columns, n connecting struts per column and $n(m-1)/2$ connecting struts.

57. The stent of claim 23, wherein the first and second expansion columns are each unbroken, continuous column structures.

58. The stent of claim 23, wherein one of the first or second expansion column is a broken column structure.

59. The stent of claim 23, further comprising:

a plurality of first expansion columns;

a plurality of second expansion columns; and

a plurality of first connecting strut columns, each first connecting strut column coupling a first expansion column to a second expansion column.

60. The stent of claim 59, wherein a plurality of first expansion columns, second expansion columns and first connecting strut columns form a continuous a chain mesh strut frame pattern.

61. The stent of claim 59, wherein the plurality of first expansion columns, the plurality of second expansion col-

umns and the plurality of first connecting strut columns form an elongated structure.

62. The stent of claim 23, further comprising:

a reinforcement expansion column made of a plurality of reinforcement expansion struts, wherein each reinforcement expansion strut has a width that is greater than a width of an expansion strut in the first or second expansion columns.

63. The stent of claim 23, wherein the stent has a proximal end with a first reinforcement expansion column and a distal end with a second reinforcement expansion column.

64. The stent of claim 23, wherein the stent has a reinforcement expansion column between a proximal end and a distal end of the stent.

65. The stent of claim 23, further comprising:

a third expansion column formed of a plurality of third expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut; and

a second connecting strut column formed of a plurality of second connecting struts, each connecting strut of the second connecting strut column including a connecting strut proximal section, a connecting strut distal section and a connecting strut intermediate section, a first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the second expansion strut column, and a first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the third expansion strut column, and a second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the second expansion strut column, and a second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the third expansion strut column.

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66. The stent of claim 65, wherein the first expansion strut of the first expansion strut pair in the second expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the third expansion column.

67. The stent of claim 65, wherein the first expansion column, the second expansion column, and the first connecting strut column form a first plurality of geometric cells, and the second expansion column, the third expansion column and the second connecting strut column form a second plurality of geometric cells.

68. The stent of claim 68, wherein at least a portion of the first plurality of geometric cells and at least a portion of the second plurality of geometric cells form asymmetric cells.

69. The stent of claim 67, wherein at least a portion of the first plurality of geometric cells and at least a portion of the second plurality of geometric cells are symmetric cells.

70. The stent of claim 67, wherein each geometric cell of the first plurality includes a proximal looped slot and a distal looped slot, and each geometric cell of the second plurality includes a proximal looped slot and a distal looped slot.

71. The stent of claim 70, wherein each distal looped slot of a cell of the first plurality is juxtapositioned to a corresponding proximal looped slot of a cell of the second plurality.

72. The stent of claim 65, wherein the stent includes a proximal expansion column, a distal expansion column, a plurality of connecting struts positioned between the proximal and distal expansion columns, and a plurality of expansion columns positioned between the proximal and distal expansion columns, each expansion column being made of a plurality of juxtapositioned proximal and distal looped slots.

73. The stent of claim 23, wherein a width of the first connecting strut is equal to or less than a width of the first expansion strut of the first or second expansion columns.

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74. The stent of claim 23, wherein a width of a connecting strut of the first connecting strut column is larger than a width of a first expansion strut of the first or second expansion columns.

75. The stent of claim 23, wherein a width of the second expansion strut of the first or second expansion columns is substantially the same as the width of the first expansion strut of the first or second expansion columns.

76. The stent of claim 23, wherein the stent has a tapered diameter in an expanded state.

77. The stent of claim 23, wherein the stent has a tapered geometry extending from a proximal end to a distal end in an expanded state.

78. The stent of claim 23, wherein the stent is configured to be positioned at an exterior of an expandable balloon.

79. The stent assembly of claim 78, wherein the balloon is curved extending from a proximal end and a distal end in an expanded state.

80. The stent assembly of claim 79, wherein the balloon is tapered in an expanded state and the stent has a non-tapered geometry in an expanded state.

81. The stent assembly of claim 79, wherein the balloon and the stent are both tapered in an expanded state.

82. The stent assembly of claim 79, wherein the stent is non-tapered in an expanded state.

83. The stent assembly of claim 79, wherein the stent is tapered in an expanded state.

84. The stent of claim 79, wherein the stent in an expanded state is non-tapered, and the balloon is tapered and curved in an expanded state.

85. The stent of claim 79, wherein the stent is tapered in an expanded state, and the balloon is tapered and curved in an expanded state.

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(12) **EX PARTE REEXAMINATION CERTIFICATE** (8961st)

United States Patent
Jang

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- (54) **INTRAVASCULAR STENT**
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Related U.S. Application Data

- (63) Continuation-in-part of application No. 08/824,142, filed on Mar. 25, 1997, and a continuation-in-part of application No. 08/824,866, filed on Mar. 25, 1997, and a continuation-in-part of application No. 08/824,865, filed on Mar. 25, 1997.
- (60) Provisional application No. 60/017,484, filed on Apr. 26, 1996.

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A61F 2/00 (2006.01)
A61F 2/06 (2006.01)

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(58) **Field of Classification Search** None
See application file for complete search history.

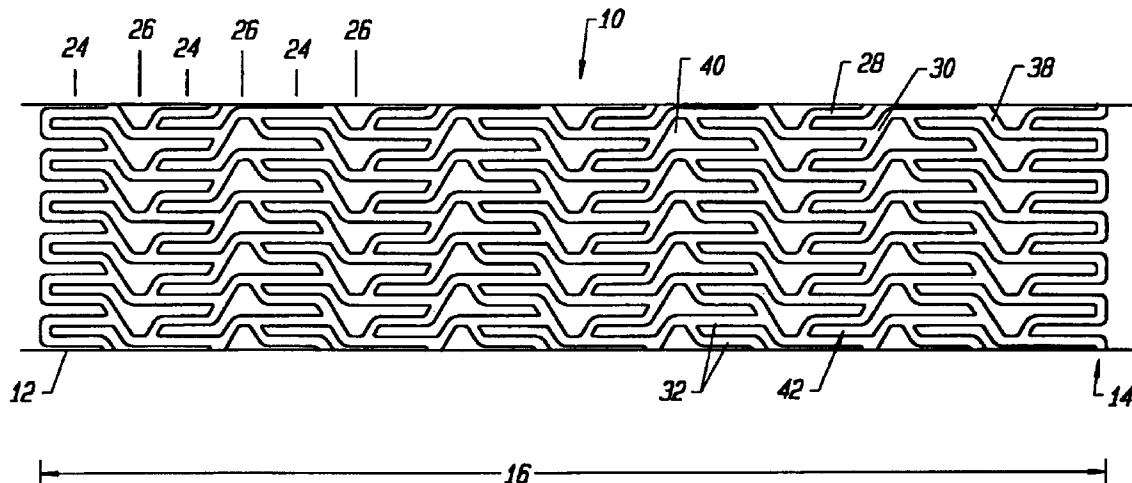
(56) **References Cited**

To view the complete listing of prior art documents cited during the proceedings for Reexamination Control Numbers 90/009,598 and 90/011,439, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner—Cary Wehner

(57) **ABSTRACT**

A stent in a non-expanded state has a first expansion strut pair consisting of a first expansion strut positioned adjacent to a second expansion strut and a joining strut which couples the first and second expansion struts at a distal end of the first expansion strut pair. A plurality of the first expansion strut pair form a first expansion column. A second expansion strut pair consists of a first expansion strut positioned adjacent to a second expansion strut and a joining strut couples the first and second expansion struts at a proximal end of the second expansion strut pair. A plurality of the second expansion strut pair form a second expansion column. A first connecting strut includes a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section. The first connecting strut proximal section is coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section is coupled to the proximal end of the second expansion strut pair of the second expansion column. A plurality of the first connecting struts form a first connecting strut column that couples the first expansion column to the second expansion column. A length of the first connecting strut proximal section is equal to a length of the first connecting strut distal section, and a length of the first connecting strut intermediate section is greater than the length of the first connecting strut proximal and distal sections.



1
EX PARTE
REEXAMINATION CERTIFICATE
ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS
INDICATED BELOW.

2
AS A RESULT OF REEXAMINATION, IT HAS BEEN
DETERMINED THAT:

5 The patentability of claim **36** is confirmed.
Claims **23** and **24** are cancelled.
Claims **1-22**, **25-35** and **37-85** were not reexamined.

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