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(54) STENT WITH DUAL SUPPORT STRUCTURE

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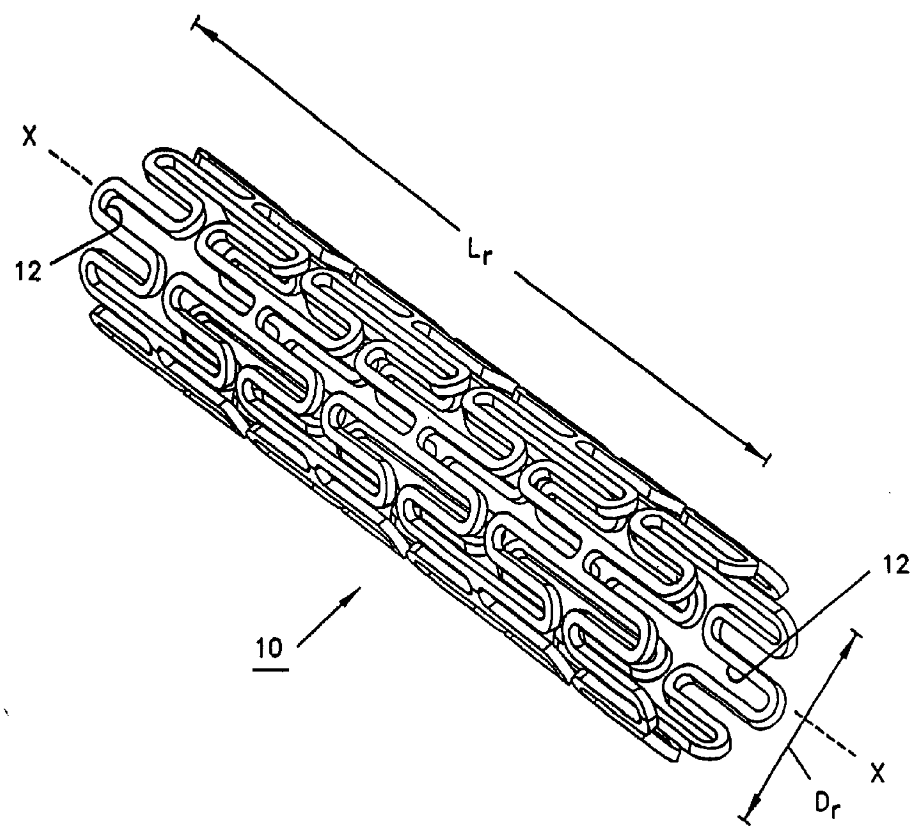
CPC ***A61F 2/86*** (2013.01); *A61F 2250/001* (2013.01)

(57) **ABSTRACT**

A intraluminal stent comprises a reticulated tube having an un-deployed diameter and expandable to an enlarged diameter. The tube includes a structural beam extending between first and second ends. The structural beam changes from a first geometry to a second geometry when the tube changes from the un-deployed diameter to the enlarged diameter. The structural beam includes first and second longitudinal elements each extending at least partially between the first and second ends and with a spacing between the first and second elements. Each of said first and second elements changes from the first geometry to the second geometry when the tube changes from the un-deployed diameter to the enlarged diameter for the spacing to remain substantially unchanged as the tube changes from the un-deployed diameter to the enlarged diameter.



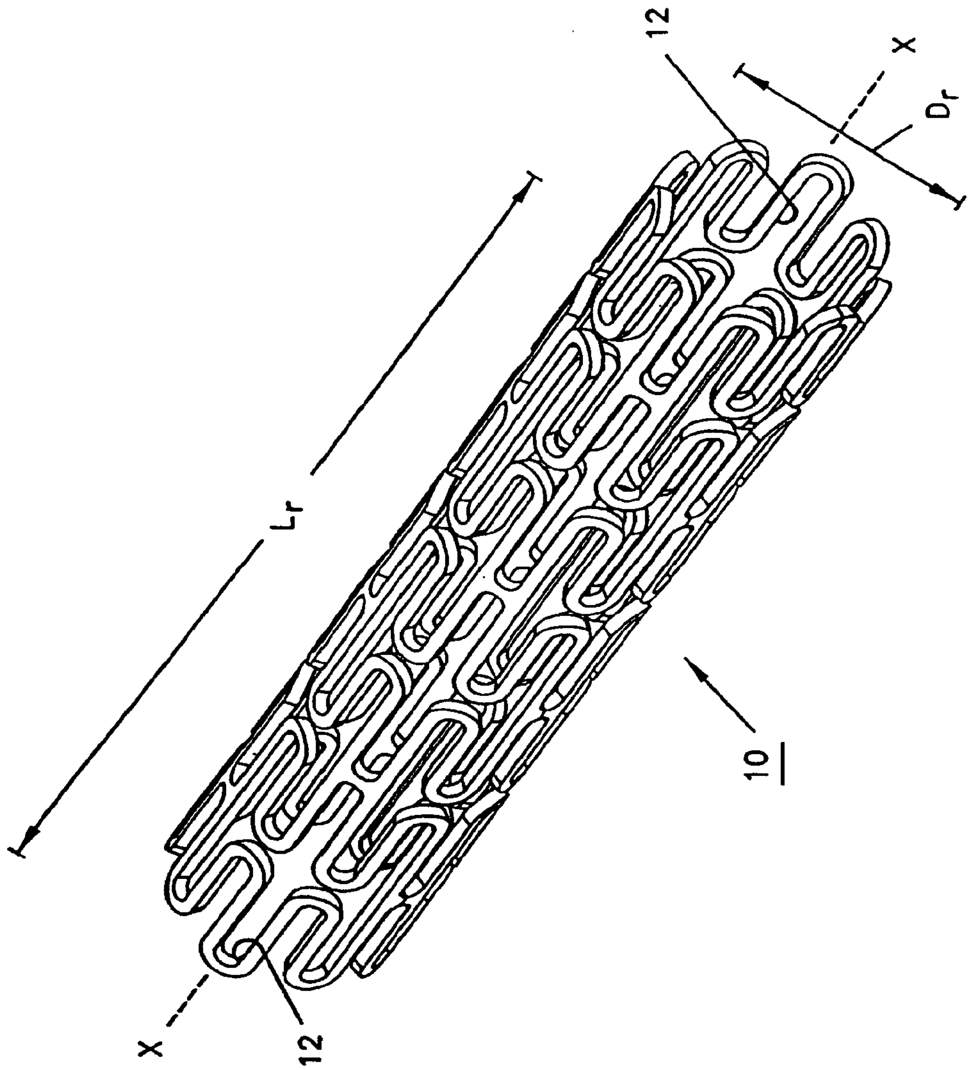


FIG. 1

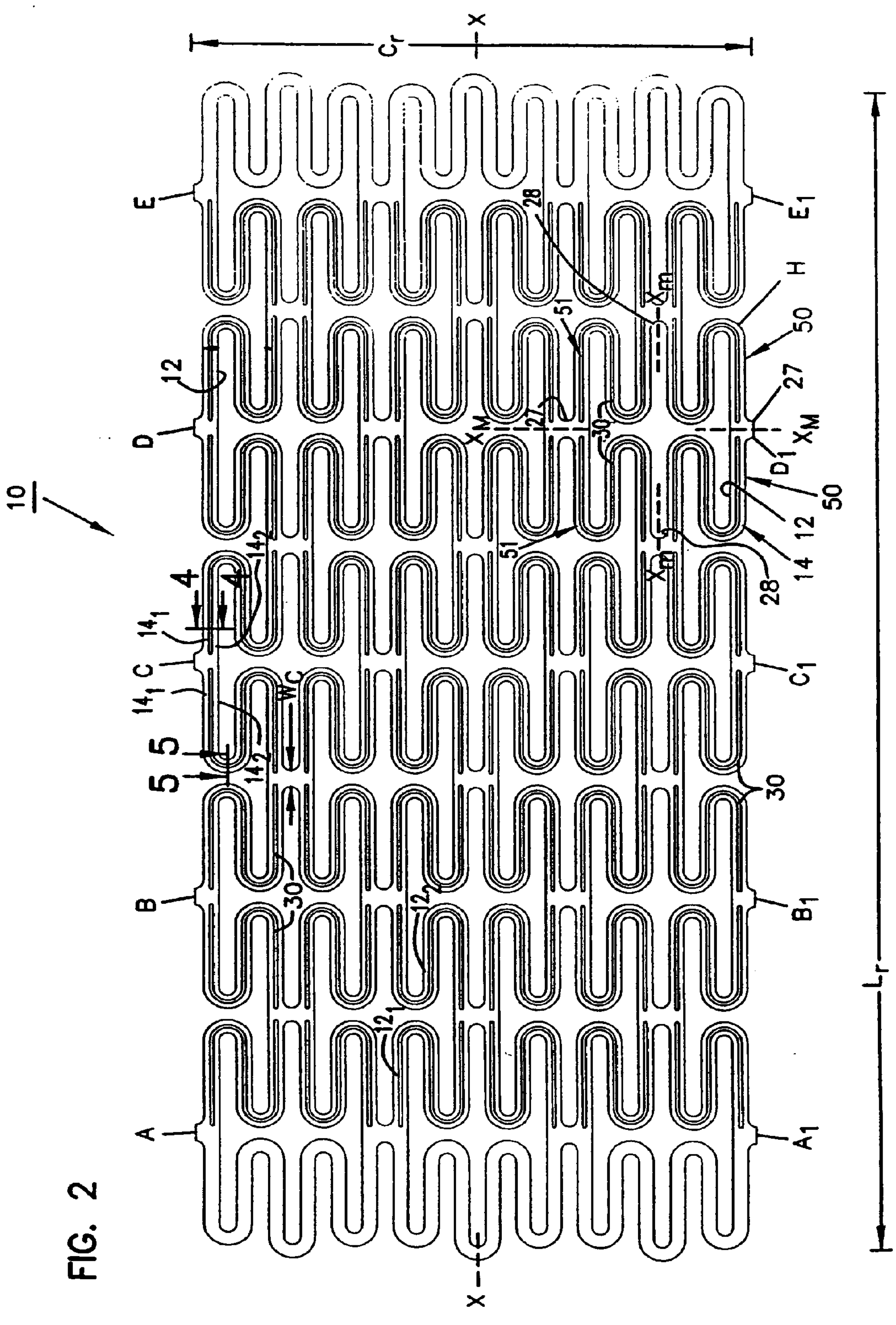


FIG. 2

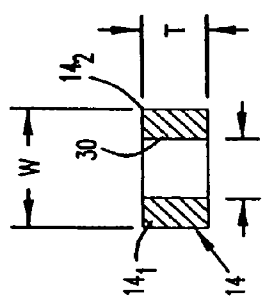


FIG. 4

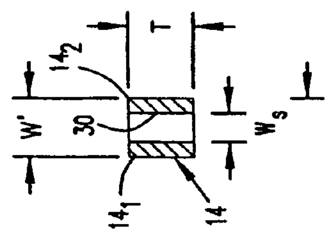


FIG. 5

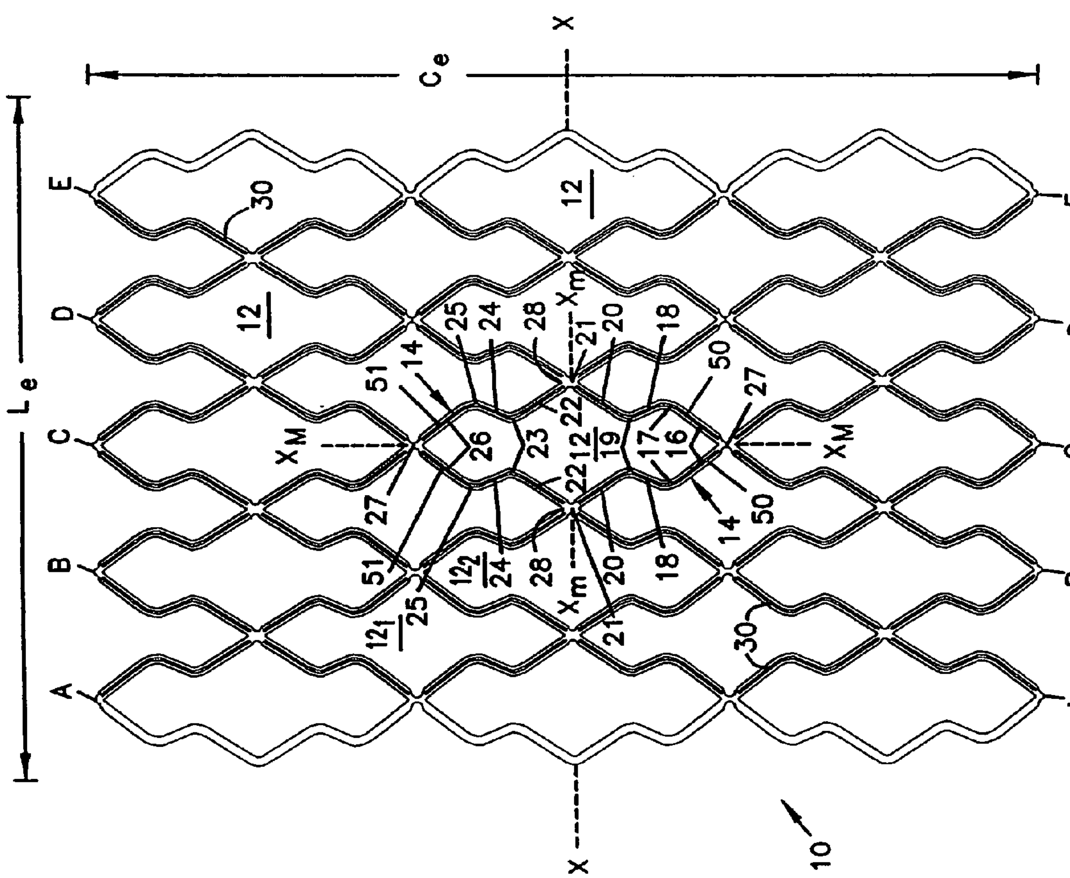
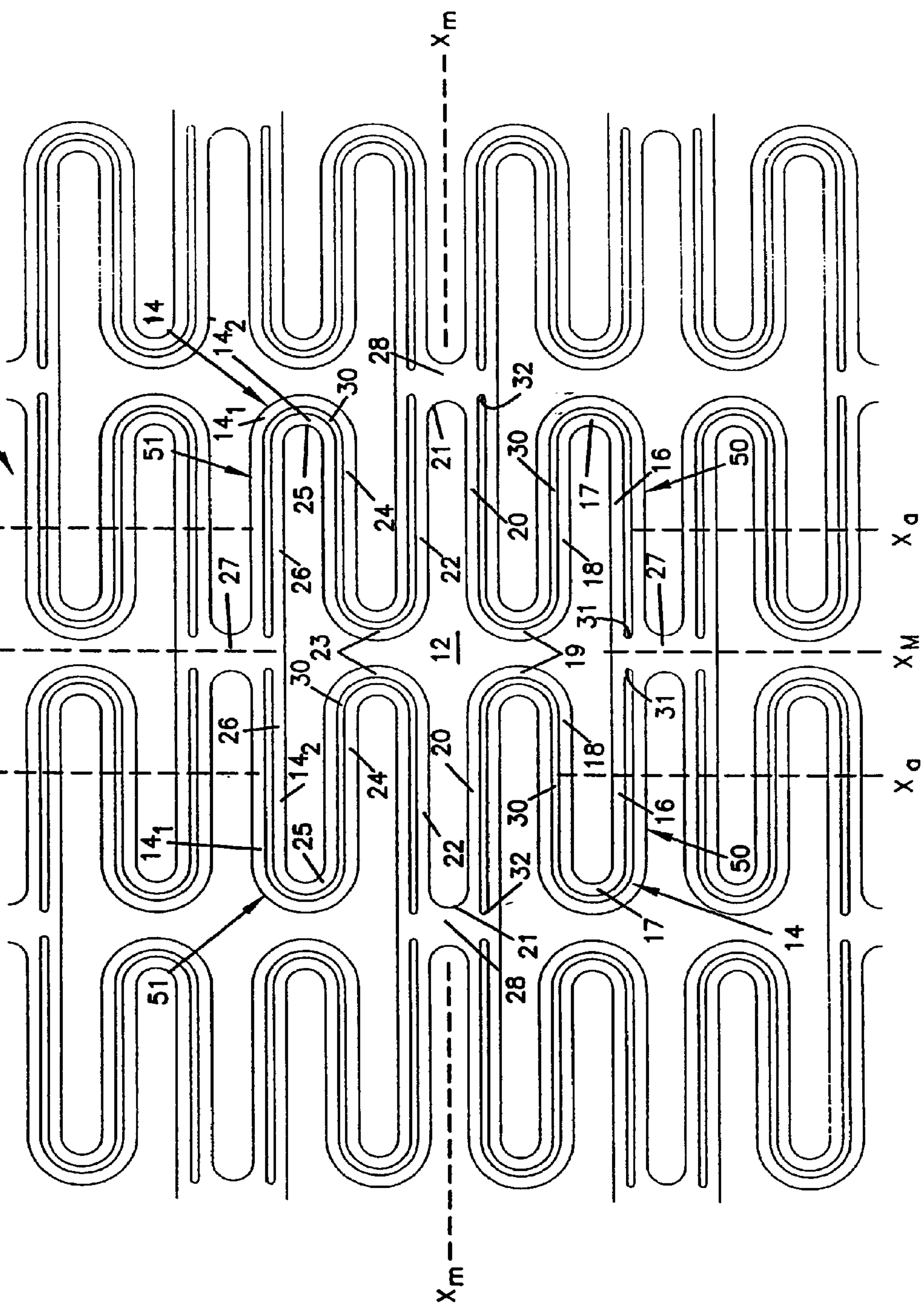


FIG. 3


10
12
14
14_1
14_2
16
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118
19
20
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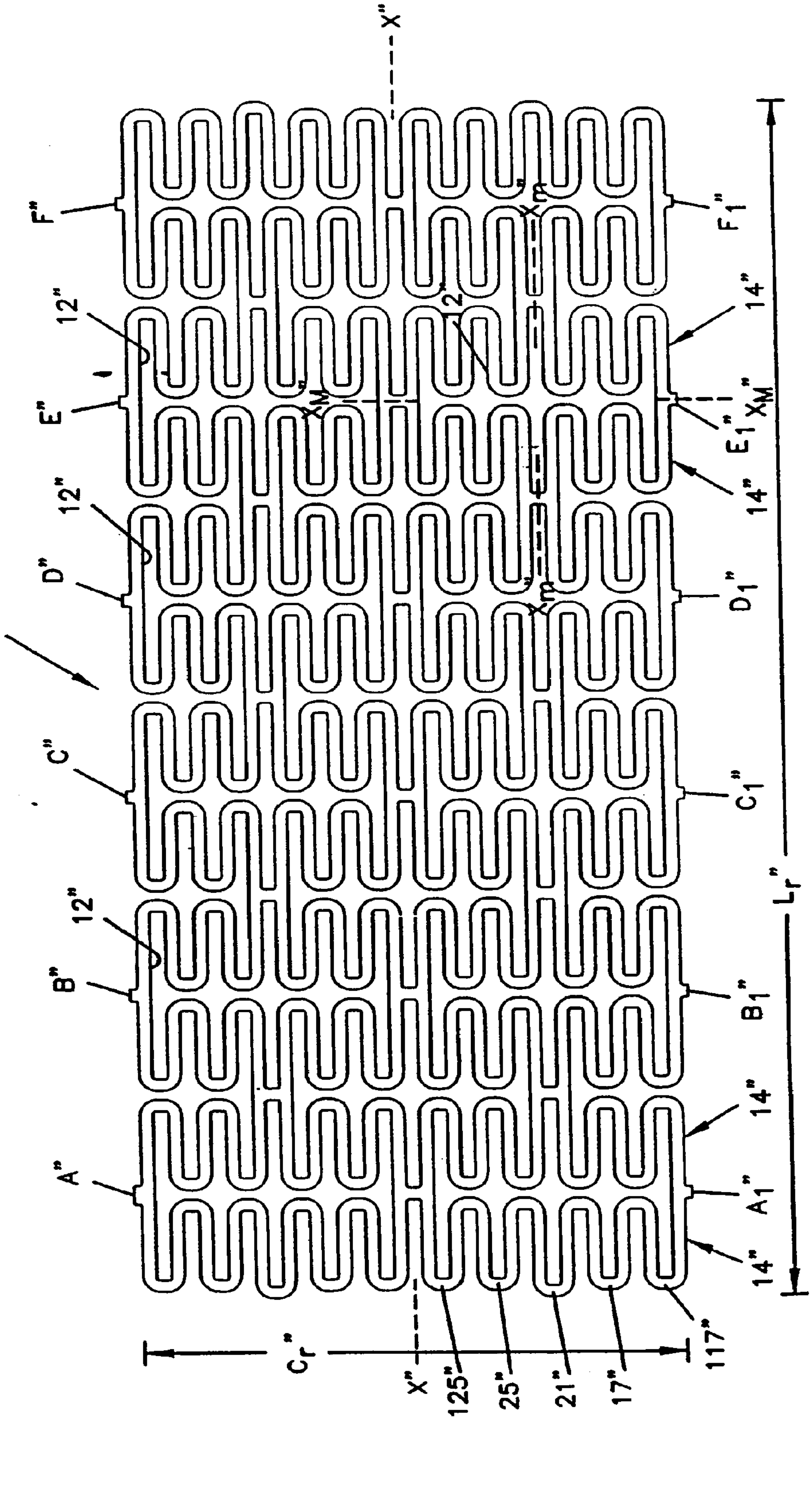
28
30
31
32
50
51
X_a
X_M
X_m

FIG. 6

FIG. 7



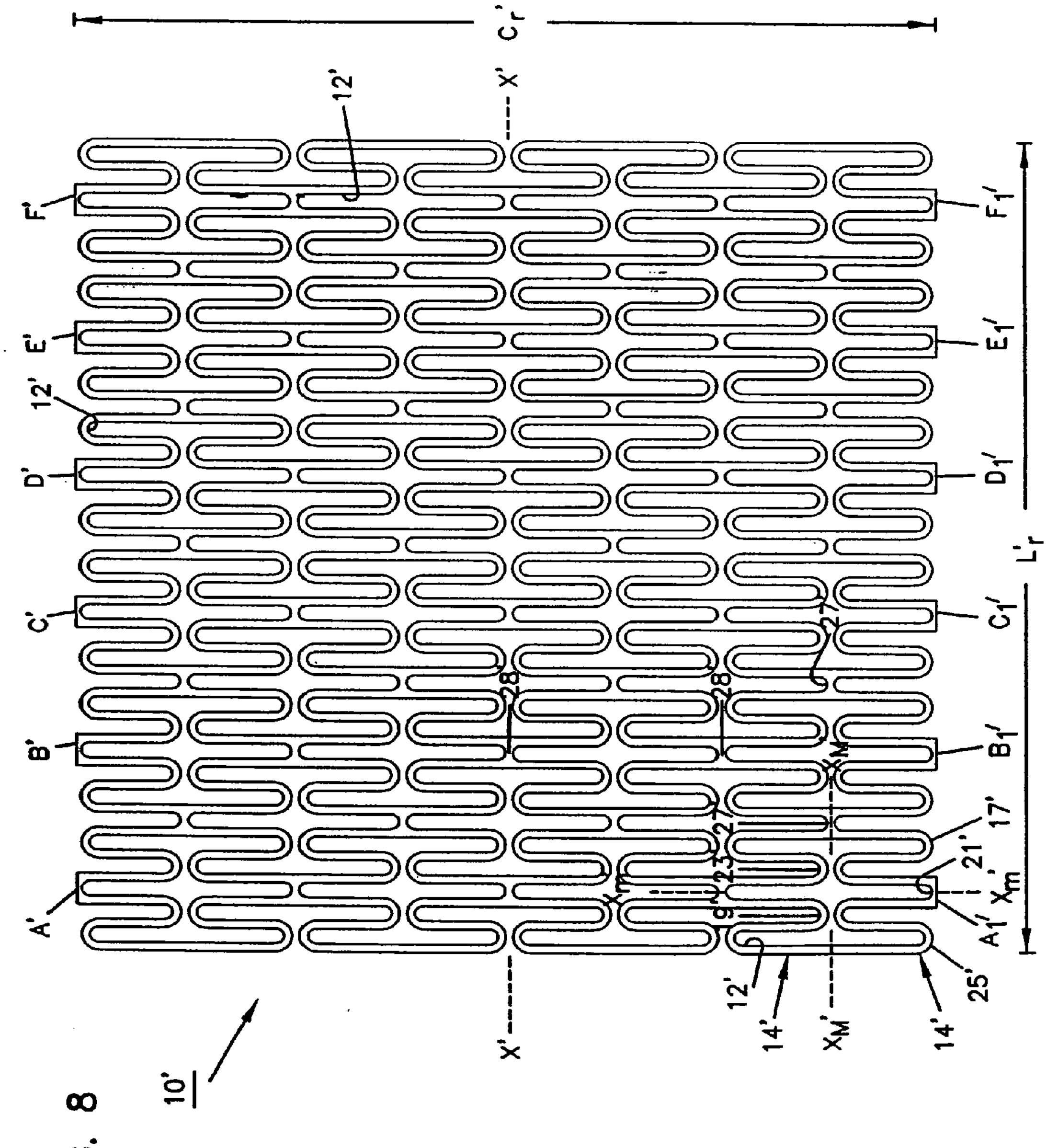


FIG. 8

FIG. 9

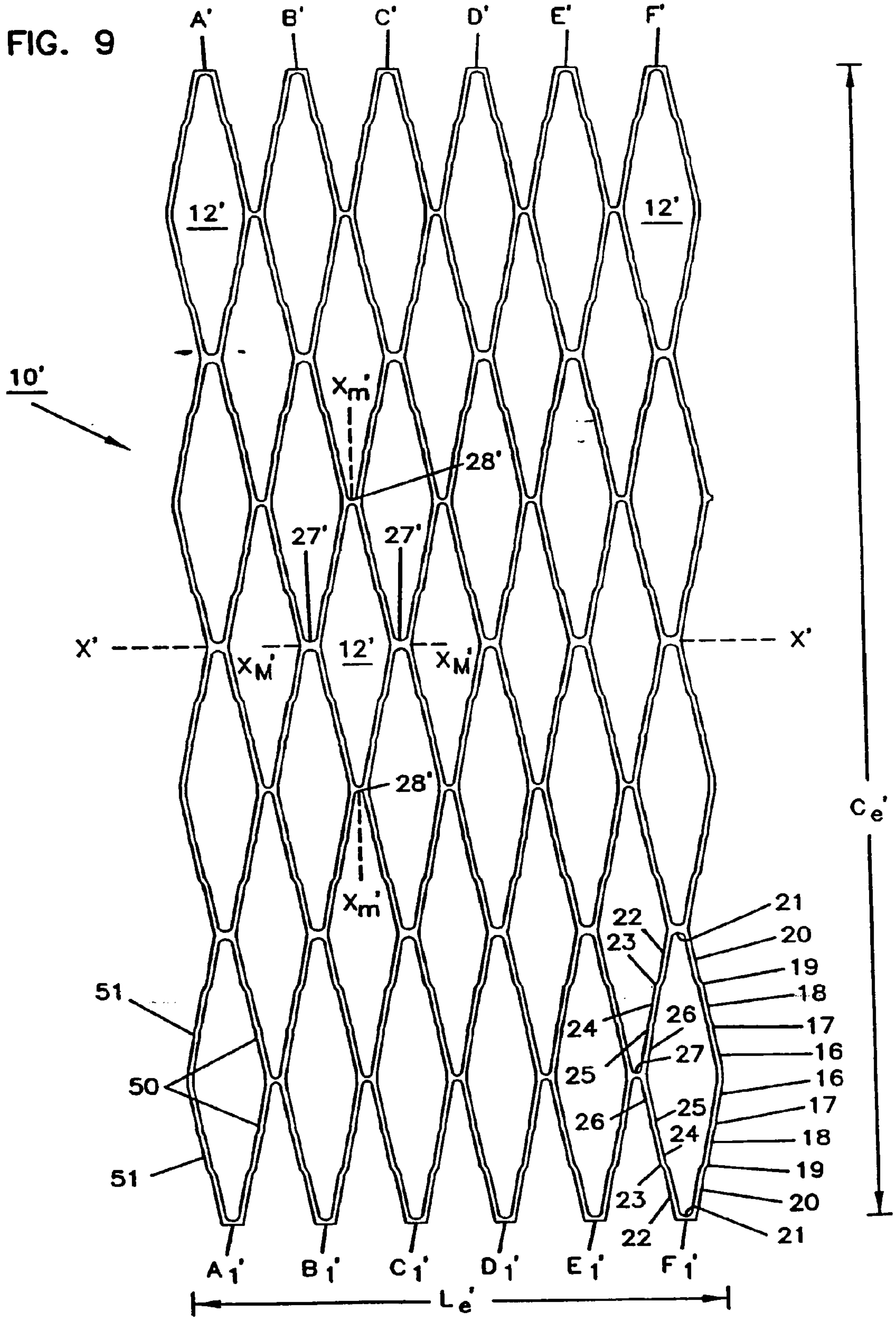
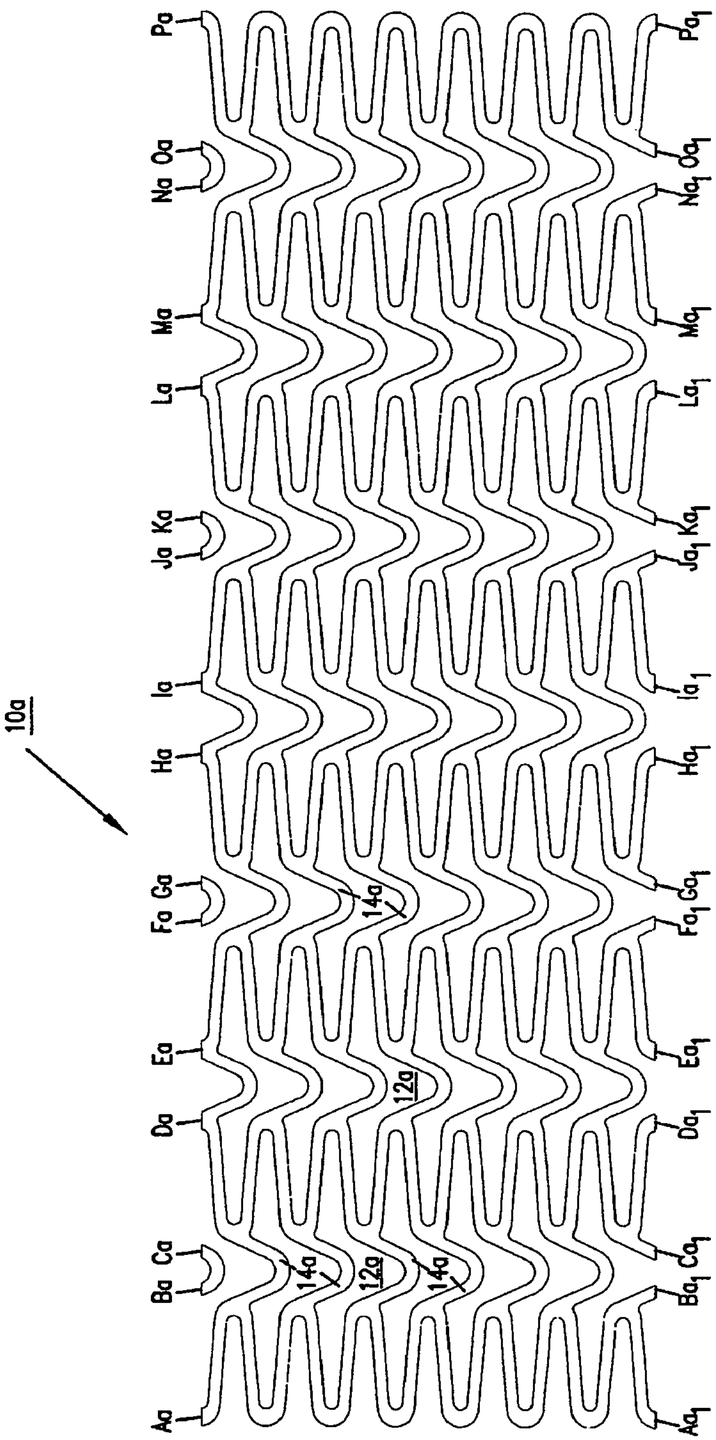

A'
B'
C'
D'
E'
F'
12'
12'
10'
X_m'
28'
27'
27'
X'
X_M'
12'
X_M'
X'
28'
X_m'
C_e'
21
22
20
23
19
18
51
24
26
17
16
50
25
27
16
17
26
25
18
24
51
19
23
20
22
21
A_1'
B_1'
C_1'
D_1'
E_1'
F_1'
L_e'

FIG. 10

--PRIOR ART--



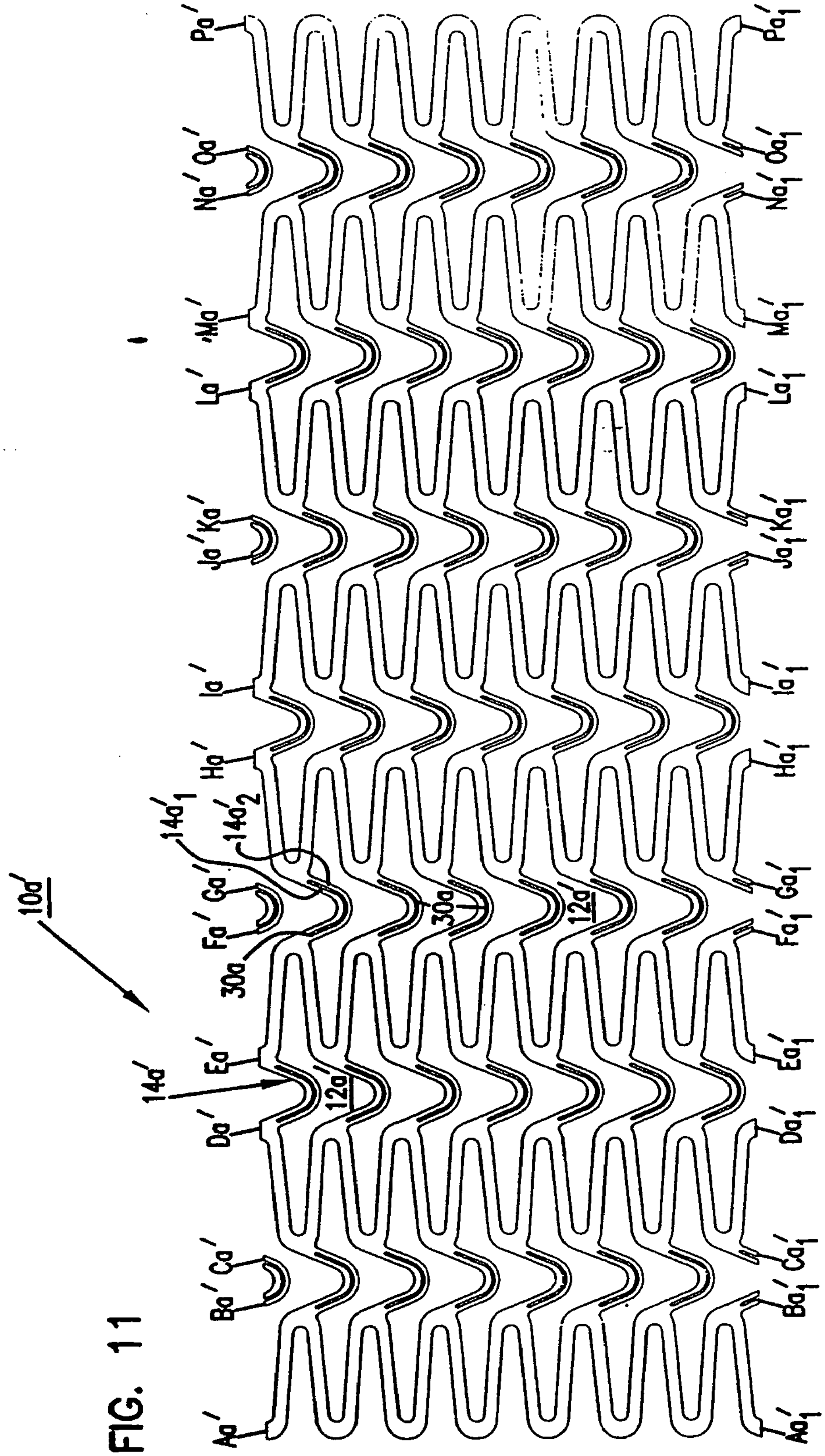

10a'
14a'
12a'
30a
14a'1
14a'2
Aa'
Ba'
Ca'
Da'
Ea'
Fa'
Ga'
Ha'
Ia'
Ja'
Ka'
La'
Ma'
Na'
Oa'
Pa'
Aa'1
Ba'1
Ca'1
Da'1
Ea'1
Fa'1
Ga'1
Ha'1
Ia'1
Ja'1
Ka'1
La'1
Ma'1
Na'1
Oa'1
Pa'1

FIG. 11

--PRIOR ART--

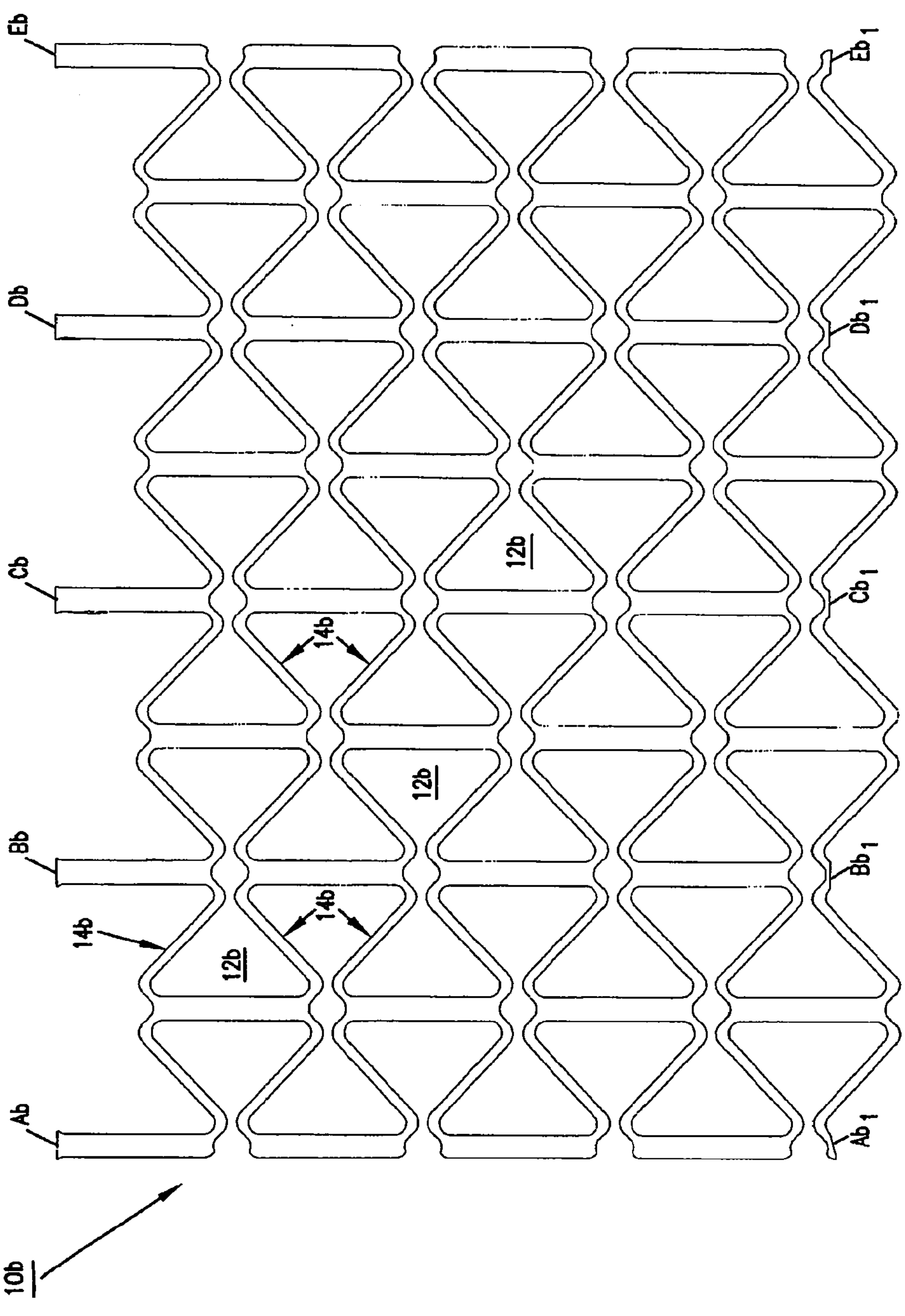


FIG. 12

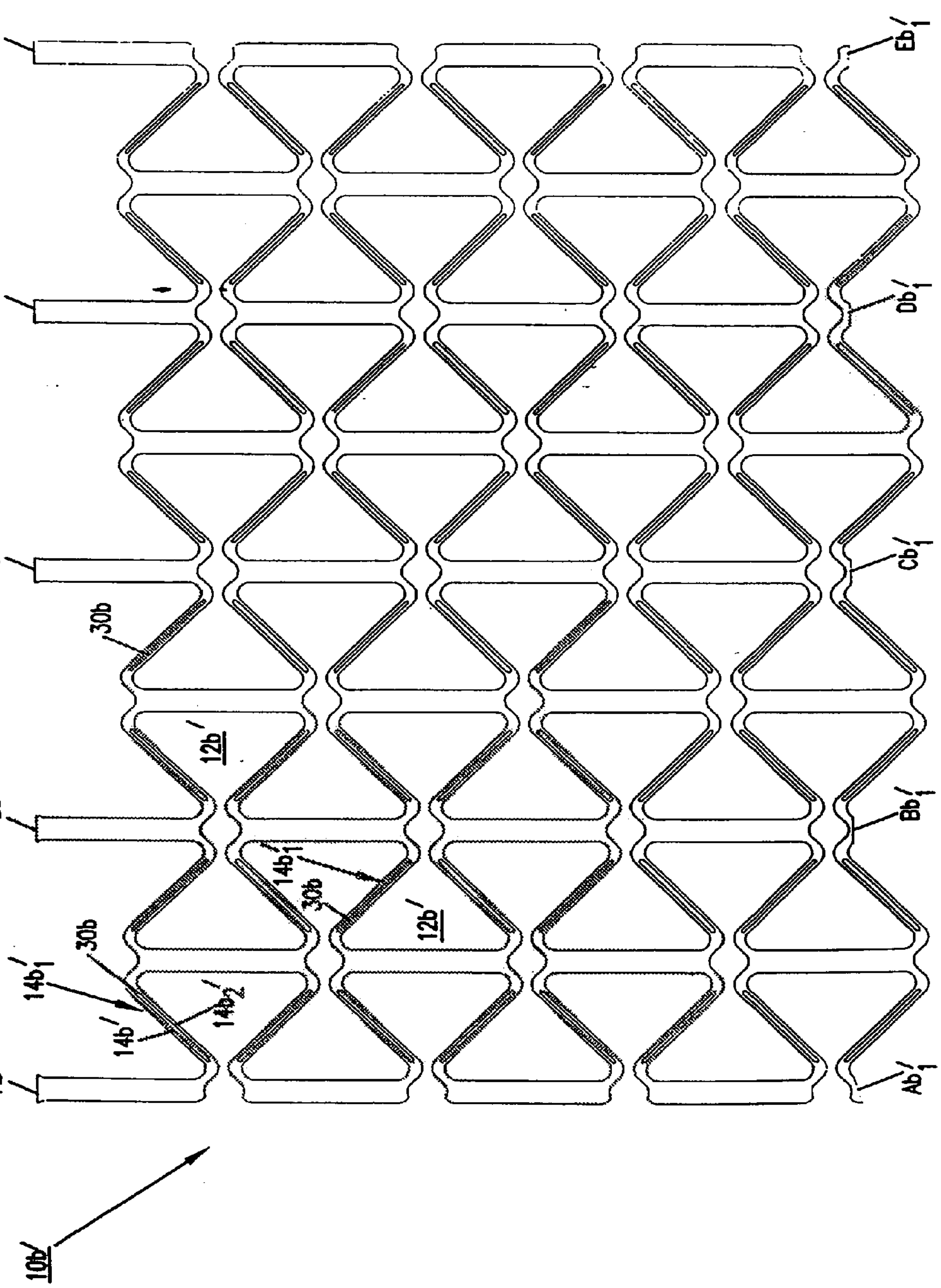


FIG. 13

STENT WITH DUAL SUPPORT STRUCTURE

I. CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application is a continuation-in-part of copending and commonly assigned U.S. patent application Ser. No. 09/049,486 filed Mar. 27, 1998, entitled "STENT" and naming Paul J. Thompson as sole inventor.

II. BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention pertains to stents for use in intraluminal applications. More particularly, this invention pertains to a novel structure for such stents.

[0004] 2. Description of the Prior Art

[0005] Stents are widely used for numerous applications where the stent is placed in the lumen of a patient and expanded. Such stents may be used in coronary or other vasculature, as well as other body lumens.

[0006] Commonly, stents are cylindrical members. The stents expand from reduced diameters to enlarged diameters. Frequently, such stents are placed on a balloon catheter with the stent its the reduced-diameter state. So placed, the stent is advanced on the catheter to a placement site. At the site, the balloon is inflated to expand the stent to the enlarged diameter. The balloon is deflated and removed, leaving the enlarged diameter stent in place. So used, such stents are used to expand occluded sites within a patient's vasculature or other lumen.

[0007] Examples of prior art stents are numerous. For example, U.S. Pat. No. 5,449,373 to Pinchasik et al. teaches a stent with at least two rigid segments joined by a flexible connector. U.S. Pat. No. 5,695,516 to Fischell teaches a stent with a cell having a butterfly shape when the stent is in a reduced-diameter state. Upon expansion of the stent, the cell assumes a hexagonal shape.

[0008] In stent design, it is desirable for the stent to be flexible along its longitudinal axis to permit passage of the stent through arcuate segments of a patient's vasculature or other body lumen. Preferably, the stent will lave at most minimal longitudinal shrinkage when expanded and will resist compressive forces once expanded.

III. SUMMARY OF THE INVENTION

[0009] According to a preferred embodiment of the present invention, an intraluminal stent is disclosed. The stent comprises a reticulated tube having an un-deployed diameter and expandable to an enlarged diameter. The tube includes a structural beam extending between first and second ends. The structural beam changes from a first geometry to a second geometry when the tube changes from the un-deployed diameter to the enlarged diameter. The structural beam includes first and second longitudinal elements each extending at least partially between the first and second ends and with a spacing between the first and second elements. Each of said first and second elements changes from the first geometry to the second geometry when the tube changes from the un-deployed diameter to the enlarged diameter for the spacing to remain substantially unchanged as the tube changes from the un-deployed diameter to the enlarged diameter.

IV. BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. **1** is a perspective view of a first embodiment of a stent according to the present invention shown in a rest diameter state and showing a plurality of stent cells each having a major axis perpendicular to an axis of the stent;

[0011] FIG. **2** is a plan view of the stent of FIG. **1** as it would appear if it were longitudinally split and laid out flat;

[0012] FIG. **3** is the view of FIG. **2** following expansion of the stent to an enlarged diameter;

[0013] FIG. **4** is a view taken along line **4-4** in FIG. **2**;

[0014] FIG. **5** is a view taken along line **5-5** in FIG. **2**;

[0015] FIG. **6** is an enlarged view of a portion of FIG. **2** illustrating a cell structure with material of the stent surrounding adjacent cells shown in phantom lines;

[0016] FIG. **7** is the view of FIG. **2** showing an alternative embodiment of the present invention with a cell having five peaks per longitudinal segment;

[0017] FIG. **8** is the view of FIG. **2** showing an alternative embodiment of the present invention with a major axis of the cell being parallel to an axis of the stent;

[0018] FIG. **9** is the view of FIG. **5** following expansion of the stent to as enlarged diameter;

[0019] FIG. **10** is a plan view of a first prior art stent as it would appear if it were longitudinally split and laid out flat;

[0020] FIG. **11** is the view of FIG. **10** with the stent modified for support beams to include parallel, spaced elements in accordance with the present invention;

[0021] FIG. **12** is a plan view of a second prior art stent as it would appear if it were longitudinally split and laid out flat; and

[0022] FIG. **13** is the view of FIG. **12** with the stent modified for support beams to include parallel, spaced elements in accordance with the present invention.

V. DESCRIPTION OF THE PREFERRED EMBODIMENT

[0023] Referring now to the several drawing figures in which identical elements are numbered identically, a description of the preferred embodiment of the present invention will now be provided. Where several embodiments are shown, common elements are similarly numbered and not separately described with the addition of apostrophes to distinguish the embodiments.

[0024] As will be more fully described, the present invention is directed to a novel support beam for an expandable stent. The support beam is applicable to a wide variety of stent designs. In a preferred embodiment, the support beam will be used as a longitudinal segment in a stent as described in the aforementioned U.S. patent application Ser. No. 09/049,486 filed Mar. 27, 1998, entitled "STENT" and naming Paul J. Thompson as sole inventor. Therefore, such a stent will now be described with reference to FIGS. **1** to **9**. Subsequently, the use of the novel beam will be described in use with other stent designs (i.e., those shown is U.S. Pat. No. 5,449,373 to Pinchasik et al. and U.S. Pat. No. 5,695,516 to Fischell) to illustrate the broad range of applicability of the novel support beam to a wide range of other stent designs.

[0025] FIG. **1** illustrates a stent **10** having a rest length L, and an un-deployed or reduced diameter D_r. The stent **10** is of the design shown in the aforementioned U.S. patent application. The slot of the novel beam construction, as will be described, is not shown in FIG. **1**.

[0026] For ease of illustration, the stent **10** is shown flat in FIG. **2** which illustrates a rest circumference C_r ($C_r = \pi D_r$). In FIG. **2**, locations A, B, C, D and E are shown severed from their normally integrally formed locations A_1, B_1, C_1, D_1 and E_1. This permits the stent **10** to be shown as if it were severed at normally integrally formed locations A-A_1, B-B_1, C-C_1, D-D_1 and E-E_1 and laid flat. FIG. **6** is an enlarged portion of the view of FIG. **2** to better illustrate a cell structure as will be described.

[0027] The stent **10** is a reticulated, hollow tube. The stent **10** may be expanded from the rest diameter D_r (and corresponding rest circumference C_r) to an expanded or enlarged diameter. FIG. **3** is a view similar to FIG. **2** (i.e., illustrating the expanded stent **10** as it would appear if longitudinally split and laid flat). Since FIG. **3** is a two-dimensional representation, the enlarged diameter is not shown. However, the enlarged circumference C_e is shown as well as a length L_e following expansion. The expanded diameter is equal to C_e/π.

[0028] As will be discussed length L_e is preferably not more than minimally smaller (e.g., less than 10% smaller) than length L_r. Ideally, L_e equals L_r.

[0029] The material of the stent **10** defines a plurality of cells **12**. The cells **12** are bounded areas which are open (i.e., extend through the wall thickness of the stent **10**). The stent **10** may be formed through any suitable means including laser or chemical milling. In such processes, a hollow cylindrical tube is milled to remove material and form the open cells **12**.

[0030] The cells **12** have a longitudinal or major axis X_M-X_M and a transverse or minor axis X_m-X_m. In the embodiments of FIGS. **1-3**, the major axis X_M-X_M is perpendicular to the longitudinal cylindrical axis X-X of the stent **10**. In the embodiments of FIGS. **8** and **9**, the major axis X_M'-X_M' is parallel to the longitudinal cylindrical axis X'-X' of the stent **10'**. The cell **12** is symmetrical about axes X_M-X_M and X_m-X_m.

[0031] The cell **12** is defined by portions of the tube material including first and second longitudinal segments or support beams **14**. The beams **14** each have a longitudinal axis X_a-X_a (shown in FIG. **6**). The beams' longitudinal axes X_a-X_a are parallel to and positioned on opposite sides of the cell major axis X_M-X_M.

[0032] Referring to FIG. **6**, each of longitudinal beams **14** has an undulating pattern to define a plurality of peaks **17**, **21**, **25** and valleys **19**, **23**. The peaks **17**, **21**, **25** are spaced outwardly from the longitudinal axes X_a-X_a and the valleys **19**, **23** are spaced inwardly from the longitudinal axes X_a-X_a. As used in this context, "inward" and "outward" mean toward and away from, respectively, the cell's major axis X_M-X_M.

[0033] Each of the peaks **17**, **21**, **25** and valleys **19**, **23** is a generally semi-circular arcuate segment. The peaks **17**, **21**, **25** and valleys **19**, **23** are joined by parallel and spaced-apart straight segments **16**, **18**, **20**, **22**, **24** and **26** which extend perpendicular to the major axis X_M-X_M. Linearly aligned straight end portions **16**, **26** of opposing segments **14** are joined at first and second longitudinal connection locations **27** spaced apart on me major axis X_M-X_M. First and second transverse connection locations **28** are spaced apart on the minor axis X_m-X_m. The first and second transverse connection locations **28** are positioned at the apices of the center peaks **21** of the longitudinal beams **14**.

[0034] Slots **30** are formed through the complete thickness of each of the beams **14**. The slots **30** extend between first and second ends **31**, **32**. The first ends **31** are adjacent the longitudinal connection locations **27**. The second ends **32** are adjacent the transverse connection locations **28**. The slots **30** divide the beams **14** into first and second parallel elements $\mathbf{14_1}$, $\mathbf{14_2}$.

[0035] Except as will be described, the beams **14** have uniform cross-sectional dimensions throughout their length as illustrated in FIG. **4**. By way of non-limiting example, the width W and thickness T of the straight line segments **16**, **18**, **20**, **22**, **24** and **26** are about 0.0065 inch (about 0.16 mm) and about 0.0057 inch (about 0.14 mm), respectively. The width W includes the widths (each of equal width) of the two elements $\mathbf{14_1}$, $\mathbf{14_2}$ plus the width W_S of the slot **30**. By way of a non-limiting example, the width W_S is in the range of 0.001 to 0.0025 inch. By way of another non-limiting example, the width W_S is less than 0.005 inch.

[0036] For reasons that will be described, the width W' (FIG. **5**) at the apices of the peaks **17**, **21**, **25** and valleys **19**, **23** is narrower than width W (in the example given, narrow width W' is about 0.0055 inch or about 0.13 mm). The width of the peaks **12**, **21**, **25** and valleys **19**, **23** gradually increases from width W' at the apices to width W at the straight segments **16**, **18**, **20**, **22**, **24** and **26**. At the longitudinal and transverse connection locations **27**, **28**, the width W_C (shown in FIG. **2**) is preferably equal to or less than the common width W. Preferably, the width W_S of slot **30** remains constant throughout its length.

[0037] The combined lengths of segments **16-20** to the apex of peak **21** represent a path length **50** from longitudinal connection location **27** to transverse connection location **28**. Similarly the combined lengths of the other arcuate and straight segments **22-26** to the apex of peak **21** represent identical length path lengths **51** of identical geometry from longitudinal connection locations **27** to transverse connection locations **28**. Each of the path lengths **50**, **51** is longer than a straight-line distance between the transverse and longitudinal connection locations **27**, **28**. As will be described, the straight-line distance between the transverse and longitudinal connection locations **27**, **28** increases as the diameter of the stent **10** is expanded. The path lengths **50**, **51** are sized to be not less than the expanded straight-line distance.

[0038] The stent **10** includes a plurality of identical cells **12**. Opposite edges of the segments **14** define obliquely adjacent cells (such as cells $\mathbf{12_1}$, $\mathbf{12_2}$ in FIG. **2**). Cells **12** having major axes X_M-X_M collinear wife the major axis X_M-X_M of cell **12** are interconnected at the longitudinal connection locations **27**. Cells having minor axes collinear with the minor axis X_m-X_m of cell **12** are interconnected at the transverse connection locations **28**.

[0039] As mentioned, the stent **10** in the reduced diameter of FIG. **1** is advanced to a site in a lumen. The stent **10** is then expanded at the site. The stent **10** may be expanded through any conventional means. For example, the stent **10** in the reduced diameter may be placed on the balloon tip of a catheter. At the site, the balloon is expanded to generate radial forces on the interior of the stent **10**. The radial forces urge the stent **10** to radially expand without appreciable longitudinal expansion or contraction. Plastic deformation of the material of the stent **10** (e.g., stainless steel) results in the stent **10** retaining the expanded shape following subsequent deflation of the balloon. Alternatively, the stent **10** may be formed of a super-elastic or shape memory material (such as nitinol—a well-known stent material which is an alloy of nickel and titanium).

[0040] As the stent **10** expands, the path lengths **50**, **51** straighten to accommodate the expansion. During such change in geometry of the path lengths **50**, **51**, each of the elements $\mathbf{14}_1$, $\mathbf{14}_2$ similarly changes in geometry so that. At all times, the elements $\mathbf{14}_1$, $\mathbf{14}_2$ are mutually parallel and separated by spacing **30**.

[0041] FIG. **3** illustrates the straightening of the path lengths **50**, **51**. In FIG. **3**, the stent **10** has been only partially expanded to an expanded diameter less than a maximum expanded diameter. At a maximum expanded size, the path lengths **50**, **51** are fully straight. Further expansion of the stent **10** beyond the maximum expanded size would result in narrowing of the minor axis X_m-X_m (i.e., a narrowing of a separation between the transverse connection locations and a resulting narrowing of the length L_r of the stent) or would require stretching and thinning of the stent material.

[0042] As shown in FIG. **3**, during expansion of the stent **10**, the straight segments **16**, **18**, **20**, **22**, **24** and **26** are substantially unchanged. The straightening of the path lengths **50**, **51** results in bending of the arcuate peaks **17**, **21**, **25** and valleys **19**, **23**. Since the width W' of the peaks **17**, **21**, **25** and valleys **19**, **23** is less than the width W of the straight segments **16**, **18**, **20**, **22**, **24** and **26**, the arcuate peaks **17**, **21**, **25** and valleys **19**, **23** are less stiff than the straight segments **16**, **18**, **20**, **22**, **24** and **26** and, therefore, more likely to deform during expansion.

[0043] As the geometry of the beams **14** changes during expansion, the geometry of the first and second elements $\mathbf{14}_1$, $\mathbf{14}_2$ similarly changes so that the elements $\mathbf{14}_1$, $\mathbf{14}_2$ remain in mutually parallel relation both before and after expansion. As used in this application, the term "mutually parallel" means the spacing **30** between the elements $\mathbf{14}_1$, $\mathbf{14}_2$ is substantially constant throughout the length of the elements $\mathbf{14}_1$, $\mathbf{14}_2$. The elements $\mathbf{14}_1$, $\mathbf{14}_2$ and beam **14** may be curved or straight throughout their lengths.

[0044] As the stent **10** expands, the cells **12** assume a diamond shape shown in FIG. **3**. Since the expansion forces are radial, the length of the major axis X_M-X_M (i.e., the distance between the longitudinal connection locations **27**) increases. The length of the minor axis X_m-X_m (and hence the length of the stent **10**) remains unchanged.

[0045] The stent **10** is highly flexible. To advance to a site, the axis X-X of the stent **10** must bend to navigate through a curved lumen. Further, for placement at a curved site in a lumen, the stent **10** must be sufficiently flexible to retain a curved shape following expansion and to bend as the lumen bends over time. The stent **10**, as described above, achieves these objections.

[0046] When bending on its axis X-X, the stent **10** tends to axially compress on the inside of the bend and axially expand on the outside of the bend. The present design permits such axial expansion and contraction. The novel cell geometry **12** results in an accordion-like structure which is highly flexible before and after radial expansion. Further, the diamond shape of the cells **12** after radial expansion resists constricting forces otherwise tending to collapse the stent **10**.

[0047] The dual support structure of the elements separated by the slots increases flexibility without reducing resistance to compression forces. Further, during expansion and during flexing of the stent on its axis, the use of parallel, spaced elements $\mathbf{14}_1$, $\mathbf{14}_2$ results in lower stress levels than would be experienced by a solid beam.

[0048] Numerous modifications are possible. For example the stent **10** may be lined with either an inner or outer sleeve (such as polyester fabric or ePTFE) for tissue growth. Also, the stent may be coated with radiopaque coatings such as platinum, gold, tungsten or tantalum. In addition to materials previously discussed, the stent may be formed of any one of a wide variety of previous known materials including, without limitation, MP35N, tantalum, platinum, gold, Elgiloy and Phynox.

[0049] While three cells **12** are shown in FIG. **2** longitudinally connected surrounding the circumference C, of the stent, a different number could be so connected to vary the properties of the stent **10** as a designer may elect. Likewise, while each column of cells **12** in FIG. **2** is shown as having three longitudinally connected cells **12**, the number of longitudinally connected cells **12** could vary to adjust the properties of the stent. Also, while each longitudinal segment **14** is shown as having three peaks **17**, **21**, **25** per longitudinal segment **14**, the number of peaks could vary. FIG. **7** illustrates a stent **10"** with a cell **12"** having five peaks **117"**, **17"**, **21"**, **25"** and **125"** per longitudinal segment **14"**. Preferably, the longitudinal segment will have an odd number of peaks so that the transverse connection points are at art apex of a center peak. In FIG. **7**, no slot is shown in the beams **14"** for ease of illustration.

[0050] FIGS. **8** and **9** illustrate an alternative embodiment where the major axis X_M'-X_M' of the cells **12'** are parallel with the cylindrical axis X'-X' of the stent **10'**. In FIG. **9**, the expanded stent **10'** is shown at a near fully expanded state where the path lengths **50'**, **51'** are substantially linear. In FIGS. **1** and **9**, no slots are shown in the beams **14'** for ease of illustration.

[0051] FIGS. **10** and **12** illustrate prior art stent designs. FIG. **10** is a stent **10*a*** as shown in U.S. Pat. No. 5,449,373 to Pinchasik et al. and FIG. **12** is a stent **10*b*** as shown in U.S. Pat. No. 5,695,516 to Fischell. Stent **10*a*** is shown flat as if longitudinally split at locations Aa-Aa_1 through Pa-Pa_1. Similarly, Stent **10*b*** is shown flat as if longitudinally split at locations Ab-Ab_1 through Eb-Eb_1.

[0052] Both of the designs of FIGS. **10** and **12** include solid structural beams **14*a***, **14*b***. Beams **14*a*** are curved when the stent **10*a*** is in a reduced diameter state. The beams **14*a*** cooperate to define cells **12*a***. The curved beams **14*a*** straighten when the stent **10*a*** expands. The beams **14*b*** are straight and cooperate to define a butterfly-shaped cell **12*b***. Upon expansion, the beams **14*b*** remain straight but pivot for the cell **12*b*** to assume a hexagon shape upon expansion.

[0053] The dual support structure aspect of the present invention is applicable to prior art stents such as those shown in FIGS. **10** and **12**. FIGS. **11** and **13** show the prior art stents of FIGS. **10** and **11**, respectively, modified according to the dual support structure aspect of the present invention. Specifically, beams **14*a*'**, **14*b*'** are provided with slots **30*a***, **30*b*** to divide the beams into parallel, spaced first and second elements $\mathbf{14}a_1$', $\mathbf{14}a_2$' and $\mathbf{14}b_1$', $\mathbf{14}b_2$' having the benefits previously described.

[0054] From the foregoing, the present invention has been shown in a preferred embodiment. Modifications and equivalents are intended to be included within the scope of the appended claims.

What is claimed is:

1. An intraluminal stent comprising:

a reticulated tube having an un-deployed diameter and expandable to an enlarged diameter, said tube having a stent axis;

said tube including a structural beam extending between first and second ends;

said structural beam changing from a first geometry to a second geometry when said tube changes from said un-deployed diameter to said enlarged diameter;

said structural beam including first and second longitudinal elements each extending at least partially between said first and second ends and with a spacing between the first and second elements;

each of said first and second elements changing from said first geometry to said second geometry when said tube changes from said un-deployed diameter to said enlarged diameter for said spacing to remain substantially unchanged as said tube changes from said un-deployed diameter to said enlarged diameter.

2. An intraluminal stent according to claim **1** wherein said first and second elements are mutually parallel both before and after changing of said tube from said un-deployed diameter to said enlarged diameter.

3. An intraluminal stent according to claim **1** wherein said first and second elements each extend substantially an entire length of said structural beam between said first and second ends.

4. An intraluminal stent according to claim **1** wherein a plurality of disconnected slots are formed through said structural beam to define a plurality of parallel first and second elements between said first and second ends.

5. An intraluminal stent according to claim **1** wherein said beam and said first and second elements are curved.

6. An intraluminal stent according to claim **1** wherein said beam and said first and second elements are straight.

7. An intraluminal stent according to claim **1** wherein:

said beam is one of a plurality of beams with opposing surfaces defining an open cell bounded by said beams, said cell having a major axis and a minor axis;

said plurality of beams including first and second longitudinal beams each having:

a. a longitudinal axis extending parallel to and positioned on opposite sides of said cell major axis; and

b. an undulating pattern to define a plurality of peaks and valleys spaced outwardly and inwardly, respectively, from said longitudinal axes;

said first and second longitudinal beams interconnected at opposite ends thereof.

8. A stent according to claim **7** further comprising:

first and second longitudinal connection locations at interconnection points of said interconnected first and second longitudinal beams for connection of said cell to first and second longitudinally adjacent cells, respectively; and

first and second transverse connection locations on said first and second longitudinal beams, respectively, for connection of said cell to first and second transversely adjacent cells, respectively.

9. A stent according to claim **7** wherein path lengths of said longitudinal beams from said first and second transverse connection locations in said first and second longitudinal connection locations following expansion of said stent is substantially equal to or less than said lengths prior to said expansion.

10. A stent according to claim **7** wherein:

said cell is substantially identical to adjacent cells;

said major axis of said cell is linearly aligned with major axes of said first and second longitudinally adjacent cells;

said minor axis of said cell is linearly aligned with minor axes of said first and second transversely adjacent cells;

opposing surfaces of cell defining portions of said cell, said longitudinally adjacent cells and said transversely adjacent cells cooperate to define at least in part obliquely adjacent cells.

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