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(54) STENT WITH ACTIVELY VARYING RING DENSITY

STENT MIT AKTIV VARIIERENDER RINGDICHTE

ENDOPROTHÈSE AVEC DENSITÉ ANNULAIRE VARIANT DE FAÇON RÉACTIVE

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(56) References cited:

**US-A1- 2003 176 914 US-A1- 2006 224 234
US-A1- 2007 150 046 US-A1- 2007 276 464
US-A1- 2011 238 156**

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Description

BACKGROUND

[0001] The present invention relates to stents having a radial stiffness that varies along the length of the stent. Specifically, the invention relates to a stent that actively changes the density of rings in different zones along the axial length of the stent when the stent is expanded from a compressed condition to an expanded condition.

[0002] Surgical stents have long been known which can be surgically implanted into a body lumen, such as an artery, to reinforce, support, repair or otherwise enhance the performance of the lumen. For example, in cardiovascular surgery it is often desirable to place a stent in the coronary artery at a location where the artery is damaged or is susceptible to collapse. The stent, once in place, reinforces that portion of the artery allowing normal blood flow to occur through the artery. One form of stent which is particularly desirable for implantation in arteries and other body lumens is a cylindrical stent which can be radially expanded from a first smaller diameter to a second larger diameter. Such radially expandable stents can be inserted into the artery by being located on a catheter and introduced internally through the arterial pathways of the patient until the unexpanded stent is located where desired. The catheter is fitted with a balloon or other expansion mechanism which exerts a radial pressure outward on the stent causing the stent to expand radially to a larger diameter. Such expandable stents exhibit sufficient rigidity after being expanded that they will remain expanded after the catheter has been removed. An example of a stent known in the art is shown in FIG. 4 and FIG. 5. With initial reference to FIG. 4, the stent 50 shown there generally comprises a plurality of radially expandable cylindrical elements or rings 52 disposed generally coaxially along the axis 2 of the stent and interconnected by elements 54, 56 disposed between adjacent cylindrical elements. While FIG. 4 shows the stent 50 in a compressed or unexpanded condition suitable for delivery into the vasculature of a patient, FIG. 5 shows the same stent 50 in an expanded condition after placement and expansion in the vasculature.

[0003] Yet, known prior art stents suffer from a variety of drawbacks when certain types of deficiency or damage in an artery is encountered by a surgeon. For example, a surgeon may encounter an arterial situation where a stent is required to have greater radial support stiffness at the ends of the stent, and less radial support stiffness in the middle between the two ends. Another situation may be encountered requiring a stent having a greater radial support stiffness in the middle, and less radial support stiffness at the ends.

[0004] Certain stents have been developed to satisfy these requirements, but they suffer from drawbacks. For example, one approach describes a stent with greater radial support stiffness in the middle of the stent, wherein the struts are made thicker in the middle of the stent and

thinner towards the ends. Another approach describes a stent with varying radial strength, wherein the desired effect is accomplished by increasing the width of the struts, or increasing the length of a cylindrical element.

5 Yet another approach describes a stent in which the structural members are provided with regions having different widths, and tapering widths of selected segments. However, these solutions may result in a stent that is expensive to manufacture, and has non-uniform bending characteristics about the longitudinal axis and this latter aspect may introduce complications during delivery. Yet another approach describes a stent of differentiated stiffness that is achieved with the use of a superelastic material that transitions between a relatively soft and mal-
10 leable phase to a stiffer phase at a transition temperature that is adjustable along the length of the stent. By differentially adjusting the transition temperature of different portions of the stent, a differentiation in the stiffness of the structure is achieved upon the stent being subjected to body temperature. However, this solution entails complex differentiated metallurgical application in a single stent in order to achieve the desired result.

[0005] Prior art stents US 2007/276464 and US 2007/150046 show stents where different zones of the stents have differing strut connections and thus differing stiffness.

[0006] Thus there is a need in the art for a simple and effective stent that possesses varying degrees of radial support stiffness over its length, that is easy to manufacture, and has substantially uniform longitudinal flexibility. The present invention addresses these and other needs.

SUMMARY OF THE INVENTION

[0007] In a preferred embodiment, the invention is an expandable axially elongate stent comprising a plurality of undulating ring elements configured to be expandable from an unexpanded condition to an expanded condition, the ring elements being positioned one adjacent to another along an axis. Each ring element includes a plurality of struts having an orientation in relation to the axis and each strut is connected to an adjacent strut by a curved elbow. Each curved elbow has a concave portion and a convex portion. A first zone of the stent includes a plurality of ring elements, not less than three in number, and each ring element in the first zone is connected to an adjacent ring element in the first zone by a connector extending from a convex portion of one ring to a convex portion of an adjacent ring. Furthermore a second zone of the stent includes a plurality of ring elements, not less than three in number, and each ring element in the second zone is connected to an adjacent ring element in the second zone by a connector extending from a concave portion of one ring to a concave portion of an adjacent ring. As will be explained in greater detail below, this configuration has the result that, upon expansion, the first zone shortens in length and thereby increases the ring density, and hence the radial support stiffness, of the first zone. At the

same time, upon expansion the second zone increases in length, and thereby decreases the ring density, and hence the radial support stiffness, of the second zone.

[0008] In one example, not within the scope of the claims the first zone may be an end zone of the stent, and the second zone may be a middle zone adjacent the first zone. (As used herein, the term "adjacent," as applied to both rings and zones, is used to mean one alongside another and not separated by an additional ring element.) Under this configuration, a third zone may be added adjacent the second zone, having the configuration of the first zone in which each of a plurality of ring elements in the third zone is connected to an adjacent ring element in the third zone by a connector extending from a convex portion of one ring to a convex portion of an adjacent ring. Under this configuration, the stent may have end zones that have a greater radial support stiffness than in the middle zone.

[0009] In yet another example, not part of the invention, the second zone may be an end zone of the stent, and the first zone may be a middle zone adjacent the second zone. Under this configuration, a third zone may be added adjacent the first zone, having the configuration of the second zone, in which each of a plurality of ring elements in the third zone is connected to an adjacent ring element in the third zone by a connector extending from a concave portion of one ring to a concave portion of an adjacent ring. Under this configuration, the stent may have two end zones that have a smaller radial support stiffness than in the middle zone.

[0010] Further embodiments include that the connectors in the first zone are oriented parallel to the stent axis, and the connectors in the second zone are oriented parallel to the stent axis. This parallel configuration allows an improved predictability over the final length of the stent after expansion compared with the unexpanded condition.

[0011] In yet further embodiments of the invention all the ring elements in the stent in an unexpanded condition are substantially similar to each other in geometric shape. This feature provides the stent with improved uniformity of flexion along the length of the stent. Additionally, and adding to the same effect, all the ring elements in the stent in an unexpanded condition may be distributed at substantially even spacing over the axial length of the stent

[0012] In a preferred embodiment, the stent may include a middle zone of the stent positioned adjacent the first zone and which includes a plurality of ring elements, not less than three in number, and each ring element in the middle zone is connected to an adjacent ring element in the middle zone by at least one connector extending from a concave portion of one ring to a convex portion of an adjacent ring. Additionally, the stent may include a second end zone which includes a plurality of ring elements and each ring element in the second end zone is connected to an adjacent ring element in the second end zone by at least one connector extending from a concave

portion of one ring to a concave portion of an adjacent ring.

[0013] The stent of the invention may be used for supporting the wall of a vessel. The method comprises inserting within the vessel an unexpanded stent comprising a plurality of undulating ring elements configured to be expandable from an unexpanded condition to an expanded condition. The stent includes a first notional zone comprising a plurality of adjacent ring elements, not less than three in number, that are distributed along the stent with a first spacing. As used herein, "spacing" means the distance from the axial centerpoint of one ring to the axial centerpoint of an adjacent ring. Preferably, the spacing between all rings in a zone may be substantially the same when the stent is in the unexpanded condition, but this is not a requirement of the term "spacing." The stent also includes a second notional zone comprising a plurality of adjacent ring elements, not less than three in number, that are distributed along the stent by a second spacing. The method further includes expanding the stent, and thereby, causing the plurality of ring elements in the first zone to redistribute to a third spacing that is smaller than the first spacing; and further, causing the plurality of ring elements in the second zone to redistribute to a fourth spacing that is larger than the second spacing.

[0014] In some examples the step of causing the plurality of ring elements in the first zone to redistribute to a third spacing includes causing ring elements in an end zone of the stent to redistribute to the third spacing. Further, causing the plurality of ring elements in the second zone to redistribute to a fourth spacing includes causing ring elements in a middle zone adjacent the end zone to redistribute to the fourth spacing. By these steps, a stent may be configured to expand so that the rings in the end zones bunch together upon expansion to provide a stent with enhanced radial support stiffness in the end zones, whereas rings in the middle zone spread apart upon expansion to provide a stent with reduced radial support stiffness in the middle zone.

[0015] However, in an alternative example causing the plurality of ring elements in the first zone to redistribute to a third spacing includes causing ring elements in a middle zone of the stent to redistribute to the third spacing. Additionally, causing the plurality of ring elements in the second zone to redistribute to a fourth spacing includes causing ring elements in an end zone adjacent the middle zone to redistribute to the fourth spacing. By these steps, a stent may be configured to expand so that the rings in the end zone spread apart upon expansion to provide a stent with reduced radial support stiffness in the end zone, whereas rings in the middle zone bunch together upon expansion to provide a stent with increased radial support stiffness in the middle.

[0016] In yet a further exemplary method expanding the stent may be configured to cause the plurality of ring elements in a middle zone to substantially maintain the ring spacing in the middle zone, while the rings in an end zone are caused to reduce the ring spacing upon expansion.

sion. Under this configuration, a stent may have end zones that are caused to increase their ring density upon expansion, while the middle zone retains the same ring density upon expansion. Thus, the resulting expanded stent may have an end zone with enhanced radial support stiffness compared with the middle zone. This variation allows the physician to select a stent that will have, upon expansion, greater radial support stiffness in the middle zone than compared with the stent of the first embodiment in which the ring density in the middle zone decreases upon expansion.

[0017] Thus it may be seen that under the various examples described here the geometric properties of the rings and their respective connector elements may be strategically utilized to provide a stent that actively reconfigures the spacing of ring elements in different zones of the stent to provide a stent with the desired ring densities, and hence different radial support stiffness, in different zones of the stent. In some embodiments, one or more end zones are given greater radial support stiffness than a middle zone, while in other embodiments, a middle zone may be given greater radial support stiffness than an end zone.

[0018] These and other advantages of the present invention will become apparent when read in conjunction with the figures and the detailed description of the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019]

FIG. 1 is an elevational view, partially in section, of a stent similar to that of the invention which is mounted on a delivery catheter and disposed within a damaged artery.

FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent is expanded within a damaged artery, pressing the damaged lining against the arterial wall.

FIG. 3 is an elevational view, partially in section showing the expanded stent within the artery after withdrawal of the delivery catheter.

FIG. 4 is a perspective view of a known expandable stent, shown in an unexpanded condition.

FIG. 5 is a perspective view of the known stent of FIG. 4, shown in an expanded condition.

FIG. 6 is a schematic "rolled out" view (in which a planar view is shown of a cylindrical surface) of a cylindrical stent having features of the present invention, shown in an unexpanded condition.

FIG. 7 is a schematic rolled out view of the stent of

FIG. 6, shown in an expanded condition.

FIG. 8 is a schematic rolled out view of a further example of a stent having features of the present invention, shown in an unexpanded condition.

FIG. 9 is a schematic rolled out view of the stent of FIG. 8, shown in an expanded condition.

FIG. 10 is a schematic rolled out view of a yet a further example of a stent having features of the present invention, shown in an unexpanded condition.

FIG. 11 is a schematic rolled out view of the stent of FIG. 10, shown in an expanded condition.

FIG. 12 is a detail view showing an aspect of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0020] With reference to the figures, a stent is described having features of the present invention.

[0021] As an initial explanation, FIG. 1 illustrates a stent 100 incorporating features of the invention which is mounted onto a delivery catheter 11. The stent generally comprises a plurality of radially expandable cylindrical elements 112 disposed generally coaxially and interconnected by elements 124, 126 disposed between adjacent cylindrical elements. (Better seen in FIGS. 6 and 7.) The delivery catheter 11 has an expandable portion or balloon 14 for expanding of the stent 100 within an artery 15. The artery 15, as shown in FIG. 1, has a dissected lining 16 which has occluded a portion of the arterial passageway. While this dissection is one possible defect that may be repaired with the stent of the current invention, its use is not so limited, but may also, for example, be used for treatment of arterial stenosis or plaque buildup. In areas with excess and varying plaque burden is found, a stent with varying radial stiffness along the axial length may be needed, a feature of the invention that is described more fully herein.

[0022] The delivery catheter 11 onto which the stent 100 is mounted, is essentially the same as a conventional balloon dilatation catheter used for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as Surlyn® manufactured by the Polymer Products Division of the Du Pont Company. Other polymers may also be used. In order for the stent 100 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 100 is compressed onto the balloon. A retractable protective delivery sleeve 20 may be provided to further ensure that the stent stays in place on the expandable portion of the delivery catheter 11 and prevent abrasion of the body lumen by the open surface

of the stent 100 during delivery to the desired arterial location. Other means for securing the stent 100 onto the balloon 14 may also be used, such as providing collars or ridges on the ends of the working portion, i.e. the cylindrical portion, of the balloon.

[0023] The delivery of the stent 100 may be accomplished in the following manner. The stent 100 may be first mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The balloon 14 may be slightly inflated to secure the stent 100 onto the exterior of the balloon. The catheter-stent assembly may be introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown). A guidewire 18 may be disposed across the damaged arterial section with the detached or dissected lining 16 and then the catheter-stent assembly may be advanced over a guidewire 18 within the artery 15 until the stent 100 may be directly under the detached lining 16. The balloon 14 of the catheter may be expanded, expanding the stent 100 against the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 is preferably expanded slightly by the expansion of the stent 100 to seat or otherwise fix the stent 100 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough.

[0024] The stent 100 may serve to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 100 from an elongated tubular member, the undulating component of the cylindrical elements of the stent 100 may be relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements 112 are pressed into the wall of the artery 15 and as a result do not interfere with the blood flow through the artery 15. The cylindrical elements 112 of stent 100 which are pressed into the wall of the artery 15 will eventually be covered with endothelial cell growth which further minimizes blood flow interference. The undulating portion of the cylindrical sections 112 provide good tacking characteristics to prevent stent movement within the artery. Furthermore, the closely spaced cylindrical elements 112 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15 as illustrated in FIGS. 2 and 3.

[0025] In the examples of FIG. 6 through FIG. 11, a stent includes a plurality of interconnected undulating rings 112, each configured according to known principles to be capable of being compacted to a reduced or unexpanded diameter suitable for delivery within the vasculature of a patient (as, for example, in FIG. 6), and of being expanded to an enlarged diameter suitable for scaffolding the vasculature at a desired location (as in FIG. 7). Each ring 112 includes a plurality of struts 114 having an orientation to the axis 101 (as seen in FIG. 3) of the stent and each strut is connected to an adjacent

strut by a curved elbow 116. Due to this curve, each elbow 116 has a concave side 118 and a convex side 120 as seen in FIG. 12.

[0026] In some embodiments, the rings 112 of the stent may all be substantially similar to each other in geometric shape, width, thickness, and metallurgical composition. As used herein, the term "substantially" similar in geometric shape, or otherwise, means that each dimensions on one ring are within 20% of the dimensions on another ring. In some embodiments, when the stent 100 is in an unexpanded diameter, the rings 112 may be distributed at substantially even spacing over the axial length of the stent (as seen in FIGS. 6, 8 and 10), thereby tending to provide the stent with a generally uniform axial flexibility for delivery within the vasculature of a patient.

[0027] FIGS. 6 and 7 exemplify a stent 100 not of the present invention. This example has two notional end zones A and C which are configured differently than a middle zone B positioned between the end zones. As will be described herein, the end zones A, C are configured so that, when expanded, they provide the stent with a greater radial support stiffness than the middle zone B. The term "radial support stiffness" is used herein to mean the ability to withstand radially inward forces per unit length of the stent. The term "end zone" is used herein to mean a zone of the stent that includes a terminal end of the stent. The term "middle zone" as used herein is used to mean a zone of the stent that is not an end zone.

[0028] FIG. 6 shows a schematic "rolled out" view of a cylindrical stent having features of the present embodiment, in which a planar view is shown of a cylindrical surface, of the geometric configuration of the cylindrical stent 100 of the present embodiment in an unexpanded condition. FIG. 7 shows (also in a rolled out view) the same stent 100 in an expanded condition, and is drawn to a smaller scale than FIG. 6.

[0029] The advantages of this example are achieved as follows: With regard to the end zones A and C, each ring 112 in an end zone is connected to an adjacent ring by way of a connector 124 that connects a convex portion 120 of an elbow 116 of one ring 112 to a convex portion 120 of an elbow of an adjacent ring. This means that any two adjacent rings in the end zones are connected to each other across a small gap between the two rings and as a result the connector 124 is relatively short, or in some examples the connector 124 may have a negligible or zero notional "length" thus allowing the rings to connect to each other directly at convex points. This configuration of a direct connection between rings is also within the scope of the term connector 124 as used herein.

[0030] An end zone includes not less than three rings. The significance of such "convex to convex" connection is that, when the stent 100 is expanded, it adopts a configuration that is exemplified in FIG. 7, where it is seen that adjacent rings 112 that are connected to each other by a "convex to convex" connection configuration are necessarily drawn towards each other as the stent is expanded. Thus, for example, the distances p1, q1 and r1

separate the axial centerpoints of the rings in the left end zone of the unexpanded stent 10 shown in FIG. 6. When expanded to the configuration shown in FIG. 7, the axial centerpoints of the rings become separated by the distances p_2 , q_2 and r_2 , each of which is necessarily smaller than the corresponding distances of the unexpanded configuration. The advantage of this effect will be described more fully below.

[0031] With regard to the middle zone B, each ring 112 in the middle zone is connected to an adjacent ring by way of a connector 126 that connects a concave side 118 of an elbow 116 on one ring 112 to a concave side of an elbow on an adjacent ring. This "concave to concave" connection configuration means that any two adjacent rings in the middle zone B are connected to each other across a relatively large space between structure on the two adjacent rings.

[0032] A middle zone B includes not less than three rings 112, and each ring in the middle zone is connected to an adjacent ring in the middle zone in such "concave to concave" configuration. The significance of such connection is that, when the stent 100 is expanded, it adopts a configuration exemplified in FIG. 7 in which adjacent rings that are connected to each other are necessarily caused to move away from each other when the stent is expanded. Thus, the distances s_1 , t_1 , u_1 , v_1 , w_1 separate the axial centerpoints of the rings 112 in the middle zone of the unexpanded stent 10 shown in FIG. 6. When expanded to the configuration shown in FIG. 7, the axial centerpoints of the rings become separated by the distances s_2 , t_2 , u_2 , v_2 , w_2 each of which is larger than the corresponding distances of the unexpanded configuration.

[0033] Thus, according to the description and explanation set forth above, the expansion of the stent 100 from the unexpanded condition to the expanded condition results in the following advantages. The end zones A, C of the stent contract in axial length. This contraction upon expansion has the effect of increasing the number of rings 112 per unit of axial length of the stent in the end zones compared with the unexpanded condition -- and thereby increases the "ring density" in those zones compared with the ring density in the unexpanded condition. At the same time, the stent expansion results in the middle zone B increasing in axial length and therefore decreasing the ring density in that portion compared with the ring density in the unexpanded condition. As used herein, the term "ring density" means the number of rings per unit length of stent. It will be appreciated that an appropriate selection of the number of rings in the end zones and the middle zone can result in the overall length of the stent 100 remaining substantially constant during expansion because the shortening effect of the end zones A, C will be offset by the lengthening effect of the middle zone B. This provides a first advantage of the example because despite the local redistribution of ring spacing over the length of the stent caused by expansion, the stent's overall length may nevertheless remain constant

and thus may allow a physician to appropriately select the length of the unexpanded stent to match the length of the arterial lesion. Further, as a second advantage arising upon expansion of the stent, the increased ring density in the end zones A, C results in an increased radial support stiffness in those zones while the decreased ring density in the middle zone B causes a reduced radial support stiffness in that zone.

[0034] In a second example, shown in FIGS. 8 and 9, the stent 102 of has two notional ends zones E and G which are configured different than a middle zone F positioned between the end zones. The end zones E, G of this example are configured as the middle zone B of the previous example, and the middle zone F of this embodiment is configured as the end zones A, C of the previous example. Thus, the middle zone F is configured so that, when expanded, it provides the stent with a greater radial support stiffness than the end zones E, G.

[0035] Described in detail, each ring 112 in the end zones is connected to an adjacent ring by way of a connector 126 that connects a concave side 118 of an elbow 116 on one ring 112 to a concave side of an elbow on an adjacent ring. This "concave to concave" connection configuration means that any two adjacent rings in an end zone are connected to each other across a large space between structure on the two rings. The end zones E, G include not less than three rings 112, and each ring in an end zone is connected to an adjacent ring in an end zone in such "concave to concave" configuration. The significance of such connection is that, when the stent 102 is expanded, it adopts a configuration exemplified in FIG. 9 in which adjacent rings that are connected to each other are necessarily caused to move away from each other when the stent is expanded. Thus, for example, the distances a_1 , b_1 separate the axial centerpoints of the rings 112 in the end zone of the unexpanded stent 10 shown in FIG. 8. When expanded to the configuration shown in FIG. 9 (drawn to a smaller scale than FIG. 8), the axial centerpoints of the rings become separated by the distances a_2 , b_2 , each of which is larger than the corresponding distances of the unexpanded configuration.

[0036] With regard to the middle zone F, each ring 112 in the middle zone is connected to an adjacent ring by way of a connector 124 that connects a convex portion 120 of an elbow 116 of one ring 112 to a convex portion 120 of an elbow of an adjacent ring. This means that any two adjacent rings in the middle zone F of this embodiment are connected to each other across a small gap between the two rings and as a result the connector 124 is relatively short. The middle zone includes not less than three rings. The significance of such "convex to convex" connection is that, when the stent 102 is expanded, it adopts a configuration that is exemplified in FIG. 9, where it is seen that adjacent rings 112 that are connected to each other by a "convex to convex" connection configuration are necessarily drawn towards each other as the stent is expanded. Thus, the distances c_1 , d_1 , e_1 , f_1 , g_1 ,

and h1 separate the axial centerpoints of the rings in the center zone of the unexpanded stent 102 shown in FIG. 8. When expanded to the configuration shown in FIG. 9, the axial centerpoints of the rings become separated by the distances c2, d2, e2, f2, and h2, each of which is necessarily smaller than the corresponding distances of the unexpanded configuration.

[0037] This provides a first advantage of this example of stent 102 because despite the local redistribution of ring spacing over the length of the stent caused by expansion, the stent's overall length may (if the correct number of rings are selected for each zone) nevertheless remain constant and thus may allow a physician to appropriately select the length of the unexpanded stent to match the length of the arterial lesion. Further, as a second advantage arising upon expansion of the stent, the decreased ring density in the end zones E, G results in a decreased radial support stiffness in those zones while the increased ring density in the middle zone F causes an increased radial support stiffness in that zone.

[0038] The advantages arise where the needs of the surgeon in relation to the vascular condition before her are the converse of those with regard to the use of the first embodiment.

[0039] In a third example, shown in FIGS. 10 and 11, the stent 104 of this embodiment has two notional ends zones J and L which are configured differently than a middle zone K positioned between the end zones. The end zones of this example are configured the same as the end zones of the first embodiment 100 (FIGS. 6 and 7) but the middle zone K of this embodiment is configured so that, when expanded, it does not tend to lengthen or shorten.

[0040] Specifically, with regard to the middle zone K, each ring 112 in the middle zone is connected to an adjacent ring by way of a connector 128 that connects a convex portion 120 of an elbow 116 of one ring 112 to a concave portion 118 of an elbow of an adjacent ring. Preferably, the middle zone of this embodiment includes not less than three rings 112. The significance of such "convex to concave" connection is that, when the stent 104 is expanded, it adopts a configuration that is exemplified in FIG. 11, where it is seen that adjacent rings 112 that are connected to each other by a "convex to concave" connection configuration necessarily maintain the spacing between the rings as the stent is expanded. Thus, the distances aa1, and bb1 separate the axial centerpoints of the rings in the left end zone of the unexpanded stent 104 shown in FIG. 10. When expanded to the configuration shown in FIG. 11, the axial centerpoints of the rings become separated by the distances aa2, and bb2, each of which is substantially the same as the corresponding distances of the unexpanded configuration. This permits a stent that, upon expansion, has increased ring density in the end zones, and thus increased radial support stiffness in the end zones J, L compared to the middle zone K.

[0041] In a variation of the example shown in FIG. 11,

and the preferred embodiment one of the end zones may, instead of being comprised of rings connected to each other by "convex to convex" connection, may be comprised of rings connected by "concave to concave" connection. It will be appreciated that, according to the principles of the invention, in this embodiment the stent will have a gradually decreasing radial stiffness extending from one end to the other. A first end zone will be radially stiffer than an adjacent middle zone, which in turn will be stiffer than a second end zone.

[0042] Thus, there is described an advantageous system that provides a solution to problems encountered in the prior art. The present invention may, of course, be carried out in other specific ways than those herein set forth without departing from the essential characteristics of the invention. For example, combinations of the different kinds of zone described may be combined with each other in sequences not expressly stated or illustrated, and thus, the present embodiments are to be considered in all respects as illustrative and not restrictive, while the scope of the invention is set forth in the claims that follow.

Claims

1. An expandable axially elongate stent (100) comprising:

a plurality of undulating ring elements (112) configured to be expandable from an unexpanded condition to an expanded condition, the ring elements (112) being positioned one adjacent to another along an axis, wherein, each ring element (112) includes a plurality of struts (114) having an orientation in relation to the axis and each strut (114) is connected to an adjacent strut (114) by a curved elbow (116); and each curved elbow has a concave portion (118) and a convex (120) portion, further wherein, a first end zone of the stent includes a plurality of ring elements (112), not less than three in number, and each ring element (112) in the first end zone is connected to an adjacent ring element (112) in the first end zone by at least one connector (124) extending from a convex (120) portion of one ring to a convex (120) portion of an adjacent ring (112); further wherein, a middle zone of the stent positioned adjacent the first end zone includes a plurality of ring elements (112), not less than three in number, and each ring element (112) in the middle zone is connected to an adjacent ring element (112) in the middle zone by at least one connector (124) extending from a concave (118) portion of one ring (112) to a convex (120) portion of an adjacent ring (112), and further wherein a second end zone of the stent

includes a plurality of ring elements (112) and each ring element (112) in the second end zone is connected to an adjacent ring element (112) in the second end zone by at least one connector (124) extending from a concave (118) portion of one ring to a concave (118) portion of an adjacent ring,
 whereby the stent when expanded presents a gradually decreasing radial stiffness extending from said first end zone to said second end zone.

2. The stent of claim 1, wherein the at least one connector (120) in the first end zone is oriented parallel to the stent axis.
3. The stent of claim 1, wherein the at least one connector (124) in the middle zone is oriented parallel to the stent axis.
4. The stent of claim 1, wherein all the ring elements (112) in the stent (110) in an unexpanded condition are substantially similar to each other in geometric shape.
5. The stent of claim 1, wherein all the ring elements (112) in the stent (100) in an unexpanded condition are distributed at substantially even intervals over the axial length of the stent (100).

Patentansprüche

1. Ausziehbarer axial lang gestreckter Stent (100), umfassend:

mehrere gewellte Ringelemente (112), die dazu ausgestaltet sind, aus einem nicht ausgezogenen Zustand in einen ausgezogenen Zustand ausziehbar zu sein, wobei die Ringelemente (112) einander benachbart entlang einer Achse angeordnet sind, wobei jedes Ringelement (112) mehrere Streben (114) aufweist, die eine Ausrichtung bezogen auf die Achse aufweisen, und jede Strebe (114) durch ein gekrümmtes Winkelstück (116) mit einer benachbarten Strebe (114) verbunden ist; und jedes gekrümmte Winkelstück einen konkaven Abschnitt (118) und einen konvexen Abschnitt (120) aufweist,
 wobei ferner ein erster Endbereich des Stents mehrere, zahlenmäßig nicht weniger als drei, Ringelemente (112) aufweist und jedes Ringelement (112) in dem ersten Endbereich durch mindestens ein Verbindungsstück (124), das sich von einem konvexen Abschnitt (120) eines Rings zu einem konvexen Abschnitt (120) eines benachbarten Rings (112) erstreckt, mit einem benachbarten Ringelement (112) in dem ersten

Endbereich verbunden ist;
 wobei ferner ein mittlerer Bereich des Stents, der dem ersten Endbereich benachbart angeordnet ist, mehrere, zahlenmäßig nicht weniger als drei, Ringelemente (112) aufweist und jedes Ringelement (112) in dem mittleren Bereich durch mindestens ein Verbindungsstück (124), das sich von einem konkaven Abschnitt (118) eines Rings (112) zu einem konvexen Abschnitt (120) eines benachbarten Rings (112) erstreckt, mit einem benachbarten Ringelement (112) in dem mittleren Bereich verbunden ist, und wobei ferner ein zweiter Endbereich des Stents mehrere Ringelemente (112) aufweist und jedes Ringelement (112) in dem zweiten Endbereich durch mindestens ein Verbindungsstück (124), das sich von einem konkaven Abschnitt (118) eines Rings zu einem konkaven Abschnitt (118) eines benachbarten Rings erstreckt, mit einem benachbarten Ringelement (112) in dem zweiten Endbereich verbunden ist,
 wodurch der Stent, wenn er ausgezogen ist, eine allmählich abnehmende radiale Steifigkeit aufweist, die sich von dem ersten Endbereich zu dem zweiten Endbereich erstreckt.

2. Stent nach Anspruch 1, wobei das mindestens eine Verbindungsstück (124) in dem ersten Endbereich parallel zur Stentachse ausgerichtet ist.
3. Stent nach Anspruch 1, wobei das mindestens eine Verbindungsstück (124) in dem mittleren Bereich parallel zur Stentachse ausgerichtet ist.
4. Stent nach Anspruch 1, wobei alle Ringelemente (112) in dem Stent (100) in einem nicht ausgezogenen Zustand einander in ihrer geometrischen Form im Wesentlichen ähnlich sind.
5. Stent nach Anspruch 1, wobei alle Ringelemente (112) in dem Stent (100) in einem nicht ausgezogenen Zustand in im Wesentlichen gleichmäßigen Abständen über die axiale Länge des Stents (100) verteilt sind.

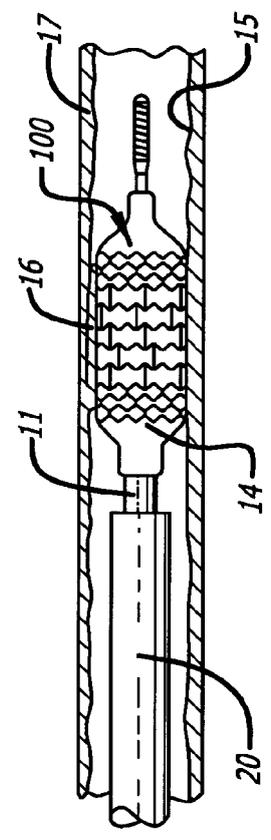
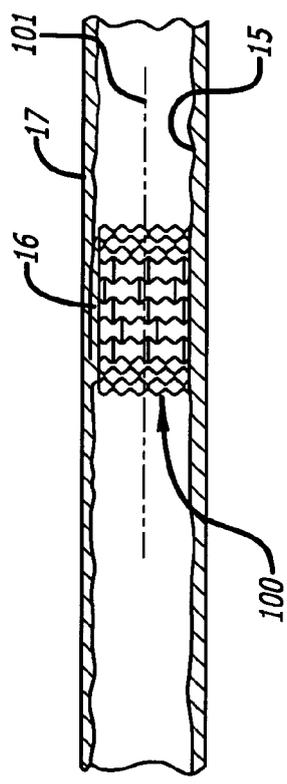
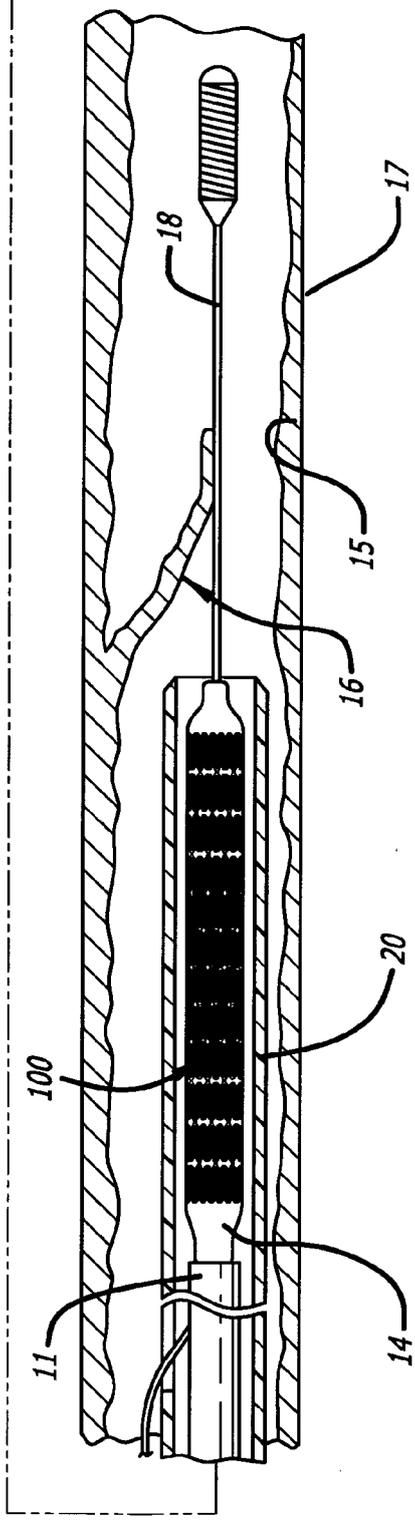
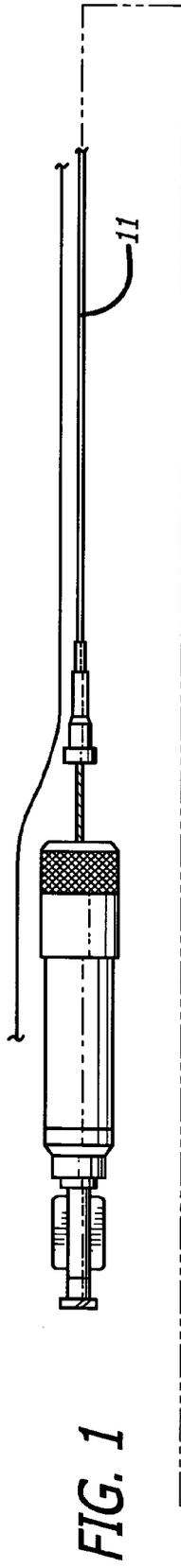
Revendications

1. Endoprothèse allongée expansible radialement (100) comprenant :

une pluralité d'éléments annulaires ondulés (112) conçus pour être extensible d'un état non dilaté à un état dilaté, les éléments annulaires (112) étant positionnés adjacents les uns par rapport aux autres le long d'un axe, dans laquelle,
 chaque élément annulaire (112) comprend une

- pluralité de croisillons (114) ayant une orientation par rapport à l'axe et chaque croisillon (114) est connecté à un croisillon adjacent (114) par un coude courbé (116) ; et
- chaque coude courbé a une partie concave (118) et une partie convexe (120) ;
- dans laquelle, en outre, une première zone terminale de l'endoprothèse comprend une pluralité d'éléments annulaires (112) dont le nombre n'est pas inférieur à trois et chaque élément annulaire (112) de la première zone terminale est connecté à un élément annulaire adjacent (118) de la première zone terminale par au moins un connecteur (124) s'étendant depuis une partie convexe (120) d'un anneau jusqu'à une partie convexe (120) d'un anneau adjacent (112) ;
- dans laquelle, en outre, une zone centrale de l'endoprothèse positionnée adjacente à la première zone terminale comprend une pluralité d'éléments annulaires (112) dont le nombre n'est pas inférieur à trois et chaque élément annulaire (112) de la zone centrale est connecté à un élément annulaire adjacent (112) de la zone centrale par au moins un connecteur (124) s'étendant depuis une partie concave (118) d'un anneau (112) jusqu'à une partie convexe (120) d'un anneau adjacent (112) ; et
- dans laquelle, en outre, une seconde zone terminale de l'endoprothèse comprend une pluralité d'éléments annulaires (112) et chaque élément annulaire (112) de la seconde zone terminale est connecté à un élément annulaire adjacent (112) de la seconde zone terminale par au moins un connecteur (126) s'étendant depuis une partie concave (118) d'un anneau jusqu'à une partie concave (118) d'un anneau adjacent, l'endoprothèse présentant à l'état dilaté une rigidité axiale diminuant radialement et s'étendant depuis ladite première zone terminale jusqu'à ladite seconde zone terminale.
2. Endoprothèse selon la revendication 1, dans laquelle l'au moins un connecteur (124) de la première zone terminale est orienté parallèlement à l'axe de l'endoprothèse.
3. Endoprothèse selon la revendication 1, dans laquelle l'au moins un connecteur (124) de la zone centrale est orienté parallèlement à l'axe de l'endoprothèse.
4. Endoprothèse selon la revendication 1, dans laquelle tous les éléments annulaires (112) de l'endoprothèse (100) en état non dilaté sont sensiblement similaires les uns aux autres par leur forme géométrique.
5. Endoprothèse selon la revendication 1, dans laquelle tous les éléments annulaires (112) de l'endopro-

thèse (100) en état non dilaté sont répartis suivant des intervalles sensiblement égaux sur la longueur axiale de l'endoprothèse (100).



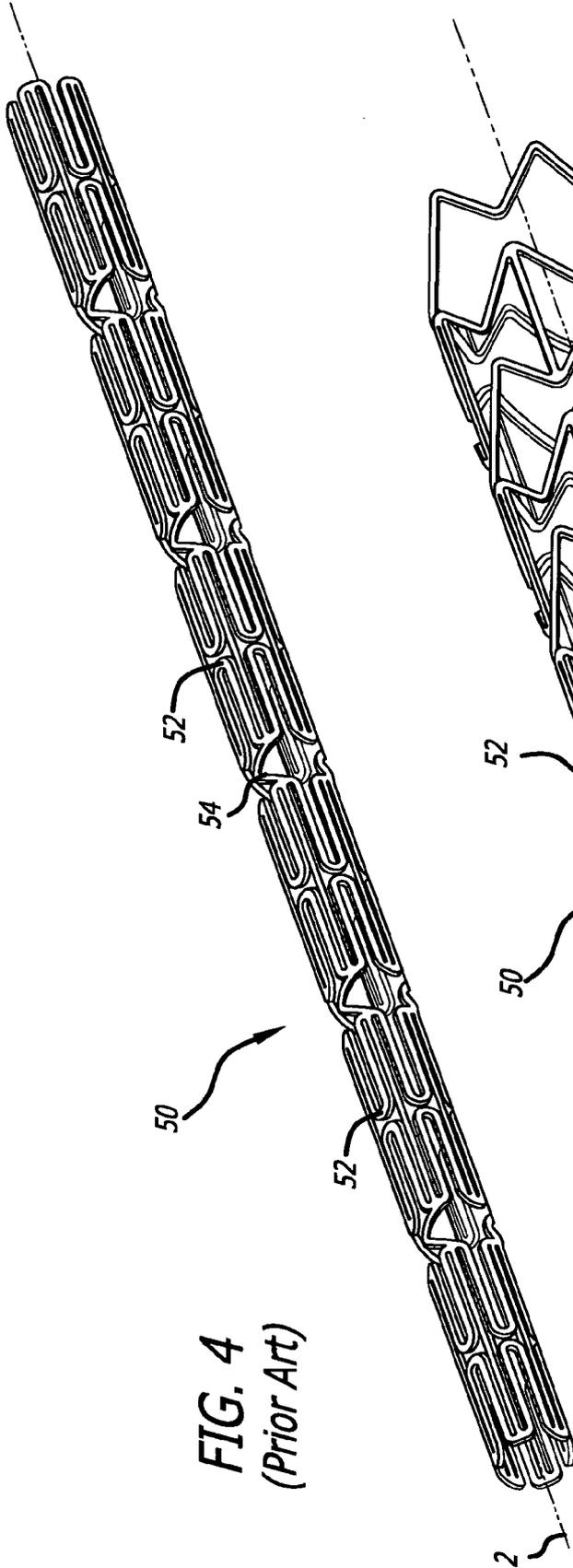


FIG. 4
(Prior Art)

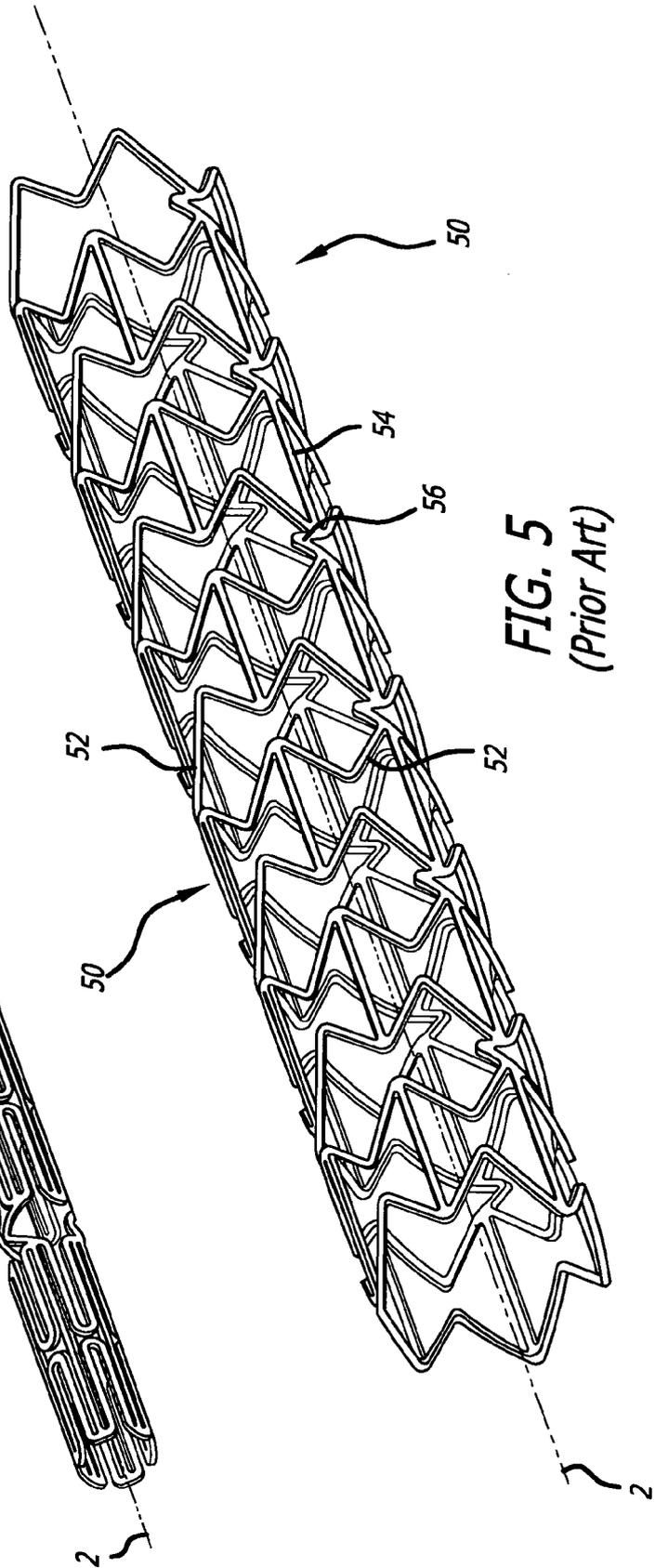
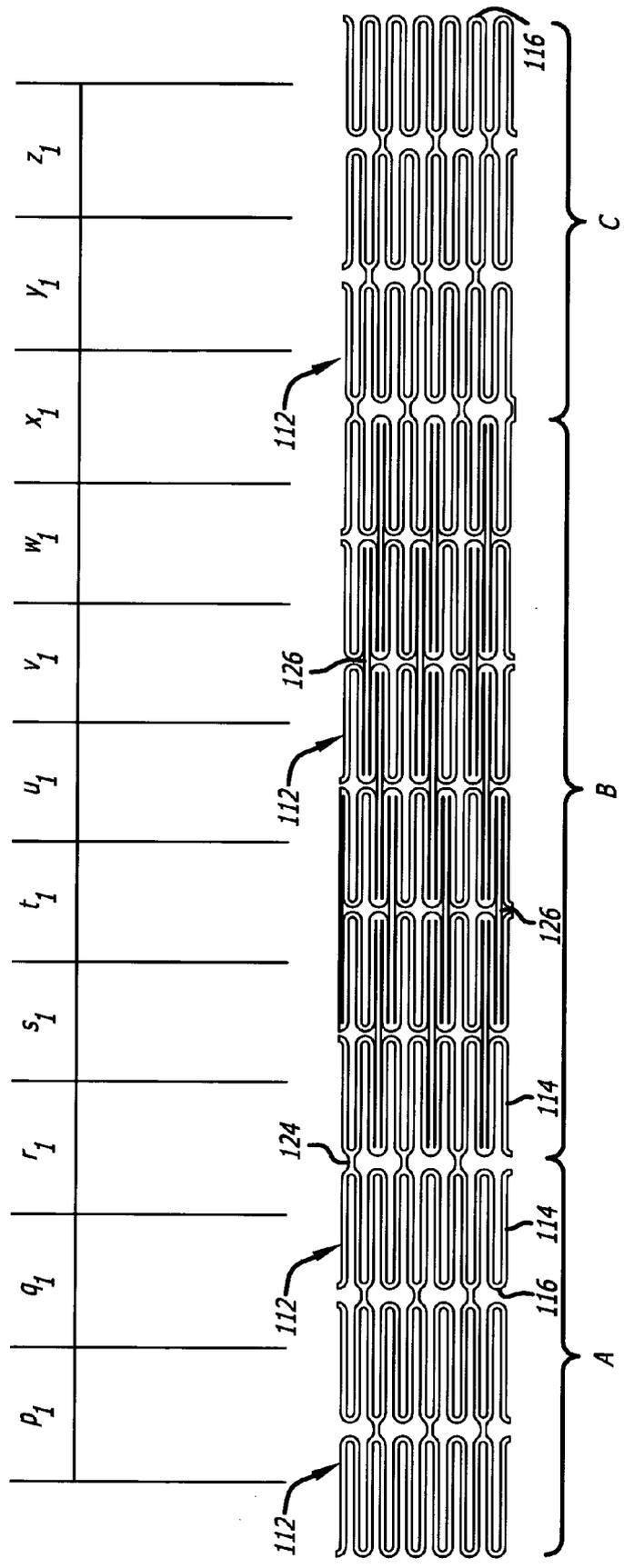


FIG. 5
(Prior Art)

100

FIG. 6



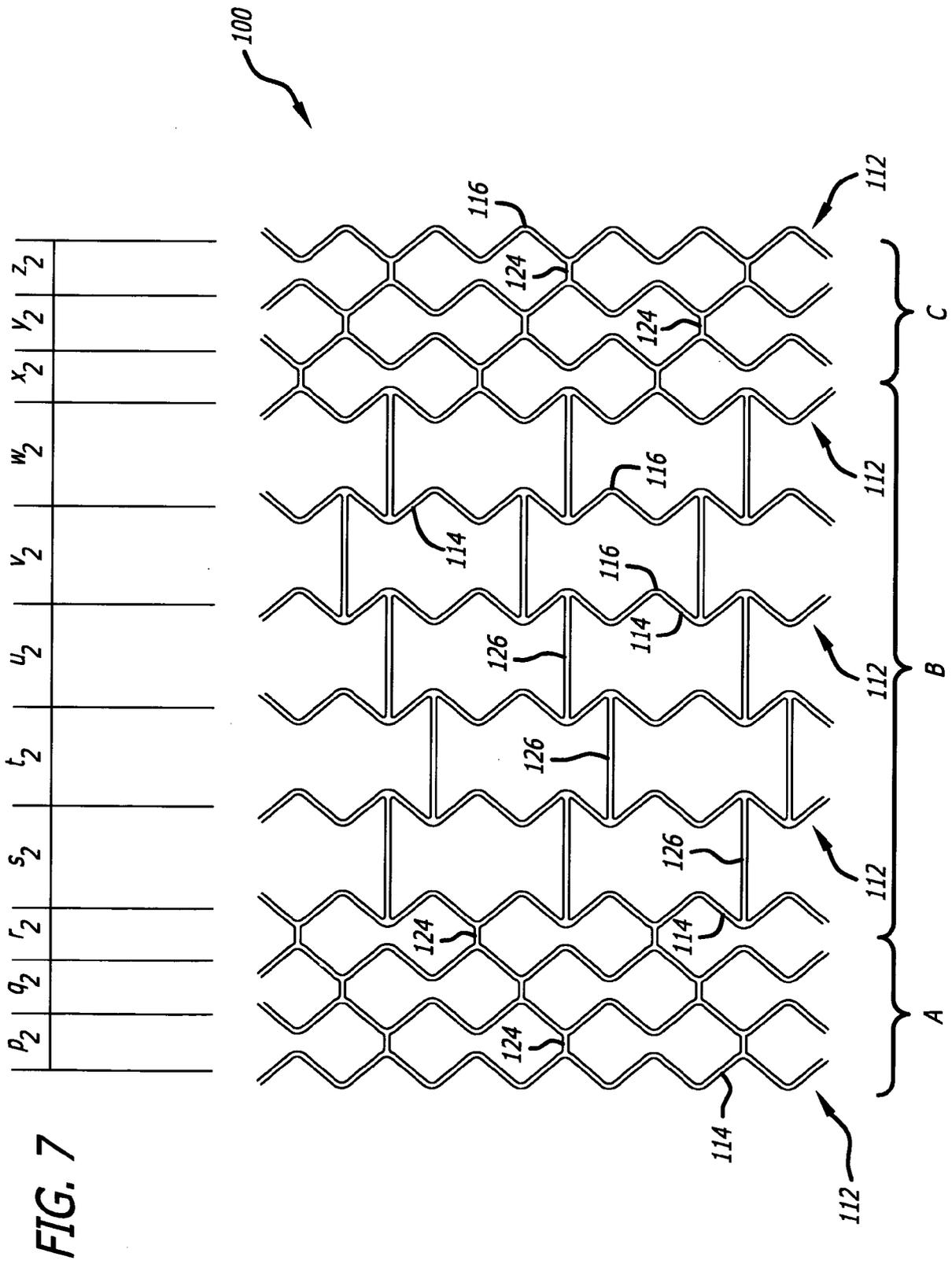
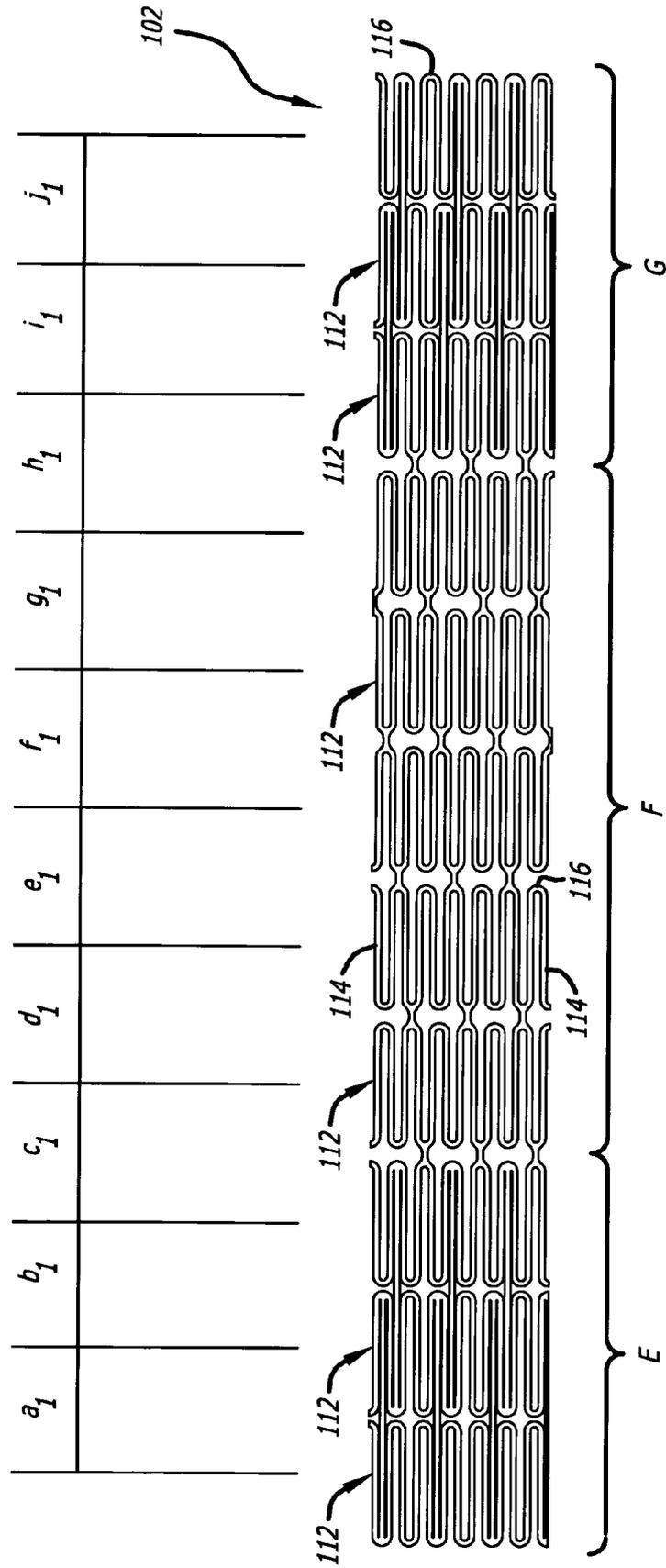


FIG. 8



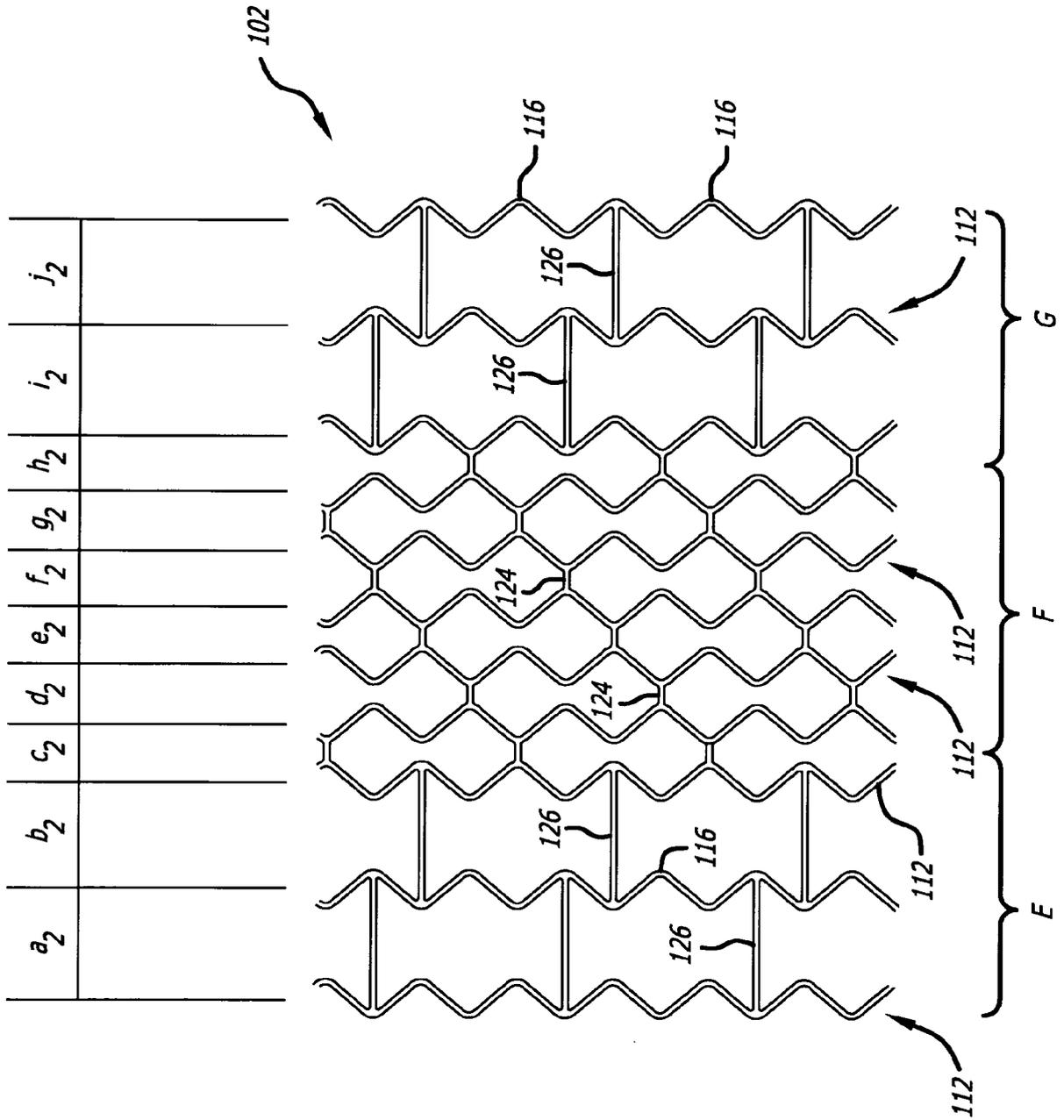


FIG. 9

104

FIG. 10

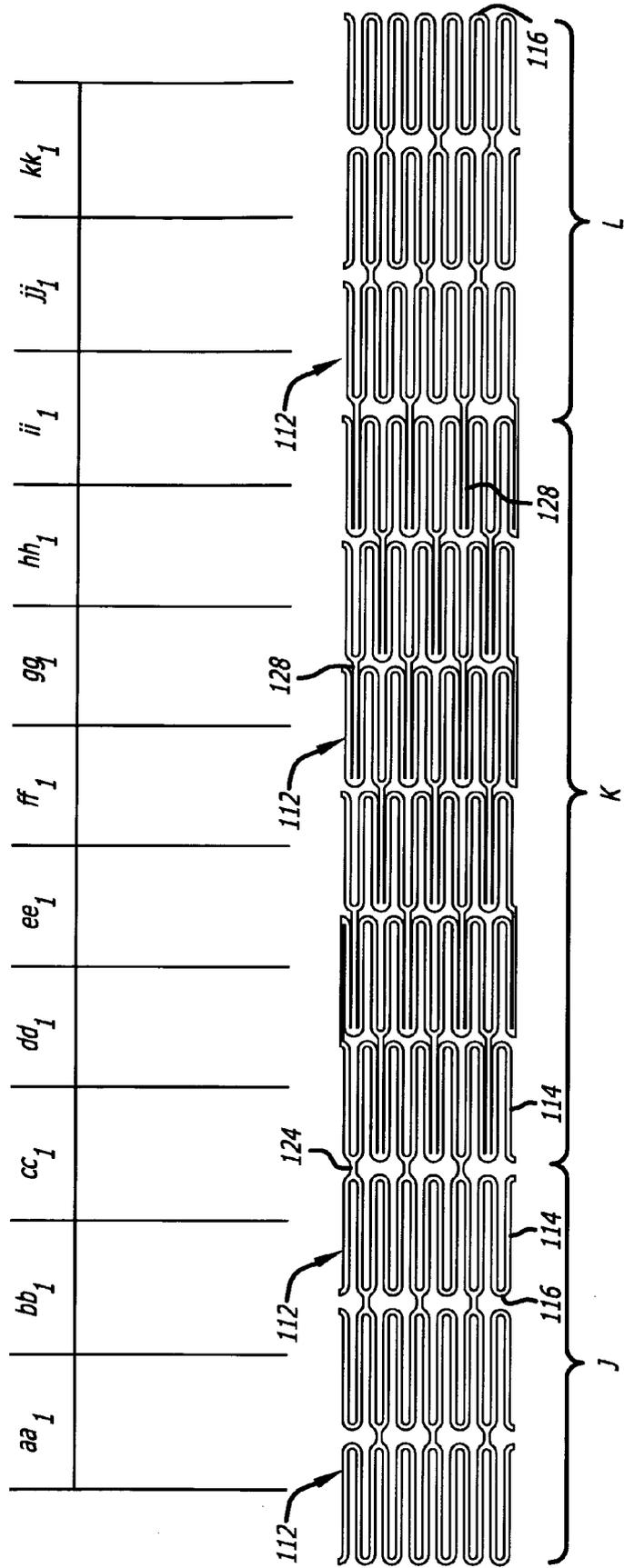


FIG. 11

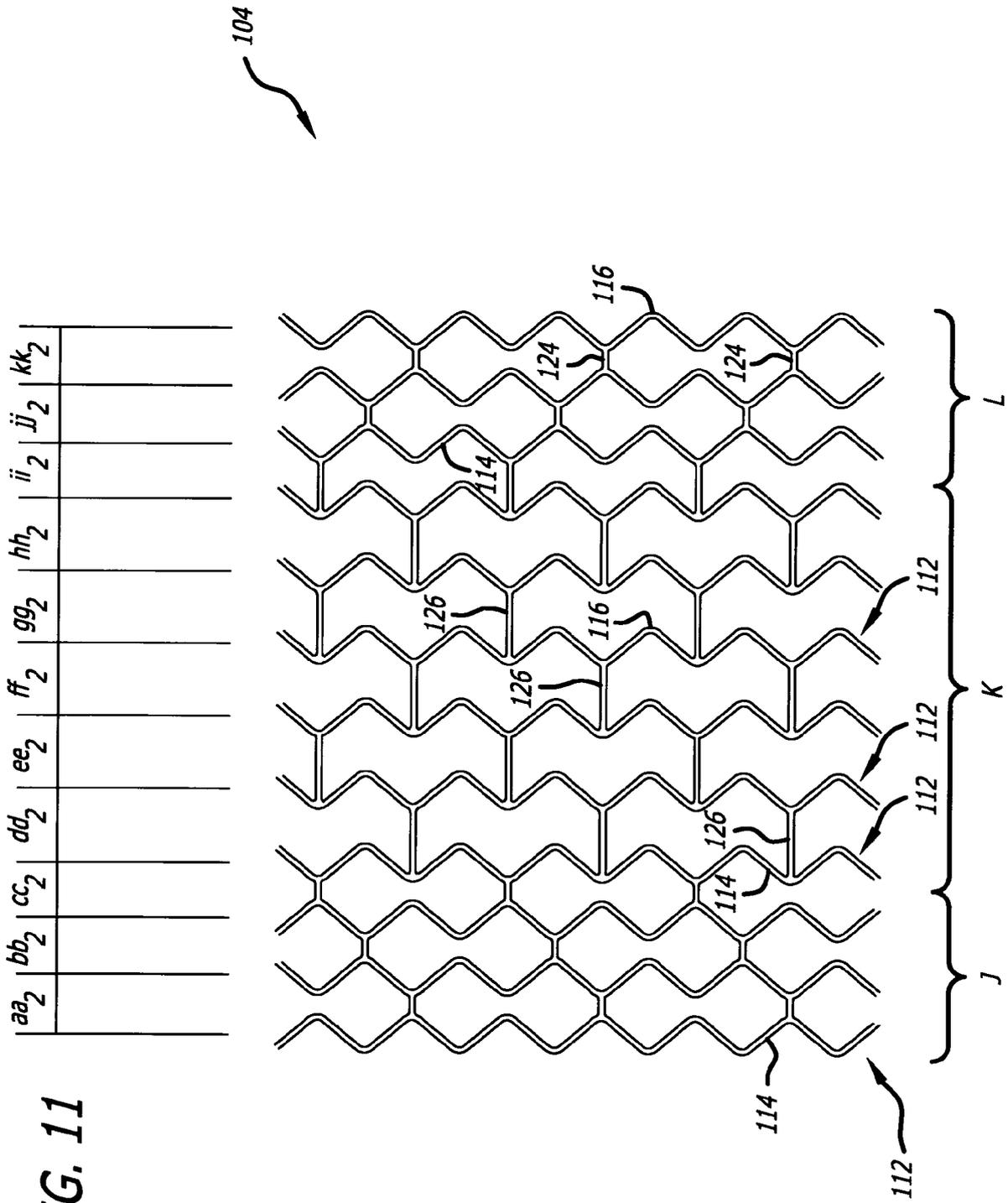
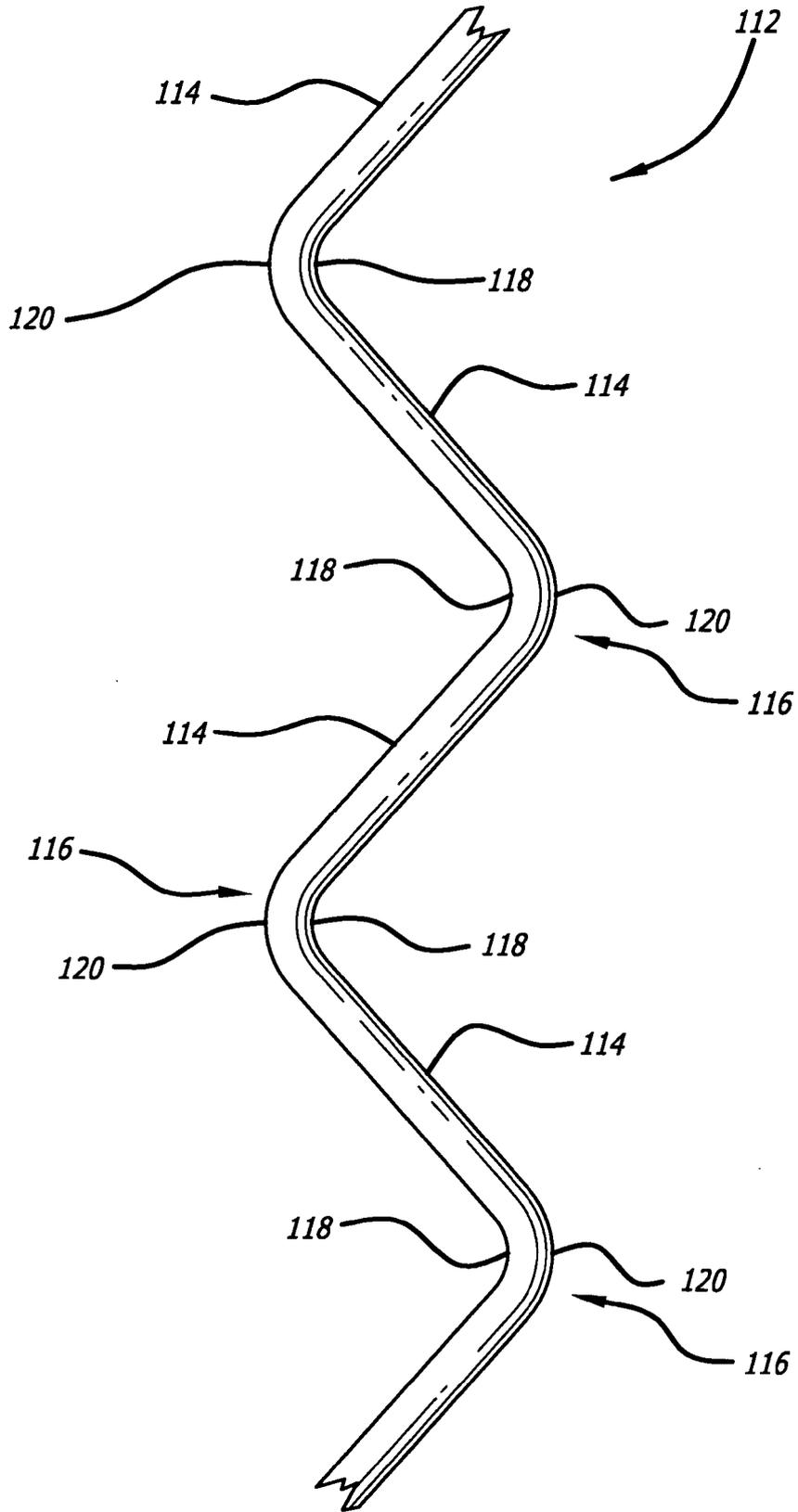


FIG. 12



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 2007276464 A [0005]
- US 2007150046 A [0005]