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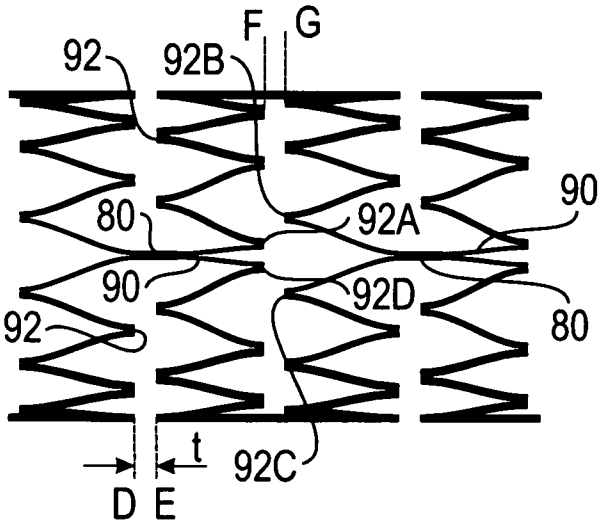
(54) **Title:** BEND-CAPABLE TUBULAR PROSTHESIS



(57) **Abstract:** Stent exhibiting a succession of turns around the axis, adjacent turns being connected by connector portions distributed around the circumference of the prosthesis, each of the turns being made up of struts that extend the length of the turn and are interspersed by inflection zones located at the axial ends of each of the turns. When the prosthesis expands radially, gaps open up between adjacent struts of each of the turns, the inflection zones being distributed regularly around the circumference so that the gaps are substantially the same size as each other around the circumference of the turn, characterised in that at least every second turn exhibits a stagger zone within which the said gap between adjacent said struts is of an individual size different from that common to the other gaps of that second turn.

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Bend-capable tubular prosthesis

Technical field

This invention relates to tubular medical prostheses that are expandable from a radially compact disposition to a radially expanded disposition. In the compact disposition, the prosthesis can by delivered to its operational site in the body, typically trans-luminally and percutaneously, using a delivery system which is a sort of catheter. Exemplary of this class of prosthesis is a nickel titanium shape memory alloy stent for a bodily lumen which is often but not always an arterial lumen. See for example the disclosure of applicant's earlier WO 01/32102.

Background

Bodily soft tissue is remarkably flexible and needs generally to be flexible. It is difficult for a metal stent to match bodily tissue for flexibility. WO 01/32102 is concerned with flexibility of the stent during its journey, from outside the body to the operational site within the body, as for example the catheter delivery system advances along a tortuous path from the point of entry in the body. However, there is also a need for metal stents (and other prostheses) that are destined to be installed at a location in the body where severe bending is to be expected. If the prosthesis could be made more tolerant of severe bending after placement, that would be attractive to doctors and their patients.

WO 01/32102 shows what could be termed a "classic" self-expanding stent structure of zig-zag stenting rings composed of struts interspersed by points of inflection and with

adjacent stenting rings linked axially by connector portions. In the compact delivery disposition of the stent (Fig. 3 of WO 01/32102) the struts of the zig-zag rings are more or less parallel to each other so that each point of inflection represents a change of direction for the material of the stenting ring of more or less 180°. As the stent expands to its deployed configuration (Fig. 4 of WO 01/32102) the radius of the stenting ring expands by movement of the struts away from each other so that gaps open up between adjacent struts, and the adjacent points of inflection move further apart (but nevertheless remain spaced at equal intervals to each other around the circumference of the stenting ring).

The connectors serve to restrain relative circumferential movement of the zig-zag rings relative to each other. Thus, if the points of inflection of adjacent stenting rings are facing each other in the compact delivery disposition of the stent, as in WO 01/32102, then so will be these points of inflection still facing each other in the expanded disposition of the stent. When an expanded stent is subject, in the body, to extreme bending, so that the longitudinal axis of the stent is no longer a straight line but a pronounced curve (as in a banana), then the facing points of inflection on the inside of the bend approach each other. The more extreme the bending, the closer the facing points of inflection become until, in the end, these facing "peaks" abut each other or rub past each other.

Any such abutment or rubbing is undesirable. One way to guard against it is to choose a stent design that can be classified as a "peak-to-valley" design rather than a "peak-to-peak" design as seen in applicant's WO 01/32102. The art is replete with suggestions for peak-to-valley designs in which the peaks of any one zig-zag stenting ring do not face corresponding peaks of the next adjacent stenting ring but, instead, are circumferentially offset to the peaks of the next adjacent stenting ring by half of the gap between two

adjacent peaks of the same ring, in the expanded disposition of the stent. Then, under extreme bending, any particular peak on the inside of the bend can advance into the V-shaped space between two peaks of the next adjacent stenting ring, without any abutment or rubbing on any portion of the material of the next adjacent stenting ring.

The present invention is concerned with the above-explained problem. It seeks to improve the in situ bend capability of stents including those seen in WO 01/32102. However, the invention also seeks to achieve this performance enhancement without sacrificing other attractive qualities of stents such as disclosed in WO 01/32102. For example, simplicity of modelling of stress distributions within the stent is attractive in the management of fatigue performance of metal stents. Manufacturing simplicity of course facilitates management of cost which should improve access to stents, for those people who need them.

Looking at WO 01/32102, one can quickly see that performance in extreme bending could be enhanced by extending the length of the portions that connect adjacent zig-zag stenting rings. The longer these "bridges" then the more the stent can bend without abutment of peaks on the inside of the bend. However, large axial gaps between adjacent stenting rings are not desirable, for then the tissue of the lumen that is being stented by the prosthesis is relatively unsupported, at least between adjacent stenting rings.

For the same reason, one seeks as far as possible to distribute the metallic material of the stent as evenly as possible over the length and circumference of the tubular envelope of the stent so that support for the stented tissue is as even and uninterrupted as possible. This of course indicates that all gaps between all adjacent struts and points of inflection of the stent matrix should be as constant as possible. Generally, one does not modulate the

strut matrix of a stent, over the length and circumference of the stent, to suit tissue variations within the stenting site. Generally, one does not seek to place a particular point on the circumference of the stent in opposition to a particular zone of tissue within the stenting site. For these reasons alone, one seeks a stent matrix that is everywhere the same over the length and circumference of the prosthesis.

In principle, the problem addressed in the present invention, and the solution here disclosed, is useful in all classes of stenting prostheses. That is to say, it works with a stent matrix that exhibits the (spiral) turns around the axis of a helical stent, as well as with a stent that features a stack of endless stenting rings. It works with balloon-expandable stents and resilient self-expanding stents as well as with nickel titanium shape memory alloy stents.

Summary of the invention

Nevertheless, according to the present invention, it is contemplated to depart from the prior good design practice, and deliberately configure the stent matrix so that it is locally different, at one point at least, around the circumference of at least every second stenting ring within the prosthesis. In short, we envisage within each stenting ring at least one location (we call it a "stagger zone") where the gap between adjacent points of inflection is smaller (but it could be greater) than the otherwise constant (or near constant) "wavelength" around the circumference of the prosthesis for that particular stenting ring.

It will be appreciated that, for any particular pair of adjacent stenting rings, even just one such abnormal gap (stagger zone) could be enough to set up a circumferential offset between the otherwise facing "peak-to-peak" points of inflection that we see in, for example, Fig. 4 of WO 01/32102. In practice, however, a design with only one

stagger zone on the circumference might not be enough to deliver the desired circumferential offset all around the circumference, especially in designs that feature a large number of struts, in any one turn around the axis of the prosthesis. Four stagger zones are likely to be enough. Designs with two, three or four such zones are presently preferred, but up to 6 stagger zones per turn are readily conceivable, the more so with stent design with a notably small mesh size in their matrix.

As mentioned above, it is the connectors between adjacent stenting rings that prevent adjacent stenting rings from rotating around the long axis of the prosthesis relative to each other and thereby preserve the designed intended relationship between facing stenting rings and their respective points of inflection. Generally, it will be convenient to incorporate the design variation that creates the abnormal gap between adjacent points of inflection with the design of the connector zone between two adjacent turns. Thus, in perhaps the simplest case, we can envisage a connector from which two struts extend into a stenting ring or turn on one side of the connector, and two other struts extend in the other axial direction, into the next adjacent stenting ring or turn. If the angle between the first two struts is "normal" for that stenting ring, but the angle between the opposite pair of struts, in the other of the two stenting rings, is much smaller than "normal", then the points of inflection circumferentially on either side of the connector, that would be facing each other in the classic construction of WO 01/32102, will be circumferentially offset from each other, because of the different angle of the struts each side of the connector. Think of the connector as the trunk of a human body, with the legs of the body slightly open and the two arms of the body. Imagine the angle between the upwardly outstretched arms significantly greater than the angle between the legs.

Rather than set out a string of statements of invention, and then repeat them in a set of claims, we opt for economy of text, refrain from reciting statements of invention, and present various aspects of the above explained inventive concept in claims appended to this description.

We have stated that setting up a "peak-to-valley" configuration of otherwise facing inflection zones is conveniently incorporated in the design of portions that connect adjacent stenting rings (or helical turns). However, one can readily envisage that the necessary offset can be created in a stagger zone that is circumferentially spaced from connectors. There is no imperative that the stagger zone must be coincident with the connector zone.

It will be evident that a stagger zone can be created in a number of different ways. One can locally manipulate the mechanical properties of the material of the stagger zone, not just be local modulation of the dimensions of the inflection points or struts within the stagger zone, relative to the rest of the circumference of the stenting ring, but could also contemplate manipulation of the mechanical properties of the material in the stagger zone by local heat treatment or even chemical treatment. It is even possible to envisage adding components to an otherwise "classic" stenting ring structure as in WO 01/32102, such as a flexible "tie" between the two struts that are destined to deliver a smaller than usual gap between adjacent points of inflection. When a painter erects an easel, there is a "piece of string" that runs between the front frame of the easel, and the rear strut of the easel, not far above the ground, where the gap between the front legs of the easel and the single rear leg of the easel rest on the ground. A classic stent such as shown in WO 01/32102 could be modified by inclusion in it of judiciously placed "pieces of string" from biologically compatible material, in order to restrain two adjacent struts of selected stenting rings of the prosthesis from opening to

the full extent that occurs for all the other struts of that particular stenting ring. (We mention this possibility not with any expectation that it will be a preferred construction, but in the recognition that competitors stimulated by the present disclosure might be obliged to turn to such constructions in the hope of avoiding the inventive concept of the present application). The motto "keep it simple" is rather powerful and the present inventors are proud of a contribution to the art that is essentially simple but should deliver a powerful enhancement of performance.

At this juncture, it is worth noting that a shape memory alloy stent is given its "remembered" configuration by a heat treatment. In the case of WO 01/32102, that heat treatment is given with the points of inflection arranged "peak-to-peak". With shape memory alloy stents embodying the present invention, however, the heat treatment is with the inflection points arranged as intended, therefore, not peak to peak, but in the circumferentially staggered arrangement brought about by the stagger zone(s).

In the context of the present invention, attention is directed to the disclosure of US/2004/0073290 and, in particular, drawings Figures 4 and 5 and the associated text. We see adjacent zig-zag stenting rings with points of inflection that are more or less "peak-to-peak" in the compact configuration of drawing Fig. 4, but not so much peak-to-peak in the expanded configuration of drawing Fig. 5. However, the struts of any particular zig-zag stenting ring are not all the same length. Some are relatively long, some are relatively short, and some are of intermediate length. By contrast, it appears that the angle that opens up between any two struts that diverge from any particular point of inflection is always the same, so that any technical effect of circumferential displacement of peak-to-peak points of inflection is accomplished not by local variation of an angle between two adjacent struts but, rather, by modulations of

the length of adjacent struts in each of the stenting rings. Putting it another way, each connector portion 24 is the intersection of two straight lines in the form of an "X" shape and this is not what is envisaged with the present invention.

Thinking about the bend capability of any particular stent design, this might be limited by peak to peak abutment on the inside of the (banana) bend but could also be restricted by incipient buckling of the stent matrix at some point on the matrix. Clearly, to obtain benefit from the present invention, the stent matrix to which it is to be applied must be capable of bending without buckling, to the extent needed to bring the benefits of the present invention into play. In general, the sparser the population of connectors, the more capacity the lattice will have to bend without buckling.

Brief description of the drawings

For a better understanding of the present invention, and to show more clearly how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:

Figs. 1 and 2 show, respectively content of Figs. 6 and 2 of US/2003/0055485, being a tubular stent structure opened out flat, seen in plan view, in respectively the radially compact and radially expanded dispositions;

Fig. 3 is a reproduction of Fig. 5 of US/2004/0073290, being a portion of a tubular stent structure, opened out flat, and in a radially expanded configuration;

Figs. 4 and 5 reproduce drawing Figs. 3 and 4 of applicant's WO 01/32102, being respectively side views of a stent structure in the radially compact and radially expanded dispositions;

Figs. 6 and 7 are corresponding views of a stent structure in accordance with the present invention; and

Figs. 8 and 9 are views corresponding to those of Figs. 4 and 5, or Figs. 6 and 7, showing another embodiment of the present invention.

Detailed description

Figs. 1 to 5 give only the most cursory impression of the wealth of stent strut matrix proposals contained within the state of the art. However, they provide enough disclosure to set the advantages of the present invention in the context of relevant prior art.

Looking first at Figs. 1 and 2, we see an example of a stent 10 which utilises circumferential support structures 12 in the form of zig-zag stenting rings. These are spaced apart along the long axis of the stent. They are made up of struts 12 interspersed by points of inflection 18 which US/2003/0055485 designates "apex portions". These apex portions are mostly free to take up positions, in the expanded Fig. 2 disposition of the stent, which are governed only by the stresses transmitted through the struts of that particular stenting ring, or transmitted to that stenting ring by the bodily tissue that presses against it. However, there are also connecting struts 16 each of which joins a selected one of the apex portions of one stenting ring with a selected apex portion of an adjacent stenting ring. From Fig. 1, we see that the connecting struts have length direction that is in the circumferential direction of the stent tube, so that the opposite ends of each particular connecting strut 16 are circumferentially spaced from each other. In the radially compact disposition of Fig. 1, the circumferentially extending connecting strut 16 spans an intervening apex portion between its two ends. However, when the stent expands

into its radially expanded configuration represented by Fig. 2, the circumferential length of the connecting strut 16 is not enough to span across an intervening apex portion, because the apex portions arranged around the circumference of any particular stenting ring have moved away from each other by an amount greater than the length of the connecting strut. By selecting a connecting strut length that is approximately half the distance between two adjacent apex portions of the same stenting ring, in the expanded configuration of the stent, one can achieve a "staggering" of the evenly spaced apex portions of one stenting ring, relative to the equal spacing of the apex portions of the next adjacent stenting ring that "faces" the stenting ring of the other end of the connecting strut.

In consequence, when the stent in its expanded configuration is subject to longitudinal compression, or when it is bent sharply (so that its longitudinal axis is not longer straight but arcuate) the facing apex portions on the inside of the bend, or that approach each other as the stent is longitudinally compressed do not butt up against each other but, instead, move into the free gap between two spaced apart apex portions of the other of the two facing stenting rings.

In US/2003/0055485, paragraph 0031, it is stated that the geometry of the stent in the radially compact delivery disposition of Fig. 1 is "highly flexible" so that it can tolerate axial compression on the inside of a bend as described above. Looking at Fig. 1 (Fig. 6 of the US publication) it is not immediately evident how the stated flexibility is provided.

We turn now to Fig. 3, which corresponds to Fig. 5 of US/2004/0073290. In this case, one can see that the connector portions between adjacent zig-zag stenting rings have a very simple construction. They are remarkably short in length but, to the extent that they have a length direction, it is

parallel to the longitudinal axis of the stent, rather than in a circumferential direction. Accordingly, there is no circumferential offset between the apex portions facing each other and connected by the connector strut 24.

Nevertheless, we see from Fig. 3, that there is a circumferential offset between unconnected apex portions of adjacent stenting rings.

The offset is accomplished by providing a range of different strut lengths in any particular stenting ring. In particular, each connector 24 is at the apex of a first pair of relatively long struts and a second pair of relatively short struts. Each stenting ring features struts of three different lengths, namely A) short, B) intermediate length and C) long. And we see from Fig. 3 how the strut length progresses around the circumference of each stenting ring in a sequence ABCCBA. We can see how the apex portions at the open end of a bifurcation between two A-struts both fall within a single gap between two C-struts of the adjacent stenting ring. This overlap occurs periodically around the circumference of the prosthesis, on each occasion midway between two adjacent connector portions 24.

In the compact disposition of the stent of Fig. 3, apex portions are "head-to-head" or "peak-to-peak" all the way around the circumference of the stenting cylinder, not just at those locations where a connector portion 24 lies between the head-to-head apex portions. In this respect, there is reduced flexibility in the compact delivery disposition of the stent device, comparable with that of the device of Fig. 1 described above. Again, it is not immediately evident how the device delivers bent flexibility in the compact delivery disposition.

The present applicant specialises in self-expanding stent devices that are formed from a tubular workpiece of nickel

titanium shape memory alloy ("NITINOL" trademark). The tube is formed into a stent precursor by forming in it a multiplicity of slits (cut by a laser) that it is convenient to provide all mutually parallel to each other and to the long axis of the tubular workpiece. One such construction can be seen in Fig. 4, this corresponding to Fig. 3 of applicant's earlier publication WO 01/32102, the contents of which are hereby incorporated by reference. Reference to the WO document will reveal how, following laser cutting, portions of the tubular workpiece are removed to leave "holes" in the slitted tube, indicated by reference 60 in Fig. 4. It will be grasped by the skilled reader that provision of these voids in the slitted tube endows the tube, in its delivery system, confined by a sheath that prevents premature self-expansion, greater flexibility for the sheath to advance along a tortuous delivery path to a site of stenting in the body.

Fig. 5 shows the expanded disposition of the Fig. 4 stent construction. A pattern of zig-zag stenting rings connected by short connecting portions 62 can be readily recognised and it can also be seen that the apex portions (here in designated "points of inflection") of adjacent zig-zag stenting rings are facing each other, not only across the connected 62 but also elsewhere around the circumference of the stenting device. Thus, when the expanded stenting device of Fig. 5 is subject to severe lengthwise compressive stress, or severe bending, there is a possibility for facing points of inflection of axially adjacent zig-zag stenting rings to approach each other closely, or even touch on the inside of the bend. The problem being tackled when the present invention was made was how to reduce the likelihood of this adverse event occurring.

One embodiment of the present invention, which does succeed in setting the facing points of inflection of adjacent

stenting rings circumferentially offset from each other, will now be described be reference to drawings Figures 6 and 7.

Fig. 6 shows a distribution of slits in a tubular workpiece opened out flat, and the similarity with the slit distribution of Fig 4 is immediately apparent. Note that Fig. 4 is a view from the side of the workpiece, and does not show the workpiece opened out flat whereas Fig. 6 shows the entire circumference of the tubular workpiece, laid out flat on the page. We see from Fig. 6 that there are two connecting struts 80 connecting any two adjacent stenting rings 82. We see at the left-hand end of Fig. 6 the terminal stenting ring 84 which has a longer slit length and is also evident in Fig. 4. We note that Fig. 4 shows the entire length of the stent whereas Fig. 6 shows only a portion of the length of the stent. Whereas the connectors 80 are interspersed by voids 60 just as in Fig. 4, there are no voids between the increased length end stenting ring 84 and its next adjacent normal length stenting ring 82'. Whereas there are two connector portions 80 between the normal length stenting rings, there are 14 connectors 86 between the end stenting ring 84 and its neighbour 82'.

Noteworthy in Fig. 6 is the pattern of length of the individual slits cut by the laser. In general, the slits have a single length, but there are two exceptions. The first exception is that the slit length is longer at the end of the tubular workpiece, to form the end stenting ring 84. One such slit is marked in Fig. 6 with reference 88. The second exception is the length of the slit that terminates at one end of each connector portion 80. One such slit, of shorter length then the others, is designated in Fig. 6 with reference 90. We need to look at Fig.7 to appreciate the consequence of short struts 90.

Fig. 7 reveals two of the many connector portions 80. Each connector 80 sits between two adjacent stenting rings at the

points of inflection 92 of any one stenting ring are all to be found on a notional circular locus that is transverse to the longitudinal axis of the stent. A gap "t" exists between any particular such circular loci D and E facing each other at periodical intervals down the length of the stent. Within these two circles, we find a circumferential offset between the spaced apart points of inflection 92 in circle E and those of the facing circle D. The offset is found everywhere except at the periodically spaced connectors (in this example there are four) 80.

Turning our attention to the next adjacent pair of facing circles F and G in Fig. 7, the origin of the circumferential offset can be seen in the opposing relationship of the points of inflection 92A, B, C and D. The gap between apex 92B and 92C on the stenting ring that includes circle G is the regular gap between two struts of "normal" length. However, because of the reduced slit length 90, the circumferential gap between points of inflection 92A and 92D is abnormally small so that both points of inflection 92A and 92D "fit" in the normal sized gap between apex 92B and 92C of circle G. In the terminology adopted in the present specification, the zone that includes points of inflection 92A, B, C and D is designated a stagger zone. From Fig. 7 it is immediately evident that providing such a stagger zone by using an abnormally short slit length has a disadvantage, namely, that the gap between points of inflection 92A and 92D is shorter than the regular gaps between other points of inflection spaced around circle F. It hardly need be stated that optimal use of material within a stent matrix calls for a regular matrix of struts, with a minimal amount of material in the radially compact delivery disposition, and a uniformed distribution of that material in the expanded configuration (all gaps the same size) so as to achieve a maximum ratio of expanded diameter to radially compress delivery diameter. Deliberately accepting a plurality of unnecessarily small gaps around the circumference of each stenting ring will have

an adverse effect on this ratio of diameters and is therefore not something of itself desirable to stent designers.

Nevertheless, the present invention is attractive, when taken in the context of balancing conflicting constraints on the stent designer. Looking at Fig. 6, one can see the evident simplicity of the stent strut and slit arrangement. The government regulatory authorities impose stringent quality requirements on stent manufacturers. For example, stents must meet stringent metal fatigue requirements. Finite element analysis of stent designs is of crucial importance. A design that is inherently simple should lend itself to reliable prediction of its properties in service. Being able to predict how a stent will perform after it has been installed in a human body is a significant advantage for stent manufacturers that compete to provide the stents most attractive to doctors and medical services.

Reference is now made to Figures 8 and 9. These have been annotated with references the same as are used in Figures 6 and 7, to identify corresponding features. Noteworthy is that there are four connectors rather than two, connecting adjacent stenting rings. Clearly, each stent ring comprises pairs of struts which are unconnected to any pairs of struts of an adjacent stent ring. Further is clear that a number of adjacent stent rings are spaced from each other. Fig. 8 shows the left-hand end of the stent whereas Fig. 9 shows the full length. Actually, the Fig. 9 stent is not the same as the Fig. 8 stent because Fig. 8 shows longer struts in the two end rings but Fig. 9 does not.

In Fig. 9, it is helpful to consider connectors 80A and 80B. The former has the asymmetric shape of all the other connectors of zig-zag rings 82. The latter has an X shape because it is part of the transition from the stagger zone rings 82 to the end ring 84 that lacks any stagger zone. Shown is that the closest end points of a pair of struts of

one stent ring and a pair of struts of another stent ring are connected.

The embodiments illustrated in Figs. 6 to 9 represent only one of a multitude of ways to bring about an angle between struts that is different from the otherwise regular angle between struts around the remainder of the circumference of any particular stenting ring. For example, one could locally modify the material of the stenting ring, either in the points of inflection at one or both ends of the struts that are to form the abnormal size gap, or by judicious modification of the dimensions of those points of inflection or the two struts running between them. Above-mentioned WO 01/32102 contemplates manual removal of individual scrap portions to create voids 60. There are voids 60 in Fig. 6. If manual intervention is to be relied upon to create the voids 60 in an embodiment of the present invention, then it would not be beyond the bounds of imagination to intervene locally, and manually, at portions of the abluminal surface of the workpiece where the properties of the material are to be modified locally in order to deliver a gap of different size, or angle of different size, between two adjacent struts of any particular stenting ring. One envisages that the material could be modified in its composition, by local application of a substance to cause a chemical reaction, or by local application of a substance to modify the microstructure of the material at that point, or by local application of heat or cooling to give the material at that location a different thermal history of that of the material of the remainder of the stenting ring.

In this context, we incorporate, by reference to it, the disclosure of WO2001/076508, from the present applicant, which explains how particular strut configurations can be created by using a jig to hold the workpiece in a particular desired configuration during the heat treatment which "sets" the "remembered" configuration of the struts in the shape

memory alloy. Thinking along these lines, one could use instead of struts of different lengths a jig that holds the struts in a configuration such as is shown in Fig. 7, when giving the workpiece its "remembered" configuration, so that it should open up at the stenting site to the remembered disposition even if the length of slit 90 is just the same as the length of all the other slits in the stenting ring.

When thinking of workpieces of every day household dimensions, such as how to prevent a door opening too far, one would use a strut between the door and the frame that has a set length corresponding to the maximum opening that one wishes to impose on the door. In the same way, one could envisage some sort of collapsing tie to impose a maximum size on the gap between points of inflection 92A and 92D, that extends between the respective struts between the slit 90. Of course, stents are very small, but by no means as small as the nanometer dimensions that are in the minds of designers of medical devices, so there seems no justification for dismissing such tie pieces as impracticable. The reality is that, as stent designs become ever more sophisticated, so the range of applications for stents becomes ever greater and, with that, the demand for stents to mimic ever more closely the flexible behaviour of the original bodily tissue, especially when called upon, from time to time, to bend tightly along its length. The challenge is to build a stent that is strong enough to perform the stenting function which is after all the reason for its surgical implantation in the body while, at the same time, rendering the prosthesis as soft and bendy as possible in all other aspects. The present invention makes a valuable contribution to this objective.

Stents need not be made of nickel titanium alloy. Another biologically compatible material familiar to stent designers is stainless steel. Great efforts are currently being made to use other materials such as biologically compatible polymers. All such stents can benefit from the present invention

regardless how they are formed. The illustrated embodiments are not limiting.

Stents need not display the same strut matrix over their entire length. We envisage embodiments in which only part of the length of the prosthesis is given the high flexibility of the present invention. Thus, there may be some turns of the stent matrix that include stagger zones, to deliver flexibility, and other parts of the length of the stent (e.g. end zones, or a mid-length portion) where high flexibility is contra-indicated, and so no stagger zones need be provided in these parts of the stent matrix.

Claims

1. A tubular prosthesis with a longitudinal axis, that is radially expandable from a radially compact delivery disposition to a radially larger deployed disposition, the prosthesis exhibiting a succession of turns around the axis, which turns are helical or endless discrete loops each having an axial length direction, adjacent turns being connected by connector portions distributed around the circumference of the prosthesis, each of the turns being made up of struts that extend the length of the turn and are interspersed by inflection zones located at the axial ends of each of the said turns such that, when the prosthesis expands radially, gaps open up between adjacent struts of each of the turns, the inflection zones being distributed regularly around the circumference so that the gaps are substantially the same size as each other around the circumference of the turn,

characterised in that

at least every second turn exhibits at least one stagger zone within which the said gap between adjacent said struts is of an individual size different from that common to the other gaps of that second turn,

whereby the inflection zones in said second turn that lie circumferentially next to the stagger zone are displaced, in accordance with the individual gap size, out of the facing relationship that obtains in the radially compact disposition of the prosthesis, with the corresponding zones of inflection in the next adjacent turn.

2. Prosthesis as claimed in claim 1, which is a stent.

3. Prosthesis as claimed in claim 1 or 2, which is a self-expanding prosthesis.

4. Prosthesis as claimed in claim 1, 2 or 3, which is made of nickel-titanium shape memory alloy.

5. Prosthesis claimed in any one of the preceding claims, wherein the stagger zone includes a said connector portion.

6. Prosthesis as claimed in claim 5, in which the connector portion corresponds to the confluence of four said struts, namely a first pair of struts in a first said turn and a second pair of struts in said second turn.

7. Prosthesis as claimed in claim 6, wherein the angle between the second pair of struts is an individual angle that differs from a regular angle between struts of said second turn in the deployed disposition, thereby to create said stagger zone.

8. Prosthesis as claimed in claim 7, wherein said individual angle is smaller than said regular angle.

9. Prosthesis as claimed in any one of the preceding claims. wherein the struts in the stagger zone have a length different from that of the struts elsewhere in said second turn.

10. Prosthesis as claimed in any one of the preceding claim, wherein each turn has from two to six stagger zones.

11. Prosthesis as claimed in any one of the preceding claims, wherein the material in the stagger zone is different from the material elsewhere in the second turn.

12. Prosthesis as claimed in claim 11, wherein the material is chemically different.

13. Prosthesis as claimed in claim 12, wherein the material is differently heat rated so as to exhibit a different crystalline microstructure.

14. Prosthesis as claimed in claim 11, wherein the material is dimensionally different.

15. Prosthesis as claimed in any one of the preceding claims, wherein each stagger zone modifies a gap size downwardly in one adjacent ring and upwardly in the next adjacent ring, thereby to double the circumferential displacement between corresponding zones of inflection of the adjacent said rings, compared with the displacement accomplished by the downward size modification alone of the upward modification alone.

16. Prosthesis as claimed in any one of the preceding claims wherein the struts are of consistent basic length, outside the stagger zones and of a different consistent non-basic length inside the stagger zones.

17. Prosthesis as claimed in any one of the preceding claims, wherein all the zones of inflection of any one turn lie on a single circle that is transverse to the said longitudinal axis of the prosthesis, both in the compact and in the radially expanded dispositions.

18. A method of forming a stent from a tube or sheet workpiece, comprising forming in the workpiece a multiplicity of slits all parallel to each other, and of a consistent basic length, so as to create a plurality of stenting ring turns composed of struts interspersed with zones of inflection

characterised by the step of forming at least one stagger zone by selecting for that zone a non-basic slit length that is different form said consistent basic length whereby, when the stent expands radially the gap that opens up, between the struts of the stagger zone, is of a size that is different form the gaps elsewhere around the circumference, thereby to displace inflection zones from their facing relationship in the radially unexpanded

configuration into a non-facing relationship in the expanded configuration of the stent.

19. Method according to claim 18, wherein the workpiece is a tube.

20. Method according to claim 18 or 19, wherein the slit forming step is a laser cutting step.

21. A stent comprising

first and second annular frames in alignment with each other to define a longitudinal axis, each annular frame having undulations circumscribing the longitudinal axis, the undulations including a plurality of struts traversing in generally opposed directions to define a plurality of end points generally aligned on a plane orthogonal to the longitudinal axis;

at least one connector member coupled to a first pair of struts of the first annular frame and a second pair of struts of the second annular frame, the first pair of struts having surfaces exposed to each other to define a first included angle different than a second included angle defined by the exposed surfaces of the second pair of struts, wherein the first and second annular frames comprise third pairs of struts and fourth pairs of struts respectively out of the plurality of struts, each third pair of struts being unconnected to any of the fourth pairs of struts.

22. The stent of claim 21, wherein the first and second frames are spaced from each other.

23. The stent of claim 21, wherein each connector member couples a first end point of the first pair of struts to a second end point of the second pair of struts, the first end point and the second end point being two closest situated end points.

24. The stent of claim 21, wherein the at least one connector member comprises a plurality of connector members and the first included angle is less than any included angle of any pairs of struts that are unconnected to the second annular frame.

25. The stent of claim 24, wherein one of the first and second annular frames is connected to a terminal annular frame having closed diamond cells to define a cylinder about the longitudinal axis.

26. A stent comprising:

first and second annular frames in alignment with each other to define a longitudinal axis, each annular frame having undulations circumscribing the longitudinal axis, the undulations including a plurality of struts traversing in generally opposed directions to define a plurality of end points disposed generally circumferentially about the longitudinal axis;

at least one connector member coupled to a first pair of struts of the first annular frame and a second pair of struts of the second annular frame, the first pair of struts having surfaces exposed to each other to define a first included angle different than a second included angle defined by the exposed surfaces of the second pair of struts so that facing end points of adjacent annular frames are circumferentially offset to each other.

27. A stent comprising:

at least three annular frames in alignment with each other to define a longitudinal axis, each annular frame having undulations circumscribing the longitudinal axis, the undulations including a plurality of struts traversing in generally opposed directions to define a plurality of end points generally aligned on a plane orthogonal to the longitudinal axis;

a first connector member coupled to a first pair of struts of a first annular frame and a second pair of struts of a second annular frame, the first pair of struts having surfaces exposed to each other to define a first included angle different than a second included angle defined by the exposed surfaces of the second pair of struts;

a second connector member coupled to a third pair of struts of the second annular frame and a fourth pair of struts of a third annular frame, the third pair of struts having surfaces exposed to each other to define a third included angle different than a fourth included angle defined by the exposed surfaces of the fourth pair of struts.

28. The stent of claim 27, wherein the second and fourth included angles are generally equal.

29. The stent of claim 28, wherein one of the annular frames is connected to a terminal annular frame having closed diamond cells to define a cylinder about the longitudinal axis.

30. The stent of claim 28, wherein one of the annular frames is connected to a terminal annular frame having closed diamond cells to define a cylinder about the longitudinal axis.

31. The stent of claim 29, wherein a connector member is disposed between every five struts including the strut connected to the connector member.

32. A stent comprising:

first and second annular frames in alignment with each other to define a longitudinal axis, each annular frame having undulations circumscribing the longitudinal axis, the undulations including a plurality of struts traversing in generally opposed directions to define a plurality of end points generally aligned on a plane orthogonal to the longitudinal axis, and the end points of one annular frame are in facing axial alignment with corresponding end points of adjacent annular frames when the stent is in an unexpanded configuration;

a first connector member coupled to a first pair of struts of a first annular frame and a second pair of struts of a second annular frame in an expanded configuration of the stent where the first pair of struts includes surfaces exposed to each other to define a first included angle different than a second included angle defined by the exposed surfaces of the second pair of struts so that the end points of one annular frame is offset in a circumferential direction

with respect to the corresponding facing end points of an adjacent annular frame in the expanded configuration of the stent.

33. Prosthesis/stent as claimed in any one of the preceding claims, in which the turns are the turns of a helical stent strut matrix.

Fig. 1

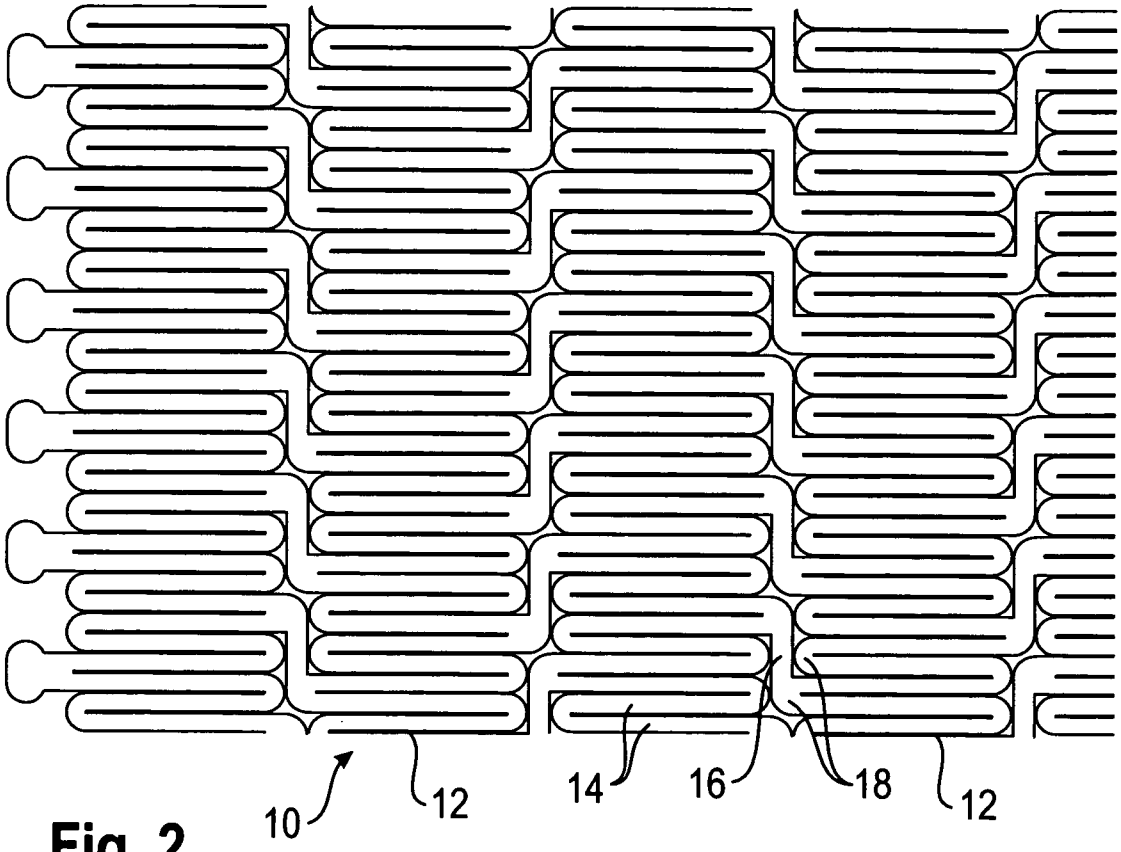
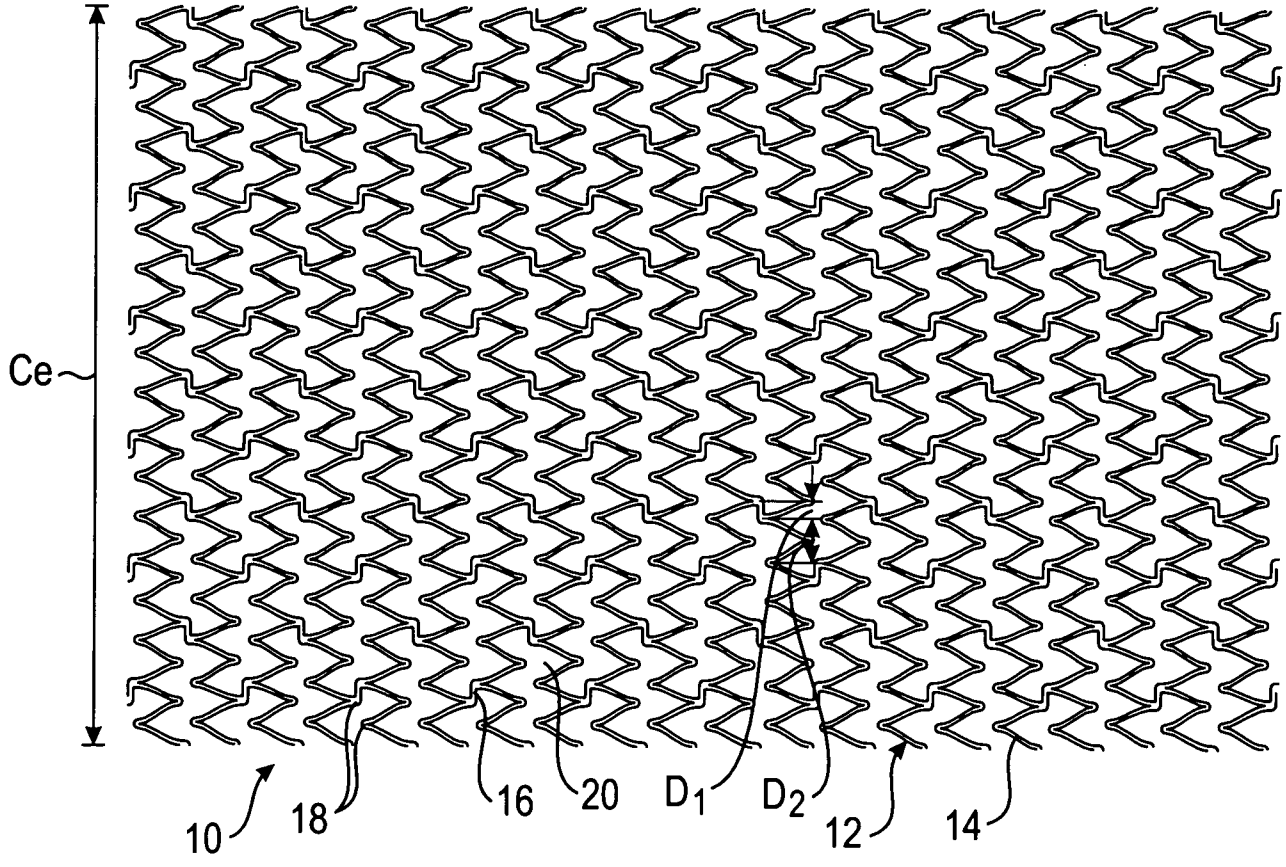


Fig. 2



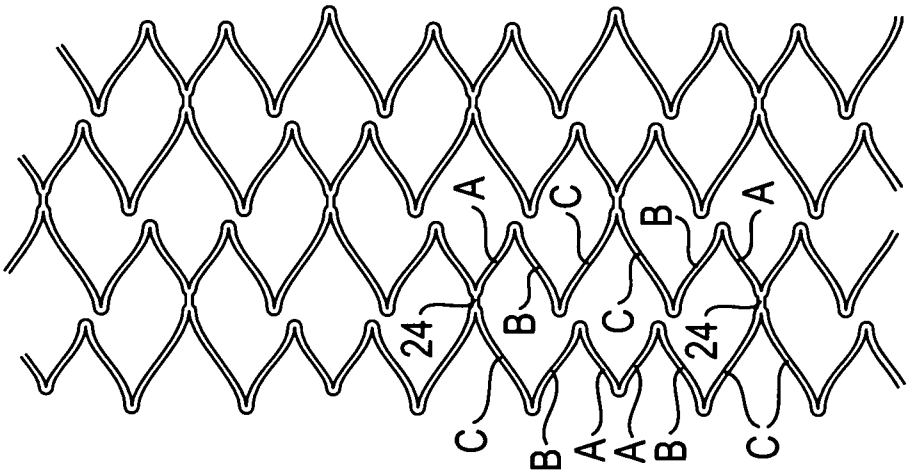


Fig. 3

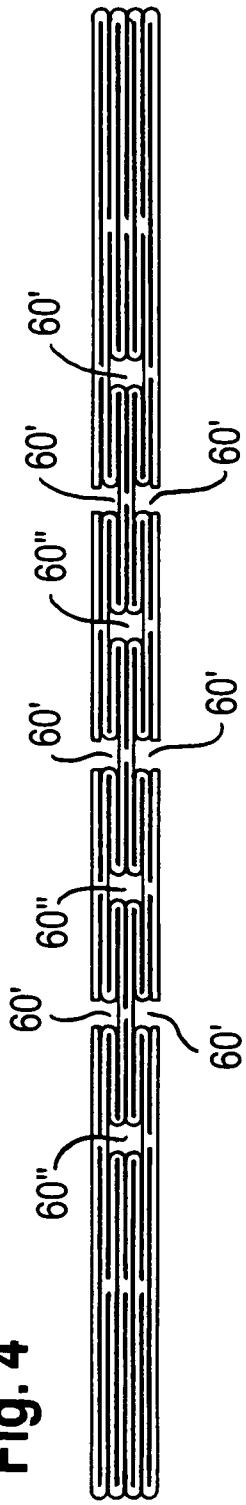


Fig. 4

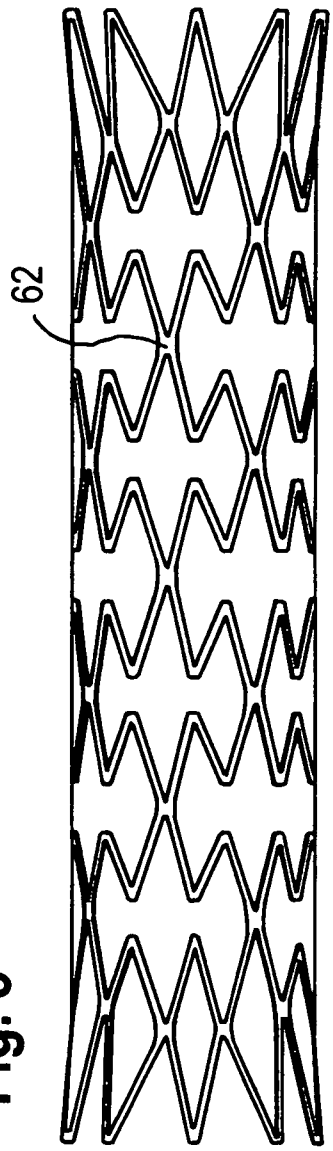


Fig. 5

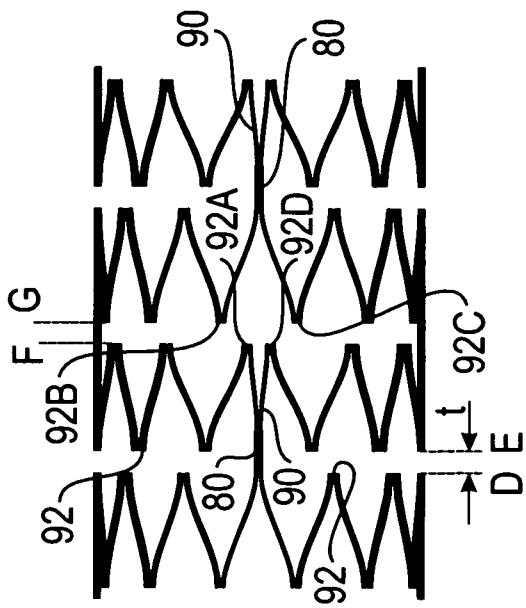
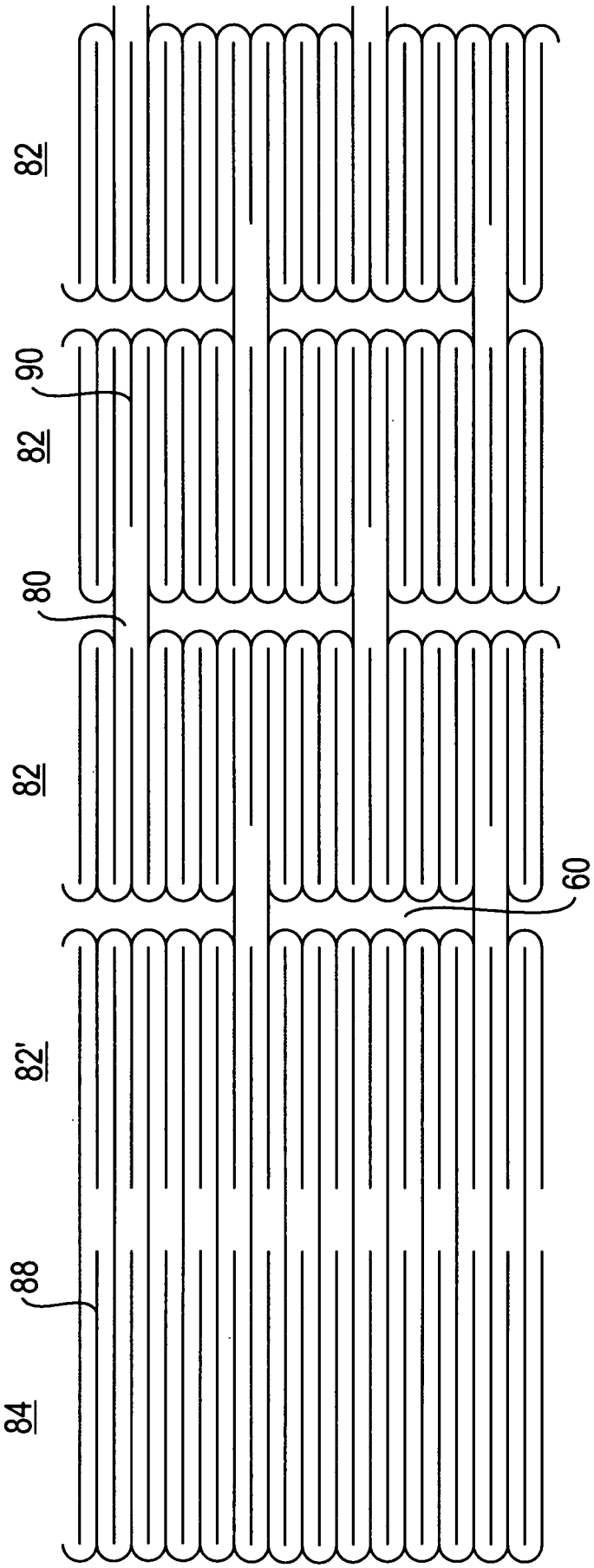


Fig. 7

Fig. 6



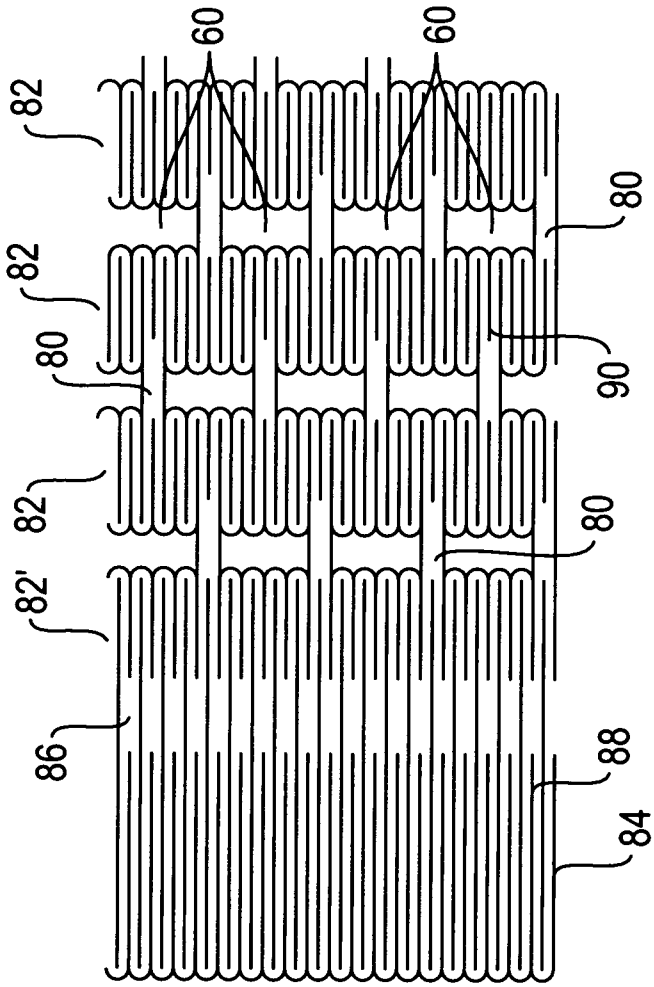

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Fig. 8

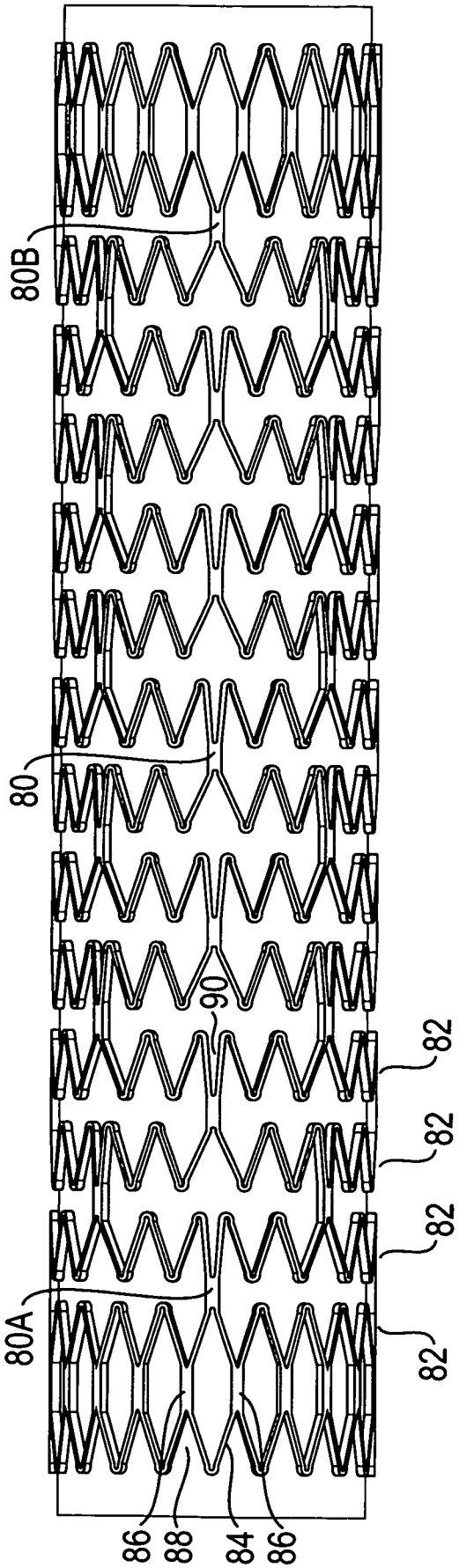
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Fig. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2007/004407

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/90

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/073290 A1 (CHOUINARD PAUL F [US]) 15 April 2004 (2004-04-15) cited in the application figures 4,5 paragraph [0049]	1-33
X	EP 1 029 517 A2 (MEDTRONIC INC [US]) 23 August 2000 (2000-08-23) figures 6a,6b,6c	1
X	WO 2005/104991 A1 (INVATEC S R L [IT]; VENTURELLI ANDREA [IT]; GHIDINI ROBERTO [IT]) 10 November 2005 (2005-11-10) figures 11,12	1
A	EP 1 034 751 A (TERUMO CORP [JP]) 13 September 2000 (2000-09-13) figure 21	1-33

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 September 2007	26/09/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Franz, Volker

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2007/004407

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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