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(56) Related Art
WO 2006/105192 A1 (BOSTON SCIENTIFIC SCIMED, INC.) 05 October 2006
WO 2003/030786 A2 (WILLIAM COOK EUROPE APS et al.) 17 April 2003
WO 2007/073413 A1 (BOSTON SCIENTIFIC SCIMED, INC.) 28 June 2007

Abstract

PROSTHESIS AND METHOD OF MANUFACTURE

A prosthesis (110; 210) comprises a plurality of stent members which are formed of strut elements (120) connected by apexes, wherein the proximal apexes (122; 226a) of a first stent member (116a; 216a) and the distal apexes (124; 224b) of a second stent member (116b; 216b) have a shaped portion which is flat or concave. The proximal apexes (122; 226a) are arranged to engage the distal apexes (124224b) when the prosthesis is subjected to longitudinal compression forces and the shaped portion of the apexes prevents interdigitation of the stent members. End marker elements (220, 320) may have similarly shaped lateral extensions (222, 322) arranged to engage the distal apexes (224a) of the first stent member.

[Figure 5]

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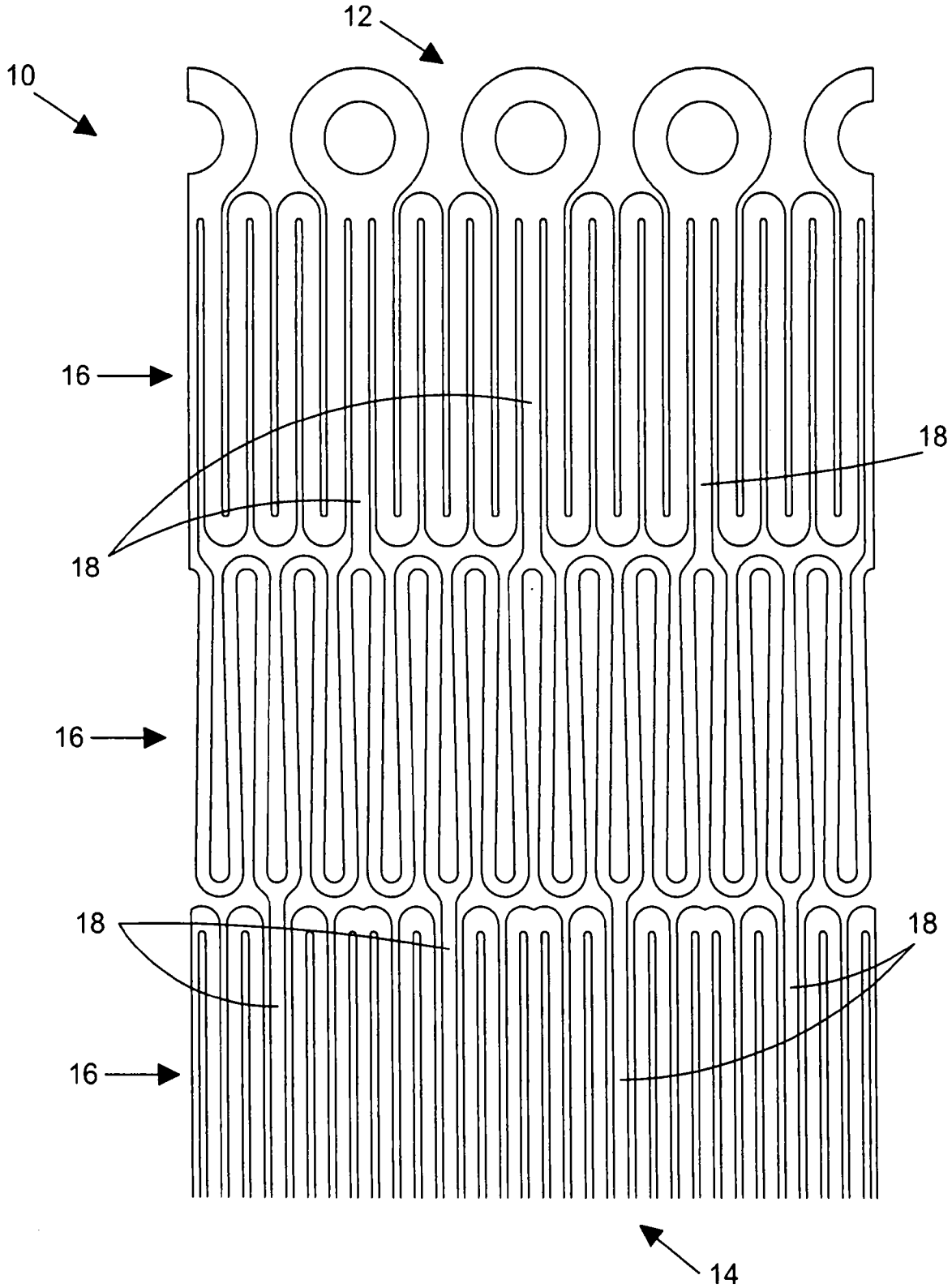

FIGURE 1

Regulation 3.2

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COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

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The following statement is a full description of this invention, including the best method of performing it known to us.

PROSTHESIS AND METHOD OF MANUFACTURE

Description

Technical Field

The present invention relates to a generally tubular prosthesis, in particular to a prosthesis comprising a plurality of stents, to a method of manufacturing such a prosthesis, and to a method of deploying such a prosthesis.

Background Art

Prostheses have been used for many years to treat a number of vascular medical conditions. Prostheses in common use comprise at least one stent and are either of the self-expandable type, made for example of a shape memory material, or separately expandable, such as by balloon expansion.

Such prostheses are designed to fit within the vasculature of the patient and need to be appropriate for the size and shape of the lumen. For this purpose, they must be conformable and must not be of a nature that they can apply against the vessel walls forces which could damage or adversely affect the functionality of the vessel or of other organs nearby.

Preferably, such prostheses have a small cross-sectional diameter and/or profile for introducing the prosthesis into the affected body lumen. A configuration which is extremely suited for implantation in a body lumen is a generally cylindrical prosthesis which can radially expand from a first, small, collapsed diameter to a second, larger, expanded diameter. Such prostheses can be deployed in a body lumen at the desired location by means of an introducer assembly, whereby the prosthesis is placed on a catheter and transported through the lumen to the desired location. The prosthesis is retained in a compressed condition by a sheath. Once the introducer assembly has been transported to the desired deployment position the sheath is withdrawn, thus releasing the prosthesis so that it can expand radially into an expanded condition. In this regard, the prosthesis

may be self-expanding or the catheter may be provided with a balloon or another expansion mechanism which exerts a radial outward pressure on the prosthesis so that the prosthesis expands to a larger diameter.

Lateral deflection in such prostheses can occur during deployment, such as when the prosthesis is longitudinally compressed as it is maneuvered into the desired location in a patient's lumen. Such lateral deflection can be problematic during deployment of the prosthesis. For example, this can distort the sheath to cause increased friction between the sheath and the lumen wall, thus hindering deployment. This may particularly be the case when the prosthesis is to be deployed in a curved lumen, such as the aortic arch, and in extreme cases lateral deflection can prevent the prosthesis from being located in the desired position. Further, such lateral deflection can be dangerous for the patient in more delicate applications, such as in smaller and more delicate vessels including, for instance, cerebral vessels.

Prostheses with various stent arrangements are disclosed in US 7637935, US 2009/0204201, WO 98/20810, US 5776181, US 2005/0149168, US 2007/0244543, US 7534258 and US 6656220.

WO 2006/105192 and WO 03/030786 disclose prostheses with stents having shaped apex portions.

Disclosure of The Invention

Aspects of the present invention seek to provide an improved prosthesis in which the aforementioned problems associated with lateral deflection are substantially reduced or overcome.

According to a first aspect of the present invention, there is provided a substantially tubular prosthesis comprising a plurality of stent members positioned longitudinally along the prosthesis, each stent member comprising a plurality of strut elements connected by apexes, the prosthesis being arranged such that the

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longitudinal compression forces, each of the proximal apexes of the first stent member and the distal apexes of the second stent member having a shaped portion which is flat or concave and having a width, so as to present a line of engagement surfaces to the distal apexes of the second stent member and the proximal apexes of the first stent member respectively, wherein the gaps between circumferentially adjacent engagement surfaces are substantially narrower than the widths of the shaped portions when the prosthesis is in a compressed configuration.

The shaped portion of the apexes advantageously prevents interdigitation of adjacent stent members when the prosthesis is subjected to longitudinal compression forces.

In a preferred embodiment the shaped portions are substantially planar, and may be substantially perpendicular to the longitudinal direction of the prosthesis.

The proximal apexes of the first stent member may be substantially parallel to the distal apexes of the second stent member.

The strut elements may be substantially straight, and may be substantially parallel when the prosthesis is in a compressed configuration.

In an embodiment, each stent member is spaced apart from an adjacent stent member by at least one connector.

Alternatively, or in addition, the stent members may be fastened to a graft material to form a stent graft. The stent members may be fastened to the graft such that each stent member is spaced apart from an adjacent stent member.

When the stent members are spaced apart from an adjacent stent member by at least one connector, the prosthesis advantageously further comprises at least one

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engagement member located at an end of the prosthesis, the engagement member comprising a lateral extension which extends adjacent the distal apexes of the first stent member such that the lateral extension engages the distal apexes of the first stent member when the prosthesis is subjected to longitudinal compression forces, the lateral extension being shaped to form a substantially planar engagement surface facing the distal apexes of the first stent member.

This arrangement maximises the potential contact area between the engagement member and the distal apexes of the first stent member, and causes the engagement member to engage the distal apexes of the first stent member. The distal apexes are prevented from pushing past the lateral extension, and this arrangement allows a portion of the longitudinal compression force to be distributed to parts of the prosthesis that are not directly connected to the connector.

According to a second aspect of the present invention, there is provided a method of manufacturing a substantially tubular prosthesis, the method comprising the steps of: forming a plurality of stent members positioned longitudinally along the prosthesis, wherein each stent member comprises a plurality of strut elements connected by apexes; arranging the prosthesis such that the proximal apexes of a first stent member engage the distal apexes of a longitudinally adjacent second stent member when the prosthesis is subjected to longitudinal compression forces; and forming each of the proximal apexes of the first stent member and the distal apexes of the second stent member to have a shaped portion which is flat or concave and to have a width, so as to present a line of engagement surfaces to the distal apexes of the second stent member and the proximal apexes of the first stent member respectively, wherein the gaps between circumferentially adjacent engagement surfaces are substantially narrower than the widths of the shaped portions when the prosthesis is in a compressed configuration.

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According to a third aspect of the present invention, there is provided a generally tubular prosthesis comprising a plurality of stent members positioned longitudinally along the prosthesis, each stent member comprising a plurality of strut elements connected by apexes, the prosthesis being arranged such that the proximal apexes of a first stent member engage the distal apexes of an adjacent second stent member when the prosthesis is subjected to longitudinal compression forces, wherein at least the proximal apexes of the first stent member or the distal apexes of the second stent member have a shaped portion which is flat or concave.

Advantageously, both the proximal apexes of the first stent member and the distal apexes of the second stent member may have a shaped portion which is flat or concave. The shaped portions may be substantially planar.

The proximal apexes of the first stent member may be arranged to engage the distal apexes of the adjacent second stent member when the longitudinal compression forces are of a predetermined magnitude.

According to a fourth aspect of the present invention, there is provided a method of manufacturing a substantially tubular prosthesis, the method comprising the steps of: forming a plurality of stent members positioned longitudinally along the prosthesis, wherein each stent member comprises a plurality of strut elements connected by apexes; arranging the prosthesis such that the proximal apexes of a first stent member engage the distal apexes of an adjacent second stent member when the prosthesis is subjected to longitudinal compression forces; and forming at least the proximal apexes of the first stent member or the distal apexes of the second stent member to have a shaped portion which is flat or concave.

The prosthesis may be formed into a stent graft in which the stent members are fastened to a graft material.

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The connectors may be arranged such that the proximal apexes of the first stent member are arranged to engage the distal apexes of the adjacent second stent member when the longitudinal compression forces are of a predetermined magnitude.

Also described is a method of deploying a substantially tubular prosthesis comprising a plurality of stent members positioned longitudinally along the prosthesis, each stent member comprising a plurality of strut elements connected by apexes, the prosthesis being arranged such that the proximal apexes of a first stent member engage the distal apexes of an adjacent second stent member when the prosthesis is subjected to longitudinal compression forces, wherein at least the proximal apexes of the first stent member or the distal apexes of the second stent member have a shaped portion which is flat or concave, the method comprising the step of moving the prosthesis longitudinally through a body lumen of a patient during which the proximal apexes of the first stent member engage or come into engagement with the distal apexes of the second stent member, and longitudinal forces are transmitted via the engaged apexes during further longitudinal movement.

Brief Description of the Drawings

Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings of which:

Figure 1 shows a developed view of a portion of a prior art prosthesis;

Figure 2 shows a detailed portion of the prosthesis of Figure 1;

Figure 3 shows detail of the prosthesis of Figure 1 in schematic form, when the prosthesis is experiencing longitudinal compression;

Figure 4 shows an arrangement of a portion of a prosthesis in accordance with a

first embodiment of the present invention;

Figure 5 shows a detailed portion of the prosthesis of Figure 4;

Figures 6 to 8 show modified apex portions of prostheses in accordance with the present invention;

Figure 9a shows a portion of a prosthesis in accordance with a second embodiment of the present invention; and

Figure 9b shows a modification of the prosthesis of Figure 9a.

Description of the Preferred Embodiments

For the purposes of this disclosure, the term "prosthesis" means any replacement for a body part or function of that body part. It can also be used to refer to a device that enhances or adds functionality to a physiological system.

The term "stent" or "stent member" means any device or structure that adds rigidity, expansion force or support to a prosthesis or body lumen.

The term "stent graft" refers to a prosthesis comprising a graft material that forms a lumen through at least a portion of its length and has a number of stent members attached thereto.

Further, when used in connection with description of a stent, stent graft or other implantable medical device or prosthesis, the term "proximal" refers to a part or position closest to the patient's heart, that is upstream in the direction of blood flow, when the prosthesis is in situ, while the term "distal" refers to a part or position furthest from the heart.

In general, prostheses according to the present invention may comprise a plurality

of longitudinally spaced apart stents. Each stent may be formed from a resilient wire such as Nitinol wire and may be of generally zig-zag shape, comprising a plurality of struts with a bend between each pair of struts.

Nitinol is a shape memory metal formed from a nickel-titanium (NiTi) alloy that "remembers" its geometry. The wire may be formed into the desired zig-zag shape and then heat treated to retain that shape. After cooling, if it is deformed, it will return to the desired zig-zag shape. Thus, stents formed from such material are able to be radially compressed, for example so as to allow their deployment, and will return to a desired expanded form once the compression forces have been removed.

Referring now to Figure 1 of the accompanying drawings, a portion of a prior art prosthesis 10 is shown. The prosthesis 10 comprises a distal end 12 and a proximal end 14, with a plurality of stent members or stents 16 spaced apart along the length of the prosthesis 10. Each stent 16 is spaced apart from the adjacent stent(s) 16 in the longitudinal direction of the prosthesis 10 by connectors 18. The connectors 18 are flexible enough to allow for curvature of the prosthesis 10 during longitudinal compression such as that experienced during deployment.

As can be seen from Figure 2, each stent 16 is formed from a plurality of struts 20 with a bend between each pair of struts 20. The bends form apexes, and the stents 16 are arranged such that the proximal apexes 22 of one stent 16a are facing the distal apexes 24 of the adjacent stent 16b. Adjacent stents 16a, 16b are in a staggered arrangement in which the proximal apexes 22 of one stent 16a are laterally offset from the distal apexes 24 of the adjacent stent 16b. The apexes are of generally rounded form.

Only two stents 16a and 16b are shown in Figure 2, although this is for clarity purposes only and it will be understood that the prosthesis 10 may in reality comprise more stents 16 spaced apart along the length of the prosthesis 10.

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The prior art prosthesis 10 shown in Figure 2 is in the compressed configuration. The prosthesis 10 will be in this configuration during its deployment in a lumen, and will in practice be held in the compressed configuration by means of a sheath (not shown) which forms a part of the introducer assembly.

Once the introducer assembly is in the desired deployment position, the sheath is withdrawn, thus releasing the prosthesis 10 so that it can expand radially into an expanded condition. The sheath can then be withdrawn completely from the patient.

During deployment of the prosthesis 10, the compressed prosthesis 10 will be pushed longitudinally through the patient's vasculature by the introducer assembly. The prosthesis 10 will be subjected to longitudinal compression forces, and will thus experience longitudinal compression. When the prosthesis 10 is subjected to such longitudinal compression forces, the proximal apexes 22 of the stent 16a move towards the distal apexes 24 of the adjacent stent 16b such that the space between adjacent stents diminishes.

There are also situations in which the prosthesis may be subjected to longitudinal compression forces other than during deployment. One such situation is when the prosthesis is under development and is being tested by a design engineer in a laboratory. Another situation in which the prosthesis may be subjected to longitudinal compression forces is when the prosthesis is being tested after manufacture, to establish whether or not the manufactured prosthesis is fit for purpose prior to this prosthesis being made available for installation in a patent.

The connectors 18 must be flexible enough to allow for curvature of the prosthesis 10 during deployment. As such, the connectors are not stiff enough to prevent engagement of adjacent stents 16a, 16b.

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Continued longitudinal compression of the prosthesis 10, to the magnitude of that experienced during deployment (whether this compression results from deployment of the prosthesis or not), causes adjacent stents 16a, 16b to firstly engage and then to interdigitate or wedge. That is to say, the proximal apexes 22 of one stent 16a will push past the distal apexes 24 of the adjacent stent 16b such that the struts 20 lie next to each other in the radial direction and the stents 16a, 16b overlap. The rounded form of the proximal 22 and distal 24 apexes allows the apexes to push past each other and interdigitate.

Figure 3 shows, schematically, a portion of the prosthesis 10 in the compressed configuration, under the influence of longitudinal compression forces. The stents 16a, 16b are beginning to interdigitate as described above. Such interdigitation causes lateral deflection of the prosthesis 10. It will be understood that this lateral deflection will be magnified if interdigitation occurs throughout the prosthesis 10.

Such lateral deflection of the prosthesis 10 during deployment thereof is undesirable, as it can cause the prosthesis 10 to press upon the inner surface of the sheath to cause increased friction between the outer surface of the sheath and the lumen wall, thus hindering deployment. This may particularly be the case when the prosthesis 10 is to be deployed in a curved lumen, such as the aortic arch, and in extreme cases lateral deflection can prevent the stent from being located in the desired position. Further, such lateral deflection can be dangerous for the patient in more delicate applications, such as in smaller and more delicate vessels including, for instance, cerebral vessels.

This lateral deflection may be compounded by the action of the connectors 18 when subjected to longitudinal compression. In this regard, the connectors 18 deform under longitudinal compression and this deformation could cause at least a portion of the connectors 18 to press upon the inner surface of the sheath to further increase the friction between the outer surface of the sheath and the lumen wall, thus further hindering deployment.

Figure 4 shows a portion of a prosthesis 110 according to an embodiment of the present invention. As with the prior art prosthesis shown in Figures 1 to 3, the prosthesis 110 comprises a distal end 112 and a proximal end 114, with a plurality of stents 116 spaced apart along the length of the prosthesis 110.

Each stent 116 is spaced apart from the adjacent stent(s) 116 in the longitudinal direction of the prosthesis 110 by connectors 118. The connectors 118 are flexible enough to allow for curvature of the prosthesis 110 during deployment. Each stent 116 is spaced apart from the adjacent stent(s) 116 in the longitudinal direction of the prosthesis 110 by a distance "d". In this embodiment, "d" is 0.1 mm. The longitudinal length of the stents 116 in this embodiment is 2 mm. As such, the distance "d" is 5% of the longitudinal length of the stents 116.

As can be seen from Figure 5, each stent 116 is formed into a generally zig-zag shape, and comprises a plurality of struts 120 with an apex 122, 124 between each pair of struts 120. The struts 120 are substantially straight. The apexes 122, 124 have a generally flat or flattened shape, that is to say that, instead of forming a generally rounded bend, the apexes between pairs of struts 120 form a more flattened, planar shape. In the present embodiment, the connection between pairs of struts 120 is substantially straight. The stents 116 are arranged such that the proximal apexes 122 of one stent 116a are facing the distal apexes 124 of the adjacent stent 116b, and the shaped or flat portions of the proximal apexes 122 and distal apexes 124 are substantially parallel. Further, the shaped or flat portions of the proximal apexes 122 and distal apexes 124 are substantially perpendicular to the longitudinal direction of the prosthesis 110.

Adjacent stents 116a, 116b are in a staggered arrangement in which the proximal apexes 122 of one stent 116a are laterally offset from the distal apexes 124 of the adjacent stent 116b.

Figure 5 shows a detailed portion of the prosthesis 110 in the compressed configuration. When in this compressed configuration, each strut 120 lies substantially parallel in side-by-side relation to each other strut 120 of the same stent 116. The prosthesis 110 is in the compressed configuration during its deployment in a lumen, and is in practice held in the compressed configuration by means of a sheath (not shown) which forms a part of the introducer assembly.

During deployment, the compressed prosthesis 110 is pushed longitudinally through the patient's vasculature by the introducer assembly. The prosthesis 110 is subjected to longitudinal compression forces, and thus experiences longitudinal compression. The flat shape of the proximal 122 and distal 124 apexes provides respective abutment surfaces for adjacent stents 116a, 116b, such that when the prosthesis 110 is subjected to such longitudinal compression forces the flat and parallel surfaces of the proximal apexes 122 of the stent 116a engage and abut the flat and parallel surfaces of the distal apexes 124 of the adjacent stent 116b.

There are also situations in which the prosthesis may be subjected to longitudinal compression forces other than during deployment. Examples of such situation are during development of the prosthesis and during testing of the prosthesis after manufacture, as described hereinbefore.

Engagement of the shaped or flat proximal apexes 122 of one stent 116a with the shaped or flat distal apexes 124 of the adjacent stent 116b also acts to prevent excessive deformation of the connectors 118.

An advantage of the above described arrangement is therefore that the proximal apexes 122 of one stent 116a are prevented from pushing past the distal apexes 124 of the adjacent stent 116b. Thus, interdigitation of the struts 120 is avoided. The avoidance of interdigitation in this way leads in turn to a prevention of lateral deflection of the prosthesis 110 during longitudinal compression, for example during deployment of the prosthesis 110. The integrity of the prosthesis 110 shape

is therefore maintained during deployment.

Another advantage of the above described arrangement is that excessive deformation of the connectors 118 is prevented. Deformation of the connectors could in itself lead to lateral deflection of the prosthesis 110.

A further advantage of the above described arrangement is that the effect of the prosthesis 110 upon the sheath during deployment is substantially reduced or eliminated. As a result, friction between the sheath and the lumen wall, which can be problematic and/or dangerous during deployment of the prosthesis 110, is substantially reduced or eliminated.

In addition, it is believed that the arrangement described herein will lead to a decrease in the force required to deploy the prosthesis. It is therefore believed that the present invention will find application in drug eluting stents, such as the present applicant's Zilver PTX stents, which are known to cause a significant increase in the force necessary for deployment of the stent. That is to say, the increased force necessary for deployment of a drug eluting stent may be at least partially negated by arranging the stent in accordance with the present invention.

In a modified arrangement, the stents may be formed from any suitable shape memory alloy. Alternatively, the stents may be formed from a metal such as stainless steel, or a suitable plastics material.

In a further modified arrangement, the stents may be stitched or otherwise fastened onto a tubular graft material, thus forming a stent graft. In this arrangement, connectors are not required to position the stents longitudinally along the prosthesis.

Further, although in the preferred embodiment the stents are spaced apart by a distance "d" of 0.1 mm, in modified arrangements the spacing "d" may be at least

zero and may be 0.2 mm or less, and is preferably 0.1 mm or less. As such, the stents could be in contact even when the prosthesis is not subjected to longitudinal compression forces.

In addition, the longitudinal length of the stents is 2 mm in the preferred embodiment, however the stent length may be at least 1 mm, preferably at least 1.4 mm, and may be 3 mm or less, preferably 2.5 mm or less.

Although the shaped apexes in the preferred embodiment are flat, in modifications the shaped apexes could take on another form. The shaped portion may comprise the whole of, or a part of, the apex. The apexes are shaped such that the apexes of one stent engage or abut the apexes of an adjacent stent, and are thus prevented from pushing past the apexes of the adjacent stent, when the prosthesis is subjected to longitudinal compression forces. Examples of alternative forms of shaped apexes are concave (see Figure 6), castellated (see Figure 7) and undulating (see Figure 8). In these alternate forms, at least a portion of the apex is flat or concave.

In addition, although the apexes of adjacent stents are shown as staggered in the preferred embodiment of Figures 4 and 5 and in the alternative embodiments shown in Figures 6 to 8, in a modification the apexes of one stent may be in line with the apexes of the adjacent stent in the longitudinal direction.

In a further modified arrangement, the stents could be spaced apart from the neighbouring stent(s) by a spacing "d" which is of the order of between zero and 20% of the longitudinal length of the stents. It will be appreciated that a zero spacing corresponds to the apexes being in contact with each other even before longitudinal compression occurs.

Figure 9a shows a portion of a prosthesis 210 according to a second embodiment of the present invention. The prosthesis 210 comprises a distal end 212 and a

proximal end, with a plurality of stents 216a, 216b spaced apart along the length of the prosthesis 210. In this embodiment, markers 220 are provided at the proximal and/or distal ends of the prosthesis 210 to assist the physician in positioning the prosthesis during a medical procedure. These markers 220 are also used as engagement members, so as to provide a contact surface at the end(s) of the prosthesis 210 that may be pushed against, for example when the prosthesis 210 is longitudinally compressed, so that the prosthesis 210 structure itself is not directly pushed against. The markers/engagement members 220 shown in Figure 9a include lateral extensions 222 which extend from the body of the engagement members 220 such that the lateral extensions 222 are located adjacent the distal apexes 224a of the stent 216a (that is, the apexes which are located at the distal end 212 of the prosthesis 210). These lateral extensions 222 are provided so as to increase the potential contact area between the engagement members 220 and the apexes 224a, and to cause the engagement members 220 to engage the apexes 224a, thus preventing the apexes 224a from pushing past the lateral extensions 222 of the engagement members 220.

In addition, the proximal apexes 226a of the stent 216a and the distal apexes 224b of the stent 216b have a generally flat or flattened shape, that is to say that, instead of forming a generally rounded bend, the apexes between pairs of struts form a more flattened, planar shape. The stents 216a, 216b are arranged such that the proximal apexes 226a of one stent 216a face the distal apexes 224b of the adjacent stent 216b, and the shaped or flat portions of the proximal apexes 226a and distal apexes 224b are substantially parallel. Further, the shaped or flat portions of the proximal apexes 226a and distal apexes 224b are substantially perpendicular to the longitudinal direction of the prosthesis 210.

Figure 9b shows a modification of the embodiment shown in Figure 9a. Only those elements which have been modified have been given reference numerals in Figure 9b; all other elements are similar to those described in connection with

Figure 9a. In this modification, the engagement members 320 are modified in that the surfaces of the lateral extensions 322 which face the apexes 324a are planar. The distal apexes 324a of the stent 316a are also modified so as to have a generally flat or flattened shape, such that the distal apexes 324a of the stent 316a are similar to the proximal apexes 226a and distal apexes 224b shown in Figure 9a. This modification further increases the likelihood of engagement between the planar lateral extensions 322 of the engagement member 320 and the flattened distal apexes 324a of the stent 316a when the prosthesis is subjected to longitudinal compression forces, thus preventing the distal apexes 324a from pushing past the lateral extensions 322.

With prior art arrangements such as that shown in Figure 1, longitudinal compression force applied to the prosthesis via the engagement member(s) would be concentrated only on the connector associated with a particular engagement member and the struts adjacent thereto, that is those structural members which are directly connected to an engagement member. Such a concentration of force can lead to bending and deformation of the connector and struts as the prosthesis is longitudinally compressed, for example as it is pushed into a delivery system or released from the delivery system for implantation.

The arrangements shown in Figures 9a and 9b cause the longitudinal compression force to be distributed to struts which are not directly connected to the engagement member in addition to those connectors and struts which are directly connected to an engagement member. The longitudinal compression force is thus directed to more of the structural members of the prosthesis, and thus laterally across the prosthesis. In addition, due to the flat shape of the stent apexes, longitudinally adjacent stent members are caused to engage upon the application of a longitudinal compression force. Such engagement causes the applied force to be distributed longitudinally throughout the prosthesis as well as being spread out laterally. The combination of a shaped engagement member and shaped apexes can therefore be seen to work synergistically to distribute the

compression force both laterally and longitudinally throughout the prosthesis.

Because the longitudinal compression force is spread out more evenly across the prosthesis, bending and deformation of the connectors and struts of the prosthesis is minimised. This is especially advantageous when prostheses of longer length are used, since such prostheses typically require the application of greater pushing forces due to increased friction.

The disclosures in British patent application number 1102859.4, from which this application claims priority, and in the abstract accompanying this application are incorporated herein by reference.

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Claims

1. A substantially tubular prosthesis (110; 210) comprising a plurality of stent members (116, 116a, 116b; 216a, 216b; 316a) positioned longitudinally along the prosthesis, each stent member comprising a plurality of strut elements (120) connected by apexes (122, 124; 224a, 224b, 226a; 324a), the prosthesis being arranged such that the proximal apexes (122; 226a) of a first stent member (116a; 216a) engage the distal apexes (124; 224b) of a longitudinally adjacent second stent member (116b; 216b) when the prosthesis is subjected to longitudinal compression forces, each of the proximal apexes of the first stent member and the distal apexes of the second stent member having a shaped portion which is flat or concave and having a width, so as to present a line of engagement surfaces to the distal apexes of the second stent member and the proximal apexes of the first stent member respectively, wherein the gaps between circumferentially adjacent engagement surfaces are substantially narrower than the widths of the shaped portions when the prosthesis is in a compressed configuration.

2. A prosthesis according to claim 1, wherein the shaped portions are substantially planar.

3. A prosthesis according to claim 2, wherein the shaped portions are substantially perpendicular to the longitudinal direction of the prosthesis (110; 210).

4. A prosthesis according to claim 2 or 3, wherein the proximal apexes (122; 226a) of the first stent member (116a; 216a) are substantially parallel to the distal apexes (124; 224b) of the second stent member (116b; 216b).

5. A prosthesis according to any preceding claim, wherein the strut elements (120) are substantially parallel when the prosthesis is in a compressed configuration.

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6. A prosthesis according to any preceding claim, wherein each stent member (116, 116a, 116b; 216a, 216b; 316a) is spaced apart from an adjacent stent member by at least one connector (118).

7. A prosthesis according to claim 6, further comprising at least one engagement member (220; 320) located at an end of the prosthesis, the engagement member comprising a lateral extension (222; 322) which extends adjacent the distal apexes (224a; 324a) of the first stent member (216a; 316a) such that the lateral extension engages the distal apexes of the first stent member when the prosthesis is subjected to longitudinal compression forces, the lateral extension being shaped to form a substantially planar engagement surface facing the distal apexes of the first stent member.

8. A prosthesis according to any preceding claim, wherein the stent members (116, 116a, 116b; 216a, 216b; 316a) are fastened to a graft material to form a stent graft.

9. A prosthesis according to claim 8, wherein the stent members (116, 116a, 116b; 216a, 216b; 316a) are fastened to the graft such that each stent member is spaced apart from an adjacent stent member.

10. A method of manufacturing a substantially tubular prosthesis (110; 210), the method comprising the steps of:

forming a plurality of stent members (116, 116a, 116b; 216a, 216b; 316a) positioned longitudinally along the prosthesis, wherein each stent member comprises a plurality of strut elements (120) connected by apexes (122, 124; 224a;, 224b, 226a; 324a);

arranging the prosthesis such that the proximal apexes (122; 226a) of a first stent member (116a; 216a) engage the distal apexes (124; 224b) of a longitudinally adjacent second stent member (116b; 216b) when the prosthesis is

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subjected to longitudinal compression forces; and

forming each of the proximal apexes of the first stent member and the distal apexes of the second stent member to have a shaped portion which is flat or concave and to have a width, so as to present a line of engagement surfaces to the distal apexes of the second stent member and the proximal apexes of the first stent member respectively, wherein the gaps between circumferentially adjacent engagement surfaces are substantially narrower than the widths of the shaped portions when the prosthesis is in a compressed configuration.

11. A method according to claim 10, wherein the shaped portions are formed to be substantially planar.

12. A method according to claim 11, wherein the shaped portions are formed to be substantially perpendicular to the longitudinal direction of the prosthesis (110; 210).

13. A method according to claim 11 or 12, wherein the proximal apexes (122; 226a) of the first stent member (116a; 216a) are formed to be substantially parallel to the distal apexes (124; 224b) of the second stent member (116b; 216b).

14. A method according to any one of claims 10 to 13, wherein the stent members (116, 116a, 116b; 216a, 216b; 316a) are formed such that the strut elements (120) are substantially parallel when the prosthesis (110; 210) is in a compressed configuration.

15. A method according to any one of claims 10 to 14, wherein the prosthesis (110; 210) is formed such that each stent member (116, 116a, 116b; 216a, 216b; 316a) is spaced apart from an adjacent stent member by at least one connector (118).

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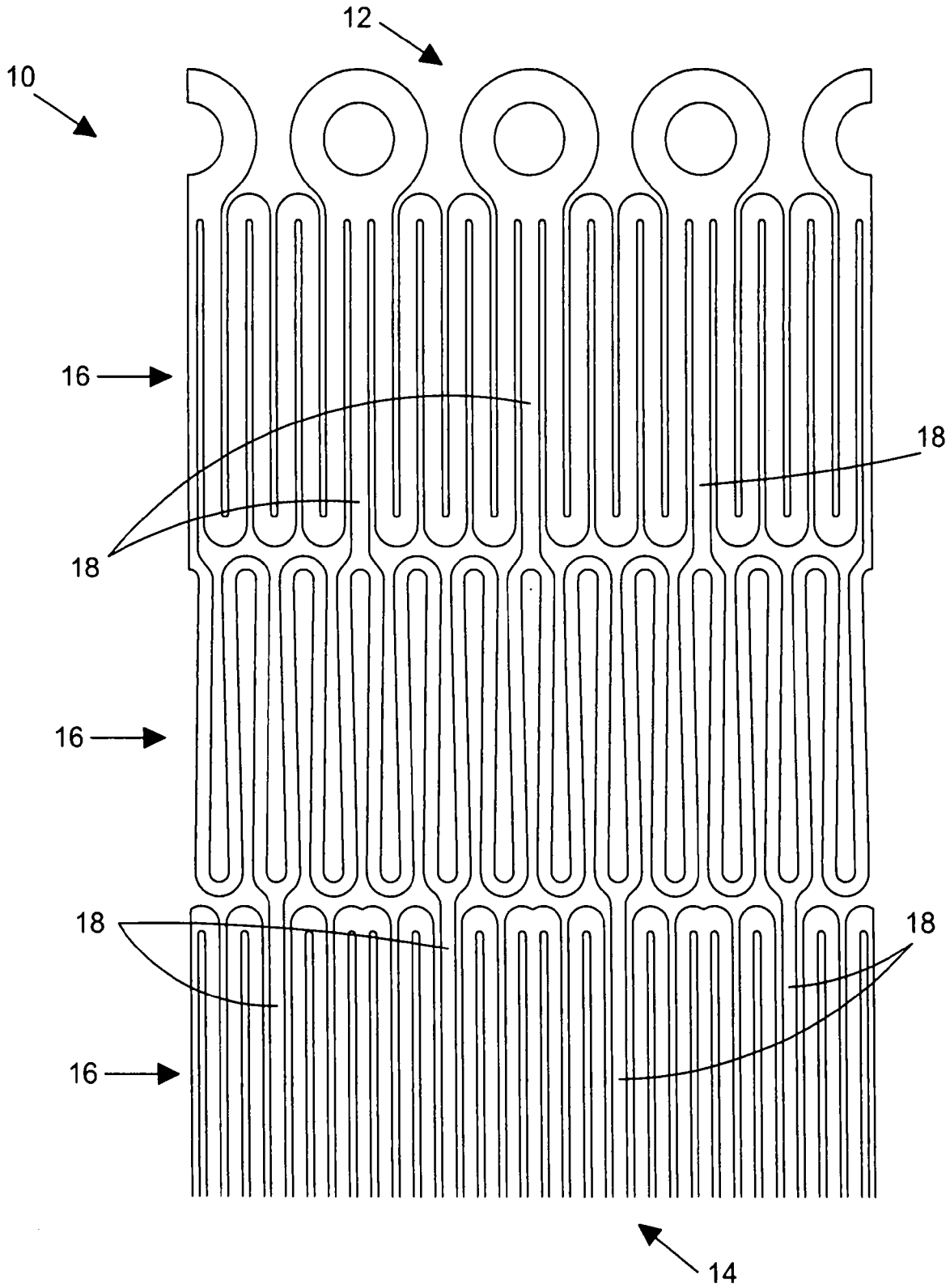

FIGURE 1

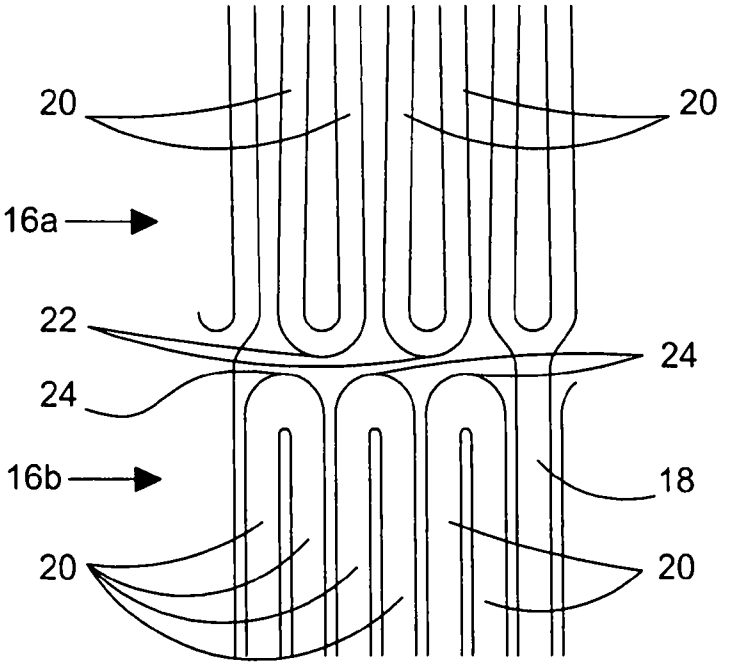

FIGURE 2

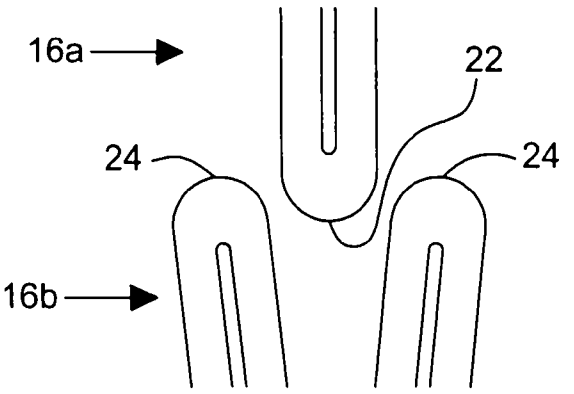

FIGURE 3

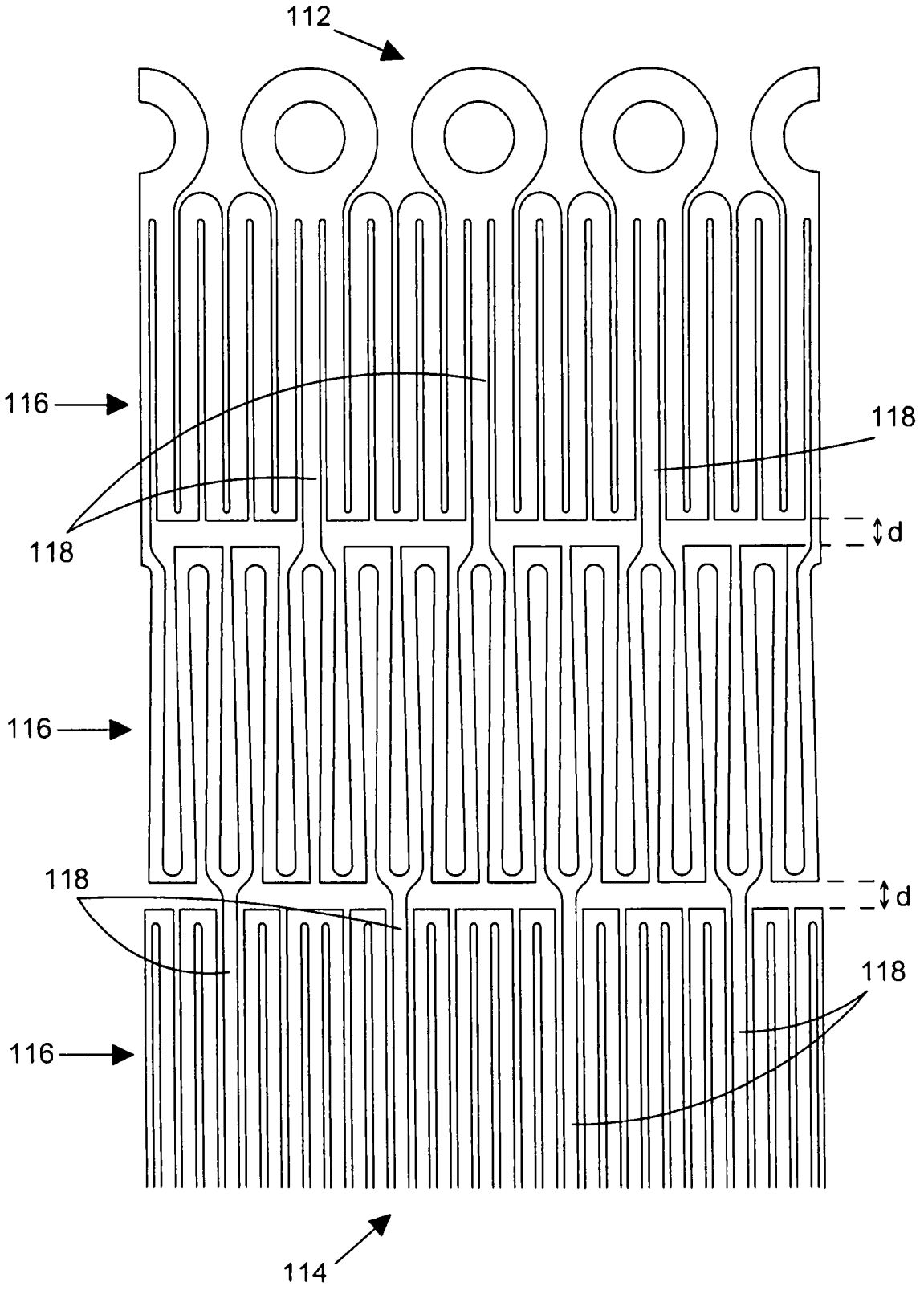

FIGURE 4

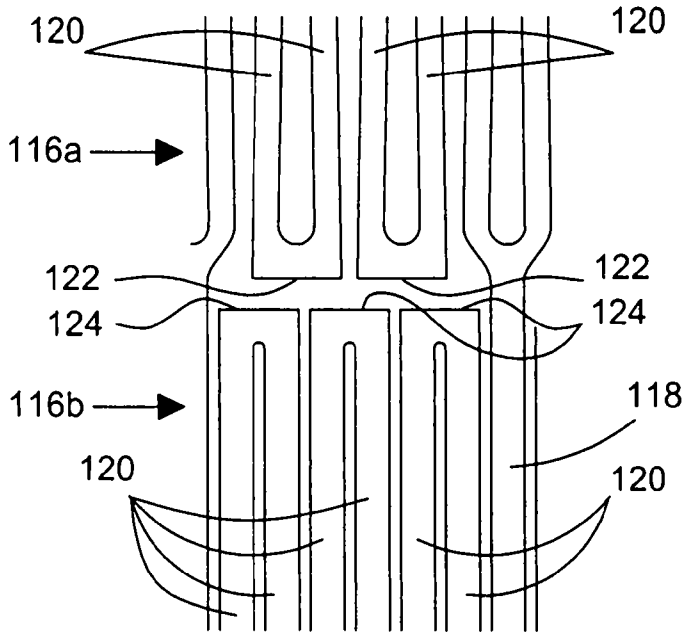

FIGURE 5

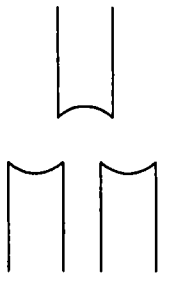

FIGURE 6

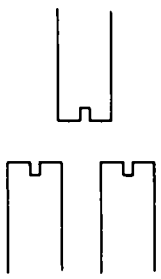

FIGURE 7

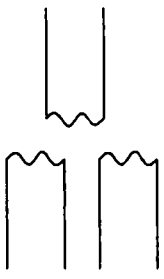

FIGURE 8

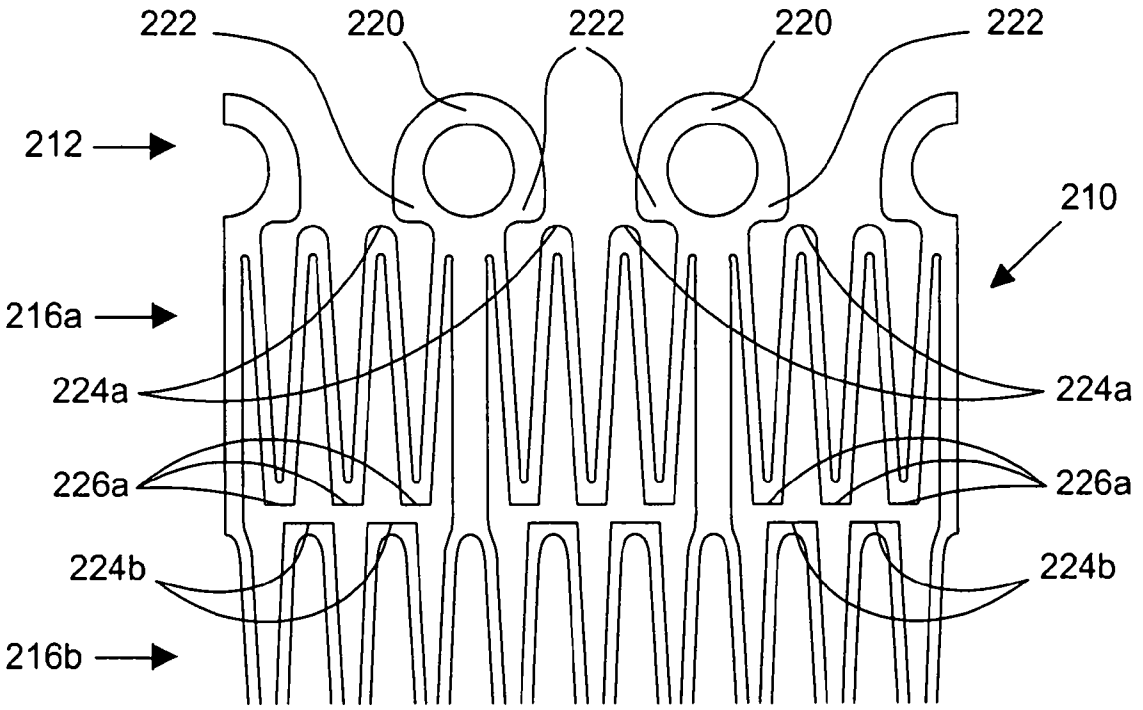

FIGURE 9a

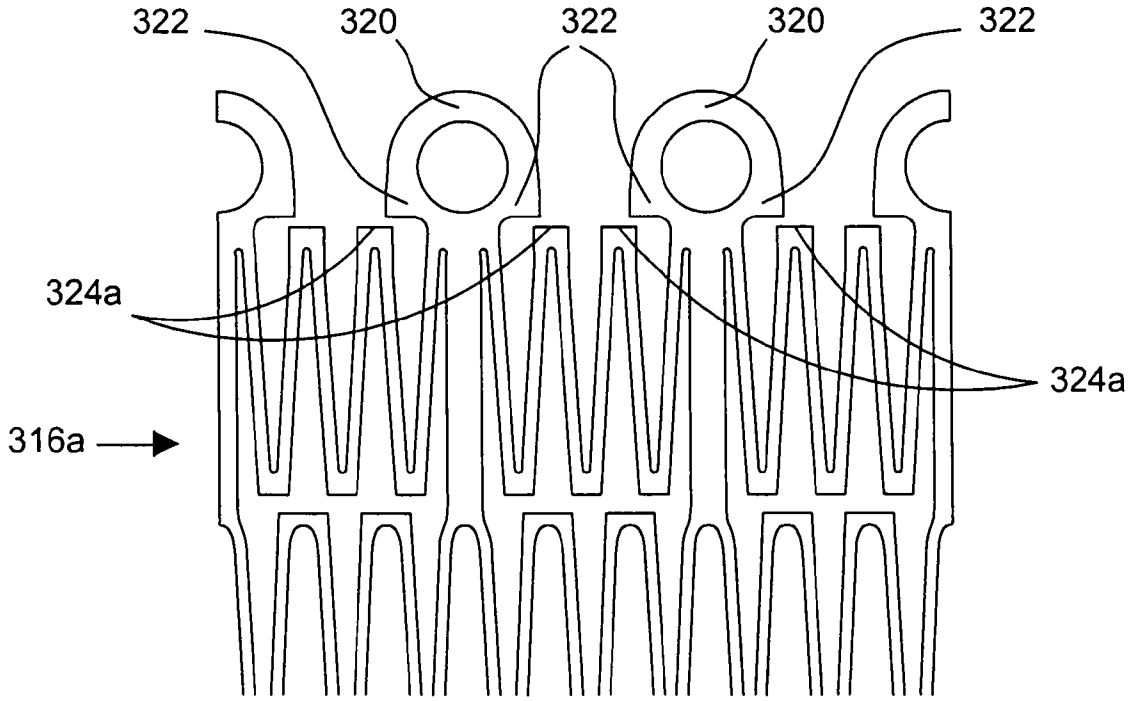

FIGURE 9b