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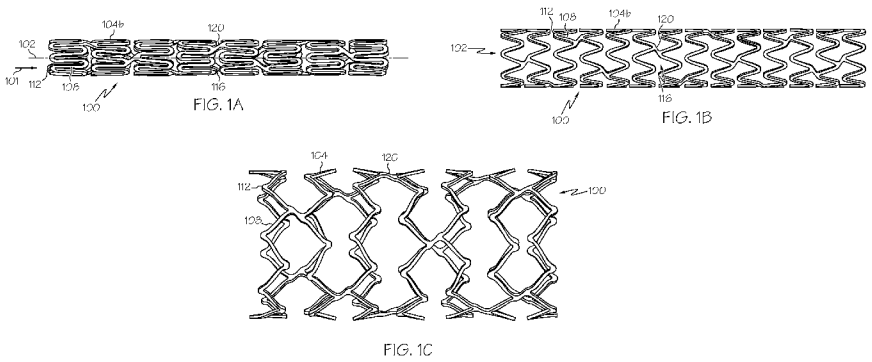

(57) Abstract: An expandable medical framework for implantation in a mammalian body comprises a plurality of serpentine bands and connector columns. Each serpentine band comprises alternating straight band struts and turns. Each connector column comprises a plurality of connector struts and connects adjacent serpentine bands. The turns of a serpentine band comprise connected turns and unconnected turns, each connected turn having a connector strut extending therefrom. Each unconnected turn has no connector struts extending therefrom. The serpentine bands at the ends of the framework are each connected to an intermediate serpentine band via four or more connector struts which are equally spaced about the circumference of the expandable medical framework. Each two adjacent intermediate serpentine bands is connected one to the other via two connector struts which are equally spaced about the circumference of the expandable medical framework.

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STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This Application claims priority from U.S. Application No. 61/427689, filed on December 28, 2010, the entire contents of which is hereby incorporated by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

In some embodiments this invention relates to implantable medical devices, their manufacture, and methods of use.

2. Description of the Related Art

A stent is a medical device introduced to a body lumen and is well known in the art. Typically, a stent is implanted in a blood vessel at the site of a stenosis or aneurysm endoluminally, i.e. by so-called "minimally invasive techniques" in which the stent in a radially reduced configuration, optionally restrained in a radially compressed configuration by a sheath and/or catheter, is delivered by a stent delivery system or "introducer" to the site where it is required. The introducer may enter the body from an access location outside the body, such as through the patient's skin, or by a "cut down" technique in which the entry blood vessel is exposed by minor surgical means.

Stents, grafts, stent-grafts, vena cava filters and, more generally, expandable medical frameworks, and similar implantable medical devices, are radially expandable endoprostheses, which are typically intravascular implants capable of being implanted transluminally and enlarged radially after being introduced percutaneously. Stents, grafts, stent grafts and other expandable medical frameworks, may be implanted in a variety of body lumens or vessels, such as within the vascular system, urinary tracts, bile ducts, fallopian tubes, coronary vessels, secondary vessels, etc. These devices may be used for a variety of purposes including to reinforce body vessels and to

prevent restenosis following angioplasty in the vascular system. They may be self-expanding, expanded by an internal radial force, such as when mounted on a balloon, or a combination of self-expanding and balloon expandable (hybrid expandable).

Any of the above-mentioned devices may be created by methods including cutting or etching a design from a tubular stock or from a flat sheet. The flat sheet may subsequently be rolled. They may also be made from one or more interwoven wires or braids.

The art referred to and/or described herein is not intended to constitute an admission that any patent, publication or other information referred to herein is "prior art" with respect to this invention. In addition, this section should not be construed to mean that a search has been made or that no other pertinent information as defined in 37 C.F.R. 1.56(a) exists.

All US patents and applications and all other published documents mentioned anywhere in this application are incorporated herein by reference in their entirety.

Without limiting the scope of the invention a brief summary of some of the claimed embodiments of the invention is set forth below. Additional details of the summarized embodiments of the invention and/or additional embodiments of the invention may be found in the Detailed Description of the Invention below.

A brief abstract of the technical disclosure in the specification is provided as well only for the purposes of complying with 37 C.F.R. 1.72. The abstract is not intended to be used for interpreting the scope of the claims.

BRIEF SUMMARY OF THE INVENTION

The invention is directed to an expandable medical framework for implantation in a mammalian body. The framework comprises a plurality of serpentine bands including intermediate serpentine bands and end serpentine bands. The intermediate serpentine bands are disposed between the end serpentine bands. Each serpentine band comprises a plurality of alternating straight band struts and turns.

The expandable medical framework also comprises a plurality of connector columns. Each connector column comprises a plurality of connector struts. Each connector column is disposed between and connects two serpentine bands. Each connector strut is connected at one end to a turn of one serpentine band and connected at the other end to a turn of another serpentine band.

The turns of a serpentine band of the expandable medical framework comprise connected turns and unconnected turns. Each connected turn has a connector strut extending therefrom. Each unconnected turn does not have any connector struts extending therefrom.

Each of the end serpentine bands is connected to one of the intermediate serpentine bands via four or more connector struts which are equally spaced about the circumference of the expandable medical framework.

Each two adjacent intermediate serpentine bands is connected one to the other via two connector struts which are equally spaced about the circumference of the expandable medical framework.

The invention is also directed to a stent for implantation in a mammalian body. The stent comprises a plurality of serpentine bands including intermediate serpentine bands and end serpentine bands. The intermediate serpentine bands are disposed between the end serpentine bands. Each serpentine band comprises a plurality of alternating straight band struts and turns.

The stent also comprises a plurality of connector columns. Each connector column comprises a plurality of connector struts. Each connector column is disposed between and connects two serpentine bands. Each connector strut is connected at one end to a turn of one serpentine band and connected at the other end to a turn of another serpentine band. Within a connector column, each connector strut is oriented at the same angle relative to a longitudinal axis bisecting the connected turn from which the connector strut extends. The angle alternates from connector column to connector column.

The turns of a serpentine band comprise connected turns and unconnected turns. Each connected turn has a connector strut extending therefrom. No connector struts extend from any of the unconnected turns.

Desirably, the connector struts are straight. Each connector strut within a connector column is oriented at the same angle relative to a longitudinal axis bisecting the connected turn from which the connector strut extends, said angle reversing from connector column to connector column.

Each of the end serpentine bands is connected to one of the intermediate serpentine bands via a plurality of connector struts to define, desirably, either four or five equally sized cells disposed about the circumference of the stent.

Each two adjacent intermediate serpentine bands is connected one to the other via a plurality of connector struts to define, desirably, two equally sized cells disposed about the circumference of the stent.

These and other embodiments which characterize the invention are pointed out with particularity in the claims annexed hereto and forming a part hereof. However, for further understanding of the invention, its advantages and objectives obtained by its use, reference should be made to the drawings which form a further part hereof and the accompanying descriptive matter, in which there are illustrated and described further embodiments of the invention.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

A detailed description of the invention is hereafter described with specific reference being made to the drawings.

FIG. 1a shows a side view of an expandable medical framework in the form of a crimped stent.

FIG. 1b shows a side view of an expandable medical framework in the form of a stent as cut.

FIG. 1c shows a side view of an expandable medical framework in the form of a stent in an expanded state.

FIG. 2 shows a flat view of an inventive expandable medical framework in the form of a stent as cut.

FIG. 3 shows a flat view of an inventive expandable medical framework in the form of a stent as cut.

FIG. 4 shows a flat view of an inventive expandable medical framework in the form of a stent as cut.

FIG. 5 shows a side view of small portion of an expandable medical stent.

FIG. 6 shows a cross-section of the stent of FIG. 5 taken along 6-6.

FIG. 7 shows an individual strut of the expandable medical framework of FIGS 2-4.

FIG. 8 is a cross-sectional view of a catheter carrying an expandable medical device in the form of a stent.

FIG. 8A shows an enlarged view of the distal end of the catheter of Fig. 8.

DETAILED DESCRIPTION OF THE INVENTION

While this invention may be embodied in many different forms, there are described in detail herein specific embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

For the purposes of this disclosure, like reference numerals in the figures shall refer to like features unless otherwise indicated.

In one aspect, the invention is directed to an expandable medical framework, shown at 100 in Fig. 1a, for implantation in a mammalian body. Typically, the framework will be sized and configured for implantation in the human body. The expandable medical framework, is in the form of a tube with a flowpath 101 therethrough. Longitudinal axis 102 extends through the tube. As shown in Fig. 1a the expandable medical framework, in the form of a stent, is in a crimped state. Fig. 1b depicts an inventive expandable medical framework, in the form of a stent as cut. Fig. 1c depicts an inventive expandable medical framework, in the form of an expanded stent.

As shown in a crimped state in Fig. 1a, and in an as-cut state in Figs. 1b, and 2-4, and in an expanded state in Fig. 1c, expandable medical framework 100, in the form of a stent, comprises a plurality of serpentine bands 104 including end serpentine bands 104a and intermediate serpentine bands 104b. Intermediate serpentine bands 104b are disposed between end serpentine bands 104a. Each serpentine band 104 comprises a plurality of alternating band struts 108 and turns 112. Desirably band struts 108 are straight. Turns 112 desirably are rounded. In other embodiments, the turns may be generally elliptical, square or pointed or any other configuration.

As shown at least in Fig. 2, turns 112 include proximal turns 112a which are located at a proximal end of a serpentine band 104 and distal turns 112b which are located at a distal end of a serpentine band 104. The proximal turns may also be referred to as troughs or valleys. The distal turns may also be referred to as peaks.

Expandable medical framework 100 also comprises a plurality of connector columns 116. Each connector column 116 comprises a plurality of connector struts 120. Each connector column 116 is disposed between and connects two serpentine bands 104. Each connector strut 120 is connected at one end to a turn 112,

typically a proximal turn 112a of one serpentine band 104 and connected at the other end to a turn 112, typically a distal turn 112b of another serpentine band 104.

The turns 112 of a serpentine band of the expandable medical framework comprise connected turns 112c and unconnected turns 112d. Each connected turn 112c has a connector strut 120 extending therefrom. Each unconnected turn does not have any connector struts extending therefrom. The only struts extending from an unconnected turn are the two band struts which are joined by the unconnected turn. Connected turns may be located at a proximal end of a serpentine band, at a distal end of a serpentine band or at both the proximal and distal ends of a serpentine band.

Each of the end serpentine bands 104a is connected to one of the intermediate serpentine bands 104b via four or more connector struts 120 which are equally spaced about the circumference of the expandable medical framework. Figs. 2 and 3 show an expandable medical framework with four connector struts connecting the two end-most serpentine bands at either end of the stent. Fig. 4 shows an expandable medical framework with five connector struts connecting the two end-most serpentine bands at either end of the stent.

As shown in Figures 2-4, each two adjacent intermediate serpentine bands 104b is connected one to the other via two connector struts 120 which are equally spaced about the circumference of the expandable medical framework.

Desirably, the ratio of the width W shown in Fig. 2, of the connector strut 120, as measured along the connector strut 120 in a non-radial direction normal to the length of the connector strut 120, to the width of the band strut 108, as measured along the band strut 108 in a non-radial direction normal to the length of the band strut 108, will range from 1.1 to 1.4.

Each turn 112 has a width, which may be measured along a longitudinal line bisecting the turn 112. Desirably, the ratio of the width of a turn 112 to the width of a band strut 108 is 1.6 to 1.8.

As further shown in Figures 2-4, connector struts 120 within a connector column are all oriented at the same angle 124 relative to a longitudinal axis 126 bisecting two connected struts 108. Connector struts 120 in adjacent connector columns 116 are oppositely oriented. Thus, angle 124a of connector struts 120 in connector column 116a and angle 124b of connector struts 120 in connector column 116b are identical, however, they point in opposite directions relative to the longitudinal axis bisecting the connected turn from which the connector strut extends. Typically, this

angle will be between 35° and 50° relative to a longitudinal axis bisecting the connected turn from which the connector strut extends. Angle 124 is also depicted in Fig. 5. Because Fig. 5 is a side view, only one of the two connectors between adjacent serpentine bands is visible.

Typically, as shown in Figures 6 and 7, band struts 108 have outer surfaces 128 with rounded edges 136. The outer surface is the surface which points radially outward. The inner surface 132 faces radially inward. The band struts in 108 are straight. Desirably, other than the rounding of the edges of the band strut and any curvature inherent in the tubular nature of the stent, there is no other curvature to the band strut.

Typically, unconnected turns 112 each have an outer radius 140 as measured on the outside of the unconnected turn 112 of between 0.0035 inches and 0.0050 inches.

The expandable medical framework will, desirably, have a thickness, as measured in a radial direction, of between 0.0025 inches and 0.0034 inches.

In the expandable medical framework of Figures 2 and 3, each serpentine band has sixteen band struts 108. As previously discussed, two connector struts 120 connect intermediate serpentine bands 104b and four connector struts 120 connect the end serpentine bands 104a and an intermediate serpentine band 104b. This arrangement results in only three turns 112 of a serpentine band 104 being disposed between adjacent connector struts 120 connecting an end serpentine band 104a to an intermediate serpentine band 104b. This amounts to one peak and two troughs on one of the connected serpentine bands and two peaks and one trough on the other of the two serpentine bands.

This arrangement also results in only seven turns 112 of a serpentine band 104 being disposed between adjacent connector struts 120 connecting an intermediate serpentine band 104b to an adjacent intermediate serpentine band 104b. This amounts to three peaks and four troughs on one of the connected serpentine bands and four peaks and three troughs on the other of the two serpentine bands.

The four connector struts 120 between the end serpentine bands 104a and the intermediate serpentine bands 104b are equally spaced about the circumference of the expandable medical framework. Each interconnected intermediate serpentine band and end serpentine band has four equally sized cells 144 disposed about the circumference of the stent.

Similarly, the two connector struts 120 between the intermediate serpentine bands 104b are equally spaced about the circumference of the expandable medical framework. Each two interconnected intermediate serpentine bands has two equally sized cells 144 disposed about the circumference of the stent.

In the expandable medical framework of Fig. 4, each serpentine band has twenty band struts 108. As previously discussed, two connector struts 120 connect intermediate serpentine bands 104b and five connector struts 120 connect the end serpentine bands 104a and an intermediate serpentine band 104b. This arrangement results in only three turns 112 of a serpentine band being disposed between adjacent connector struts 120 connecting an end serpentine band 104a to an intermediate serpentine band 104b. This amounts to one peak and two troughs on one of the connected serpentine bands and two peaks and one trough on the other of the two serpentine bands.

This arrangement also results in only nine turns 112 of a serpentine band being disposed between adjacent connector struts 120 connecting an intermediate serpentine band 104b to an adjacent intermediate serpentine band 104b. This amounts to four peaks and five troughs on one of the connected serpentine bands and five peaks and four troughs on the other of the two serpentine bands.

The five connector struts 120 between the end serpentine bands 104a and the intermediate serpentine bands 104b are equally spaced about the circumference of the expandable medical framework. Each interconnected intermediate serpentine band and end serpentine band has five equally sized cells 144 disposed about the circumference of the stent.

Similarly, the two connector struts 120 between the intermediate serpentine bands 104b are equally spaced about the circumference of the expandable medical framework. Each two interconnected intermediate serpentine bands have two equally sized cells 144 disposed about the circumference of the stent.

The expandable medical frameworks can have any suitable number of serpentine bands. A serpentine band can span any suitable distance along the length of the expandable framework. Similarly, a connector strut can span any suitable distance along the length of the expandable framework.

The expandable medical framework of Figures 2-4 is shown in the as cut state of the stent 100. In use, the stents may be provided in a reduced diameter configuration carried by a catheter. When provided in such a configuration such, as by

crimping the stent, as shown by way of example in Fig. 1a, the band struts 108 of the stent may optionally extend parallel to the longitudinal axis 102 of the stent or close to parallel to the longitudinal axis 102 of the stent. The angle formed between adjacent band struts will be reduced compared to the angle in the as cut configuration. When in the fully expanded configuration, the angle formed between adjacent band struts may be the same as, greater than or less than that shown in Figs. 2-4.

The expandable medical frameworks can be of uniform outer and/or inner diameter or they can be provided with a variable outer and/or inner diameter. For example, the outer and/or inner diameters can include a taper at one or both ends of the framework. Optionally, one end or both ends can have a larger outer and/or inner diameter than the middle of the expandable medical framework. Optionally, one end or both ends can have a smaller outer and/or inner diameter than the middle of the expandable medical framework.

The inventive expandable medical frameworks are depicted as having a single flowpath extending therethrough. However, the inventive expandable medical frameworks may also be used as a part of a bifurcated medical framework such as, but not limited to, a bifurcated stent. Any of the expandable medical frameworks can serve as a branch of or as main body portion of a bifurcated expandable medical framework in general and a bifurcated stent in particular.

It is within the scope of the invention for the expandable medical frameworks disclosed herein to be balloon-expandable or otherwise mechanically expandable, self-expanding or a combination of balloon expandable and/or mechanically expandable and self-expanding. Thus, stents, grafts, stent-grafts, vena cava filters and other medical devices made in accordance with the invention may be balloon-expandable or otherwise mechanically expandable, self-expanding or a combination of balloon expandable and/or mechanically expandable and self-expanding. Desirably, they will be balloon expandable.

Any of the inventive expandable medical frameworks disclosed herein may be made from any suitable biocompatible materials including one or more polymers, one or more metals or combinations of polymer(s) and metal(s). Examples of suitable materials include biodegradable materials that are also biocompatible.

The expandable medical frameworks can have one or more components constructed from one or more metals, polymers or combinations thereof that are corrodible so as to dissolve, dissociate or otherwise break down in the body without ill

effect. Examples of such materials have been referred to as being degradable, biodegradable, biologically degradable, erodable, bioabsorbable, bioresorbable, and the like. Biodegradable material will generally undergo breakdown or decomposition into harmless compounds as part of a normal biological process. Suitable biodegradable materials include polylactic acid, polyglycolic acid (PGA), collagen or other connective proteins or natural materials, polycaprolactone, hylauric acid, adhesive proteins, co-polymers of these materials as well as composites and combinations thereof and combinations of other biodegradable polymers. Other polymers that may be used include polyester and polycarbonate copolymers.

Examples of suitable metals include, but are not limited to, stainless steel, titanium, tantalum, platinum, tungsten, gold and alloys of any of the above-mentioned metals. Examples of suitable alloys include platinum-chromium alloys, platinum-iridium alloys, cobalt-chromium alloys including Elgiloy and Phynox, MP35N alloy and nickel-titanium alloys, for example, Nitinol. Examples of biodegradable alloys, such as magnesium alloys and zinc alloys, are disclosed in US 6854172 and US 2006/0052864, the entire contents of which are hereby incorporated herein by reference.

The inventive expandable medical frameworks may be made of shape memory materials such as superelastic Nitinol or spring steel, or may be made of materials which are plastically deformable. In the case of shape memory materials, the expandable medical frameworks may be provided with a memorized shape and then deformed to a reduced diameter shape. The expandable medical framework may restore itself to its memorized shape upon being heated to a transition temperature and having any restraints removed therefrom.

In addition to or in place of the above materials, the inventive expandable medical frameworks may comprise ceramics.

The inventive expandable medical frameworks may include a coating or other portion of radiopaque material in one or more desired locations to allow for visualizing the device under X-rays. Examples of suitable locations for the radiopaque material include one or more ends of the framework and/or the middle of the framework. The expandable medical frameworks may likewise be provided with MRI sensitive markers to enhance MRI visibility under desired MRI imaging techniques.

The inventive expandable medical frameworks may be created by methods including laser or mechanical cutting or etching a design from a tubular stock

or from a flat sheet. In the case of a flat sheet, the sheet may subsequently be rolled into tubular form. Optionally, the long edges of the sheet may be joined together, optionally by welding, to form a closed expandable medical framework. Alternatively, the edges may be left unsecured to one another. Any other suitable technique which is known in the art or which is subsequently developed may also be used to manufacture the inventive expandable medical frameworks disclosed herein.

The inventive expandable medical frameworks may be polished and cleaned as necessary using any suitable technique which is known in the art or which is subsequently developed.

Optionally, at least a portion of the expandable medical framework may be configured to include one or more mechanisms for the delivery of a therapeutic agent. Often the agent will be in the form of a coating or other layer (or layers) of material placed on a surface region of the expandable medical framework, which is adapted to be released at the site of the expandable medical framework's implantation or areas adjacent thereto.

A therapeutic agent may be a drug or other pharmaceutical product such as non-genetic agents, genetic agents, cellular material, etc. Some examples of suitable non-genetic therapeutic agents include but are not limited to: anti-thrombogenic agents such as heparin, heparin derivatives, vascular cell growth promoters, growth factor inhibitors, Paclitaxel, etc. Some other examples of therapeutic agents include everolimus and sirolimus, their analogs and conjugates. Where an agent includes a genetic therapeutic agent, such a genetic agent may include but is not limited to: DNA, RNA and their respective derivatives and/or components; hedgehog proteins, etc. Where a therapeutic agent includes cellular material, the cellular material may include but is not limited to: cells of human origin and/or non-human origin as well as their respective components and/or derivatives thereof. The therapeutic agent may be provided by itself or in conjunction with a polymer agent. The polymer agent may be a polystyrene-polyisobutylene-polystyrene triblock copolymer (SIBS), polyethylene oxide, silicone rubber and/or any other suitable substrate. The inventive expandable medical frameworks may include one or more of the above-mentioned therapeutic agents and/or polymers.

The expandable medical frameworks disclosed herein may be delivered to a desired bodily location via a catheter. Stent 100 is shown schematically, in Figure 8, being carried on catheter 200 including balloon 204 at the distal end of the catheter.

In the case of balloon expandable medical frameworks including stents and stent-grafts, the catheter will include a balloon and the expandable medical framework will be disposed about the balloon. The balloon will typically be expanded once the expandable medical framework is delivered to a desired location in the body. This will result in expansion of the expandable medical framework. The balloon may then be deflated and the catheter repositioned within the body or withdrawn therefrom.

In the case of a mechanically expandable medical framework, including stents and stent-grafts, the catheter will include a mechanism capable of mechanically expanding the expandable medical framework. The mechanism will typically be expanded once the expandable medical framework is delivered to a desired location in the body. This will result in expansion of the expandable medical framework. The catheter may then be repositioned within the body or withdrawn therefrom.

In the case of a self-expanding expandable medical framework, including stents and stent-grafts, the catheter will typically include a sheath disposed about the expandable medical framework. Once the sheath is withdrawn or retracted from expandable medical framework, the expandable medical framework will self-expand. The catheter may then be repositioned within the body or withdrawn therefrom.

The invention is also directed to the combination of an expandable medical framework and a catheter. The catheter may be any of those disclosed above or any other suitable catheter.

The invention is also directed to a catheter with any of the inventive expandable medical frameworks disclosed herein disposed at or near the distal end thereof. The expandable medical framework may be disposed about a balloon in the case of balloon expandable medical frameworks. The expandable medical framework may be disposed within a sheath in the case of self-expandable expandable medical frameworks.

The invention is also directed methods of delivering an expandable medical framework to a desired location in a body and methods of treating a portion of a body. The method involves providing a catheter carrying an expandable medical framework disclosed herein, using the catheter to delivering the expandable medical framework to the desired bodily location and deploying the expandable medical framework at the desired bodily location.

Where the expandable medical framework is a balloon expandable stent, the stent, the balloon will be inflated at the desired bodily location and the stent thereby deployed.

Where the expandable medical framework is a self-expandable stent, a sheath covering the stent is retracted at the desired bodily location and the stent thereby deployed.

Following deployment, the catheter is withdrawn from the body.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. The various elements shown in the individual figures and described above may be combined or modified for combination as desired. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to".

Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below. This completes the description of the invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

Claims

1. An expandable medical framework for implantation in a mammalian body comprising:

a plurality of serpentine bands including intermediate serpentine bands and end serpentine bands, the intermediate serpentine bands disposed between the end serpentine bands, each serpentine band comprising a plurality of alternating straight band struts and turns; and

a plurality of connector columns, each connector column comprising a plurality of connector struts, each connector column disposed between and connecting two serpentine bands, each connector strut connected at one end to a turn of one serpentine band and connected at the other end to a turn of another serpentine band,

the turns of a serpentine band comprising connected turns and unconnected turns, each connected turn having a connector strut extending therefrom, each unconnected turn not having a connector strut extending therefrom;

each of the end serpentine bands connected to one of said intermediate serpentine bands via four or more connector struts which are equally spaced about the circumference of the expandable medical framework,

each two intermediate serpentine bands which are adjacent one another are connected one to the other via two connector struts, the two connector struts being equally spaced about the circumference of the expandable medical framework.

2. The expandable medical framework of claim 1 in the form of a balloon-expandable or self-expanding stent.

3. The expandable medical framework of claim 2 in the form of a balloon-expandable stent.

4. The expandable medical framework of claim 3, wherein each of the end serpentine bands are connected to one of said intermediate serpentine bands by four connector struts which are equally spaced about the circumference of the stent.

5. The expandable medical framework of claim 4, wherein the connector struts within a connector column are all oriented at the same angle relative to the longitudinal axis and the connector struts in a connector column adjacent thereto are all oppositely oriented relative to said angle.

6. The expandable medical framework of claim 5, wherein the straight band struts have outer surfaces facing radially outward and inner surfaces facing radially inward, wherein the outer surfaces have rounded edges.

7. The expandable medical framework of claim 6, wherein the unconnected turns each have an outer radius as measured on the outside of the unconnected turn, wherein the outer radius is between 0.0035 inches and 0.0050 inches.

8. The expandable medical framework of claim 7 having a thickness as measured in a radial direction of between 0.0025 inches and 0.0034 inches.

9. The expandable medical framework of claim 8 wherein the angle of the connector struts in the connector column alternates between 35 degrees relative to a longitudinal axis bisecting the connected turn from which the connector strut extends and 50 degrees relative to a longitudinal axis bisecting the connected turn from which the connector strut extends.

10. The expandable medical framework of claim 9, wherein each serpentine band has sixteen struts and wherein there only three turns disposed between adjacent connector struts connecting an end serpentine band to an intermediate serpentine band.

11. The expandable medical framework of claim 3, wherein each end serpentine band is connected to one of said intermediate serpentine bands by five connector struts which are equally spaced about the circumference of the stent.

12. The expandable medical framework of claim 11, wherein the connector struts within a connector column are all oriented at the same angle relative to the longitudinal axis and the connector struts in a connector column adjacent thereto are all oppositely oriented relative to said angle.

13. The expandable medical framework of claim 12, wherein the straight band struts have outer surfaces facing radially outward and inner surfaces facing radially inward, wherein the outer surfaces have rounded edges.

14. The expandable medical framework of claim 13, wherein the unconnected turns each have an outer radius as measured on the outside of the unconnected turn, wherein the outer radius is between 0.0035 inches and 0.0050 inches.

15. The expandable medical framework of claim 14 having a thickness as measured in a radial direction of between 0.0025 inches and 0.0034 inches.

16. The expandable medical framework of claim 15, wherein the angle of the connector struts in the connector column alternates between 35 degrees relative to a longitudinal axis bisecting the connected turn from which the connector strut extends and 50 degrees relative to a longitudinal axis bisecting the connected turn from which the connector strut extends.

17. The expandable medical framework of claim 9, wherein each serpentine band has twenty struts and wherein there are only three turns disposed between adjacent connector struts connecting an end serpentine band to an intermediate serpentine band.

18. A stent for implantation in a mammalian body comprising:

a plurality of serpentine bands including intermediate serpentine bands and end serpentine bands, the intermediate serpentine bands disposed between the end serpentine bands, each serpentine band comprising a plurality of alternating straight band struts and turns; and

a plurality of connector columns, each connector column comprising a plurality of connector struts, each connector column disposed between and connecting two serpentine bands, each connector strut connected at one end to a turn of one serpentine band and connected at the other end to a turn of another serpentine band, each connector strut within a connector column oriented at the same angle relative to a longitudinal axis bisecting the connected turn from which the connector strut extends, said angle alternating from connector column to connector column,

the turns of a serpentine band comprising connected turns and unconnected turns, each connected turn having a connector strut extending therefrom, each unconnected turn not having any connector struts extending therefrom, the connector struts being straight, each connector strut within a connector column oriented at the same angle relative to a longitudinal axis bisecting the connected turn from which the connector strut extends, said angle reversing from connector column to connector column;

each of the end serpentine bands connected to one of said intermediate serpentine bands a plurality of connector struts to define either four or five equally sized cells disposed about the circumference of the stent,

each two intermediate serpentine bands which are adjacent one another are connected one to the other via a plurality of connector struts to define two equally sized cells disposed about the circumference of the stent.

19. The stent of claim 18 having a thickness as measured in a radial direction of between 0.0025 inches and 0.0034 inches.

20. The stent of claim 19, wherein there are only three turns disposed between adjacent connector struts connecting an end serpentine band to an intermediate serpentine band.

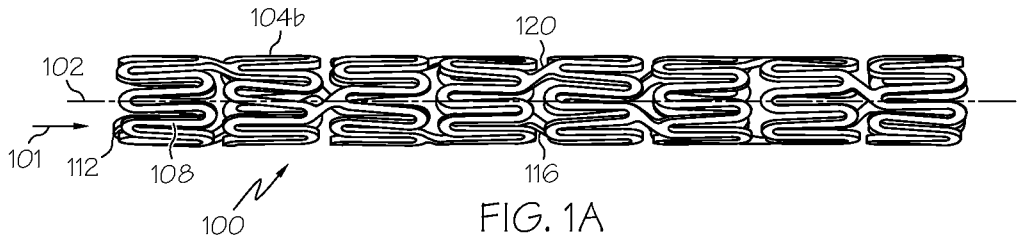


FIG. 1A

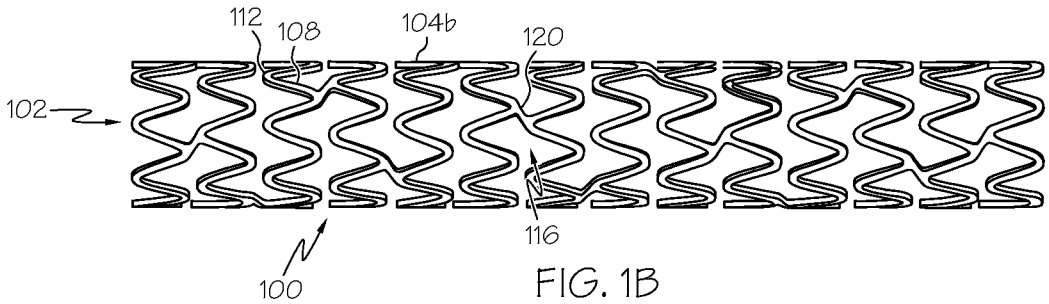


FIG. 1B

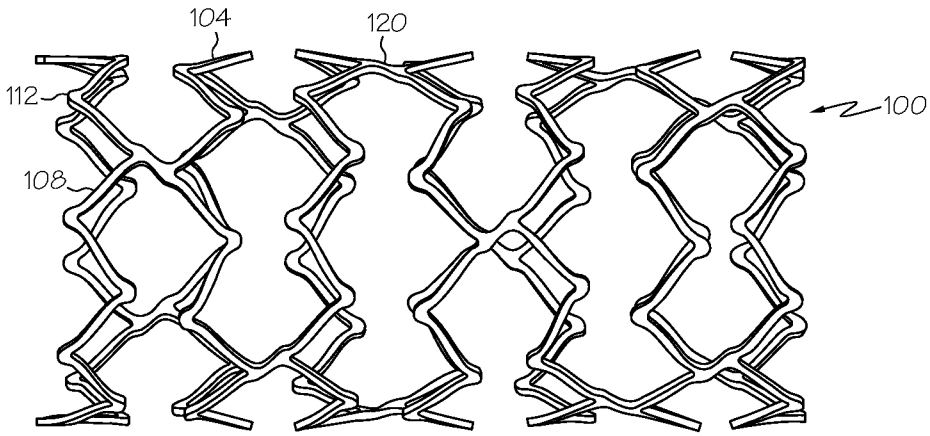
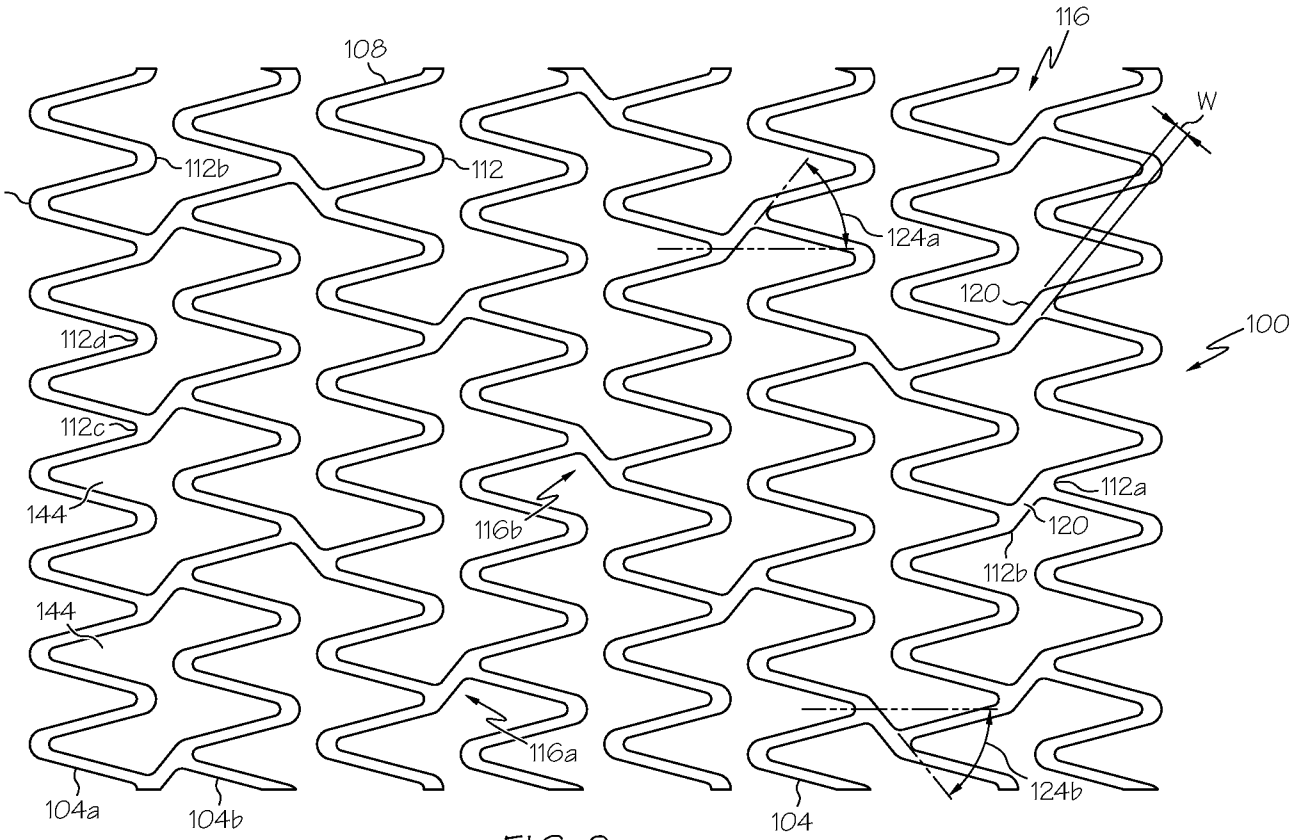


FIG. 1C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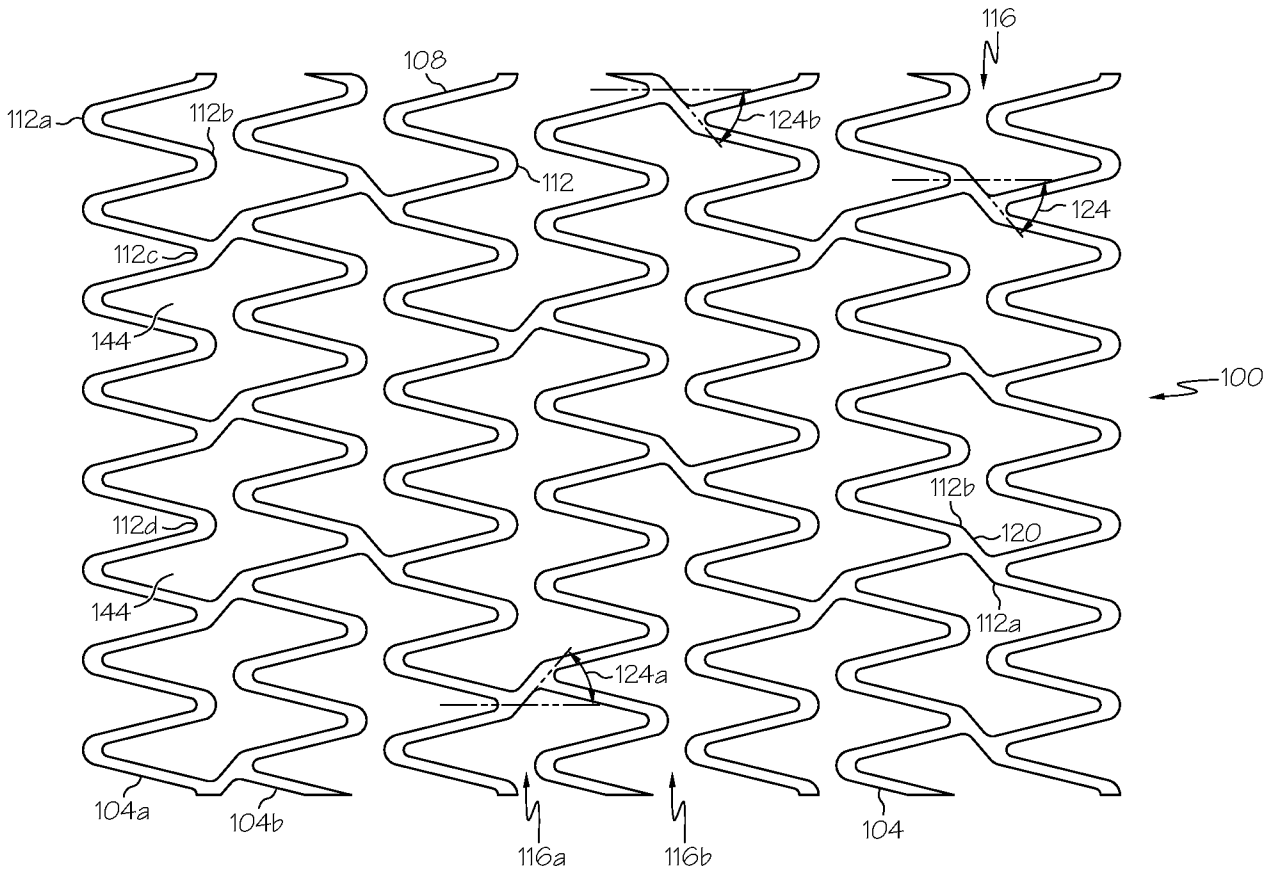
104
124b

FIG. 2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116b
104

FIG. 3

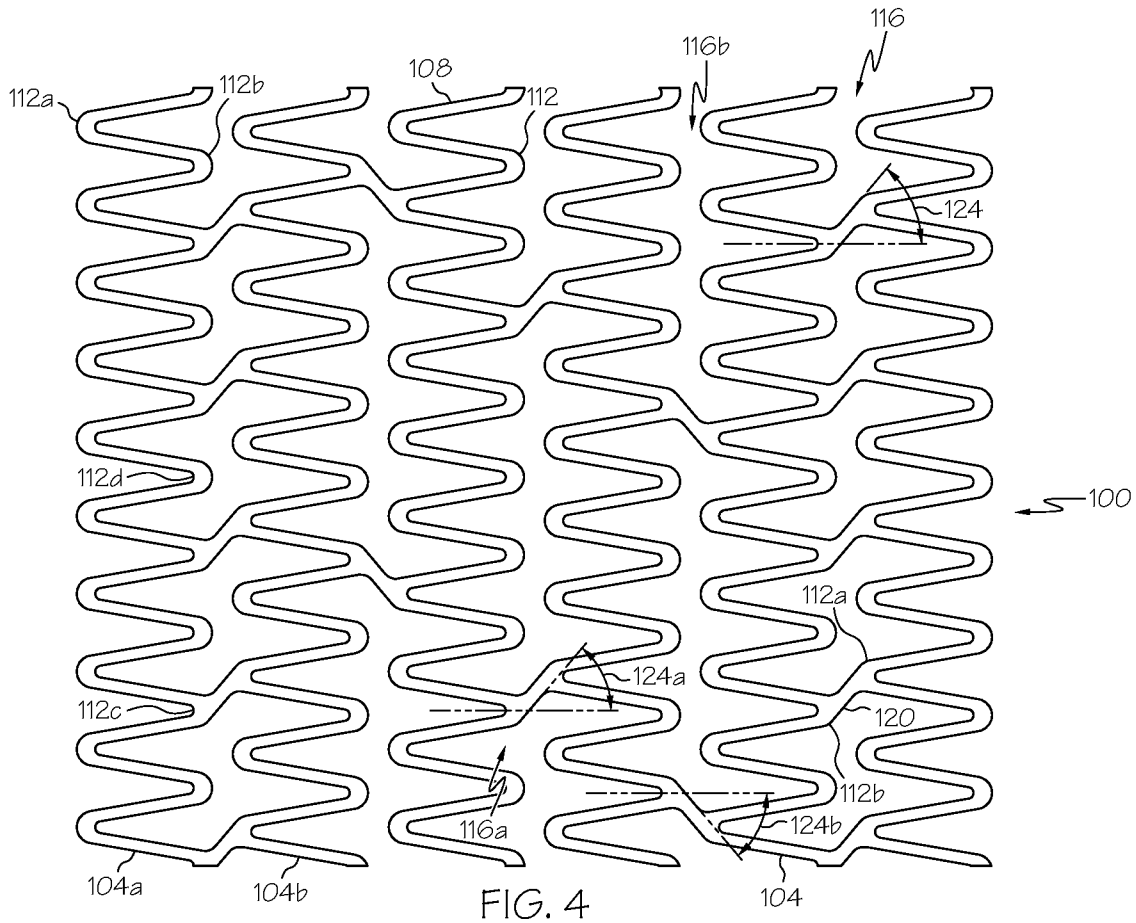
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FIG. 4

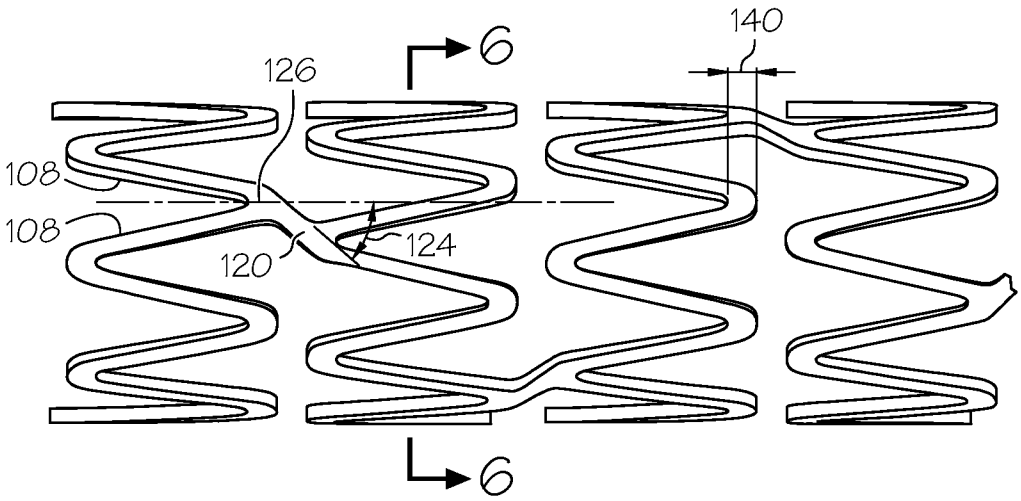

FIG. 5

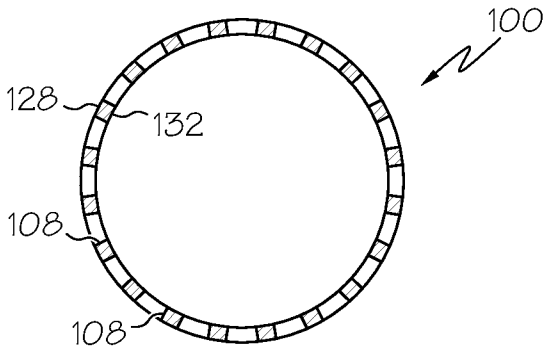

FIG. 6

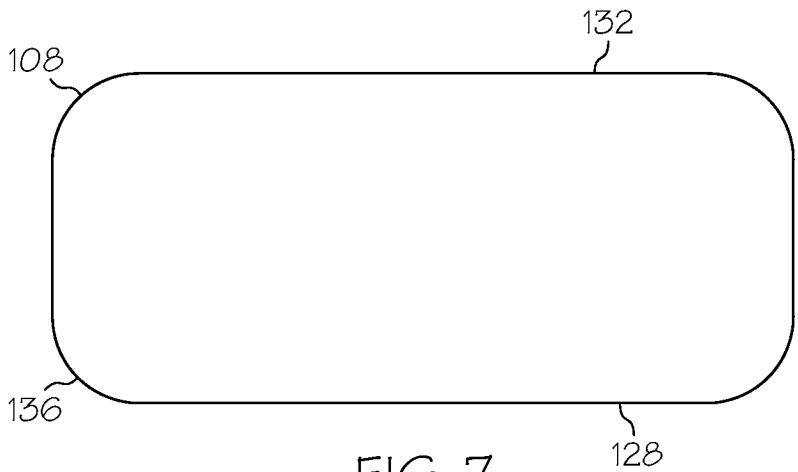

FIG. 7

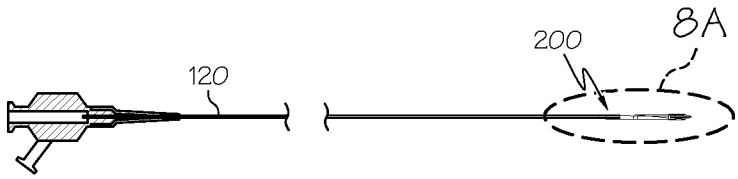

FIG. 8

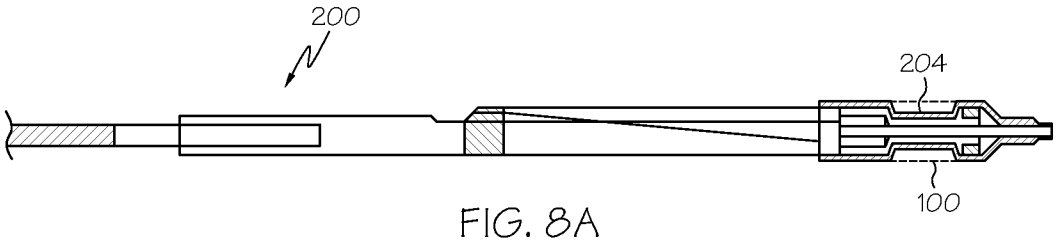

FIG. 8A

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/052720

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/90
ADD.

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	WO 2007/131798 A1 (ANGIOMED AG [DE]; SCHLUN MARTIN [DE]; ZIPSE ACHIM [DE]; WACK THILO [DE) 22 November 2007 (2007-11-22)	1-8,10, 11
Y	figures 5-9 page 11, paragraph 5 - page 16, paragraph 3 -----	9,12-20
Y	EP 1 719 479 A2 (BOSTON SCIENT LTD [BB]) 8 November 2006 (2006-11-08) paragraph [0069] - paragraph [0071]; figure 1a -----	9,12-20
A	US 2004/243216 A1 (GREGORICH DANIEL [US]) 2 December 2004 (2004-12-02) figures 1,2,11,12 paragraph [0042] - paragraph [0050] paragraph [0078] - paragraph [0081] ----- -/--	1-20

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

[X] See patent family annex.

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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
10 November 2011	17/11/2011

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, Fax: (+31-70) 340-3016	Mary, Céline

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/052720

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97/25937 A1 (JANG G DAVID [US]) 24 July 1997 (1997-07-24) claims 1-9 -----	1-20

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/052720

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007131798 A1	22-11-2007	CA 2652214 A1	22-11-2007
		EP 2020966 A1	11-02-2009
		JP 2009537192 A	29-10-2009
		US 2010298921 A1	25-11-2010
		WO 2007131798 A1	22-11-2007
EP 1719479 A2	08-11-2006	NONE	
US 2004243216 A1	02-12-2004	AT 471131 T	15-07-2010
		CA 2521226 A1	09-12-2004
		EP 1626677 A2	22-02-2006
		JP 2007500051 A	11-01-2007
		US 2004243216 A1	02-12-2004
		US 2007010872 A1	11-01-2007
		WO 2004105644 A2	09-12-2004
WO 9725937 A1	24-07-1997	NONE	