(12) STANDARD PATENT (11) Application No. **AU 2007284361 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Stent graft extension

(51) International Patent Classification(s)
A61F 2/06 (2006.01)

(21) Application No: **2007284361** (22) Date of Filing: **2007.08.20**

(87) WIPO No: **WO08/021556**

(30) Priority Data

(31) Number	(32) Date	(33) Country
60/838,963	**2006.08.18**	**US**

(43) Publication Date: **2008.02.21**
(44) Accepted Journal Date: **2012.06.14**

(71) Applicant(s)
Cook Incorporated;William A. Cook Australia Pty. Ltd.

(72) Inventor(s)
Ducke, Werner D.;Hartley, David Ernest

(74) Agent / Attorney
Madderns Patent & Trade Mark Attorneys, GPO Box 2752, Adelaide, SA, 5001

(56) Related Art
US 6033435 A (PENN et al) 7 March 2000
US 2003/0199967 A1 (HARTLEY et al) 23 October 2003
WO 2005/032340 A1 (SECANT MEDICAL LLC)
US 6945992 B2 (GOODSON et al) 20 September 2005

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 February 2008 (21.02.2008)

PCT

(10) International Publication Number
WO 2008/021556 A1

(51) International Patent Classification:
A61F 2/06 (2006.01)

(21) International Application Number:
PCT/US2007/018409

(22) International Filing Date: 20 August 2007 (20.08.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/838,963 18 August 2006 (18.08.2006) US

(71) Applicants *(for all designated States except US)*: **WILLIAM A. COOK AUSTRALIA PTY. LTD.** [AU/AU]; 12 Electronics Street, Brisbane Technology Park, Eight Mile Plains, Brisbane, Queensland 4113 (AU). **COOK INCORPORATED** [US/US]; 750 North Daniel's Way, P.O. Box 489, Bloomington, IN 47402-0489 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **HARTLEY, David, Ernest** [AU/AU]; 2 View Street, Subiaco, Westaustralia 6008 (AU). **DUCKE, Werner, D.** [AU/AU]; 4 Mattison Way, Greenwood, Western Australia 6024 (AU).

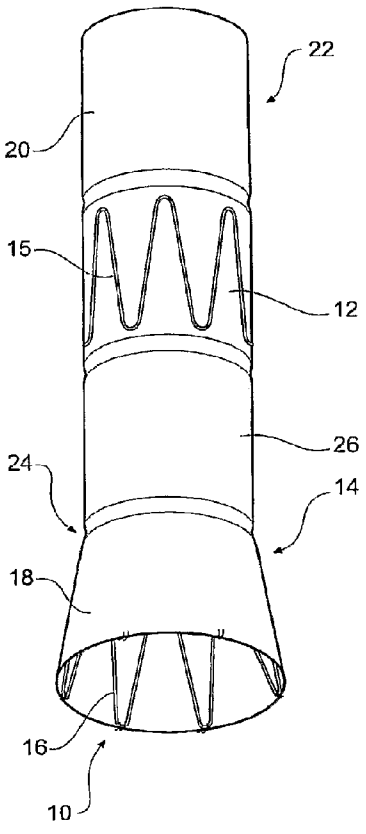
(74) Agent: **GODLEWSKI, Richard, J.**; P.O. Box 2269, Bloomington, IN 47402-2269 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,

[Continued on next page]

(54) Title: STENT GRAFT EXTENSION



(57) Abstract: A leg extension (10) for a stent grafting system to connect between an aortic graft (120) and an iliac graft (180). The leg extension is a tubular body (12) of a biocompatible graft material with self-expanding stents (15) connected along the length of the tubular body and the tubular body having a distal end (24) with a connection region (14). The connection region has a flared stent (16) defining an external frusto-conical surface to provide a connection arrangement to engage within an internally flared portion (90) of an iliac graft.

WO 2008/021556 A1

FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

STENT GRAFT EXTENSION

Description

Technical Field

This invention relates to a medical device and more particularly to a medical device for use in relation to endovascular surgery. A stent graft extension and, more particularly, an iliac extension with a flared cuff are disclosed.

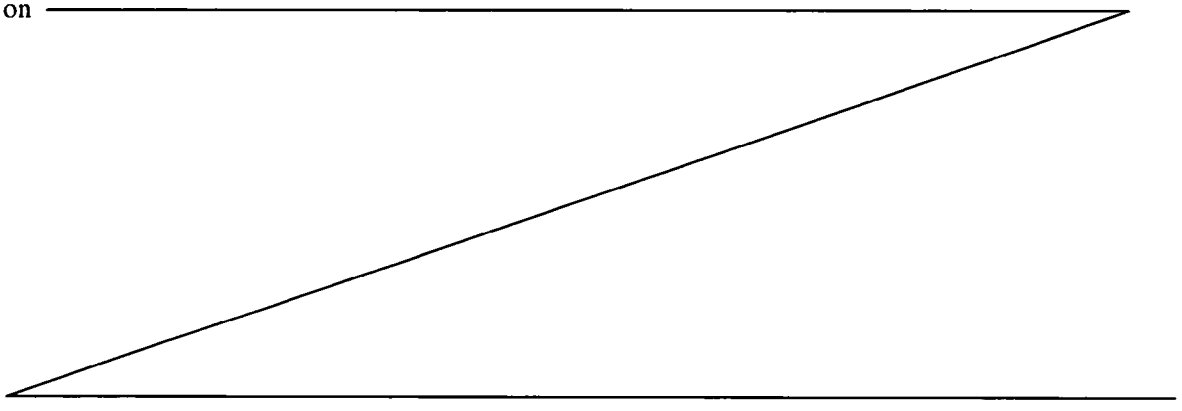
Background of the Invention

There have been used bifurcated stent grafts for treating abdominal aortic aneurysms. Such stent grafts include a tubular body to extend in the aorta towards the renal arteries of a patient and usually a shorter leg and a longer leg with, once the bifurcated graft is deployed, an extension leg provided to extend down one iliac artery from the shorter leg with the longer leg extending down the other iliac artery.

In some cases of aneurysm, however, the aneurysm extends beyond the aortic bifurcation and down one at least of the iliac arteries. In such cases a separate branched iliac stent graft is deployed in the common iliac artery to allow for blood flow into the internal iliac and down the external iliac artery from the common iliac artery. There remains, however, the problem of connecting this branched iliac stent graft with the bifurcated stent graft in the aortic region.

A particular problem with stent grafting in the common iliac region is that there is only a relatively short distance distally of the aortic bifurcation in which to make a connection and it is desirable that as secure as possible a connection is provided.

Branched iliac stent grafts that may be used with the stent graft extension described herein are described in two United States Patent Applications. US 60/686,252 (published as US 2006/0287704 and WO 2006/130755) discloses a side branch stent graft having a main tubular body and a tubular side branch that is affixed into the main tubular body so that the lumen of the side branch is in fluid communication with the lumen of the main body. External zig-zag stents are on



the main body proximally and distally of the side branch. At least one internal zig-zag stent is at the distal end of the main body. A reinforcing ring is around the proximal end of the main body and stitched thereto. This feature and other features disclosed in US 2006/0287704 and WO 2006/130755 could be used with the subject matter of the present application, and the disclosures of US 2006/0287704 and WO 2006/130755 are herewith incorporated in their entirety into this specification.

US 60/838,776 filed 18 August 2006 and entitled "Configuration of Branched Stent Grafts" discloses a stent graft with at least two adjacent fenestrations in a tubular body. A tube extends into the body from each of the at least two fenestrations. The tubes are joined and open into a single larger tube within the tubular body. The disclosure of US 60/838,776 is incorporated in the present application in its entirety.

Typical branched aortic bifurcation stent grafts are described in WO 98/53761, which discloses an introducer for a prosthesis that retains the prosthesis so that each end can be moved independently. These features and other features disclosed in WO 98/53761 could be used with the subject matter of the present application and the disclosure of WO 98/53761 is herewith incorporated in its entirety into this specification.

US 10/396,676 (published as US 2003/0199967) and WO 03/082153 disclose a stent graft with a fenestration in the tubular wall thereof. A tube extends from the fenestration into the main lumen and is in fluid communication therewith. An extension leg stent graft can be deployed from a branch vessel into the fenestration to seal in the tube. A flared guide associated with the fenestration can be provided interiorly or exteriorly. This feature and other features disclosed in US 2003/0199967 and WO 2003/082153 could be used with the subject matter of the present application, and the disclosures of US 2003/0199967 and WO 2003/082153 are herewith incorporated in their entirety into this specification.

US 60/405,769 and US 10/645,095 (published as US 2004/0082990) and WO 2004/017867) disclose prostheses or stent grafts suitable for

endoluminal deployment. These prostheses and other features disclosed in US 2004/0082990 and WO 2004/017867 could be used with the subject matter of the present application and the disclosures of US 2004/0082990 and WO 2004/017867 are herewith incorporated in their entirety into this specification.

U.S. Patent No. 6,695,875 (also published as US 2004/0260383) discloses a main stent graft body and a separate attachment graft tube that extends proximally therefrom. The attachment graft tube has a proximal attachment stent for infrarenal attachment of the assembly to the aorta. These features and other features disclosed in U.S. Patent No. 6,695,875 and US 2004/0260383 could be used with the subject matter of the present application and the disclosures of U.S. Patent No. 6,695,875 and US 2004/0260383 are herewith incorporated in their entirety into this specification.

Throughout this specification the term distal with respect to a portion of the aorta, a deployment device or a prosthesis means the end of the aorta, deployment device or prosthesis further away in the direction of blood flow away from the heart and the term proximal means the portion of the aorta, deployment device or end of the prosthesis nearer to the heart. When applied to other vessels similar terms such as caudal and cranial should be understood.

Summary of the Invention

In one form therefore, although this may not necessarily be the broadest or only form, a first aspect of the present invention may reside in a leg extension for a stent grafting system, the leg extension including a tubular body of a biocompatible graft material, the tubular body having a proximal end with an outside sealing surface, a plurality of self-expanding stents connected to the tubular body along the length thereof with at least one self-expanding stent within the tubular body at the proximal end and the tubular body including a distal end with a connection region, the connection region including a flared stent defining an external frusto-conical surface extending therefrom to provide a connection arrangement to engage within an internally flared portion of an iliac graft, whereby the leg extension is able to connect a pre-deployed branched iliac stent graft to a pre-deployed aortic bifurcation stent graft.

It will be seen that by preferred embodiments of this invention, there is provided an iliac extension stent graft which at its distal end can connect into an internally flared portion of a pre-deployed branched iliac graft and at its proximal end can extend up into a leg of a bifurcated aortic stent graft. By providing the proximal end with the outside sealing surface the proximal end of the stent graft can be variably positioned into the leg of a bifurcated stent graft to provide the required fluid connection between the pre-deployed branched iliac stent graft to the pre-deployed aortic bifurcation stent graft.

The flared stent is preferably a zigzag style Gianturco stent which may be formed from stainless steel, Nitinol or other suitable materials.

The flared stent can in one embodiment be formed as a self-expanding stent including a resilient wire, the resilient wire including a plurality of struts and a bend between each strut, the stent as formed being substantially planar and in use being able to be formed into a substantially flared form with at least the first strut and the last strut overlapping.

The flared stent can be formed from a resilient wire including a plurality of struts and a bend between each strut, the stent as formed being in a substantially planar form and the ends joined by welding or other suitable technique.

In one form of the invention, the flared stent may be a bare stent extending from the distal end of the tubular body.

Alternatively the flared stent can be a covered stent comprising a cover of a graft material.

In one form, the cover may be fastened, preferably by stitching, along at least part of the line of the wire of the zigzag stent in effect to form a series of petals flaring out from the tubular body or the cover may extend between all or some of the distal bends of the flared stent.

There can be further included a ring stent at the distal end of the connection region fastened to the distal bends of the flared stent and/or to the cover of the connection region.

The proximal region with the outside sealing surface may be of a length of one, two or more stents within the tubular body. Similarly the distal sealing

region may be of a length of one, two or more stents within the tubular body.

According to a second aspect of the present invention, there is provided a leg extension stent graft for a stent grafting system, the leg extension including a tubular body of a biocompatible graft material, the tubular body having a proximal end with an outside sealing surface, a plurality of self-expanding stents connected to the tubular body along the length thereof with at least one self-expanding stent within the tubular body at the proximal end and the tubular body having a distal end with a connection region, the connection region including a flared self-expanding stent including a resilient wire, the resilient wire including a plurality of struts and a distal bend between each strut at a distal end of the flared stent and including a ring stent at the distal end of the connection region fastened to the distal bends of the flared stent and including a frusto-conical cover of a biocompatible graft material on the flared self-expanding stent thereby defining an external frusto-conical sealing surface extending therefrom whereby to provide a connection and sealing arrangement to engage within an internally flared portion of an iliac graft, whereby the leg extension can connect a pre-deployed branched iliac stent graft to a pre-deployed aortic bifurcation stent graft.

The biocompatible material from which the tubular body and the cover of the connection region is preferably non-porous so that it does not leak or sweat under physiologic forces. The graft material is preferably made of woven or knitted polyester (Vascutek Ltd., Renfrewshire, Scotland, UK). Other biocompatible fabrics, non-woven materials and porous sheets may be used as the graft material. Examples of biocompatible polymers from which porous sheets can be formed include polyesters, such as poly(ethylene terephthalate), polylactide, polyglycolide and copolymers thereof; fluorinated polymers, such as PTFE, expanded PTFE and poly(vinylidene fluoride); polysiloxanes, including polydimethyl siloxane; and polyurethanes, including polyetherurethanes, polyurethane ureas, polyetherurethane ureas, polyurethanes containing carbonate linkages and polyurethanes containing siloxane segments. In addition, materials that are not inherently biocompatible may be subjected to surface modifications in order to render the materials biocompatible. Examples of surface modifications

include graft polymerization of biocompatible polymers from the material surface, coating of the surface with a crosslinked biocompatible polymer, chemical modification with biocompatible functional groups, and immobilization of a compatibilizing agent such as heparin or other substances. Thus, any polymer that may be formed into a porous sheet can be used to make a graft material, provided the final porous material is biocompatible. Polymers that can be formed into a porous sheet include polyolefins, polyacrylonitrile, nylons, polyaramids and polysulfones, in addition to polyesters, fluorinated polymers, polysiloxanes and polyurethanes as listed above. Preferably the porous sheet is made of one or more polymers that do not require treatment or modification to be biocompatible. The graft material may include a biocompatible polyurethane. Examples of biocompatible polyurethanes include THORALON® (Thoratec, Pleasanton, CA), BIOSPAN®, BIONATE®, ELASTHANE™, PURSIL™ and CARBOSIL™ (Polymer Technology Group, Berkeley, CA). As described in US 2002/0065552, incorporated herein by reference, THORALON® is a polyetherurethane urea blended with a siloxane-containing surface modifying additive. Specifically, the polymer is a mixture of base polymer BPS-215 and an additive SMA-300. The graft material may also include extracellular matrix materials. The "extracellular matrix" is a collagen-rich substance that is found in between cells in animal tissue and serves as a structural element in tissues. It is typically a complex mixture of polysaccharides and proteins secreted by cells. The extracellular matrix can be isolated and treated in a variety of ways. Following isolation and treatment, it is referred to as an "extracellular matrix material," or ECMM. ECMMs may be isolated from submucosa (including small intestine submucosa), stomach submucosa, urinary bladder submucosa, tissue mucosa, renal capsule, dura mater, liver basement membrane, pericardium or other tissues. Purified tela submucosa, a preferred type of ECMM, has been previously described in U.S. Patent Nos. 6,206,931, 6,358,284 and 6,666,892 as a bio-compatible, non-thrombogenic material that enhances the repair of damaged or diseased host tissues. U.S. Patent Nos. 6,206,931, 6,358,284 and 6,666,892 are incorporated herein by reference. Purified submucosa extracted from the small intestine ("small intestine

submucosa" or "SIS") is a more preferred type of ECMM for use in preferred embodiments of this invention. Another type of ECMM, isolated from liver basement membrane, is described in U.S. Patent No. 6,379,710, which is incorporated herein by reference. ECMM may also be isolated from pericardium, as described in U.S. Patent No. 4,502,159, which is also incorporated herein by reference. Irrespective of the origin of the graft material, the graft material can be made thicker by making multi-laminate constructs, for example SIS constructs as described in U.S. Patent Nos. 5,968,096; 5,955,110; 5,885,619; and 5,711,969. All of these disclosures are incorporated herein by reference.

Brief Description of the Drawing

Preferred embodiments are now described, by way of example only, and with reference to the accompanying drawings, in which:

Figure 1 shows an embodiment of a leg extension for a stent grafting system;

Figure 2 shows an embodiment of a leg extension for a stent grafting system;

Figure 3 shows an embodiment of a leg extension for a stent grafting system;

Figure 3A shows detail of the flared stent of the embodiment of Figure 3 in a laid flat configuration;

Figure 3B shows detail of the flared stent of the embodiment of Figure 3 in a frusto-conical configuration;

Figure 4 shows an embodiment of a leg extension for a stent grafting system;

Figure 5A shows an embodiment of a leg extension for a stent grafting system;

Figure 5B shows a form of flared stent for use in particular with the embodiment shown in Figure 5A;

Figure 6 shows an embodiment of a leg extension for a stent grafting system;

Figure 7 shows an outside view of a connection between a branched iliac

stent graft and a leg extension for a stent grafting system;

Figure 8 shows a longitudinal cross sectional view of the connected components shown in Figure 7; and

Figure 9 shows a schematic view of a stent grafting system incorporating a leg extension assembled within the vasculature of a patient.

Detailed Description

Now looking more closely at the drawings and more particularly Figure 1 it will be seen that a first embodiment of a leg extension 10 for a stent grafting system according to a preferred embodiment of the present invention comprises a tubular body 12 of a biocompatible graft material with the tubular body supported by self-expanding stents 15. A connection region 14 comprising a flared stent 16 in this embodiment covered by a graft material cover 18 is at the distal end 24 of the leg extension 10.

The tubular body has a external proximal sealing surface 20 at its proximal end 22. The external proximal sealing surface has self-expanding stents within the tubular body. The distal end 24 also has a sealing surface 26. The distal sealing surface has self expanding stents within the tubular body. The external proximal sealing surface 20 is able to seal within the leg of a bifurcated stent graft and the distal sealing surface 26 is able to seal within the proximal end of a branched iliac stent graft as is discussed below.

Although the leg extension 10 has been shown as being of a particular length, the length may vary and hence the number of intermediate stents 12 and the length of the tubular body can vary. There may be one, two or more self-expanding stents within the sealing regions 20 and 26 and one, two or more self-expanding stents 15 outside the tubular body 12 between the sealing regions 20 and 26.

Figure 2 shows another embodiment according to the present invention in which the leg extension 30 is substantially similar to that shown in Figure 1 except that at the distal end 32 of the connection portion 18 there is a resilient ring 34 formed from a shape memory metal, such as nickel alloy Nitinol™, stitched to the cover 18 by stitching 36 as well as being attached to the distal bends 33

of the flared stent 16. The resilient ring 34 assists in maintaining the flare in the connection portion and hence maintaining a connection as discussed above.

Figure 3 shows a still further embodiment of a leg extension according to the present invention. In this embodiment the leg extension 40 comprises a tubular body 42 of a biocompatible graft material with an uncovered stent 44 providing the connection region 46. The uncovered stent 44 is a self-expanding stent formed into a zig-zag frusto-conical configuration and is connected by the bends at the narrower end 43 of the stent to one end of the tubular body 42 such that it forms the flared configuration to comprise the connection region 46.

Figure 3A shows detail of the flared stent of the embodiment of Figure 3 in a laid flat configuration and Figure 3B shows detail of the flared stent of the embodiment of Figure 3 in a frusto-conical configuration. In this embodiment the stent 44 comprises struts 47, proximal bends 48a and distal bends 48b between the struts. The stent is initially formed into a flat configuration from a shape memory metal wire as shown in Figure 3A and then after heat treatment is formed into a frusto-conical shape and has a welded, adhered or crimped scarf joint 49 to connect the ends of the wire into a continuous zig-zag shape.

Figure 4 shows a still further embodiment of a leg extension according to the present invention. The leg extension 50 has a tubular body 52 of a biocompatible graft material and the connection region 54 comprises a zig-zag stent 56 which is partially covered by a biocompatible graft material 58. In this embodiment alternate gaps between pairs of adjacent struts are left bare or uncovered.

Figure 5A shows a still further embodiment of a stent graft according to the present invention. In this embodiment the leg extension stent graft 60 comprises a tubular body 62 of biocompatible graft material with a four lobed stent 64 fastened to the distal end 66. A covering of graft material 68 is stitched along the struts of the four lobed stent 64 to provide a petal effect. The stent 64 is a self expanding stent formed into a zig-zag configuration from a shape memory metal such as the nickel alloy Nitinol™.

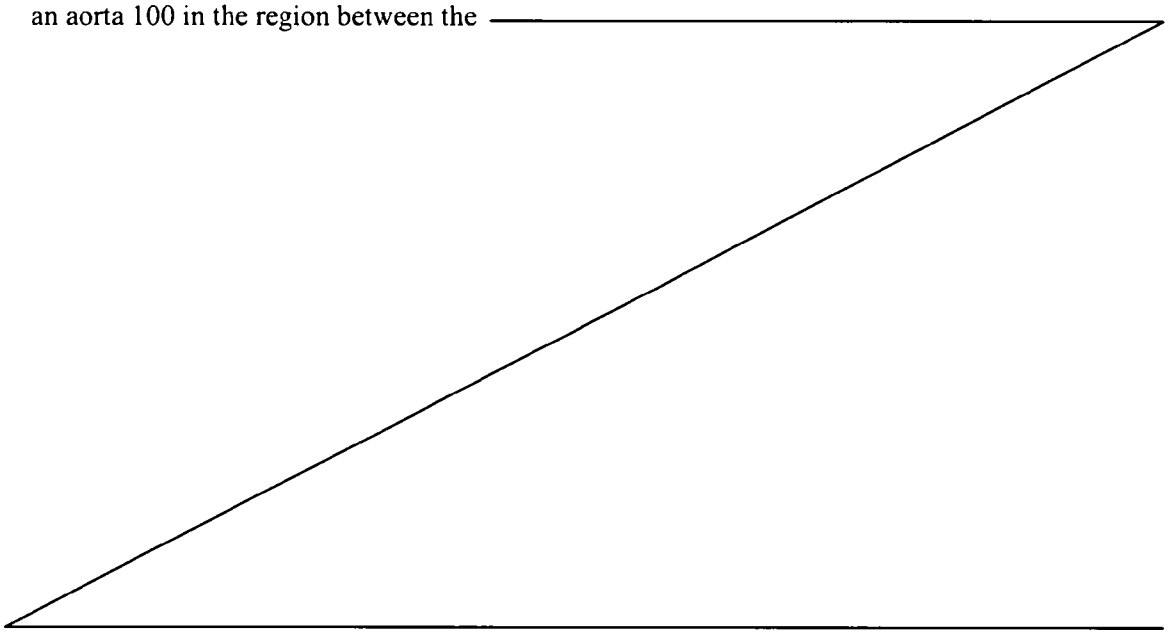
Figure 5B shows the form of stent according to the embodiment of the

invention shown in Figure 5A. It can be seen that the stent 64 is formed from a single length of nitinol wire which commences at a loop 70 adjacent a bend 70a and forms a series of struts 74 with bends 76 in between them for two circuits before terminating at loop 72 adjacent to bend 72a with an overlap of one extra strut. The Nitinol™ wire may be 0.15mm diameter. The Nitinol™ wire is formed into the four lobed frusto-conical shape and then heat treated to memorise that shape.

Figure 6 shows a still further embodiment of a leg extension according to the present invention. In this embodiment the leg extension 61 comprises a tubular body 63 of a biocompatible graft material with an uncovered stent 65 providing the connection region 67. The uncovered stent 65 is a self-expanding stent formed into a zig-zag frusto-conical configuration and is connected by the bends 69 at the narrower end of the stent to one end of the tubular body 63 such that it forms the flared configuration to comprise the connection region 67. To assist the stent 65 to maintain the flared configuration a ring 68 formed from a shape memory metal such as a nickel alloy Nitinol™ is stitched to the outer bends 69a by stitching 71.

Figure 7 and Figure 8 show one arrangement by which a leg extension may be connected into a branched iliac stent graft. The branched iliac stent graft 80 comprises a tubular body 82 of a biocompatible graft material and a side arm 84 extending from the tubular body. At the proximal end of the tubular body is a ring reinforcement 86. The leg extension 10 of the type shown in Figure 1 extends into the lumen of the iliac graft 80 at the proximal end 81 of the branched iliac stent graft 80 and extends into the tubular body 82 until the flared connection region 14 fits into the wider portion 90 where the side arm 84 extends from the tubular body 82. With the flared portion extending into the expanded portion 90 on the tubular body 82 a good connection between the two components is obtained which is more difficult to dislodge or to pull out.

Figure 9 shows a schematic view of the vasculature of a patient particularly showing the aorta and aortic bifurcation extending down towards the iliac arteries. The vasculature comprises an aorta 100 in the region between the



renal arteries 102 and the aortic bifurcation 104. Common iliac arteries 106 and 108 extend from the aortic bifurcation 104. The common iliac arteries 106 and 108 each bifurcate into internal iliac arteries 110 and 112 and external iliac arteries 114 and 116 respectively. The aorta 100 has an aneurysm 118 which also extends down the common iliac artery 106 towards the iliac bifurcation 117.

To traverse the aneurysm a bifurcated aortic stent graft 120 has been deployed into the aorta 100. The proximal end 122 of the bifurcated stent graft 120 is engaged onto a non-aneurysed portion 124 of the aorta just distal of the renal arteries. To ensure good fixation the stent graft 120 includes a supra renal exposed stent 126 with barbs 128 engaging the wall of the aorta proximal of the renal arteries 102.

The stent graft 120 has a short leg 130 and a long leg 132 extending from a bifurcation 134 at its distal end 136. The long leg 132 has a sealing surface 138 at its distal end and this engages in a sealing manner into an non-aneurysed portion of the common iliac artery 108.

The aneurysm in the common iliac artery 106 requires the placement of an iliac stent graft 140 with a branch 142 from which a covered extension piece 144 can extend down the internal iliac artery 110. The distal end 148 of the iliac stent graft 140 engages in a sealing manner into an non-aneurysed portion of the external iliac artery 114.

The short leg 130 does not extend down to the aortic bifurcation and hence an iliac extension piece 150 is provided, which goes between the short leg 130 of the bifurcated aortic stent graft 120 and the proximal end 152 of the iliac stent graft 140. Suitable iliac extension pieces 150 are described herein.

The iliac extension piece 150 can be any of the embodiments shown in Figures 1 to 6 depending upon the requirements of a particular situation. The leg extension 150 extends into the lumen of the branched iliac graft 140 at the proximal end 152 of the branched iliac stent graft 140 and extends into the tubular body thereof until its flared connection region fits into the wider portion of the branched iliac stent graft where the side arm 142 extends from the tubular body. With the flared portion extending into the expanded portion on the tubular

body a good connection between the two components is obtained even though there is a relatively short overlap.

In practice the order of placement of the various components of the stent grafting system in the case where there is an aneurysm which extends down into one of the common iliac arteries is as follows:

Deploy the branched iliac stent graft;

Deploy the internal iliac extension;

Deploy the bifurcated aortic stent graft;

Deploy the iliac extension piece according to preferred embodiments of the present invention.

Throughout this specification various indications have been given as to the scope of this invention but the invention is not limited to any one of these but may reside in two or more of these combined together. The examples are given for illustration only and not for limitation.

Throughout this specification and the claims that follow unless the context requires otherwise, the words 'comprise' and 'include' and variations such as 'comprising' and 'including' will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

The disclosures in US 60/838,963, from which the present application claims priority, and in the Abstract accompanying this application are incorporated herein by reference.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A leg extension stent graft in combination with an iliac stent graft, the iliac stent graft comprising a first tubular body of a biocompatible graft material, the first tubular body comprising a proximal end and a distal end, a side arm extending from the first tubular body between the proximal end and the distal end, the side arm defining on the tubular body, where the side arm extends from the first tubular body, a wider portion of the first tubular body, the wider portion increasing in size away from the proximal end, the leg extension stent graft comprising a second tubular body of a biocompatible graft material, the second tubular body having a proximal end with an outside sealing surface, a plurality of self-expanding stents connected to the second tubular body along the length thereof with at least one self-expanding stent within the second tubular body at the proximal end and the second tubular body having a distal end comprising a connection region, the connection region comprising a flared stent defining an external frusto-conical surface extending from the distal end of the second tubular body, the flared stent comprising a frusto-conical configuration with a narrower proximal end and a wider distal end, the flared stent thereby providing a connection arrangement with the connection region of the leg extension stent graft being engaged within the iliac stent graft from the proximal end thereof wherein the flared stent defining an external frusto-conical surface is engaged within the wider portion of the first tubular body, whereby the leg extension stent graft provides a connection between the branched iliac stent graft and a pre-deployed aortic bifurcation stent graft.

2. A leg extension stent graft as in Claim 1, wherein the flared stent (16) is a zigzag style stent.

3. A leg extension stent graft as in Claim 1 or 2, wherein the flared stent is formed from a material selected from the group consisting of stainless steel and nitinol metal.

4. A leg extension stent graft as in Claim 1, 2 or 3, wherein the flared stent (16) is a self-expanding stent including a resilient wire, the resilient wire forming a plurality of struts with a bend between each strut, the stent, as formed, being substantially planar.

5. A leg extension stent graft as in Claim 4, wherein the stent, in use, is able to be formed into a substantially flared form with at least the first strut and the last strut overlapping.

6. A leg extension stent graft as in Claim 4 or 5, wherein the stent as formed is in a substantially planar form and the ends joined by welding or other suitable technique.

7. A leg extension stent graft as in Claim 4, 5 or 6, including a ring stent (34) at the distal end of the connection region (14) fastened to the distal bends of the flared stent.

8. A leg extension stent graft as in Claim 7, wherein the flared stent (16) includes a cover (18) of graft material and a distal end of the cover is fastened to the ring stent.

9. A leg extension stent graft as in any one preceding claim wherein the flared stent is a bare stent extending from the distal end of the tubular body.

10. A leg extension stent graft as in any one preceding claim wherein the flared stent further comprises a frusto-conical cover of a biocompatible graft material.

11. A leg extension stent graft as in Claim 10 wherein the cover is stitched along at least part of the line of the wire of stent to in effect form a series of petals flaring out from the tubular body.

12. A leg extension stent graft as in Claim 10 wherein the cover is stitched along at least part of the line of the wire of stent to in effect form a series of petals flaring out from the tubular body and the cover extends between some of the distal bends of the flared stent.

13. A leg extension stent graft as in Claim 1 wherein the flared stent is a self-expanding stent formed from a resilient wire, the resilient wire comprising a plurality of struts with a proximal bend between each strut at the proximal end of the flared stent and a distal bend between each strut at the distal end of the flared stent, and further including a wire ring at a distal end of the connection region, the wire ring being fastened to the distal bends of the flared stent to assist the flared stent to maintain the frusto-conical configuration, the proximal bends being fastened to the distal ends of the second tubular body.

14. A leg extension stent graft as in Claim 1 wherein the flared stent comprises a frusto-conical cover of a biocompatible graft material and a distal end of the frusto-conical cover is stitched to the wire ring.

15. A branched iliac stent graft-aortic bifurcation stent graft connection piece substantially as hereinbefore describes with reference to the accompanying drawings.

16. A stent grafting system including a branched iliac stent graft and an aortic bifurcation stent graft wherein the branched iliac stent graft and the aortic bifurcation stent graft are connected by a connection piece substantially as hereinbefore describes with reference to the accompanying drawings.

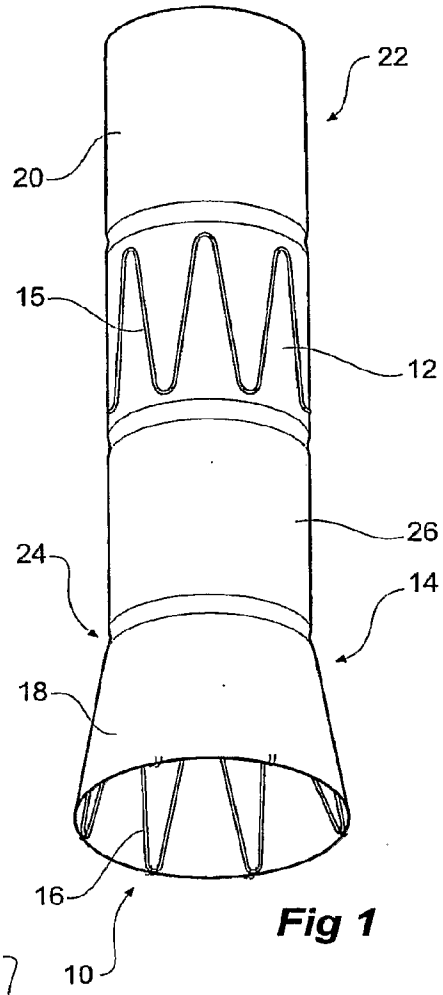


Fig 1

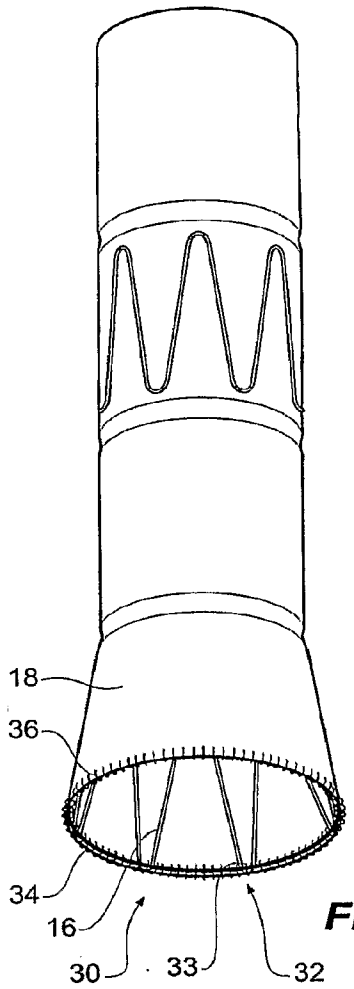


Fig 2

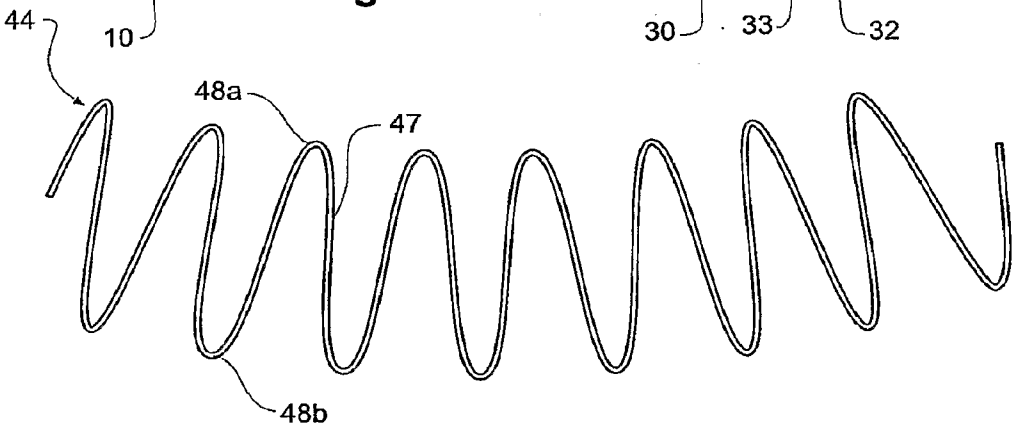


Fig 3A

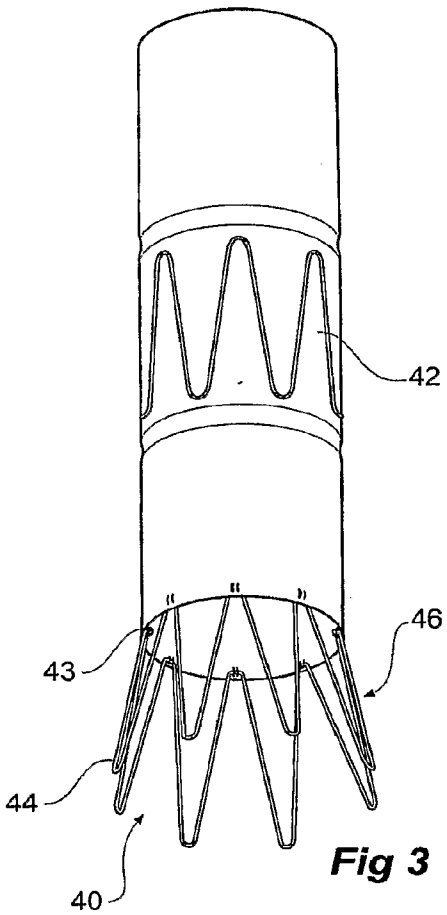


Fig 3

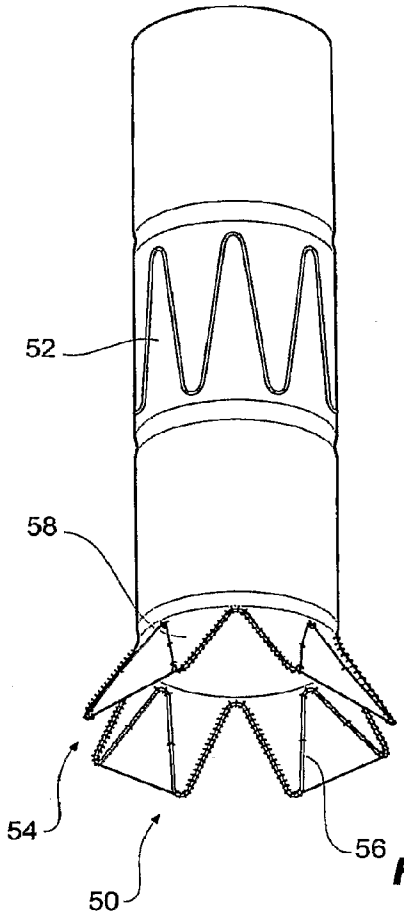


Fig 4

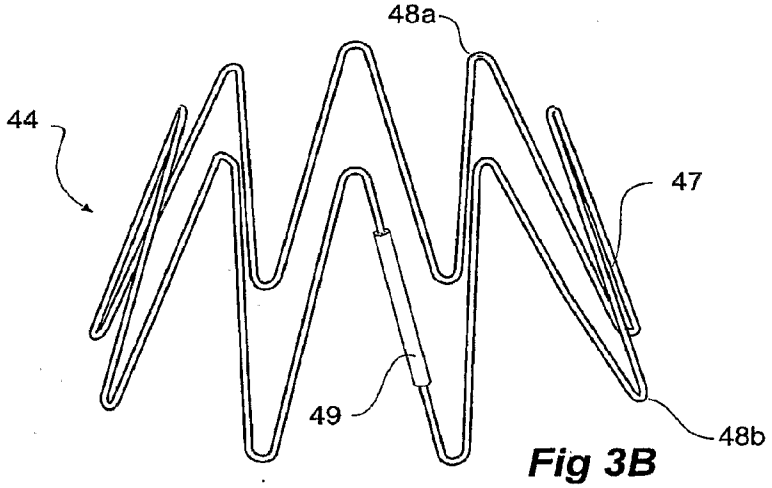


Fig 3B

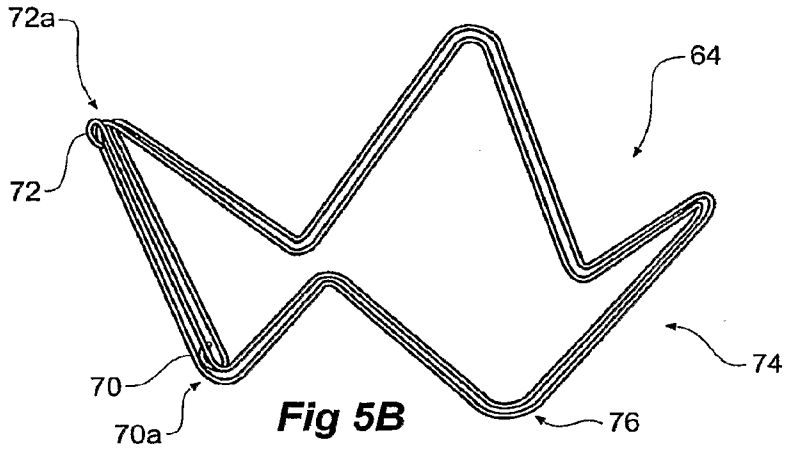


Fig 5B

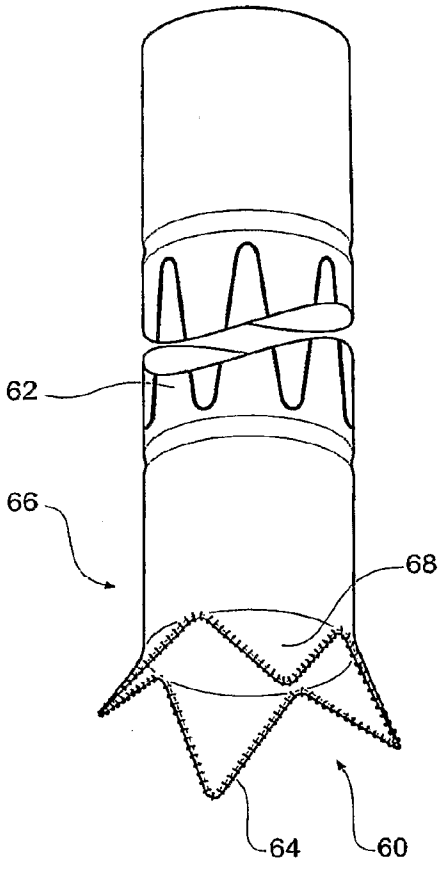


Fig 5A

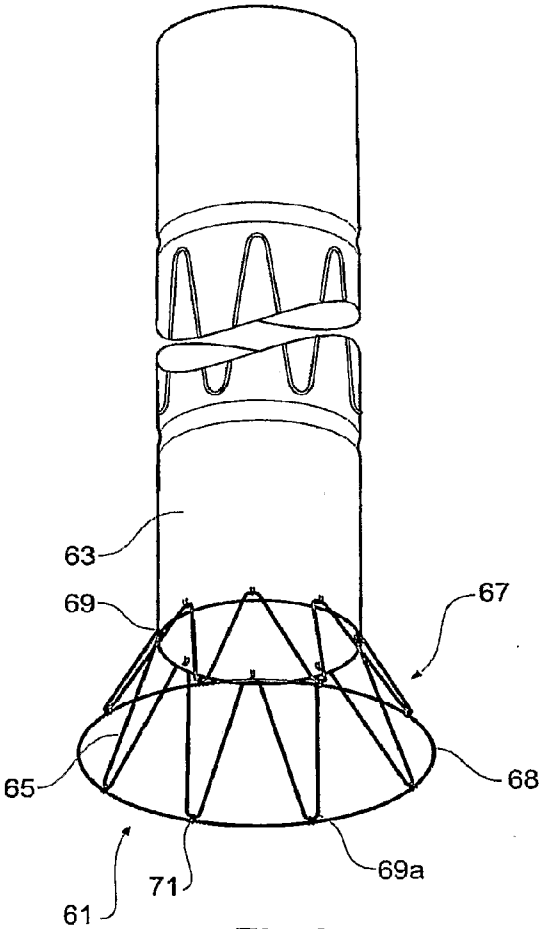


Fig 6

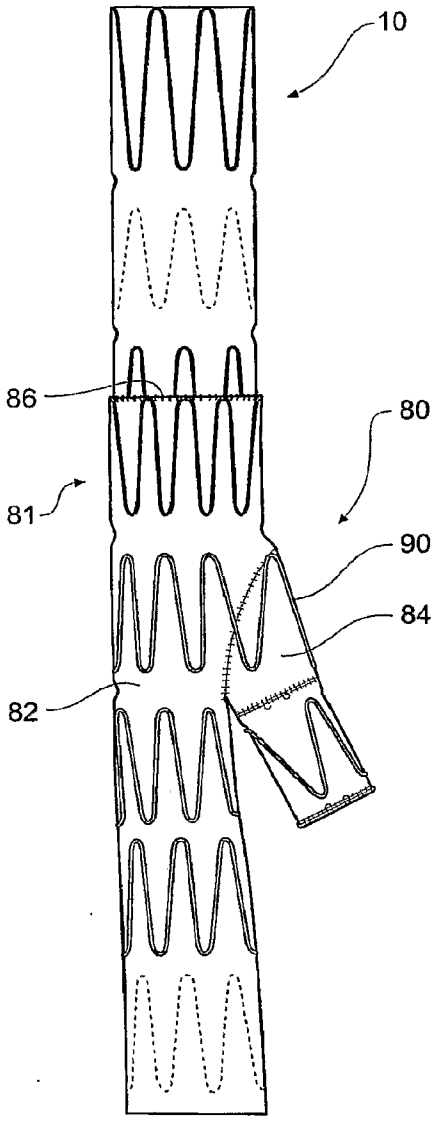


Fig 7

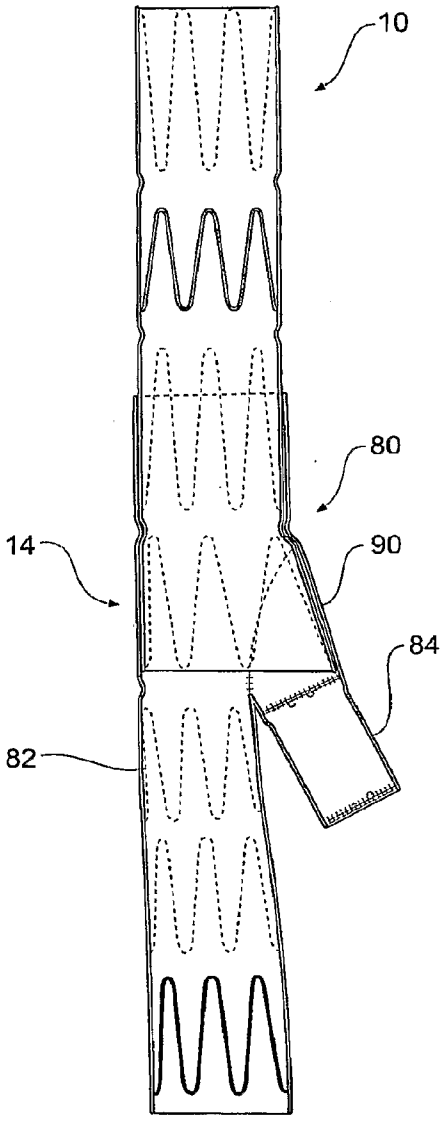


Fig 8

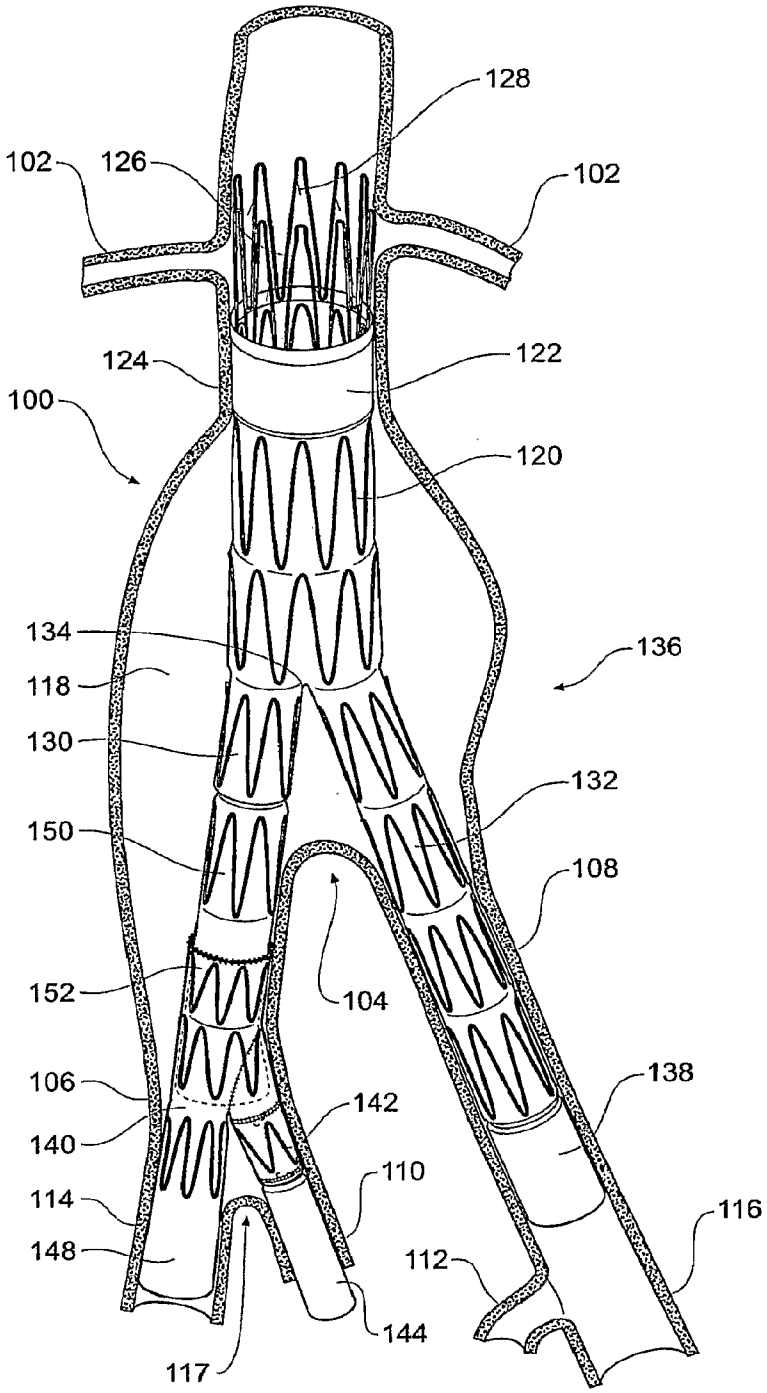

128
102
126
102
124
122
100
120
134
136
118
130
132
150
108
152
104
106
138
142
140
110
114
116
148
112
144
117

Fig 9