

(19)



(11)

EP 2 231 066 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
26.04.2017 Bulletin 2017/17

(51) Int Cl.:
A61F 2/07 ^(2013.01) **A61B 17/12** ^(2006.01)
A61B 17/132 ^(2006.01)

(21) Application number: **08861980.4**

(86) International application number:
PCT/IL2008/001621

(22) Date of filing: **15.12.2008**

(87) International publication number:
WO 2009/078010 (25.06.2009 Gazette 2009/26)

(54) EXTRA-VASCULAR WRAPPING FOR TREATING ANEURYSMATIC AORTA IN CONJUNCTION WITH ENDOVASCULAR STENT-GRAFT

EXTRAVASCULÄRE WICKEL ZUR BEHANDLUNG DER ANEURYSMATISCHEN AORTA IN VERBINDUNG MIT ENDOVASKULÄREM STENT-TRANSPLANTAT

ENVELOPPE EXTRAVASCULAIRE POUR LE TRAITEMENT D'UN ANÉVRISME DE L'AORTE EN ASSOCIATION AVEC UN STENT-GREFFON ENDOVASCULAIRE

(84) Designated Contracting States:
**AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HR HU IE IS IT LI LT LU LV MC MT NL NO PL PT
RO SE SI SK TR**

(30) Priority: **15.12.2007 US 14031 P**

(43) Date of publication of application:
29.09.2010 Bulletin 2010/39

(73) Proprietor: **Endospan Ltd.
42505 Netanya (IL)**

(72) Inventor: **SHALEV, Alon
43587 Ra'anana (IL)**

(74) Representative: **Lecomte & Partners
P.O. Box 1623
1016 Luxembourg (LU)**

(56) References cited:
**WO-A1-98/06355 WO-A1-99/34748
US-A- 5 843 170 US-A1- 2006 069 426
US-A1- 2007 213 805 US-A1- 2007 237 973**

EP 2 231 066 B1

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

FIELD OF THE INVENTION

[0001] The present invention generally pertains to an extra-vascular wrapping in the vicinity of the aneurysm neck and specifically the renal arteries for allowing the performance of endovascular aneurysm repair - EVAR - on patients either with aneurysms close to the renal arteries or with type I endoleaks, and methods thereof.

BACKGROUND OF THE INVENTION

[0002] US patent application 61014031 to the inventor.

[0003] An aneurysm is a localized, blood-filled dilation (bulge) of a blood vessel caused by disease or weakening of the vessel wall. Left untreated, the aneurysm will frequently rupture, resulting in loss of blood through the rupture and death.

[0004] Aneurysms may involve arteries or veins and have various causes. They are commonly further classified by shape, structure and location. Aortic aneurysms are the most common form of arterial aneurysm and are life threatening. The aorta is the main artery which supplies blood to the circulatory system. The aorta arises from the left ventricle of the heart, passes upward and bends over behind the heart, and passes down through the thorax and abdomen. Among other arterial vessels branching off the aorta along its path, the abdominal aorta supplies two side vessels to the kidneys, the renal arteries. Below the level of the renal arteries, the abdominal aorta continues to about the level of the fourth lumbar vertebrae (or the navel), where it divides into the iliac arteries. The iliac arteries, in turn, supply blood to the lower extremities and perineal region.

[0005] It is common for an aortic aneurysm to occur in that portion of the abdominal aorta between the renal arteries and the iliac arteries. This portion of the abdominal aorta is particularly susceptible to weakening, resulting in an aortic aneurysm. Such an aneurysm is often located near the iliac arteries. An aortic aneurysm larger than about 5 cm in diameter in this section of the aorta is ominous. Left untreated, the aneurysm may rupture, resulting in rapid, and usually fatal, hemorrhaging. Typically, a surgical procedure is not performed on aneurysms smaller than 5 cm because no statistically demonstrated benefit exists in performing such procedures.

[0006] Aneurysms in the abdominal aorta are associated with a particularly high mortality rate; accordingly, current medical standards call for urgent operative repair when aneurysm diameter is larger than 5 cm. Abdominal surgery, however, results in substantial stress to the body. Although the mortality rate for an aortic aneurysm is extremely high, there is also considerable mortality and morbidity associated with open surgical intervention to repair an aortic aneurysm.

[0007] Repair of an aortic aneurysm by surgical means is a major operative procedure. Substantial morbidity ac-

companies the procedure, resulting in a protracted recovery period. Further, the procedure entails a substantial risk of morbidity and mortality, mostly due to the cardiopulmonary bypass employed in such a procedure.

[0008] Therefore, less invasive methods have been introduced to attempt to treat an aortic aneurysm without the attendant risks of intra-abdominal surgery. Among them are inventions such as US 4,562,596 which discloses an aortic graft constructed for intraluminal insertion; US 4,787,899 teaches an intraluminal grafting system includes a hollow graft which has a plurality of staples adapted proximate its proximal end. The system includes a guide for positioning the proximal end of the graft upstream in a lumen which may be a blood vessel or artery; and US 5,042,707 which presents a stapler, adapted to be inserted into a blood vessel and moved to a desired position therealong, and having a selectively-articulatable distal marginal end portion used to staple a graft to the interior wall of the blood vessel.

[0009] Hence, although in recent years certain techniques have been developed that may reduce the stress, morbidity, and risk of mortality associated with surgical intervention to repair aortic aneurysms, none of the systems that have been developed effectively treat the aneurysm and exclude the affected section of aorta from the pressures and stresses associated with circulation. None of the devices disclosed in the references provide a reliable and quick means to reinforce an aneurysmal artery. In addition, all of the prior references require a sufficiently large section of healthy aorta surrounding the aneurysm to ensure attachment of the graft. The neck of the aorta at the cephalad end (i.e., above the aneurysm) is usually sufficient to maintain a graft's attachment means. However, when an aneurysm is located near the iliac arteries, there may be an ill-defined neck or no neck below the aneurysm. Such an ill-defined neck would have an insufficient amount of healthy aortic tissue to which to successfully mount a graft. Furthermore, much of the abdominal aorta wall may be calcified which may make it extremely difficult to attach the graft to the wall.

[0010] Shortcomings of the presently available endovascular stent-graft products include endoleaks, anatomic variability, anatomic non-conformity, migration/dislocation, discontinuities of endoluminal profile and thrombogenicity.

[0011] Endoleaks are caused by passage of blood into the aneurysmal space subsequent to stent-graft placement. Research has exposed yet another problem which indicates that the necks of the post-surgical aorta increase in size for approximately twelve months, regardless of whether the aneurysm experiences dimensional change. This phenomenon can result in perigraft leaks and graft migration. Anatomic variability: although sizing of "tube" or "bifurcated" grafts is radiographically assessed prior to surgery, it is necessary for the surgeon to have a large selection of graft lengths and diameters on hand to ensure an appropriate surgical outcome. Anatomic non-conformity: placement of a circularly-profiled

graft with an associated fixation device within an essentially "ovoid"-profiled vessel. Migration/dislocation also caused due to the use of attachment means which fasten only to the insubstantial, structurally compromised (diseased) intima and media levels of the vessel wall. Discontinuities of endoluminal profile are potential contributors to hemodynamic disturbances that might lead to non laminar, or even turbulent flow regimen. This in turn can contribute to increased clot formation. Thrombogenicity: manufactured of synthetic polymers, contemporary vascular liners present a luminal surface that is typically far more thrombogenic than the native arterial intimal tissue such devices cover

[0012] Unfavorable anatomy relating to the neck of the aneurysm is the most common reason for patients being rejected for EVAR. Short or absent infrarenal neck, large aortic diameters, and excessive angulation at this level are the main problems.

[0013] Furthermore, progressive expansion of the aneurysm sac associated with type I endoleak can lead to compromise of seal at the neck and is the principal indication for secondary intervention for this condition.

[0014] Means and method for repairing aortic aneurysms, especially an implementable kit and methods thereof useful for treating an aneurysmatic abdominal aorta, avoiding the dislocation of the implanted kit along the aorta, are still a long felt need.

[0015] US patent application published US 5,843,170 relates to an apparatus for securing on blood vessel a vascular graft containing a retention system, according to the preamble of claim 1. International patent application published WO 99/34748 relates to an implantable structure for treating an aortic aneurysm comprising a band as extra-vascular wrapping. Said band can be formed a knitted textile material.

SUMMARY OF THE INVENTION

[0016] The invention relates to a kit as defined by the claims. Insofar as the terms "invention" and/or "embodiment" are used in the following, and/or features are presented as being optional, this should be interpreted in such a way that the only protection sought is that of the invention as claimed. Methods of using the kit are presented as a way to understand the invention and do not form part of the invention. It is one object of the invention to disclose an implantable kit for treating an aneurysmatic abdominal aorta of a human subject. The kit comprises an endovascular stent-graft (ESG) and an extra-vascular wrapping (EVW). The ESG comprises a structural member (ESG-SM) adjustable between a radially-expanded state and a radially-compressed state; and, a fluid flow guide (FFG) formed of textile strands, substantially impervious to fluids and adjustable between an expanded state and a radially-compressed state; the FFG including a proximal region along which the fluid flow guide is tubular to provide a primary conduit; the FFG being disposed adjacent to the ESG-SM and being securably at-

tached thereto. The EVW is having at least one structural member (EVW-SM), e.g., 1,2,4,12, etc, capable of reversibly interchanging between (i) a generally cylindrical expanded state characterized by an inner diameter and a length in the direction of the aorta suitable for surrounding at least an effective portion of the implanted ESG; and (ii) a deformed state suitable for laparoscopic delivery of the EVW from a location outside of the subject's body to a location around the aorta, and vice versa.

[0017] It is in the scope of the invention wherein the EVW further comprises at least one medical textile member (e.g., 1,2,4,12 etc) adapted to at least partially encircle a segment of the aneurysmatic aorta in proximity to the renal arteries. the medical textile member being disposed adjacent to the EVW-SM and being securably attached thereto.

[0018] It is further in the scope of the invention wherein the EVW is adapted by means of size and shape to wrap the aorta in a non-continuous manner.

[0019] It is also in the scope of the invention wherein the deformed state of the EVW-SM comprises at least one of the following characteristics: (i) longitudinal deformability, adapted to reduce the length in the direction of the aorta and hence allow insertion of the EVW into a laparoscopic channel; and, (ii) circular-to-linear deformability, adapted to convert the generally cylindrical to a generally linear configuration, so as to provide the EVW to be pushed through a generally straight laparoscopic channel.

[0020] It is another object of the invention to disclose a secured implantable kit for treating an aneurysmatic abdominal aorta of a human subject, comprises at least two attachable elements: an ESG and an EVW. The ESG comprises (i) a structural member (ESG-SM) adjustable between a radially-expanded state and a radially-compressed state; and, (ii) a fluid flow guide (FFG) formed of textile strands, substantially impervious to fluids and adjustable between an expanded state and a radially-compressed state; the FFG including a proximal region along which the fluid flow guide is tubular to provide a primary conduit; the FFG being disposed adjacent to the ESG-SM and being securably attached thereto. The EVW is having at least one structural member (EVW-SM) e.g., 1,2,4,12 etc, capable of reversibly interchanging between (i) a generally cylindrical expanded state characterized by an inner diameter and a length in the direction of the aorta suitable for surrounding at least an effective portion of the implanted ESG; and (ii) a deformed state suitable for laparoscopic delivery of the EVW from a location outside of the subject's body to a location around the aorta, and vice versa. The EVW-SM and either the ESG-SM or FFG are in attachment therebetween so that dislocation of the implanted kit along the aorta is avoided

[0021] It is in the scope of the invention wherein the attachment comprises reversible attachment.

[0022] It is also in the scope of the invention wherein the EVW additionally comprises a plurality of fastening means, adapted to secure the EVW over the aneurys-

matic aorta.

[0023] It is also in the scope of the invention wherein the fastening means are selected from a group consisting of threads, screws, hooks, zips, fasteners, clips, flaps, clasps, springs, clasps, staplers, grips, zippers, hooks and corresponding eyes, hook and loop reclosable fastener squares, hook and loop reclosable fastener strips, hook and loop reclosable fastener dots, hooks-and-loops, e.g., Velcro™-type fasteners, straps, holes and string, sutures, wires, cables, tabs, poppers, nails, buttons and corresponding button holes, press buttons brackets, glues, adhesives, or any combination thereof.

[0024] It is also in the scope of the invention wherein the attachment is provided by a means of one or more physical members (e.g. utilizing hooks, pins etc) connecting directly between the ESG and the EVW.

[0025] It is in the scope of the invention wherein the EVW-SM and ESG-SM are adapted by means of size and shape to be interlocked therebetween (e.g., providing the elements as two adjacent pieces of a puzzle).

[0026] It is also in the scope of the invention wherein the medical textile member of EVW comprises at least one (e.g., 1, 2, 4, 12 etc) internal macroporous layer and at least one (e.g., 1,2,4,12 etc) external microporous layer.

[0027] It is also in the scope of the invention wherein the internal macroporous layer is adapted by means of size and shape to be positioned directly over the aneurysmatic abdominal aorta, and comprises voids dimensioned to allow free tissue ingrowth therethrough.

[0028] It is also in the scope of the invention wherein the internal macroporous layer is a polymer mesh characterized by a pores ranging in dimension from about 100 µm to about 2 mm.

[0029] It is in the scope of the invention wherein the external microporous layer, is made of a smoothly surfaced material, designed to prevent scar tissue formation and attachment thereto and thereby prevent internal organs from sticking thereto.

[0030] It is also in the scope of the invention wherein the external microporous layer is adapted by means of size and shape to be sparsely attached to the internal macroporous layer, so as to allow the free tissue ingrowth while preventing scar tissue formation and attachment to the microporous layer.

[0031] It is also in the scope of the invention wherein at least one of the internal macroporous layer and external microporous layer comprises attaching means, the means are selected from a group consisting of threads, holes, screws, hooks, zips, fasteners, clips, flaps, clasps, springs, clasps, grips, zippers, hooks-and-loops e.g., Velcro™-type fasteners, sutures, straps, strings, wires, cables, tabs, poppers, nails, buttons, brackets, glue, adhesives, or any combination thereof.

[0032] It is also in the scope of the invention wherein the EVW in it's the expanded state is in the form of a cylinder, the cylinder is adapted for placement adjacently below renal arteries of the aorta.

[0033] It is also in the scope of the invention wherein the EVW in it's the expanded state comprises one or more, complete or partial, interruptions; the cylinder is adapted for placement adjacently above and below renal arteries of the aorta.

[0034] It is also in the scope of the invention wherein the interruptions in cylinder are adapted to allow passage of the renal arteries.

[0035] It is also in the scope of the invention wherein the interruptions in cylinder are adapted to allow passage of an inferior mesenteric artery exiting from the aorta.

[0036] It is also in the scope of the invention wherein the interruptions in cylinder are adapted to allow passage of a celiac artery exiting from the aorta.

[0037] It is also in the scope of the invention wherein the EVW-SM is made of a super-elastic metal.

[0038] It is also in the scope of the invention wherein the super-elastic metal is Nitinol.

[0039] It is also in the scope of the invention wherein length of EVW in its the expanded state is in the range between about 1 to 3 centimeters.

[0040] It is also in the scope of the invention wherein wherein the inner diameter of EVW in its the expanded state is in the range between about 2 to 4 centimeters.

[0041] Another object of the present invention is to disclose an extra-vascular ring (EVR) adapted to at least partially encircle a segment of an aneurysmatic aorta of a human subject in proximity to the renal arteries. The EVR comprises a generally cylindrical inner surface, an outer surface and a structural member; the inner surface and the outer surface are attached therebetween. The fastening means adapted to secure the EVR over the aneurysmatic aorta; EVR is capable of having an expanded state and a deformed state. The EVR in its the expanded state is adapted for extra-vascular positioning around the aorta and the EVR in its deformed state is adapted for laparoscopic delivery from a location outside the subject's body to a location around the aorta; the inner surface defining a lumen that is characterized by a proximal circumference, a distal circumference and a length in the proximal to distal direction; the outer surface is characterized by a proximal circumference, a distal circumference and a length in the proximal to distal direction; the inner surface comprises a macroporous medical textile member, comprises voids dimensioned to allow free tissue ingrowth therethrough, and the outer surface comprises a microporous medical textile member that is made of a smoothly surfaced material, designed to inhibit scar tissue formation and attachment thereto and thereby prevent internal organs from sticking thereto. The structural member connected either to the inner surface or to the outer surface.

[0042] It is also in the scope of the invention wherein the EVR further comprises a plurality of fastening means, e.g., 1, 2, 4, 12, 50 etc.

[0043] It is also in the scope of the invention wherein the EVR further comprises a plurality of radially projecting attachment means (e.g., 1, 2, 4, 12 etc). The attachment

means being adapted to secure the EVR either to the aorta or to an endovascular aortic stent-graft.

[0044] It is also in the scope of the invention wherein the inner surface and the outer surface are substantially concentrically aligned.

[0045] It is also in the scope of the invention wherein the inner surface and the outer surface are radially spaced by a distance in the range between about 2 to 5 millimeters.

[0046] It is also in the scope of the invention wherein the proximal circumference of outer surface substantially coincides with the proximal circumference of inner surface.

[0047] It is also in the scope of the invention wherein the distal circumference of outer surface substantially coincides with the distal circumference of inner surface.

[0048] It is also in the scope of the invention wherein the outer surface is substantially tubular.

[0049] It is also in the scope of the invention wherein the structural member is made of a superelastic metal.

[0050] It is also in the scope of the invention wherein the inner surface and the outer surface are attached thereto via a plurality of spacing members, the spacing members being connected to the structural member.

[0051] It is also in the scope of the invention wherein the spacing members are substantially oriented in the radial direction.

[0052] It is another object of the present invention to disclose a method for treating an aneurysmatic aorta. The method comprises steps selected from the following: (a) identifying a subject having a medical condition indicative of an unacceptably high risk of rupture of an aneurysm of the abdominal aorta; (b) providing an implantable kit as defined in any of the above; (c) introducing the EVW in its the deformed state through a laparoscopic working channel to an abdominal location adjacent to renal arteries of the abdominal aorta; (d) laparoscopically positioning the EVW around the aorta, in vicinity to renal arteries; and (e) endovascularly placing the endovascular stent-graft (ESG) into the aneurysmatic aorta in the subject.

[0053] It is also in the scope of the invention wherein the ESG and the EVW are attachable therebetween and wherein method further comprises step (f); step (f) comprises attaching the EVW and the ESG therebetween in a manner that a dislocation of the implanted kit along the aorta is avoided.

[0054] It is also in the scope of the invention wherein the attachable comprises reversibly attachable and wherein the attaching comprises reversibly attaching.

[0055] It is also in the scope of the invention wherein the step of identifying a subject having a medical condition indicative of an unacceptably high risk of rupture of an aneurysm of the abdominal aorta comprises identifying a subject having a medical condition indicative of an unacceptably high risk of rupture of an aneurysm of the abdominal aorta and the aneurysm reaching about 2 centimeters or less to a closest renal artery of the subject.

[0056] It is also in the scope of the invention wherein the aforesaid method further comprises the steps of (a) upon identification of Type I endoleak - introducing the EVW in a deformed state through a laparoscopic working channel to an abdominal location adjacent to renal arteries of the abdominal aorta of the subject and laparoscopically positioning the EVW around the aorta, in vicinity to renal arteries.

[0057] It is another object of the invention to disclose a method for treating an aneurysmatic aorta. The method comprises steps selected from the following: (a) identifying a subject having a medical condition indicative of an unacceptably high risk of rupture of an aneurysm of the abdominal aorta; (b) providing a fastened implantable kit for treating an aneurysmatic abdominal aorta, comprises at least the elements of ESG, EVW, and plurality (e.g., 1,2,4,12,50 etc.) of fastening means, adapted to secure the EVW over the aneurysmatic aorta; (c) introducing the EVW in the deformed state through a laparoscopic working channel to an abdominal location adjacent to renal arteries of the abdominal aorta of the subject; (d) laparoscopically positioning the EVW around the aorta, in vicinity to renal arteries; (e) connecting the corresponding fastening means therebetween; and, (f) endovascularly placing the ESG into the aneurysmatic aorta

[0058] It is also in the scope of the invention wherein the step of identifying a subject having a medical condition indicative of an unacceptably high risk of rupture of an aneurysm of the abdominal aorta comprises identifying a subject having a medical condition indicative of an unacceptably high risk of rupture of an aneurysm of the abdominal aorta and the aneurysm reaching about 2 centimeters or less to a closest renal artery of the subject.

[0059] It is also in the scope of the invention wherein the method further comprises the steps of (a) upon identification of Type I endoleak - introducing the EVW in a deformed state through a laparoscopic working channel to an abdominal location adjacent to renal arteries of the abdominal aorta of the subject and laparoscopically positioning the EVW around the aorta, in vicinity to renal arteries and connecting the corresponding fastening means to one another.

BRIEF DESCRIPTION OF THE FIGURES

[0060] The present invention will now be described, by way of example only, with respect to the accompanying figures, wherein:

FIGS. 1A to 1D depict different variants of fasteners according to few embodiments of the invention;
FIG. 2 depicts an EVR according to another embodiment of the invention;
FIG. 3 depicts an EVR according to yet another embodiment of the invention
FIG. 4 depicts an EVR according to yet another embodiment of the invention;
FIG. 5 depicts an EVR according to yet another em-

bodiment of the invention;

FIG. 6 depicts an EVR according to yet another embodiment of the invention;

FIG. 7 depicts an EVR according to yet another embodiment of the invention;

FIG. 8A depicts an extra-vascular wrapping (135), which include a structural member (140) and a medical textile member (141);

FIG. 8B depicts an abdominal aorta (130), a right renal artery (131), a left renal artery (132), over which the extra-vascular wrapping (135) of figure 8a is positioned, adjacently below the renal arteries (131, 132) and is adapted to allow renal arteries (131, 132) to exit thereabove;

FIG. 9A depicts an isometric view of the structural member of the extra vascular wrapping;

FIG. 9B depicts an axial view of the structural member of the extra vascular wrapping;

FIG. 9C depicts a side view of the structural member of the extra vascular wrapping;

FIG. 9D depicts a view of a circularly-to-linearly deformed structural member of the extra vascular wrapping; and

FIG. 9E depicts a view of a circularly-to-linearly deformed and a longitudinally deformed structural member of the extra vascular wrapping.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0061] The following description is provided, alongside all chapters of the present invention, so as to enable any person skilled in the art to make use of the invention and sets forth the best modes contemplated by the inventor of carrying out this invention. Various modifications, however, will remain apparent to those skilled in the art, since the generic principles of the present invention have been defined specifically to provide an implementable kit and EVR for treating an aneurysmatic abdominal aorta and methods thereof.

[0062] It is one embodiment of the invention wherein an implementable kit for treating an aneurysmatic abdominal aorta is disclosed. The kit comprises at least two attachable elements: an endovascular stent-graft (ESG) and an extra-vascular wrapping (EVW). The ESG comprises a structural member (ESG-SM) adjustable between an expanded state and a radially-deformed state; and a fluid flow guide (FFG) formed of textile strands, substantially impervious to fluids and adjustable between an expanded state and a radially-deformed state; the FFG including a proximal region along which the fluid flow guide is tubular to provide a primary conduit. The EVW comprises an extra-vascular wrapping (EVW), the EVW having at least one (e.g., 1,2,4,12 etc) structural member (EVW-SM), capable of reversibly interchanging between (i) an expanded state characterized by an inner diameter and a length in the direction of the aorta suitable for surrounding at least an effective portion of the implanted ESG; and (ii) a deformed state suitable for lapar-

oscopic delivery to a location around the aorta, and vice versa. The EVW-SM and either the ESG-SM or FFG are at least reversibly attachable in a manner that a dislocation of the implanted kit along the aorta is avoided.

[0063] It is another embodiment of the invention wherein a secured kit is disclosed. Here, the aforesaid EVW additionally comprises a plurality (e.g., 1, 2, 4, 12, 50 etc) of fastening means, adapted to secure the EVW over the aneurysmatic aorta. The fastening means are selected in a non-limiting manner from a group consisting of threads, screws, hooks, zips, fasteners, clips, flaps, clasps, springs, clasps, staplers, grips, zippers, hooks and corresponding eyes, hook and loop reclosable fastener squares, hook and loop reclosable fastener strips, hook and loop reclosable fastener dots, hooks-and-loops, e.g., Velcro™-type fasteners, straps, holes and string, wires, cables, tabs, poppers, nails, buttons and corresponding button holes, press buttons brackets, glues, adhesives, or any combination thereof.

[0064] It is well in the scope of the invention, wherein the term '**secured**' refers interchangeably to at least two different relevant meanings, namely:

- (a) securing of the EVW to the aorta; and
- (b) securing (or otherwise attaching) of the EVW to the ESG.

[0065] It is well in the scope of the invention, wherein the term '**endoleak**' refers to Type I Endoleak, which comprises a failure to seal attachment sites of an endovascular stent-graft to the native vessels. This is widely recognized as the type of endoleak that is most closely linked to rupture and is therefore the most aggressively treated

[0066] Another embodiment of the invention wherein an extra-vascular ring (EVR) is disclosed. The EVR is adapted to at least partially encircle a segment of an aneurysmatic aorta in proximity to the renal arteries. The EVR comprises a substantially tubular inner surface, an outer surface and a plurality of fastening means; the inner surface and the outer surface are attached thereto; the fastening means adapted to secure the EVR over the aneurysmatic aorta. The EVR is capable of having an expanded state and a deformed state. The EVR in its the expanded state is adapted for extra-vascular positioning around an aorta and the EVR in its the deformed state is adapted for laparoscopic delivery to a location around the aorta. The inner surface defining a lumen that is characterized by a proximal circumference, a distal circumference and a length in the proximal to distal direction; the outer surface is characterized by a proximal circumference, a distal circumference and a length in the proximal to distal direction. The inner surface comprises (i) a macroporous medical textile member, comprises voids dimensioned to allow free tissue ingrowth therethrough, and (ii) a structural member connected thereto. The outer surface comprises (i) a microporous medical textile member that is made of a smoothly surfaced material, designed to prevent scar tissue formation and attachment

thereto and thereby prevent internal organs from sticking thereto and (ii) a structural member disposed therein and attached thereto.

[0067] Still another embodiment of the invention wherein method for treating an aneurysmatic aorta. The method comprises steps selected from the following: (a) identifying a subject having a medical condition indicative of an unacceptably high risk of rupture of an aneurysm of the abdominal aorta; (b) obtaining an implementable kit as defined in any of the above; (c) introducing the EVW in a deformed state through a laparoscopic working channel to an abdominal location adjacent to renal arteries of the abdominal aorta of the subject; (d) laparoscopically positioning the EVW around the aorta, in vicinity to renal arteries; (e) introducing a healing period of no less than 1 week; (f) endovascularly placing the Endovascular stent-graft (ESG) into the aneurysmatic aorta in the subject; and (g) at least reversibly detaching the EVW-SM and either the ESG-SM or FFG in a manner that a dislocation of the implanted kit along the aorta is avoided.

[0068] A further embodiment of the invention wherein another method for treating an aneurysmatic aorta is disclosed. The method comprises steps selected from the following: (a) identifying a subject having a medical condition indicative of an unacceptably high risk of rupture of an aneurysm of the abdominal aorta; (b) obtaining a fastened implementable kit for treating an aneurysmatic abdominal aorta, as defined above, namely a kit comprises a plurality of fastening means, adapted to secure the EVW over the aneurysmatic aorta; (c) introducing the EVW in a deformed state through a laparoscopic working channel to an abdominal location adjacent to renal arteries of the abdominal aorta of the subject; (d) laparoscopically positioning the EVW around the aorta, in vicinity to renal arteries; (e) connecting the corresponding fastening means to one another; (f) introducing a healing period of no less than 1 week; (g) endovascularly placing the ESG into the aneurysmatic aorta in the subject; and (h) securing the kit by fastening the fastening means and hence at least reversibly detaching the EVW-SM and either the ESG-SM or FFG in a manner that a dislocation of the implanted kit along the aorta is avoided. Reference is now made to the figures schematically presenting in a non-limiting manner out-of-scale presentations of various embodiments of the invention. **FIGS. 1A to 1D** depict different variants of fasteners: hooks and loops reclosable fastener stripes (e.g. hooks) and hatched stripes denote the complementary (e.g. loops) type of hooks and loops reclosable fastener stripes;

[0069] **FIG. 2** depicts an Extra Vascular Ring wherein the inner surface (10) and the outer surface (11) are concentrically aligned and are radially spaced by a substantially constant distance.

[0070] **FIG. 3** depicts an Extra Vascular Ring comprising an inner surface (20) and an outer surface (16) wherein the distal circumference of outer surface (25) substantially coincides with the distal circumference of inner surface (24) and wherein the proximal circumference of out-

er surface (23) substantially coincides with the proximal circumference of its inner surface (22).

[0071] **FIG. 4** depicts an abdominal aorta (100), a right renal artery (101), a left renal artery (102), a celiac artery (103) and an inferior mesenteric artery (104). An extra-vascular wrapping (105) is positioned adjacently below the renal arteries.

[0072] **FIG. 5** depicts an abdominal aorta (110), a right renal artery (111), a left renal artery (112), a celiac artery (113) and an inferior mesenteric artery (114). Further depicted is an extra-vascular wrapping having a distal section (115) that is positioned adjacently below the renal arteries (111, 112) and a proximal section (117) that is positioned adjacently below the renal arteries (111, 112) and a bridging section (116) that connects between the distal section (115) and the proximal section (117).

[0073] **FIG. 6** depicts an abdominal aorta (120), a right renal artery (121), a left renal artery (122), a celiac artery (123) and an inferior mesenteric artery (124). An extra-vascular wrapping (125) is positioned adjacently below the renal arteries and is adapted to allow renal arteries (121, 122) to exit through a substantially side-looking recesses in extra-vascular wrapping (125).

[0074] **FIG. 7** depicts an abdominal aorta (130), a right renal artery (131), a left renal artery (132), a celiac artery (133) and an inferior mesenteric artery (134). An extra-vascular wrapping (135) is positioned adjacently below the renal arteries (131, 132) and is adapted to allow renal arteries (131, 132) to exit through a substantially side-looking recesses in extra-vascular wrapping (135).

[0075] The extra-vascular wrapping (135) further allows the celiac artery (133) and the inferior mesenteric artery (134) to exit through a substantially forward-looking recess.

[0076] **FIG. 8A** depicts an extra-vascular wrapping (135), which include a structural member (140) and a medical textile member (141).

[0077] **FIG. 8B** depicts an abdominal aorta (130), a right renal artery (131), a left renal artery (132), over which the extra-vascular wrapping (135) of figure 8a is positioned, adjacently below the renal arteries (131, 132) and is adapted to allow renal arteries (131, 132) to exit thereabove.

[0078] **FIG. 9A** depicts an isometric view of the structural member of the extra vascular wrapping.

[0079] **FIG. 9B** depicts an axial view of the structural member of the extra vascular wrapping.

[0080] **FIG. 9c** depicts a side view of the structural member of the extra vascular wrapping.

[0081] **FIG. 9D** depicts a view of a circularly-to-linearly deformed structural member of the extra vascular wrapping.

[0082] **FIG. 9E** depicts a view of a circularly-to-linearly deformed and a longitudinally deformed structural member of the extra vascular wrapping, so that it facilitates insertion of the extra vascular wrapping into a laparoscopic channel.

Claims

1. An implantable kit for treating an aneurysmatic abdominal aorta (110, 120, 130) of a human subject, the kit comprising:
 - a. an endovascular stent-graft, ESG, comprising:
 - i. a structural member, ESG-SM, adjustable between a radially-expanded state and a radially-compressed state; and
 - ii. a fluid flow guide, FFG formed of textile strands, substantially impervious to fluids and adjustable between an expanded state and a radially-compressed state; said FFG including a proximal region along which the fluid flow guide is tubular to provide a primary conduit; and said FFG being disposed adjacent to said ESG-SM and being securely attached thereto; and
 - b. an extra-vascular wrapping (125, 135), EVW, said EVW (125, 135) comprising at least one structural member, EVW-SM, capable of reversibly interchanging between (i) a generally cylindrical expanded state **characterized by** an inner diameter and a length in the direction of said aorta (110, 120, 130) suitable for surrounding at least an effective portion of said implanted ESG; and (ii) a deformed state suitable for laparoscopic delivery of said EVW (125, 135) from a location outside of said subject's body to a location around said aorta (110, 120, 130), and *vice versa*, **characterized in that** said EVW (125, 135) further comprises at least one medical textile member (141) adapted to at least partially encircle a segment of said aneurysmatic aorta in proximity to the renal arteries, said medical textile member (141) (a) being disposed adjacent to said EVW-SM and being securely attached thereto, and
 said medical textile member (141) further (b) comprises at least one internal macroporous layer and at least one external microporous layer.
2. The kit according to claim 1, wherein said EVW (125, 135) is adapted by means of size and shape to wrap said aorta (110, 120, 130) in a non-continuous manner.
3. The kit according to claim 1, wherein said deformed state of said EVW-SM comprises at least one of the following characteristics:
 - a. longitudinal deformability, adapted to reduce said length in the direction of said aorta and hence allow insertion of said EVW (125, 135) into a laparoscopic channel; and
 - b. circular-to-linear deformability, adapted to convert said generally cylindrical to a generally linear configuration, so as to provide the EVW (125, 135) to be pushed through a generally straight laparoscopic channel.
4. The kit according to claim 1, wherein said EVW-SM and either said ESG-SM or said FFG are in attachment therebetween so that dislocation of the kit along the aorta is avoided.
5. The kit according to claim 4 wherein said EVW-SM and either said ESG-SM or said FFG are in reversible attachment therebetween, and wherein said attachment is provided by one or more physical members connecting directly between said ESG and said EVW (125, 135).
6. The kit according to claim 5, wherein said EVW (125, 135) additionally comprises a plurality of fastening elements, adapted to secure said EVW (125, 135) over said aneurysmatic aorta, which fastening elements are selected from the group consisting of: threads, screws, hooks, zips, fasteners, clips, flaps, springs, clasps, staplers, grips, zippers, hooks and corresponding eyes, hook and loop reclosable fastener squares, hook and loop reclosable fastener strips, hook and loop reclosable fastener dots, hooks-and-loops, straps, holes and string, sutures, wires, cables, tabs, poppers, nails, buttons and corresponding button holes, press buttons brackets, glues, adhesives, or any combination thereof.
7. The kit according to claim 5, wherein said EVW-SM and said ESG-SM are adapted by means of size and shape to be interlocked therebetween.
8. The kit according to claim 1, wherein said internal macroporous layer is adapted by means of size and shape to be positioned directly over said aneurysmatic abdominal aorta, and comprising voids dimensioned to allow free tissue ingrowth therethrough, and wherein said internal macroporous layer is a polymer mesh **characterized by** a pores ranging in dimension from about 100 μm to about 2 mm.
9. The kit according to claim 1, wherein said external microporous layer comprises a smoothly surfaced material, configured to prevent scar tissue formation and attachment thereto and thereby prevent internal organs from sticking thereto, and wherein said external microporous layer is adapted by means of size and shape to be sparsely attached to said internal macroporous layer, so as to allow said free tissue ingrowth while preventing scar tissue formation and attachment to said microporous layer.

10. The kit according to claim 1, wherein at least one of said internal macroporous layer and said external microporous layer comprises attaching elements, said elements selected from the group consisting of: threads, holes, screws, hooks, zips, fasteners, clips, flaps, clasps, springs, grips, zippers, hooks-and-loops, sutures, straps, strings, wires, cables, tabs, poppers, nails, buttons, brackets, glue, adhesives, or any combination thereof. 5
11. The kit according to claim 1, wherein said EVW (125, 135) when in said expanded state is in the form of a cylinder, wherein said cylinder is adapted for placement adjacently below renal arteries of said aorta (110, 120, 130), wherein said EVW (125, 135) when in said expanded state comprises one or more complete or partial interruptions, and wherein said cylinder is adapted for placement adjacently above and below said renal arteries of said aorta (110, 120, 130). 10
12. The kit according to claim 1, wherein said cylinder comprises interruptions adapted to allow passage of at least one artery selected from the group consisting of: (a) said renal arteries; (b) an inferior mesenteric artery exiting from said aorta (110, 120, 130); (c) a celiac artery exiting from said aorta (110, 120, 130) or (d) any combination thereof. 15
13. The kit according to claim 1, wherein said EVW-SM comprises a super-elastic metal. 20
14. The kit according to claim 13, wherein said super-elastic metal is Nitinol. 25
15. The kit according to claim 1, wherein said length of said EVW-SM when in said expanded state is between 1 to 3 centimeters, and wherein said inner diameter of said EVW-SM when in said expanded state is in the range between 2 to 4 centimeters. 30

Patentansprüche

1. Implantierbares Set zur Behandlung einer aneurysmatischen Bauchorta (110, 120, 130) eines menschlichen Patienten, wobei das Set umfasst:
- a. einen endovaskulären Stent-Graft, ESG, umfassend:
- i. ein Strukturelement, ESG-SE, das zwischen einem radial expandierten Zustand und einem radial komprimierten Zustand anpassbar ist; und
- ii. ein Flüssigkeitsstromführungsteil, FSF, das aus Textilsträngen gebildet, im Wesentlichen flüssigkeitsundurchlässig und zwischen einem expandierten Zustand und einem radial komprimierten Zustand anpassbar ist; wobei das FSF einen proximalen Bereich beinhaltet, entlang dessen das Flüssigkeitsstromführungsteil röhrenförmig ist, um einen primären Kanal bereitzustellen; und wobei das FSF benachbart zu dem ESG-SE angeordnet und fest daran angebracht ist; und
- b. einen extravaskulären Wickel (125, 135), EVW, wobei der EVW (125, 135) mindestens ein Strukturelement, EVW-SE, umfasst, das fähig ist, reversibel zu wechseln zwischen (i) einem generell zylindrischen expandierten Zustand, **gekennzeichnet durch** einen Innendurchmesser und eine Länge in der Richtung der Aorta (110, 120, 130), die geeignet sind, um mindestens einen effektiven Teil des implantierten ESGs zu umgeben; und (ii) einem verformten Zustand, der zur laparoskopischen Zuführung des EVWs (125, 135) von einer Position außerhalb des Körpers des Patienten zu einer Position um die Aorta (110, 120, 130) und *vice versa* geeignet ist, **dadurch** gekennzeichnet, dass der EVW (125, 135) weiter mindestens ein medizinisches Textilelement (141) umfasst, das dazu eingerichtet ist, mindestens ein Segment der aneurysmatischen Aorta in der Nähe der Nierenarterien zu umschließen, wobei das medizinische Textilelement (141) (a) benachbart zu dem EVW-SE angeordnet ist und fest daran angebracht ist, und
- das medizinische Textilelement (141) weiter (b) mindestens eine interne makroporöse Schicht und mindestens eine externe mikroporöse Schicht umfasst.
2. Set nach Anspruch 1, wobei der EVW (125, 135) mittels Größe und Form dazu eingerichtet ist, die Aorta (110, 120, 130) auf nicht kontinuierliche Weise zu umhüllen.
3. Set nach Anspruch 1, wobei der verformte Zustand des EVW-SE mindestens eines der folgenden Merkmale umfasst:
- a. Verformbarkeit in Längsrichtung, welche dazu eingerichtet ist, die Länge in der Längsrichtung der Aorta zu reduzieren und dadurch die Einbringung des EVWs (125, 135) in einen Laparoskopiekanal zuzulassen; und
- b. Verformbarkeit von kreisförmig zu linear, welche dazu eingerichtet ist, die generell zylindrische in eine generell lineare Konfiguration umzuwandeln, um den EVW (125, 135) zum Hindurchdrücken durch einen generell geraden Laparoskopiekanal bereitzustellen.

4. Set nach Anspruch 1, wobei das EVW-SE und entweder das ESG-SE oder das FSF dazwischen befestigt sind, sodass eine Dislokation des Sets entlang der Aorta vermieden wird.
5. Set nach Anspruch 4, wobei das EVW-SE und entweder das ESG-SE oder das FSF reversibel dazwischen befestigt sind und wobei diese Befestigung durch ein oder mehr technische Elemente bereitgestellt wird, die direkt zwischen dem ESG und dem EVW (125, 135) anschließen.
6. Set nach Anspruch 5, wobei der EVW (125, 135) zusätzlich eine Vielzahl von Befestigungselementen umfasst, die zur Befestigung des EVWs (125, 135) über der aneurysmatischen Aorta eingerichtet sind, welche Befestigungselemente aus der Gruppe ausgewählt sind, bestehend aus: Gewinden, Schrauben, Haken, Zippverschlüssen, Schnellverschlüssen, Clips, Laschen, Federn, Hakenverschlüssen, Nieten, Klammern, Reißverschlüssen, Haken und entsprechenden Ösen, wiederverschließbaren Klettband-Verschlussquadranten, wiederverschließbaren Klettband-Verschlussstreifen, wiederverschließbaren Klettband-Verschlusspunkten, Klettbändern, Riemen, Löchern und Schnur, chirurgischen Nähten, Drähten, Kabeln, Schlaufen, Druckknöpfen, Nägeln, Knöpfen und entsprechenden Knopflöchern, Druckknopfbügeln, Leimen, Klebstoffen oder gleich welcher Kombination davon.
7. Set nach Anspruch 5, wobei der EVW-SE und das ESG-SE mittels Größe und Form dazu eingerichtet sind, dazwischen verriegelt zu werden.
8. Set nach Anspruch 1, wobei die interne makroporöse Schicht mittels Größe und Form dazu eingerichtet ist, direkt über der aneurysmatischen Bauchaorta angeordnet zu werden, und Hohlräume umfasst, die dazu dimensioniert sind, freies Einwachsen von Gewebe dort hindurch zuzulassen, und wobei die interne makroporöse Schicht ein Polymernetz ist, das durch Poren gekennzeichnet ist, die sich in der Größe von ungefähr 100 µm bis auf ungefähr 2 mm belaufen.
9. Set nach Anspruch 1, wobei die externe mikroporöse Schicht ein Material mit glatter Oberfläche umfasst, das dazu eingerichtet ist, die Bildung von Narbengewebe und die Bindung daran zu verhindern und dadurch zu verhindern, dass innere Organe daran anhaften, und wobei die externe mikroporöse Schicht mittels Größe und Form dazu eingerichtet ist, spärlich an der internen makroporösen Schicht befestigt zu sein, um freies Einwachsen von Gewebe zuzulassen, während Narbengewebebildung und Befestigung an der mikroporösen Schicht verhindert

werden.

10. Set nach Anspruch 1, wobei mindestens eines der internen makroporösen Schicht und der externen mikroporösen Schicht Befestigungselemente umfasst, wobei diese Elemente aus der Gruppe ausgewählt sind, bestehend aus: Gewinden, Löchern, Schrauben, Haken, Zippverschlüssen, Schnellverschlüssen, Clips, Laschen, Hakenverschlüssen, Federn, Klammern, Reißverschlüssen, Klettbändern, chirurgischen Nähten, Riemen, Schnüren, Drähten, Kabeln, Schlaufen, Druckknöpfen, Nägeln, Knöpfen, Bügeln, Leim, Klebstoffen oder gleich welcher Kombination davon.
11. Set nach Anspruch 1, wobei der EVW (125, 135), wenn er sich in dem expandierten Zustand befindet, in Form eines Zylinders vorliegt, wobei der Zylinder zur Anbringung benachbart unterhalb von Nierenarterien der Aorta (110, 120, 130) eingerichtet ist, wobei der EVW (125, 135), wenn er sich in dem expandierten Zustand befindet, eine oder mehrere vollständige oder teilweise Unterbrechungen umfasst, und wobei der Zylinder zur Anbringung benachbart ober- und unterhalb der Nierenarterien der Aorta (110, 120, 130) eingerichtet ist.
12. Set nach Anspruch 1, wobei der Zylinder Unterbrechungen umfasst, die dazu eingerichtet sind, das Hindurchführen mindestens einer Arterie zu gestatten, ausgewählt aus der Gruppe, bestehend aus: (a) den Nierenarterien; (b) einer aus der Aorta (110, 120, 130) austretenden unteren Eingeweidearterie; (c) einer aus der Aorta (110, 120, 130) austretenden Bauchhöhlenarterie oder (d) gleich welcher Kombination davon.
13. Set nach Anspruch 1, wobei das EVW-SE ein superelastisches Metall umfasst.
14. Set nach Anspruch 13, wobei das superelastische Metall Nitinol ist.
15. Set nach Anspruch 1, wobei die Länge des EVW-SEs, wenn es sich im expandierten Zustand befindet, zwischen 1 und 3 Zentimeter beträgt, und wobei der Innendurchmesser des EVW-SEs, wenn es sich im expandierten Zustand befindet, im Bereich zwischen 2 und 4 Zentimetern liegt.

Revendications

1. Nécessaire implantable pour traiter un anévrisme aortique abdominal (110, 120, 130) d'un sujet humain, le nécessaire comprenant :
 - a. une greffe endovasculaire, ESG,

comprenant :

- i. un élément structurel, ESG-SM, réglable entre un état déployé en direction radiale et un état comprimé en direction radiale ; et
 - ii. un guide d'écoulement de fluide, FFG, réalisé à partir de fils textiles, essentiellement imperméable aux fluides et que l'on peut régler entre un état déployé et un état comprimé en direction radiale, ledit FFG englobant une zone proximale le long de laquelle le guide d'écoulement de fluide possède une forme tubulaire pour procurer un conduit primaire, et ledit FFG est disposé en position adjacente audit ESG-SM tout en y étant fermement fixé ; et
 - b. une enveloppe extravasculaire (125, 135), EVW, ladite EVW (125, 135) comprenant au moins un élément structurel, ESG-SM, possédant une capacité de permutation réversible entre (i) un état déployé généralement cylindrique **caractérisé par** un diamètre interne et une longueur dans la direction de ladite aorte (110, 120, 130) appropriés pour entourer au moins une portion effective de ladite ESG implantée ; et (ii) un état déformé approprié pour l'alimentation laparoscopique de ladite EVW (125, 135) à partir d'un endroit situé à l'extérieur du corps dudit sujet jusqu'à un endroit situé autour de ladite aorte (110, 120, 130), et *vice versa*, **caractérisé en ce que** ladite EVW (125, 135) comprend en outre au moins un élément textile médical (141) conçu pour encercler au moins en partie un segment dudit anévrisme aortique à proximité des artères rénales, ledit élément textile médical (141) (a) étant disposé en position adjacente audit EVW-SM tout en y étant fermement fixé et ledit élément textile médical (141) (b) comprenant en outre au moins une couche macroporeuse interne et au moins une couche microporeuse externe.
2. Nécessaire selon la revendication 1, dans lequel ladite EVW (125, 135) est conçue, en ce qui concerne sa dimension et sa configuration, pour envelopper ladite aorte (110, 120, 130) d'une manière non continue.
 3. Nécessaire selon la revendication 1, dans lequel ledit état déformé dudit EVW-SM comprend au moins une des caractéristiques suivantes :
 - a. une aptitude à la déformation en direction longitudinale, conçue pour réduire ladite longueur dans la direction de ladite aorte et permettant par conséquent l'insertion de ladite EVW (125, 135) dans un canal laparoscopique ; et
 - b. une aptitude à la déformation circulaire-vers-linéaire, conçue pour convertir ladite configuration généralement cylindrique en une configuration généralement linéaire de façon à conférer à la EVW (125, 135) une capacité d'être poussée à travers un canal laparoscopique généralement rectiligne.
 4. Nécessaire selon la revendication 1, dans lequel ledit EVW-SM et, soit ledit ESG-SM, soit ledit FFG, sont fixés entre eux de façon à éviter une désarticulation du nécessaire le long de l'aorte.
 5. Nécessaire selon la revendication 4, dans lequel ledit EVW-SM et, soit ledit ESG-SM, soit ledit FFG, sont fixés entre eux de manière réversible, et dans lequel ladite fixation est fournie par un ou plusieurs éléments physiques reliant directement entre eux ladite ESG et ladite EVW (125, 135).
 6. Nécessaire selon la revendication 5, dans lequel ladite EVW (125, 135) comprend en outre plusieurs éléments de fixation conçus pour fixer ladite EVW (125, 135) par-dessus ledit anévrisme aortique, les éléments de fixation en question étant choisis parmi le groupe constitué par : des fils, des vis, des crochets, des fermetures à glissière, des attaches, des pinces, des pattes, des ressorts, des vrilles, des agrafes, des griffes, des fermetures éclair, des crochets et des oeillets correspondants, des carrés de fixation refermables de type velcro, des bandes de fixation refermables de type velcro, des points de fixation refermables de type velcro, des crochets-et-boucles, des sangles, des trous et ficelles, des fils de suture, des fils métalliques, des câbles, des pattes, des boutons-pression, des clous, des boutons et des trous de boutons correspondants, des supports de boutons-pression, des colles, des adhésifs, ou l'une quelconque de leurs combinaisons.
 7. Nécessaire selon la revendication 5, dans lequel ledit EVW-SM et ledit ESG-SM sont conçus, en ce qui concerne leur dimension et leur configuration, à des fins de verrouillage réciproque.
 8. Nécessaire selon la revendication 1, dans lequel ladite couche macroporeuse interne est conçue en ce qui concerne sa dimension et sa configuration pour venir se disposer directement par-dessus ledit anévrisme aortique abdominal, et comprenant des vides dimensionnés pour y permettre une croissance interne de tissu sans entrave, et dans lequel ladite couche macroporeuse interne est un treillis polymère **caractérisé par** des pores dont les dimensions se situent dans la plage d'environ 100 μm à environ 2 mm.
 9. Nécessaire selon la revendication 1, dans lequel la-

dite couche microporeuse externe comprend une matière du type à surface lisse, configurée pour empêcher la formation de tissu cicatriciel et la fixation de ce dernier à ladite couche pour ainsi empêcher des organes internes d'y adhérer, et dans lequel ladite couche microporeuse externe est conçue en ce qui concerne sa dimension et sa configuration pour être faiblement fixée à ladite couche macroporeuse interne, de façon à permettre une croissance interne de tissu sans entrave, tout en empêchant une formation de tissu cicatriciel et la fixation de ce dernier à ladite couche microporeuse.

dite longueur dudit EVW-SM, lorsqu'il se trouve dans ledit état déployé, s'élève entre 1 et 3 cm, et dans lequel ledit diamètre interne dudit EVW-SM, lorsqu'il se trouve dans ledit état déployé, se situe dans la plage entre 2 et 4 cm.

10. Nécessaire selon la revendication 1, dans lequel au moins une desdites couches choisies parmi ladite couche macroporeuse interne et ladite couche microporeuse externe comprend des éléments de fixation, lesdits éléments étant choisis parmi le groupe constitué par : des fils, des trous, des vis, des crochets, des fermetures à glissière, des attaches, des pinces, des pattes, des vrilles, des ressorts, des griffes, des fermetures éclair, des crochets-et-boucles, des fils de suture, des sangles, des cordons, des fils métalliques, des câbles, des pattes, des boutons-pression, des clous, des boutons, des supports, des colles, des adhésifs, ou l'une quelconque de leurs combinaisons.
11. Nécessaire selon la revendication 1, dans lequel ladite EVW (125, 135), lorsqu'elle se trouve dans ledit état déployé, se présente sous la forme d'un cylindre, ledit cylindre étant conçu pour venir se placer en position adjacente en dessous des artères rénales de ladite aorte (110, 120, 130), dans lequel ladite EVW (125, 135), lorsqu'elle se trouve dans ledit état déployé, comprend une ou plusieurs interruptions complètes ou partielles, et dans lequel ledit cylindre est conçu pour venir se placer en position adjacente au-dessus et en dessous desdites artères rénales de ladite aorte (110, 120, 130).
12. Nécessaire selon la revendication 1, dans lequel ledit cylindre comprend des interruptions conçues pour permettre le passage d'au moins une artère choisie parmi le groupe constitué par : (a) lesdites artères rénales ; (b) une artère mésentérique inférieure qui sort de ladite aorte (110, 120, 130) ; (c) une artère coeliaque qui sort de ladite aorte (110, 120, 130) ; ou (d) l'une quelconque de leurs combinaisons.
13. Nécessaire selon la revendication 1, dans lequel ledit EVW-SM comprend un métal superélastique.
14. Nécessaire selon la revendication 13, dans lequel ledit métal est du nitinol.
15. Nécessaire selon la revendication 1, dans lequel la-

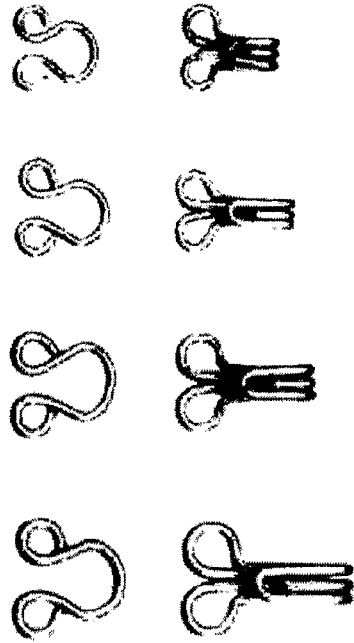


FIG. 1A
Dress hooks & eyes

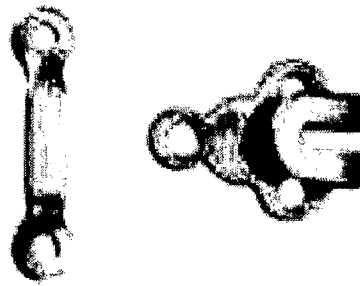


FIG. 1B
Skirt hooks & eyes

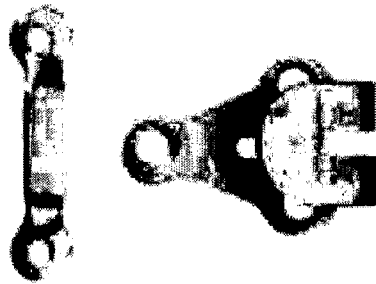


FIG. 1C
Heavy duty hooks & eyes



FIG. 1D
Coat hooks & eyes

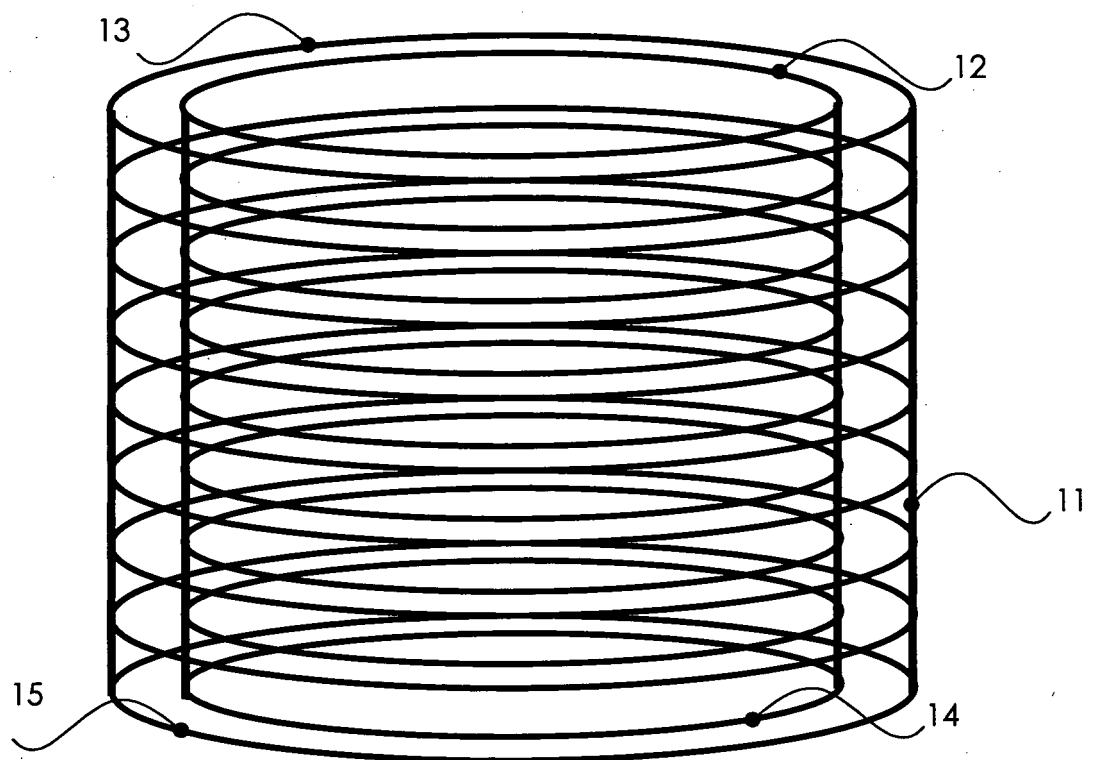


FIG. 2

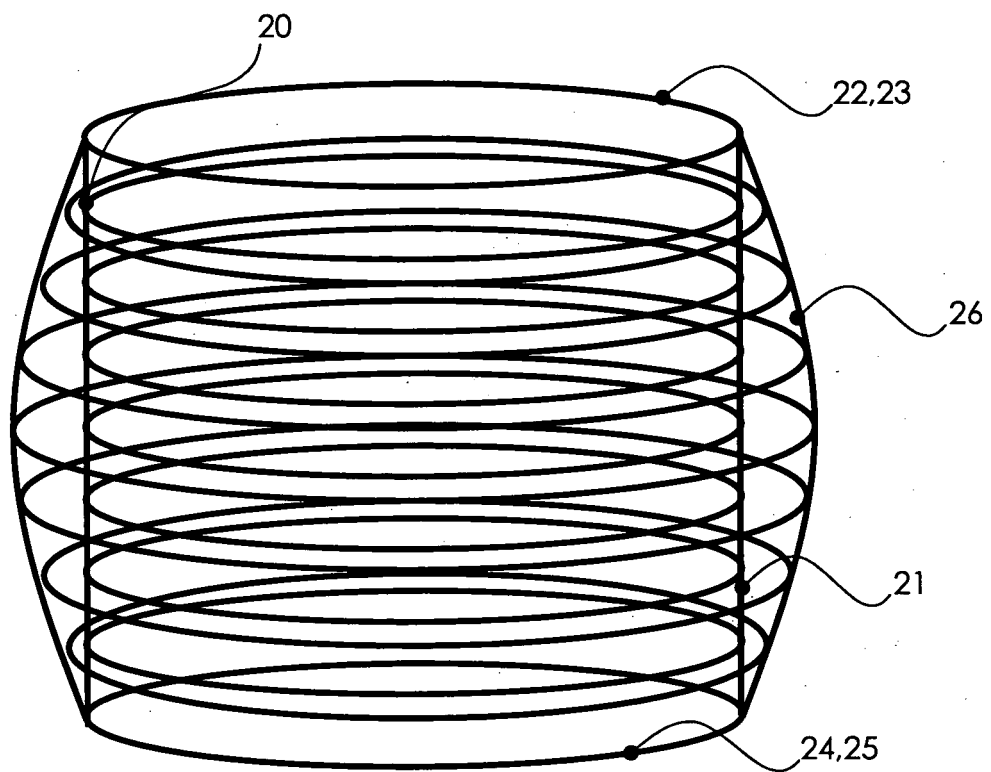


FIG. 3

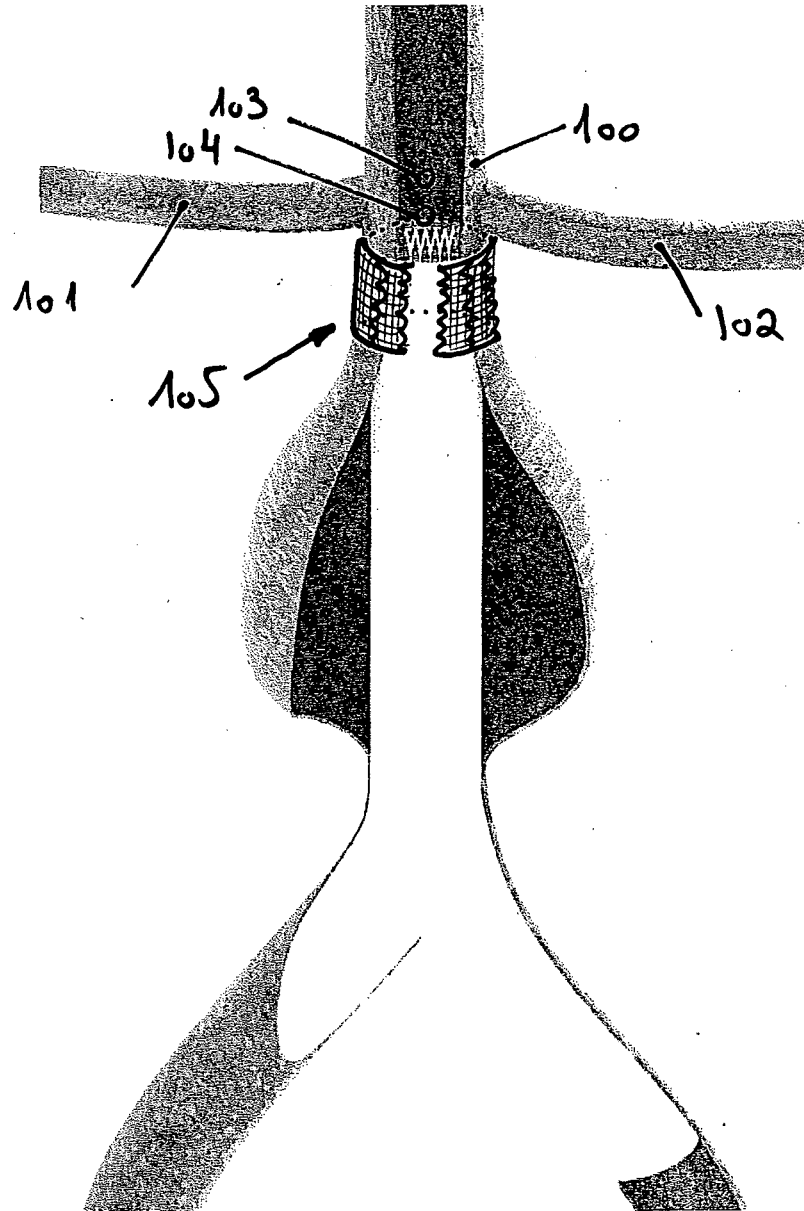


FIG. 4

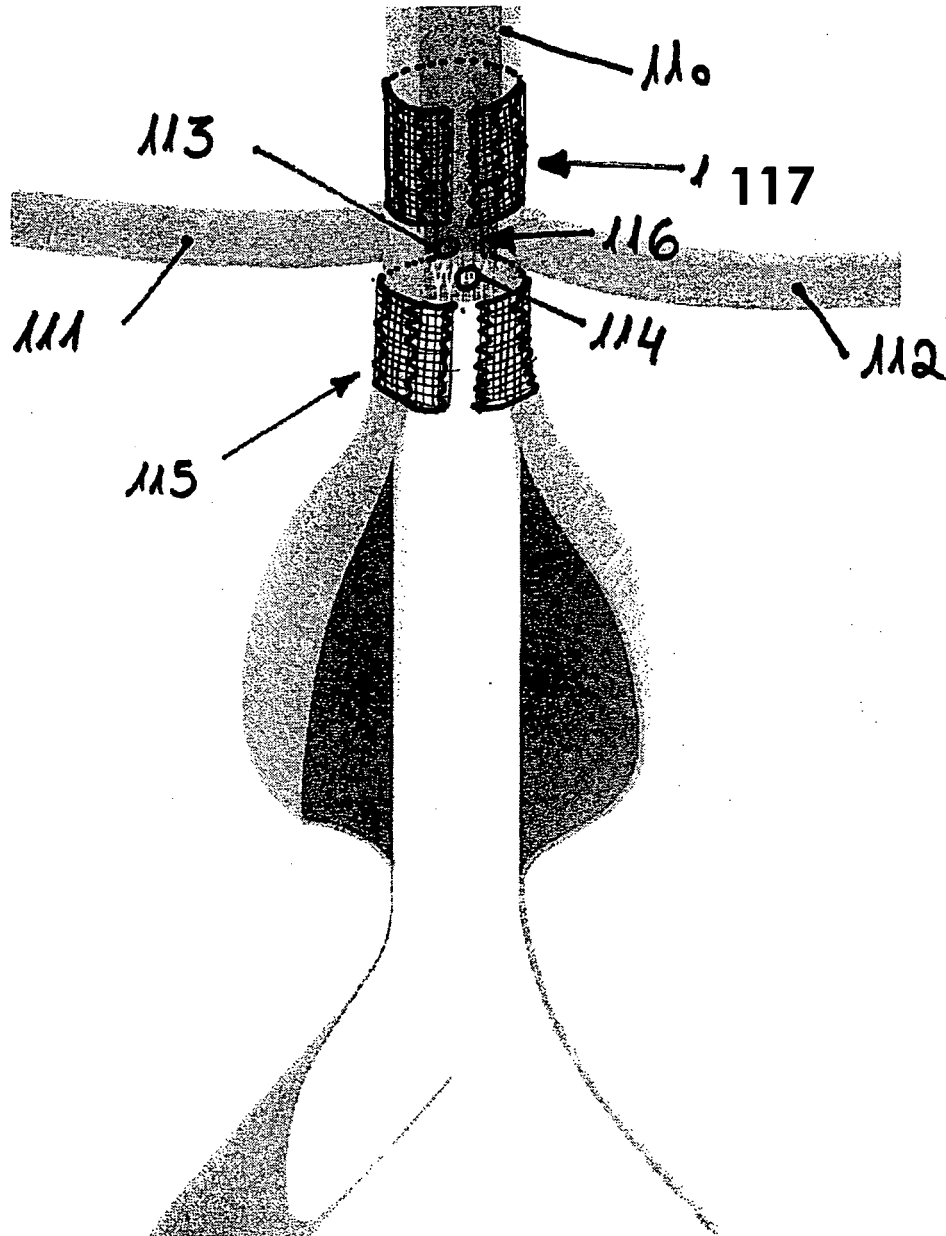


FIG. 5

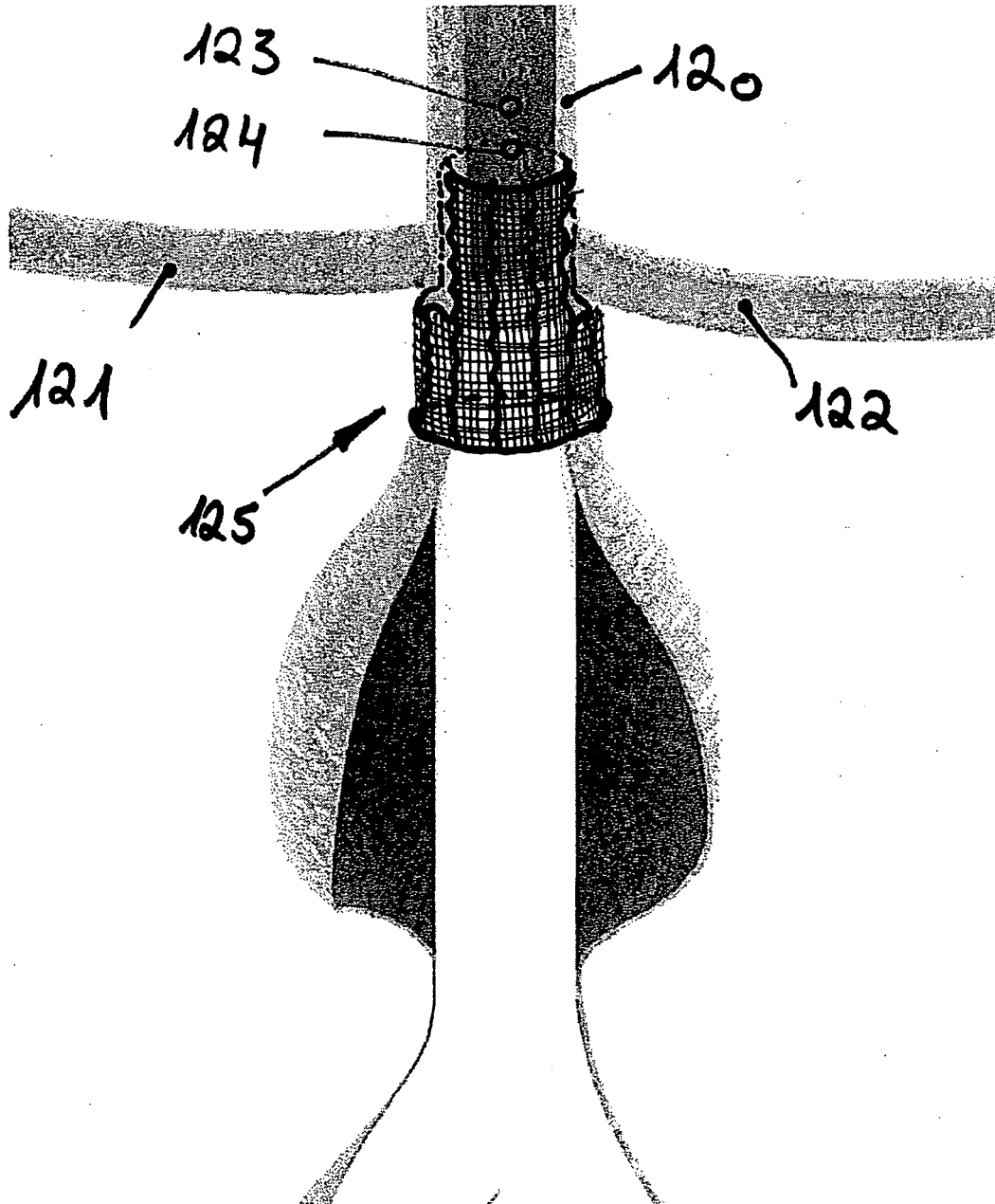


FIG. 6

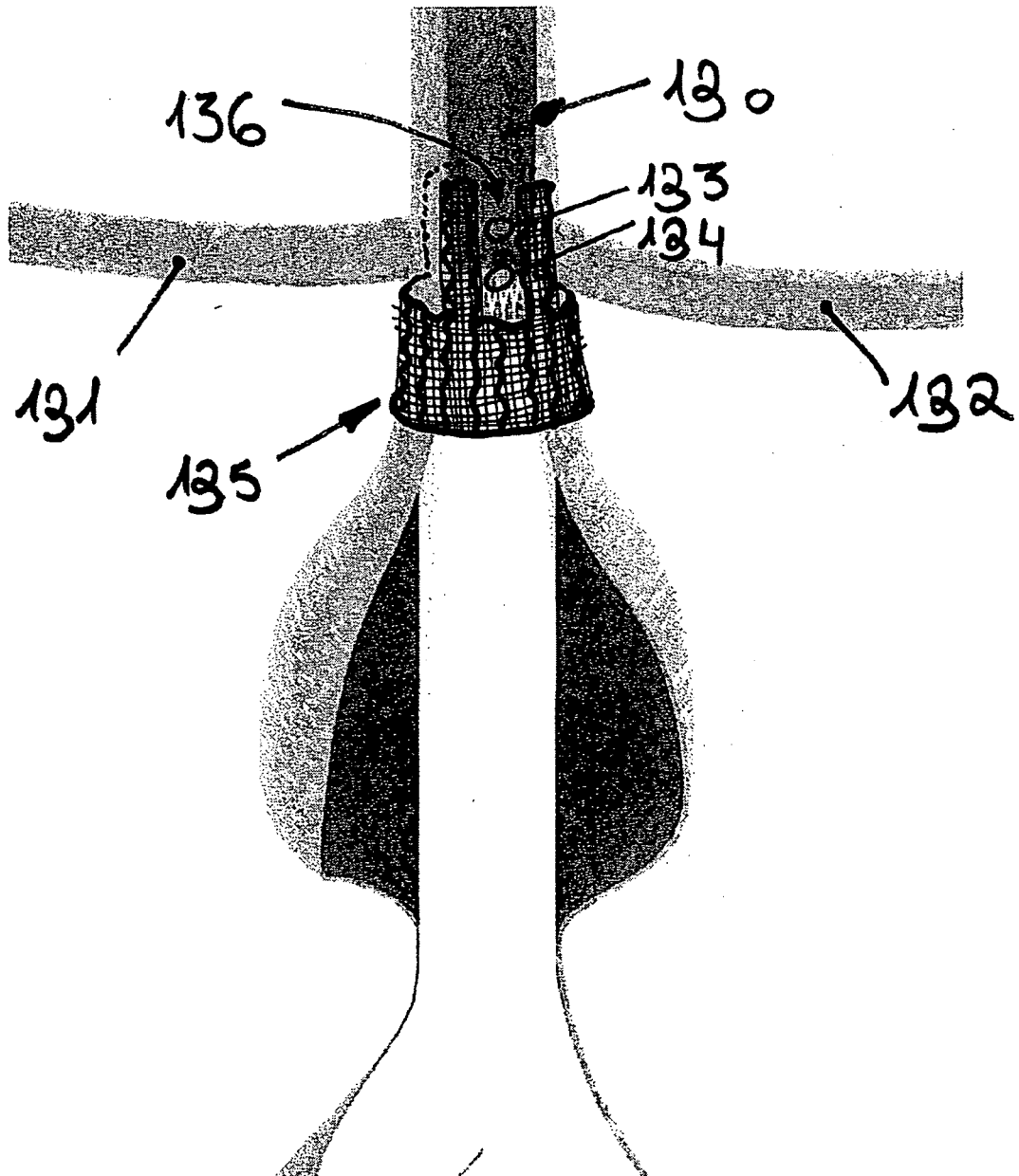


FIG. 7

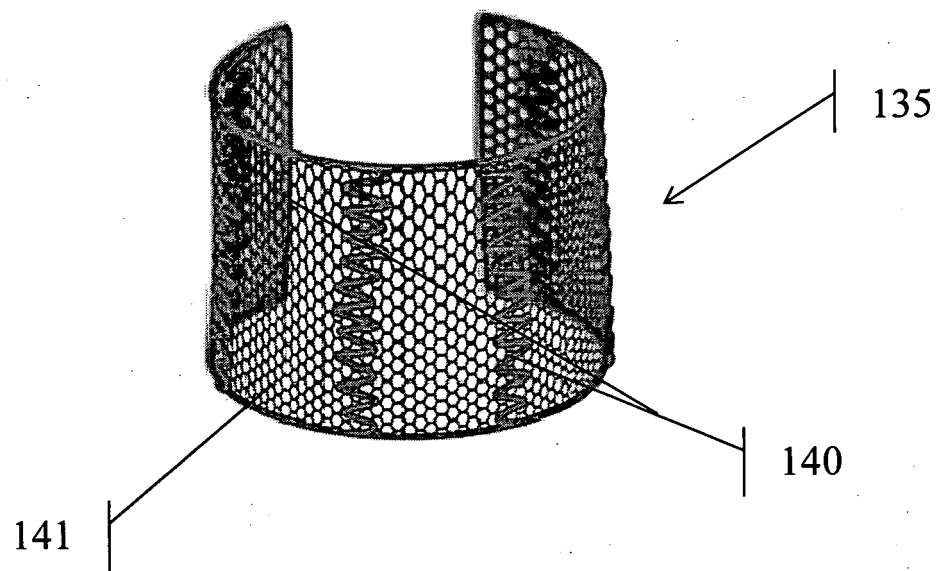


FIG. 8A

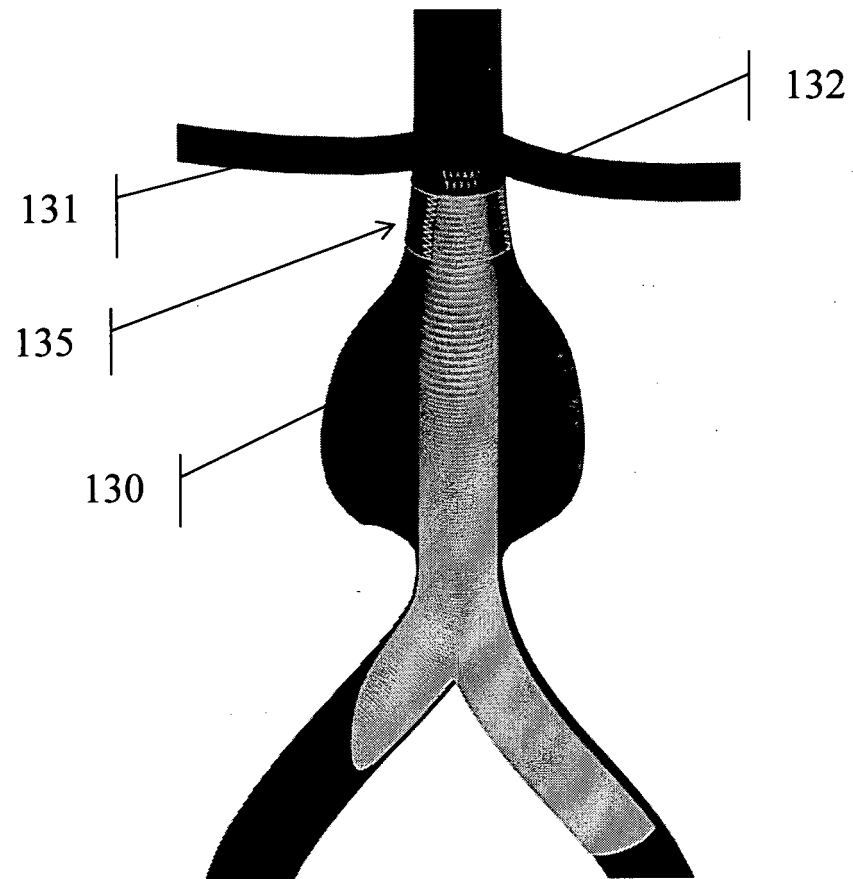


FIG. 8B

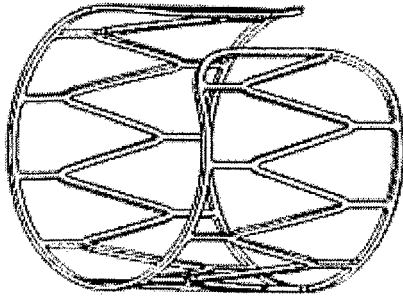


FIG. 9A

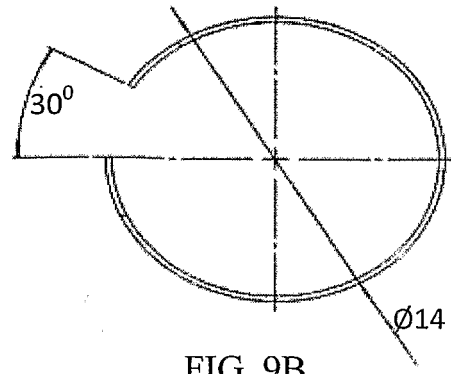


FIG. 9B

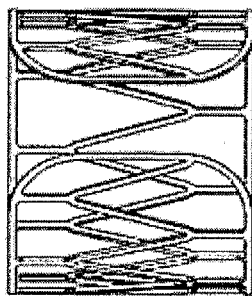


FIG. 9C

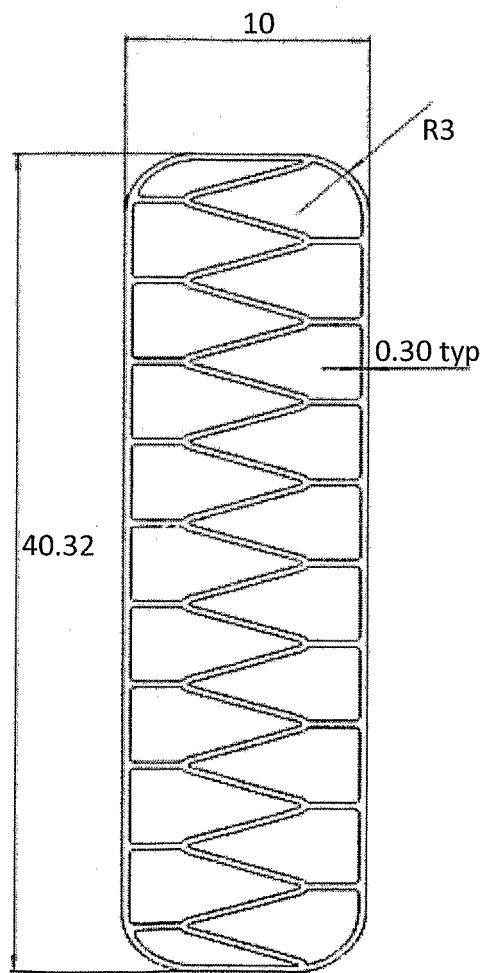


FIG. 9D

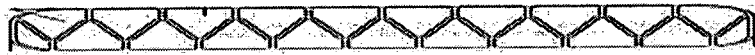


FIG. 9E

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 61014031 B [0002]
- US 4562596 A [0008]
- US 4787899 A [0008]
- US 5042707 A [0008]
- US 5843170 A [0015]
- WO 9934748 A [0015]

专利名称(译)	血管外包装用于治疗动脉瘤主动脉与血管内支架移植物联合治疗		
公开(公告)号	EP2231066B1	公开(公告)日	2017-04-26
申请号	EP2008861980	申请日	2008-12-15
[标]申请(专利权)人(译)	恩多斯潘有限公司		
申请(专利权)人(译)	ENDOSPAN LTD.		
当前申请(专利权)人(译)	ENDOSPAN LTD.		
[标]发明人	SHALEV ALON		
发明人	SHALEV, ALON		
IPC分类号	A61F2/07 A61B17/12 A61B17/132		
CPC分类号	A61F2/06 A61B17/12 A61B17/12113 A61B17/12168 A61F2/07 A61F2220/0008		
优先权	61/014031 2007-12-15 US		
其他公开文献	EP2231066A2 EP2231066A4		
外部链接	Espacenet		

摘要(译)

一种用于治疗动脉瘤性腹主动脉的系统，包括 (a) 血管外包装 (EVW)，其包括 (i) 至少一个医用纺织品构件，其适于至少部分地环绕肾动脉附近的主动脉段，以及 (ii) 结构构件，其中EVW适于腹腔镜输送，和 (b) 血管内支架移植物 (ESG)，其包括 (i) 可压缩结构构件，和 (ii) 附接的基本上不透流体的流体导流器 (FFG) 于此。还描述了适于环绕动脉瘤颈部的血管外环 (EVR)。进一步描述了治疗腹主动脉瘤的方法，包括腹腔镜输送血管外包装 (EVW) 和血管内放置血管内支架 - 移植物 (ESG)。还描述了治疗I型内漏的方法。

