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(54) Title: EXTRA-VASCULAR WRAPPING FOR TREATING ANEURYSMATIC AORTA IN CONJUNCTION WITH ENDOVASCULAR STENT-GRAFT AND METHODS THEREOF

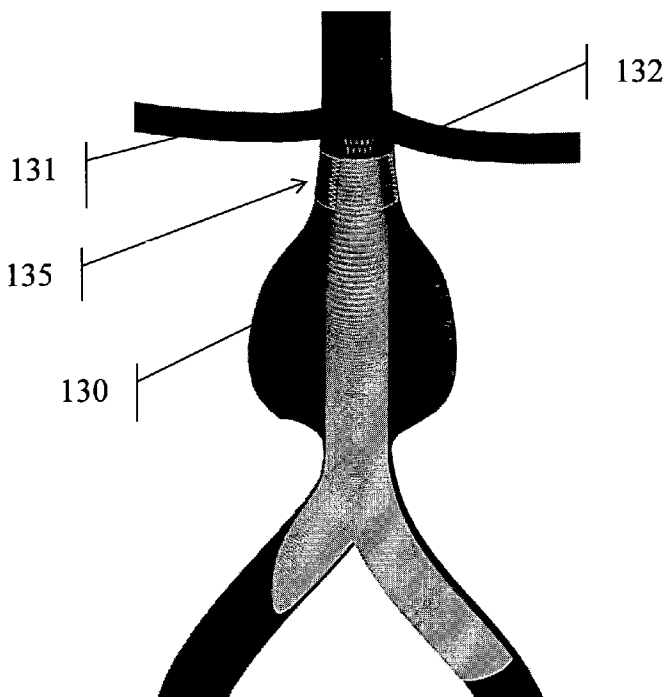


FIG. 8B

(57) Abstract: A system for treating an aneurysmatic abdominal aorta, comprising (a) an extra-vascular wrapping (EVW) comprising (i) at least one medical textile member adapted to at least partially encircle a segment of aorta in proximity to the renal arteries, and (ii) a structural member, wherein EVW is adapted for laparoscopic delivery, and (b) an endovascular stent-graft (ESG) comprising (i) a compressible structural member, and (ii) a substantially fluid impervious fluid flow guide (FFG) attached thereto. Also described is an extra-vascular ring (EVR) adapted to encircle the neck of an aortic aneurysm. Further described are methods for treating an abdominal aortic aneurysm, comprising laparoscopically delivering the extra-vascular wrapping (EVW) and endovascularly placing an endovascular stent-graft (ESG). Also described are methods to treat a type I endoleak.

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**EXTRA-VASCULAR WRAPPING FOR TREATING ANEURYSMATIC AORTA IN
CONJUNCTION WITH ENDOVASCULAR STENT-GRAFT AND METHODS
THEREOF**

FIELD OF THE INVENTION

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

US patent application 61014031 to the inventor is incorporated hereby by reference in its entirety.

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.

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.

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.

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. Repair of an aortic aneurysm by surgical means is a major operative procedure. Substantial morbidity accompanies 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.

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.

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.

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

Endoleaks are caused by passage of blood into the aneurismal 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

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.

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.

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.

SUMMARY 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 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.

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.

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.

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.

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

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

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 aneurysmatic aorta.

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, claspers, springs, claspers, 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., VelcroTM-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.

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.

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).

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.

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.

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.

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.

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.

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., VelcroTM-type fasteners, sutures, straps, strings, wires, cables, tabs, poppers, nails, buttons, brackets, glue, adhesives, or any combination thereof.

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.

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.

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

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.

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.

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

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

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.

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.

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.

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.

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.

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

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.

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.

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.

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

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

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.

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

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.

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.

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

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.

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.

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

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.

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

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 embodiment 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

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.

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 laparoscopic 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.

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., VelcroTM-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.

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.

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

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 may 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 may 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.

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.

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;

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.

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

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.

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).

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).

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). 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.

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.

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 of a human subject, 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; said FFG being disposed adjacent to said ESG-SM and being securably attached thereto; and,
 - b. an extra-vascular wrapping (EVW), said EVW having 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 suitable for surrounding at least an effective portion of said implanted ESG; and (ii) a deformed state suitable for laparoscopic delivery of said EVW from a location outside of said subject's body to a location around said aorta, and vice versa.
2. The kit of claim 1, wherein said EVW further comprising at least one medical textile member adapted to at least partially encircle a segment of said aneurysmatic aorta in proximity to the renal arteries. said medical textile member being disposed adjacent to said EVW-SM and being securably attached thereto
3. The kit of claim 1, wherein said EVW is adapted by means of size and shape to wrap said aorta in a non-continuous manner.
4. The kit of 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 into a laparoscopic channel;
 - b. circular-to-linear deformability, adapted to convert said generally cylindrical to a generally linear configuration, so as to provide the EVW to be pushed through a generally straight laparoscopic channel.

5. A secured implantable kit for treating an aneurysmatic abdominal aorta of a human subject, comprising at least two attachable elements:
 - 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; said FFG being disposed adjacent to said ESG-SM and being securably attached thereto; and,
 - b. an extra-vascular wrapping (EVW), said EVW having 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 suitable for surrounding at least an effective portion of said implanted ESG; and (ii) a deformed state suitable for laparoscopic delivery of said EVW from a location outside of said subject's body to a location around said aorta, and vice versa; wherein said EVW-SM and either said ESG-SM or FFG are in attachment therebetween so that dislocation of the implanted kit along the aorta is avoided.
6. The kit according to claim 5 wherein said attachment comprising reversible attachment.
7. A secured kit according to claim 6, wherein said EVW additionally comprising a plurality of fastening means, adapted to secure said EVW over said aneurysmatic aorta.
8. The secured kit of claim 7, wherein said 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., VelcroTM-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.
9. The secured kit according to claim 6, wherein said attachment is provided by a means of one or more physical members connecting directly between said ESG and said EVW.

10. The secured kit according to claim 6, wherein said EVW-SM and ESG-SM are adapted by means of size and shape to be interlocked therebetween.
11. The kit according to claim 2, wherein said medical textile member of EVW comprising at least one internal macroporous layer and at least one external microporous layer.
12. The kit according to claim 11, 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.
13. The kit according to claim 12, wherein said internal macroporous layer is a polymer mesh characterized by a pores ranging in dimension from about 100 μm to about 2 mm.
14. The kit according to claim 11, wherein said 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.
15. The kit according to claim 11, 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.
16. The kit according to claim 11, wherein at least one of said internal macroporous layer and external microporous layer comprising attaching means, said 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., VelcroTM-type fasteners, sutures, straps, strings, wires, cables, tabs, poppers, nails, buttons, brackets, glue, adhesives, or any combination thereof.
17. The kit according to claim 1, wherein said EVW in its said expanded state is in the form of a cylinder, said cylinder is adapted for placement adjacently below renal arteries of said aorta.
18. The kit according to claim 1, wherein said EVW in its said expanded state comprises one or more, complete or partial, interruptions; said cylinder is adapted for placement adjacently above and below renal arteries of said aorta.
19. the kit according to claim 18 wherein said interruptions in cylinder are adapted to allow passage of said renal arteries.

20. the kit according to claim 18 wherein said interruptions in cylinder are adapted to allow passage of an inferior mesenteric artery exiting from said aorta.
21. the kit according to claim 18 wherein said interruptions in cylinder are adapted to allow passage of a celiac artery exiting from said aorta.
22. The kit according to claim 1, wherein said EVW-SM is made of a super-elastic metal.
23. The kit according to claim 22, wherein said super-elastic metal is Nitinol.
24. The kit according to claim 1, wherein said length of EVW in its said expanded state is in the range between about 1 to 3 centimeters.
25. The kit according to claim 1, wherein said inner diameter of EVW in its said expanded state is in the range between about 2 to 4 centimeters.
26. 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, comprising a generally cylindrical inner surface, an outer surface and a structural member; said inner surface and said outer surface are attached therebetween; EVR is capable of having an expanded state and a deformed state; said EVR in its said expanded state is adapted for extra-vascular positioning around said aorta and said EVR in its deformed state is adapted for laparoscopic delivery from a location outside said subject's body to a location around said aorta; said inner surface defining a lumen that is characterized by a proximal circumference, a distal circumference and a length in the proximal to distal direction; said outer surface is characterized by a proximal circumference, a distal circumference and a length in the proximal to distal direction; said inner surface comprising a macroporous medical textile member, comprising voids dimensioned to allow free tissue ingrowth therethrough, and said outer surface comprising 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; said structural member connected either to said inner surface or to said outer surface.
27. The EVR according to claim 26 further comprising a plurality of fastening means.
28. the EVR according to claim 26 further comprising a plurality of radially projecting attachment means, said attachment means being adapted to secure said EVR either to said aorta or to an endovascular aortic stent-graft.

29. The EVR according to claim 26 wherein said inner surface and said outer surface are substantially concentrically aligned.
30. The EVR according to claim 26 wherein said inner surface and said outer surface are radially spaced by a distance in the range between about 2 to 5 millimeters.
31. The EVR according to claim 26 wherein said proximal circumference of outer surface substantially coincides with said proximal circumference of inner surface.
32. The EVR according to claim 26 wherein said distal circumference of outer surface substantially coincides with said distal circumference of inner surface.
33. The EVR according to claim 26 wherein said outer surface is substantially tubular.
34. The EVR according to claim 26 wherein said structural member is made of a superelastic metal.
35. The EVR according to claim 26 wherein said inner surface and said outer surface are attached thereto via a plurality of spacing members, said spacing members being connected to said structural member.
36. The EVR according to claim 26 wherein said spacing members are substantially oriented in the radial direction.
37. A method for treating an aneurysmatic aorta, comprising the steps of:
 - 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 for treating an aneurysmatic abdominal aorta, comprising at least two elements:
 - i. an endovascular stent-graft (ESG) comprising:
 - a. a structural member (ESG-SM) adjustable between a radially-expanded state and a radially-compressed state; and,
 - b. 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; said FFG being disposed adjacent to said ESG-SM and being securably attached thereto; and,

- ii. an extra-vascular wrapping (EVW), said EVW having 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 suitable for surrounding at least an effective portion of said implanted ESG; and (ii) a deformed state suitable for laparoscopic delivery of said EVW from a location outside of said subject's body to a location around said aorta, and vice versa;
 - c. introducing said EVW in its said deformed state through a laparoscopic working channel to an abdominal location adjacent to renal arteries of said abdominal aorta;
 - d. laparoscopically positioning said EVW around said aorta, in vicinity to renal arteries; and
 - e. endovascularly placing said endovascular stent-graft (ESG) into said aneurysmatic aorta in said subject.
38. The method according to claim 37 wherein said ESG and said EVW are attachable therebetween and wherein method further comprising a step (f); step (f) comprising attaching said EVW and said ESG therebetween in a manner that a dislocation of either element of said implantable kit along said aorta is avoided
39. The method according to claim 38, wherein said attachable comprising reversibly attachable and wherein said attaching comprising reversibly attaching.
40. The method according to claim 37, 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 comprising identifying a subject having a medical condition indicative of an unacceptably high risk of rupture of an aneurysm of the abdominal aorta and said aneurysm reaching about 2 centimeters or less to a closest renal artery of said subject.
41. A method for treating an aneurysmatic aorta, comprising the steps of:
- a. identifying an aortic endoleak in a subject implanted with an endovascular stent-graft (ESG); said ESG comprising (a) a structural member (ESG-SM) adjustable between a radially-expanded state and a radially-compressed state; and (b) a fluid flow guide (FFG) formed of textile strands, substantially impervious to fluids that is disposed adjacent to said ESG-SM and being securably attached thereto.

- b. providing 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, comprising a generally cylindrical inner surface, an outer surface and a structural member; said inner surface and said outer surface are attached therebetween; EVR is capable of having an expanded state and a deformed state; said EVR in its said expanded state is adapted for extra-vascular positioning around said aorta and said EVR in its deformed state is adapted for laparoscopic delivery from a location outside said subject's body to a location around said aorta; said inner surface defining a lumen that is characterized by a proximal circumference, a distal circumference and a length in the proximal to distal direction; said outer surface is characterized by a proximal circumference, a distal circumference and a length in the proximal to distal direction; said inner surface comprising a macroporous medical textile member, comprising voids dimensioned to allow free tissue ingrowth therethrough, and said outer surface comprising 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; said structural member connected either to said inner surface or to said outer surface.
 - c. introducing said EVR in its said deformed state through a laparoscopic working channel to an abdominal location adjacent to renal arteries of said abdominal aorta; and
 - d. laparoscopically positioning said EVR around said aorta, in vicinity to renal arteries;
42. A method for treating an aneurysmatic aorta, comprising the steps of:
- 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 fastenable implantable kit for treating an aneurysmatic abdominal aorta, comprising at least three elements:
 - i. an endovascular stent-graft (ESG) comprising:
 - a. a structural member (ESG-SM) adjustable between an expanded state and a radially-compressed state; and,

- b. 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,
 - ii. an extra-vascular wrapping (EVW), said EVW having 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 suitable for surrounding at least an effective portion of said implanted ESG; and (ii) a deformed state suitable for laparoscopic delivery of said EVW from a location outside of said subject's body to a location around said aorta, and vice versa;
 - iii. a plurality of fastening means, adapted to secure said EVW over said aneurysmatic aorta.
 - c. introducing said EVW in said deformed state through a laparoscopic working channel to an abdominal location adjacent to renal arteries of said abdominal aorta of said subject;
 - d. laparoscopically positioning said EVW around said aorta, in vicinity to renal arteries;
 - e. connecting said corresponding fastening means therebetween; and,
 - f. endovascularly placing said ESG into said aneurysmatic aorta.
- 43. The method according to claim 42, 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 comprising identifying a subject having a medical condition indicative of an unacceptably high risk of rupture of an aneurysm of the abdominal aorta and said aneurysm reaching about 2 centimeters or less to a closest renal artery of said subject.
- 44. A method for treating an aneurysmatic aorta, comprising the steps of:
 - a. identifying an aortic endoleak in a subject implanted with an endovascular stent-graft (ESG); said ESG comprising (a) a structural member (ESG-SM) adjustable between a radially-expanded state and a radially-compressed state; and (b) a fluid flow guide (FFG) formed of textile strands, substantially impervious to fluids that is disposed adjacent to said ESG-SM and being securably attached thereto.

- b. providing a fastenable 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, comprising a generally cylindrical inner surface, an outer surface, a structural member and a plurality of fastening means; said inner surface and said outer surface are attached therebetween; said fastening means adapted to secure said EVR over said aneurysmatic aorta; EVR is capable of having an expanded state and a deformed state; said EVR in its said expanded state is adapted for extra-vascular positioning around said aorta and said EVR in its deformed state is adapted for laparoscopic delivery from a location outside said subject's body to a location around said aorta; said inner surface defining a lumen that is characterized by a proximal circumference, a distal circumference and a length in the proximal to distal direction; said outer surface is characterized by a proximal circumference, a distal circumference and a length in the proximal to distal direction; said inner surface comprising a macroporous medical textile member, comprising voids dimensioned to allow free tissue ingrowth therethrough, and said outer surface comprising 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; said structural member connected either to said inner surface or to said outer surface.
 - c. introducing said EVR in its said deformed state through a laparoscopic working channel to an abdominal location adjacent to renal arteries of said abdominal aorta; and
 - d. laparoscopically positioning said EVR around said aorta, in vicinity to renal arteries; and
 - e. connecting said corresponding fastening means therebetween;
45. The method according to claim 37, wherein step (e) precedes steps (c) and (d)
46. The method according to claim 42, wherein step (f) precedes steps (c), (d) and (e)

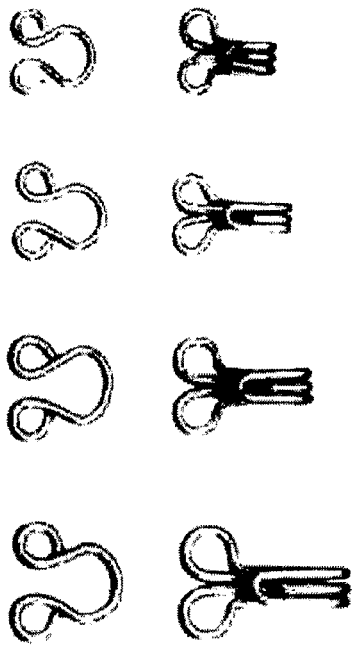


FIG. 1A
Dress hooks & eyes

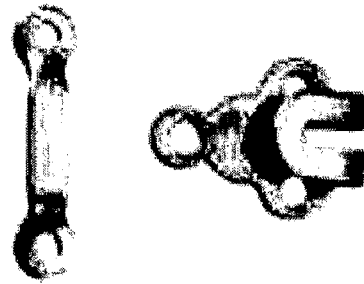


FIG. 1B
Skirt hooks & eyes

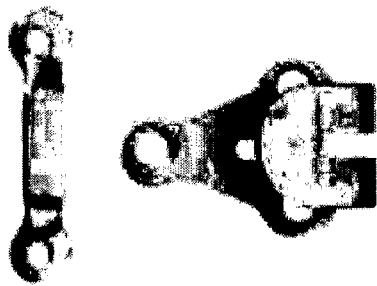


FIG. 1C
Heavy duty hooks & eyes



FIG. 1D
Coat hooks & eyes

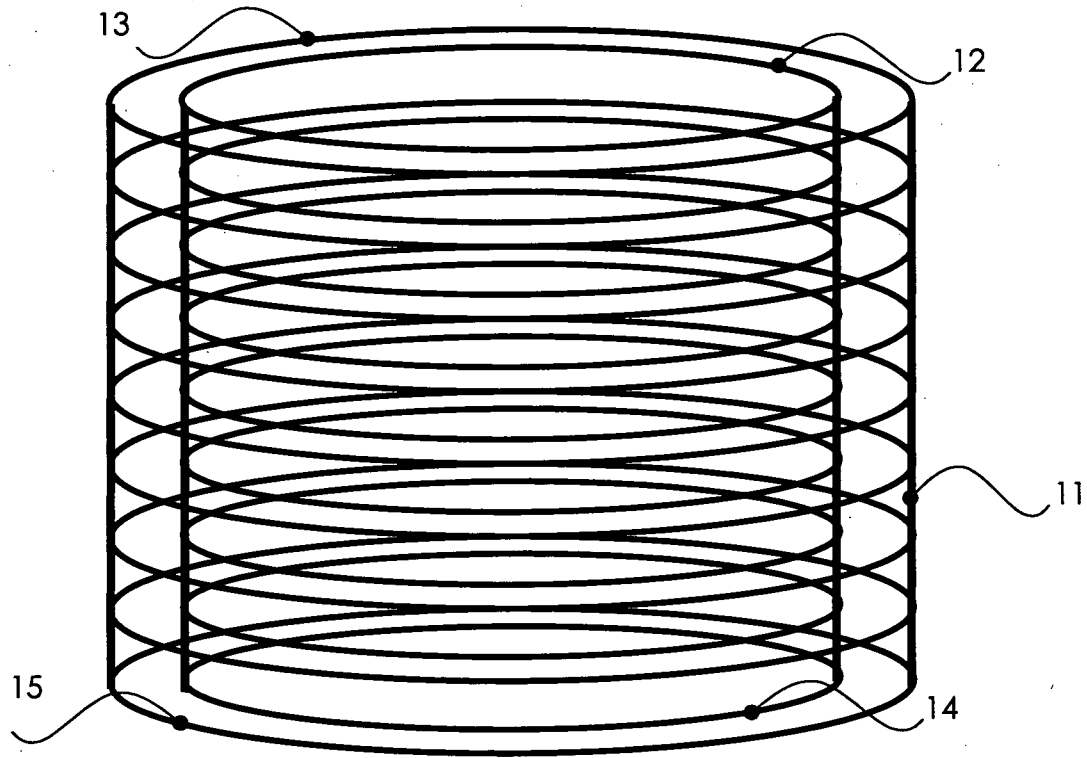


FIG. 2

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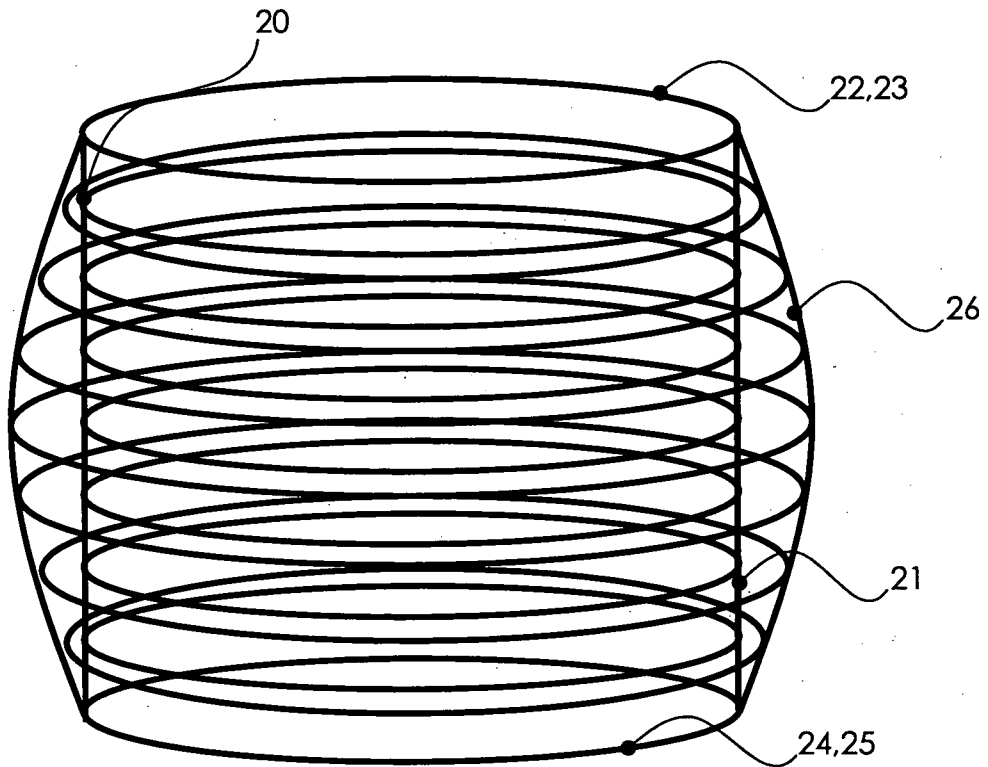


FIG. 3

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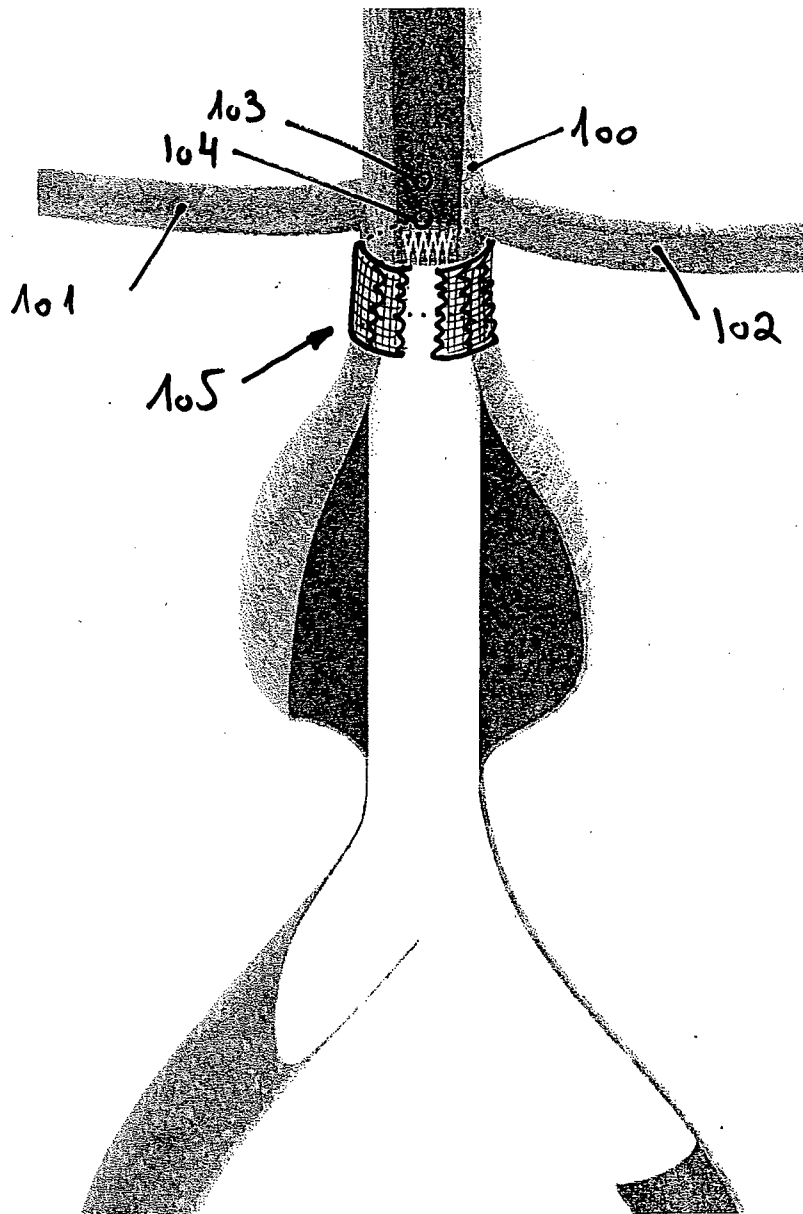


FIG. 4

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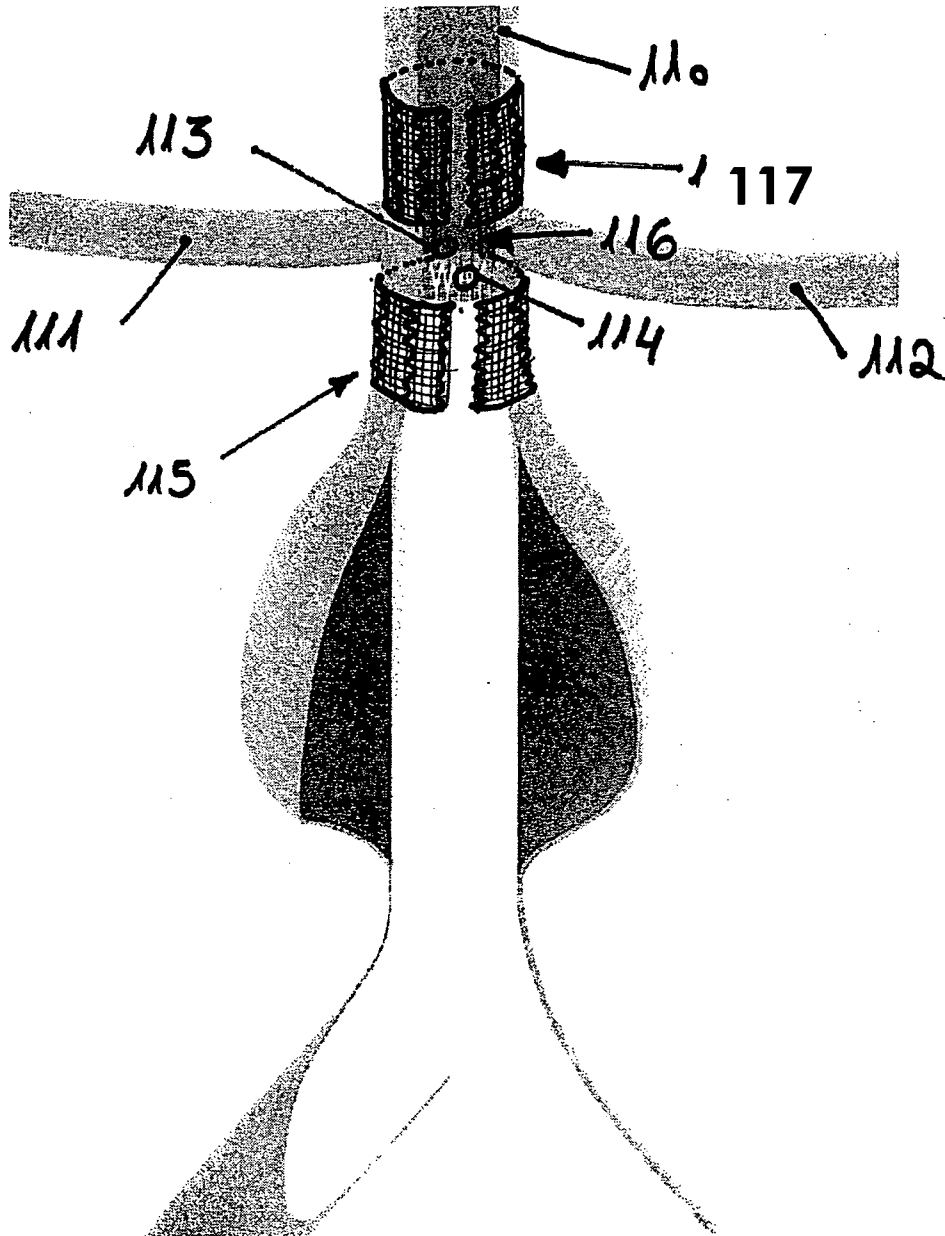


FIG. 5

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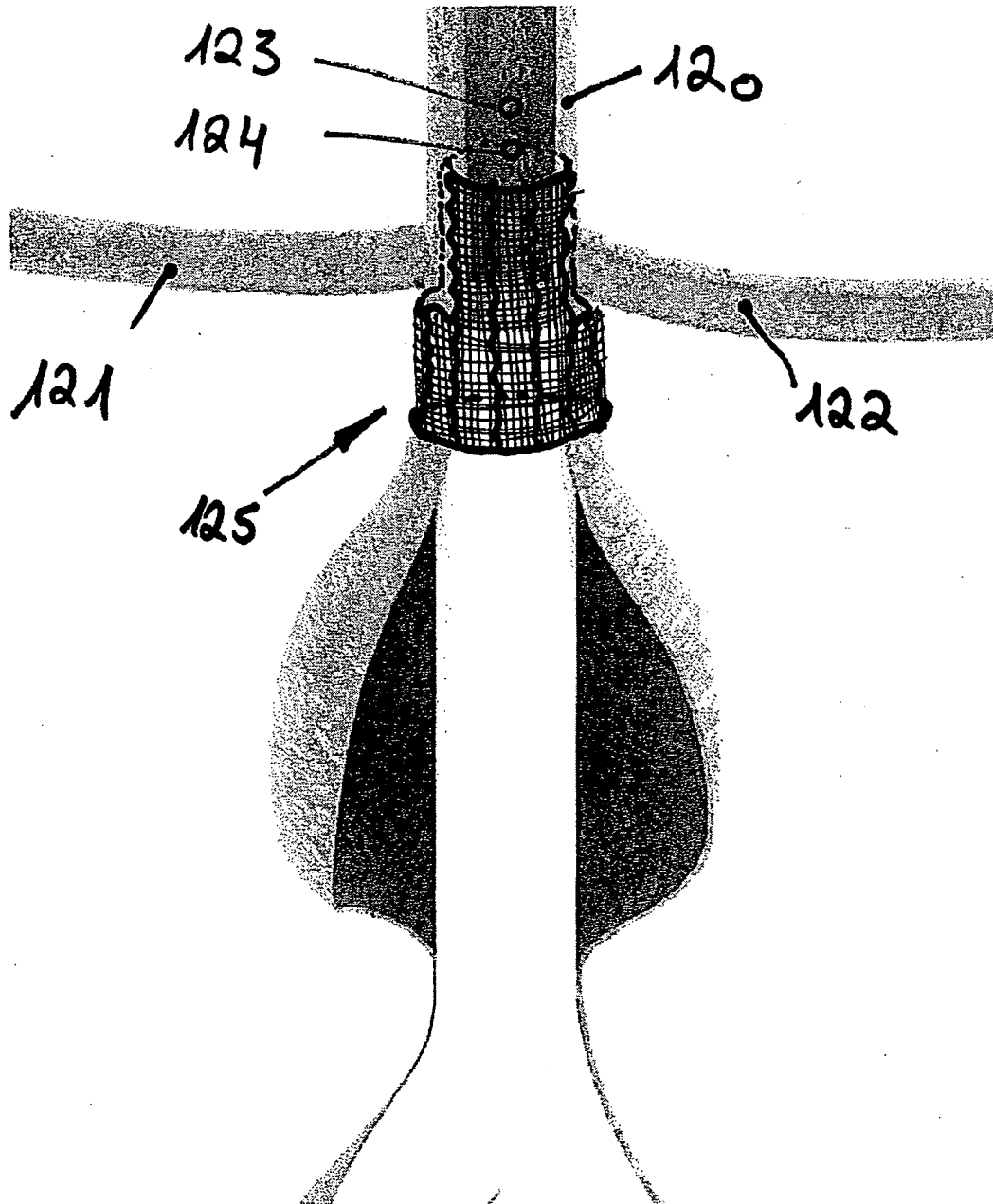


FIG. 6

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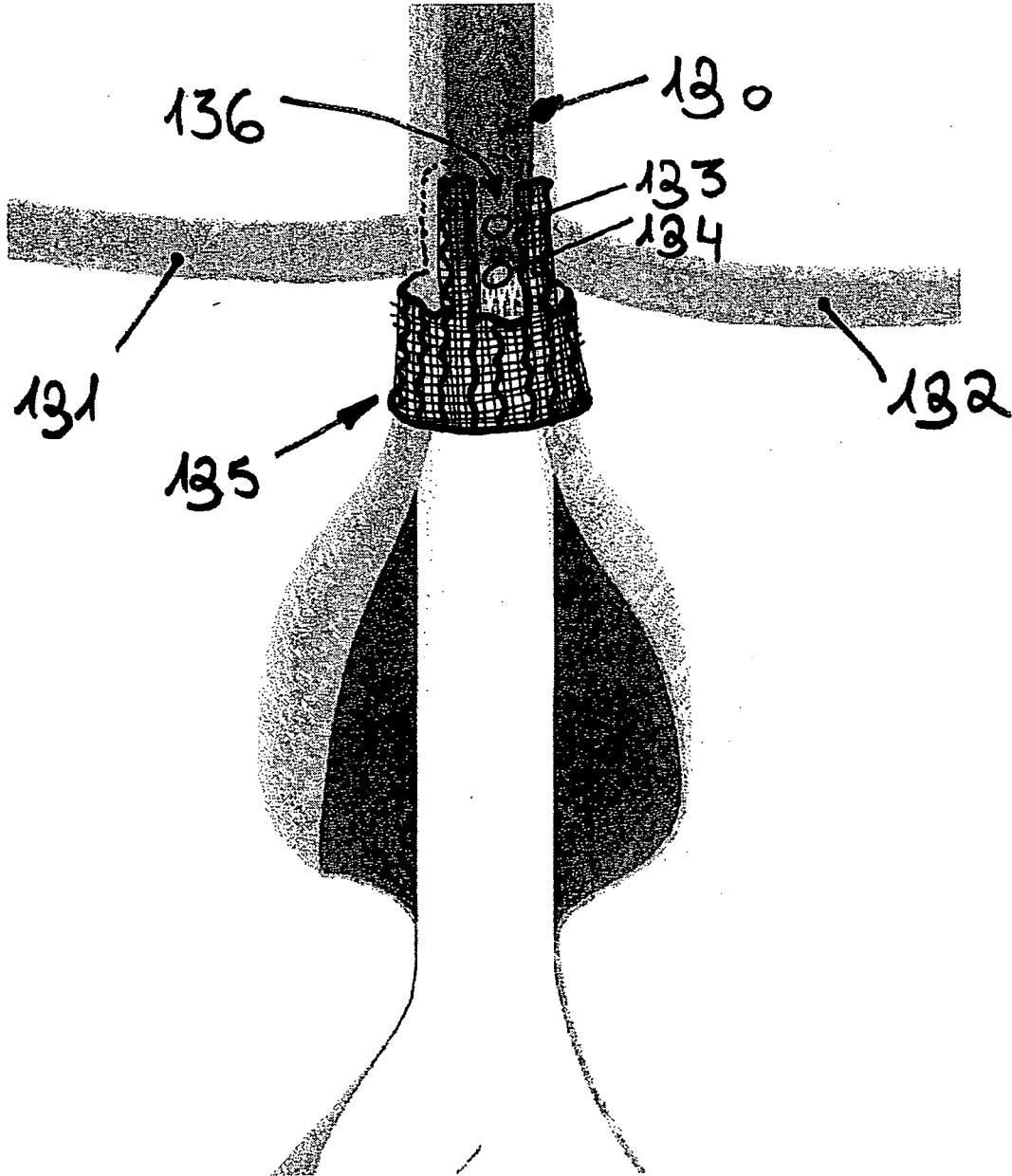


FIG. 7

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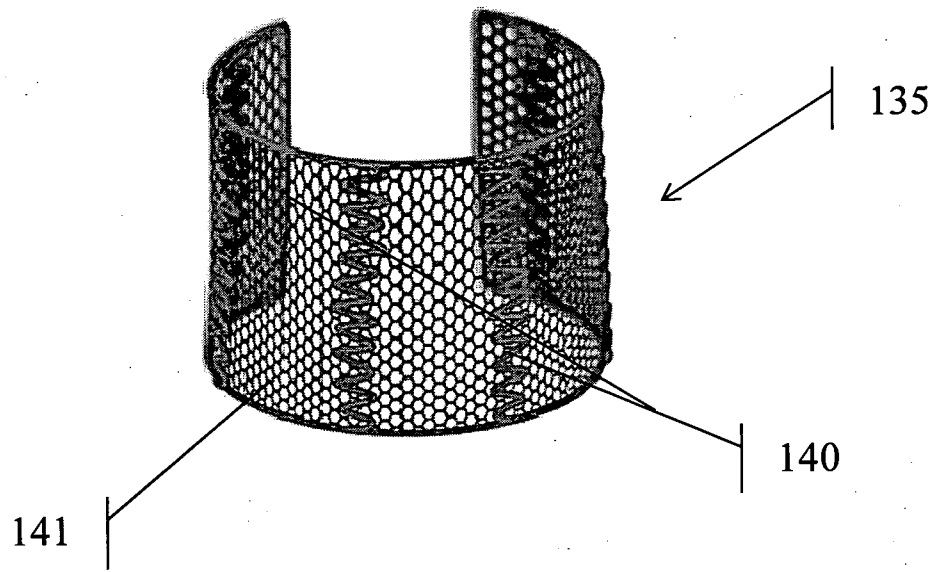


FIG. 8A

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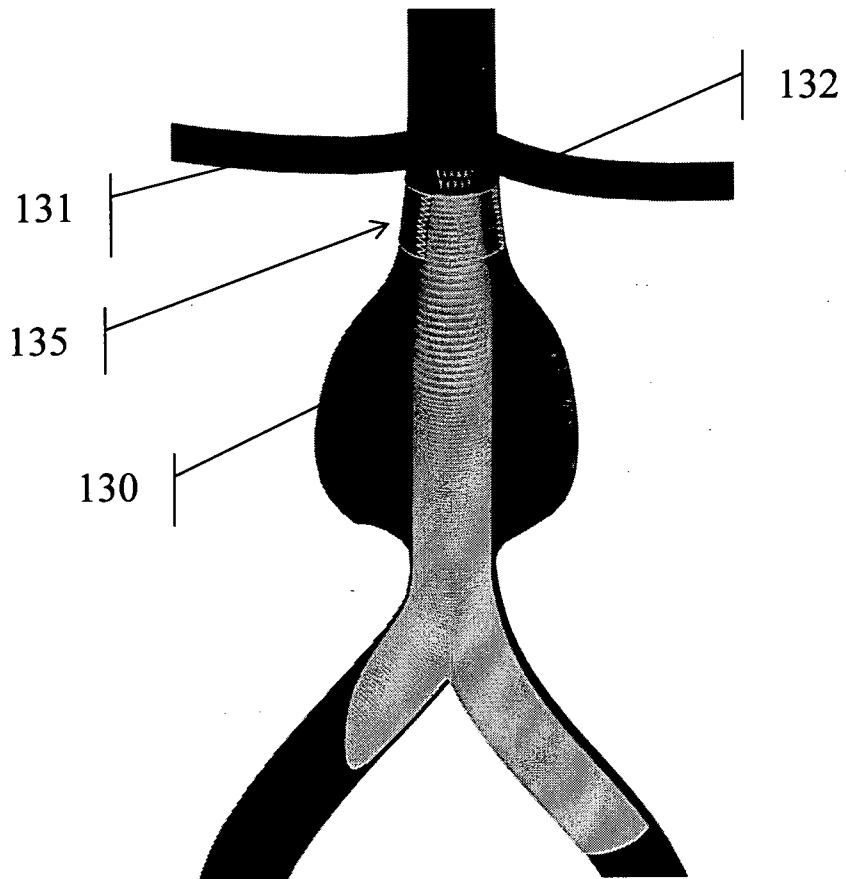


FIG. 8B

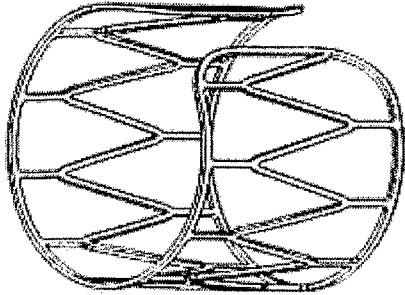


FIG. 9A

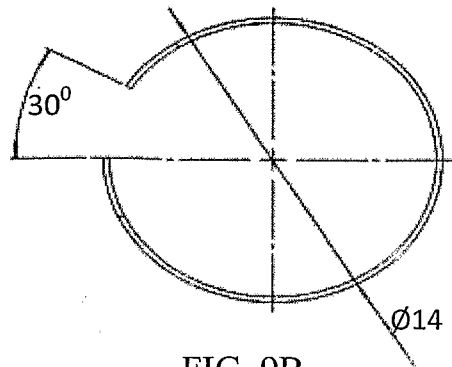


FIG. 9B

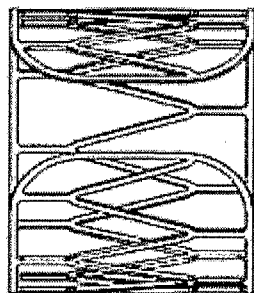


FIG. 9C

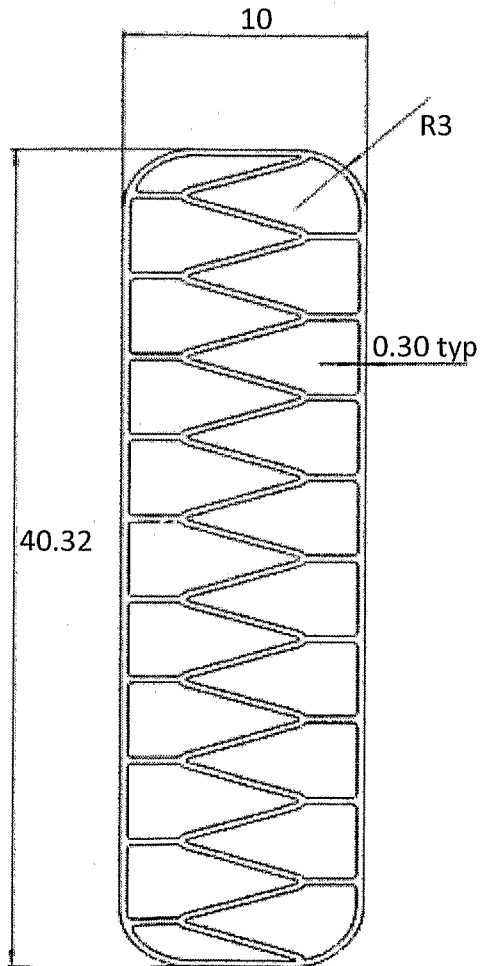


FIG. 9D

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FIG. 9E

| | | | |
|----------------|---|---------|------------|
| 专利名称(译) | 用于治疗动脉瘤性主动脉的血管外包裹物与血管内支架移植物及其方法相结合 | | |
| 公开(公告)号 | EP2231066A2 | 公开(公告)日 | 2010-09-29 |
| 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 | A61F2/06 A61F2/07 A61B17/12 A61B17/132 | | |
| CPC分类号 | A61B17/12 A61B17/12113 A61B17/12168 A61F2/07 A61F2220/0008 A61F2/06 | | |
| 代理机构(译) | LECOMTE , DIDIER | | |
| 优先权 | 61/014031 2007-12-15 US | | |
| 其他公开文献 | EP2231066A4 EP2231066B1 | | |
| 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) 血管外包裹 (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裹 (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。