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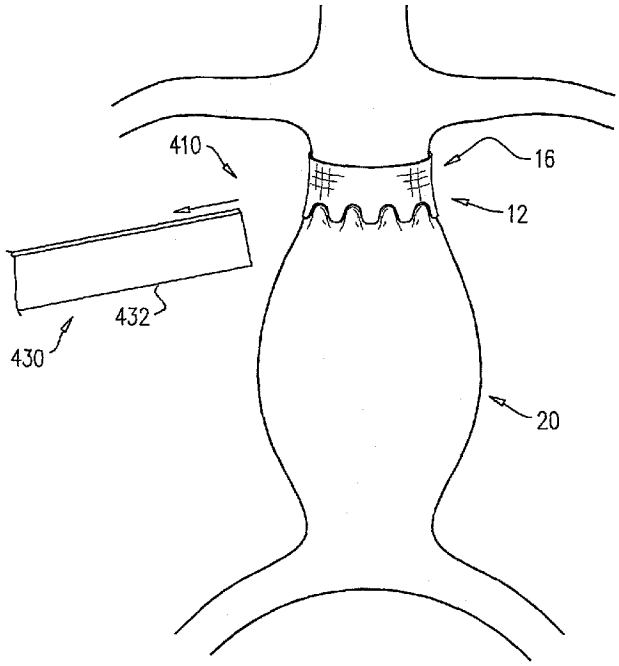
(54) Title: REDUCED-STRAIN EXTRA- VASCULAR RING FOR TREATING AORTIC ANEURYSM

FIG. 9C



(57) Abstract: Apparatus (10) is provided that includes an extra-vascular ring (12) and an endo vascular stent-graft (14). The ring (12) comprises a structural member (30), which is configured to assume an elongate hollow shape (32), which has first and second longitudinal ends (40, 42), and is suitable for placement at least partially around an aorta (20) so as to provide a generally cylindrical landing zone. The endovascular stent-graft (14) is suitable for endovascular placement inside the aorta (20) such that a portion of the stent-graft (14) is positioned against an internal wall of the aorta (20) at the landing zone provided by the structural member (30). If the structural member (30) is unrolled to a planar shape (82), one side (90) of the planar shape (82) is defined by the first longitudinal end (40), and at least the first longitudinal end (40) has a profile that defines a series of curved portions and has no singularities or discontinuities, which profile extends along at least 50% of the first longitudinal end (40).

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REDUCED-STRAIN EXTRA-VASCULAR RING FOR TREATING AORTIC ANEURYSM

CROSS-REFERENCE TO RELATED APPLICATIONS

The present patent application claims priority from US Provisional Application 61/448,199, filed March 2, 2011, which is assigned to the assignee of the present application and is incorporated herein by reference.

FIELD OF THE APPLICATION

The present invention relates generally to implantable medical devices, and specifically implantable vascular bands.

BACKGROUND OF THE APPLICATION

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 are commonly classified by shape, structure and location. Aortic aneurysms are the most common form of arterial aneurysm and are life-threatening. It is common for an aortic aneurysm to occur in the portion of the abdominal aorta between the renal arteries and the iliac arteries. Aneurysms in the abdominal aorta are associated with particularly high mortality; 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.

Therefore, less invasive techniques have been developed to treat an aortic aneurysm without the attendant risks of intra-abdominal surgery. These techniques include transvascularly introducing an endovascular stent-graft into the aorta. The neck of the aorta at the cephalad end (i.e., above the aneurysm) is usually sufficient to maintain attachment of a stent-graft to the wall of the aorta. 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 may provide insufficient healthy aortic tissue to which to successfully mount a stent-graft. Furthermore, much of the abdominal aorta wall

may be calcified which may make it difficult to attach the stent-graft to the aortic wall. Unfavorable anatomy relating to the neck of the aneurysm is the most common reason for patients being rejected for Endovascular Repair of Abdominal Aortic Aneurysm (EVAR). A 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 the seal at the neck and is the principal indication for secondary intervention for this condition.

PCT Publication WO 2009/078010 to Shalev, and US Patent Application Publication 2010/0292774 in the national stage thereof, which are assigned to the assignee of the present application and is incorporated herein by reference, describe 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 the 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. US Provisional Application 61/014,031, filed December 15, 2007, from which the above-referenced applications claim priority, is also incorporated herein by reference.

SUMMARY OF THE APPLICATION

In some applications of the present invention, an extra-vascular ring is provided for deployment around a neck of an aneurysmal aorta, in order to create a generally cylindrical landing zone for an endovascular stent-graft. The endovascular stent-graft is endovascularly deployed in the aorta, spanning an aneurysm thereof, such that a portion of the endovascular stent-graft is positioned against an internal wall of aorta at the landing zone provided by the extra-vascular ring. The landing zone helps create a non-leaking seal between the stent-graft and the wall of the aorta. The extra-vascular ring thus helps secure the aneurismal neck from widening and/or leaking.

The extra-vascular ring is configured to evenly distribute the pressures and

stresses on the partially-dilated tissue of the aortic aneurysm neck. To this end, a structural member of the ring is configured to assume an elongate hollow shape that has first and second longitudinal ends. At least the first longitudinal end has a profile that defines a series of curved portions and has no singularities or discontinuities, which profile extends around at least 50% of the first longitudinal end. The profile serves to homogeneously distribute the strain on the aortic tissue at the first longitudinal end of the ring. The profile provides spaces into which the excess circumference of the aorta can expand, rather than folding inwardly.

For some applications, the profile is a corrugated profile that defines a series of smooth undulations. For these applications, the smooth undulations are shaped so as to define alternating curved peaks and curved valleys. For some applications, the curved peaks are not sharp or traumatic; for example, they may have a radius of curvature equal to at least 3% of the length of the first longitudinal end, when the structural member is in a relaxed state. For some applications, the structural member comprises a plurality of stent struts.

Typically, the structural member is configured to generally not be longitudinally expansible if unrolled to a planar shape, one side of which is defined by the first longitudinal end of the structural member, and accordingly not to be radially expansible when the structural member has the elongate hollow shape. The alternating curved peaks and curved valleys of the corrugated profile of the longitudinal end are not configured to compress or stretch in a direction parallel to the longitudinal end. In other words, the curved peaks are not configured to bend or flex when the structural member is longitudinal stretched.

For some applications, such as in order to provide the longitudinal stability described in the previous paragraph, when the structural member has the planar shape, at least one of the stent struts extends completely alongside at least two of the undulations (i.e., two of the curved peaks and two of the curved valleys), such that the strut substantially prevents longitudinal stretching of the at least two of the undulations. For some applications, when the structural member has the planar shape, the strut has a length equal to at least 90% of the length of the first longitudinal end.

There is therefore provided, in accordance with an application of the present invention, apparatus for attachment to an aorta of a patient, the apparatus including:

an extra-vascular ring, which includes a structural member, which is configured to assume an elongate hollow shape, which has first and second longitudinal ends, and is suitable for placement at least partially around the aorta so as to provide a generally cylindrical landing zone; and

an endovascular stent-graft, which is suitable for endovascular placement inside the aorta such that a portion of the endovascular stent-graft is positioned against an internal wall of the aorta at the landing zone provided by the structural member,

wherein, if the structural member is unrolled to a planar shape, one side of the planar shape is defined by the first longitudinal end of the structural member, and at least the first longitudinal end has a profile that defines a series of curved portions and has no singularities or discontinuities, which profile extends along at least 50% of the first longitudinal end.

For some applications, the profile is a corrugated profile that defines a series of smooth undulations. For some applications, the corrugated profile has a substantially sinusoidal form.

For some applications, the first and second longitudinal ends are curved at least partially around a longitudinal axis defined by the elongate hollow shape, and the smooth undulations are shaped so as to define alternating curved peaks and curved valleys, which curved peaks extend in a direction away from the second longitudinal end and have a radius of curvature equal to at least 3% of a length of the first longitudinal end measured around the longitudinal axis, when the structural member is in a relaxed state.

For some applications, the smooth undulations are shaped so as to define alternating curved peaks and curved valleys, which curved peaks extend in a direction away from the second longitudinal end, and, if the structural member is unrolled to the planar shape, a radius of curvature of the curved peaks changes by less than 10% if the structural member, while having the planar shape, is longitudinally stretched from a relaxed state by application of a greatest force that is insufficient to cause plastic deformation of the structural member.

For some applications, the structural member includes a plurality of stent struts, and, if the structural member is unrolled to a planar shape, at least one of the stent struts extends completely alongside at least two of the undulations, such that the strut substantially prevents longitudinal stretching of the at least two of the undulations. For

some applications, the at least one of the stent struts geometrically encompasses at least one straight line segment that is parallel to the one side and extends completely alongside the at least two of the undulations, when the structural member has the planar shape. For some applications, the at least one of the stent struts is straight when the structural has the planar shape. For some applications, the structural member has the planar shape, the at least one stent strut has a length, measured in a direction parallel to the one side, equal to at least 90% of a length of the one side.

For some applications, if the structural member is unrolled to the planar shape, the first longitudinal end of the structural member has a length that varies by less than 20% if the structural member, while having the planar shape, is longitudinally stretched from a relaxed state by application of a greatest force that is insufficient to cause plastic deformation of the structural member.

For some applications, the profile defines the series of curves interspersed with one or more straight portions.

For any of the applications described above, the structural member may be configured to assume the elongate hollow shape when in a relaxed state.

For any of the applications described above, the structural member may include a super-elastic material.

For any of the applications described above, the structural member may include a shape memory material.

For any of the applications described above, if the structural member is unrolled to the planar shape, the first longitudinal end may have a length that is equal to between 30 and 120 mm; and the elongate hollow shape may have a longitudinal length, measured parallel to a central longitudinal axis of the elongate hollow shape, that equals between 10 and 40 mm.

For any of the applications described above, the structural member, when having the elongate hollow shape, is shaped so as to define a gap that extends longitudinally along an entire longitudinal length of the elongate hollow shape from the first longitudinal end to the second longitudinal end, For some applications, the structural member is shaped so as to define (a) a first extension, which first extension defines at least one slot, and (b) a second extension, which is shaped so as to define a tab adapted to fit into the at

least one slot, such inserting the tab into the slot closes the gap. For some applications, the extra-vascular ring further includes one or more fastening elements for closing the gap.

For any of the applications described above, the apparatus may further include a hollow, generally tubular delivery shaft, in which the extra-vascular ring is removably disposed with the structural member in a deformed state. For some applications, the structural member is configured to automatically transition from the deformed state to a relaxed state as the structural member is deployed from the delivery shaft.

For any of the applications described above, the elongate hollow shape may be generally cylindrical.

There is further provided, in accordance with an application of the present invention, a method including:

providing an extra-vascular ring, which includes a structural member, which is configured to assume an elongate hollow shape, which has first and second longitudinal ends, wherein, if the structural member is unrolled to a planar shape, one side of the planar shape is defined by the first longitudinal end of the structural member, and at least the first longitudinal end has a profile that defines a series of curved portions and has no singularities or discontinuities, which profile extends along at least 50% of the first longitudinal end; and

placing the extra-vascular ring at least partially around a neck of an aneurysmal aorta of a patient so as to provide a generally cylindrical landing zone, such that the profile homogenously distributes strain on aortic tissue at the first longitudinal end of the structural member.

For some applications, the method further includes placing an endovascular stent-graft inside the aorta such that a portion of the endovascular stent-graft is positioned against an internal wall of the neck at the landing zone provided by the structural member.

For some applications, placing the extra-vascular ring includes advancing, to an external surface of the aorta, a hollow, generally tubular delivery shaft, in which the extra-vascular ring is removably disposed with the structural member in a deformed state. For some applications, advancing the delivery shaft includes advancing the delivery shaft through a laparoscopic working channel to an abdominal location adjacent to renal

arteries of the aorta, and laparoscopically placing the extra-vascular stent around the neck of the abdominal aorta in a vicinity of the renal arteries.

For some applications, placing the extra-vascular ring includes identifying the patient as suffering from an aneurysm of an abdominal aorta, and treating the aortic aneurysm by placing the extra-vascular ring at least partially around the neck of the abdominal aorta.

For some applications, providing the extra-vascular ring includes providing the extra-vascular ring in which the profile is a corrugated profile that defines a series of smooth undulations. For some applications, providing the extra-vascular ring includes providing the extra-vascular ring in which the corrugated profile has a substantially sinusoidal form.

For some applications, providing the extra-vascular ring includes providing the extra-vascular ring in which the first and second longitudinal ends are curved at least partially around a longitudinal axis defined by the elongate hollow shape, and the smooth undulations are shaped so as to define alternating curved peaks and curved valleys, which curved peaks extend in a direction away from the second longitudinal end and have a radius of curvature equal to at least 3% of a length of the first longitudinal end measured around the longitudinal axis, when the structural member is in a relaxed state.

For some applications, providing the extra-vascular ring includes providing the extra-vascular ring in which the smooth undulations are shaped so as to define alternating curved peaks and curved valleys, which curved peaks extend in a direction away from the second longitudinal end, and wherein, if the structural member is unrolled to the planar shape, a radius of curvature of the curved peaks changes by less than 10% if the structural member, while having the planar shape, is longitudinally stretched from a relaxed state by application of a greatest force that is insufficient to cause plastic deformation of the structural member.

For some applications, providing the extra-vascular ring includes providing the extra-vascular ring in which the structural member includes a plurality of stent struts, and, if the structural member is unrolled to the planar shape, at least one of the stent struts extends completely alongside at least two of the undulations, such that the strut substantially prevents longitudinal stretching of the at least two of the undulations. For some applications, providing the extra-vascular ring includes providing the extra-vascular

ring in which the at least one of the stent struts geometrically encompasses at least one straight line segment that is parallel to the one side and extends completely alongside the at least two of the undulations, when the structural member has the planar shape. For some applications, providing the extra-vascular ring includes providing the extra-vascular ring in which the at least one of the stent struts is straight when the structural has the planar shape. For some applications, providing the extra-vascular ring includes providing the extra-vascular ring in which, when the structural member has the planar shape, the at least one stent strut has a length, measured in a direction parallel to the one side, equal to at least 90% of a length of the one side.

For some applications, providing the extra-vascular ring includes providing the extra-vascular ring characterized in that, if the structural member is unrolled to the planar shape, the first longitudinal end of the structural member has a length that varies by less than 20% if the structural member, while having the planar shape, is longitudinally stretched from a relaxed state by application of a greatest force that is insufficient to cause plastic deformation of the structural member.

For some applications, providing the extra-vascular ring includes providing the extra-vascular ring in which the profile defines the series of curved portions interspersed with one or more straight portions.

For some applications, providing the extra-vascular ring includes providing the extra-vascular ring in which the structural member is configured to assume the elongate hollow shape when in a relaxed state.

For some applications, providing the extra-vascular ring includes providing the extra-vascular ring in which the elongate hollow shape is generally cylindrical.

The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of an endovascular stent-graft system, in accordance with an application of the present invention;

Fig. 2 is a schematic illustration of a structural member of an extra-vascular ring of the endovascular stent-graft system of Fig. 1, in accordance with an application of the

present invention;

Figs. 3A-B are schematic illustrations of the extra-vascular ring of Fig. 2 deployed around a neck of an aneurysmal aorta, in accordance with an application of the present invention;

Figs. 3C-D are schematic illustrations of another extra-vascular ring deployed around a neck of an aneurysmal aorta, in accordance with an application of the present invention;

Figs. 4A-B are schematic illustrations of an extra-vascular ring deployed around a neck of an aneurysmal aorta, as known in the prior art;

Fig. 5 is a schematic illustration of a structural member of the extra-vascular ring of Fig. 2 in a planar unrolled state, in accordance with an application of the present invention;

Fig. 6 is a schematic illustration of another configuration of the structural member of the extra-vascular ring of Fig. 2 in the planar unrolled state, in accordance with an application of the present invention;

Fig. 7 is a schematic illustration of yet another configuration of the structural member of the extra-vascular ring of Fig. 2 in the planar unrolled state, in accordance with an application of the present invention;

Figs. 8A-B are schematic illustrations of two additional configurations of the extra-vascular ring of Fig. 2, in accordance with respective applications of the present invention; and

Figs. 9A-D are schematic illustrations of a delivery system and method for delivering the extra-vascular ring of Fig. 2 around an aorta, in accordance with an application of the present invention.

DETAILED DESCRIPTION OF APPLICATIONS

Fig. 1 is a schematic illustration of an endovascular stent-graft system 10, in accordance with an application of the present invention. System 10 comprises an extra-vascular ring 12 and, for some applications, an endovascular stent-graft 14. When deployed around a neck 16 of an aneurysmal aorta 20, extra-vascular ring 12 creates a generally cylindrical landing zone for endovascular stent-graft 14 (which optionally is

bifurcated, as shown). As shown in Fig. 1, endovascular stent-graft 14 is endovascularly deployed in aorta 20, spanning an aneurysm 22 thereof, such that a portion (e.g., a superior distal portion) of endovascular stent-graft 14 is positioned against an internal wall of aorta 20 at the landing zone provided by the extra-vascular ring. The landing zone helps create a non-leaking seal between the stent-graft and the wall of the aorta. Extra-vascular ring 12 thus helps secure the aneurismal neck from widening and/or leaking. Typically, the landing zone is generally resistant to dilation. Extra-vascular ring 12 comprises a structural member 30 and, optionally, a textile member 402, such as described hereinbelow with reference to Figs. 8A-B.

Fig. 2 is a schematic illustration of structural member 30 of extra-vascular ring 12, in accordance with an application of the present invention. Structural member 30 is configured to assume an elongate hollow shape 32, as shown in Fig. 2, which, for example, may be generally cylindrical. Elongate hollow shape 32 is suitable for placement at least partially around aorta 20 so as to provide the landing zone. Elongate hollow shape 32 has first and second longitudinal ends 40 and 42. Extra-vascular ring 12 is configured to be placed around aorta 20 oriented with first longitudinal end 40 inferior to second longitudinal end 42, typically with first longitudinal end 40 positioned at an inferior end of neck 16 and second longitudinal end 42 positioned at a superior end of neck 16.

At least first longitudinal end 40 of structural member 30 has a profile that defines a series of curved portions and has no singularities or discontinuities, which profile extends around at least 50% of first longitudinal end 40 (i.e., along at least 50% of a length L1 of first longitudinal end 40 measured around elongate hollow shape 32), such as at least 75%, or 100%. The curved portions rise and fall with respect to a direction that is parallel to a longitudinal axis 48 defined by the elongate hollow shape 32. Equivalently, if structural member 30 is unrolled to a planar shape 82, such as described hereinbelow with reference to Figs. 5-7, one side of planar shape 82 is defined by first longitudinal end 40, and at least first longitudinal end 40 has the profile that defines the series of curved portions and has no singularities or discontinuities, and the profile extends along at least 50% of first longitudinal end 40, such as at least 75%, or 100%.

For some applications in which the profile extends around or along (depending on whether the structural member is rolled or unrolled) less than 100% of first longitudinal

end 40, the profile is provided along two or more portions that are non-contiguous around or along the first longitudinal end. For example, the profile may be provided along two portions that are non-contiguous with each other, each of which extends around or along between 20% and 40% of first longitudinal end 40. For other applications in which the profile extends around or along less than 100% of first longitudinal end 40, the corrugate profile is provided on a single contiguous portion around or along a portion of the first longitudinal end. Typically, any portions of first longitudinal end 40 along which the profile is not provided are not shaped to have any singularities, discontinuities, or sharp changes in direction, e.g., are straight if structural member 30 is unrolled to planar shape 82, such as described hereinbelow with reference to Figs. 5-7.

For some applications, the profile is a corrugated profile that defines a series of smooth undulations 46. As used herein, including in the claims, the term "corrugated" means having any shape comprising a series of smooth undulations that have no singularities, discontinuities, or sharp changes in direction. Therefore, the corrugated profile does not include any sharp, and thus traumatic, features. For example, the term "corrugated" does not include within its scope sawtooth and square-wave forms. The corrugated profile is provided along first longitudinal end 40 as described in the previous paragraph. For some applications, the corrugated profile has a substantially sinusoidal form (which includes the series of curved portions). Alternatively or additionally, for some applications, at least first longitudinal end 40 of structural member 30 has a waved profile.

As can be seen in Fig. 2, first and second longitudinal ends 40 and 42 are curved at least partially around longitudinal axis 48. Smooth undulations 46 of first longitudinal end 40 are shaped so as to define alternating curved peaks 50 and curved valleys 52. Peaks 50 extend in a direction away from second longitudinal end 42. (Each of the smooth undulations is shaped so as to define exactly one of curved peaks 50 adjacent to exactly one of curved valleys 52.) For some applications, the corrugated profile is shaped so as to define at least 3, no more than 10, and/or between 3 and 10 undulations 46, each of which undulations is shaped so as to define exactly one curved peak 50 and exactly one curved valley 52. For some applications, curved peaks 50 do not include any straight portions. Alternatively or additionally, for some applications, curved valleys 52 do not include any straight portions.

For some applications, curved peaks 50 are not sharp or traumatic; for example, they may have a radius of curvature R_C equal to at least 1.5% (e.g., at least 3%) of length L1 of first longitudinal end 40 measured around longitudinal axis 48, when structural member 30 is in a relaxed state (radius of curvature R_C is measured along the outer surface of the curved peak, as indicated in Fig. 2). (Length L1 is circumferential, i.e., curved, when structural member 30 has elongate hollow shape 32, as shown in Fig. 2. The length is also labeled in Fig. 5, in which the structural member is shown in a planar unrolled state.) For some applications, length L1 is at least 30 mm, no more than 120 mm, and/or between 30 and 120 mm, such as 85 mm. For example, length L1 may be 80 mm, in which case radius of curvature R_C may be at least 1.27 mm. For some applications, elongate hollow shape 32 has a longitudinal length (measured parallel to longitudinal axis 48) of at least 10 mm, no more than 40 mm, and/or between 10 and 40 mm, such as 15 mm.

Elongate hollow shape 32 has an inner diameter D suitable for surrounding a vessel, such as an aorta, e.g., a descending aorta, such as for treating an aortic aneurysm, i.e., large enough to surround the aorta at the point of attachment of extra-vascular ring 12 and small enough such that upon closure, the inner surface of the elongate hollow shape 32 (which may be cylindrical, as mentioned above) makes direct or indirect contact at least partially with the outer surface of the aorta being treated. For applications in which extra-vascular ring 12 further comprises a textile member 402, such as described hereinbelow with reference to Figs. 8A-B, elongate hollow shape 32 makes indirect contact at least partially with the outer surface of the aorta being treated, via the textile member. For example, inner diameter D may be at least 2 cm, no more than 4 cm, and/or between 2 and 4 cm. For some applications, radius of curvature R_C of curved peaks 50 is equal to at least 5% (e.g., at least 10%) of inner diameter D when ring 12 is placed around neck 16.

Reference is now made to Figs. 3A-B, which are schematic illustrations of extra-vascular ring 12 deployed around neck 16 of aneurysmal aorta 20, in accordance with an application of the present invention. Fig. 3B is a cross-sectional view of ring 12 and aorta 20 along line IIIB—IIIB of Fig. 3A. The corrugated profile of longitudinal end 40 serves to evenly distribute the pressures and stresses on the partially-dilated tissue of neck 16, in particular on the section of the aorta in the vicinity of longitudinal end 40 of ring 12. The corrugated profile serves to homogeneously distribute the strain on the aortic tissue at the

first longitudinal end of the ring. As can be seen in Figs. 3A-B, the corrugated profile effectively diffuses the strain on the aortic wall. The corrugated profile provides spaces into which the excess circumference of the aorta can expand, rather than folding inwardly as described hereinbelow with reference to Figs. 4A-B.

Reference is made to Figs. 3C-D, which are schematic illustrations of an extra-vascular ring 112 deployed around neck 16 of aneurysmal aorta 20, in accordance with an application of the present invention. Fig. 3D is a cross-sectional view of ring 112 and aorta 20 along line IIID—IIID of Fig. 3C. Other than as described below, extra-vascular ring 112 is generally similar to extra-vascular ring 12 described hereinabove and hereinbelow, and may include any of the features of extra-vascular ring 12 described hereinabove and/or hereinbelow. The profile of first longitudinal end 40 of extra-vascular ring 112 includes the series of curved portions interspersed with one or more straight portions 114. The profile does not have any sharp changes in direction. For example, one or more peaks of the undulations may be shaped so as to define a straight portion 114A, and/or one or more valleys of the undulations may be shaped so as to define a straight portion 114B. It is noted that the profile of first longitudinal end 40 of extra-vascular ring 112 is not a square-wave form, because there are no sharp changes in direction, such as right angles, in the profile. The profile of longitudinal end 40 serves to minimize the pressures and stresses on the tissue of the aorta, in particular on the section of the aorta in the vicinity of longitudinal end 40 of ring 112. The profile serves to homogeneously diffuse the strain on the aortic tissue at the longitudinal ends of the ring. As can be seen in Figs. 3C-D, the profile effectively diffuses the strain on the aortic wall. The profile provides spaces into which the excess circumference of the aorta can expand, rather than folding inwardly as described hereinbelow with reference to Figs. 4A-B.

Reference is made to Figs. 4A-B, which are schematic illustrations of an extra-vascular ring 70 deployed around neck 16 of aneurysmal aorta 20, as known in the prior art. Fig. 4B is a cross-sectional view of ring 70 and aorta 20 along line IVB—IVB of Fig. 4A. Both longitudinal ends 72 and 74 of ring 70 have a straight profile, as known in the prior art. As can be seen, in order to close ring 70, it is necessary to place a substantial amount of strain on aorta 20. As shown in Fig. 4B, this strain can lead to collapse or deformation of part of the aortic wall, which may result, for example, in one or more portions 80 of the wall folding inwardly.

Reference is again made to Figs. 1, 2, and 3A-B, and additionally to Fig. 5, which is a schematic illustration of structural member 30 of extra-vascular ring 12 in a planar unrolled state, in accordance with an application of the present invention. Extra-vascular ring 12 is shown in a relaxed state in Fig. 5. Typically, extra-vascular ring 12 is configured to transition between the open planar unrolled state shown in Fig. 5 (or the other configurations described hereinbelow with reference to Figs. 6 or 7), and the rolled state shown in Figs. 1, 2, and 3A-B. For some applications, extra-vascular ring 12 is placed in the planar unrolled state for delivery in a catheter to the extra-aortic site, such as described hereinbelow with reference to Fig. 9A, and transitions (typically, automatically) to the rolled state around the aorta upon being deployed from the catheter, such as described hereinbelow with reference to Figs. 9B-C.

Structural member 30 of ring 12 comprises a material suitable for use in treatment of aortic aneurysms and that is capable of being transitioned between an open planar state and a rolled state. For some applications, structural member 30 comprises a shape-memory material or a superelastic material. For example, the shape-memory material may comprise a nickel-titanium alloy such as Nitinol, (which is also super-elastic over a defined temperature range). For some applications, structural member 30 is configured to assume the rolled, elongate hollow shape when in a relaxed state. For some applications, structural member 30, while in its open planar state is rolled into a ring (such as shown in Fig. 2) of a desired diameter and then heated to fix its dimensions (optionally, the structural member is quickly quenched, e.g., in water, to prevent aging effects).

Alternatively, structural member 30 comprises another material with properties that make it suitable for treatment of aortic aneurysm. Non-limiting examples of such properties include biocompatibility, tensile strength, flexibility, and workability. For some applications, the structural member comprises one or more of these materials (e.g., a biocompatible polymer), and is introduced into the patient by rolling the structural member into a cylinder of small enough diameter to enable introduction by laparoscopic methods, unrolling it *in situ*, wrapping it around the aorta, and securing it, such as using any of the methods described hereinbelow.

For some applications, structural member 30 comprises a plurality of stent struts 80. For some applications, the stent struts have a thickness of between 0.1 and 1 mm, such as 0.30 mm.

If structural member 30 is unrolled to planar shape 82, such as shown in Fig. 5, one side 90 of the planar shape is defined by first longitudinal end 40 of structural member 30, and another side 92 of the planar shape is defined by second longitudinal end 42 of structural member 30.

For some applications, length L1 of side 90 (corresponding to first longitudinal end 40) varies by less than 20% (e.g., less than 10%) if the structural member, while having planar shape 82, is longitudinally stretched from a relaxed state by application of a greatest force that is insufficient to cause plastic deformation of the structural member. (Application of a force greater than this greatest force will result in plastic deformation of the structural member, in which case the length might increase substantially before breaking.) In other words, structural member 30 is configured to generally not be longitudinally expansible when it has planar shape 82, and accordingly not to be radially expansible when it has elongate hollow shape 32. Alternating curved peaks 50 and curved valleys 52 of the corrugated profile of longitudinal end 40 are not configured to compress or stretch in a direction parallel to longitudinal end 40. (In order to clarify the term "parallel" in this context, it is noted that undulations 46 of the corrugated profile are disposed about a straight line when the structural member has planar shape 82; the direction is parallel to this line; the term "parallel" should also be understood in this way hereinbelow and in the claims.) For some applications, radius of curvature R_C of curved peaks 50 changes by less than 10% (e.g., less than 5%) if the structural member, while having planar shape 82, is longitudinally stretched from a relaxed state by application of a greatest force that is insufficient to cause plastic deformation of the structural member. In other words, curved peaks 50 are not configured to bend or flex when the structural member is longitudinal stretched.

For some applications, such as in order to provide the longitudinal stability described in the previous paragraph, when structural member 30 has planar shape 82, at least one 84 of stent struts 80 extends completely alongside at least two of undulations 46 (i.e., two of curved peaks 50 and two of curved valleys 52), such that strut 84 substantially prevents longitudinal stretching of the at least two of the undulations. For some applications, when structural member 30 has planar shape 82, strut 84 has a length L3, measured in a direction parallel to side 90, equal to at least 90% of length L1 of side 90, such as equal to length L1. For some applications, a plurality of stent struts 80 extend completely alongside at least two of undulations 46, such as two of stent struts 80, or three

of stent struts 80, as labeled struts 84, 86, and 88 in Fig. 5.

For some applications, stent strut 84 geometrically encompasses at least one straight line segment 94 that is parallel to side 90 and extends completely alongside the at least two of undulations 46, when structural member 30 has planar shape 82. In other words, strut 84 is shaped such that a straight line segment could be drawn on the strut completely alongside the at least two of undulations 46. It is to be understood that straight line segment 94 is an abstract geometric construct provided for purposes of describing the shape of strut 84, rather than a physical element of structural member 30, and thus is typically not actually drawn on the structural member. For some applications, stent strut 84 is straight when structural member 30 is unrolled to planar shape 82.

Reference is still made to Fig. 5. For some applications, planar shape 82 of extra-vascular ring 12 is generally rectangular, with two substantially parallel short sides 96 and 98 and two long sides 90 and 92, each of which is substantially perpendicular to the short sides. For some applications, side 92 (i.e., the side not shown as corrugated) is straight. In other embodiments, both long sides 90 and 92 have respective corrugated profiles along at least 50% of their respective lengths, such as along at least 75%, e.g., 100%, of their respective lengths (configuration not shown). For some applications, planar shape 82 has rounded corners, as shown in Fig. 5 (and Figs. 6 and 7).

For some applications, the edges of stent struts 80 are at least partially rounded smooth, such as by chemical erosion or electro-chemical erosion, as is known in the stent art. For clarity of illustration, this rounding is not shown in Fig. 5 (or Figs. 2, 6, 7, and 8A-B).

Reference is again made to Fig. 2. For some applications, longitudinal axis 48 is substantially parallel to short sides 96 and 98 of structural member 30, and long sides 90 and 92 form upper and lower faces of elongate hollow shape 32; for applications in which elongate hollow shape 32 is cylindrical, the long sides form the (open) circular upper and lower faces of the cylinder. As a result, the corrugated profile is transverse to longitudinal axis 48 when structural member 30 is in its rolled state. As described below, the ring is brought to its final diameter after its insertion into the patient's body.

Reference is again made to Fig. 5. For some applications, stent struts 80 are shaped so as to define a plurality of missing portions of structural member 30, i.e., openings through structural member 30. In the exemplary configuration shown in Fig. 5,

structural member 30 is shaped so as to define an outer substantially contiguous border 105, which may, for example have a width of about 1.50 ± 0.05 mm. In each of respective central portions 120 (typically the central 3 mm) of short sides 96 and 98, border 105 is recessed by two rounded portions 115, and may be narrower than the remainder of the border (e.g., 0.7 mm in width).

For some applications, a central portion of structural member is shaped so as to define a plurality of missing portions 130, two sides of which missing portions are substantially parallel to long side 92. A blow-up in Fig. 5 shows a detailed view of the edge of one of these missing portions 130, including a separating stent strut 135 between them (in the configuration shown, this separating stent strut is curved and has a typical width of about 0.7 mm).

For some applications, structural member 30 is shaped so as to define missing portions 140 along long side 90 (which has the profile), between undulations 46 and stent strut 84 (described above). For some applications, structural member 30 is shaped so as to define two missing portions 150 nearest short sides 96 and 98, each of which may have the shape of a rectangle truncated by a curve along the side nearest first missing portion 140. Detailed views of missing portions 140 and 150 are shown in respective blow-ups in Fig. 5, in accordance with respective applications of the present invention.

For some applications, structural member 30 is shaped so as to define a series of triangular missing portions 160 with one side parallel to long side 92 and having alternating orientations, between central missing portions 130 and the inside of border 105 (e..g, between struts 86 and 88, described hereinabove).

For some applications, structural member 30 is shaped so as to define a plurality of small (e.g., circular) missing portions 170, which may, for example have a typical diameter of 0.5 +/- 0.1 mm. For some applications, missing portions 170 are located on all areas of the structural member at which the material has a width sufficient to support these missing portions. Optionally, missing portions 170 are substantially centered with respect to the width of stent struts 80.

For some applications, the missing portions described above serve one or more of four purposes. First, the missing portions may reduce the weight of structural member 30. Second, the missing portions may reduce the amount of material needed to construct structural member 30. Third, the missing portions may allow free tissue ingrowth

therethrough. Fourth, the missing portions may be arranged to enhance flexibility of the structural member. It is to be understood that the particular arrangement of missing portions 130 and 170 are shown in the figures by way of example and not limitation, and that other arrangements that achieve the same or similar purposes will be apparent to those skilled in the art who have read the present application, and are within the scope of the present invention.

Reference is now made to Fig. 6, which is a schematic illustration of another configuration of structural member 30 of extra-vascular ring 12 in the planar unrolled state, in accordance with an application of the present invention. In this configuration, structural member 30 comprises, in addition to the elements described above with reference to Figs. 1, 2, 3A-B, and 5, a tab 200 at one of short sides 96 and 98, and an extension 210 at the other one of short sides 96 and 98. Extension 210 is shaped so as to define a plurality of slots 220. For some applications, an overall length L4 of structural member 30, including tab 200 and extension 210 is at least 30 mm, no more than 150 mm, and/or between 30 and 150 mm, such as about 108 mm; for example, the tab may add about 13 mm to the length of the structural member, and the extension may add about 10 to 20 mm. For some applications, a width W1 of the tab is about 8.75 mm, a width W2 of slots 220 is about 12 mm, and a height H of the slots is about 1.5 mm. (Length L1 of first longitudinal end 40 is to be understood herein, including in the claims, as excluding the length of tab 200 and the length of extension 210.)

Reference is now made to Fig. 7, which is a schematic illustration of yet another configuration of structural member 30 of extra-vascular ring 12 in the planar unrolled state, in accordance with an application of the present invention. As in the configuration described hereinabove with reference to Fig. 6, in this configuration structural member 30 comprises a tab-and-slot assembly, which includes a tab 300 and an extension 310. Extension 310 is shaped so as to define slots 320 that include respective flexible flaps 322 that aid in securing tab 300 when the ring is closed. Typically, the overall dimensions of the configuration of Fig. 7 are substantially the same as those of the configuration of Fig. 6. (Length L1 of first longitudinal end 40 is to be understood herein, including in the claims, as excluding the length of tab 300 and the length of extension 310.)

Reference is made to Figs. 2, 5, 6, and 7. For some applications, when extra-vascular ring 12 is brought from its planar, unrolled open state (such as shown in Figs. 5,

6, and 7) to its rolled state (such as shown in Fig. 2), a gap 400 remains between short sides 96 and 98. When structural member 30 has elongate hollow shape 32, gap 400 typically extends longitudinally along an entire longitudinal length of elongate hollow shape 32 from first longitudinal end 40 to second longitudinal end 42. Short sides 96 and 98 are not brought into contact with each other, and the ring is not otherwise closed, until the ring has been put in place around the patient's aorta. Instead the final closure of the ring (which closes gap 400) is effected after the ring has been put into place around the patient's aorta. In the case of the configuration described with reference to Fig. 6, the closure is effected by inserting tab 200 into slots 220, while in the case of the configuration described with reference to Fig. 7, the closure is effected by inserting tab 300 into slots 320.

Reference is now made to Figs. 1-3D and 5-7. Structural member 30 may be made by any method known in the art. By way of example and not limitation, the structural member may be fabricated from a rectangular blank by removing the missing portions by any standard means such as punching, stamping, milling, or laser cutting. The curved corners, if provided, and the profile of at least first longitudinal end 40 may produced by any standard means such as cutting or stamping. Alternatively, by way of example and not limitation, the structural member may be cast or molded on a form.

Reference is now made to Figs. 8A-B, which are schematic illustrations of two additional configurations of extra-vascular ring 12, in accordance with respective applications of the present invention. Extra-vascular ring 12 may implement either of these configurations in combination with any of the configurations described hereinabove, including with reference to Figs. 2, 5, 6, and 7. In these configurations, extra-vascular ring 12 further comprises a textile member 402, securely attached to and at least partially covering structural member 30 (typically an inner surface of the ring). Textile member 402 comprises an implantable-grade, biologically-compatible fabric, and may comprise, for example, a polyester, a polyethylene (e.g., a poly-ethylene-terephthalate), a polypropylene mesh, a polymeric film material (e.g., polytetrafluoroethylene), a polymeric textile material (e.g., woven polyethylene terephthalate (PET)), natural tissue graft (e.g., saphenous vein or collagen), or a combination thereof. For some applications, textile member 402 comprises a macroporous medical textile member mention, such as described in US Patent Application Publication 2010/0292774 to Shalev, which is assigned to the assignee of the present application and is incorporated herein by reference.

Alternatively or additionally, extra-vascular ring 12 comprises an external microporous layer, such as described in the '774 publication.

For some applications, as shown in Fig. 8A, textile member 402 is shaped so as to define portions 404 that extend between adjacent curved peaks 50. Portions 404 are configured to provide sufficient slack to allow the excess circumference to expand into the spaces provided by the corrugated profile, as described hereinabove with reference to Figs. 3A-B. For other applications, as shown in Fig. 8B, textile member 402 does not define portions 404, but rather is shaped so as to provide open areas between adjacent curved peaks 50. For example, the edge of the textile member may coincide with and have the same shape as the corrugated profile; in this configuration, a first longitudinal end of extra-vascular ring 12 coincides with first longitudinal end 40 of structural member 30, such that the first longitudinal end of extra-vascular ring 12 has the profile that defines the series of curved portions and has no singularities or discontinuities, e.g., the corrugated profile. Alternatively, the textile member may partially extend between adjacent curved peaks 50 (configuration not shown).

Reference is now made to Figs. 9A-D, which are schematic illustrations of a delivery system 410 and method for delivering extra-vascular ring 12 around aorta 20, in accordance with an application of the present invention. Delivery system 10 may be used for delivering extra-vascular ring 12 around aorta 20 (as shown) or other tissue, such as an organ, e.g., as a tubular organ, e.g., another blood vessel or a nerve. Delivery system 410 comprises a catheter 430, which comprises an outer pull-back shaft 432 having generally rectangular cross sections. The outer pull-back shaft serves as a delivery shaft. Extra-vascular ring 12 is initially removably disposed within outer pull-back shaft 432, with the extra-vascular ring in a deformed generally planar state, as shown in Figs. 5, 6, or 7. Alternatively, extra-vascular ring 12 is in a rolled state when initially disposed within the outer pull-back shaft (configuration not shown), in which case outer pull-back shaft 432 typically does not have generally rectangular cross sections.

During a first stage of an implantation procedure performed using delivery system 410, a surgeon creates a working channel, typically laparoscopically or hand-assisted laparoscopically, to an external surface of a portion of a target organ, such as aorta 20, e.g., neck 16 of an aneurysmal aorta, such as a sub-renal neck 16 immediately inferior (e.g., caudally adjacent) to the renal arteries, as shown in Figs. 9A-D, or a supra-renal

neck, an ascending aortic neck, or a neck adjacent the right subclavian artery (locations not shown). The surgeon advances a distal portion of delivery system 410 to the target organ, such as aorta 20, as shown in Fig. 9A. Typically, the surgeon advances a distal end 436 of outer pull-back shaft 432 slightly beyond the far side of the aorta, such that that outer pull-back shaft 432 is tangential to the aorta, as shown in Fig. 9A.

As shown in Fig. 9B, the surgeon subsequently proximally withdraws pull-back shaft 432, while simultaneously preventing proximal movement of extra-vascular ring 12 using a stopper shaft. The stopper shaft is not shown in Fig. 9B; the stopper shaft may be implemented using techniques described in PCT Application PCT/IL2012/000083, filed February 16, 2012, entitled, "Vascular bands and delivery systems therefor," which is assigned to the assignee of the present application and is incorporated herein by reference, with reference to Figs. 3A-14C thereof. Techniques described herein may also be implemented in combination with other techniques described in the '083 application, and/or with techniques described in US Patent Application Publication 2010/0292774, which is assigned to the assignee of the present application and is incorporated herein by reference.

Withdrawal of the pull-back shaft deploys extra-vascular ring 12 from distal end 436 of pull-back shaft 432. The extra-vascular ring is configured to assume a curved shape upon deployment, and thus wraps around the organ, e.g., the aorta, as the ring is deployed, as shown in Fig. 9B. For some applications, the ring is self-curling, and, to this end, typically comprises a shape memory material, such as a super-elastic metal, e.g., Nitinol, which is heat-set to assume the curled configuration, e.g., a circularly-, helically-, or spirally-bent configuration. For some applications, structural member 30 is configured to automatically transition from the deformed state to a relaxed state as the structural member is deployed from pull-back shaft 432.

Fig. 9C shows pull-back shaft 432 and extra-vascular ring 12 after the ring has been fully deployed from the shaft. As can be seen, the ring encircles at least a portion of the organ, e.g., the aorta, such as only a portion of or the entire organ. As can also be seen, the surgeon has oriented ring 12 such that first longitudinal end 40 is inferior to second longitudinal end 42, with first longitudinal end 40 positioned at an inferior end of neck 16 and second longitudinal end 42 positioned at a superior end of neck 16.

When deployed around neck 16 of an aneurysmal aorta, extra-vascular ring 12

creates a landing zone for endovascular stent-graft 14 (which optionally is bifurcated, as shown). As shown in Fig. 9D, endovascular stent-graft 40 is deployed in the aorta, spanning an aneurysm 22 thereof. A distal portion of the stent-graft is positioned against the internal wall of the aorta at the landing zone. The landing zone provided by extra-vascular ring 12 helps create a non-leaking seal between the stent-graft and the wall of the aorta. Extra-vascular ring 12 thus helps secure aneurismal neck 16 from widening and/or leaking. Optionally, intra-vascular ring 12 is secured or otherwise attached (optionally, reversibly) to intravascular stent-graft 14, in order to prevent dislocation of the ring and the intravascular stent-graft along the aorta.

Alternatively, for some applications, endovascular stent-graft 14 is implanted first, and subsequently extra-vascular ring 12 is placed around the aorta.

For some applications, after placement around the aorta, elongate hollow shape 32 of extra-vascular ring 12 subtends an arc of less than 360 degrees, i.e., does not fully surround the aorta. Alternatively, the elongate hollow shape is circumferentially complete upon placement around the aorta.

For some applications, a method for treating an aortic aneurysm comprises (a) identifying a subject having an aneurysm of the abdominal aorta; (b) providing extra-vascular ring 12 in any of the configurations described herein; and (c) positioning the ring around the aorta, inferior to the renal arteries, optionally laparoscopically. Typically, the ring is compressed to a deformed state during delivery and positioning. The method may further comprise providing intravascular stent-graft 14, and placing the intravascular stent-graft into the aneurysmatic aorta in the subject, optionally laparoscopically. For some applications, identifying the subject having the aneurysm of the abdominal aorta comprises identifying the subject having the aneurysm of the abdominal aorta that is likely to rupture. For some applications, identifying the subject having the aneurysm of the abdominal aorta that is likely to rupture defining an aneurysm of the abdominal aorta that is likely to rupture as an aneurysm that is located within about 2 cm of a renal artery, and determining that the abdominal aneurysm is within about 2 cm of a renal artery of the subject.

For some applications, after placing extra-vascular ring 12 around the aorta, the ring is closed using a closure assembly that comprises one or more fastening elements, such as tab 200 and extension 210, described hereinabove with reference to Fig. 6, or tab

300 and extension 310, described hereinabove with reference to Fig. 7. Alternatively, the ring may be closed using other fastening techniques. By way of example and not limitation, the ring may be closed using fastening elements selected from the 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, hook-and-loop fasteners such as Velcro-type fasteners, straps, holes and string, sutures, wires, cables, tabs, poppers, nails, buttons and corresponding button holes, press button brackets, glues, adhesives, or any combination thereof.

As used in the present application, including in the claims, "tubular" means having the form of an elongate hollow object that defines a conduit therethrough. A "tubular" structure may have varied cross-sections therealong, and the cross-sections are not necessarily circular. For example, one or more of the cross-sections may be generally circular, or generally elliptical but not circular, or circular.

As used herein, terms referring to polygonal figures (e.g., triangles or rectangles) are to be understood as including substantially polygonal figures with rounded corners and/or substantially polygonal figures bounded by curves other than straight lines. As a non-limiting example, the term "triangle" includes shapes such as those of the triangular portions 160, described hereinabove with reference to Fig. 5, which have rounded corners.

Furthermore, descriptions of geometric shapes in terms of their ideal geometry are not intended to limit the invention to the ideal geometry, but may include deviations from the ideal geometry that are produced when the invention is used in practice. As a non-limiting example, rolling a rectangle so that two opposite sides meet will form a cylinder. In the description herein, the rolling of a substantially rectangular piece into a substantially cylindrical ring may be treated as if the piece and the ring are ideal geometric figures. The scope of the invention however includes cases where in practice the substantially cylindrical ring thus formed is oblique, such as because of imperfections in manufacturing or errors by the surgeon. Such terms as, for example, "longitudinal axis" and "transverse" are intended only as a means of providing a description of the invention that is sufficiently detailed so as to be understood by one of ordinary skill in the art. With reference to geometrical figures, the term "substantially" is taken to mean that

the object in question would be recognized by one of ordinary skill in the art as being intended to have the constraints implied by the term modified by the word "substantially." Unless explicitly stated to the contrary, descriptions of geometrical figures are not intended to imply that the figures thus created are within any specific maximum deviation from the ideal structure.

The scope of the present invention includes embodiments described in the following applications, which are assigned to the assignee of the present application and are incorporated herein by reference. In an embodiment, techniques and apparatus described in one or more of the following patent applications are combined with techniques and apparatus described herein:

- PCT Application PCT/IL2008/000287, filed March 5, 2008, which published as PCT Publication WO 2008/107885 to Shalev et al., and US Application 12/529,936 in the national stage thereof, which published as US Patent Application Publication 2010/0063575 to Shalev et al.
- US Provisional Application 60/892,885, filed March 5, 2007
- PCT Application PCT/IL2007/001312, filed October 29, 2007, which published as PCT Publication WO/2008/053469 to Shalev, and US Application 12/447,684 in the national stage thereof, which published as US Patent Application Publication 2010/0070019 to Shalev
- US Provisional Application 60/991,726, filed December 2, 2007
- PCT Application PCT/IL2008/001621, filed December 15, 2008, which published as PCT Publication WO 2009/078010, and US Application 12/808,037 in the national stage thereof, which published as US Patent Application Publication 2010/0292774
- US Provisional Application 61/219,758, filed June 23, 2009
- US Provisional Application 61/221,074, filed June 28, 2009
- PCT Application PCT/IB2010/052861, filed June 23, 2010, which published as PCT Publication WO 2010/150208, and US Application 13/380,278 in the national stage thereof
- PCT Application PCT/IL2010/000549, filed July 8, 2010, which published as PCT

Publication WO 2011/004374

- PCT Application PCT/IL2010/000564, filed July 14, 2010, which published as PCT Publication WO 2011/007354, and US Application 13/384,075 in the national stage thereof
- PCT Application PCT/IL2010/000917, filed November 4, 2010, which published as PCT Publication WO 2011/055364
- PCT Application PCT/IL2010/000999, filed November 30, 2010, which published as PCT Publication WO 2011/064782
- PCT Application PCT/IL2010/001018, filed December 2, 2010, which published as PCT Publication WO 2011/067764
- PCT Application PCT/IL2010/001037, filed December 8, 2010, which published as PCT Publication WO 2011/070576
- PCT Application PCT/IL2010/001087, filed December 27, 2010, which published as PCT Publication WO 2011/080738
- PCT Application PCT/IL2011/000135, filed February 8, 2011, which published as PCT Publication WO 2011/095979
- PCT Application PCT/IL2011/000801, filed October 10, 2011
- US Application 13/031,871, filed February 22, 2011, which published as US Patent Application Publication 2011/0208289
- PCT Application PCT/IL2012/000083, filed February 16, 2012

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

CLAIMS

1. Apparatus for attachment to an aorta of a patient, the apparatus comprising:

an extra-vascular ring, which comprises a structural member, which is configured to assume an elongate hollow shape, which has first and second longitudinal ends, and is suitable for placement at least partially around the aorta so as to provide a generally cylindrical landing zone; and

an endovascular stent-graft, which is suitable for endovascular placement inside the aorta such that a portion of the endovascular stent-graft is positioned against an internal wall of the aorta at the landing zone provided by the structural member,

wherein, if the structural member is unrolled to a planar shape, one side of the planar shape is defined by the first longitudinal end of the structural member, and at least the first longitudinal end has a profile that defines a series of curved portions and has no singularities or discontinuities, which profile extends along at least 50% of the first longitudinal end.

2. The apparatus according to claim 1, wherein the profile is a corrugated profile that defines a series of smooth undulations.

3. The apparatus according to claim 2, wherein the corrugated profile has a substantially sinusoidal form.

4. The apparatus according to claim 2, wherein the first and second longitudinal ends are curved at least partially around a longitudinal axis defined by the elongate hollow shape, and wherein the smooth undulations are shaped so as to define alternating curved peaks and curved valleys, which curved peaks extend in a direction away from the second longitudinal end and have a radius of curvature equal to at least 3% of a length of the first longitudinal end measured around the longitudinal axis, when the structural member is in a relaxed state.

5. The apparatus according to claim 2, wherein the smooth undulations are shaped so as to define alternating curved peaks and curved valleys, which curved peaks extend in a direction away from the second longitudinal end, and wherein, if the structural member is unrolled to the planar shape, a radius of curvature of the curved peaks changes by less than 10% if the structural member, while having the planar shape, is longitudinally stretched from a relaxed state by application of a greatest force that is insufficient to cause

plastic deformation of the structural member.

6. The apparatus according to claim 2, wherein the structural member comprises a plurality of stent struts, and wherein, if the structural member is unrolled to the planar shape, at least one of the stent struts extends completely alongside at least two of the undulations, such that the strut substantially prevents longitudinal stretching of the at least two of the undulations.

7. The apparatus according to claim 6, wherein the at least one of the stent struts geometrically encompasses at least one straight line segment that is parallel to the one side and extends completely alongside the at least two of the undulations, when the structural member has the planar shape.

8. The apparatus according to claim 6, wherein the at least one of the stent struts is straight when the structural has the planar shape.

9. The apparatus according to claim 6, wherein, when the structural member has the planar shape, the at least one stent strut has a length, measured in a direction parallel to the one side, equal to at least 90% of a length of the one side.

10. The apparatus according to claim 1, wherein, if the structural member is unrolled to the planar shape, the first longitudinal end of the structural member has a length that varies by less than 20% if the structural member, while having the planar shape, is longitudinally stretched from a relaxed state by application of a greatest force that is insufficient to cause plastic deformation of the structural member.

11. The apparatus according to claim 1, wherein the profile defines the series of curves interspersed with one or more straight portions.

12. The apparatus according to any one of claims 1-11, wherein the structural member is configured to assume the elongate hollow shape when in a relaxed state.

13. The apparatus according to any one of claims 1-11, wherein the structural member comprises a super-elastic material.

14. The apparatus according to any one of claims 1-11, wherein the structural member comprises a shape memory material.

15. The apparatus according to any one of claims 1-11,

wherein, if the structural member is unrolled to the planar shape, the first

longitudinal end has a length that is equal to between 30 and 120 mm, and

wherein the elongate hollow shape has a longitudinal length, measured parallel to a central longitudinal axis of the elongate hollow shape, that equals between 10 and 40 mm.

16. The apparatus according to any one of claims 1-11, wherein the structural member, when having the elongate hollow shape, is shaped so as to define a gap that extends longitudinally along an entire longitudinal length of the elongate hollow shape from the first longitudinal end to the second longitudinal end,

17. The apparatus according to claim 16, wherein the structural member is shaped so as to define (a) a first extension, which first extension defines at least one slot, and (b) a second extension, which is shaped so as to define a tab adapted to fit into the at least one slot, such inserting the tab into the slot closes the gap.

18. The apparatus according to claim 16, wherein the extra-vascular ring further comprises one or more fastening elements for closing the gap.

19. The apparatus according to any one of claims 1-11, further comprising a hollow, generally tubular delivery shaft, in which the extra-vascular ring is removably disposed with the structural member in a deformed state.

20. The apparatus according to claim 19, wherein the structural member is configured to automatically transition from the deformed state to a relaxed state as the structural member is deployed from the delivery shaft.

21. The apparatus according to any one of claims 1-11, wherein the elongate hollow shape is generally cylindrical.

22. A method comprising:

providing an extra-vascular ring, which includes a structural member, which is configured to assume an elongate hollow shape, which has first and second longitudinal ends, wherein, if the structural member is unrolled to a planar shape, one side of the planar shape is defined by the first longitudinal end of the structural member, and at least the first longitudinal end has a profile that defines a series of curved portions and has no singularities or discontinuities, which profile extends along at least 50% of the first longitudinal end; and

placing the extra-vascular ring at least partially around a neck of an aneurysmal

aorta of a patient so as to provide a generally cylindrical landing zone, such that the profile homogenously distributes strain on aortic tissue at the first longitudinal end of the structural member.

23. The method according to claim 22, further comprising placing an endovascular stent-graft inside the aorta such that a portion of the endovascular stent-graft is positioned against an internal wall of the neck at the landing zone provided by the structural member.

24. The method according to claim 22, wherein placing the extra-vascular ring comprises advancing, to an external surface of the aorta, a hollow, generally tubular delivery shaft, in which the extra-vascular ring is removably disposed with the structural member in a deformed state.

25. The method according to claim 24, wherein advancing the delivery shaft comprises advancing the delivery shaft through a laparoscopic working channel to an abdominal location adjacent to renal arteries of the aorta, and laparoscopically placing the extra-vascular stent around the neck of the abdominal aorta in a vicinity of the renal arteries.

26. The method according to claim 22, wherein placing the extra-vascular ring comprises identifying the patient as suffering from an aneurysm of an abdominal aorta, and treating the aortic aneurysm by placing the extra-vascular ring at least partially around the neck of the abdominal aorta.

27. The method according to claim 22, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which the profile is a corrugated profile that defines a series of smooth undulations.

28. The method according to claim 27, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which the corrugated profile has a substantially sinusoidal form.

29. The method according to claim 27, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which the first and second longitudinal ends are curved at least partially around a longitudinal axis defined by the elongate hollow shape, and wherein the smooth undulations are shaped so as to define alternating curved peaks and curved valleys, which curved peaks extend in a direction away from the second longitudinal end and have a radius of curvature equal to at least 3% of a length of the first

longitudinal end measured around the longitudinal axis, when the structural member is in a relaxed state.

30. The method according to claim 27, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which the smooth undulations are shaped so as to define alternating curved peaks and curved valleys, which curved peaks extend in a direction away from the second longitudinal end, and wherein, if the structural member is unrolled to the planar shape, a radius of curvature of the curved peaks changes by less than 10% if the structural member, while having the planar shape, is longitudinally stretched from a relaxed state by application of a greatest force that is insufficient to cause plastic deformation of the structural member.

31. The method according to claim 27, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which the structural member includes a plurality of stent struts, and, if the structural member is unrolled to the planar shape, at least one of the stent struts extends completely alongside at least two of the undulations, such that the strut substantially prevents longitudinal stretching of the at least two of the undulations.

32. The method according to claim 31, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which the at least one of the stent struts geometrically encompasses at least one straight line segment that is parallel to the one side and extends completely alongside the at least two of the undulations, when the structural member has the planar shape.

33. The method according to claim 31, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which the at least one of the stent struts is straight when the structural has the planar shape.

34. The method according to claim 31, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which, when the structural member has the planar shape, the at least one stent strut has a length, measured in a direction parallel to the one side, equal to at least 90% of a length of the one side.

35. The method according to claim 22, wherein providing the extra-vascular ring comprises providing the extra-vascular ring characterized in that, if the structural member is unrolled to the planar shape, the first longitudinal end of the structural member has a

length that varies by less than 20% if the structural member, while having the planar shape, is longitudinally stretched from a relaxed state by application of a greatest force that is insufficient to cause plastic deformation of the structural member.

36. The method according to claim 22, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which the profile defines the series of curved portions interspersed with one or more straight portions.

37. The method according to claim 22, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which the structural member is configured to assume the elongate hollow shape when in a relaxed state.

38. The method according to claim 22, wherein providing the extra-vascular ring comprises providing the extra-vascular ring in which the elongate hollow shape is generally cylindrical.

FIG. 1

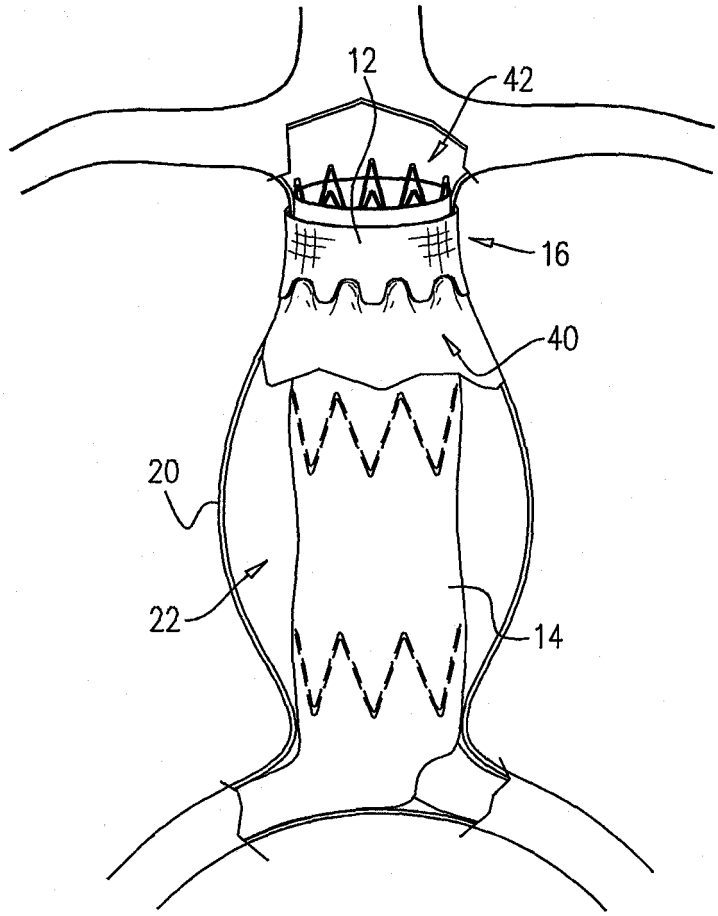


FIG. 2

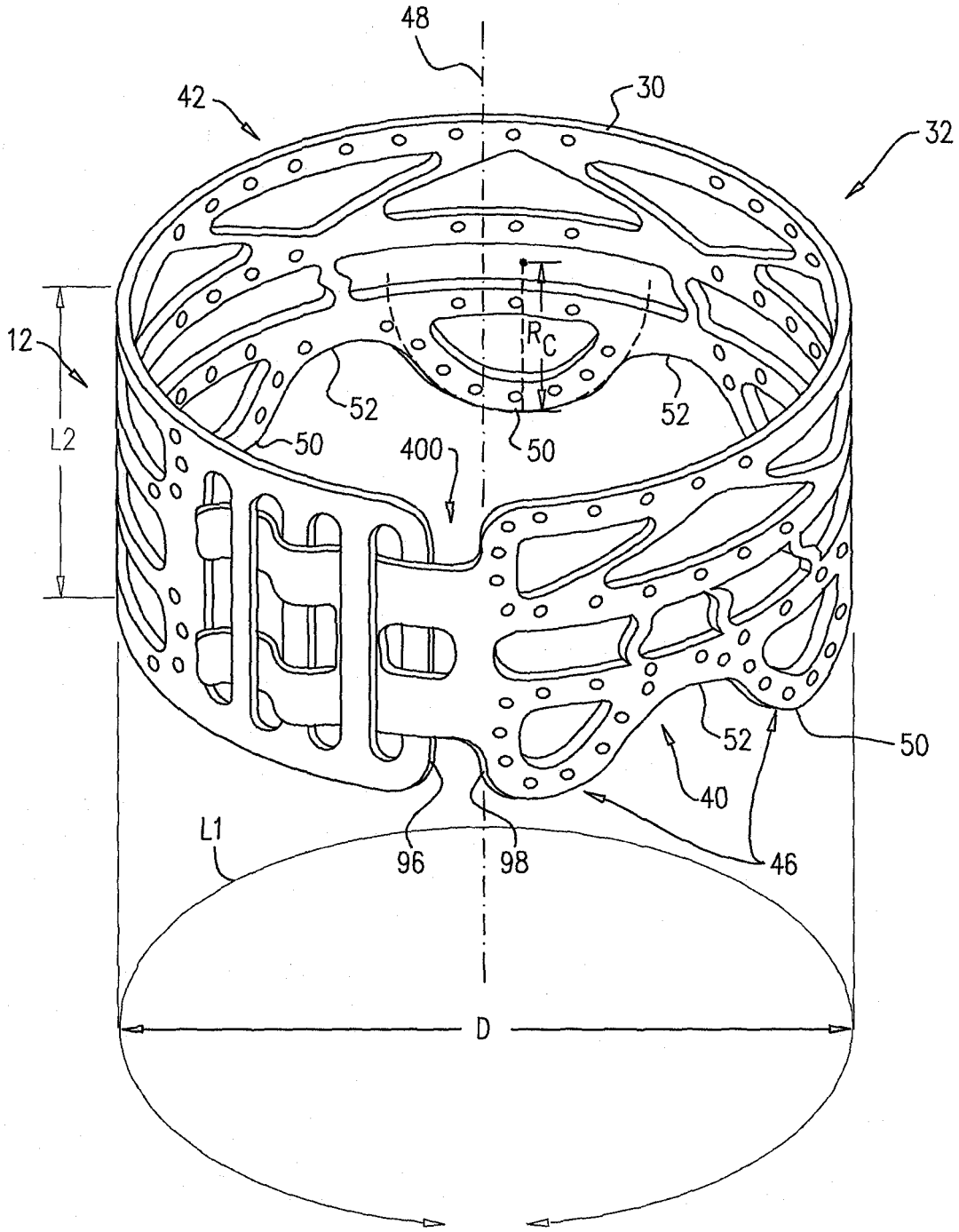


FIG. 3A

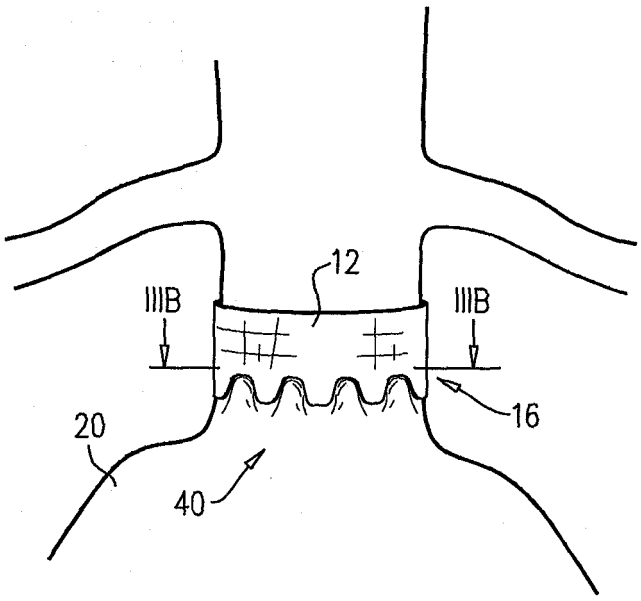


FIG. 3B

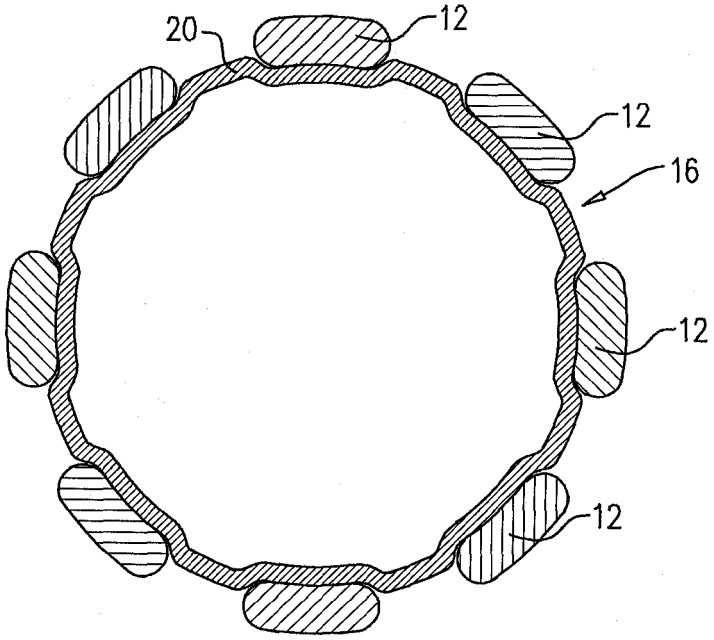


FIG. 3C

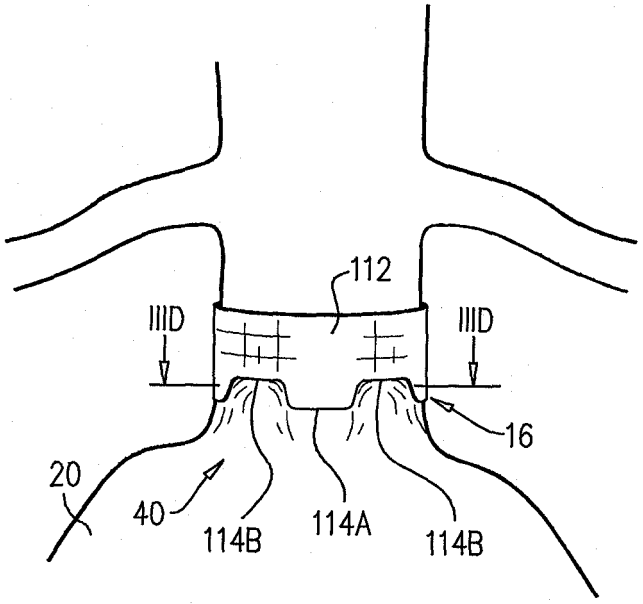


FIG. 3D

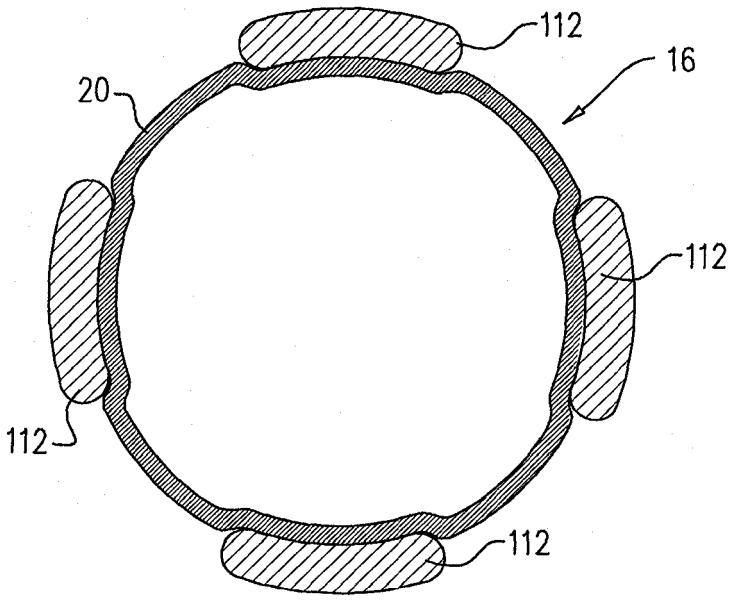


FIG. 4A
(PRIOR ART)

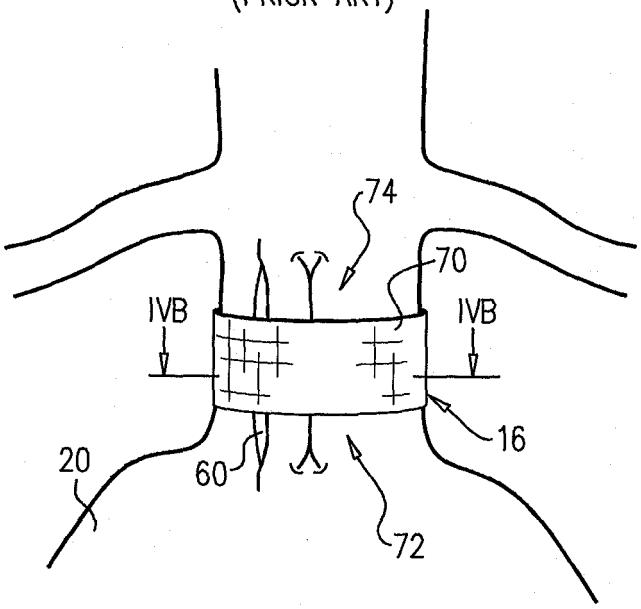
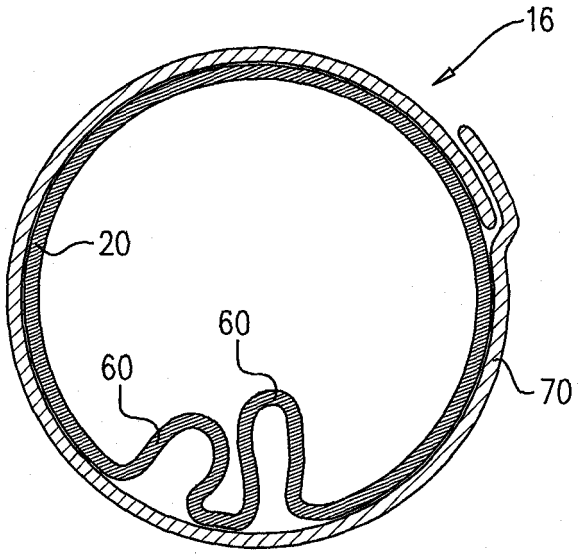
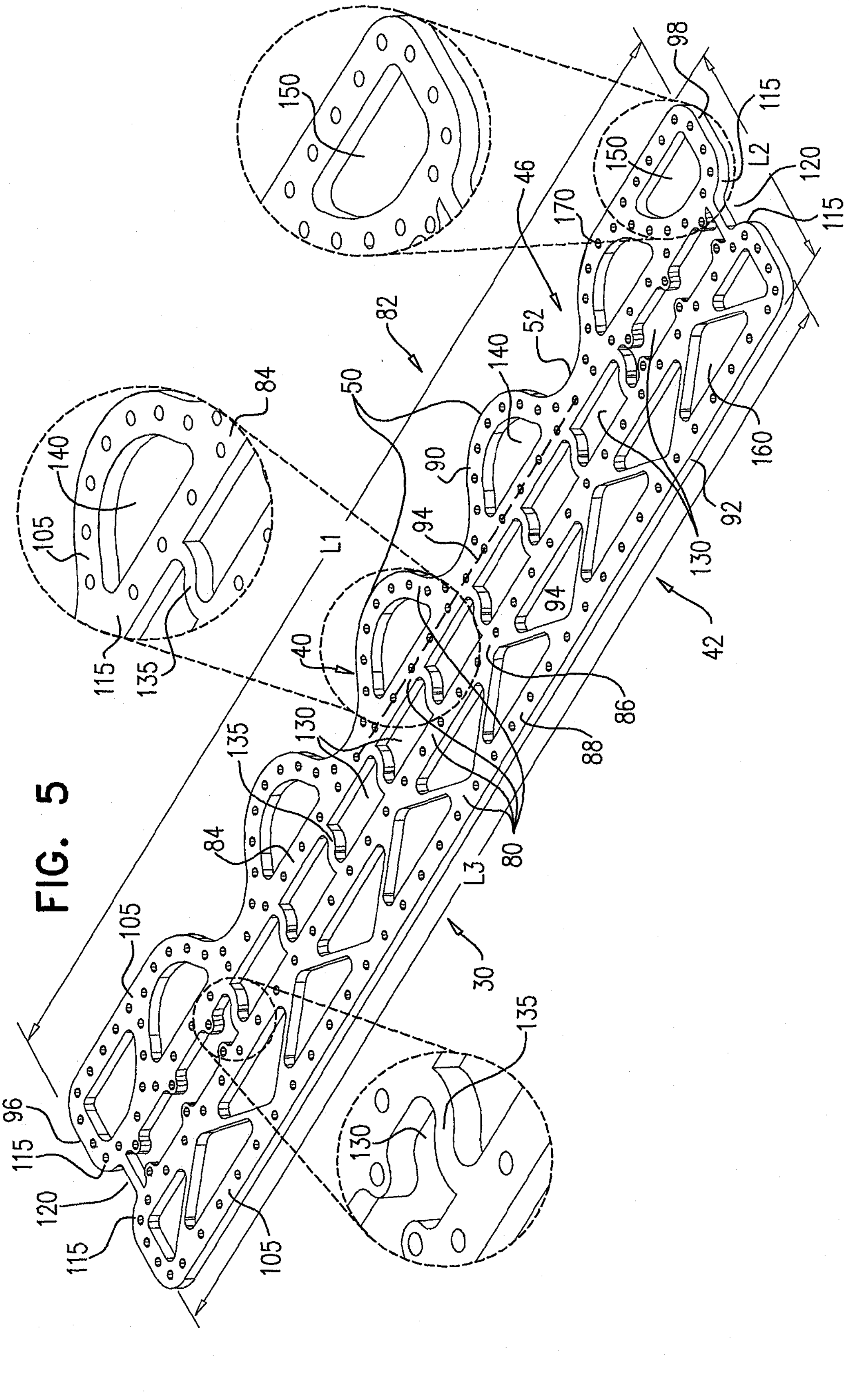


FIG. 4B
(PRIOR ART)

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L1
40
94
86
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92
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L3
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30
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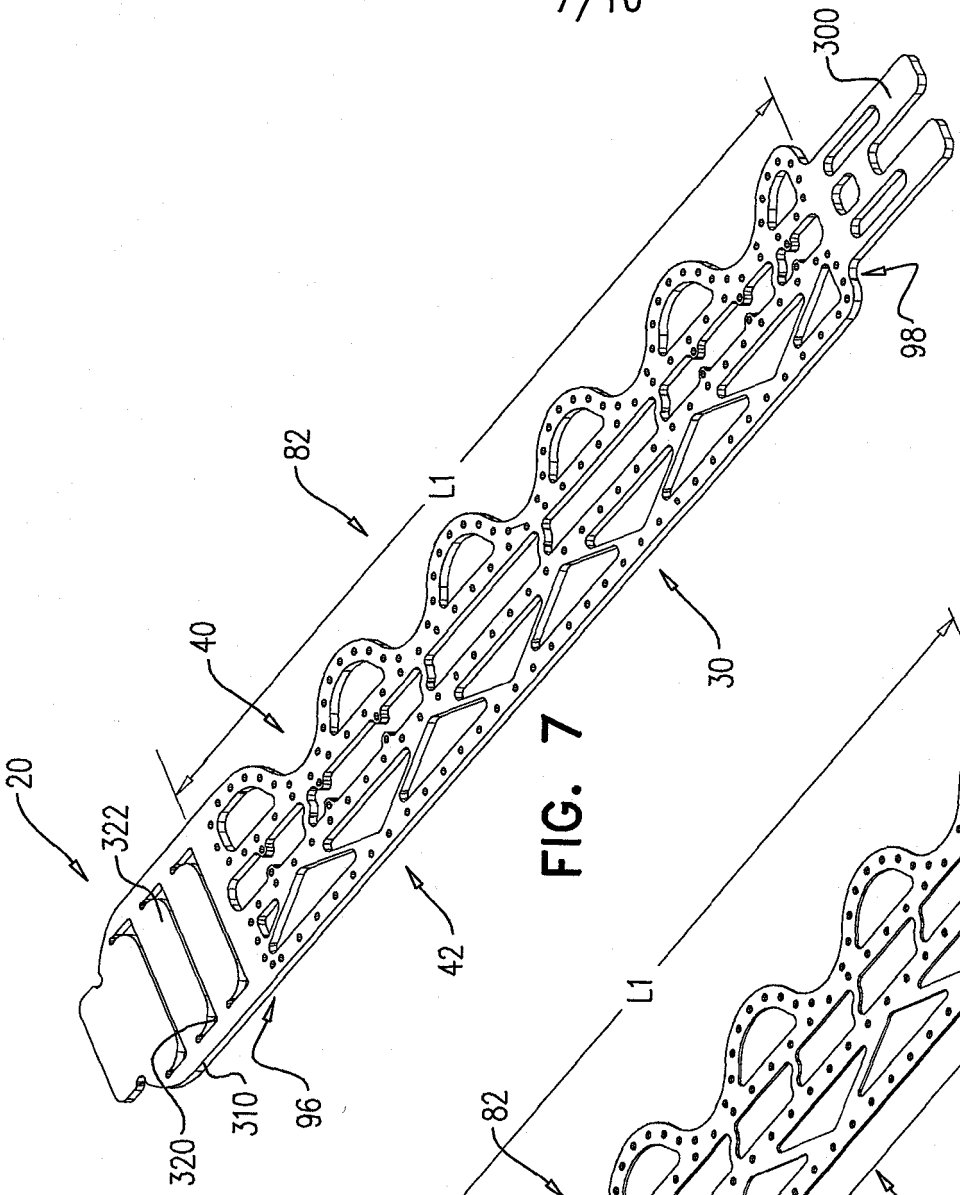
105
135
130

FIG. 5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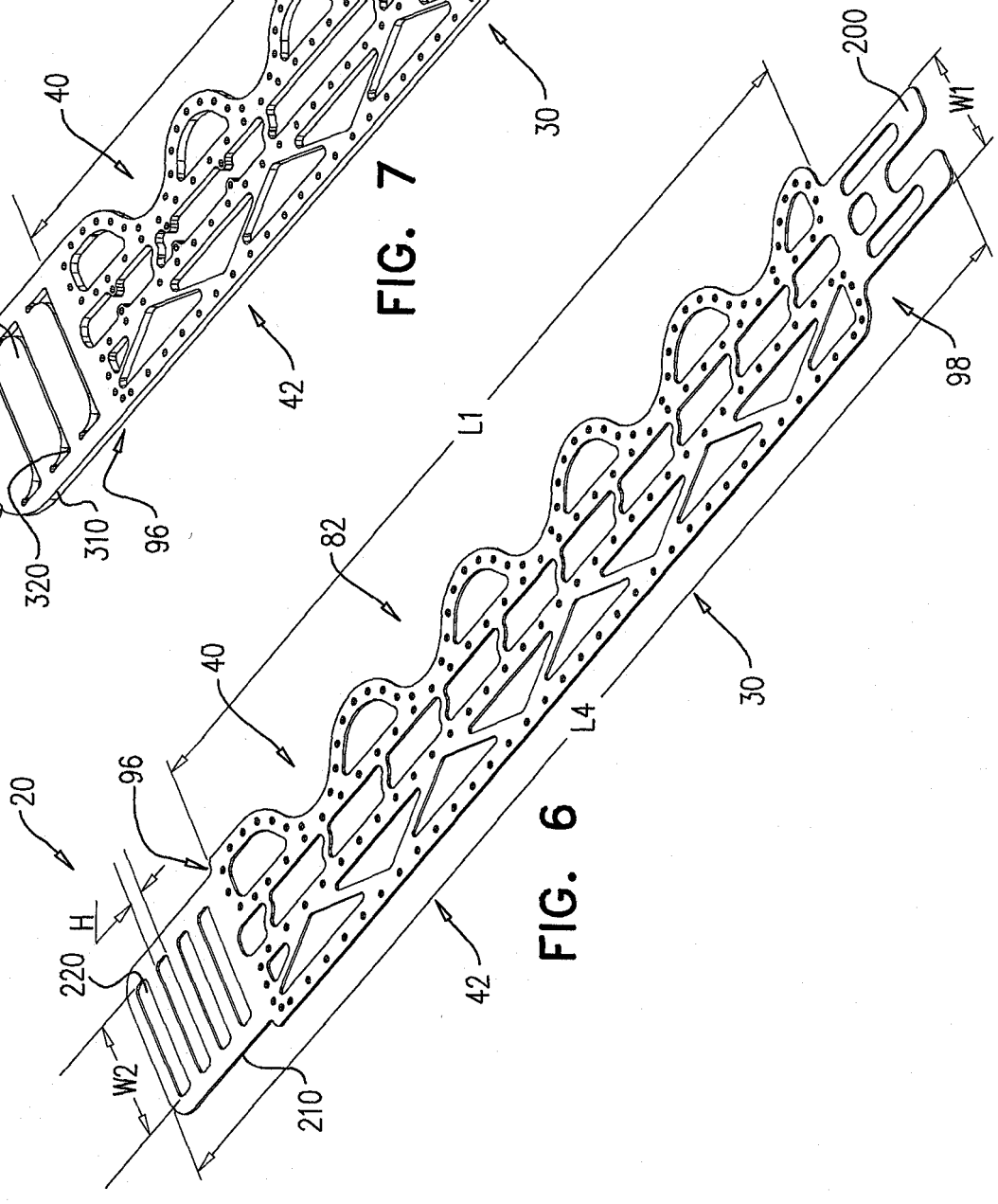
310
96

FIG. 7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W1
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L4
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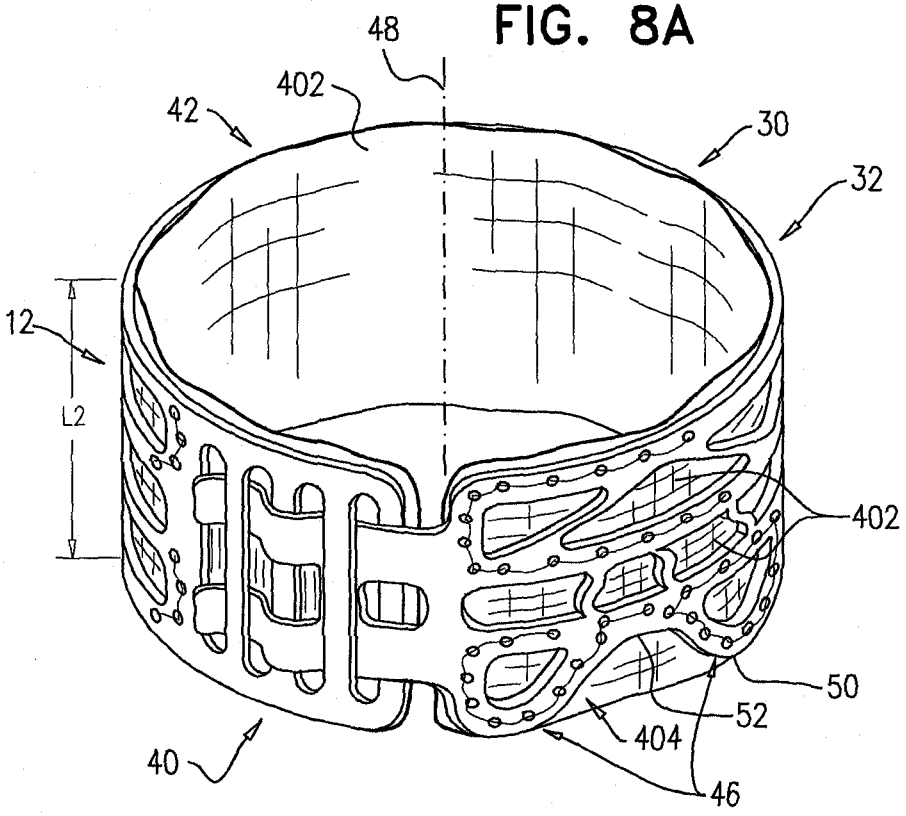
96
H
220
W2
210
42

FIG. 6

FIG. 8A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32
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L2
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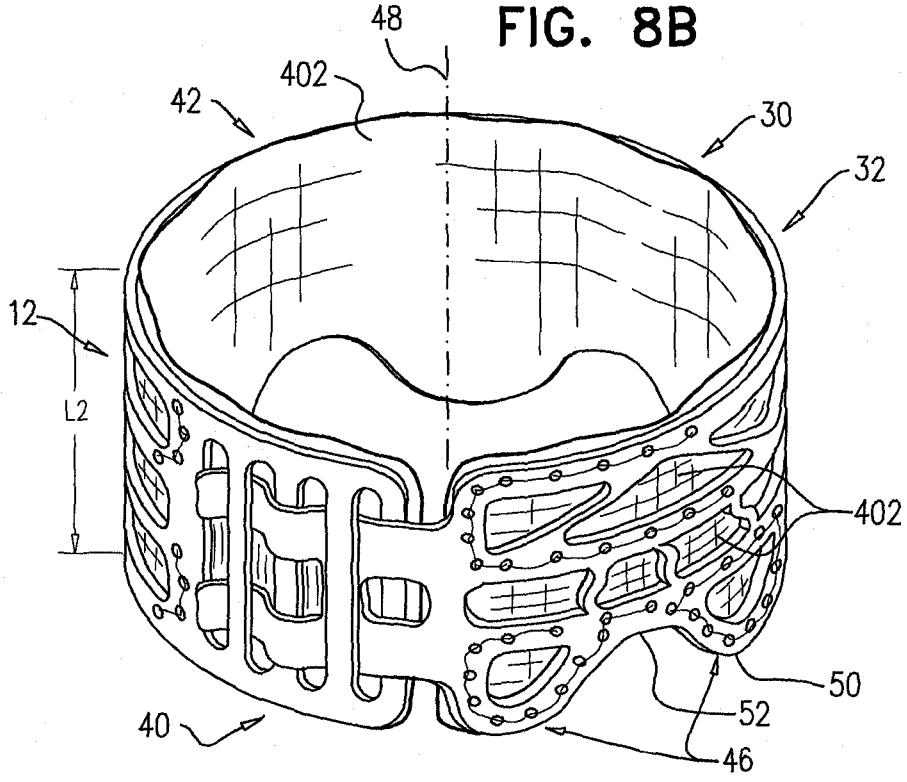
46

FIG. 8B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L2
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40
46

FIG. 9B

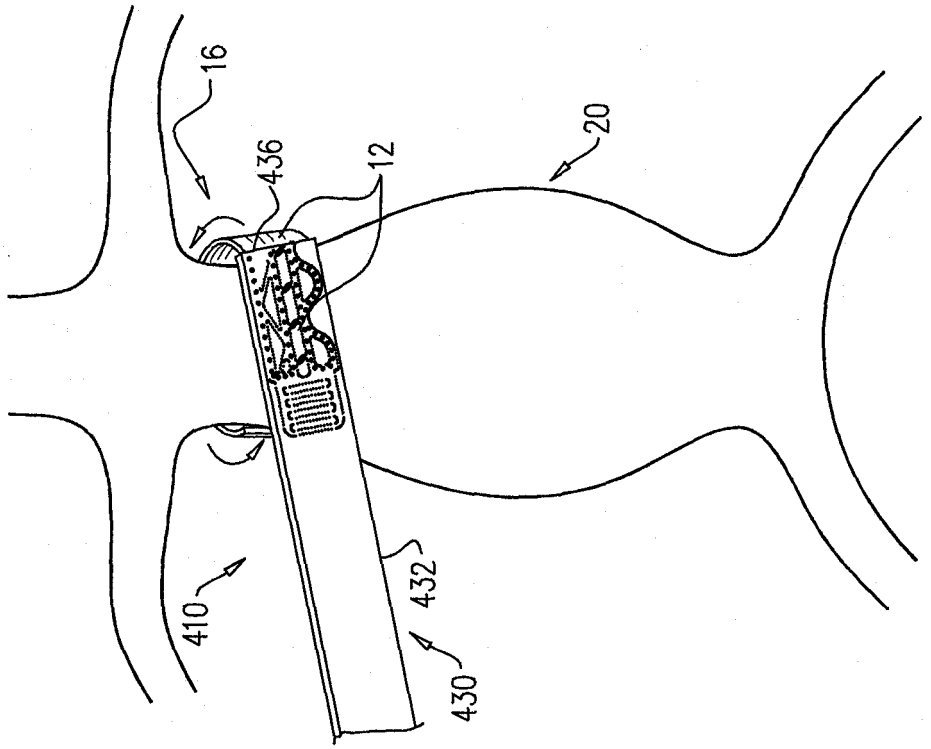


FIG. 9A

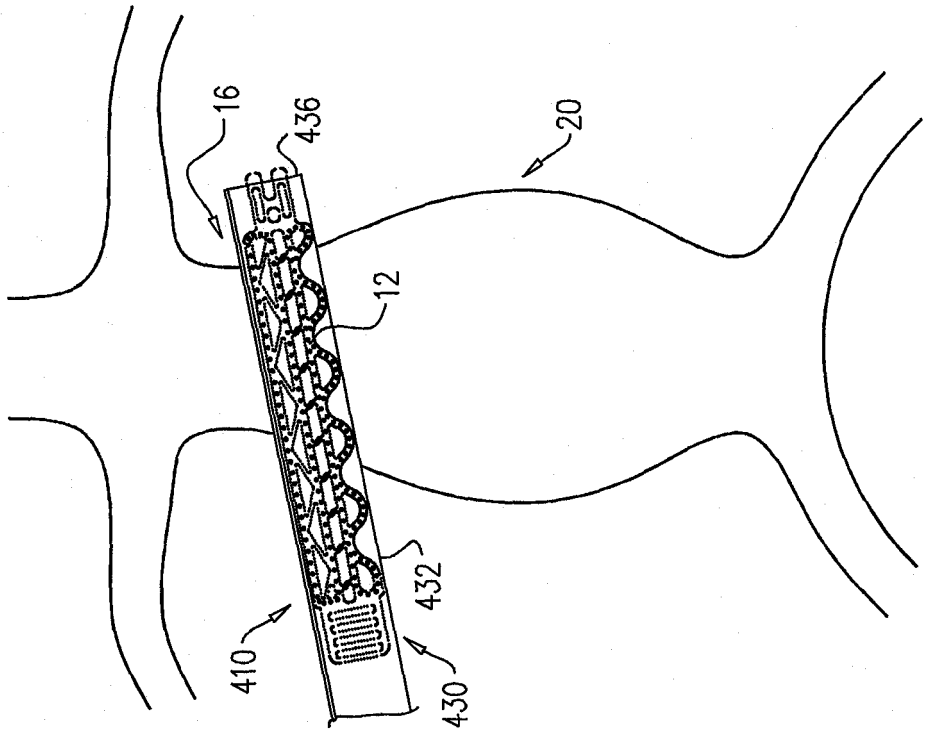


FIG. 9D

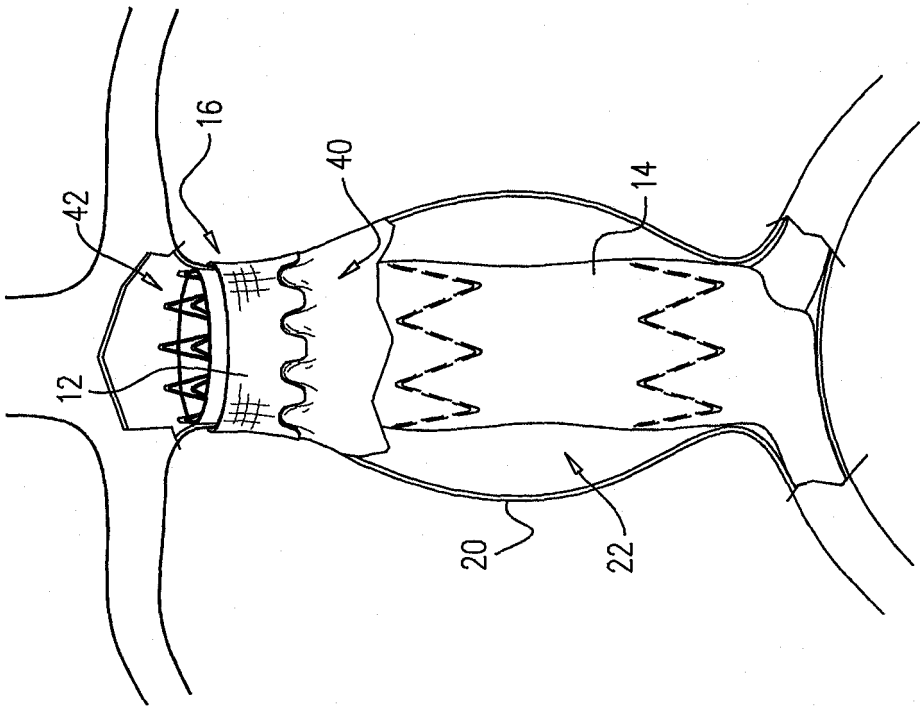
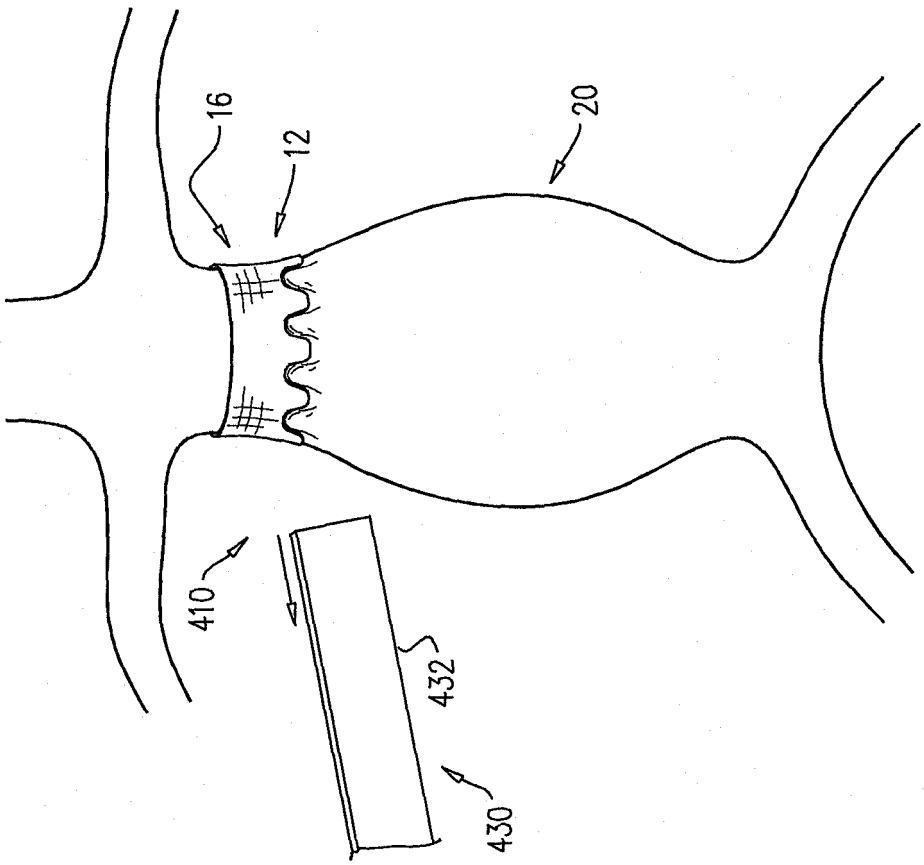


FIG. 9C



INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2012/000095

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/06 (2012.01)
USPC - 623 /1.14
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 2/06 (2012.01)
USPC - 623/1.13, 1.14, 1.3, 1.31

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/0292774 A1 (SHALEV) 18 November 2010 (18.11.2010) entire document	1-38

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
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"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 July 2012	17 JUL 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

专利名称(译)	减少血管外环用于治疗主动脉瘤		
公开(公告)号	EP2680788A4	公开(公告)日	2014-12-10
申请号	EP2012752054	申请日	2012-03-01
[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 A61F2/89 A61F2/93		
CPC分类号	A61F2/93 A61B17/12013 A61F2/07 A61F2/89 A61F2220/0025 A61F2220/0041 A61F2220/005 A61F2220/0066 A61F2220/0075 A61F2220/0083 A61F2230/0054		
优先权	61/448199 2011-03-02 US		
其他公开文献	EP2680788A1		
外部链接	Espacenet		

摘要(译)

提供了装置（10），其包括血管外环（12）和血管内支架 - 移植物（14）。环（12）包括结构构件（30），其构造成呈细长中空形状（32），其具有第一和第二纵向端部（40,42），并且适于至少部分地围绕主动脉放置（20）以便提供大致圆柱形的着陆区。血管内支架 - 移植物（14）适于在主动脉（20）内进行血管内放置，使得支架 - 移植物（14）的一部分在由着陆区提供的着陆区处抵靠主动脉（20）的内壁定位。结构构件（30）。如果结构构件（30）展开成平面形状（82），则平面形状（82）的一侧（90）由第一纵向端（40）和至少第一纵向端（40）限定。具有限定一系列弯曲部分并且没有奇点或不连续的轮廓，该轮廓沿着第一纵向端部（40）的至少50％延伸。