

(21) Application No: 2215295.3

(22) Date of Filing: 17.10.2022

(71) Applicant(s):
Cook Medical Technologies LLC
750 North Daniels Way, Bloomington 47404, Indiana,
United States of America

(72) Inventor(s):
Erik Edelboe Rasmussen
Bent Oehlenschlaeger

(74) Agent and/or Address for Service:
Williams Powell
44 Prospect Place, BROMLEY, Kent, BR2 9HN,
United Kingdom

(51) INT CL:
A61F 2/07 (2013.01) A61F 2/82 (2013.01)
A61F 2/86 (2013.01) A61F 2/89 (2013.01)

(56) Documents Cited:
EP 3395295 A1 WO 2020/074598 A1
US 20210369439 A1 US 20200352703 A1
US 20180200089 A1 US 20090043377 A1

(58) Field of Search:
INT CL A61F
Other: WPI, EPODOC, PATENT-SEARCH

(54) Title of the Invention: **Stent graft assembly**
Abstract Title: **STENT GRAFT ASSEMBLY**

(57) A stent graft for deployment in the aortic arch comprising a plurality of expandable stent rings along a length of tubular graft material (10) and at least one fenestration (60). The stent rings include at least a proximal (20), distal (90) and intermediate stent. The at least one fenestration is provided in a side wall of the graft material, configured for alignment with a junction of the left subclavian artery and for deployment of a side-branch. At least one intermediate stent ring is a fenestration-supporting stent ring (70), wherein the stent ring is a zig-zag stent. Proximal and distal apices of the stent ring are connected to each other by a plurality struts. At least one of the distal apices is a fenestration supporting apex having a larger radius of curvature than the proximal apices. At least one fenestration is provided between two struts of the fenestration-supporting stent ring, defining two sides of the fenestration. The fenestration has a proximal edge connecting the proximal ends of the two sides of the fenestration, the proximal edge including at least a portion that is substantially perpendicular to the longitudinal axis of the stent graft.

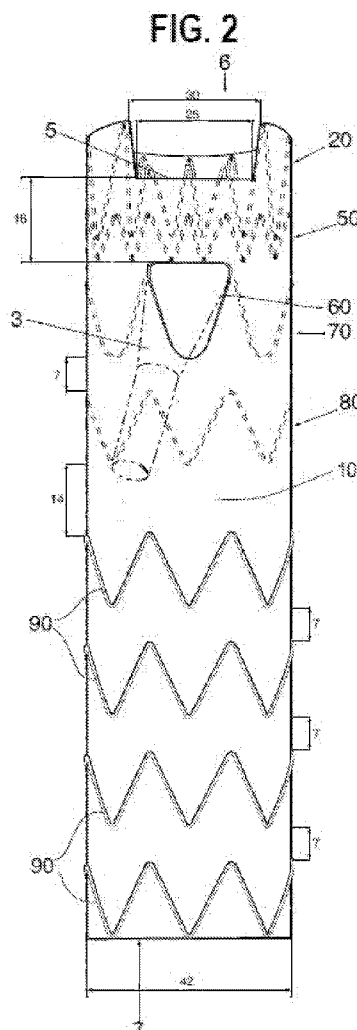


FIG. 1

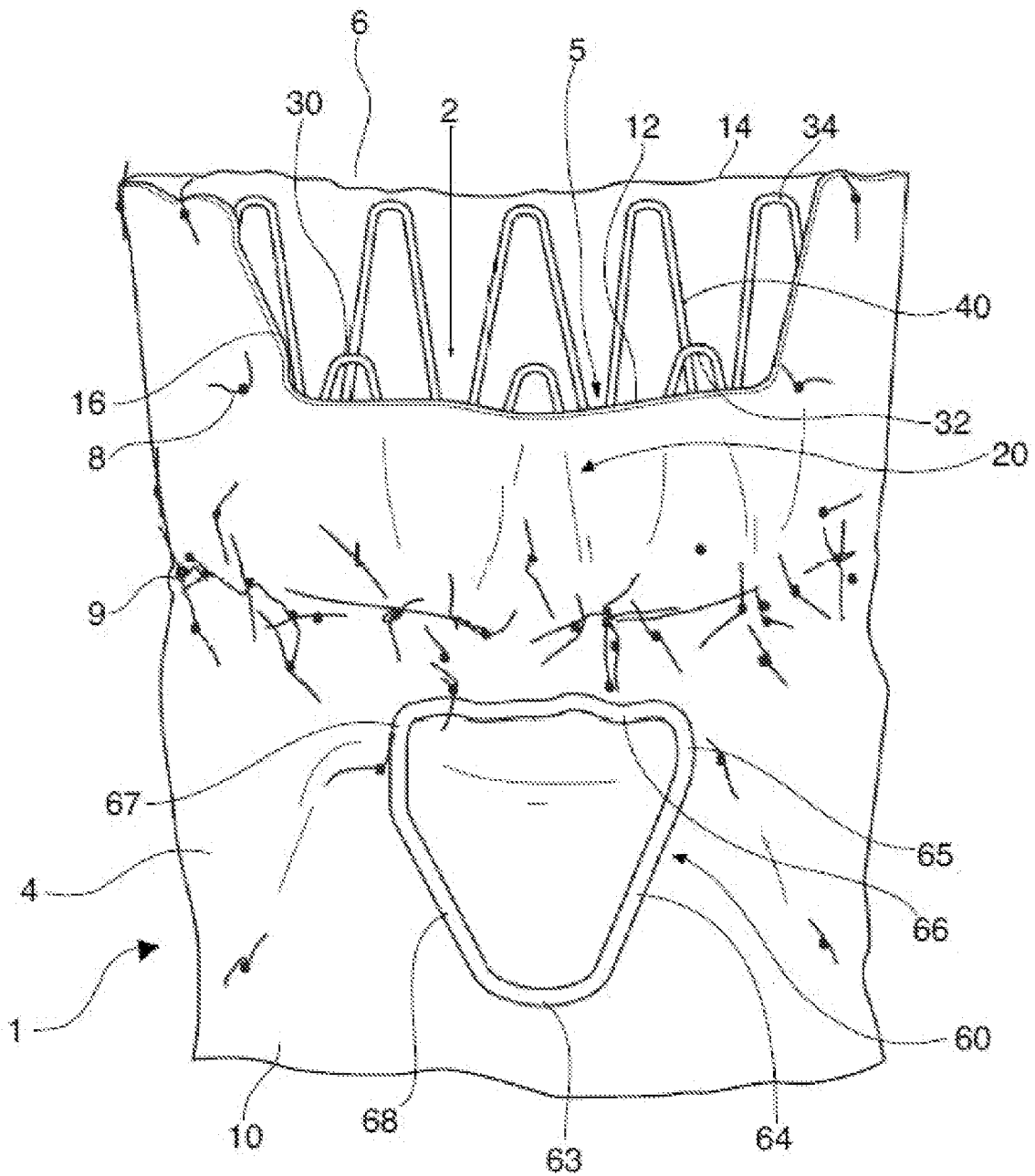


FIG. 2

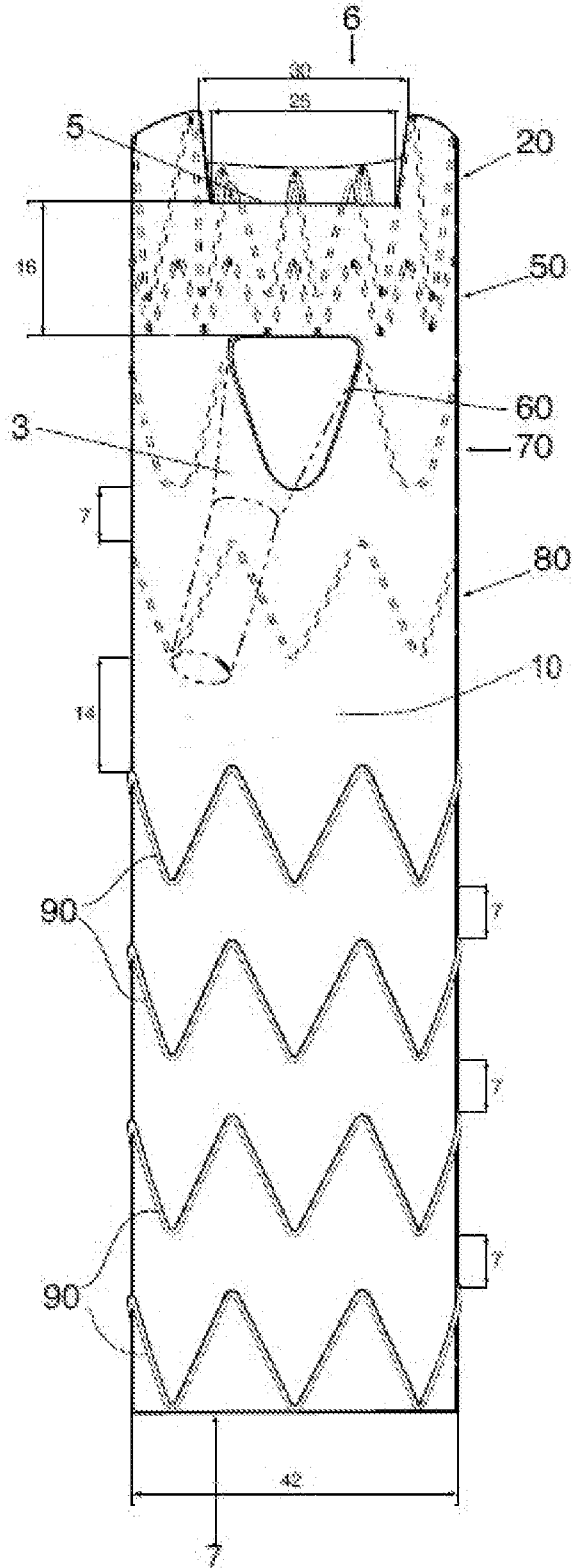


FIG. 3

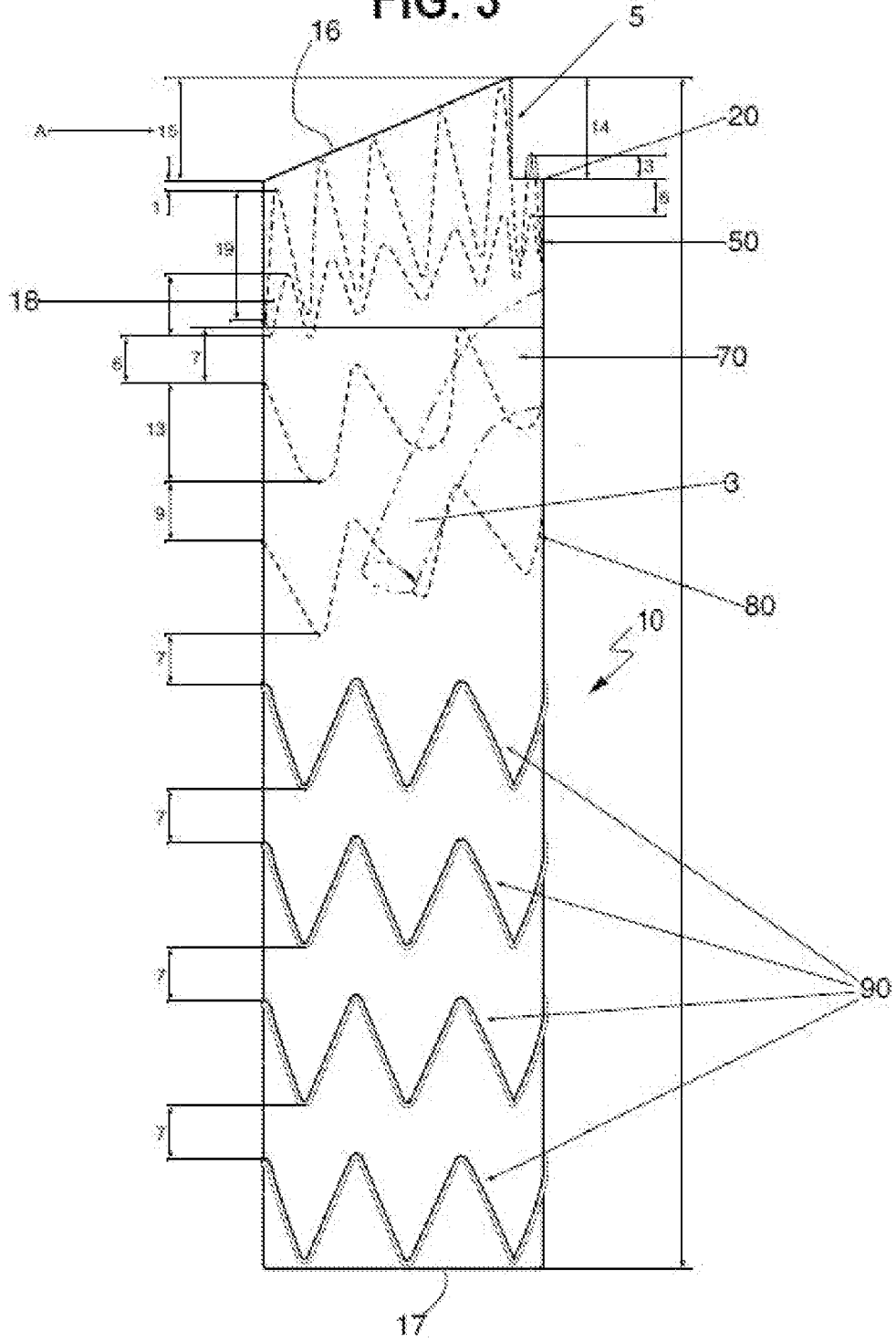


FIG. 4

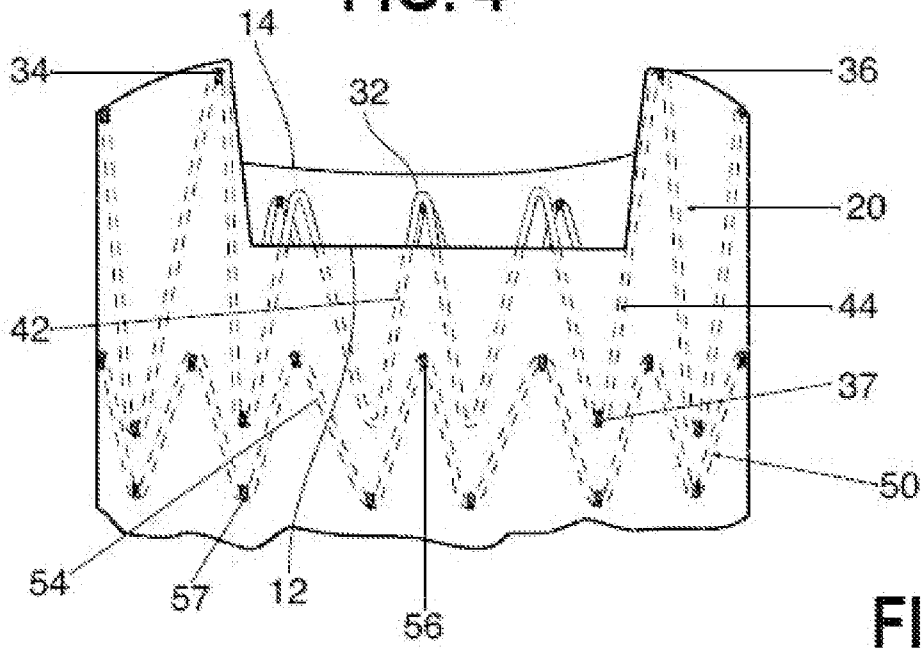


FIG. 5

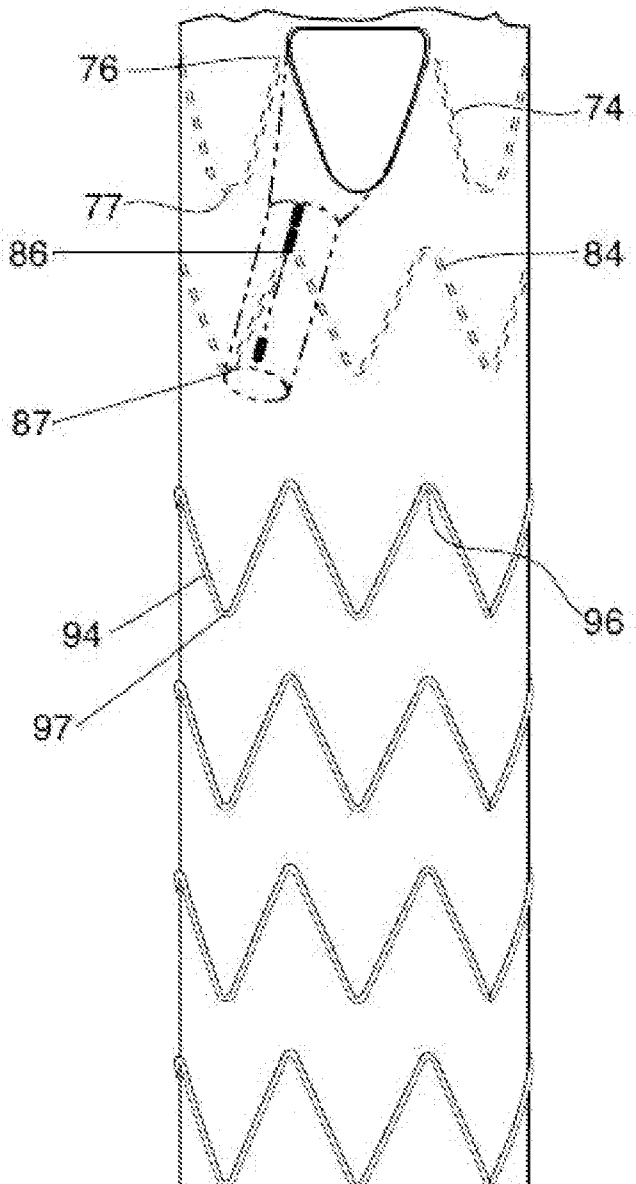


FIG. 6

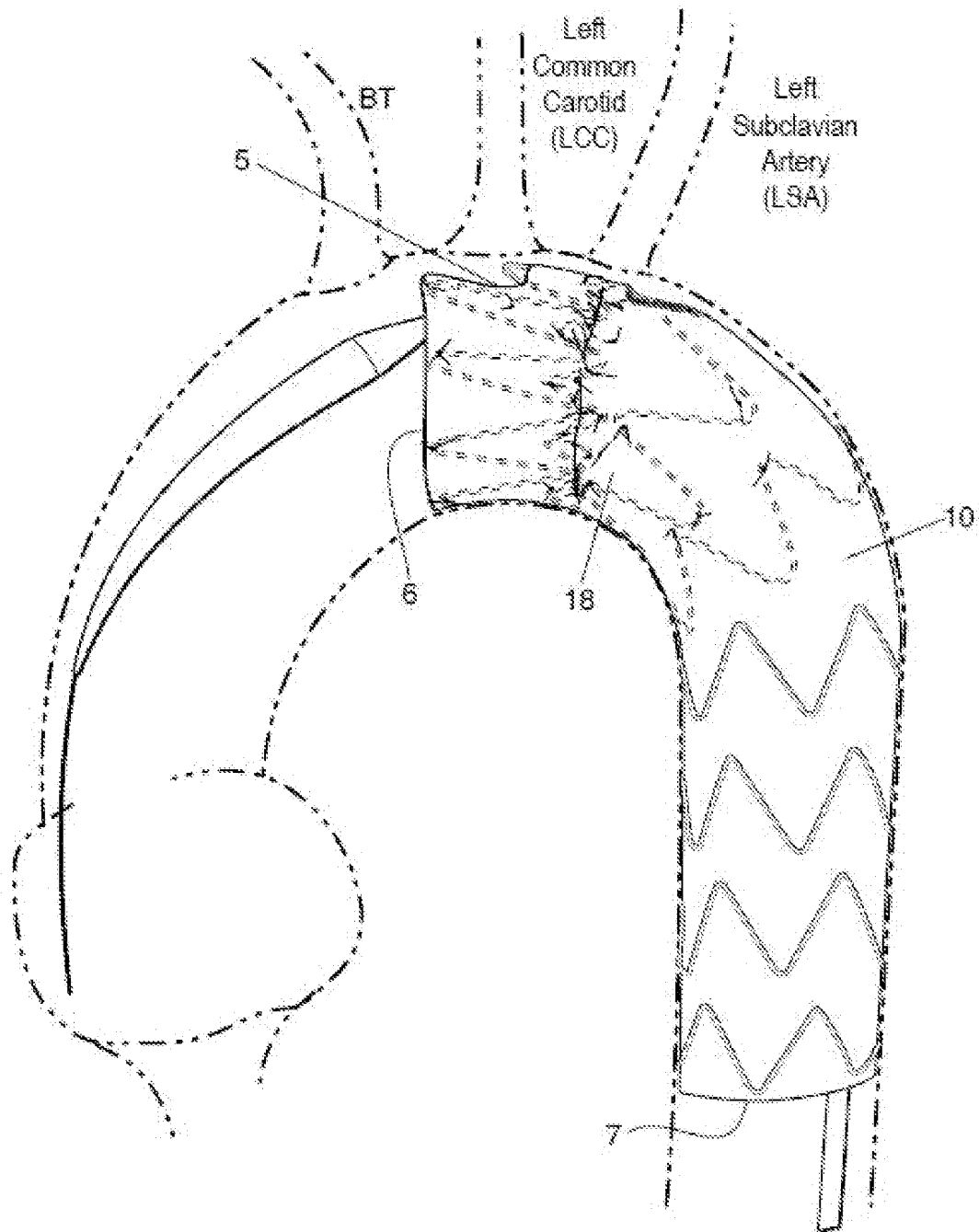
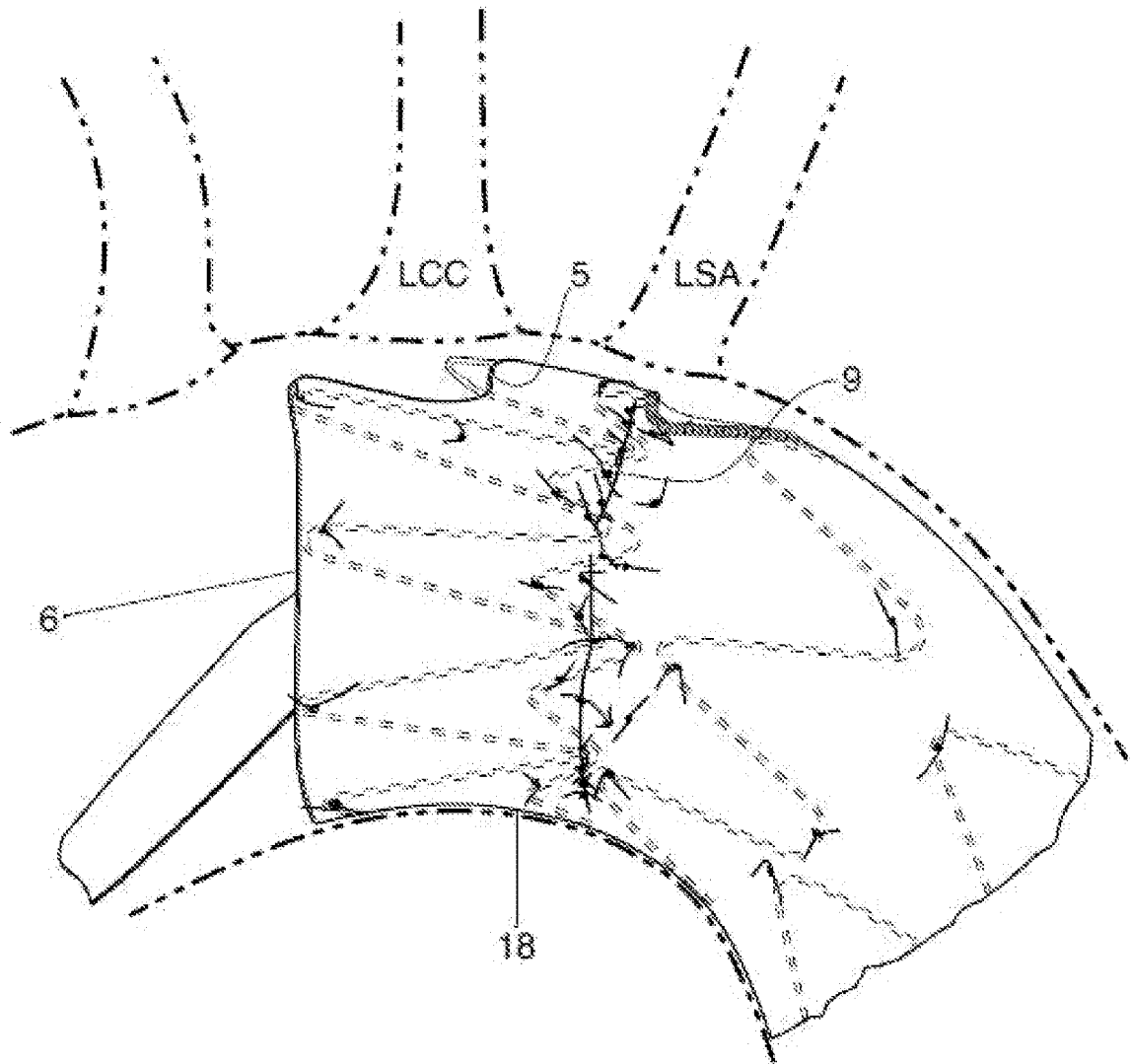


FIG. 7



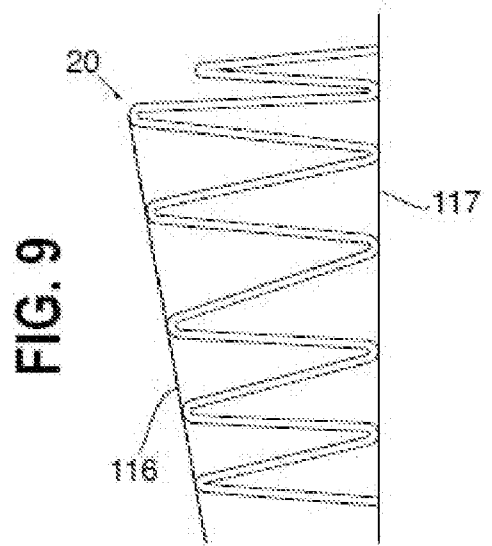
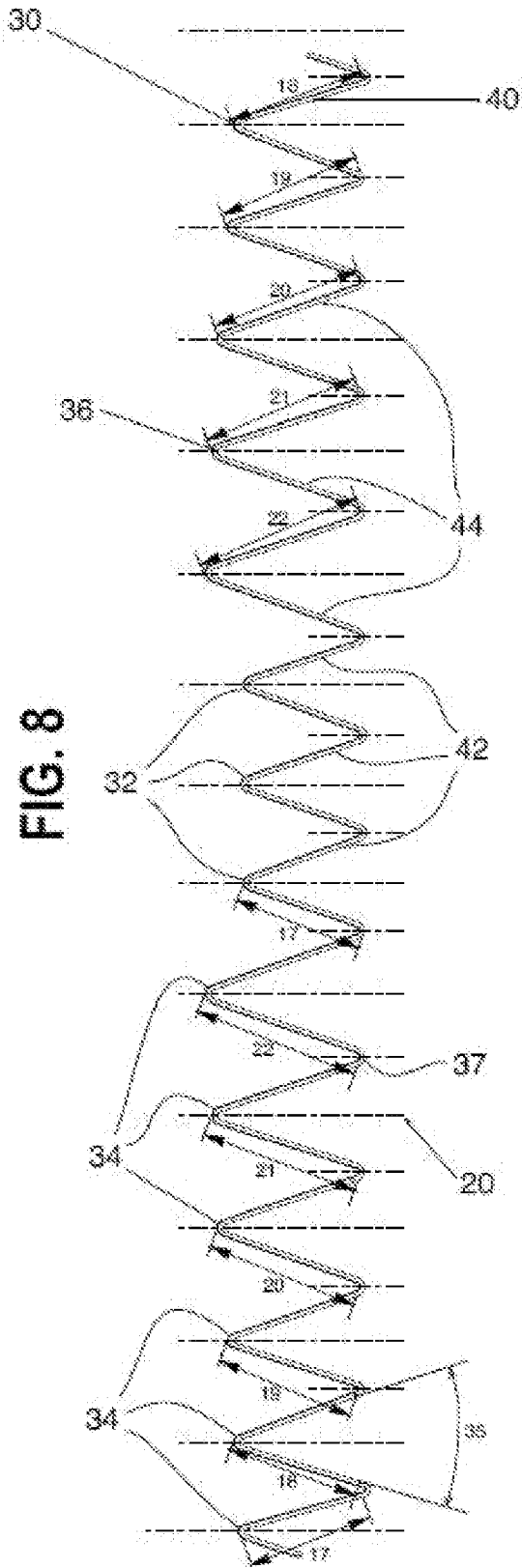


FIG. 10

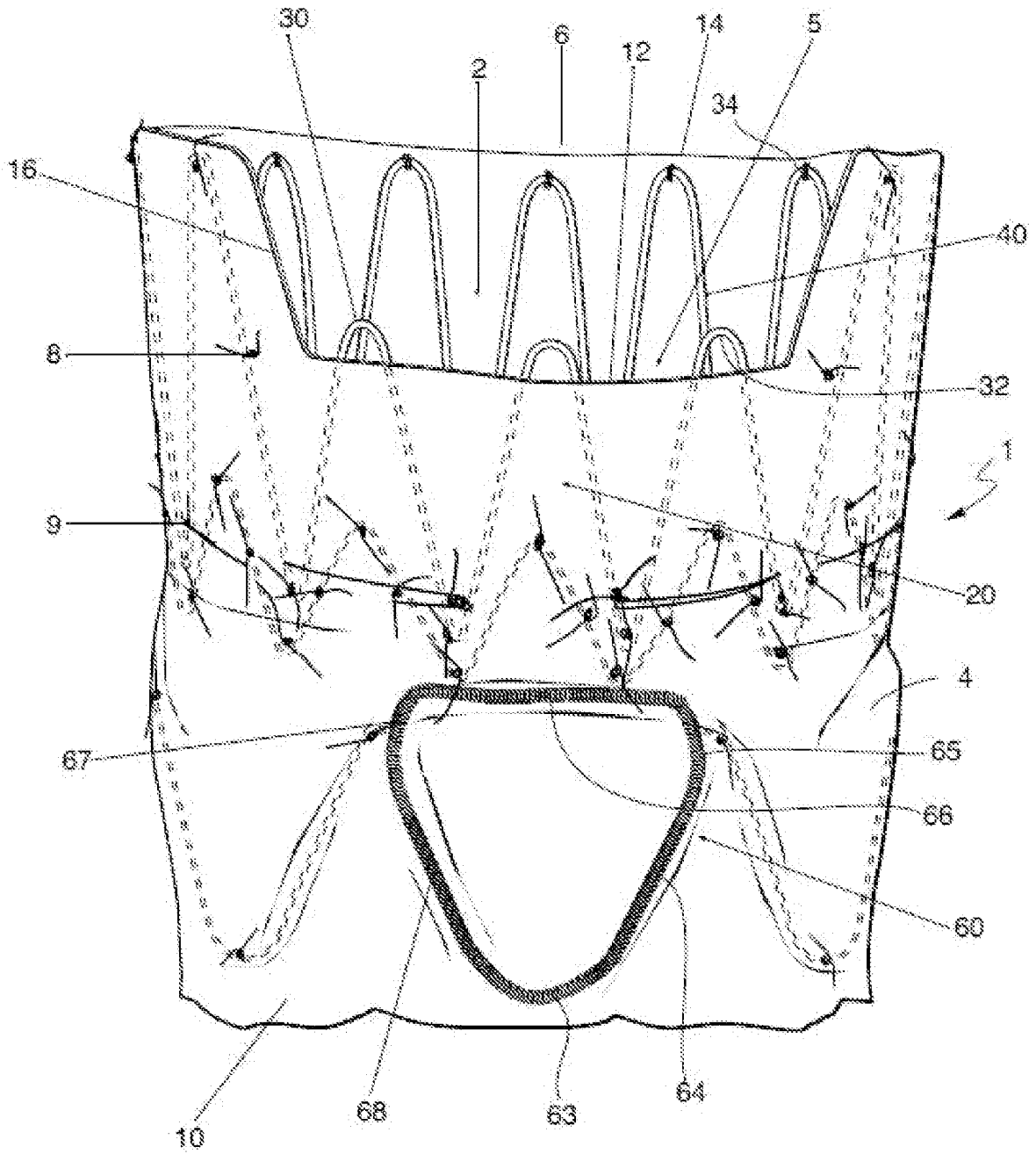


FIG. 11

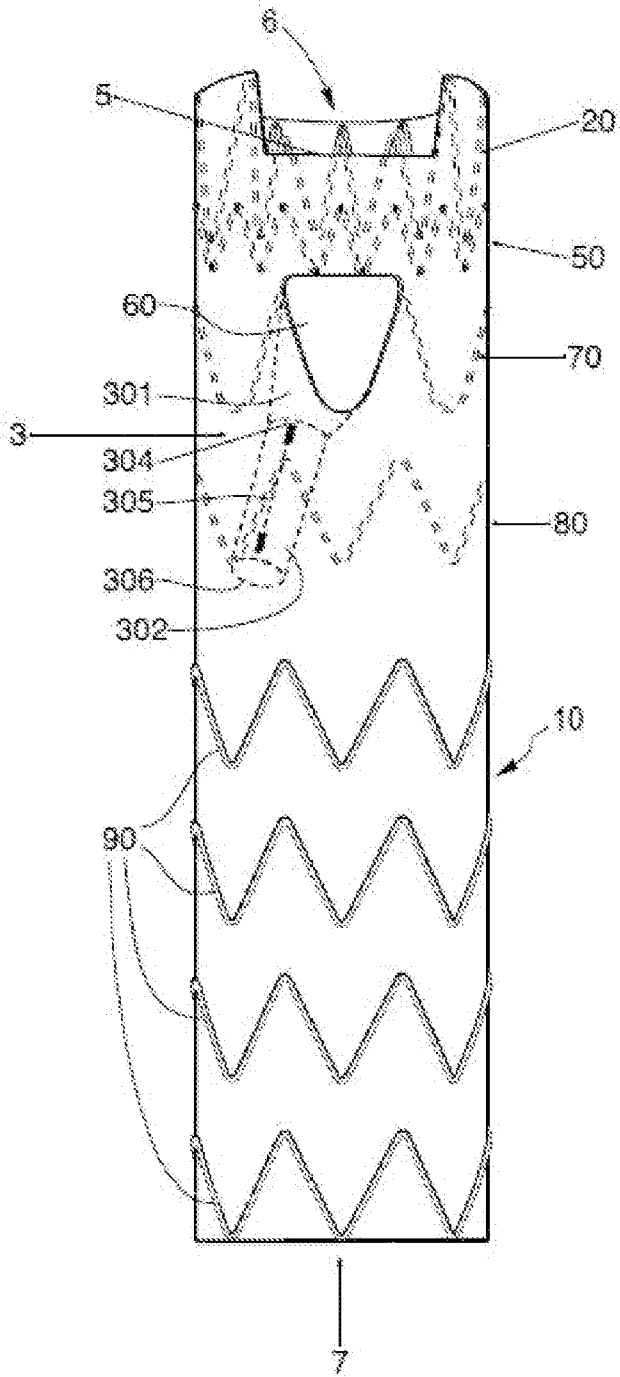
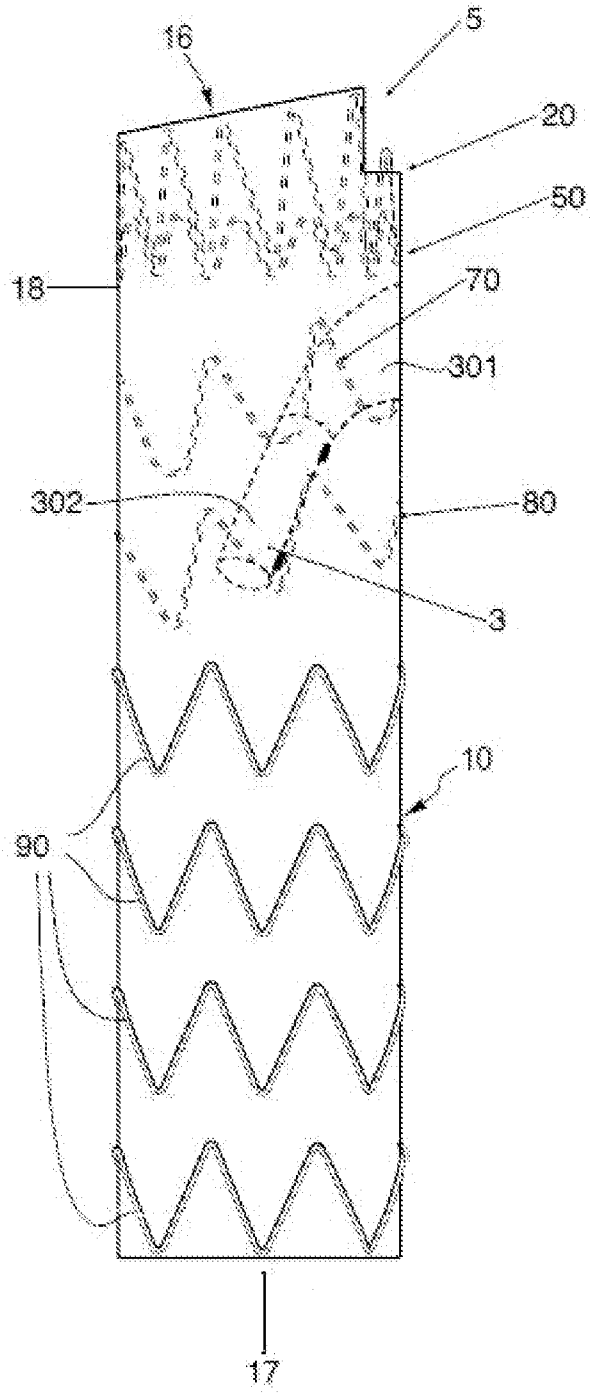


FIG. 12



STENT GRAFT ASSEMBLY

FIELD OF THE INVENTION

The present invention relates to an endoluminally implantable medical device and a method of use thereof. The endoluminally implantable medical
5 device may be for insertion into the vasculature of a human.

BACKGROUND

Endoluminal prostheses, such as stents and stent-grafts, may be used for
treating damaged or diseased vessels in the body of a human. For example, a
stent-graft may be used for repairing an aneurysm in the thoracic or abdominal
10 aorta. Such a stent-graft is placed inside the vessel and provides some or all of
the functionality of the original, healthy vessel.

One of the challenges of designing and using an endoluminal prosthesis is
providing sufficient sealing of the prosthesis against the wall of the vessel. Where
a prosthesis is deployed in a blood vessel, if the seal is insufficient it can result in
15 leakage of blood flow between the prosthesis and the vessel wall – commonly
referred to as an endoleak – which can impair treatment of the patient as the
aneurysm may not be depressurised and may grow.

Achieving sufficient sealing of a prosthesis is made more challenging where
the vessel has a high degree of curvature. Achieving sufficient sealing of a
20 prosthesis is also made more challenging where the area of healthy tissue
available for the prosthesis to seal against – also known as the landing zone – is
limited. For example, where the region for repair is located adjacent, or even
between, branches of the vessel the landing zone may be severely restricted.
Further, in regions with such challenging topologies, there is also an increased
25 risk that stents of the prosthesis can cause trauma to the tissue of the vessel
wall.

A particularly challenging region for treatment has been found to be the
aortic arch. In practice, there is difficulty in designing and deploying a prosthesis
that can accommodate the challenging topology of the aortic arch.

SUMMARY

The present invention seeks to provide an improved endoluminally implantable medical device and method.

5 According to a first aspect of the invention, there is provided an endoluminally implantable medical device, comprising: a graft having a proximal end and a distal end, the proximal end including first and second circumferential regions, the first circumferential region having a scallop; and a stent disposed at the proximal end of the graft, the stent comprising a plurality of stent units including first and second stent units, each stent unit comprising first and second
10 struts connected by a proximal apex; wherein the proximal apex of the first stent unit is more rounded than the proximal apex of the second stent unit; wherein the plurality of stent units includes at least one scallop unit and at least one body unit, wherein each scallop unit has a proximal apex located at the scallop and each body unit has a proximal apex located in the second circumferential region;
15 wherein the first stent unit is a scallop unit of the at least one scallop unit and the second stent unit is a body unit of the at least one body unit.

It is preferred that the plurality of stent units includes at least one supporting unit having a proximal apex located in the second circumferential region, and the first and second struts of each of the at least one scallop unit are shorter than the
20 first and second struts of each of the at least one supporting unit.

Preferably, the second stent unit is diametrically opposite the first stent unit.

The proximal apex of each of the at least one scallop unit may be disposed proximally of a distal end of the scallop and uncovered by graft material.

25 According to a second aspect of the invention, there is provided an endoluminally implantable medical device, comprising: a graft having a proximal end and a distal end, the proximal end including first and second circumferential regions, the first circumferential region having a scallop; a stent disposed at the proximal end of the graft, the stent comprising a plurality of stent units, each stent unit comprising first and second struts connected by a proximal apex; wherein
30 the plurality of stent units includes at least one scallop unit and at least one supporting unit, where the proximal apex of each scallop unit is located at the scallop and the proximal apex of each supporting unit is located in the second circumferential region; the first and second struts of each of the at least one

scallop unit are shorter than the first and second struts of each of the at least one supporting unit; and the proximal apex of each of the at least one scallop unit is disposed proximally of a distal end of the scallop and uncovered by graft material.

5 It is preferred that at least one scallop unit has a proximal apex which is more rounded than the proximal apex of each of the at least one supporting unit. Preferably, the plurality of stent units includes at least one supporting unit having a proximal apex located in the second circumferential region and each of the at least one supporting unit supports the scallop.

10 Preferably, the plurality of stent units includes at least one supporting unit having a proximal apex located in the second circumferential region and each of the at least one supporting unit is adjacent to the scallop, wherein optionally the at least one supporting unit includes a supporting unit disposed on each side of the scallop.

15 It is preferred that the plurality of stent units includes at least one supporting unit having a proximal apex located in the second circumferential region and the proximal apex of each of the at least one scallop unit is disposed distally of the proximal apex of each of the at least one supporting unit. Preferably, the proximal apex of each scallop unit is more rounded than the proximal apex of a diametrically opposite body unit. The proximal apex of each scallop unit is preferably more rounded than the proximal apex of each supporting unit. In some embodiments, the proximal apex of each scallop unit is more rounded than the proximal apex of each supporting unit and the proximal apex of each body unit.

25 It is preferred that the plurality of stent units includes at least one supporting unit having a proximal apex located in the second circumferential region and the proximal apex of each of the at least one supporting unit is overlapped by graft material. Further, the proximal apex of each of the at least one supporting unit is preferably disposed at a proximal edge of the graft.

30 At least a majority of each of the at least one scallop unit is preferably overlapped by graft material.

The proximal apex of each scallop unit is in the first circumferential region.

In embodiments, the proximal apex of each scallop unit is at a distal end of

the scallop.

The stent of the device according to any preceding statement can further comprise a plurality of distal apices, each stent unit of the stent being connected to a neighbouring stent unit by a distal apex. It is preferred that a plurality of the distal apices are located in the second circumferential region and are disposed longitudinally level with or distally of a distal end of the scallop. Further, it is preferable that at least a majority of the distal apices of the stent are disposed longitudinally level with or distally of the distal end of the scallop. In some embodiments, all of the distal apices of the stent are disposed longitudinally level with or distally of the distal end of the scallop. It is also preferred that the distal apices of the stent are substantially aligned with one another.

The proximal apex of each of the at least one scallop unit is preferably more rounded than each distal apex of the stent in the first circumferential region. In some embodiments, the proximal apex of each scallop unit is more rounded than each of the distal apices of the stent.

Optionally, the distal set of apices of the stent all have the same radius of curvature. In some embodiments, all the apices of the stent that are located in the second circumferential region have the same radius of curvature.

In embodiments, apices of the stent that are more rounded have a greater radius of curvature.

It is preferred that the stent is an endmost stent.

The first and second circumferential regions may make up a complete circumference of the graft. The first circumferential region may be coterminous with the scallop.

Preferably, at least a majority of the stent is overlapped by graft material. Preferably, each of the at least one supporting unit is completely covered by graft material. One or more of the at least one scallop unit may be partially overlapped by graft material.

According to a third aspect of the invention there is provided an endoluminally implantable medical device, comprising: a graft having a proximal end and a distal end, the proximal end including first and second circumferential regions, the first circumferential region having a scallop; a stent disposed at the proximal end of the graft, the stent comprising a plurality of stent units, each stent

unit comprising first and second struts connected by a proximal apex; wherein the plurality of stent units includes a plurality of scallop units and at least one body unit, wherein each scallop unit has a proximal apex located at the scallop and each body unit has a proximal apex located in the second circumferential region.

The endoluminally implantable medical device can incorporate any of the optional features of the first or second aspects.

In some embodiments, the endoluminally implantable medical device of any preceding statement is configured for implantation into a curved lumen.

In some embodiments, the stent is a first stent and has a length from a first end to a second end, the first end being the proximal end and the second end being the distal end, wherein the length of the first stent increases in both circumferential directions from an inner curve region of the device and provides the first stent with a wedge shape. The inner curve region is configured to be deployed on the inside of a curve of a lumen.

In some embodiments, the graft is a tubular graft and the stent is around the graft. In some embodiments, the first end of the first stent is adjacent to the first end of the graft.

The proximal end of the graft may be slanted with respect to a sidewall of the graft and form an obtuse angle with respect to the sidewall at the inner curve region.

In a preferred embodiment, the inner curve region of the device is substantially diametrically opposite the scallop.

Additionally, the device may comprise any of the optional features of the fourth aspect.

In embodiments, the device has a first stent. The first stent may be an endmost stent disposed at the proximal end of the graft. It may be that at least a majority of the first stent is covered by graft material. The first stent may be the stent of any preceding statement.

In some embodiments, the device comprises a second stent adjacent to and distal of the first stent.

In embodiments, each of the first and second stents comprises a plurality of proximal peaks and distal valleys, adjacent peaks and valleys being connected

by struts. In embodiments, peaks of the first stent are provided by the stent units recited above. In other words, within each stent adjacent peaks and valleys are connected by struts.

5 The graft may cover at least a majority of each of a plurality of interstices between peaks of the first stent.

A strut of the second stent may be shorter than a strut of the first stent. A peak of the second stent may be nested between valleys of the first stent.

Additionally, the device may comprise any of the optional features of the fifth aspect.

10 According to a fourth aspect of the invention, there is provided an implantable medical device configured for implantation into a curved lumen, the device including a tubular graft and a first stent around the graft; the graft having a first end, a second end and a sidewall; the first stent having a length from a first end to a second end, the first end of the first stent being adjacent to the first end
15 of the graft, the length of the first stent increasing in both circumferential directions from an inner curve region of the device and providing the first stent with a wedge shape; wherein the first end of the graft is slanted with respect to the sidewall and forms an obtuse angle with respect to the sidewall at the inner curve region; wherein the inner curve region is configured to be deployed on the
20 inside of a curve of a lumen.

It is preferred that the first end of the graft aligns with the first end of the first stent around at least a majority of a circumference of the first end of the graft.

25 The first end of the graft is preferably substantially equidistant from the first end of the first stent around at least a majority of a circumference of the first end of the graft.

In some embodiments, the device has a proximal end and a distal end, and the first end of the stent has a taper such that the longitudinal location of the first end of the stent increases in a proximal-distal direction in both circumferential directions from the inner curve region of the device. In a preferred embodiment,
30 the first stent includes a plurality of apices at the first end thereof, wherein the taper comprises, in each circumferential direction from the inner curve region, at least three apices at the first end of the first stent offset from each other in the proximal-distal direction. Preferably, the at least three apices are adjacent

apices. The taper is preferably linear.

In a practical embodiment, the taper provides an offset of from about 5mm to about 20mm, more preferably from about 10mm to about 20mm, more preferably from about 13 to about 17mm, most preferably of about 15mm.

5 The first end of the graft preferably has substantially the same taper as the first end of the stent.

In embodiments of the device according to any preceding statement, it is particularly advantageous for the taper to be configured so that the first end of the first stent deploys substantially perpendicular to the curve of the lumen.

10 The first end of the graft can be configured so that the first end of the graft deploys substantially perpendicular to the curve of the lumen.

The first stent may be an internal stent around an interior of the graft.

In one embodiment, the first end of the graft is the proximal end of the graft, the first end of the first stent is the proximal end of the first stent, the second end of the graft is the distal end of the graft, and the second end of the first stent is the distal end of the first stent.

The first stent can include a scallop at the first end thereof, preferably configured to be deployed on the outside of a curve of a lumen.

20 The device according to any preceding statement can include at least one further stent spaced from the first stent.

The graft may include a scallop at the first end, preferably configured to be deployed on the outside of a curve of a lumen.

25 The first stent may be an endmost stent disposed at the first end of the graft. It may be that the first end of the graft is proximal and the second end of the graft is distal.

In some embodiments, the device includes a second stent adjacent to the first stent. The second stent may be distal of the first stent. In embodiments, each of the first and second stents comprises a plurality of proximal peaks and distal valleys, adjacent peaks and valleys being connected by struts.

30 The graft may cover at least a majority of each of a plurality of interstices between peaks of the first stent.

A peak of the second stent may be nested between valleys of the first stent. A strut of the second stent may be shorter than a strut of the first stent.

Additionally, the device may comprise any of the optional features of the fifth aspect.

5 In some embodiments, the first end of the graft includes first and second circumferential regions, the first circumferential region having a scallop. The scallop may be substantially diametrically opposite the inner curve region of the device.

In embodiments, the first end of the graft is the proximal end and the second end of the graft is the distal end. The first stent may be disposed at the proximal end of the graft.

10 In embodiments, the first stent comprises a plurality of stent units including first and second stent units, each stent unit comprising first and second struts connected by a proximal apex. The proximal apex of the first stent unit may be more rounded than the proximal apex of the second stent unit.

15 The plurality of stent units may include at least one scallop unit and at least one body unit, where each scallop unit has a proximal apex located at the scallop and each body unit has a proximal apex located in the second circumferential region. The first stent unit may be a scallop unit of the at least one scallop unit and the second stent unit may be a body unit of the at least one body unit.

20 The plurality of stent units preferably includes at least one scallop unit and at least one supporting unit, wherein the proximal apex of each scallop unit is located at the scallop and the proximal apex of each supporting unit is located in the second circumferential region, and the first and second struts of each of the at least one scallop unit are preferably shorter than the first and second struts of each of the at least one supporting unit.

25 The proximal apex of each of the at least one scallop unit may be disposed proximally of a distal end of the scallop and uncovered by graft material.

30 The plurality of stent units may include a plurality of scallop units and at least one body unit, wherein each scallop unit has a proximal apex located at the scallop and the each body unit has a proximal apex located in the second circumferential region.

Additionally, the device may comprise any of the optional features of the first and second aspects, wherein reference to the stent is to be taken as reference to the first stent.

According to a fifth aspect of the invention, there is provided an endoluminally implantable medical device comprising: a graft having a proximal end and a distal end; a first stent, the first stent being an endmost stent disposed at the proximal end of the graft; and a second stent adjacent to the first stent;
5 wherein each of the first and second stents comprises a plurality of proximal peaks and distal valleys, adjacent peaks and valleys being connected by struts; the graft covers at least a majority of each of a plurality of interstices between peaks of the first stent; a strut of the second stent is shorter than a strut of the first stent; and a peak of the second stent is nested between valleys of the first
10 stent.

In embodiments, the first and second stents are longitudinally separated.

Preferably, first and second struts adjoining the nested peak of the second stent are shorter than neighbouring first and second struts adjoining the adjacent valleys of the first stent.

15 In some embodiments, the second stent is configured to produce a lower radial force than the first stent.

In some embodiments, the graft comprises a scallop at its proximal end.

In some embodiments, the graft further comprises a fenestration, the fenestration being located closer to the distal end of the graft than the second
20 stent is and disposed adjacent to the second stent. Preferably, the struts and apices of the second stent form a ring and at least a majority of the struts of the second stent are shorter than a first strut of the first stent. Preferably, the struts and apices of the first stent form a ring and every strut of the second stent is shorter than every strut of the first stent.

25 Preferably, a plurality of peaks of the second stent are nested between valleys of the first stent. The nesting is preferably radially symmetric. Preferably, the plurality of nested peaks of the second stent includes at least first and second neighbouring peaks of the second stent each nested under a respective peak of the first stent. Preferably, at least a majority of the peaks of the second stent are
30 nested between valleys of the first stent. More preferably, each peak of the second stent is nested between valleys of the first stent. More preferably, each peak of the second stent is nested between a respective pair of valleys of the first stent.

In some embodiments, first and second struts adjoining each nested peak of the second stent are shorter than first and second struts adjoining the adjacent valleys of the first stent.

5 In some embodiments, the proximal end of the graft includes first and second circumferential regions, the first circumferential region having a scallop.

In embodiments, the first stent comprises a plurality of stent units including first and second stent units, each stent unit comprising first and second struts connected by a proximal apex. Each proximal apex of the first stent may be a peak of the first stent. Each valley of the first stent may be a distal apex formed
10 by adjoining stent units of the first stent.

The proximal apex of the first stent unit may be more rounded than the proximal apex of the second stent unit.

The plurality of stent units may include at least one scallop unit and at least one body unit, wherein each scallop unit has a proximal apex located at the
15 scallop and each body unit has a proximal apex located in the second circumferential region. The first stent unit is preferably a scallop unit of the at least one scallop unit and the second stent unit is preferably a body unit of the at least one body unit.

The plurality of stent units preferably includes at least one scallop unit and
20 at least one supporting unit, wherein the proximal apex of each scallop unit is located at the scallop and the proximal apex of each supporting unit is located in the second circumferential region.

The first and second struts of each of the at least one scallop unit are preferably shorter than the first and second struts of each of the at least one
25 supporting unit.

The proximal apex of each of the at least one scallop unit may be disposed proximally of a distal end of the scallop and uncovered by graft material.

The plurality of stent units may include a plurality of scallop units and at least one body unit, wherein each scallop unit has a proximal apex located at the
30 scallop and each body unit has a proximal apex located in the second circumferential region.

Additionally, the device may comprise any of the optional features of the first and second aspects, wherein reference to the stent is to be taken as

reference to the first stent.

In some embodiments, the device is configured for implantation into a curved lumen. In embodiments, the graft is a tubular graft.

5 In embodiments, the device includes a first stent around the graft. The first stent may be the first stent according to any preceding statement.

10 In some embodiments, the first stent has a length from a first end to a second end, wherein the length of the first stent increases in both circumferential directions from an inner curve region of the device and provides the first stent with a wedge shape. The first end of the first stent may be adjacent to the proximal end of the graft.

The proximal end of the graft may be slanted with respect to a sidewall of the graft. The proximal end of the graft may form an obtuse angle with respect to the sidewall at the inner curve region.

15 In embodiments, the inner curve region of the device is configured to be deployed on the inside of a curve of a lumen.

Additionally, the device may comprise any of the optional features of the fourth aspect.

The device of any preceding aspect may be referred to as a stent graft.

The graft is in the form of a tubular graft body.

20 In embodiments, the device is a stent graft for deployment in the aortic arch.

The graft of any preceding aspect may comprise a fenestration provided in a side wall of the graft.

25 In embodiments, the first end of the graft is proximal and the second end of the graft is distal.

The fenestration may have a proximal edge connecting proximal ends of two sides of the fenestration. The proximal edge preferably includes at least a portion that is substantially perpendicular to the longitudinal axis of the graft.

30 The device of any preceding aspect may comprise a plurality of expandable stent rings arranged along a length of tubular graft material of the graft. The plurality of expandable stent rings may include at least a proximal stent ring at or near a proximal end of the tubular graft material and a distal stent ring at or near a distal end of the tubular graft material, and at least one intermediate stent ring between the proximal stent ring and the distal stent ring.

The proximal stent ring may be the first stent of any preceding aspect. One of the at least one intermediate stent ring may be the second stent of any preceding aspect. The distal stent ring may be an additional stent, being the distally endmost stent of the device.

5 The at least one intermediate stent ring may include a fenestration-supporting stent ring. In embodiments, the fenestration-supporting stent ring is a zig-zag stent having a plurality of proximal apices and a plurality of distal apices, the proximal and distal apices connected to each other by a plurality of stent struts extending therebetween. In embodiments, the proximal apices of the
10 fenestration-supporting stent ring form peaks and the distal apices of the fenestration-supporting stent ring form valleys.

In some embodiments, at least one of the distal apices of the fenestration-supporting stent ring is a fenestration-supporting apex. The fenestration-supporting apex preferably has a larger radius of curvature than the proximal
15 apices of the fenestration-supporting stent ring.

In a preferred embodiment, the fenestration is provided between two struts of the fenestration-supporting stent ring, the combination of two struts and the fenestration-supporting apex of the fenestration-supporting stent ring defining two sides and a distal end of the fenestration.

20 In a particular embodiment, the fenestration is configured for alignment with a junction of the left subclavian artery and for deployment of a side-branch therethrough.

The fenestration may be aligned with a lumen of an internal branch graft located within a lumen of the stent graft. The internal branch graft may extend
25 from the fenestration within the lumen of the stent graft in a distal direction.

Additionally, the device may comprise any of the optional features of the sixth and seventh aspects.

According to a sixth aspect of the invention, there is provided a stent graft for deployment in the aortic arch including: a plurality of expandable stent rings
30 arranged along a length of tubular graft material, the plurality including at least a proximal stent ring at or near a proximal end of the tubular graft material and a distal stent ring at or near a distal end of the tubular graft material, and at least one intermediate stent ring between the proximal stent ring and the distal stent

ring; at least one fenestration provided in a side wall of the tubular graft material, the fenestration configured for alignment with a junction of the left subclavian artery and for deployment of a side-branch therethrough; wherein at least one intermediate stent ring is a fenestration-supporting stent ring, wherein the
5 fenestration-supporting stent ring is a zig-zag stent having a plurality of proximal apices and a plurality of distal apices, the proximal and distal apices connected to each other by a plurality of stent struts extending therebetween, wherein at least one of the distal apices is a fenestration-supporting apex having a larger radius of curvature than the proximal apices; wherein at least one fenestration is
10 provided between two struts of the fenestration-supporting stent ring, the combination of two struts and the fenestration-supporting apex of the fenestration-supporting stent ring defining two sides and the distal end of the fenestration; and wherein the fenestration has a proximal edge connecting the proximal ends of the two sides of the fenestration, the proximal edge including at
15 least a portion that is substantially perpendicular to the longitudinal axis of the stent graft.

Preferably, a sealing stent ring is provided adjacent to the proximal edge of the fenestration.

In embodiments, the sealing stent ring is a zig-zag stent having proximal
20 and distal apices, and optionally the proximal edge of the fenestration does not extend proximally of the distal apices of the sealing stent ring.

In some embodiments, only a single fenestration is provided in the side wall of the tubular graft material.

The fenestration is preferably aligned with and distal of a scallop at the
25 proximal end of the stent graft, a sealing zone being provided therebetween.

The fenestration supporting stent ring may be arranged around the tubular graft material at an angle such that the fenestration-supporting apex is located proximally of the circumferentially opposite distal apices of the fenestration-supporting stent ring.

30 In a preferred embodiment, the tubular graft material is tapered at its proximal end, wherein the fenestration-supporting stent ring is angled in the tubular graft body at an angle that matches the angle of the taper of the proximal end of the tubular graft material.

A plurality of the distal apices may have a larger radius of curvature than the proximal apices. It may be that all of the distal apices have a larger radius of curvature than the proximal apices.

5 Preferably, at least the fenestration-supporting apex has a radius of curvature of 2 mm to 4.5 mm, most preferably about 3.75 mm. The distal apices of the fenestration supporting stent ring may all have a radius of curvature of 2 mm to 4.5 mm, more preferably about 3.75 mm. Preferably, some or all of the proximal apices of the fenestration-supporting stent ring have a radius of curvature of 0.5 mm to 1.5 mm, most preferably about 0.75 mm.

10 A preferred embodiment of the stent graft includes a branch graft extending distally from the fenestration and internally of the tubular graft material.

The branch graft may be angled with respect to the tubular graft material of the stent graft such that as the branch graft extends distally it also extends laterally from the fenestration. The branch graft is preferably angled by an angle
15 in the range of 5 to 45 degrees, as measured from the central longitudinal axis of the stent graft, most preferably by an angle of about 16 degrees.

Preferably, the branch graft has a proximal portion having a proximal longitudinal axis and a distal portion having a distal longitudinal axis, wherein the proximal longitudinal axis of the proximal portion intersects with a longitudinal
20 axis of the stent graft at an acute angle, and wherein the distal longitudinal axis of the distal portion intersects with a longitudinal axis of the stent graft at an acute angle, the acute angle between the distal longitudinal axis and the longitudinal axis of the stent graft being smaller than the acute angle between the proximal longitudinal axis and the longitudinal axis of the stent graft.

25 In a preferred embodiment, a most proximal portion of the branch graft is generally frustoconical and a most distal portion of the branch graft is cylindrical. The most proximal portion of the branch graft may be the proximal portion recited above and the most distal portion of the branch graft may be the distal portion recited above.

30 According to a seventh aspect of the invention, a stent graft is provided for deployment in the aortic arch including: a plurality of expandable stent rings arranged along a length of tubular graft material, the plurality including at least a proximal stent ring at or near a proximal end of the tubular graft material and a

distal stent ring at or near a distal end of the tubular graft material, and at least one intermediate stent ring between the proximal stent ring and the distal stent ring; at least one fenestration provided in a side wall of the tubular graft material, the fenestration configured for alignment with a junction of the left subclavian artery and for deployment of a side-branch therethrough; wherein the fenestration is aligned with a lumen of an internal branch graft located within the lumen of the stent graft; wherein the internal branch graft extends from the fenestration within the lumen of the stent graft in a distal direction.

The internal branch graft may be angled within the lumen of the stent graft such that as the internal branch graft extends distally it also extends laterally from the fenestration. The internal branch graft is preferably angled by an angle in the range of 5 to 45 degrees, as measured from the central longitudinal axis of the stent graft, most preferably by an angle of about 16 degrees.

Preferably, the internal branch graft has a proximal portion having a proximal longitudinal axis and a distal portion having a distal longitudinal axis, wherein the proximal longitudinal axis of the proximal portion intersects with a longitudinal axis of the stent graft at an acute angle, and wherein the distal longitudinal axis of the distal portion intersects with a longitudinal axis of the stent graft at an acute angle, the acute angle between the distal longitudinal axis and the longitudinal axis of the stent graft being smaller than the acute angle between the proximal longitudinal axis and the longitudinal axis of the stent graft.

In a preferred embodiment, a most proximal portion of the internal branch graft is generally frustoconical and a most distal portion of the internal branch graft is cylindrical. The most proximal portion of the internal branch graft may be the proximal portion recited above and the most distal portion of the internal branch graft may be the distal portion recited above.

In embodiments, the length of tubular graft material forms a graft having a proximal end and a distal end. In embodiments, the device has a first stent. The first stent may be an endmost stent disposed at the proximal end of the graft.

The first stent may be the proximal stent ring.

In some embodiments, the device comprises a second stent adjacent to and distal of the first stent. The second stent may be one of the at least one intermediate stent rings.

In embodiments, each of the first and second stents comprises a plurality of proximal peaks and distal valleys. In embodiments, adjacent peaks and valleys of each of the first and second stents are connected by struts.

5 Preferably, the graft covers at least a majority of each of a plurality of interstices between peaks of the first stent.

A peak of the second stent may be nested between valleys of the first stent. A strut of the second stent may be shorter than a strut of the first stent.

Additionally, the device may comprise any of the optional features of the fifth aspect.

10 In embodiments, the stent graft is an implantable medical device configured for implantation into a curved lumen. In embodiments, the stent graft is an implantable medical device including a tubular graft and a first stent around the graft. In embodiments, the tubular graft has a first end, a second end, and a sidewall.

15 The first stent may be the proximal stent ring, one of the at least one intermediate stent rings, or the distal stent ring.

The first stent has a length from a first to a second end. The length of the first stent may increase in both circumferential directions from an inner curve region of the device and provide the first stent with a wedge shape. The first end
20 of the first stent may be adjacent to the first end of the graft.

The first end of the graft may be slanted with respect to the sidewall. The first end of the graft may form an obtuse angle with respect to the sidewall at the inner curve region.

In embodiments, the first end of the graft is the proximal end and the
25 second end of the graft is the distal end. In embodiments, the inner curve region is configured to be deployed on the inside of a curve of a lumen. The lumen may be the aortic arch.

Additionally, the device may comprise any of the optional features of the fourth aspect.

30 In embodiments, the proximal stent ring comprises a plurality of stent units including first and second stent units, each stent unit comprising first and second struts connected by a proximal apex. The proximal apex of the first stent unit may be more rounded than the proximal apex of the second stent unit.

In some embodiments, the proximal end of the tubular graft material includes first and second circumferential regions, the first circumferential region having a scallop. The proximal stent ring may be disposed at the proximal end of the tubular graft material.

5 The plurality of stent units may include at least one scallop unit and at least one body unit, wherein each scallop unit has a proximal apex located at the scallop and each body unit has a proximal apex located in the second circumferential region. The first stent unit may be a scallop unit of the at least one scallop unit and the second stent unit may be a body unit of the at least one
10 body unit.

 The plurality of stent units may include at least one scallop unit and at least one supporting unit, where the proximal apex of each scallop unit is located at the scallop and the proximal apex of each supporting unit is located in the second circumferential region, Preferably, the first and second struts of each of
15 the at least one scallop unit are shorter than the first and second struts of each of the at least one supporting unit. The proximal apex of each of the at least one scallop unit may be disposed proximally of a distal end of the scallop and uncovered by graft material.

 The plurality of stent units may include a plurality of scallop units and at
20 least one body unit, wherein each scallop unit has a proximal apex located at the scallop and each body unit has a proximal apex located in the second circumferential region.

 Additionally, the device may comprise any of the optional features of the first and second aspects, wherein reference to the stent is to be taken as
25 reference to the proximal stent ring.

 According to a seventh aspect of the invention, there is provided an implantable medical device configured for implantation into a curved lumen, the device including a tubular graft; the graft having a first end, a second end, and a sidewall; wherein the first end of the graft is slanted with respect to the sidewall
30 and forms an obtuse angle with respect to the sidewall at an inner curve region of the device; wherein the inner curve region is configured to be deployed on the inside of a curve of a lumen.

 Additionally, the device may comprise any of the optional features of the

preceding aspects.

According to another aspect of the invention, there is provided a method comprising: inserting a device according to any preceding aspect into the vasculature of a human; and deploying the device into the aortic arch.

5 The method may further comprise deploying the device into the aortic arch such that a distal end of the scallop is aligned between the subclavian and carotid arteries.

According to another aspect of the invention, there is provided a deployment system configured to deploy the device of any preceding aspect,
10 including: an introducer configured to deploy the device in a curved lumen; the device being mounted on the introducer such that the inner curve region is arranged to be deployed on the inside of a curve of a lumen. The introducer preferably includes a pre-curved cannula.

According to another aspect of the invention, there is provided a method of
15 deploying a device according to any preceding aspect in a curve of a lumen, optionally using the deployment system recited above, the method including deploying the device with the inner curve region on the inside of the curve of the lumen.

The method preferably includes deploying the wedge-shaped stent of the
20 device so that the first end of the wedge-shaped stent and/or the first end of the graft deploys substantially perpendicular to the curve of the lumen. The lumen may be the aortic arch, preferably between the ascending and descending aorta.

According to another aspect of the invention, there is provided a method
25 comprising: inserting a device according to any preceding aspect into the vasculature of a human; and deploying the device into the aortic arch.

The method may further comprise deploying the device into the aortic arch such that the stent having one or more nested peaks is positioned between the subclavian and carotid arteries.

BRIEF DESCRIPTION OF THE DRAWINGS

30 Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a view of a proximal portion of a prosthesis according to an

embodiment of the invention;

Figures 2 and 3 are schematic diagrams showing front and profile views of the prosthesis of Figure 1;

5 Figures 4 and 5 are enlarged schematic diagrams of portions of the prosthesis of Figure 1;

Figure 6 shows the prosthesis of Figures 1-5 in a partially deployed state, as it would be when placed within the aortic arch of a patient;

Figure 7 shows the prosthesis of Figures 1-6 in a fully deployed state, as it would be when deployed within the aortic arch of a patient;

10 Figure 8 is a schematic diagram of a stent according to a second embodiment of the invention;

Figure 9 is a second schematic diagram of the stent of Figure 8;

Figure 10 is a view of a proximal portion of a prosthesis including the stent of Figures 8 and 9;

15 Figures 11 and 12 show front and profile views of the second embodiment of the prosthesis as shown in Figure 10.

DETAILED DESCRIPTION

A number of embodiments are described in detail below.

20 In this disclosure, the terms 'proximal' and 'distal' refer to opposite directions with respect to a prosthesis. 'Proximally' means in a direction from a distal toward a proximal end of the prosthesis and 'distally' means in a direction from a proximal toward a distal end of the prosthesis.

25 The particular embodiments described below are configured such that the proximal end is in use closest to the patient's heart, meaning that in these embodiments the term 'proximal' refers to a location which in use is closest to the patient's heart and the term distal refers to a location which in use is farthest from a patient's heart. However, other embodiments can be configured such that the distal end is in use closest to the patient's heart.

30 Figures 1-7 show an endoluminally implantable medical device in the form of a prosthesis 1. In this embodiment, the prosthesis 1 is configured for implantation into a curved lumen, in this embodiment into the aortic arch as is described below. In other embodiments, the prosthesis 1 can be configured for

implantation into lumens with different topologies, curved or not. Except as otherwise indicated, the prosthesis is described in an expanded condition. The prosthesis 1 comprises a graft in the form of a tubular graft body 10 including a sidewall 4 with an internal lumen 2 therethrough. The graft body 10 has a proximal end 6 and a distal end 7. The graft body 10 in this embodiment is made of a woven polyester fabric, but in other embodiments it can be made of any suitable flexible and biocompatible material.

With reference to Figures 2 and 3, in this embodiment, the prosthesis 1 includes a series of stents 20, 50, 70, 80, 90, which are described in detail below. The stents are distributed longitudinally along the graft body 10. Each of the stents comprises a plurality of peaks and valleys connected in a zig-zag arrangement to form a ring around the graft body 10, on the inside or outside of the graft body 10, or within the graft body 10 itself, with adjacent peaks and valleys being connected by struts. The peaks and valleys are also referred to as apices. It will be understood that the term 'peaks' generally refers to one set of apices (proximal or distal) and the term 'valleys' refers to the other set of apices. In the embodiments described, the term 'peaks' is used for proximal apices and the term 'valleys' is used for distal apices; however, it will be appreciated that in other embodiments the terms can be used the other way around. In the embodiments shown in the figures, each stent is a self-expanding stent, some of which are made of stainless steel and some of which are made of Nitinol. However, other materials or forms of stent can also be used. For example, in other embodiments, any of the stents can be made of stainless steel or a shape memory alloy, such as Nitinol. In some embodiments, the stents can be balloon-expandable. Other embodiments of the prosthesis 1 can include any combination of stents from the group of stents 20, 50, 70, 80, and 90.

The stents 20, 50, 70, 80, 90 are fastened to the graft body 10 with stitches 8, as shown in Figure 1. The stitches 8 in this embodiment are made of braided polyester and monofilament polypropylene suture. In other embodiments, any other suitable forms of attachment or stitch materials can be used for any of the stents.

A scallop 5 is located at the proximal end 6 of the graft body 10, as shown in Figure 1. The scallop 5 is a cut-out or bight in the material of the graft body 10.

The scallop 5 is sized and shaped so that, when the prosthesis 1 is deployed at a target region in a vessel of a human, the scallop 5 accommodates the opening of an adjacent branch vessel. That is, the scallop 5 is sized and shaped so that its edge forms a seal around the opening of a branch vessel without occluding the opening with graft material. In this embodiment, once the prosthesis 1 is in its fully deployed state within the aortic arch of a patient, the graft material at the edge of the scallop 5 will be adjacent to the perimeter of the opening of the left common carotid artery. In the fully deployed state, a distalmost part of the scallop 5 is positioned between the openings of the left subclavian artery (LSA) and the left common carotid (LCC) artery, as shown in Figure 7. The scallop 5 in this embodiment tapers in width from a maximum width at a proximal end to a minimum width at a distal end. A transverse edge at the distal end of the scallop 5 in this embodiment is substantially parallel to the edge of the graft material at the distal end 7 of the graft body 10. In other embodiments it can be more curved or angular in shape than shown. In some embodiments, the scallop 5 can be formed of a single curve. In some embodiments, the scallop 5 can be horseshoe-shaped.

The dimensions of the scallop 5 can be tailored according to the target vessel. As shown in Figure 2, in this embodiment the scallop 5 has a maximum width of 30mm, at its proximal end, and a minimum width of 25mm, at its distal end. The scallop 5 in this embodiment has a depth of 14mm from its distal end to its proximal end, the proximal end of the scallop 5 being at the proximal end 6 of the graft body 10, as shown in Figure 3. In other embodiments, the width and depth of the scallop 5 can be any suitable size to accommodate the opening of a target vessel. For embodiments intended to be deployed in the aortic arch, it is preferred that scallop 5 is configured to allow for a proximal sealing zone of 10-20mm, where the proximal sealing zone is the zone between the scallop 5 and a nearest fenestration, in this embodiment fenestration 60 described in detail below. Although stent 20 at the level of the scallop provides some sealing, the proximal sealing zone provides the majority of the sealing. The size of the sealing zone can be varied to be suitable for the distance between the vessels in the patient. The sealing zone is preferably at least 10mm, more preferably at least 15mm. In this embodiment the sealing zone is 16mm.

Returning to Figure 1, at the proximal end 6 of the prosthesis 1 the graft material forms a proximal edge 16, which runs around the circumference of the graft body 10. The scallop 5 defines first and second circumferential regions 12,14 at the proximal end 6. The first circumferential region 12 coincides and is coterminous with the scallop 5 and the second circumferential region 14 makes up the remainder of the circumference such that the first and second circumferential regions make up a complete circumference of the prosthesis. The first circumferential region 12 is smaller than the second circumferential region 14, meaning the second circumferential region 14 makes up a majority of the circumference of the graft at the proximal end 6.

A first stent of the prosthesis 1 is a proximal stent 20, which is an endmost stent disposed at the proximal end 6 of the graft body 10. The proximal stent 20 comprises sets of bends or apices 30 connected by struts 40. The apices 30 of the proximal stent 20 include a set of proximal apices 36 and a set of distal apices 37, as shown in Figure 4. The set of proximal apices 36 includes scallop apices 32, which are located in the first circumferential region 12 (in other words at the scallop 5), and body apices 34, which are located in the second circumferential region 14 (in other words circumferentially outside the scallop 5).

The proximal stent 20 can therefore be said to comprise a plurality of stent units, each stent unit comprising first and second struts 40 connected by a proximal apex 36. Neighbouring stent units are connected by distal apices 37 to form a stent ring. The plurality of stent units includes scallop units and body units, where each scallop unit has a proximal apex located at the scallop (in the first circumferential region 12) and each body unit has a proximal apex located in the second circumferential region 14. Each scallop unit comprises a pair of struts 40 connected by a scallop apex 32. Similarly, each body unit comprises a pair of struts 40 connected by a body apex 34. The body units that are adjacent to the scallop, which support the scallop, and in particular support the sides of the scallop 5, are referred to as supporting units. Of the supporting units, the struts that are adjacent to the scallop run along the edge of the scallop. A supporting unit is disposed on each side of the scallop 5.

In the embodiment shown, the proximal stent 20 is an internal stent; in other words, it is disposed around an interior surface of the graft body 10. However, in

other embodiments, it can be an external stent or it can be disposed within the thickness of the graft material.

In the particular embodiment shown, the proximal stent 20 has twenty-eight apices 30, fourteen of which are proximal apices 36 and fourteen of which are distal apices 37, although in practice this can be varied for example in dependence on the prosthesis diameter. In other embodiments there can be any suitable number of apices 30. It is preferred that there are the same number of proximal apices 36 and distal apices 37, but it is not necessary. Similarly, of the fourteen proximal apices 36 in the embodiment shown, there are three scallop apices 32 and eleven body apices 34; however, the number of scallop apices can be varied based on the size of the scallop. In other embodiments there can be any number of scallop apices 32 and any number of body apices 34, provided of course that the scallop apices can be located within the first circumferential region, that is at the scallop 5. It is preferred, however, that there are more body apices 34 than there are scallop apices 32.

The body apices 34 are all disposed at the proximal edge 16 of the graft material, as best shown in Figure 1. It is preferred that all the body apices 34 are disposed at the proximal edge 16 of the graft material in order to most effectively seal the proximal end 6 of the graft body 10. However, in other embodiments, the body apices 34 can be variously disposed further distally or proximally than shown.

The scallop apices 32 are disposed distally of the body apices 34 that are adjacent to the scallop 5. In particular, it has been found to be beneficial that the scallop apices 32 do not extend all the way to the most proximal end of the graft body 10. This arrangement reduces the stent struts and apices in the scallop 5 that might otherwise impinge upon the vessel wall at the location of the branch vessel and thereby reduces the possibility of trauma or damage to the vessel. In this manner, the proximal stent 20 can itself be said to include a scallop at its proximal end in the region of the scallop 5 in the graft body 10.

The set of distal apices 37 are all disposed distally of the distal end of, in particular of a distalmost edge of, the scallop 5, as can be seen in Figures 2, 3, and 4. It is preferred that all of the distal apices 37, or at least a majority thereof, are disposed at least longitudinally level with, or distally of, a distal end of or a

distalmost point on the scallop 5, which improves the ability of the proximal stent 20 to seal the full perimeter of the scallop 5. In this embodiment, the distal apices 37 are also all aligned with one another. In this embodiment, the longitudinal positions of the distal apices 37 vary around the circumference of the graft body 10. In particular, the distal apices 37 are most distal at an inner curve region 18 of the prosthesis 1, where the inner curve region 18 is the region configured to be deployed in the inside of the curve of the body lumen. The distal apices 37 linearly become more proximal in both circumferential directions away from the inner curve region 18 such that they are most proximal diametrically opposite the inner curve region 18. In this way, the distal apices describe an ellipse which lies in a plane which is non-perpendicular to the longitudinal axis of the prosthesis.

In other embodiments, the distal apices can all be longitudinally level.

Furthermore, in other embodiments, the distal apices can be unaligned.

The scallop apices 32 are located at the distal end of the scallop 5. Referring again to Figures 1 and 4, the body apices 34 are all covered, that is to say overlapped, by graft material. The scallop apices 32 in the embodiment shown, however, extend proximally of the proximal edge 16 of the graft body 10 at the scallop 5, in other words extend proximally of the distal end of the scallop, uncovered by the graft material. As a result, a majority, but not all, of the proximal stent 20 is covered by graft material. Nevertheless, the graft covers at least a majority of each of the interstices between the peaks of the proximal stent 20. In other words, the spaces between struts 40 adjoining neighbouring proximal apices 36 of the proximal stent 20 are each substantially or completely overlapped by graft material.

In some embodiments, the apices 30 of the proximal stent 20 may not extend beyond the graft material (that is to say that the proximal stent may be entirely covered by graft material). This can be the case for example where the proximal stent is made of Nitinol. However, it has been found to be beneficial in some embodiments such as the embodiment of Figure 1 to incorporate scallop apices 32 that extend beyond the graft material, the reasons for which are explained below.

As described above, the apices 30 of the proximal stent 20 are connected by struts 40. Each of the scallop apices 32 is connected to neighbouring distal

apices 37 by first and second scallop apex struts 42. Similarly, the body apices 34 are each connected to neighbouring distal apices 37 by first and second body apex struts 44.

5 In this embodiment, the struts 40 vary in length around the circumference of the proximal stent 20, creating a taller segment and a shorter segment of the stent. In particular, struts at the scallop are shorter than the struts adjacent to the scallop at each side. In other words, the first and second struts of each scallop unit are shorter than the first and second struts of each supporting unit.

10 The shorter scallop apex struts 42 reduce the volume of stent material at the scallop 5 to keep the scallop substantially clear. At the same time, the longer struts of the supporting units help to support and seal the prosthesis adjacent to the scallop.

15 The scallop apex struts 42 are preferably short to avoid, as far as possible, obstructing the scallop. However, in practice, it has been found that it is beneficial for a minimum strut length to be used to achieve improved flexibility and elasticity of the stent and avoid undesired plastic deformation in use, particularly in the region of a branch vessel. The minimum strut length depends on the dimensions of the target vessel and the material of the struts. The minimum strut length in some embodiments, such as the embodiment of Figure 20 1, results in the scallop apices 32 extending beyond the graft material, as shown in Figure 1. Despite this, at least a majority of each of the scallop units is overlapped by graft material. Furthermore, as indicated above, it should be appreciated that it is not necessary in all embodiments for the scallop apices to extend beyond the graft material. In some embodiments, for example where the 25 proximal stent is made of Nitinol, the minimum strut length is such that the scallop apices 32 can be positioned distally of the proximal edge 16 and distal end of the scallop and thereby be covered by graft material. In the embodiment shown, the strut length of the scallop units is 17mm.

30 The scallop apex struts 42 of the embodiment shown in Figures 1-7 are shorter than a majority of the body apex struts 44. In other embodiments, the scallop apex struts 42 are all shorter than any of the body apex struts 44. However, it is particularly beneficial that the scallop apex struts 42 are shorter than the body apex struts 44 that are adjacent to the scallop (in other words

those in the supporting units as described above). In some embodiments, the scallop apex struts 42 are shorter than just those pairs of body apex struts 44 adjacent to the scallop. In other words, it is particularly beneficial that the first and second struts of the scallop units are shorter than the first and second struts of the supporting units. In the embodiment shown, the scallop apex struts 42 are all the same length, but in other embodiments they can be of different lengths.

In this embodiment, the apices 30 are not uniform around the circumference of the proximal stent 20. Stents typically have apices of consistent radii of curvature around their circumference, which produce uniform radial forces around the stent. The proximal stent 20 in the embodiment shown, however, has apices 30 of different radii of curvature around its circumference. In particular, the proximal stent 20 includes at least one scallop unit with a proximal apex which is more rounded or has a greater radius of curvature than the proximal apex of at least one preferably substantially diametrically opposite body unit. In this embodiment, the scallop apices 32 all have a greater radius of curvature than each of the body apices 34. The increased roundedness of the scallop apices 32 better distributes the radial force exerted by the stent at those apices, making them blunter and reducing the vessel pressure/area, thereby reducing the potential traumatic or erosive effect of the scallop apices 32 on the tissue of the vessel wall. It may also assist with sealing.

In this embodiment, the scallop apices 32 are also more rounded than all the other apices 30 of the proximal stent 20. The less rounded body apices 34 and distal apices 37 relatively reduce the volume and increase the elasticity of the proximal stent 20. This effect is particularly beneficial in the region of the stent 20 circumferentially opposite the scallop 5, which in use is positioned at the interior of the curvature in the vessel. In this embodiment, the distal set of apices all have the same radius of curvature. Furthermore, in this embodiment, all the apices of the stent that are located in the second circumferential region have the same radius of curvature.

In the preferred embodiment shown in Figures 1-7, each of the scallop apices 32 has a radius of curvature of 1mm, each of the body apices 34 has a radius of curvature of 0.5mm, and each of the distal apices 37 has a radius of curvature of 0.5mm. It has been found to be particularly advantageous for the

scallop apices 32 to have a radius of curvature approximately double that of the body apices 34. In embodiments, the scallop apices may have 1.5 to 2.5 times the radius of curvature of the body apices 34. It has been found to be even more advantageous still for the scallop apices 32 to have a radius of curvature approximately double that of all the remaining apices 30 (namely the body apices 34 and the distal apices 37). In embodiments, the scallop apices may have 1.5 to 2.5 times the radius of curvature of the remaining apices.

It is to be noted that the scallop apices 32 need not all have the same radius of curvature in every embodiment. Similarly, the body apices 34 do not all need to have the same radius of curvature as one another. Similarly, the distal apices 37 do not all need to have the same radius of curvature in every embodiment.

In this embodiment, the proximal stent 20 has a proximal-distal length from a proximal end of the stent 20 to a distal end of the stent 20 which varies around the circumference of the prosthesis 1, as shown in Figure 3.

In particular, the length of the proximal stent increases in both circumferential directions from the inner curve region 18 of the prosthesis 1, providing the proximal stent 20 with a wedge shape.

Furthermore, the proximal end of the proximal stent 20 has a taper such that the longitudinal location of the first end of the stent increases in a proximal-distal direction in both circumferential directions from the inner curve region. In particular, the longitudinal location of the first end of the stent becomes more proximal in both circumferential directions from the inner curve region. The taper tapers away from the scallop 5.

In addition, in this embodiment the proximal end of the graft body (effectively the plane of the end of the graft body) is slanted with respect to the sidewall 4 (and the longitudinal axis of the graft body) so that it forms an obtuse angle with respect to the sidewall 4 at the inner curve region 18 at the proximal end of the graft body. In this embodiment, the proximal end of the graft body 10 aligns with the proximal end of the proximal stent 20 around at least a majority of the circumference of the proximal end of the graft body 10, in this embodiment around the entirety of the proximal end of the graft body 10 except for the scallop 5. In particular, the proximal end of the graft body 10 is substantially equidistant

from the proximal end of the proximal stent 20 around at least a majority of the circumference of the proximal end of the graft body 10, in this embodiment around the entirety of the proximal end of the graft body 10 except for the scallop 5. The majority of the proximal end 6 of the graft body 10 lies on a flat plane which is generally parallel to a plane on which the body apices 34 are arranged. In particular and as described above, in this embodiment, all of the body apices 34 are at the proximal edge 16 of the graft material, and in particular are about 1mm from the edge 16. The body apices can be slightly further spaced from the proximal edge of the graft material, but are preferably all within 2mm of the proximal edge of the graft material.

In more detail, among the struts 40, the body apex struts 44 vary in length around the circumference of the proximal stent 20, as shown in Figure 3. In this embodiment, pairs of body apex struts 44 nearer the scallop 5 are longer than those farther from the scallop 5, a pair of body apex struts 44 being two body apex struts 44 that meet at a common proximal apex 32, otherwise referred to as a stent unit. The length of each successive pair of body apex struts 44 is varied linearly so that the body apices 34 are arranged in a straight line. The body apices 34 nearest the scallop 5 extend farther proximally than those circumferentially opposite the scallop 5, creating the taper, shown in Figure 3 as an offset A. Figure 3 shows the tapered profile and wedge shape when the prosthesis 1 is viewed in profile. The proximal end 6 of the graft body 10 is also tapered in the second circumferential region 14 according to the same profile and taper. The lengths of the body apex struts 44 vary by equal increments to both sides of the scallop 5 so that the proximal stent 20 is bilaterally symmetric.

As can be seen in Figure 3, in this embodiment the taper at the proximal end of the proximal stent 20 comprises, in each circumferential direction from the inner curve region 18, the body apices 34 being offset from each other in the proximal-distal direction and being disposed in increasingly proximal locations. In this embodiment, all of the body apices 34 contribute to the taper; however, in other embodiments, one or more body apices 24 may be out of line while still retaining an overall taper. It is preferred that the taper comprises, in each circumferential direction from the inner curve region, at least three preferably adjacent apices at the first end of the first stent offset from each other in the

manner described. The offsets between adjacent body apices 34 are substantially the same to form a linear taper. In this embodiment, the taper, that is the offset A, is 15mm, which has been found to provide optimum performance. Preferably, the taper is from about 5mm to about 20mm, more preferably from about 10mm to about 20mm, most preferably from about 13mm to about 17mm.

With a stent-graft that has stents with struts of uniform length around its circumference, adjacent stents may interfere with one another in a curved section of a vessel. When such a stent-graft is deployed in a tortuous vessel, there is therefore a greater possibility that it will sit proud of the vessel wall – extending tangentially from the curvature of the vessel – leading to incomplete sealing and poor alignment within the vessel.

By contrast, the wedge shape of the proximal stent 20 accommodates the curvature of the prosthesis 1 when positioned in a curved vessel, such as the aortic arch. In its deployed state, the prosthesis 1 is oriented within the vessel so that the narrow end of the wedge shape is located at the interior of the curve of the vessel. The wedge shape and taper are configured so that, when the prosthesis 1 is deployed, the line formed by the body apices 34 – and also the proximal end of the graft body, in particular the proximal edge 16 of the graft body 10 in the second circumferential region 14 – deploys substantially perpendicularly to the curve of the vessel, as shown in Figure 7. In this way, the proximal stent 20 of the prosthesis 1 exerts against the vessel wall at an optimum angle, enabling the graft material of the prosthesis 1 to seal flush against the vessel wall.

In this embodiment, the proximal stent 20 has body apex struts 44 that vary in length from 19mm, at the pair of struts (or stent unit) circumferentially opposite the scallop 5, to 27mm, at the pairs of struts (or stent unit) nearest the scallop 5; the length of each pair of body apex struts 44 increasing by an increment of 2mm per successive body apex 34. The lengths of the body apex struts 44 that form the wedge shape can be tailored according to the length of the expected attachment area and the optimum angle of taper for the vessel geometry.

Figures 8, 9, and 10 show a further embodiment of the stent 20. This embodiment of the stent 20 is the same as the proximal stent 20 in Figures 1-7 in all aspects except the lengths of its struts 40. Figure 8 shows the variation in

length of the struts 40 around the circumference of the stent 20. In this embodiment, the body apex struts 44 of the stent 20 taper in length from 22mm, at the pairs of struts (or stent units) nearest a scallop apex 32, to 17mm, at the pair of struts (or stent unit) farthest from a scallop apex 32; the length of successive pairs of body apex struts 44 varying by an increment of 1mm per body apex 34. The body apices 34 are arranged along a line 116 and the distal apices 37 are arranged along a line 117. This creates a wedge shape profile in the stent 20 as shown in Figure 9. By comparison to the proximal stent 20 of Figures 1-7, the proximal end of the stent in this embodiment can provide a shallower taper or offset A in the wedge shape of the stent 20. Figure 10 shows the further embodiment of the proximal stent 20 disposed at the proximal end of the prosthesis 1. In all other aspects, the prosthesis 1 of Figure 10 is the same as that of Figures 1-7.

Other embodiments of the stent 20 can have body apex struts 44 of any length suitable for the target vessel.

In other embodiments, the variation in length between the body struts 44 can be non-linear. Furthermore, it is not excluded that a proportion of the body apices 34 can be variously disposed farther proximally or distally, and/or a proportion of the body apex struts 44 can be variously shorter or longer than the described arrangement while still providing a generally wedge-shaped stent and taper. It has been found to be particularly advantageous for the proximally endmost stent of the prosthesis 1 to utilise a wedge shape. However, any of the other stents of the prosthesis 1 can also, or alternatively, have a wedge shape.

It should be appreciated that some advantages provided by features of the proximal stent 20 can be achieved independently of any or all of the other components of the prosthesis 1, for example without the scallop 5 and fenestration 60.

Similarly, it should be appreciated that some advantages achieved by the variation in roundedness of the apices 30 of the proximal stent 20 can be realised without a variation in the lengths of the struts 40 of the proximal stent 20. Equally, some advantages achieved by the variation in length of the struts 40 can be realised without a variation in the roundedness of the apices 30. Similarly, some advantages achieved by the difference in length between the scallop apex

struts 42 and body apex struts 44 can be realised without a variation in length between the body apex struts 44. Similarly, some advantages achieved by the wedge shape of the proximal stent 20 can be achieved without scallop apex struts 42 or scallop apices 34.

5 With reference to Figures 2, 3, and 4, the prosthesis also includes a nested (or sealing) stent 50, disposed distally of and adjacent to the proximal stent 20. The nested stent 50 has a set of proximal apices 56 and a set of distal apices 57 connected by struts 54. The struts 54 and apices 56,57 form a series of peaks and valleys. In contrast to the proximal stent 20, the nested stent 50 is radially
10 symmetric. In particular, in the embodiment shown, the nested stent 50 has struts 54 of uniform length and apices 56,57 with uniform radius of curvature around its circumference. In this embodiment, in contrast to the other stents of the prosthesis 1, the nested stent 50 is made of Nitinol. However, as described above, in other embodiments the nested stent 50 can be made of stainless steel
15 or any other suitable stent material. Further, because the nested stent 50 in this particular embodiment is made of Nitinol it is correspondingly also made of a thinner gauge of wire than the stainless steel proximal stent 20 is, though this is not necessary in every embodiment.

 The proximal apices 56 of the nested stent 50 are positioned so that each
20 peak of the nested stent 50 is nested between a respective pair of valleys of the proximal stent 20 (in other words between neighbouring pairs of distal apices 37). In this way, the nested stent 50 provides increased flexibility and increased control of the radial force, and can improve sealing at the proximal portion of the prosthesis 1 for example by reducing graft infolding. This can allow for a proximal
25 stent 20 with fewer apices to be used which can be better for the patient. The nested stent 50 can also enable better control of the deployment of the prosthesis 1 and help the prosthesis 1 to keep its structure after having been crimped in a sheath for delivery.

 In other embodiments, only some of the proximal apices 56 of the nested
30 stent 50 are nested between distal apices 37 of the proximal stent 20, although preferably at least a majority of the proximal apices are nested between distal apices of the proximal stent 20 and it is preferred that the nesting is radially symmetric, as it is in the embodiment of Figure 1. Similarly, in some

embodiments, two or more proximal apices 56 of the nested stent 50 can be nested between the same pair of distal apices 37 of the proximal stent 20. However, it has been found to be particularly advantageous for each of the proximal apices 56 to be nested between a respective pair of distal apices 37 of the proximal stent 20.

The struts 54 of the nested stent 50 are shorter than the struts 40 of the proximal stent 20. In this embodiment every strut of the nested stent 50 is shorter than every strut of the proximal stent 20. In other embodiments, not every strut of the nested stent 50 needs to be shorter than every strut of the proximal stent 20 but preferably at least a majority of the struts of the nested stent are shorter than a first strut, preferably a body apex strut, of the proximal stent 20.

As described above, in the embodiment shown the nested stent 50 is made of Nitinol and the proximal stent 20 is made of stainless steel. As a result, the nested stent 50 in this particular embodiment produces a generally lower radial force than the proximal stent 20. However, in other embodiments, either or both of the nested stent 50 and proximal stent 20 can be made of stainless steel or Nitinol, or any other suitable stent materials.

It should be appreciated that, in other embodiments, any other stents of the prosthesis 1 could also or alternatively have a stent nested with them in this way. In particular, some advantages provided by the nested configuration can be achieved without features of the proximal stent 20 such as the variation in roundedness of the apices 30 or the variation in the length of the struts 40. A regular zig-zag stent, for example, disposed at any location in a graft, could similarly be configured in a nested arrangement with a nested stent as described above. This nesting is particularly advantageous for stents that have a sealing function (that is, those stents that act to seal the graft material against the vessel wall).

The graft body 10 also includes a fenestration 60. As shown in Figure 1, the fenestration 60 is circumferentially aligned with and distal of the scallop 5. The fenestration 60 is sized and positioned so that, when the prosthesis 1 is in its fully deployed state, the fenestration 60 will accommodate the opening of a branch vessel. In the embodiment shown, the prosthesis 1 is designed to be deployed in

the aortic arch, at which point the fenestration 60 aligns with the opening of the left subclavian artery.

In the aortic arch particularly, the landing zone available for a stent-graft is challengingly small. In particular, the distance between the left subclavian and left common carotid arteries, and therefore the distance available between the scallop 5 and fenestration 60, is very short. In the embodiment shown in Figures 1-7, the length between the scallop 5 and the fenestration 60 is 16mm. In other embodiments, the length between the scallop 5 and fenestration 60 could be any value suitable to accommodate the distance between openings of neighbouring branches in the target vessel. As described above, for embodiments intended to be deployed in the aortic arch, it is preferred that the scallop 5 is configured to allow for a proximal sealing zone of 10-20mm.

The fenestration 60 is triangular or trianguloid (in other words substantially triangular) in shape. In this embodiment, the fenestration 60 resembles a triangle with rounded corners: it is formed by three substantially straight edges or sides 64,66,68 which are joined by three rounded corners 63,65,67. The fenestration 60 is oriented so that it has a top proximal side 66 which is aligned transverse to the longitudinal axis of the graft body 10 (which extends between the proximal end 6 and the distal end 7). The proximal side 66 includes at least a portion that is substantially perpendicular to the longitudinal axis of the graft body 10. The proximal side 66 connects the proximal ends of the two remaining sides 64,68, which converge to a distal apex at the distal end 63 of the fenestration 60. The flat top of the fenestration 60, formed by the proximal side 66, allows a greater proportion of the fenestration area to be positioned closer to the scallop 5 than would be the case for, for example, a circular or elliptical fenestration. The U-shape formed by the converging sides 64,68 also acts as a funnel or guide that aids in the positioning of an introducer assembly into the fenestration 60 for cannulation of a side branch therethrough.

In some embodiments, the graft body 10 can include a fenestration 60 and not a scallop 5. In other embodiments, the graft body 10 can include a scallop 5 and not a fenestration 60.

The nested stent 50 is provided adjacent to the proximal edge 66 of the fenestration 60. In practice, it is disposed proximally of the fenestration 60,

positioned so that the distal apices 57 of the nested stent 50 are disposed adjacent to the proximal edge 66 of the fenestration 60. As with the scallop apices 32, it is preferred that the distal apices 57 are located adjacent to the edge of the graft material without extending across or into the fenestration 60, in order to maximise use of the limited sealing zone available, and maximise sealing in this sealing zone, without occluding the branch vessel opening with stent material. Therefore, in the preferred embodiment shown, the distal apices 57 do not extend beyond the graft material at the proximal edge 66 of the fenestration 60. Equally, the proximal edge 66 of the fenestration 60 does not extend proximally of the distal apices 57 of the nested stent 50.

The prosthesis 1 includes an internal branch graft 3, as shown faintly in Figures 2 and 3, and highlighted in Figures 11 and 12 (which show the second embodiment of the prosthesis 1 of Figure 10, the graft 10 of which, by comparison to the first embodiment of Figures 1-7, has a shallower taper at the proximal end 6 but is otherwise identical). The branch graft 3 extends from the fenestration 60 distally inside the graft body 10. In other words, the internal branch graft 3 extends from the fenestration within the lumen 2 of the stent graft in a distal direction. The branch graft 3 is generally tubular, comprising an internal lumen in communication with the fenestration 60 and the internal lumen 2 of the graft body 10. In this embodiment, the branch graft 3 is made of a woven polyester fabric, but other embodiments can be made of any suitable flexible and biocompatible material. The internal branch graft 3 is provided to assist in guiding a catheter between the internal lumen 2 of the graft body 10 and a branch vessel adjacent to the fenestration 60. In use, a cannula and/or extension graft may be introduced through either the proximal or distal end of the internal branch graft 3 in order to deploy an extension graft in the branch vessel adjacent to the fenestration. For example, a cannula carrying an extension graft may be introduced via the subclavian artery, and from there through the fenestration and the proximal end of the internal branch graft and into the internal branch graft 3. The extension graft can then be deployed so that it spans from the internal branch graft 3 to the branch vessel. In another embodiment, the cannula carrying the extension graft can be introduced through the distal end of the internal branch graft and from there out of the proximal end of the internal branch graft

into the branch vessel. The extension graft can then be deployed so that it spans from the internal branch graft 3 to the branch vessel.

5 The internal branch graft 3 in this embodiment has two distinct portions: a proximal portion 301 and a distal portion 302. The proximal portion 301 has a proximal longitudinal axis and the distal portion 302 has a distal longitudinal axis. The proximal longitudinal axis of the proximal portion 301 intersects with the longitudinal axis of the stent graft at an acute angle and the distal longitudinal axis of the distal portion 302 intersects with the longitudinal axis of the stent graft at an acute angle. The acute angle between the distal longitudinal axis and the longitudinal axis of the stent graft is smaller than the acute angle between the proximal longitudinal axis and the longitudinal axis of the stent graft. This creates a dog-leg or elbow in the internal branch graft 3, as can be seen best in Figure 12.

15 The provision of proximal and distal portions 301,302 for the internal branch graft 3, which have larger and smaller acute angles, respectively, provides a smoother transition between the angle of the left subclavian artery and that of the longitudinal axis of the stent graft. Having the internal branch graft 3 extend distally within the lumen 2 of the stent graft provides for easier cannulation of the left subclavian artery therethrough. However, having the transitional proximal portion of the internal branch graft 3 avoids an abrupt 90 degree angle between the axis of the left subclavian artery and that of the stent graft. This helps to avoid kinking of devices such as stents being introduced into the left subclavian artery.

25 In this embodiment, the internal branch graft 3 as a whole is also angled diagonally such that as it extends distally within the internal lumen 2 it also extends laterally from the fenestration 60, as can be seen in Figure 11. This angulation or twist of the internal branch graft 3 further contributes to providing an easier path and reducing the possibility of kinking, for example, of the small stents being introduced into the artery. The angle of the twist is preferably from 5 to 45 degrees relative to the central longitudinal axis of the graft body 10, measured from the distal longitudinal axis of the distal portion 302 of the branch graft. In this embodiment, the angle of twist is 16 degrees.

30 The proximal portion 301 and the distal portion 302 of the internal branch graft 3 also differ in their proportions; the distal portion 302 is cylindrical and

comparatively elongate and slender, whereas the proximal portion 301 is generally frustoconical, tapering from a larger diameter at its proximal end (where it meets the fenestration 60) to a smaller diameter (matching that of the distal portion 302) at its distal end. The shape of the proximal portion 301 aids the clinician in accessing the internal branch graft 3 with a cannula and/or extension graft, and the shape of the distal portion 302 helps to guide the cannula and/or extension graft more precisely into the target artery. In this embodiment, the proximal and distal portions 301,302 are of the same length (as measured along their respective longitudinal axes from a proximal end to a distal end) but their lengths are not particularly limited and the proximal and distal portions 301,302 do not need to be of the same length.

In this embodiment, the distal portion 302 of the internal branch graft 3 includes a supporting structure which helps to maintain its shape and patency. The supporting structure is implemented in a known way, and includes a proximal D-ring 304, a distal O-ring 306, and a pair of opposing struts 305 which connect the O-ring and the D-ring along the longitudinal axis of the distal portion 302. The supporting structure in this embodiment is made of Nitinol. Other embodiments can have any suitable supporting structure. Some embodiments do not have a supporting structure.

In the embodiment shown, there is a single fenestration 60 in the graft body 10 and a single branch graft 3. In other embodiments, there could be any number of fenestrations and branch grafts. In some embodiments, there could be no fenestration or branch graft. In some embodiments, the prosthesis could comprise a fenestration but not a branch graft.

The prosthesis 1 also comprises a fenestration-supporting stent 70, aligned longitudinally with the fenestration 60. The fenestration supporting stent 70 has a plurality of proximal apices 76 and a plurality of distal apices 77, the proximal and distal apices being connected to each other by a plurality of stent struts 74 extending therebetween, as shown in Figures 2, 3, and 5.

The fenestration 60 is provided between two struts 74 of the fenestration-supporting stent 70, the combination of two struts 74 and a distal apex 77 of the fenestration-supporting stent 70 defining two sides 64,68 and the distal end 63 of the fenestration.

The fenestration-supporting stent 70 thereby partially surrounds and supports the fenestration 60. In particular, a distal apex 77 and two neighbouring struts 74 of the fenestration-supporting stent 70 form two sides 64,68 and the distal apex at the distal end 63 of the triangular fenestration 60. A pair of proximal apices 77 of the fenestration-supporting stent 70 coincide with the corners 65,67 at the proximal end of the fenestration 60. It is noted that, in this embodiment, there is not an additional support at the proximal side 66. However, it is not excluded that in other embodiments a support member can be provided across the proximal side 66 to further support the proximal side 66.

10 The fenestration-supporting stent 70 in this embodiment is positioned internally of the graft material, but in other embodiments it can be external.

The distal apices 77 of the fenestration-supporting stent 70 have larger radii of curvature than the proximal apices 76. In particular, the distal apices 77 all have a radius of curvature which matches the curvature of the distal corner 63 of the triangular fenestration 60. In some embodiments, not all of the distal apices 77 need have a larger radius of curvature than the proximal apices 76, but at least the fenestration-supporting apex of the fenestration-supporting stent ring is formed by a distal apex 77 having a larger radius of curvature than the proximal apices 76 of the fenestration-supporting stent 70. In this embodiment, the distal apices 77 have a radius of curvature of 3.75 mm and the proximal apices 76 have a radius of curvature of 0.75 mm. Other embodiments can have different radii of curvature. Preferred ranges are 2 mm to 4.5 mm for the distal apices and 0.5 mm to 1.5 mm for the proximal apices.

25 The larger radius of curvature of the distal apices 77 of the fenestration-supporting stent 70 creates a large fenestration area, improving the ability of the stent 70 to accommodate a branch extension graft inserted therethrough without constricting or impeding the graft.

30 The prosthesis 1 also includes an auxiliary stent 80, located distally of the fenestration supporting stent 70. The auxiliary stent 80 is a regular zig-zag stent, having a set of proximal apices 86 and a set of distal apices 87 which are connected by struts 84, as shown in Figure 5.

The prosthesis 1 also includes a series of external body stents 90, distributed along a distal portion of the graft body 10, between the auxiliary stent

80 and the distal end 7. The body stents 90 are regular zig-zag stents, each having a set of proximal apices 96 and a set of distal apices 97 which are connected by struts 94, as shown in Figure 5. Unlike the other stents of the prosthesis 1 shown, the body stents 90 are in this embodiment disposed on the
5 outside of the graft body 10, although they can in other embodiments be internal or disposed within the thickness of the graft material. The body stents 90 are spaced equally apart from one another and circumferentially aligned, that is to say in phase, with one another. In the embodiment shown in Figures 2, and 3, and 5, there are four body stents 90, positioned so that the distal apices 97 of
10 one stent are offset 7mm longitudinally from the proximal apices 96 of the next. In other embodiments, there could be any number of body stents 90 and the spacing between them could be any suitable distance. The distalmost of the body stents 90 is disposed at the distal end 7 of the graft body 10 so that its distal apices 97 extend to a distal edge 17 of the graft material.

15 In this embodiment, proximal and distal sets of apices of the proximal stent 20 (excluding the scallop apices), nested stent 50, and fenestration-supporting stent 70 are each arranged in a plane that is angled from a perpendicular cross-section of the graft body 10 (in other words angled relative to the distal end 7). This creates a slanted alignment of the sets of apices of each stent in the graft
20 body 10 when viewed in profile, as shown in Figure 3.

The set of body apices 34 of the proximal stent 20, in particular, is arranged at an angle relative to the distal end 7 such that the apices 34 are aligned on a slant which matches the tapered end of the graft body 10. This further enables the prosthesis 1 to accommodate the curvature of the vessel, so that the
25 proximal stent 20 acts against the vessel wall at a desired angle in the curvature and thereby provides an improved seal. Because of the wedge-shape of the proximal stent 20 in this embodiment, the distal apices 37 are arranged at an angle which is relatively shallower than that of the body apices 34.

The proximal and distal sets of apices 53 of the nested stent 50 are
30 arranged at an angle which matches that of the distal apices 37 of the proximal stent 20. The proximal and distal sets of apices 73 of the fenestration supporting stent 70 are arranged at an angle which is relatively steeper than that of the apices 53 of the nested stent 50. This creates a greater spacing between the

fenestration supporting stent 70 and the nested stent 50 circumferentially opposite the scallop (in other words, at the inner curve region 18) than nearest the scallop. This is beneficial to allow for the curvature of the prosthesis without interference between the stents at the inner curve region.

5 It should be appreciated that the struts of the stents that are angled in this way are not angled internally into the lumen 2 (that is, they remain flush with the sidewall 4 of the graft body 10). Where an optimal seal is achieved, the internal lumen 2 of the prosthesis 1 will exactly align with the vessel. In other
10 embodiments of the prosthesis 1, any combination of the stents 20, 50, 70, 80, 90 could be angled in this way. Some embodiments have no stents that are slanted or angled in this way.

 Although not shown, the prosthesis 1 of the described embodiments is combined with an introducer configured for deployment of the prosthesis 1 in a curved lumen, whereby the prosthesis is mounted on the introducer in a
15 compressed condition such that the inner curve region 18 is arranged to be deployed on the inside of the curve of the lumen. The introducer in these embodiments includes a pre-curved cannula (not shown), although this is not essential. The wedge shaped proximal stent 20 is mounted on the introducer so
20 that the narrow end of the wedge shape is arranged to be deployed on the interior of the curve of the vessel, thereby providing accurate orientation in the vessel.

 Returning to Figure 1, the prosthesis 1 of the described embodiments is also combined with conformance ties 9. The conformance ties 9 are disposed circumferentially around the proximal stent 20 and are operable to contract the
25 proximal stent 20 radially onto the introducer, where they are held by a release wire (not shown) to releasably maintain this constricted configuration.

 The conformance ties 9 comprise a loop arrangement to reduce the diameter around the distal end of the proximal stent 20 to lead to an angled position or conical configuration of the proximal stent. The diameter reducing
30 loop arrangement comprises first and second loop elements.

 The first loop element includes a first end and a second end, and a strand section between the first and second ends. The first loop element includes a loop at the second end. In the embodiment shown in the figures, the first loop

element consists of a single strand which passes from the first end to the second end, where it loops back on itself to the first end, thereby forming a loop at the second end. In this way, the first loop element includes a first strand section from the first end to the second end of the first loop element and a second strand section from the second end to the first end of the first loop element. However, in other embodiments, the first loop element can include a loop at the second end without the strand section necessarily being part of a single strand which loops all the way back to the first end. For example, the strand can be tied to itself at a point between the first and second ends, for example by the second strand section extending from the second end and being tied to the first strand section between the first and second ends of the first loop element.

The first end of the first loop element is attached at a distal end of the proximal stent 20, in this embodiment to a distal part of the proximal stent 20, although in other embodiments it can be attached to the graft body 10. In the embodiment shown in the figures, the first end of the first loop element is tied to the proximal stent 20 with a knot at a first distal apex 37 of the proximal stent 20. Furthermore, in the embodiment shown in the figures, owing to the fact that the strand of the first loop element loops all the way back to the first end, both ends of the strand are tied to the proximal stent 20 at the first distal apex 37 of the proximal stent 20. In particular, the first end of the first loop element, and therefore both ends of the strand of the first loop element, are tied to a strut 40 of the proximal stent 20 at the first distal apex 37.

The second loop element includes a first end and a second end, and a strand section between the first and second ends. The second loop element is similar to the first loop element already described. The second loop element is attached at the distal end of the proximal stent 20, in this embodiment to a distal part of the proximal stent in the same manner as described above for the first loop element, although, as for the first loop element, in other embodiments the first end of the second loop element can be attached to the graft body 10. In the embodiment shown in the figures the second loop element is attached at the first distal apex 37, which is the same apex to which the first end of the first loop element is attached. In other embodiments, it is possible for the first ends of the first and second loop elements to be attached at different apices, but this would

provide less effective diameter restriction.

The first and second loop elements, in particular the first and second strand sections thereof, are configured to pass or be wrapped circumferentially around the distal end of the proximal stent in opposite directions from the respective first
5 ends such that the second ends of the first and second loop elements can meet in a constricting configuration. The constricting configuration can restrict the diameter of the distal end of the proximal stent.

The second ends can be retained by a release wire (not shown) in the constricting configuration to maintain a constricted diameter at the distal end of
10 the proximal stent. In the embodiment shown in the figures, the first and second loop elements, in particular the strand sections thereof, are between them configured to pass around the entire circumference of the graft body 10 at the distal end of the proximal stent 20 in the constricting configuration. Each of the first and second loop elements is configured to pass circumferentially around a
15 part of the circumference of the graft body 10 at the distal end of the proximal stent 20 in the constricting configuration. In the embodiment shown, the release wire and first and second loops meet at a point longitudinally aligned with (that is, at the same position circumferentially as) the scallop 5 and fenestration 60.

In the embodiment shown in the figures, the first and second loop elements,
20 in particular the strand sections thereof, pass circumferentially around the distal end of the proximal stent 20 in opposite directions, and overlap each distal apex 37 which they pass such that between them they overlap every distal apex 37 of the proximal stent in the constricting configuration.

The size of the loop elements determine the size of the diameter reduction
25 of the distal end of the proximal stent 20 in the constricting configuration and the angle of the conical shape created. The lengths of the loop elements may vary depending on the (expanded) diameter of the prosthesis 1.

In the embodiment shown in the figures, in the constricting configuration the first and second loop elements pass circumferentially around the distal end of the
30 proximal stent 20 in opposite directions, and the strand sections thereof are attached to the graft body 10 and/or the proximal stent 20 at a majority of the respective distal apices 37 of the proximal stent which they pass. In other words, at a majority of the distal apices 37 of the proximal stent 20, the proximal stent

and/or the graft body is attached to one or other of the first and second loop elements. The number of distal apices at which the strand sections are attached is enough to allow the strand sections to contract the stent without slipping down. In the embodiment shown in the figures, the strand sections of the loop elements are attached to the graft body by penetrating the graft material at the respective apices.

The attachment of the strand sections of the first and second loop elements to the graft body 10 and/or the proximal stent 20 at distal apices 37 of the proximal stent can serve to control the loop elements to prevent them sliding off the distal end of the proximal stent and to make sure the loop elements do not get caught when released. Furthermore, as a result of their attachment to the graft body 10 at distal apices 37 of the proximal stent 20, the loop elements can only slide in the direction around the graft and not along the length of the graft.

In the embodiment shown in the figures, in the constricting configuration each of the first and second loop elements passes a set of distal apices 37 of the proximal stent 20 and is attached to the graft body 10 at a majority of the distal apices of the respective set by the loop element, in particular the strand sections thereof, weaving through the graft material at each of those distal apices. In the embodiment shown in the figures, at each of the distal apices at which it is attached to the graft body, the first and second strand sections of the respective loop element penetrate the graft body 10 and pass from external of the graft body 10 to internal of the graft body 10, pass around one of the struts 40 of the proximal stent 20 at the distal apex and then pass from internal of the graft body 10 to external of the graft body 10. In other words, the strand sections of the loop elements pass radially internally of the graft body 10 around one of the two struts 40 at a majority of the distal apices of the respective set of distal apices 37 of the proximal stent 20 but otherwise pass circumferentially around the graft body 10 externally to the graft body 10. Nevertheless, it is possible in other embodiments for the loop elements to be attached to the proximal stent and/or the graft body 10 in a different manner.

As can be seen, in the embodiment shown in the figures, each of the first and second loop elements is attached to the graft body and/or proximal stent only at the distal end of the proximal stent.

Of course, in embodiments in which the second strand section does not pass all the way back to the first end of the respective loop element, it may be only the first strand section which passes circumferentially around the distal end of the proximal stent and is attached to the graft body and/or proximal stent.

5 In some embodiments, it is possible for the loop elements to be substantially unattached to the graft body or proximal stent except at their first ends. However, this is not preferred for the reasons discussed. Furthermore, although in the embodiment shown in the figures the first and second strand sections of each loop element are attached to the graft body and/or the proximal
10 stent at a majority of the distal apices of the proximal stent which they pass, in other embodiments just one or other of the strand sections can be so attached. Furthermore, it is not excluded that the first and/or second strand section of the first and/or second loop element can be attached to the proximal stent and/or graft body at a plurality of locations around the circumference of the graft body
15 other than at distal apices of the proximal stent. However, attachment at distal apices is preferable for efficient constriction of the distal end of the proximal stent.

 In the constricting configuration, the first and second loop elements together extend around the entire circumference of the graft body 10 and distal end of the
20 proximal stent 20 and the first loop element passes through the loop at the second end of the second loop element, allowing for a release wire to pass through the loop at the second end of the first loop element to hold the first and second loop elements in the constricting configuration. Owing to the location of the first and second loop elements around the distal end of the proximal stent,
25 the diameter reducing loop arrangement is configured to constrict the distal apices of the proximal stent and cause the proximal stent to adopt a substantially conical or frustoconical shape. This conical or frustoconical shape allows the proximal sealing stent to deploy in a more angular position, which leads to a better conformance to the aortic curve.

30 In the embodiment shown in the figures the first and second loop elements are made from thread which is green braided PTFE impregnated polyester fibre suture. Other materials can be used in other embodiments; however, the first and second loop elements are preferably each provided by a suture and most

preferably by a single strand thereof.

In the embodiment shown in the figures, only the proximal stent 20 is encircled with conformance ties 9. However, in other embodiments, one or more of the other stents may have diameter-reducing ties. The distal-most stent may optionally have a conventional retention arrangement configured to be released in a conventional manner. However, this is not critical and details are therefore not described herein.

In use, a release wire (not shown) is passed through the loop at the second end of the first loop element, externally to the graft body 10. As a result, both the loop elements are attached to the release wire and each other. They are held by the release wire in the constricting configuration which pulls the distal apices of the proximal stent radially inwardly and holds the sealing stent in a substantially conical or frustoconical shape, in particular a proximally facing conical or frustoconical shape. The diameter reducing loop arrangement can be released from the constricting configuration by pulling the release wire, which releases the first and second loop elements from each other and allows their respective second ends to separate. As a result, the loop elements no longer constrict the diameter of the distal end of the proximal stent 20, which is consequently free to expand.

It is also noted that the release wire passes through the loop at the second end of the first loop element but not the loop at the second end of the second loop element. In other embodiments, it can pass through the loops at the second ends of both the first and second loop elements.

The conformance ties can have any features described in EP4026518, the contents of which are incorporated by reference in their entirety.

After being released from the introducer, the prosthesis 1 is partially deployed, whereby the proximal stent 20 is held in a reduced diameter configuration by the conformance ties 9, as shown in Figure 6. The partially deployed configuration enables a clinician to reorient and align the prosthesis 1 in the vessel before full deployment. Figure 6 shows an exemplary alignment of the prosthesis 1 in a simulated aortic arch: the proximal end 6 of the graft body 10 is distal of the brachiocephalic trunk (BT), the generally straight distal portion of the scallop 5 is aligned between the openings of the left common carotid artery

(LCC) and the left subclavian artery (LSA), and the fenestration 60 is aligned with the left subclavian artery (LSA). Once the clinician has positioned the prosthesis 1 as desired, the conformance ties 9 can be released (using a release wire as described above) to initiate the full deployment of the prosthesis 1, allowing the proximal stent 20 to expand to engage the wall of the vessel. This deployed state can be seen in Figure 7. In the embodiments shown, the prosthesis 1 is designed to deploy into a 38mm diameter vessel, the prosthesis 1 having a fully expanded diameter of 42mm and being contractible into a 22Fr (7.33mm) diameter sheath. These dimensions can be tailored to the target vessel. Other embodiments can have any suitable diameters.

It is to be noted that the particular conformance ties described in detail above are not necessary in every embodiment.

It is also to be noted that other arrangements for constricting the proximal stent 20 can be used in some embodiments.

A method of placing the prosthesis 1 in a lumen of a patient includes inserting the prosthesis 1 into the lumen of the patient endovascularly (typically from a femoral approach) and deploying the prosthesis. The lumen may be curved, in which case the prosthesis 1 is deployed so that the inner curve region is on the inside of the curve of the lumen.

The lumen will typically be in the vasculature of the patient. The embodiment of the prosthesis as shown in the figures is designed for implantation into the aortic arch, between the ascending and descending aorta. A method of placing the prosthesis 1 into the aortic arch includes: inserting the prosthesis 1, using an introducer as described above, into the vasculature of the patient; orienting the prosthesis 1 in the lumen of the aortic arch, with the inner curve region on the inside of the curve of the lumen; and, deploying the prosthesis 1 so that: the proximal stent 20 deploys substantially perpendicularly to the curve of the lumen; a distal end of the scallop 5 is aligned between the subclavian and carotid arteries; and the fenestration 60 is aligned with a junction of the left subclavian artery.

Advantages include that the prosthesis can accommodate the curvature of the aortic arch, while making sure that the stent does not harm the vessels in the curvature, supporting the left subclavian artery (LSA), and having a minimum 10-

15mm proximal sealing zone. The prosthesis can also be deployed with the sealing stent (proximal stent 20) properly aligned to the perpendicular to the vessel at the left subclavian while sealing the prosthesis within the short length of vessel available between the subclavian and the carotid, with reduced risk of erosion to the vessel.

In particular, the prosthesis can land in the small area between the subclavian and carotids, with the wedge shaped stent and tapered stent and graft end accommodating the curve of the aorta in this area and the nested stent maximising the sealing in the sealing zone.

As discussed above, the proximal stent in the preferred embodiment has a wedge shape and varying radii of curvature of apices to make sure the stent does not erode the vessel as well as enabling a 42mm stent/stent graft able to be loaded into a 22Fr (7.33mm) sheath.

Although the internal branch graft 70 of the illustrated embodiments is described as having two distinct portions, in some embodiments, more than two portions may be provided. These may have longitudinal axes intersecting with the longitudinal axis of the graft body 10 at acute angles that are progressively smaller, such that each portion has a longitudinal axis intersecting at a smaller acute angle than its adjacent proximal portion.

It should be appreciated that any of the stents described could be disposed on the outside of, the inside of, or within, the graft material of a stent-graft.

All optional and preferred features and modifications of the described embodiments and dependent claims are usable in all aspects of the invention taught herein. Further, the individual features of the dependent claims, as well as all optional and preferred features and modifications of the described embodiments, are combinable and interchangeable with one another.

The abstract accompanying this application is incorporated herein by reference.

CLAIMS

1. A stent graft for deployment in the aortic arch including:

5 a plurality of expandable stent rings arranged along a length of tubular graft material, the plurality including at least a proximal stent ring at or near a proximal end of the tubular graft material and a distal stent ring at or near a distal end of the tubular graft material, and at least one intermediate stent ring between the proximal stent ring and the distal stent ring;

10 at least one fenestration provided in a side wall of the tubular graft material, the fenestration configured for alignment with a junction of the left subclavian artery and for deployment of a side-branch therethrough;

15 wherein at least one intermediate stent ring is a fenestration-supporting stent ring, wherein the fenestration-supporting stent ring is a zig-zag stent having a plurality of proximal apices and a plurality of distal apices, the proximal and distal apices connected to each other by a plurality of stent struts extending therebetween, wherein at least one of the distal apices is a fenestration-supporting apex having a larger radius of curvature than the proximal apices;

20 wherein at least one fenestration is provided between two struts of the fenestration-supporting stent ring, the combination of two struts and the fenestration-supporting apex of the fenestration-supporting stent ring defining two sides and the distal end of the fenestration; and

25 wherein the fenestration has a proximal edge connecting the proximal ends of the two sides of the fenestration, the proximal edge including at least a portion that is substantially perpendicular to the longitudinal axis of the stent graft.

2. A stent graft as claimed in claim 1, wherein a sealing stent ring is provided adjacent the proximal edge of the fenestration.

30

3. A stent graft as claimed in claim 2, wherein the sealing stent ring is a zig-zag stent having proximal and distal apices, and wherein the proximal

edge of the fenestration does not extend proximally of the distal apices of the sealing stent ring.

4. A stent graft as claimed in claim 1, 2 or 3, wherein only a single
5 fenestration is provided in the side wall of the tubular graft material.
5. A stent graft as claimed in any preceding claim, wherein the
fenestration is aligned with and distal of a scallop at the proximal end of the
stent graft, a sealing zone being provided therebetween.
10
6. A stent graft as claimed in any preceding claim, wherein the
fenestration supporting stent ring is arranged around the tubular graft material
at an angle such that the fenestration-supporting apex is located proximally of
the circumferentially opposite distal apices of the fenestration-supporting stent
15 ring.
7. A stent graft as claimed in claim 6, wherein the tubular graft material is
tapered at its proximal end, and wherein the fenestration-supporting stent ring
is angled in the tubular graft body at an angle that matches the angle of the
20 taper of the proximal end of the tubular graft material.
8. A stent graft as claimed in any preceding claim, wherein a plurality of
the distal apices have a larger radius of curvature than the proximal apices.
- 25 9. A stent graft as claimed in any preceding claim, wherein all of the distal
apices have a larger radius of curvature than the proximal apices.
10. A stent graft as claimed in any preceding claim, wherein the
fenestration-supporting apex has a radius of curvature of 2 mm to 4.5 mm
30 and/or the proximal apices of the fenestration-supporting stent ring have a
radius of curvature of 0.5 mm to 1.5 mm.
11. A stent graft as claimed in claim 10, wherein the fenestration-
supporting apex has a radius of curvature of 3.75 mm.

12. A stent graft as claimed in claim 10 or 11, wherein the proximal apices have a radius of curvature of 0.75 mm.
- 5 13. A stent graft as claimed in any preceding claim, including a branch graft extending distally from the fenestration and internally of the tubular graft material.
- 10 14. A stent graft as claimed in claim 13, wherein the branch graft is angled with respect to the tubular graft material of the stent graft such that as the branch graft extends distally it also extends laterally from the fenestration.
- 15 15. A stent graft as claimed in claim 14, wherein the branch graft is angled by an angle in the range of 5 to 45 degrees, as measured from the central longitudinal axis of the stent graft.
- 20 16. A stent graft as claimed in any one of claims 13-15, wherein the branch graft has a proximal portion having a proximal longitudinal axis and a distal portion having a distal longitudinal axis, wherein the proximal longitudinal axis of the proximal portion intersects with a longitudinal axis of the stent graft at an acute angle, and wherein the distal longitudinal axis of the distal portion intersects with a longitudinal axis of the stent graft at an acute angle, the acute angle between the distal longitudinal axis and the longitudinal axis of the stent graft being smaller than the acute angle between the proximal longitudinal axis and the longitudinal axis of the stent graft.
- 25 17. A stent graft as claimed in any one of claims 13-16, wherein a most proximal portion of the branch graft is generally frustoconical and a most distal portion of the branch graft is cylindrical.
- 30 18. A stent graft for deployment in the aortic arch including:
a plurality of expandable stent rings arranged along a length of tubular graft material, the plurality including at least a proximal stent ring at or near a

proximal end of the tubular graft material and a distal stent ring at or near a distal end of the tubular graft material, and at least one intermediate stent ring between the proximal stent ring and the distal stent ring;

5 at least one fenestration provided in a side wall of the tubular graft material, the fenestration configured for alignment with a junction of the left subclavian artery and for deployment of a side-branch therethrough;

wherein the fenestration is aligned with a lumen of an internal branch graft located within the lumen of the stent graft;

10 wherein the internal branch graft extends from the fenestration within the lumen of the stent graft in a distal direction.

19. A stent graft as claimed in claim 18, wherein the internal branch graft is angled within the lumen of the stent graft such that as the internal branch graft extends distally it also extends laterally from the fenestration.

15

20. A stent graft as claimed in claim 19, wherein the internal branch graft is angled by an angle in the range of 5 to 45 degrees, as measured from the central longitudinal axis of the stent graft.

20 21. A stent graft as claimed in any one of claims 18-20, wherein the internal branch graft has a proximal portion having a proximal longitudinal axis and a distal portion having a distal longitudinal axis, wherein the proximal longitudinal axis of the proximal portion intersects with a longitudinal axis of the stent graft at an acute angle, and wherein the distal longitudinal axis of the distal portion intersects with a longitudinal axis of the stent graft at an acute angle, the acute angle between the distal longitudinal axis and the longitudinal axis of the stent graft being smaller than the acute angle between the proximal longitudinal axis and the longitudinal axis of the stent graft.

25

30 22. A stent graft as claimed in any one of claims 18-21, wherein a most proximal portion of the internal branch graft is generally frustoconical and a most distal portion of the internal branch graft is cylindrical.

Amendments to the claims have been filed as follows

CLAIMS

1. A stent graft for deployment in the aortic arch including:

5 a plurality of expandable stent rings arranged along a length of tubular graft material, the plurality including at least a proximal stent ring at or near a proximal end of the tubular graft material and a distal stent ring at or near a distal end of the tubular graft material, and at least one intermediate stent ring between the proximal stent ring and the distal stent ring;

10 at least one fenestration provided in a side wall of the tubular graft material, the fenestration configured for alignment with a junction of the left subclavian artery and for deployment of a side-branch therethrough;

15 wherein at least one intermediate stent ring is a fenestration-supporting stent ring, wherein the fenestration-supporting stent ring is a zig-zag stent having a plurality of proximal apices and a plurality of distal apices, the proximal and distal apices connected to each other by a plurality of stent struts extending therebetween, wherein at least one of the distal apices is a fenestration-supporting apex having a larger radius of curvature than the proximal apices;

20 wherein at least one fenestration is provided between two struts of the fenestration-supporting stent ring, the combination of two struts and the fenestration-supporting apex of the fenestration-supporting stent ring defining two sides and the distal end of the fenestration; and

25 wherein the fenestration has a proximal edge connecting the proximal ends of the two sides of the fenestration, the proximal edge including at least a portion that is substantially perpendicular to the longitudinal axis of the stent graft.

2. A stent graft as claimed in claim 1, wherein a sealing stent ring is provided adjacent the proximal edge of the fenestration.

30 3. A stent graft as claimed in claim 2, wherein the sealing stent ring is a zig-zag stent having proximal and distal apices, and wherein the proximal edge of the fenestration does not extend proximally of the distal apices of the sealing stent ring.

25 09 23

4. A stent graft as claimed in claim 1, 2 or 3, wherein only a single fenestration is provided in the side wall of the tubular graft material.
- 5 5. A stent graft as claimed in any preceding claim, wherein the fenestration is aligned with and distal of a scallop at the proximal end of the stent graft, a sealing zone being provided therebetween.
- 10 6. A stent graft as claimed in any preceding claim, wherein the fenestration supporting stent ring is arranged around the tubular graft material at an angle such that the fenestration-supporting apex is located proximally of the circumferentially opposite distal apices of the fenestration-supporting stent ring.
- 15 7. A stent graft as claimed in claim 6, wherein the tubular graft material is tapered at its proximal end, and wherein the fenestration-supporting stent ring is angled in the tubular graft body at an angle that matches the angle of the taper of the proximal end of the tubular graft material.
- 20 8. A stent graft as claimed in any preceding claim, wherein a plurality of the distal apices have a larger radius of curvature than the proximal apices.
9. A stent graft as claimed in any preceding claim, wherein all of the distal apices have a larger radius of curvature than the proximal apices.
- 25 10. A stent graft as claimed in any preceding claim, wherein the fenestration-supporting apex has a radius of curvature of 2 mm to 4.5 mm and/or the proximal apices of the fenestration-supporting stent ring have a radius of curvature of 0.5 mm to 1.5 mm.
- 30 11. A stent graft as claimed in claim 10, wherein the fenestration-supporting apex has a radius of curvature of 3.75 mm.
12. A stent graft as claimed in claim 10 or 11, wherein the proximal apices

have a radius of curvature of 0.75 mm.

5 13. A stent graft as claimed in any preceding claim, including a branch graft extending distally from the fenestration and internally of the tubular graft material.

10 14. A stent graft as claimed in claim 13, wherein the branch graft is angled with respect to the tubular graft material of the stent graft such that as the branch graft extends distally it also extends laterally from the fenestration.

15 15. A stent graft as claimed in claim 14, wherein the branch graft is angled by an angle in the range of 5 to 45 degrees, as measured from the central longitudinal axis of the stent graft.

20 25 23 16. A stent graft as claimed in any one of claims 13-15, wherein the branch graft has a proximal portion having a proximal longitudinal axis and a distal portion having a distal longitudinal axis, wherein the proximal longitudinal axis of the proximal portion intersects with a longitudinal axis of the stent graft at an acute angle, and wherein the distal longitudinal axis of the distal portion intersects with a longitudinal axis of the stent graft at an acute angle, the acute angle between the distal longitudinal axis and the longitudinal axis of the stent graft being smaller than the acute angle between the proximal longitudinal axis and the longitudinal axis of the stent graft.

25 17. A stent graft as claimed in any one of claims 13-16, wherein a most proximal portion of the branch graft is generally frustoconical and a most distal portion of the branch graft is cylindrical.



Application No: GB2215295.3

Examiner: Mr Tony Judge

Claims searched: 1-17

Date of search: 27 March 2023

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	-	EP 3395295 A1 (COOK MEDICAL TECHNOLOGIES LLC) Please see whole document.
A	-	WO 2020/074598 A1 (CANAUD et al.) Please see whole document.

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^X :

--

Worldwide search of patent documents classified in the following areas of the IPC

A61F

The following online and other databases have been used in the preparation of this search report

WPI, EPODOC

International Classification:

Subclass	Subgroup	Valid From
A61F	0002/07	01/01/2013
A61F	0002/82	01/01/2013
A61F	0002/86	01/01/2013
A61F	0002/89	01/01/2013



Application No: GB2215295.3

Examiner: Mr Tony Judge

Claims searched: 18-22

Date of search: 29 August 2023

**Patents Act 1977
Further Search Report under Section 17**

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	18-22	EP 3395295 A1 (COOK MEDICAL TECHNOLOGIES LLC) Please see figures and paragraph 18.
X	18-22	US 2021/0369439 A1 (CANAUD) Please see whole document.
X	18-22	US 2009/0043377 A1 (CLEVELAND CLINIC FOUNDATION) Please see figures and paragraphs 176 and 177.
X	18-22	US 2020/0352703 A1 (GREENBERG et al.) Please see whole document.
X	18, 19 and 22	US 2018/0200089 A1 (COOK MEDICAL TECHNOLOGIES LLC) Please see whole document.

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^X :

--

Worldwide search of patent documents classified in the following areas of the IPC

--

The following online and other databases have been used in the preparation of this search report

WPI, EPODOC, PATENT-SEARCH

International Classification:

Subclass	Subgroup	Valid From
A61F	0002/07	01/01/2013



Subclass	Subgroup	Valid From
A61F	0002/82	01/01/2013
A61F	0002/86	01/01/2013
A61F	0002/89	01/01/2013