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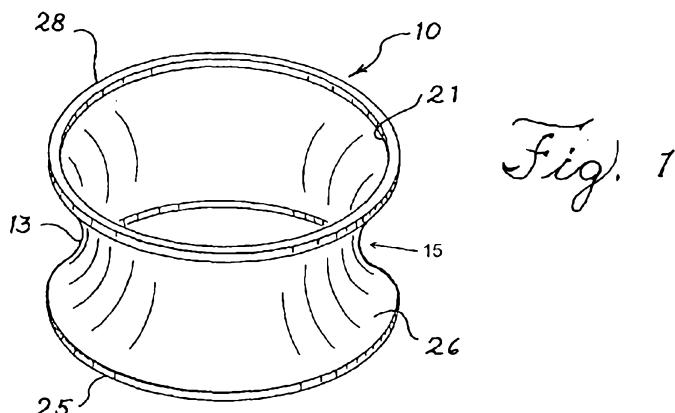
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(54) Title: STENT GRAFT FIXATION COUPLING



(57) Abstract: A small vessel stent graft (30; 62) with a fixation coupling (10; 50) that has a hyperboloid shape positioned at or near the proximal end of the graft (30; 62). The coupling (10; 50) may be deployed within the fenestration (42; 65) of a fenestrated graft (40; 60) to provide multi-directional movement without compromising the integrity of the sealing zone.

STENT GRAFT FIXATION COUPLING

DescriptionTechnical Field

5 The present invention relates to a branch vessel stent graft and to a method of deploying a system of endoluminal prostheses with a fixation coupling. In particular, it relates to a fixation joint for use with a fenestrated stent graft and a smaller branch stent that provides secure and complete rotational movement.

Background Art

10 Using stent grafts to treat aneurysms is common in the medical field. Stent grafts are deployed by accessing vasculature with a small incision in the skin and guiding a delivery system to the target area. This intraluminal delivery is less invasive and generally preferred over more intrusive forms of surgery. Multiple stent grafts may be implanted using intraluminal delivery to provide a system of interconnected stent grafts.

15 Interconnected stent grafts can be made of fenestrated grafts and smaller side branch stents, including bifurcated grafts.

Sometimes aneurysms engulf a vessel and its branch vessels, such as the aorta and the renal arteries or the aortic arch and the branch arteries. In such instances a fenestrated graft can be implanted in the main vessel while smaller branch grafts can be deployed in the branch arteries. The main vessel grafts have fenestrations that correspond with the opening of the branch vessel. The smaller branch grafts are joined with the main vessel graft at the fenestrations. Due to the torsion and rigors of the endovascular system, this juncture can be subject to significant stress.

25 Disclosure of The Invention

An endoluminal prosthesis is provided that includes a proximal end, a distal end, a body portion configured for placement in a body vessel branching from a main body vessel, and a fixation coupling. The fixation coupling may be positioned at or near the proximal end of the prosthesis and configured for placement within the 30 fenestration of a fenestrated device. The fixation coupling may include a distal non-helical ring, a proximal non-helical ring, and a hyperboloid area positioned between the rings. There may be first and second outer extents in the hyperboloid area. The

diameter of at least one of the rings may be larger than any diameter of the hyperboloid area.

Also disclosed is a method of deploying a system of endoluminal prostheses with a fixation coupling that provides angular and rotating movement in a body having a primary vessel in communication with a secondary vessel. The system may include a first prosthesis for implantation in the primary vessel that includes a tubular wall, a lumen therethrough, and a fenestration in the tubular wall. The system may also include a second prosthesis for implantation in the secondary vessel. The second prosthesis may include a fixation coupling that has a distal non-helical ring, a proximal non-helical ring, and a hyperboloid area positioned between the rings. The hyperboloid area may have first and second outer extents. The diameter of at least one of the rings may be larger than any diameter of the hyperboloid area.

The method may include deploying the first prosthesis in the primary vessel and aligning the fenestration with the secondary vessel. The fixation coupling may be deployed in the fenestration by placing the proximal non-helical ring in the lumen of the first prosthesis and abutting the proximal ring against an internal portion of the wall surrounding the fenestration. The distal non-helical ring may be placed outside the lumen of the first prosthesis and deployed such that the fenestration surrounds the hyperboloid area to form a joint.

The fixation coupling may also have a partial hyperboloid shape or bell-shape.

A branch vessel stent graft may include a distal end and a body portion configured for placement in a body vessel branching from a main body vessel. Also, there may be a proximal end configured for at least partial placement within an internal branch of a branched stent graft. A fixation coupling may be positioned at or near the proximal end of the stent graft, where the fixation coupling may have a flared proximal opening with a diameter larger than any diameter of the stent graft. Also, there may be a ring surrounding the flared proximal opening.

There is a system for repairing an anatomical vessel at the junction of a main anatomical vessel and branch anatomical vessel that comprises a primary stent graft configured for placement in the main anatomical vessel. The primary stent graft comprises a tubular graft material, at least one stent, and a fenestration with a diameter in a sidewall of the tubular graft material. The system also includes a branch

vessel stent graft that has a proximal end, a distal end, a body portion configured for placement in a body vessel branching from a main body vessel, and a fixation coupling positioned at or near the proximal end and configured for placement within the fenestration. The fixation coupling comprises a distal non-helical ring, a proximal non-helical ring, and a hyperboloid area positioned between the rings, and first and second outer extents. The diameter of at least one of the rings is larger than any diameter of the hyperboloid area and the smallest diameter of the hyperboloid area is at least the diameter of the fenestration.

Brief Description of the Drawings

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

FIG. 1 is a perspective view of a hyperboloid shaped fixation coupling;

FIG. 2 is a side view of the hyperboloid shaped fixation coupling;

15 FIG. 3 is a longitudinal cross-sectional view of a fenestrated stent graft coupled to a hyperboloid shaped fixation coupling on the proximal end of a small vessel stent graft;

FIG. 4 is a perspective view of a hyperboloid shaped fixation coupling with an elliptical ring on one end;

20 FIGS. 5A to 5F are cross sectional schematic diagrams showing the steps of deploying a stent graft having a hyperboloid shaped coupling into a renal artery and mating with a fenestrated stent graft implanted in the aorta;

FIG. 6 is a perspective view of a bell shaped fixation coupling in an internal branch;

25 FIG. 7 is an internally branched stent graft for implantation in the aortic arch; and

FIGS. 8A to 8D are cross-sectional views of the deployment steps of a secondary graft with a bell-shaped fixation coupling with a fenestrated stent graft.

Description of the Preferred Embodiments

The term "prosthesis" means any replacement for a body part or for a function of that body part or any device that enhances or adds functionality to a physiological system.

The term "graft or graft material" means a generally cannular or tubular member which acts as an artificial vessel or prosthesis. A graft by itself or with the addition of other elements, such as structural components, may be an endoluminal prosthesis. The graft may comprise a single material, a blend of materials, a weave, a laminate, or a composite of two or more materials.

The graft material is a biocompatible material that is both flexible and abrasion resistant. Furthermore, the graft material should be selected from those materials that are particularly well suited for thermoplastic deformation, such that the material may be thermoplastically fused to a stent. The woven graft material can be a woven polyester. The woven graft material may be a polyethylene terephthalate (PET), such as DACRON® (DUPONT, Wilmington, DE) or TWILLWEAVE MICREL® (VASCUTEK, Renfrewshire, Scotland). Woven polyesters, such as Dacron, possess varying degrees of porosity, where the degree of porosity may be selectively controlled based on the weaving or knitting process that is used to produce the woven polyester. Consequently, depending on the application, the porosity may be adjusted to encourage incorporation of a patient's tissue into the woven graft material, which in turn may more securely anchor the prosthesis within the patient's vessel or lumen. Furthermore, the degree of porosity may be adjusted also to provide a woven graft material that is impermeable to liquids, including blood or other physiological fluids.

Throughout this specification, when discussing the application of this invention to the aorta or other blood vessels, the term "distal," with respect to a prosthesis, is intended to refer to a location that is, or a portion of the prosthesis that when implanted is, further downstream with respect to blood flow. The term "distally" means in the direction of blood flow or further downstream. The term "proximal" is intended to refer to a location that is, or a portion of the prosthesis that when implanted is, further upstream with respect to blood flow. The term "proximally" means in the direction opposite to the direction of blood flow, or further upstream.

A branch vessel stent graft may include a proximal end, a distal end, and a body portion configured for placement in a body vessel branching from a main body vessel. For instance, the branch vessel stent graft may be placed in a renal artery, which branches from the aorta, or in the innominate artery, which branches from the aortic arch. The stent graft also includes a fixation coupling positioned at or near the proximal end and configured for placement within a fenestration of a fenestrated device. The fenestrated device may be a fenestrated stent graft that may be placed in a main blood vessel. The fixation coupling may include a distal ring, a proximal ring, and a hyperboloid area positioned between the rings. The rings may be non-helical. 5 The fixation coupling also may have first and second outer extents that are hyperboloid areas closest to the proximal and distal rings. The diameter of at least one of the rings is greater than any diameter of the hyperboloid area. 10

The hyperboloid fixation coupling 10 may include nitinol rings 25 and 28 on its proximal and distal ends that are self-expanding. The coupling 10 may be integrated 15 with a small-vessel stent graft for joining with a fenestrated stent graft. Figure 1 shows a fixation coupling 10 with two rings 25 and 28 that are placed on either side of the hyperboloid area 15. The rings 25 and 28 may include radiopaque elements to assist an operator in viewing the placement under fluoroscopy. The hyperboloid area 15 has an apex 13, or middle point, that is slightly larger in diameter than the diameter 20 of the fenestration of a fenestrated graft 40 when not implanted. As shown in Figure 3, when the coupling 10 is implanted, the apex 13 is squeezed to fit within the fenestration 42 and to provide a secure seal. The smallest diameter of the hyperboloid can be at least the diameter of the fenestration 42, and preferably larger than the diameter of the fenestration 42. The fenestration 42 may be provided with a 25 support ring surrounding the perimeter of the fenestration 42. The support ring may be made of a material that permits visualisation of the support ring during deployment of the hyperboloid area 15 within the fenestration 42. The support ring also may be of a material that expands to a larger diameter and then contracts to a smaller diameter to contact and seal against the hyperboloid area 15.

30 The fixation coupling 10 has two outer extents 21, 26 that are the outermost points on the material. The first outer extent 21 and the second outer extent 26 are immediately adjacent the distal ring 28 and proximal ring 25, respectively. The outer

extents (21, 26) have diameters that may be up to 20% larger in diameter than the apex 13. There may be couplings 10 with outer extents greater than 20% of the apex 13 diameter. When deployed, the distal ring 28 and the proximal ring 25 expand the hyperboloid area 15 about the fenestration 42. Deployment seals off the fenestration 5 42 and connects the small vessel device 30 to the fenestrated stent graft 40 as shown in Figure 3. The diameters of both rings 28, 25 may be larger than any diameter in the hyperboloid area 15. The hyperboloid area 15 of the small vessel stent graft 30 allows for multi-directional movement without compromising the integrity of the sealing zone and, thus, reduces any stress on the small vessel stent graft 30. The 10 hyperboloid area 15 may act also as a moveable joint resembling an open-ended ball joint.

Figure 4 shows a fixation coupling 10 with a distal ring 23 that is elliptical. The bottom, or proximal, ring 25 is circular. Both rings in some fixation couplings 10 described herein may also be elliptical rings. The elliptical distal ring 23 has a 15 directrix 4 that may be greater than any diameter in the hyperboloid area 15. The directrix 4 may also be greater than the fenestration diameter in the stent graft to which it may be attached. There can also be fenestrated grafts that include an elliptical fenestration.

There is a method of deploying a system of endoluminal prostheses with a 20 fixation coupling that provides angular and rotational movement in a body having a primary vessel in communication with a secondary vessel. The system may include a first prosthesis for implantation in the primary vessel with the first prosthesis having a tubular wall, a lumen therethrough, and a fenestration in the tubular wall. The system may include also a second prosthesis for implantation in the secondary vessel. This 25 second prosthesis may include a fixation coupling as described herein, where the diameter of at least one of the rings is larger than any diameter of the hyperboloid area.

The deployment methods provide accurate placement of the small vessel stent graft with fenestrated stent grafts. Tactile feedback is provided to the operator when 30 one of the rings abuts the wall around the fenestration. A fully deployed ring will not go through the fenestration and, as such, the operator will feel such resistance. This will help prevent misplacing the coupling and the small vessel stent graft. This lets the

surgeon know that the small vessel stent graft is properly placed before complete deployment.

The method may include deploying the first prosthesis 60 in a primary vessel and aligning the fenestration with a secondary vessel. The fixation coupling 10 may be deployed in the fenestration by placing the proximal ring 25 in the lumen of the first prosthesis 60 and abutting the proximal ring 25 against an internal side of the wall 67 surrounding the fenestration 65. The distal ring 28 may be placed outside the lumen of the first prosthesis 60 and deployed such that the fenestration 65 surrounds the hyperboloid area 15 to form a joint.

As shown in Figure 5A, the first prosthesis is a fenestrated graft 60 that has been implanted into a primary vessel, such as an aorta, having an aneurysm 110. The fenestration 65 is aligned with the opening of the branch vessel, such as the renal artery 100. Radiopaque markers may be used in placing the fenestrated graft 60 in the artery. A guidewire 64 is threaded through the fenestrated graft 60, through the fenestration 65, and into the renal artery. A balloon-expandable or self-expanding small vessel stent graft 62 with a fixation coupling is inserted over the guidewire 64 in Figure 5B using a delivery system 66. The delivery system 66 is advanced through the fenestration 65 and into the renal artery 100.

In Figure 5C, the delivery system 66 has been advanced until the proximal ring 25 of the fixation coupling 10 is proximal to the internal side of the wall 67 surrounding the fenestration 65 and the distal ring 28 is on the distal side of the fenestration 65. The hyperboloid section 15 is surrounded by the fenestration 65. In Figure 5D, the proximal ring 25 has been deployed while the distal ring 28 is only partially deployed. When the proximal ring 25 is pushed in a distal direction to abut the wall 67 surrounding the fenestration 65, the distal second ring 28 may be deployed fully as shown in Figure 5E. Figure 5F shows the system of endoprostheses with a fixation coupling 10 when implantation is complete.

The method also may include a step where the small vessel stent graft 62 is advanced into a branch vessel such as the renal artery 100 until the distal ring 28 is just distal to the fenestration 65 and deployed. The small vessel stent graft 62 may be pulled in a proximal direction such that the deployed distal ring 28 abuts the external side of the wall surrounding the fenestration 65. The proximal ring 25 may then be

deployed to surround the fenestration 65 with the fixation coupling 10. In another method, the proximal ring 25 can be deployed while advancing the small vessel stent graft 62 through the fenestrated graft 60. Once the proximal ring 25 abuts the wall 67 surrounding the fenestration 65, the operator can feel the obstruction. The deployed 5 proximal ring 25 provides tactile feedback when abutting the wall 67.

A branch vessel stent graft may include a distal end and a body portion configured for placement in a body vessel branching from a main body vessel. There may be a proximal end configured for at least partial placement within an internal branch of a branched stent graft. The small vessel stent graft 62 also may have a 10 fixation coupling 50 positioned at or near the proximal end, where the fixation coupling 50 includes a flared proximal opening 57 with a diameter larger than any diameter of the small vessel stent graft 62, and a ring 55 surrounding the flared proximal opening 57.

Figure 6 shows a bell-bottomed shape fixation coupling 50. This fixation 15 coupling 50 may be integrated with the proximal portion of the small vessel stent graft 62. A ring 55 is at the flared proximal opening 57 and may be stitched around the opening 57 or embedded in the graft material. The fixation coupling 50 may be self-expanding or balloon expandable. The ring 55 may include radiopaque elements and may have an elliptical shape. If the ring 55 is an ellipse, the flared proximal opening 20 57 may be an ellipse also. The directrix of an elliptical ring and the flared proximal elliptical opening may be larger than any diameter in the bell-bottomed fixation coupling 50.

The bell-bottomed shaped fixation coupling 50 may be implanted in the internal branches 92, 94, 96 of an arch branch device 90 as shown in Figure 7. The internal 25 branches 92, 94, 96 correspond, respectively, to the innominate, left common carotid, and the left subclavian arteries when the device 90 is planted in the aortic arch.

Figures 8A to 8D show steps that may be used in deploying a small vessel stent graft 62 with a bell-bottomed fixation coupling 50 into internal branch 94. A guidewire 72 is inserted through a small incision made in the patient's neck to access the left common 30 carotid artery. The guidewire 72 is advanced through the artery and then into the internal branch 94 in a proximal direction toward the heart as shown in Figure 8A. In Figure 8B, a delivery sheath 76 follows over the guidewire 72. The delivery sheath 76

- 9 -

is pulled back in Figure 8C to begin deployment of the small vessel stent graft 62 by revealing the fixation coupling 50. The fixation coupling 50 may be self-expanding or balloon expandable. The diameters of the fixation coupling 50 and the ring 55 are greater than the diameter of the internal branch 94, thus preventing the small vessel
5 stent graft 62 from withdrawing from the internal branch 94 in a distal direction away from the internal branch opening 79. Figure 8D shows the fixation coupling 50 fully deployed.

It is intended that the foregoing detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including
10 all equivalents, that are intended to define the spirit and scope of this invention.

The disclosures in US 61/092,150 from which the present application claims priority and in the abstract accompanying this application are incorporated herein by reference.

CLAIMS

1. A system for repairing an anatomical vessel at the junction of a main anatomical vessel and branch anatomical vessel including:
 - 5 a primary stent graft (40; 60) configured for placement in the main anatomical vessel, including a tubular graft material, at least one stent, a fenestration (42; 65) in a sidewall of the tubular graft material, the fenestration having a diameter;
 - 10 a branch vessel stent graft (30; 62) including:
 - a proximal end;
 - a distal end;
 - 15 a body portion configured for placement in a body vessel branching from a main body vessel; and
 - 20 a fixation coupling (10) positioned at or near the proximal end and configured for placement within the fenestration;
 - 25 wherein the fixation coupling comprises a distal non-helical ring (28) coupled to its distal end, a proximal non-helical ring (25) coupled to its proximal end, and a hyperboloid area (15) positioned between the rings, and a first outer extent (21) and a second outer extent (26), wherein the diameter or directrix (4) of both of the rings is larger than any diameter of the hyperboloid area; wherein the smallest diameter of the hyperboloid area is larger than the diameter of the fenestration; and
 - 30 where, when the fixation coupling is placed within the fenestration, the hyperboloid area provides a fluid-tight seal with the fenestration, while permitting multi-directional movement of the branch vessel stent graft.
 2. A system as claimed in claim 1, wherein the distal ring (28) is an ellipse.
 3. A system as claimed in claim 1 or 2, wherein the proximal ring (25) is an ellipse.
 4. A system as claimed in claim 1, 2 or 3, wherein the distal ring (28) includes a radiopaque element.
 5. A system as claimed in any one preceding claim, wherein the proximal ring (25) includes a radiopaque element.
 - 35 6. A system as claimed in any one preceding claim, wherein the fixation coupling (10; 50) is

deployable by balloon expansion.

7. A system as claimed in any of claims 1 to 5, wherein the fixation coupling (10; 50) is self-expanding.

5

8. A system as claimed in any one preceding claim, wherein the fixation coupling (10) is integrated with the branch vessel stent graft (30; 62).

9. A system as claimed in any one preceding claim, wherein the fenestration (42) is provided with 10 a support ring surrounding the perimeter of the fenestration.

10. A system as claimed in claim 9, wherein the support ring is of a material that permits visualisation of the support ring during deployment of the hyperboloid area (15) within the fenestration (42).

15

11. A system as claimed in claim 9 or 10, wherein the support ring is of a material that expands and then contracts to contact and seal against the hyperboloid area (15).

12. A system as claimed in any one preceding claim, wherein the fixation coupling (10) has a first 20 outer extent (21) immediately adjacent the distal ring (28) and a second outer extent immediately adjacent the proximal ring (25), and wherein the outer extents (21, 26) have diameters up to 20% larger than the smallest diameter of the hyperboloid area.

13. A method of deploying a system of endoluminal prostheses with a fixation coupling that 25 provides angular and rotating movement in a body having a primary vessel in communication with a secondary vessel, the system including:

 a first prosthesis for implantation in the primary vessel, the first prosthesis including a tubular wall, a lumen therethrough, and a fenestration in the tubular wall; and

 a second prosthesis for implantation in the secondary vessel, the second prosthesis 30 including a fixation coupling including a distal non-helical ring coupled to its distal end, a proximal non-helical ring coupled to its proximal end, and a hyperboloid area positioned between the rings, and a first outer extent and a second outer extent, and wherein the diameter or directrix (4) of both of the rings is larger than any diameter of the hyperboloid area;

 the method including:

35 deploying the first prosthesis in the primary vessel and aligning the fenestration with

the secondary vessel;

deploying the fixation coupling in the fenestration by placing the proximal non-helical ring in the lumen of the first prosthesis and abutting the proximal ring against an internal portion of the wall surrounding the fenestration; and

5 placing the distal non-helical ring outside the lumen of the first prosthesis such that the fenestration surrounds the hyperboloid area to form a joint allowing multi-directional movement of the branch vessel stent graft, wherein the hyperboloid area provides a fluid-tight seal with the fenestration when the fixation coupling is placed within the fenestration.

10 14. A method as claimed in claim 13, wherein the distal ring and/or the proximal ring is an ellipse.

15. A method as claimed in claim 13 or 14, wherein the first prosthesis and/or the second prosthesis is deployed by balloon expansion.

15 16. A method as claimed in claims, 13, 14 or 15, wherein the first prosthesis and/or the second prosthesis is self-expanding.

17. A method as claimed in any of claims 13 to 16, wherein the fixation coupling is deployed by balloon expansion.

20

18. A method as claimed in any of claims 13 to 16, wherein where the fixation coupling is self-expanding.

25

19. A method as claimed in any of claims 13 to 18, including any two or more of the following:
the distal ring and the proximal ring having a diameter larger than any diameter in the hyperboloid area;

the distal ring and/or the proximal ring being an ellipse;

the first prosthesis and/or the second prosthesis being deployed by balloon expansion;

the first prosthesis and/or a second prosthesis being self-expanding;

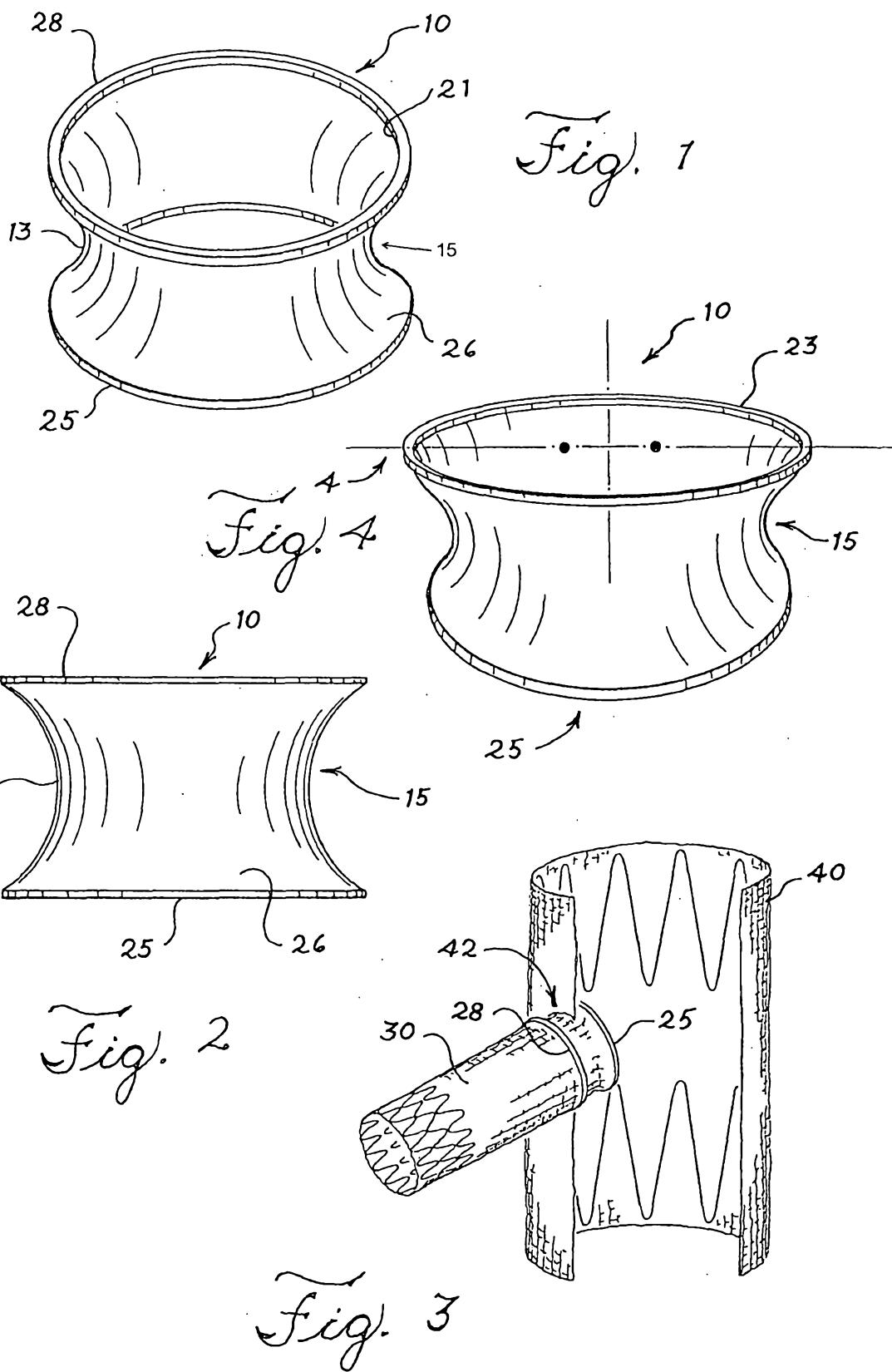
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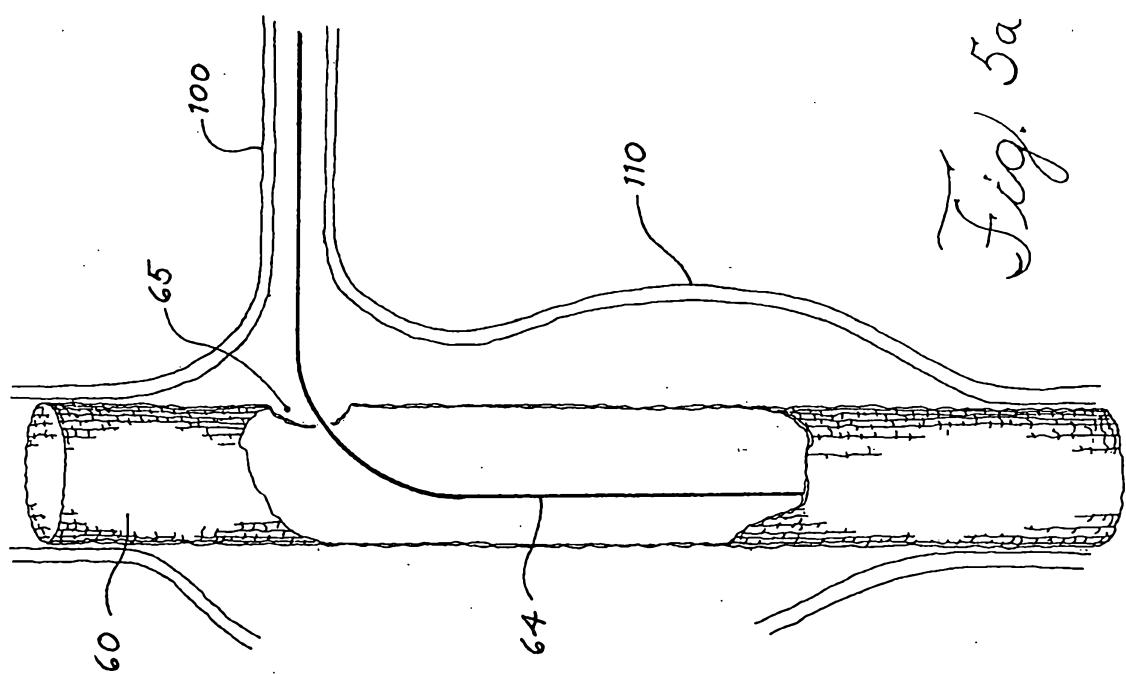
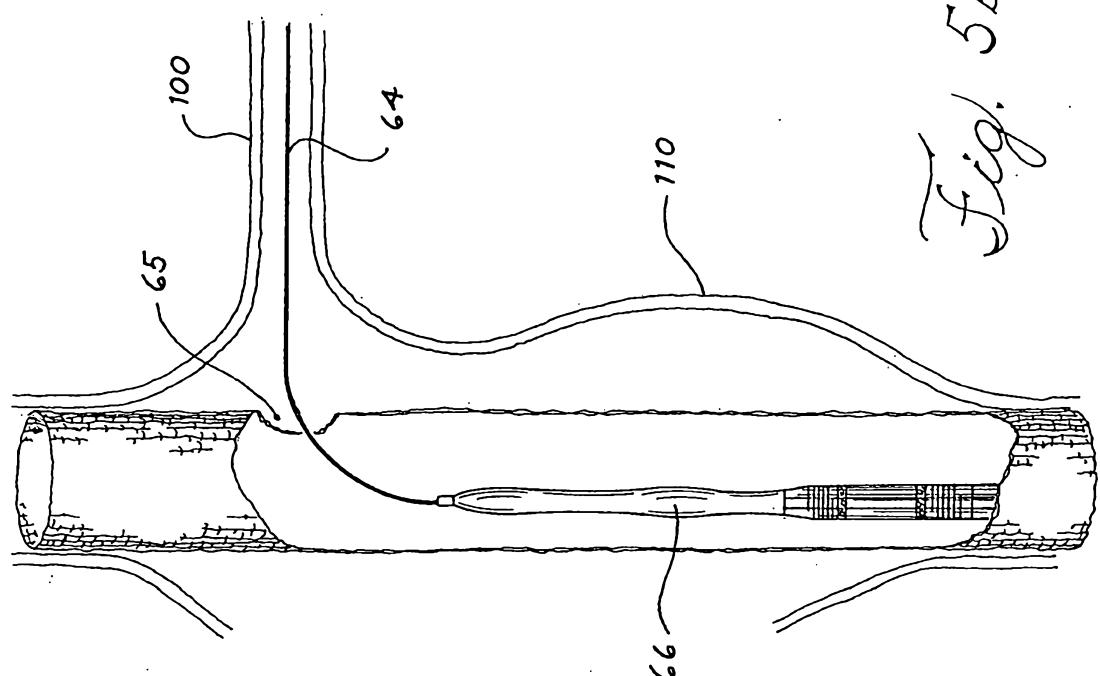
the fixation coupling being deployed by self-expansion; and

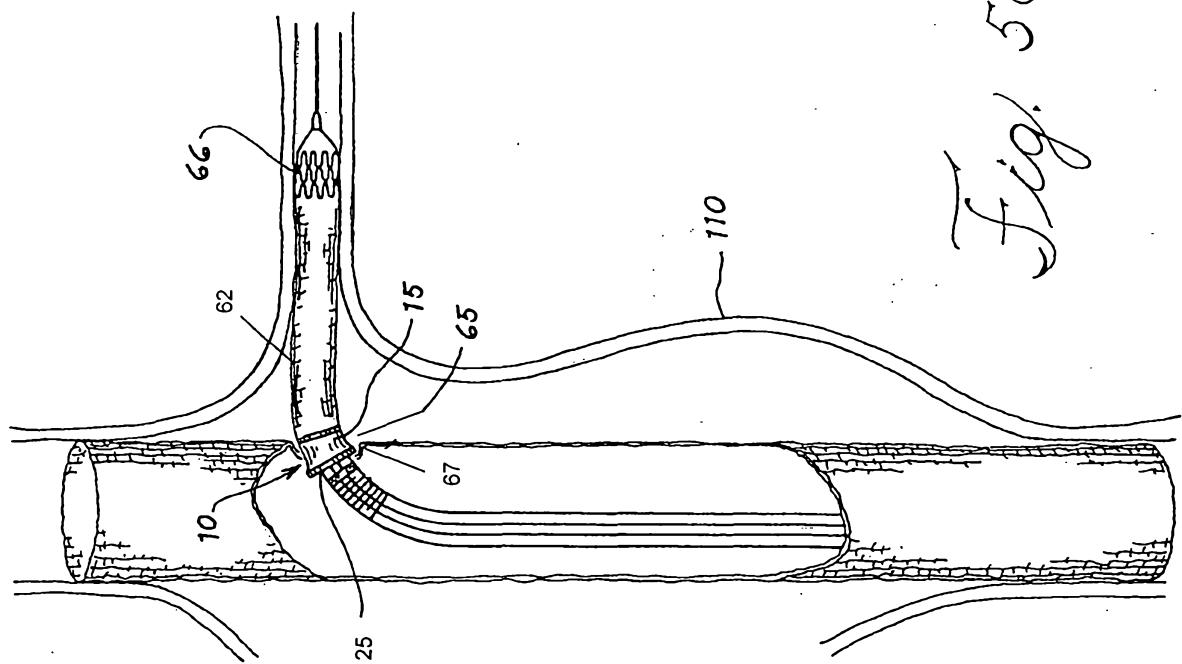
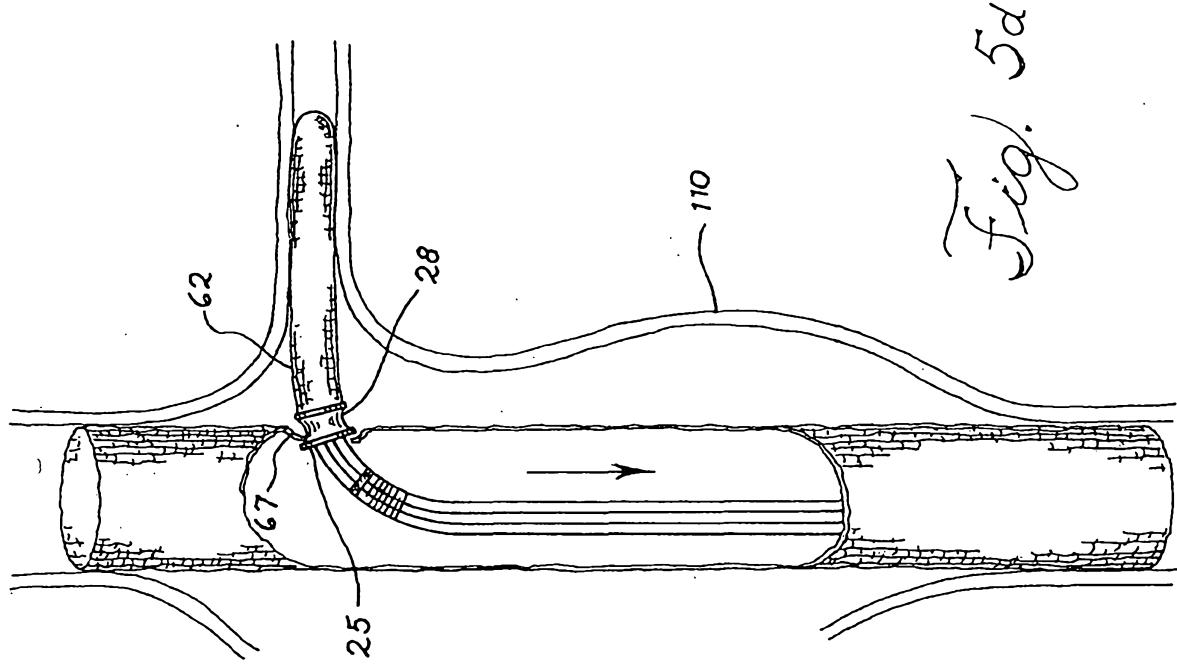
the fixation coupling being deployed by balloon expansion.

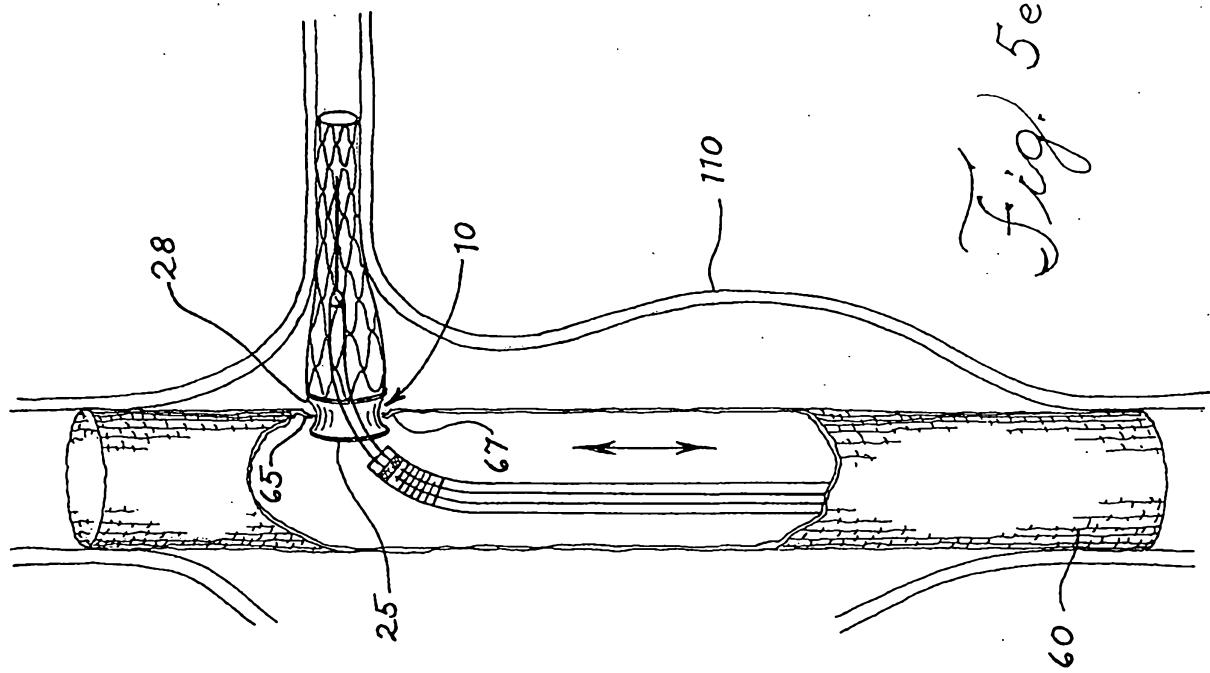
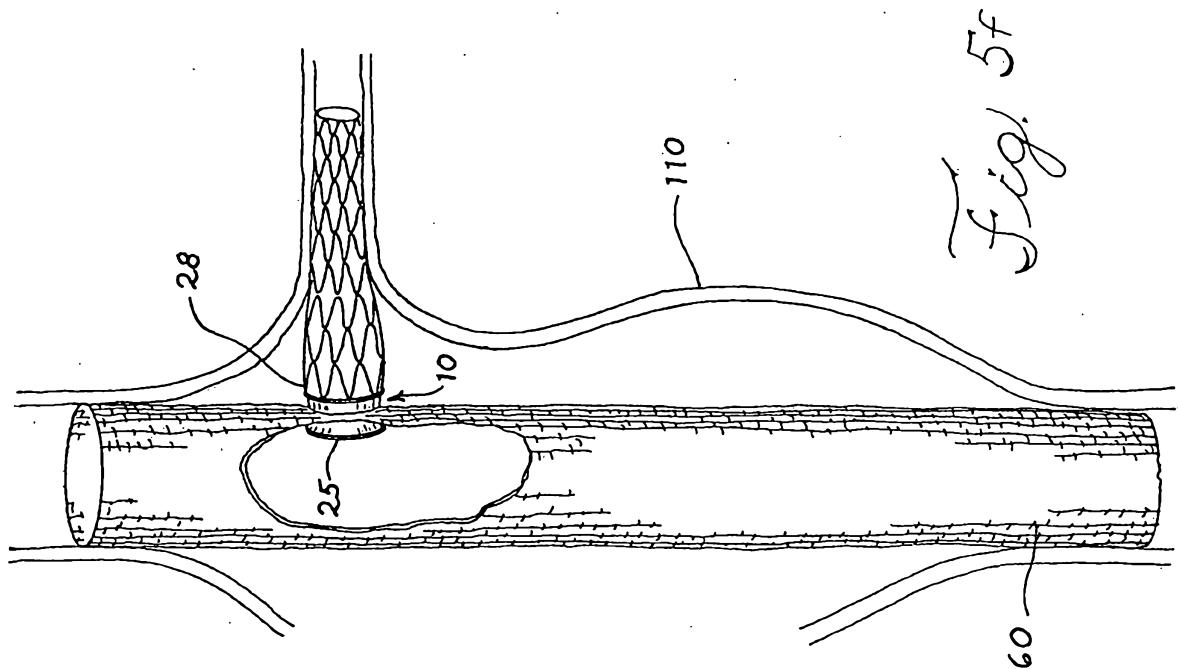
20. A method as claimed in any of claims 13 to 19, wherein the fixation coupling (10) has a first outer extent (21) immediately adjacent the distal ring (28) and a second outer extent immediately

adjacent the proximal ring (25), and wherein the outer extents (21, 26) have diameters up to 20% larger than the smallest diameter of the hyperboloid area.









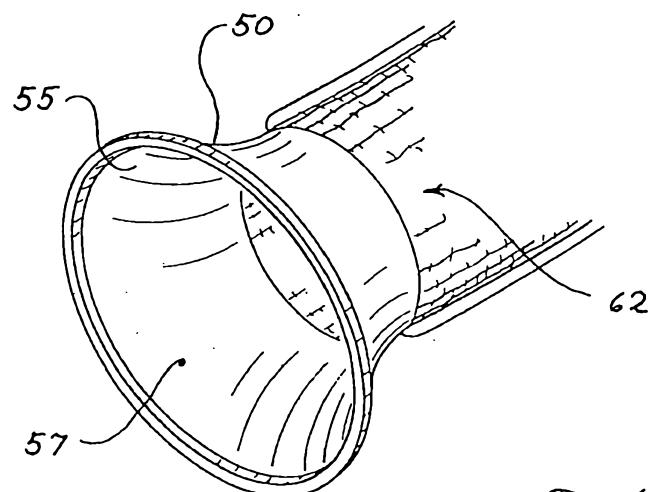


Fig. 6

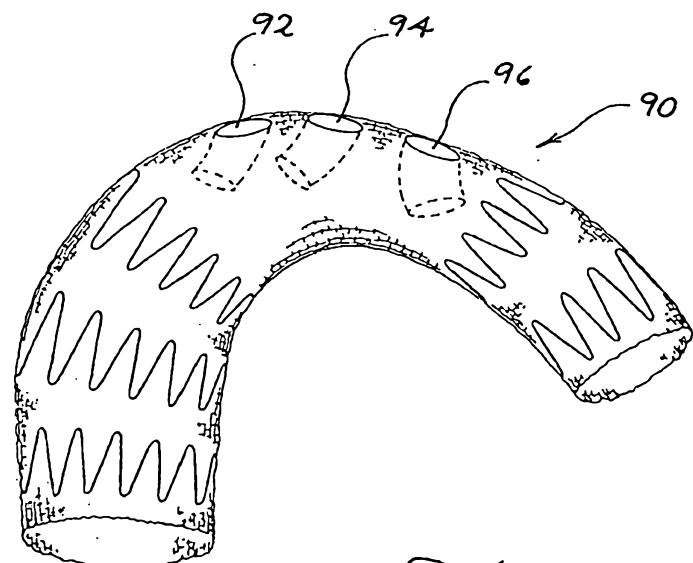


Fig. 7

