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(54) **ANEURYSM STENT**

(76) Inventors: **Michael Fulton**, Superior, CO (US); **Jeffrey Thramann**, Longmont, CO (US)

Correspondence Address:
Brian P. Kinnear
Holland & Hart
Suite 3200
555 17th Street
Denver, CO 80202 (US)

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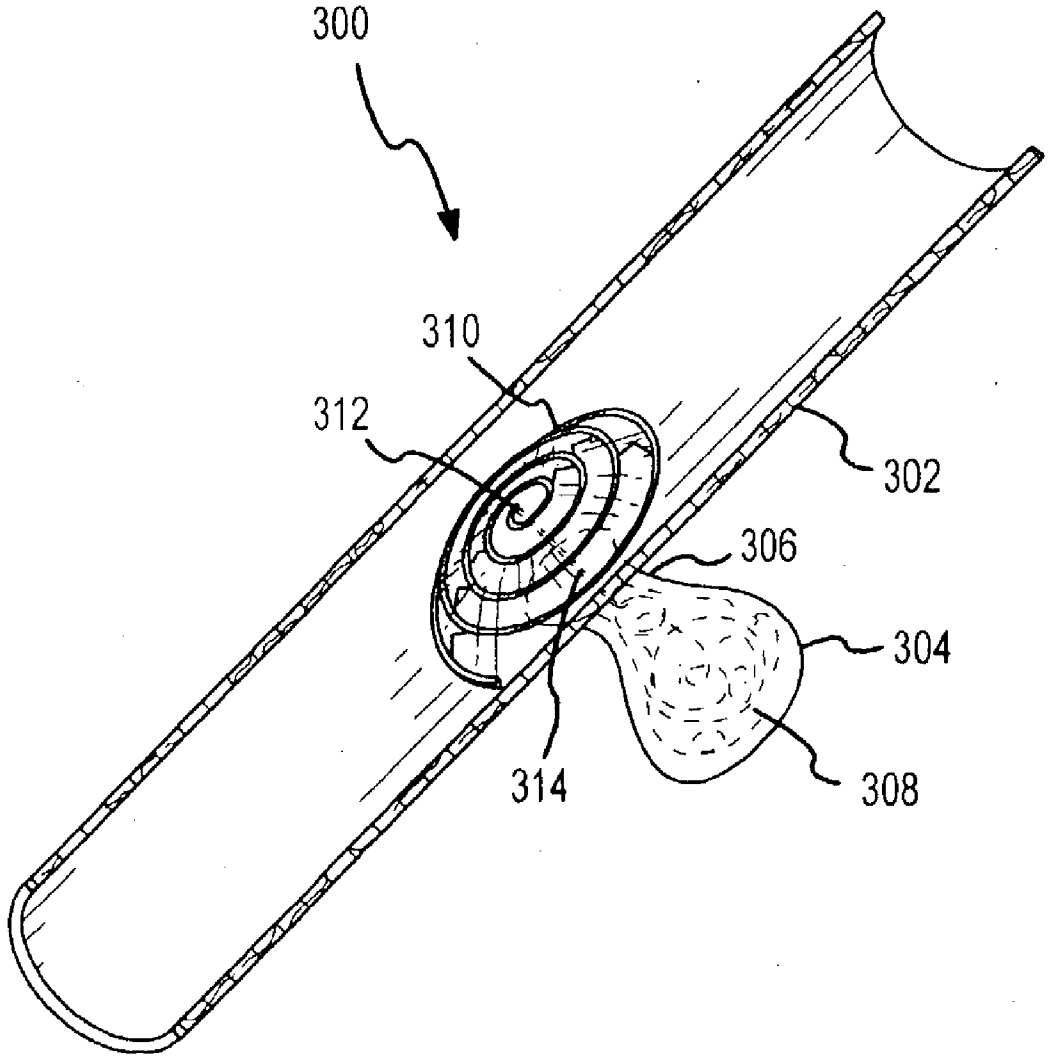
(52) **U.S. Cl.** **606/200**

(57) **ABSTRACT**

The present invention relates to an aneurysm stent having a base and connector. The base has a vessel facing side and an aneurysm facing side, and is shaped to cover an aneurysm sufficiently. The connector is coupled to the aneurysm facing side of the base such that when deployed the connector is adapted to extend partially into the aneurysm to anchor the base about the aneurysm and inhibit flow into the aneurysm.



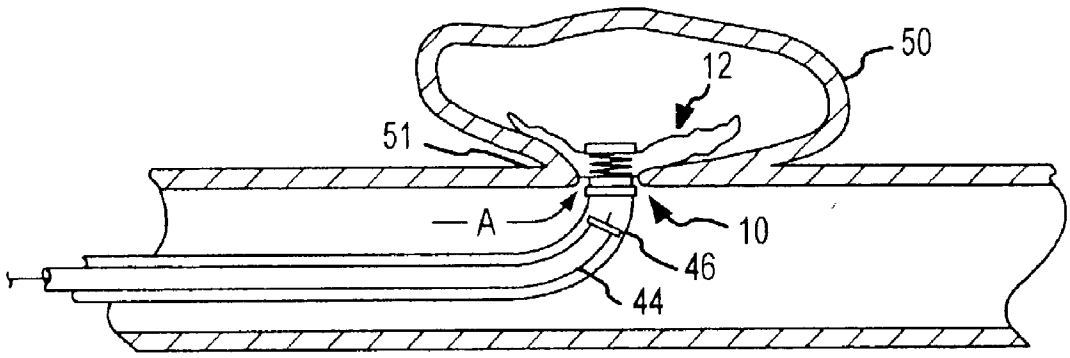


FIG.1

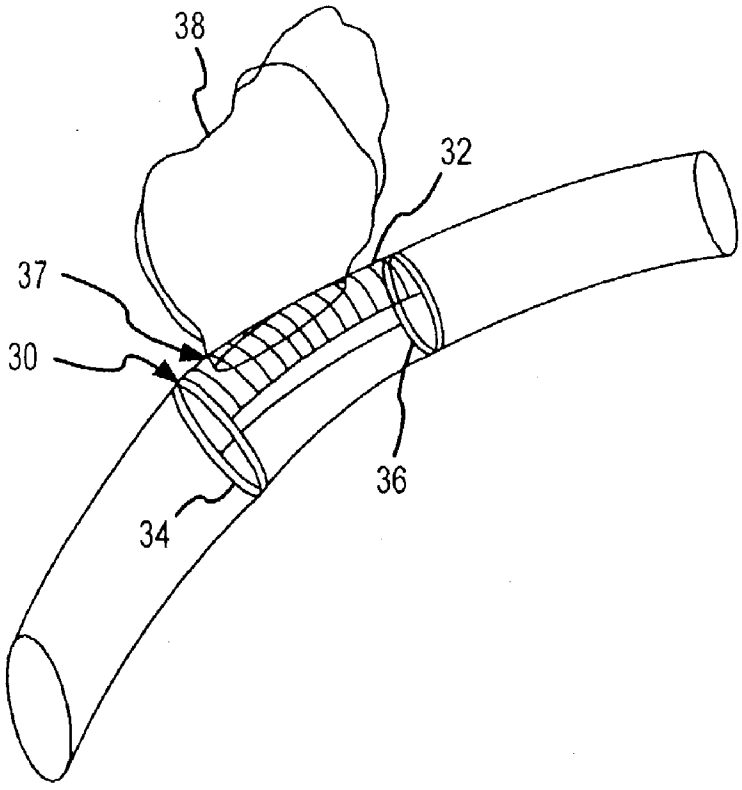


FIG.2

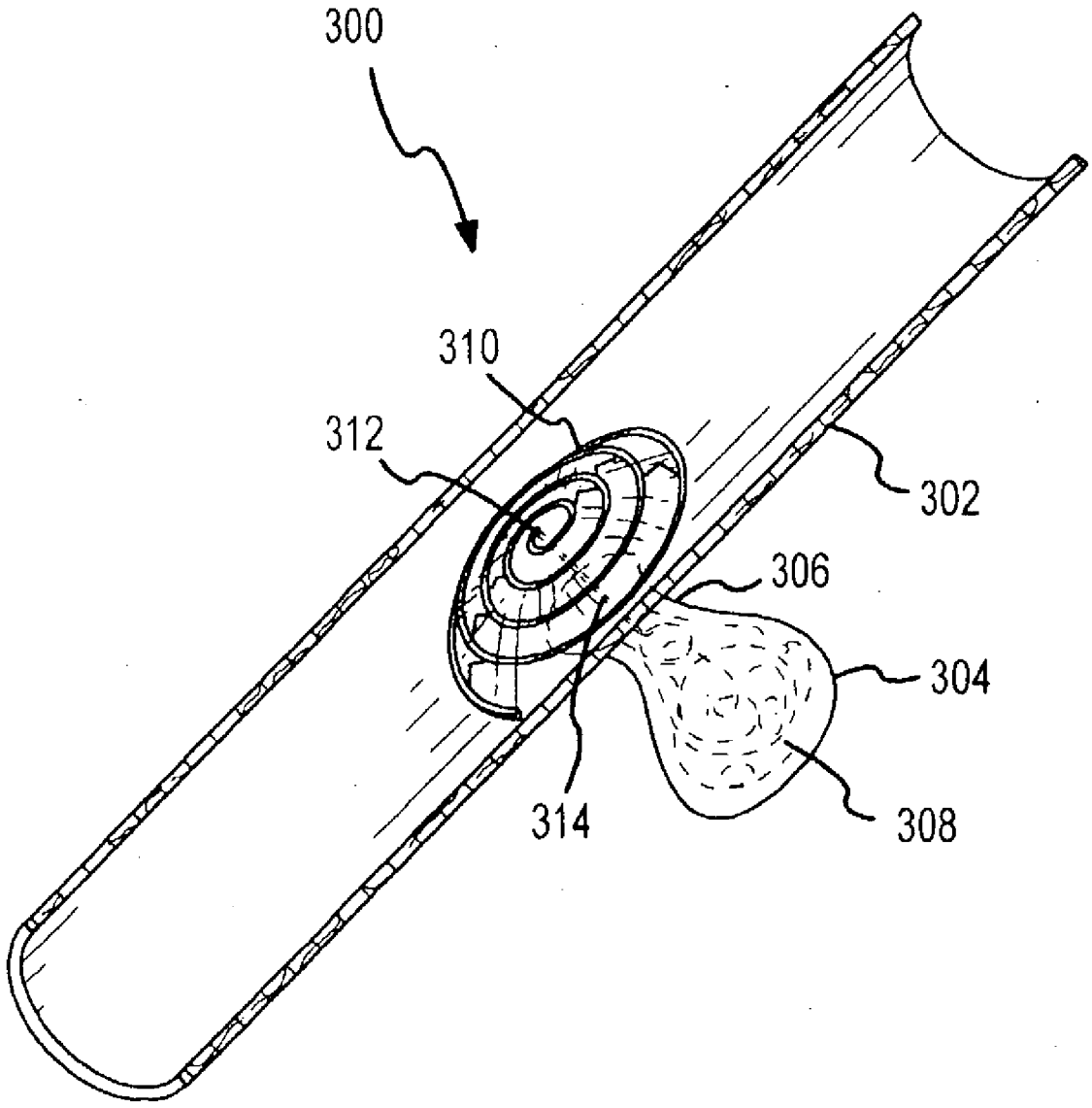


FIG.3

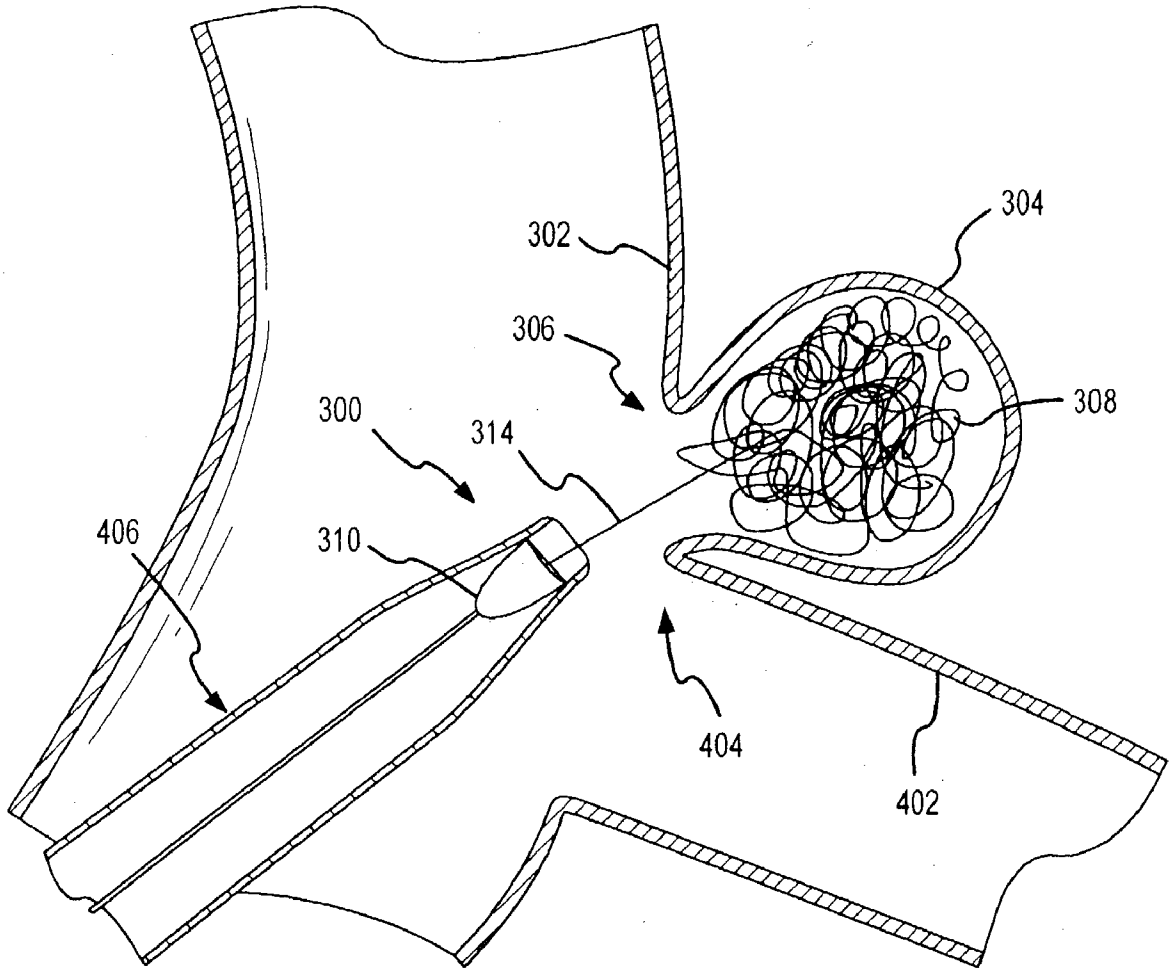


FIG.4

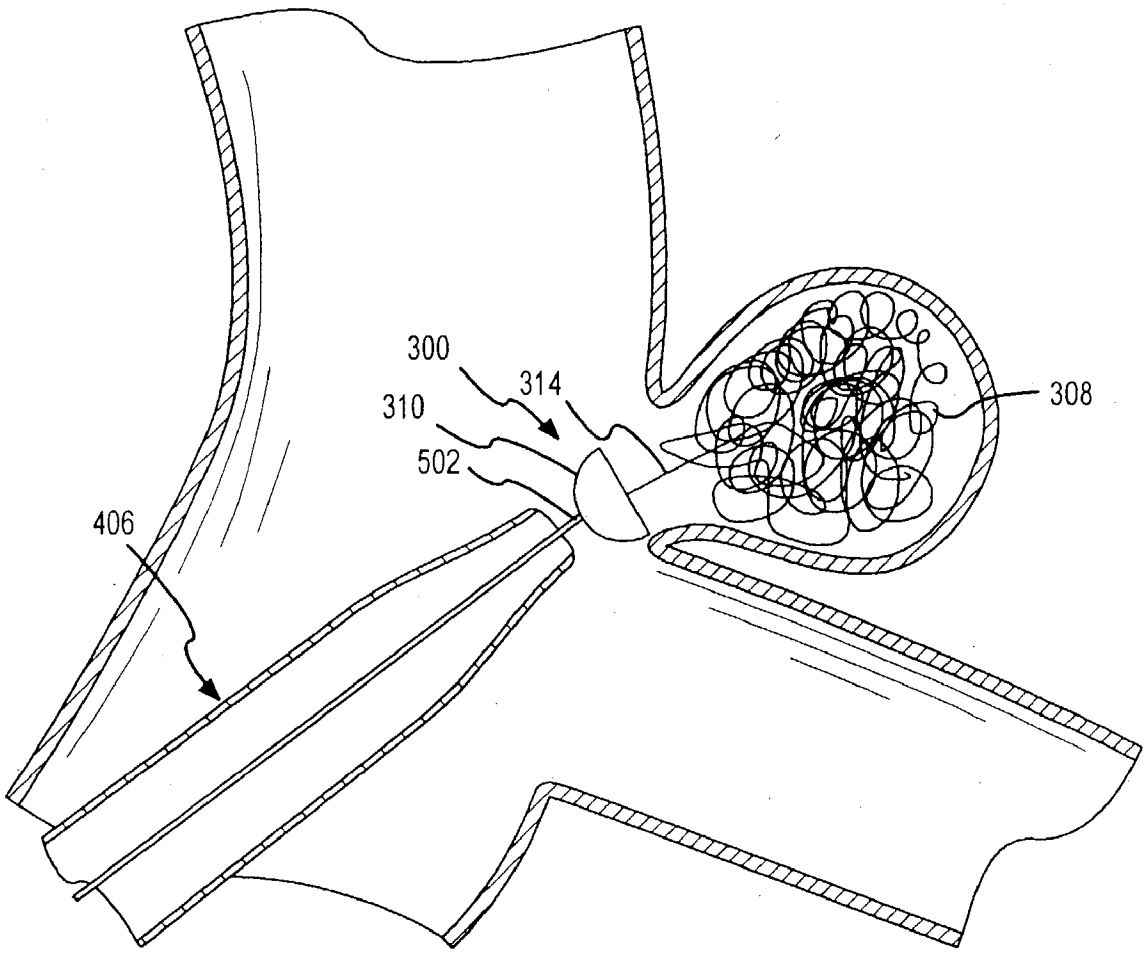


FIG.5

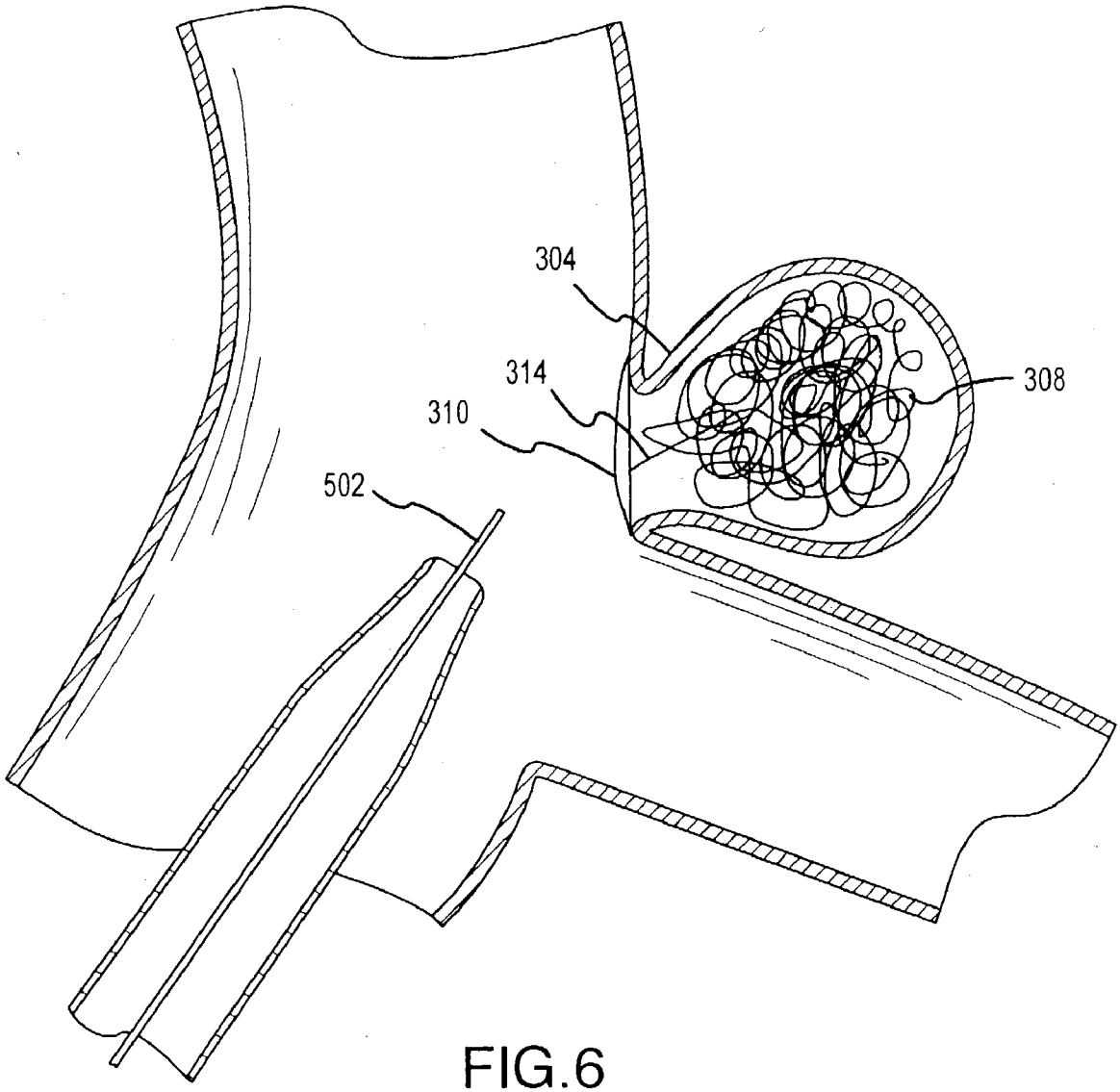


FIG.6

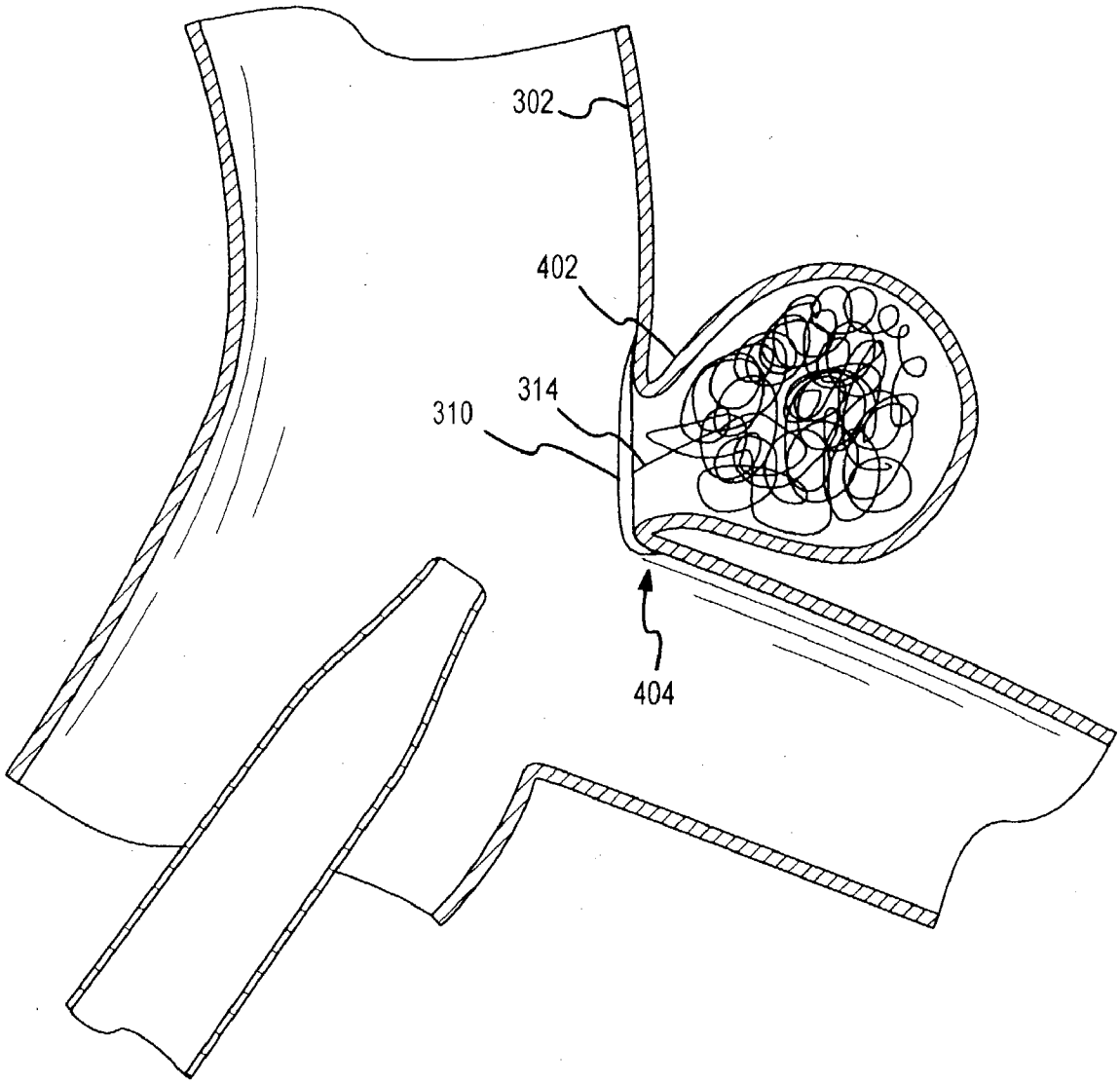


FIG.7

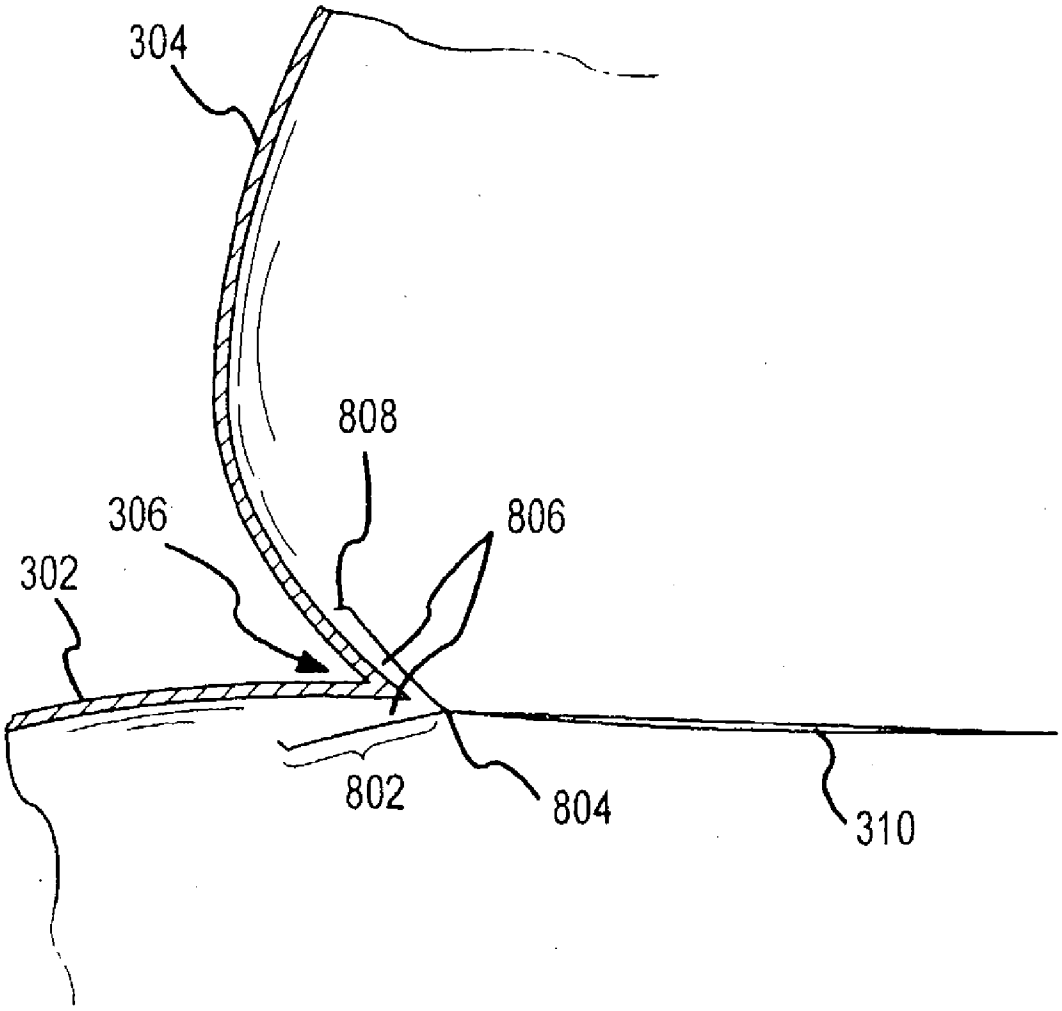


FIG.8

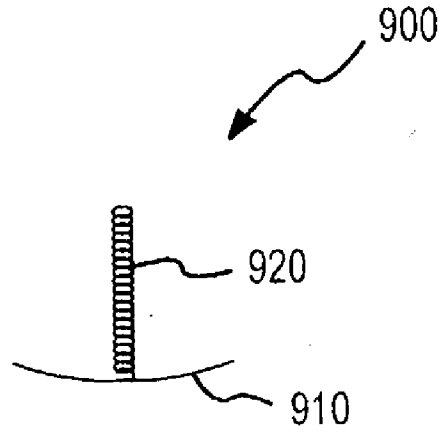


FIG.9A

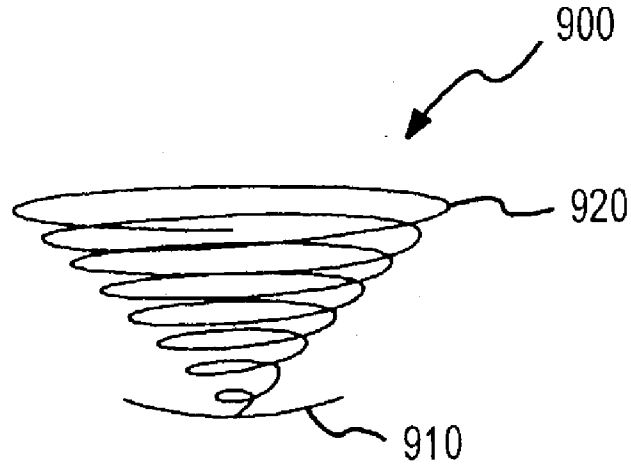


FIG.9B

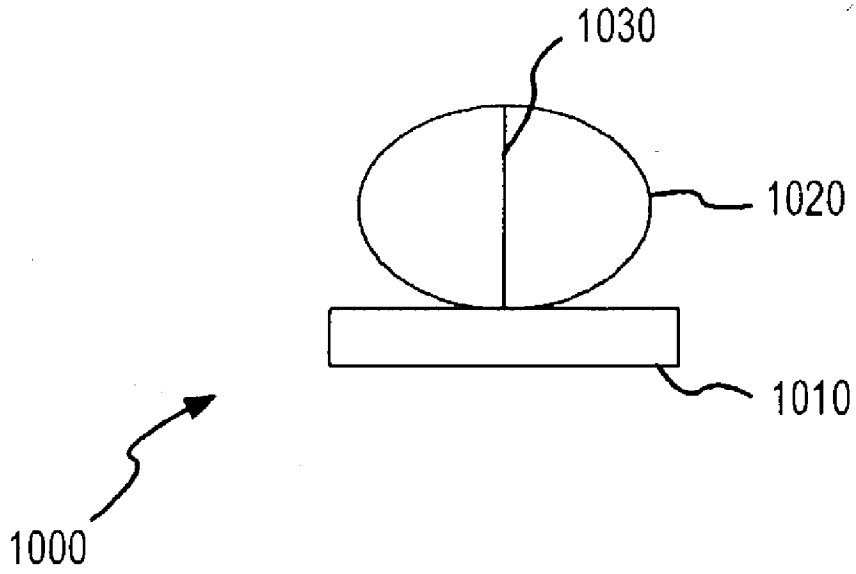


FIG.10A

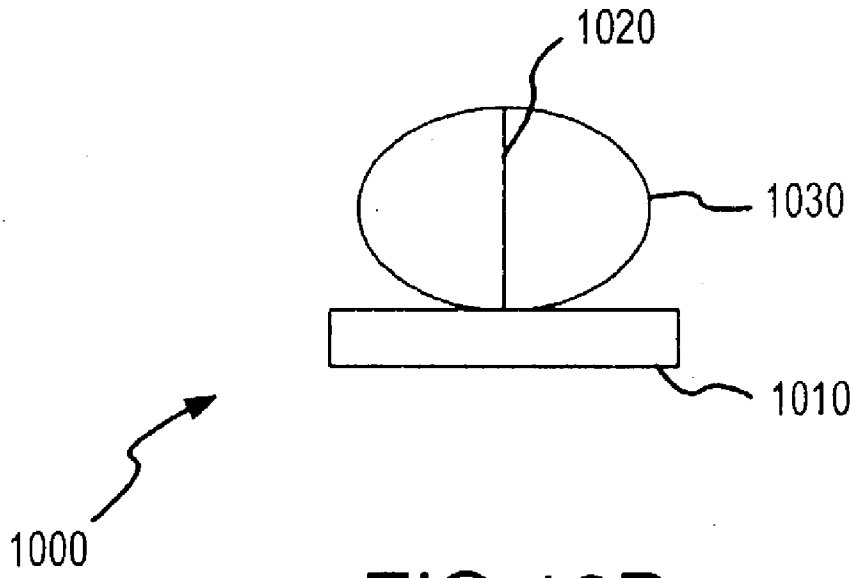


FIG.10B

ANEURYSM STENT

[0001] The present invention claims the benefit of U.S. Provisional Application Serial No. 60/404,422, filed Aug. 19, 2002, titled CEREBRAL ANEURYSM COIL STENT, incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to the surgical repair of aneurysms and, more particularly, to a patch that provides a seal between the arterial wall and a neck of the aneurysm to inhibit flow in the aneurysm.

BACKGROUND OF THE INVENTION

[0003] An aneurysm is a blood-filled dilation of a blood vessel. Major concerns with aneurysms revolve around rupturing of the arterial wall causing internal bleeding and clots breaking away from the aneurysm causing strokes.

[0004] There exist two generally approved methods of treating aneurysms. The first method of treatment includes surgical treatment. The second method of treatment includes endovascular treatment. Surgical removal of the aneurysm is sometimes not possible, leaving endovascular treatment as the only available option. Even when not the only option, endovascular treatment often is preferred because of the reduced risks and complications.

[0005] Conventionally, endovascular treatment of an aneurysm involves "packing" the aneurysm such that an endovascular occlusion is formed. Packing the aneurysm with coils, such as Guglielmi Detachable Coils (or GDCs), helps form an occlusion. While using GDCs is conventional, the aneurysm can be packed with numerous devices, such as, for example, other types of coils, balloons, glues, polymers, clotting agents, liners, or the like.

[0006] Endovascular treatment, while considered less risky than surgical treatment, has drawbacks. One drawback of endovascular treatment of the aneurysm includes the potential to over pack the aneurysm. Over packing the aneurysm can cause the material to enter the parent blood vessel, potentially inhibiting blood flow or generate undesirable pressure in the aneurysm. Also, some aneurysms have a wide connection to the blood vessel, a.k.a. wide neck aneurysms. Wide neck aneurysms have the additional risk that the occluded material will break free of the aneurysm and enter the parent blood vessel, potentially causing blockage of the parent blood vessel. Finally, clotting agents and polymers used to form occlusions in the aneurysm can seep to the parent blood vessel causing complications. Balloons and liners are intuitively pleasing as a solution, but have the potential for an inexact fit causing complications. For example, a balloon may be over inflated causing unwanted pressure or under inflated causing seepage in the aneurysm.

[0007] While the packing methods described above inhibit blood flow to the aneurysm, the aneurysm neck typically is open to the parent blood vessel. Thus, blood continues to flow to the aneurysm. To reduce the blood flow, several devices have been developed to cover the neck area of the aneurysm.

[0008] U.S. Pat. No. 6,454,780, issued Sep. 24, 2002, to Wallace, titled Aneurysm Neck Obstruction Device, shows a device designed to cover or block the neck of the aneurysm. **FIG. 1** shows the Wallace device **10** in some detail. The device **10** is placed inside aneurysm **50** using a catheter **46** and deployment tool **44**. When inside the aneurysm **50**, device **10** has walls **12** that expand or unfold to contact the inside of the aneurysm **50** and block neck **51**. But the device resides internal to aneurysm **50** allowing blood flow shown by arrow A in the parent vessel **52** to push up against the walls **12**. The upward pressure of the blood vessel on the wall **12** may allow blood from the parent vessel to seep in aneurysm **50**. Also, because the wall is internal to the aneurysm **50**, the neck **12** has the potential to expand. Other types of internal devices include liners and other neck bridges.

[0009] Devices to block the neck of the aneurysm external to the aneurysm exist also. These devices use the pressure of the blood vessel to help seat the block against the parent vessel wall and shield the neck from the blood vessel. One such device is shown in U.S. Pat. No. 6,309,367, issued Oct. 30, 2001, to Boock, titled Aneurysm Shield. The Boock device is shown in **FIG. 2**. The Boock device **30** has a cylindrical shaft **32** that covers the neck **37** of the aneurysm **38** and is anchored by anchor rings **34** and **36**. While device **30** resides external to the aneurysm it has multiple parts that could break free or deteriorate that reside in the parent vessel. While the Boock device **30** seemingly works for its intended purpose in theory, its relatively large size and surface area makes its impractical to actually use. In the brain, for example, multiple blood vessels may branch off from the location of an aneurysm. Attempting to use the Boock device would block blood flow to one or more of the branch vessels as well as the aneurysm, which makes the Boock device useful in only limited situations, if any.

[0010] Thus, it would be desirous to develop and improve internal and external aneurysm stents.

SUMMARY OF THE INVENTION

[0011] To attain the advantages and in accordance with the purpose of the invention, as embodied and broadly described herein, apparatuses to inhibit the flow of blood to an aneurysm comprise a base and connector. The base has a vessel facing side and an aneurysm facing side, and is shaped to cover an aneurysm sufficiently. The connector is coupled to the aneurysm facing side of the base such that when deployed the connector is adapted to extend partially into the aneurysm to anchor the base about the aneurysm and inhibit flow into the aneurysm.

[0012] The foregoing and other features, utilities and advantages of the invention will be apparent from the following more particular description of a preferred embodiment of the invention as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING

[0013] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the present invention, and together with the description, serve to explain the principles thereof. Like items in the drawings are referred to using the same numerical reference.

[0014] **FIG. 1** shows a prior art aneurysm device;

[0015] **FIG. 2** shows a prior art aneurysm device;

[0016] **FIG. 3** shows a perspective view of an aneurysm stent deployed in a blood vessel illustrative of the present invention;

[0017] **FIG. 4** shows a cross section of a blood vessel with an aneurysm prior to deployment of the aneurysm stent illustrated in **FIG. 3**;

[0018] **FIG. 5** shows a cross section of the aneurysm stent just prior to deployment;

[0019] **FIG. 6** shows a cross section of the aneurysm stent mostly deployed about the aneurysm;

[0020] **FIG. 7** shows a cross section of the aneurysm stent deployed;

[0021] **FIG. 8** shows a cross section of a portion of a stent consistent with the present invention;

[0022] **FIGS. 9A and 9B** show a stent consistent with the present invention; and

[0023] **FIGS. 10A and 10B** show a cross-section of a stent consistent with the present invention.

DETAILED DESCRIPTION

[0024] Some embodiments of the present invention are described with reference to FIGS. **3** to **10**B. **FIG. 3** shows an aneurysm stent **300** consistent with an embodiment of the present invention deployed. Stent **300** is deployed in a parent blood vessel **302**, which is shown as an artery but could be a vein a capillary, or the like, about aneurysm **304**. A blood flow path from vessel **302** to aneurysm **304** is provided by an aneurysm neck **306**. Neck **306** is shown as a narrow neck, but could be a wide neck. Aneurysm **304** is shown packed with conventional GDCs **308**. While shown as packed with conventional coils, aneurysm **304** could be packed with any type of packing agent, such as, for example, other types of coils, balloons, glues, polymers, clotting agents, liners, or the like. In fact, aneurysm **304** does not need to be packed at all as stent **300** blocks blood flow to aneurysm **304**. The attachment of stent **300** to cover neck **306** will depend, in part, on the type of material used to pack aneurysm **304**, if any.

[0025] With reference to **FIG. 3**, which illustrates aneurysm **304** packed with conventional GDCs **308**, stent **300** includes a base **310**, a base connection point **312**, and a connector **314**. Base **310** has opposed sides, a vessel side and a wall side (not specifically labeled). The vessel side can be covered with a graft material or other biocompatible material. The vessel side may be coated with a material to stimulate cell growth and encourage formation of a pseudo-intima. The wall side could be covered with an adhesive to assist in seating stent **300** about neck **306** by forming a seal between base **310** and vessel **302**. Base connection point **312** couples base **310** to connector **314**. Base connection point **312** does not need to exist as a separate component, but is identified for convenience to distinguish between base **310** and connector **314**. Base connection point **312** could, as a matter of design choice, be a fitting to connect base **310** and connector **314** if desired. Connector **314** can be a conventional coil material attached to base **312** that extends to GDCs **308**. When deployed, connector **314** assumes its coiled shape and engages GDCs **308** to assist in keeping stent **300** seated about neck **306**. Connector **314** could physically curl around or hook into GDCs **308** for anchoring, but connector **314** could simply pack in aneurysm **304** similar to a conventional GDC. Connector **314** could simply anchor stent **300** in place, but could also contract and pull base **310** snug against vessel **302** to firmly seat base **310** about aneurysm neck **306** further inhibiting blood flow to aneurysm **304**. While only one base connection point **312** and one connector **314** is shown in **FIG. 3**, multiple connections and connectors are possible. Also, the connections do not necessarily have to be in the center of the stent, but could be offset. It is believed greater stability will be obtained by symmetrical placement of connectors and connection points, but asymmetrical placement is possible. Multiple connectors could be attached to a single connection point as well.

[0026] Referring now to FIGS. **4-7**, a method of deploying the stent **300** will be described. Referring first to **FIG. 4**, parent vessel **302** is shown with aneurysm **304** and neck **306** existing off the main body of vessel **302**. Unlike **FIG. 3, a** second vessel **402** resides about neck **306** forming a junction **404**. While the present invention will be explained in connection with deploying stent **300** about junction **404**, stent **300** could be similarly deployed at locations with more or less junctions. First, aneurysm **304** is packed using, for example, conventional GDCs **308** in a conventional manner. Without going in much detail, GDCs **308** are placed by first directing a catheter **406** to the site of aneurysm **304**. GDCs **308** are passed through catheter **406** and packed in aneurysm **304** in a conventional manner. Once GDCs **308** are placed, stent **300** is passed through the same or a different catheter **406** using a guide wire **502 (FIG. 5)**. Stent **300** includes base **310** and connector **314**. As can be seen, base **310** is compacted to pass through catheter **406**. Also, connector **314** enters the packed GDCs **308**.

[0027] Referring now to **FIG. 5**, stent **300** has exited catheter **406** and guide wire **502** can be seen attached to stent **300**. Base **310** is approaching neck **306** and connector **314** has extended in GDCs **308** packed in aneurysm **304**. As shown, base **310** can be made of a self-expanding material that begins expanding on exiting catheter **406**. Alternatively, base **310** can be made of a material that requires activation or other manipulation to expand.

[0028] Referring now to **FIG. 6**, stent **300** is shown in the appropriate position and guide wire **502** has been withdrawn. Base **310** has expanded sufficiently to mostly block neck **306** and connector **314** has begun curling, packing, embedding or otherwise anchoring in aneurysm. For example, connector **314** can be placed about GDCs **308** as conventional packing material, connector **314** can curl and engage GDCs **308**, or the like. While one connector **314** is shown, it would be possible to have two of more connectors **314**. As described in more detail below, a number of other devices and techniques can be used to anchor stent **300** about the neck.

[0029] Referring now to **FIG. 7**, stent **300** is shown with base **310** and connector coils **314** fully deployed. In this case, base **310** is flush with the wall of vessel **302**, wraps around junction **404** and is flush with the wall of vessel **402**. Connectors **314** are engaged with GDCs **308** and, optionally, connectors **314** contract in a manner that pulls base **310** in toward GDCs **308** providing a snug seating between base **310** and vessel **302**.

[0030] The stent **300** could be made of many materials. Some material includes conventional graft material. Alter-

natively, stent **300** could be made of one or more shaped memory alloys (SMAs) or a combination of graft material and SMAs. SMAs are a group of materials that demonstrate an ability to return to some previously defined shape or size when subjected to the appropriate thermal procedure. Generally, these materials can be plastically deformed and, upon exposure to thermal manipulation, will return to the pre-deformation shape. Some SMA material is considered to be two-way shaped memory alloys because they will return to the deformed shape upon proper thermal activation. SMAs include Ag—Cd alloys, Cu—Al—Ni alloys, Cu—Sn alloys, Cu—Zn alloys, Cu—Zn—Si alloys, Cu—Zn—Sn alloys, Cu—Zn—Al alloys, In—Ti alloys, Ni—Al alloys, Ni—Ti alloys, Fe—Pt alloys, Mn—Cu alloys, Fe—Mn—Si alloys, and the like. As shown by FIGS. **4-7**, SMAs would work well for stent **300** because, for example, connectors **314** could be shaped with a predefined curl that will engage GDCs **308**. The SMA could be deformed at a predefined temperature to a straight, or substantially straight, shape to allow for connectors **314** to penetrate packed GDCs **308** in aneurysm **302**. Thermal manipulation would cause connector coils **314** to assume the original curled shape that will anchor stent **300** about aneurysm **302** and may provide a force tending to pull base **310** in towards aneurysm **302** further seating stent **300** about aneurysm **302**. Similarly, base **310** could be made of SMA. In this case, base **310** could be originally shaped to approximate the shape of the vessel(s) around aneurysm neck **304** to allow for as close a fit as possible. This would also allow use of stent **300** in areas having many vessels branching around the aneurysm.

[**0031**] As shown in FIGS. **3-7**, base **310** is shown having a circular or semicircular shape. In particular, **FIG. 3** illustrates base **310** as a coil of material that expands on deployment. The shape of base **310**, however, is largely a function of material, design choice, and the aneurysm location. Thus, stent **300** could take many shapes including triangular, rectangular, square, elliptical, conical, spherical, circular, cylindrical, or the like

[**0032**] The present invention has been described with the aneurysm packed with conventional GDC coils, as described above, the aneurysm could be packed with alternative material. For example, if the aneurysm was packed with a polymer or clotting agent, the connector or anchor could be a simple post connected to the stent and embedded in the occlusion. Base **310** connected to the post would be held in place by the occlusion. Further seating force could be supplied by using a material that contracts on activation, such as SMAs. If the aneurysm was packed with a liner or balloon, a connection post could be provided on the balloon or liner to allow attaching the stent to the balloon or liner. For example, a balloon inserted in aneurysm **302** could have a flanged lower post (similar to some helium balloons) that connector coil **314** could wrap around. In this case, if, for example, connector coil **314** was made out of SMAs, thermal activation could cause coil **314** to tighten around the post attached to the balloon and contract. The contraction would be resisted by the flange on the post tending to pull base **310** in towards aneurysm **302** to assist in seating base **310** about aneurysm **302**. Alternatively to a post, the stent could have prongs that extend along the inside walls of the aneurysm such that the expanded balloon or liner would press the prongs against the wall of the aneurysm and seat the stent. Referring to **FIG. 8**, base **310** could be designed with a clamp **802** around an edge **804** of base **310**. As shown, clamp **802** could have opposed surfaces **806** such that when deployed, surfaces **806** move together and grip vessel **302** at neck **306**. A ridge **808** could be provided to assist in the grip. Clamp **802** would be particularly useful if aneurysm **304** was not packed with anything.

[**0033**] Referring to **FIGS. 9A and 9B**, another stent **900** consistent with the present invention is shown. Stent **900** includes a base **910** and a connector **920**. Un deployed, connector **920** is a tightly wrapped coil of material. On deployment, connector **920** unwinds into a bulbous or volumous area sufficiently to anchor the stent **900**. Generally, connector **920** would expand to completely fill aneurysm space, but at a minimum the expansion should be sufficient to prevent connector **920** from pulling out of the aneurysm. As can be appreciated, stent **900** could be used to treat the aneurysm without packing material. But if packing material were used to treat the aneurysm, connector **920** would not need to expand as much.

[**0034**] **FIGS. 10A and 10B** show another stent **1000** consistent with the present invention. **FIG. 10A** shows a front plan view of a stent **1000** that includes a base **1010** and expanded connectors **1020** and **1030**. While stent **1000** is shown with two orthogonal rings as connectors **1020** and **1030**, more rings could be used. Further the rings could be cross-linked or individual rings. **FIG. 10B** shows a side plan view of stent **1000** also with expanded connectors **1020** and **1030**. As can be seen, connectors **1020** and **1030**, which are shown in the deployed state, expand to form rings that act similar to the corkscrew anchor above. Also, while shown as rings any shape is possible, such as diamond, circular, square, triangular, elliptical, helical, or the like.

[**0035**] While the invention has been particularly shown and described with reference to a preferred embodiment thereof, it will be understood by those skilled in the art that various other changes in the form and details may be made without departing from the spirit and scope of the invention.

We claim:

1. An apparatus to inhibit flow to an aneurysm, comprising:

a base having a vessel facing side and an aneurysm facing side;

the base comprising a shape sufficient to cover an aneurysm;

a connector; and

the connector coupled to the aneurysm facing side,

wherein the connector is adapted to anchor the base about the aneurysm to inhibit flow into the aneurysm.

2. The apparatus according to claim 1, wherein the connector is a coil adapted to pack in the aneurysm.

3. The apparatus according to claim 2, wherein the connector is adapted to couple to at least one of the group consisting of: GDCs, balloons, liners, polymers, and clotting agents.

4. The apparatus according to claim 1, wherein:

the base comprises an edge; and

the connector has at least a first prong, such that the edge and at least the first prong form a clamp that grips the vessel wall to seat the base about the aneurysm.

5. The apparatus according to claim 1, wherein:

the base comprises graft material.

6. The apparatus according to claim 1, wherein:

the base comprises self-expanding material such that the base can be delivered in a small package and expands on deployment to cover the aneurysm.

7. The apparatus according to claim 6, wherein the base also comprises graft material.

8. The apparatus according to claim 1, wherein the connector comprises at least one coil adapted to engage GDCs packed in the aneurysm.

9. The apparatus according to claim 8, wherein the at least one coil is made of at least a first shaped memory alloy.

10. The apparatus according to claim 9, wherein the at least one coil is deformed such that on thermal treatment the at least one coil engages GDCs and provides a force tending to seat the base about the aneurysm.

11. The apparatus according to claim 1, wherein the base is at least one of a triangular shape, a circular shape, a conical shape, a spherical shape, an elliptical shape, a rectangular shape, and an irregular shape.

12. The apparatus according to claim 1, wherein the base resides completely in the vessel.

13. The apparatus according to claim 1, wherein the aneurysm facing side is coated with an adhesive.

14. The apparatus according to claim 1, wherein the connector comprises a post to be anchored in an occlusion in the aneurysm.

15. The apparatus according to claim 1, wherein the connector comprises at least one prong extending along an interior wall of the aneurysm, the at least one prong adapted to be held in place by at least one of a balloon or liner inserted in the aneurysm.

16. The apparatus according to claim 1, wherein the base comprises at least one base coil arranged to expand on deployment.

17. The apparatus according to claim 16, wherein the at least one base coil expands on activation.

18. The apparatus according to claim 16, wherein the at least one base coil is arranged in the shape of a spiral.

19. The apparatus according to claim 16, wherein the at least one base coil comprises a shaped memory alloy that is activated on thermal manipulation.

20. The apparatus according to claim 1, wherein the vessel facing side is coated with a material to stimulate cell growth and encourage formation of a pseudointima.

21. The apparatus according to claim 1, wherein the connector is a tightly wound coil of material that expands to a corkscrew shape to anchor the stent.

22. The apparatus according to claim 1, wherein the connector is a plurality of rings that expand to anchor the stent.

23. The apparatus according to claim 22, wherein the plurality of cross-linked rings are orthogonal.

24. An aneurysm stent, comprising:

a base;

at least one connector coupled to the base;

the at least one connector adapted to be inserted into an aneurysm packed with GDCs and, upon insertion, to curl and pack into the aneurysm.

25. The aneurysm stent according to claim 24, wherein:

the at least one connector is coupled to a geometric center of the base.

26. The aneurysm stent according to claim 24, wherein:

the at least one connector is at least two connectors, each connector extending in the aneurysm.

27. The aneurysm stent according to claim 26, wherein:

the at least two connectors are coupled to the base in a symmetrical manner.

28. The aneurysm stent according to claim 24, wherein the at least one connector is made of a first shaped memory alloy.

29. The aneurysm stent according to claim 28, wherein the base is made of a second shaped memory alloy.

30. The aneurysm stent according to claim 29, wherein the first shaped memory alloy and the second shaped memory alloy are the same.

31. The aneurysm stent according to claim 30, wherein the first shaped memory alloy and the second shaped memory alloy are nitinol.

32. The aneurysm stent according to claim 24, wherein the base has a vessel side and an aneurysm side, the vessel side comprises a layer of biocompatible material that promotes permanent fixation of the stent

33. The aneurysm stent according to claim 32, wherein the biocompatible material is a graft coated with a material to stimulate cell growth and encourage formation of a pseudo-intima.

34. The aneurysm stent according to claim 32, wherein the aneurysm side has a layer of adhesive.

35. An apparatus to inhibit flow to an aneurysm, comprising:

a base having a vessel facing side and an aneurysm facing side;

the base comprising a shape sufficient to cover an aneurysm; and

means for anchoring the base about the aneurysm to inhibit flow into the aneurysm.

36. The apparatus according to claim 35, wherein the means for anchoring comprises:

at least one of a coil, a post, a prong, and a clamp.

37. A method for obstructing the flow of blood through the neck of an aneurysm, the method comprising the steps of:

passing a catheter to the site of an aneurysm;

inserting an anchor into the aneurysm;

deploying an aneurysm base to block the neck of the aneurysm; and

anchoring the aneurysm base about the neck of the aneurysm using the anchor to inhibit the flow of blood in the aneurysm.

38. The method according to claim 37, further comprising the step of:

packing material in the aneurysm to form an occlusion.

39. The method according to claim 38, wherein the anchoring step includes engaging the anchor with the packed material.

40. The method according to claim 38, wherein the anchoring step further includes the step of:

providing a seating force to assist in seating the aneurysm base about the neck of the aneurysm.

41. The method according to claim 37, further comprising the steps of:

providing an adhesive coating on the aneurysm base; and

adhering the aneurysm base to the vessel during deployment.

42. An aneurysm stent, comprising:

a base;

at least one connector coupled to the base;

the at least one connector adapted to be inserted into an aneurysm and, upon insertion, to anchor the base about a neck of the aneurysm.

43. The aneurysm stent according to claim 42, wherein the at least one connector comprises:

at least one tightly wound coil that extends from the base into the aneurysm;

the at least one tightly wound coil expands after insertion to pack the aneurysm and anchor the stent.

44. The aneurysm stent according to claim 43, wherein the at least one tightly wound coil expands into a corkscrew shape.

45. The aneurysm stent according to claim 42, wherein the at least one connector comprises at least one of a plurality of coils, a plurality of prongs, and a plurality of posts.

46. The aneurysm stent according to claim 45, wherein the plurality of cross-linked coils are orthogonal.

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