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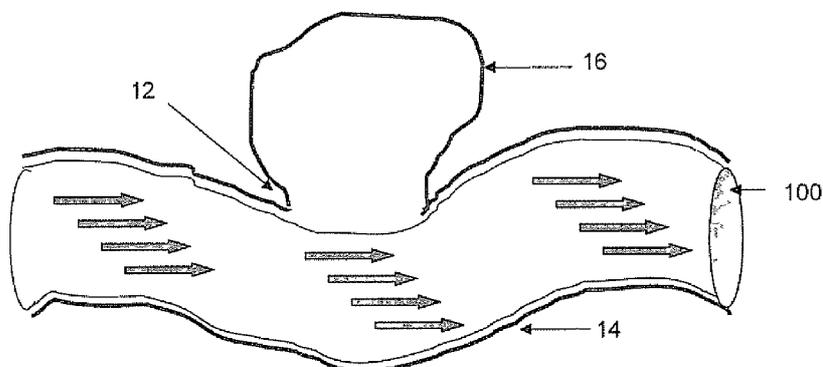
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(54) Title: METHOD AND TOOLS FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS



(57) Abstract: An apparatus and method for treating a vascular malformation in a vessel, the vascular malformation having an opening. The apparatus includes an aneurysm exclusion device ("AED") that includes at least one sleeve. The sleeve includes a shape memory material such that the AED exists in a compact form in a first state and an expanded form in a second state. The AED is placed within the vessel while in the compact form and expanded into the expanded form such that the AED occludes the opening of the vascular malformation. The AED may also include two sleeves. The sleeve may also include an opening in the sidewall.

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# METHOD AND TOOLS FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS

## STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

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Not Applicable.

## BACKGROUND

Intracranial aneurysms may be of congenital, atherosclerotic, traumatic, or mycotic origin with congenital saccular or berry aneurysms most common. The intracranial circulation is unique since relatively small vessels experience near systolic pressures and there are a  
10 numerous anatomic bifurcations that have natural gaps in the limited media, which are prone to aneurysm formation.

These developmental aneurysms generally occur at the bifurcations of major branches of the intracranial circulation, at or near the circle of Willis with an approximate frequency as  
15 follows:

- 5% at or inferior to the ophthalmic artery origin;
- 30% Anterior Communicating Artery origin;
- 20-30% Posterior Communicating Artery origin;
- 15% Basilar Artery terminus origin;
- 20 -20% Middle Cranial Artery bifurcation; and
- 5% miscellaneous locations

There are currently two approaches to the treatment of intracranial aneurysms. In the first, a surgeon performs a craniotomy and places metal clip across the neck of the aneurysm.  
25 thereby excluding the aneurysm from circulatory flow. In the second approach, the aneurysm is accessed via the brain's arterial circulation (the so called endovascular approach) with a micro-catheter. With the traditional endovascular approach, the aneurysm is treated by maneuvering a micro-catheter across the neck of the aneurysm and then filling it with various materials (coils, particles, polymer, or occasionally certain chemical sclerosing agents)

30 The second method is known as an embolization treatment since embolic materials are introduced into the aneurysm sac to occlude the aneurysm and exclude it from blood flow. There are currently no endovascular techniques or tools that allow exclusion of the aneurysm as in the surgical procedure. Rather, the current endovascular state-of-the-art relies on occlusion of the aneurysm which can be technically challenging and clinically risky.

35 For example, one endovascular technique includes installing an intravascular stent

While intravascular stents have been utilized before, they have mainly been used to treat narrowing or stenosis of vessels. These are generally made of a biologically compatible inert metal alloy that can be delivered to the site of treatment and then expanded to a desired size, approximating the inner diameter of the native vessel. The requirement of having a compact delivery form that can be expanded to a larger final form has necessitated some sort of wire mesh design for these metal stents. While these are quite useful for the treatment of stenosis, they do not lend themselves to the treatment of aneurysms. As shown in FIG. 1, the stent does not occlude the aneurysm neck and therefore does not exclude flow into the aneurysm and shown by blood flowing in the direction arrows. Therefore, there is continued risk for aneurysm rupture.

Covered stents have also been used to treat certain larger aneurysms such as those that form in the abdominal aorta. However, these covered stents are not compact enough or flexible enough to be delivered to or deployed in the smaller vessels of the intracranial circulation.

Further, the location of intracranial aneurysms complicates endovascular treatment due to the extreme tortuosity of the arterial pathways into this area. The micro-catheter must navigate as many as seven or eight acute turns to arrive at the location of a typical intracranial aneurysm. These many acute turns place significant constraints on the shape, size, and flexibility of any tools used treat aneurysms.

## BRIEF DESCRIPTION OF THE DRAWINGS

For a more detailed description of the embodiments, reference will now be made to the following accompanying drawings:

FIG. 1 is an example of a sidewall aneurysm with a conventional coiled wire or mesh metal stent;

FIG. 2 is an example of an AED excluding an aneurysm neck from circulatory flow;

FIG. 3 is an example showing an intracranial aneurysm formed at the junction of a bifurcation where one vessel divides into two or more;

FIG. 4 illustrates a multi-limbed AED excluding an aneurysm;

FIG. 5 illustrates a multi-limbed AED with differing sized exit limbs;

FIG. 6 illustrates a T-arm sleeve AED deployed and fully expanded at the bifurcation of a vessel;

FIG. 7 illustrates visualization of the AED fluoroscopically using a discontinuous

series of radiopaque beads or particles;

FIG. 8 illustrates visualization of the AED fluoroscopically using a colloidal suspension of a radiopaque material;

FIG. 9 illustrates the basilar artery; and

5 FIG. 10 illustrates a perforated aneurysm occlusion sleeve in accordance with an embodiment of the invention

## DETAILED DESCRIPTION OF THE EMBODIMENTS

In the drawings and description that follows, like parts are marked throughout the specification and drawings with the same reference numerals, respectively. The drawing  
10 figures are not necessarily to scale. Certain features of the invention may be shown exaggerated in scale or in somewhat schematic form and some details of conventional elements may not be shown in the interest of clarity and conciseness. The present invention is susceptible to embodiments of different forms. Specific embodiments are described in detail and are shown in the drawings, with the understanding that the present disclosure is to be  
15 considered an exemplification of the principles of the invention, and is not intended to limit the invention to that illustrated and described herein. It is to be fully recognized that the different teachings of the embodiments discussed below may be employed separately or in any suitable combination to produce desired results. Any use of any form of the terms "connect", "engage", "couple", "attach", or any other term describing an interaction between  
20 elements is not meant to limit the interaction to direct interaction between the elements and may also include indirect interaction between the elements described. The various characteristics mentioned above, as well as other features and characteristics described in more detail below, will be readily apparent to those skilled in the art upon reading the following detailed description of the embodiments, and by referring to the accompanying  
25 drawings.

The method described herein is an endovascular approach that does not require embolization. Rather, as shown in FIG. 2, the method includes placing an aneurysm exclusion device ("AED") 100 across the neck or orifice 12 that connects the vessel 14 to the aneurysm 16, thereby excluding the aneurysm 16 from circulatory flow. In FIG. 2, the AED  
30 100 is a flexible, nonporous expansile tube or sleeve that is small and flexible enough to be delivered or maneuvered to the area of interest in the vessel and then expanded to conform to the inner diameter of the vessel. Thus, the AED is a safer and easier way to treat certain

intiacianial aneurysms, which are particularly dangerous and life threatening. The AED 100 excludes the aneurysm from circulatory flow thereby inducing thrombosis in the aneurysm and reducing the risk of subsequent rupture.

To retain the flexibility and expansion properties, the AED 100, for example, may be made of one or more flexible shaped-memory polymers ("SMP" or "SMPs") that can be manufactured to assume a compact form in one state and an expanded form in another state. For example, in some embodiments, the AED 100 may comprise two or more SMP components having different thermal characteristics, such as oligo( $\epsilon$ -caprolactone)diol and crystallisable oligo(p-dioxanone)diol. These materials can be formed into a primary shape, reformed into a stable secondary shape, then controllably actuated to recover their primary shape. SMPs may also include a wide variety of other polymers including, without limitation, polyisoprene, segmented polyurethanes and their ionomers, copolyesters, ethylacrylate copolymers, and styrene-butadiene copolymers. Many SMPs are thermally actuated and consist of a shape-fixing matrix phase and a shape-memorizing dispersed phase. Above the actuation temperature in the shape fixing phase, the polymer can be deformed from its primary shape to a secondary shape by the application of stress, then locked into the secondary shape by cooling to below the actuation temperature. The shape memorizing phase results from physical or chemical crosslinking in the polymer, which in turn allows the SMP to remember the primary shape. When the SMP is deformed into a secondary shape from the primary shape, polymer chains in the matrix are made to shift from an equilibrium, unoriented configuration into configurations that are relatively oriented, thus decreasing the entropy of the system and requiring the application of force. Upon cooling below the actuation temperature, this non-equilibrium conformation is kinetically frozen. Upon heating through the actuation transition, recovery of the polymer from the secondary to the primary shape is driven by entropic recovery of the polymer chains in the secondary phase.

While an SMP may be the desired material for the AED 100, other materials such as a coated metal alloy sleeve or other advanced materials may also be practical, such as, for example, NITENOL<sup>®</sup> (an acronym for Nickel Titanium Naval Ordnance Laboratory). The NITENOL<sup>®</sup> material may also be manufactured as a foil and/or constructed in a deliverable ribbon format. Thus, the AED 100 may be constructed of any suitable shape memory material such that the sleeve exists in a compact form in a first state and an expanded form in a second

state

Using shape memory material, the AED 100 can be formed into a hollow flexible sleeve small enough, for example, to be delivered through the circle of Willis into the intracranial circulation by a micro-catheter. Micro-catheters commonly used in the brain range in size from 0.6 to 0.9 mm in diameter. Once the AED 100 is delivered to the vessel 14 that contains the aneurysm 16, the sleeve can be deployed and allowed to transform to its final shape and size, approximating the inner diameter of the vessel 14. For example, as shown in FIG. 2, the AED 100 can be deployed and allowed to transform to a size that is slightly larger than the inner diameter of the vessel. The AED deploys to a final diameter sufficient to engage the native wall of the vessel and thus may conform to the wall shape of the native vessel, seating tightly enough to preclude flow between the cylinder and the native vessel. As shown in FIG. 2, the AED 100 excludes the aneurysm neck 12 from circulatory flow, thereby treating the aneurysm 16. In this way the AED 100 can be used to safely treat a sidewalled aneurysm similar to the aneurysm as shown in FIG. 2, including those with an unfavorable sac-to-neck ratio, which are not easily treated by conventional endovascular techniques.

Also, in some embodiments, the AED is capable of being manufactured into a shape and size that can be maneuvered into the intracranial circulation via a routine femoral or less commonly an axillary arterial puncture. Intracranial devices deliverable to this area may be modeled after the neuroform stent that is guide wire deliverable through a 3F (0.9 mm OD) catheter that comes off-the-shelf in 3 lengths: 1 cm, 1.5 cm, and 2 cm. The length of the neuroform stent is chosen (1-2 cm) so as to maximize coverage of the neck of the aneurysm by at least 4 mm on either side of the neck orifice. Since the NITINOL<sup>®</sup> based stent can be rigid, any length greater than 2 cm may not be flexible enough to be maneuvered into the circulation at the circle of Willis. In some embodiments, the neuroform stent may also generally be selected based upon its post deployment OD as follows:

Stent OD	Vessel Diameter
3.0 mm	2.0 to 2.5 mm
3.5 mm	2.5 to 3.0 mm
4.0 mm	3.0 to 3.5 mm
4.5 mm	3.5 to 4.0 mm
5.0 mm	4.0 to 4.5 mm

Prior to deployment, the greater the flexibility of the AED 100, the higher the likelihood that

the device will be able to be maneuvered into the area of interest. Also, in some embodiments, it may be desirable that there be more expansion in diameter (pre-deployment < 0.9 mm vs post-deployment 2-5 mm) between the pre- and post-deployment states than in length. It may also be desirable in some embodiments that there be little change in length (pre-selected between 1 and 2.5 to 3 cm) between these two states.

In certain embodiments, the AED is capable of being custom manufactured to conform to a pre-determined final shape based upon 3-D volumetric CAD/CAM data. Also, the AED may be deliverable under fluoroscopic guidance with longitudinal and rotational control provided by a catheter-based delivery system as discussed further below.

If thermally activated, the AED preferably remains in its pre-deployment configuration and morphology until it is deployed and then undergoes a configuration change to its final memory state at or near physiological temperatures and remains in this final form at physiological temperatures.

Also, the AED may be made to be bio-absorbable. If so, the AED preferably remains intact until intimal re-growth or healing occurs, either due to natural processes, or under the stimulation of drug delivery mechanisms on the inner or outer surface of the device.

Post-deployment, the length of the AED may conform to a predetermined configuration that occludes the neck of the aneurysm and has adequate additional length to engage the vessel wall on either side of the neck. While a standard off-the-shelf range of sizes may suffice in many situations, the creation of these flexible expandable sleeve devices allows for custom prefabrication for a specific deployment. These can be manufactured in standard sizes that are selected to match a patient's specific anatomy. Alternatively, where a patient's specific anatomy is modeled three-dimensionally utilizing modern computer tomographic, magnetic resonance, ultrasonographic, or other modern imaging technique. The 3-D image model is downloaded electronically to a server or other site. The data is converted from DICOM format into a form that is compatible with standard engineering CAD/CAM software. A CAD/CAM model of the patient's specific anatomy is developed and used to create a CAD/CAM model for the optimal device unit. The desired AED(s) is/are then prefabricated based upon these models. The finished unit may then be shipped at least as fast as overnight to the endpoint for deployment in the patient.

The AED may also be constructed to deliver drugs to the patient. Drug delivery attributes may include factors to induce or encourage intimal healing on the inner surface or

agents to encourage thrombosis on the outer surface (especially in the case of ruptured aneurysms) or, in certain applications, the delivery of growth factors to stimulate migration of stem cells into an injured area of the brain (such as stroke or trauma). Certain pharmaceutical agents may also be added to the surfaces of the AED. These pharmaceutical agents can be added to induce certain desired effects at the point of interaction with biological tissues. For example, it may be desirable to stimulate endothelial cell growth at a surface margin of the device. In the case of treating a ruptured aneurysm, it may be desirable to stimulate thrombosis at the point of rupture while simultaneously limiting or decreasing thrombosis and/or platelet activation along the inner surface of the device. In this latter case, it may also be desirable to include agents that promote endothelial growth at the margins to aid incorporation of the sleeve into the native vessel.

A fluid-impermeable sleeve that could be either bio-absorbable or permanent, could be delivered into certain areas of the intracranial circulation, such as the middle cerebral artery, and serve as a useful drug delivery device. Certain growth factors are known to stimulate stem cells, which have been shown to aid recovery in patients who have suffered cerebral infarction. A memory polymer sleeve similar to the device in FIG. 2 could include these growth factors or other drugs (either single or multiple drugs or agents could be used) which would then be delivered into the desired circulation over an extended time.

The above discussion is meant to be illustrative of the principles and various embodiments of the present invention. Numerous variations and modifications will become apparent to those skilled in the art once the above disclosure is fully appreciated. For example, the nature of the shape memory material may be varied from those identified herein.

Additionally, many aneurysms, especially those that form in the intracranial circulation form at the bifurcation of one vessel into two or more vessels as shown by the aneurysm 16 in FIG. 3. Clearly, a simple single tube or cylinder sleeve design to treat this form of aneurysm is not adequate. Rather, a design consisting of multiple limbs is required.

For example, a covered or nonporous sleeve with multiple limbs could be deployed into each vascular limb, thereby excluding the aneurysm 16. For example, as shown in FIG. 4, a multi-limbed sleeve AED 100 can consist of two or more interlocking cylindrical sleeves 102, 106 with corresponding orifices, 104 and 108. Sleeve 106 is installed inside sleeve 102 but with a portion of sleeve 106 protruding from the orifice 104 of the sleeve 102. Inside the sleeve 102, the orifice 108 of the sleeve 104 is oriented to allow blood flow to continue

through the sleeve 102. Thus, fluid flowing into the AED 100 is able to exit the AED 100 either through the sleeve 102 or through the sleeve 104 and the AED 100 excludes the aneurysm 16 from circulatory flow, thereby treating the aneurysm 16. Thus, each limb seats well both in the native vessel lumen and at the interlocking joints of each limb so as to preclude the blood flow.

FIG. 5 demonstrates a multi-limbed AED 100 similar to the AED shown in FIG. 4, but with different sized limbs. As shown, sleeve 102 and 106 are of different sizes and orifices 104 and 108 differ in size to appropriately accommodate flow into each vascular limb. In this embodiment, the entrance into the sleeve 106 is sized so as to engage the sleeve 102 and the exiting smaller limb 106 is sized to engage the sleeve 102 orifice 104 as well as the smaller vessel. The orifice 108 of the sleeve 106 is sized to the inner diameter of the sleeve 102 and, similar to what is shown in FIG. 4, is oriented to allow blood flow to continue through the sleeve 102. Thus, fluid flowing into the AED 100 is able to exit the AED 100 either through the sleeve 102 or through the sleeve 104 and the AED 100 excludes the aneurysm 16 from circulatory flow, thereby treating the aneurysm 16.

Another example of a multiple limb AED 100 is a multi-limbed T-sleeve AED 100 that can be pre-formed and deployed as a unit, as shown in FIG. 6. The AED 100 of FIG. 6 illustrates a prefabricated T-sleeve with limbs 100a and 100b. The AED 100 is deployed and fully expanded at the bifurcation of a vessel, thereby excluding the bifurcation aneurysm 16 while maintaining flow into both vessels. Thus, fluid flowing into the AED 100 is able to exit the AED 100 either through the sleeve 100a or through the sleeve 100b and the AED 100 excludes the aneurysm 16 from circulatory flow, thereby treating the aneurysm 16.

In the case of multiple limbs, a special dual-core guide wire with inner and outer wire cores may alternatively be used to provide useful control of both vessel limbs as the device(s) is/are deployed. Both the inner and outer wire cores could be advanced or retracted independently of one another, to control access in the vessels and deployment of the sleeve device(s). The outer guide wire contains a slot and exit orifice that allows the inner core wire to be advanced or retracted independently of the outer core wire. The preferable form may be a side-exiting orifice that allows adequate purchase into with resulting control of the dominant vascular limb prior to advancing the inner core guide wire into the non-dominant vessel.

In either case of the multi-limbed AED 100 (the interlocking sleeve device or the T-

arm sleeve device), deployment may require visualization under fluoroscopic guidance in order to place the AED 100. However, polymers are generally not visible with fluoroscopy. Therefore, the AED 100 may alternatively include a colloidal suspension of radiopaque particles in the polymer matrix at the time of formation. The particles would then be visible using fluoroscopic visualization techniques. To aid rotational control during deployment, it may also be desirable to separately delineate all of the orifices 104, 108 of the AED 100.

The radiopaque markers are preferably designed in a manner that does not restrict the state changes or alter the desirable mechanical properties of the AED 100. As such, an example of radiopaque particle placement may include placing a discontinuous series of radiopaque beads or particles 110 along the margin of any openings. Any orifice within the AED 100 can also be rendered radiopaque by including discontinuous markers along the margin of the orifice. As the device expands during deployment, the discontinuity of the orifice ring marker will not inhibit expansion.

Alternatively, each AED 100 sleeve can be visualized fluoroscopically by inclusion of a colloidal suspension of a radiopaque material as shown in FIG. 8. Identification and orientation of the device may be useful for both longitudinal and rotational control of the device during deployment within the vessel. Also alternatively, a discontinuous wire of opaque metal along the margin of the orifice may suffice for visualization in the closed and opened state. It is understood that the nature and configuration of the radio-markers may also be provided in forms other than those described.

Additionally, in some instances, such as when the aneurysm is in the basilar artery, it may be desirable to create a partially or locally permeable or perforated AED. As shown in FIGS 9 and 10, AED 100 includes small perforations 120 that occur along the AED remain patent but the neck of an aneurysm may still be excluded from circulation. Figure 9 illustrates the basilar artery showing that, in some areas, it may be desirable to allow flow into branch arteries but without allowing flow into an aneurysm. The AED 100 is deployed and fully expanded in location to exclude an aneurysm while maintaining flow into branch vessels through the perforations 120. Thus, fluid flowing into the AED 100 is able to exit the AED 100 either through the perforation 120 or through the sleeve 100 itself while the AED 100 excludes any aneurysm 16 from circulatory flow, thereby treating the aneurysm.

It may also be desirable to attach special anchors to the ends of the AED 100 to aid engagement with the wall of the vessel. These anchors may be of a similar or different

material than the rest of the sleeve. The anchors may include ribs or attachment points to engage the inside wall of the vessel or any other non-smooth type outer surface or surface contour. The anchors might also include micro-pores that would allow cellular in-growth of the vessel itself. The AED may also be designed to elute certain drugs to aid engagement of the device at the margins of the vessel or to and inhibit vessel stenosis.

While specific embodiments have been shown and described, modifications can be made by one skilled in the art without departing from the spirit or teaching of this invention. The embodiments as described are exemplary only and are not limiting. Many variations and modifications are possible and are within the scope of the invention. Accordingly, the scope of protection is not limited to the embodiments described, but is only limited by the claims that follow, the scope of which shall include all equivalents of the subject matter of the claims.

## CLAIMS

## WHAT IS CLAIMED IS:

1. A method for treating a vascular malformation in a vessel, the vascular malformation having an opening, the method including:  
5            providing an aneurysm exclusion device ("AED") including a sleeve, the sleeve including a shape memory material such that the sleeve exists in a compact form in a first state and an expanded form in a second state;  
              placing the AED within the vessel while in the compact form; and  
              expanding the AED into the expanded form such that the AED occludes the  
10            opening of the vascular malformation.
2. The method of claim 1 where the sleeve includes a side orifice, the method further including:  
              placing a second sleeve including a shape memory material within the sleeve  
15            such that the second sleeve extends through the side orifice; and  
              where the second sleeve also includes a side orifice allowing fluid communication through the sleeve.
3. The method of claim 1, the sleeve further including a marker for enhancing  
20            fluoroscopic observation of the AED.
4. The method of claim 3, where the marker includes a radiopaque bead or particle along the margin of each opening in the sleeve.
- 25            5. The method of claim 3, where the marker includes a discontinuous metal wire at the margin of each opening in the sleeve.
6. The method of claim 1, the sleeve further including an opening in the sidewall, where placing the sleeve within the vessel further includes aligning the opening in the sidewall with  
30            an opening in the wall of the vessel while still occluding the opening of the vascular malformation.

7 The method of claim 1, further including:

modeling the anatomy in a specific patient to generate a data file corresponding to the shape of the vascular malformation; and

fabricating a sleeve based on the information in the data file.

5

8 The method of claim 7 where modeling the anatomy includes modeling in three dimensions using computer imaging techniques

9. An aneurysm exclusion device ("AED") for treating an aneurysm in a vessel, the  
10 aneurysm including an opening, the AED including:

a first sleeve including a shape memory material and including a first side orifice, the first sleeve existing in a compact form in a first state and an expanded form in a second state;

15 a second sleeve including a shape memory material and including a second side orifice, the second sleeve existing in a compact form in a first state and an expanded form in a second state;

the second sleeve being insertable within the first sleeve such that the second sleeve extends through the first side orifice;

20 the second side orifice being positionable to allow fluid communication through the first sleeve; and

the first and second sleeves being insertable in the vessel in their compact forms and expandable into their expanded forms such that the AED occludes the opening of the aneurysm.

25 10. The AED of claim 9 further including at least one of the first and second sleeves including a marker for enhancing fluoroscopic observation of the AED

11 The AED of claim 10, where the marker includes a radiopaque bead or particle along the margin of each opening in at least one of the first and second sleeves

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12 The AED of claim 10, where the marker includes a discontinuous metal wire at the margin of each opening in at least one of the first and second sleeves.

13. The AED of claim 9, further including the first and second sleeves being fabricated based on a modeled anatomy of a specific patient.

5 14. The AED of claim 13 where the modeled anatomy is modeled in three dimensions using computer imaging techniques.

15. An aneurysm exclusion device ("AED") for treating a vascular malformation in a vessel, the malformation including an opening, the AED including:

10 a sleeve including a shape memory material such that the AED exists in a compact form in a first state and an expanded form in a second state;

the sleeve being insertable in the vessel in the compact form and expandable into the expanded form such that the AED occludes the opening of the aneurysm;

15 the sleeve further including an opening in the sidewall of the sleeve allowing fluid flow through the opening; and

where the AED is insertable within the vessel such that the opening in the sidewall of the sleeve is alignable with an opening in the wall of the vessel while still occluding the opening of the vascular malformation.

20 16. The AED of claim 15, the sleeve including a marker for enhancing fluoroscopic observation of the AED.

17. The AED of claim 16, where the marker includes a radiopaque bead or particle along the margin of each opening in the sleeve.

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18. The AED of claim 16, where the marker includes a discontinuous metal wire at the margin of each opening in the sleeve.

19. The AED of claim 10, further including the sleeve being fabricated based on a modeled anatomy of a specific patient.

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20. The AED of claim 19 where the modeled anatomy is modeled in three dimensions using computer imaging techniques.

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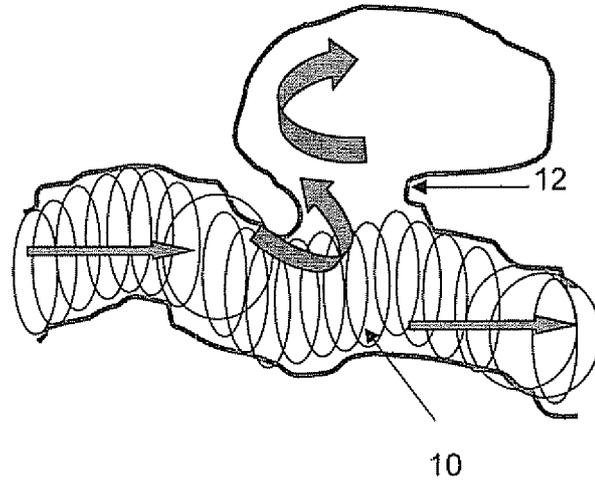


Figure 1

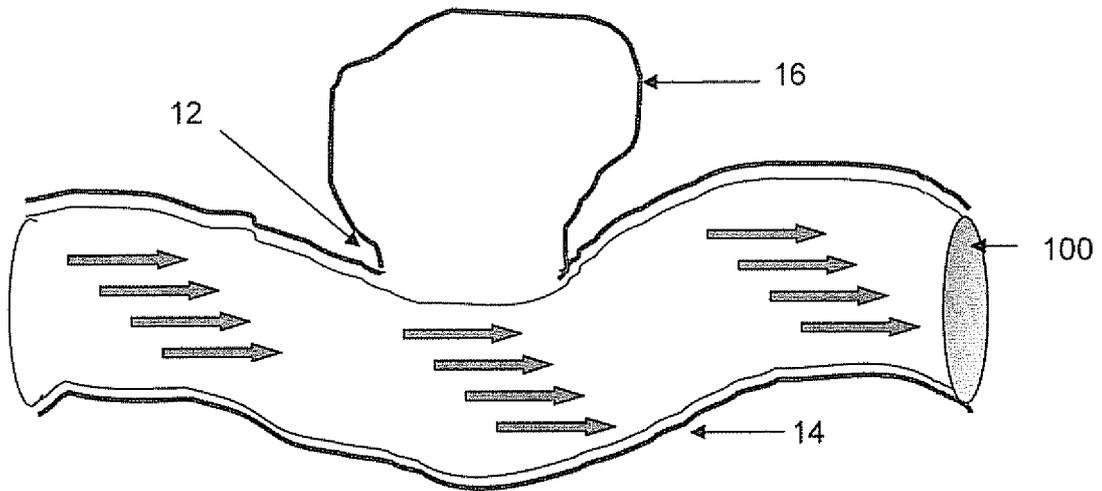


Figure 2

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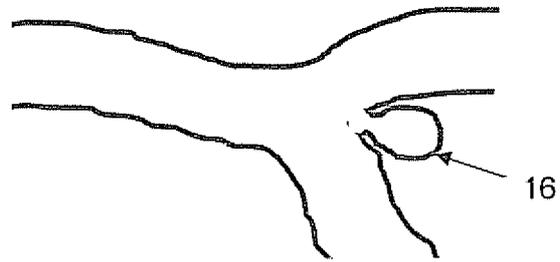


Figure 3

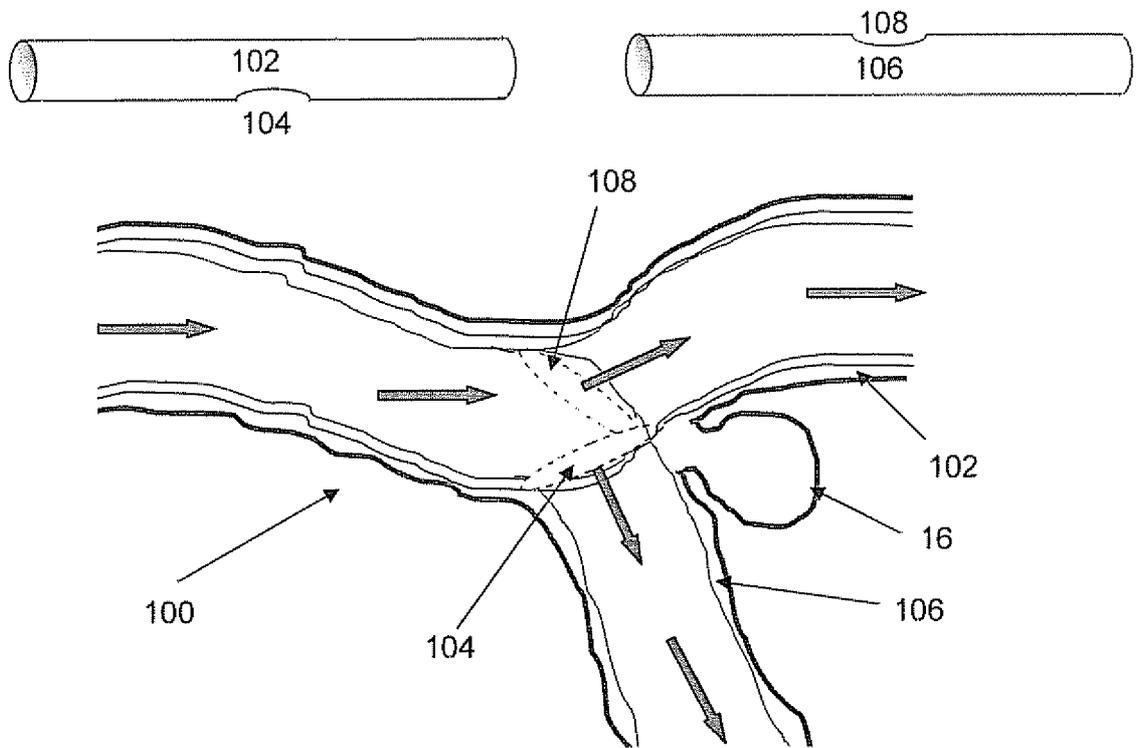


Figure 4

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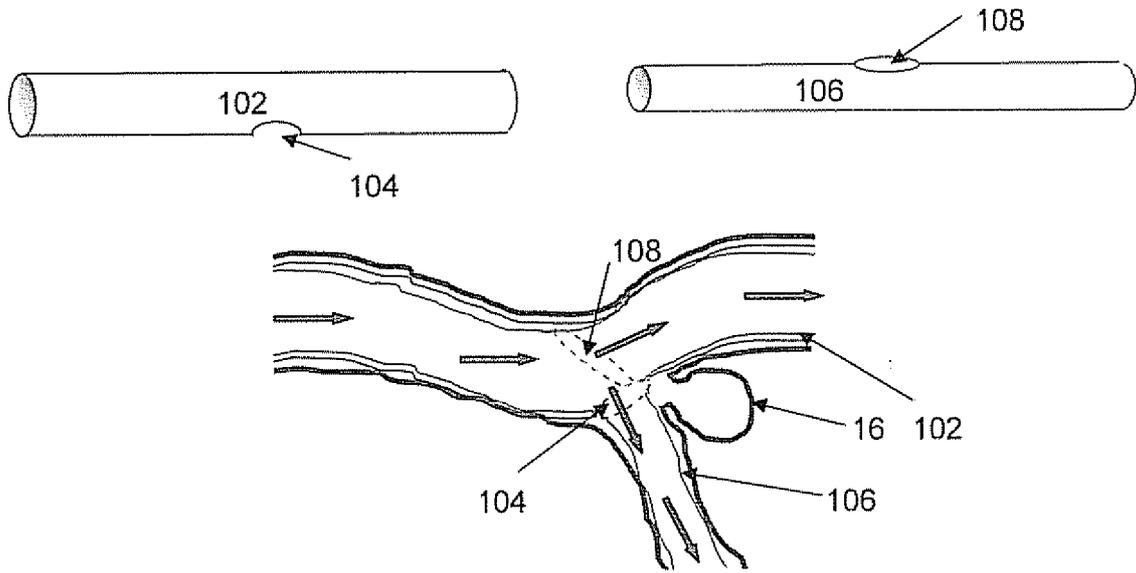


Figure 5

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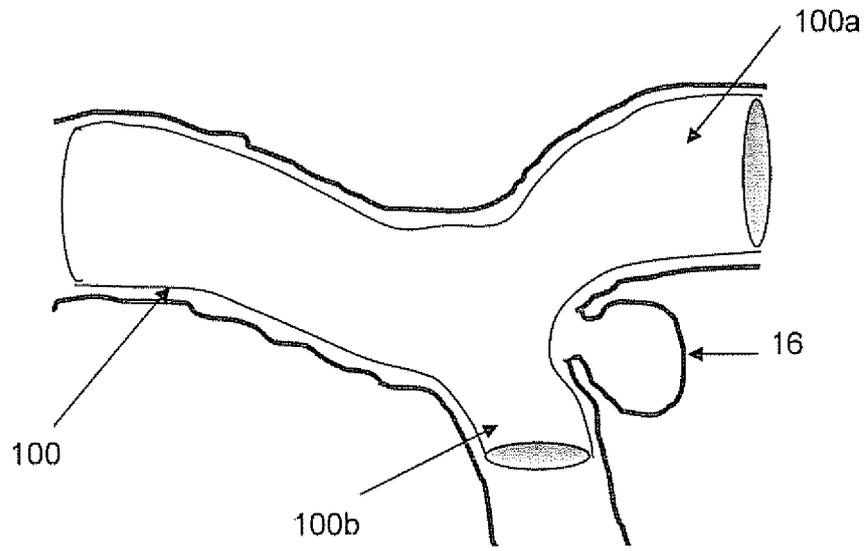


Figure 6

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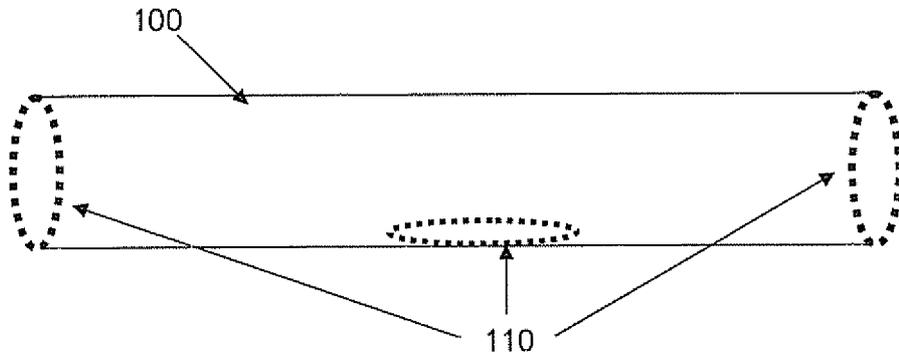


Figure 7

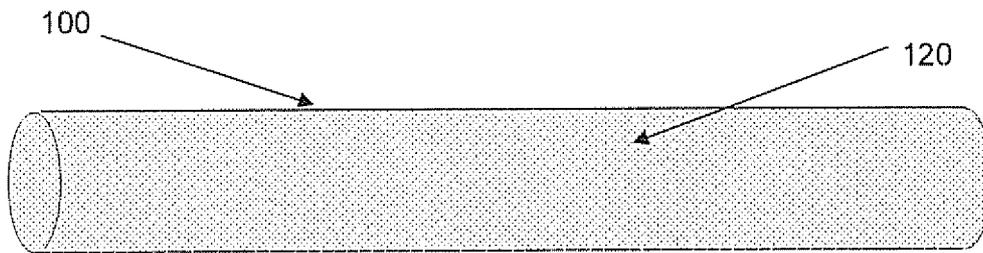


Figure 8

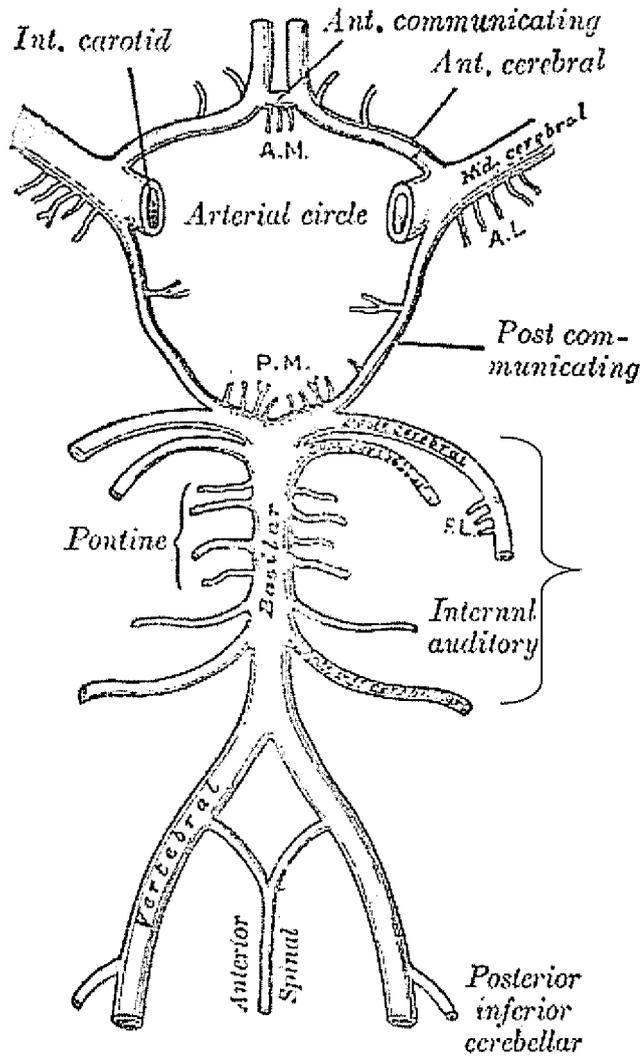


Fig 9

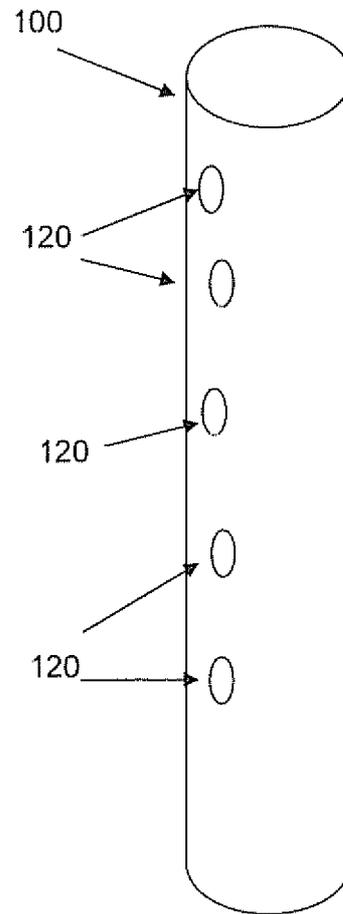


Fig. 10