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(71) Applicant: INCUMEDX, INC. [US/US]; 46790 Lakeview Blvd., Fremont, CA 94538 (US).

(72) Inventors: LE, Be, Thi; 2522 Buckhill Court, San Jose, CA 95148 (US). CHO, Tae, Hee; 3508 Brighton Ave. #1, Oakland, CA 94602 (US). VELASCO, Regina, Coeli; 972 Huntington Terrace, Fremont, CA 94536 (US). GARZA, Armando; 530 Locust Street, San Jose, CA 95110 (US).

(74) Agent: GOMEZ, Martin et al.; Goodwin Procter LLP, 100 Northern Avenue, Boston, MA 02210 (US).

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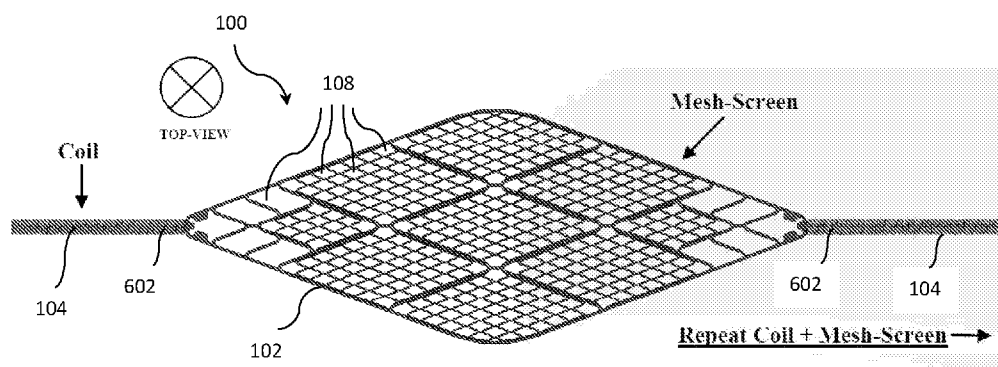


FIG. 2

(57) **Abstract:** An embolic device for treating aneurysms or other vascular disorders may be more compliant than conventional devices, while still achieving desired porosity. In particular, the device may achieve the desired porosity only at discrete sections along the length of the device where such a porosity is required (e.g., sections that will block the neck of the aneurysm upon deployment). The remaining sections of the device can be configured to increase the device's compliance. For example, the remaining sections can be formed from less material than the sections with the desired porosity. In some instances, the sections with the desired porosity are formed from mesh-screen segments and the remaining sections are formed from coil segments. In some instances, the mesh-screen segments are configured to further enhance the device's compliance. For example, the mesh-screen segment can be formed from a layered structure that achieves greater compliance than conventional braided structures.



FLOW ATTENUATION DEVICE

5 CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to and the benefit of, and incorporates herein by reference in its entirety, U.S. Provisional Patent Application No. 62/546,809, which was filed on August 17, 2017.

TECHNICAL FIELD

10 [0002] In general, various embodiments of this invention relate to embolic implants for use in the minimally-invasive treatment of aneurysms (e.g., sidewall, bifurcation, bilobed, wide-neck, etc.) and other vascular disorders and, more specifically, to an embolic implant that features certain discrete segments that achieve a desired porosity and other segments that increase the compliance of the device.

15 BACKGROUND

[0003] In general, an aneurysm is a swelling or bulge that forms a cavity in the wall of a blood vessel. One type of aneurysm is a cerebral aneurysm, which forms in an artery of the brain. A cerebral aneurysm may develop suddenly without initial symptoms, and can cause extreme pain. In general, in 15% of cerebral aneurysm cases, the patient dies suddenly upon
20 development of the cerebral aneurysm; in another 15% of cerebral aneurysm cases, the patient dies under medical treatment; and in 30% of cerebral aneurysm cases, the patient survives after treatment but feels an acute aftereffect. As such, a cerebral aneurysm (or any aneurysm) is a very concerning development.

[0004] The treatment of aneurysms and other similar vascular disorders often involves
25 the placement of microcoils within the cavity formed by the aneurysm or disorder. Doing so can cause blood to clot, prevent an additional inflow of blood, and decrease the risk of the aneurysm or disorder rupturing (i.e., an embolization). In order to be effective, an embolic

microcoil must apply pressure sufficient to prevent additional inflow of blood, but not an excessive amount of pressure that causes rupture.

[0005] A critical parameter for most embolic devices is porosity, which is a measure of the amount of fluid that can pass through the embolic device into the aneurysm. In order to achieve a desired porosity, most conventional embolic devices are formed from braided wires or mesh structures that form pores 101 of a particular size (e.g., as shown in FIG. 1). While these structures can be effective in achieving desired porosity, the amount of material they require (e.g., numerous overlapping wires) can negatively affect the compliance of the device. Compliance (sometimes referred to as “softness”) is a measure of the flexibility and conformability of the device. If an embolic device is too stiff, it can be difficult to deliver through tortuous pathways and may apply excessive pressure to the aneurysm wall, risking its rupture. Most current embolic devices give up significant compliance in order to achieve the desired porosity.

[0006] Accordingly, there is a need for an improved embolic device that achieves desired porosity without compromising significant compliance.

SUMMARY OF THE INVENTION

[0007] In various embodiments, the present invention relates to an improved embolic device that achieves a desired porosity without compromising as much compliance as conventional devices. In particular, the device leverages the fact that the desired porosity is only required at certain discrete section(s) along the length of the device (sometimes referred to herein as “porosity sections”), e.g., the section of the device that blocks the neck (or opening) of the aneurysm when the device is deployed. In this application, the term “porosity section” refers to a portion of the device having a desired porosity. In some instances, this desired porosity of the porosity section is greater than the porosity of the remaining sections of the device, but the opposite is also true in some cases. The remaining sections of the

device (sometimes referred to herein as “compliance sections”) need not have the desired porosity and can thus be configured to increase the device’s compliance. For example, the compliance sections can be formed of less material than the porosity sections. Examples of compliance sections include sections of the device located in the middle of the aneurysm cavity or along the interior wall of the aneurysm cavity upon deployment of the device.

Inclusion of the compliance sections can increase the overall compliance of the entire device and result in a device having superior compliance over current devices that unnecessarily maintain the desired porosity over their entire length.

[0008] In general, in one aspect, embodiments of the invention feature an embolic device for use in treating a vascular disorder. The embolic device can include a first coil segment, a second coil segment, and a mesh-screen segment disposed between the first coil segment and the second coil segment along a length of the embolic device.

[0009] In various embodiments, each of the first and second coil segments includes a helically wound wire. In some instances, the first and second coil segments each have a greater compliance than the mesh-screen segment. In some instances, the mesh-screen segment has a greater porosity than each of the first and second coil segments. When the mesh-screen segment is in a deployed configuration, the mesh-screen segment can be 60% to 80% porous.

[0010] In various embodiments, the mesh-screen segment includes two layers, which can have different thicknesses. In some cases, at least a portion of each of the two layers are disposed in different parallel planes. In some cases, at least a portion of each of the two layers are disposed in the same plane. In some instances, the two layers are fixed to each other. In other instances, the two layers are free to move with respect to each other. The two layers can be spaced apart from each other by a predetermined distance. Moreover, the mesh-screen segment can include through-thickness perforations. In certain instances, the

mesh-screen segment further includes a first extension portion and a second extension portion adapted to be inserted into a lumen formed by the first coil segment and the second coil segment, respectively, to couple the mesh-screen segment to the first coil segment and the second coil segment. In some cases, different portions of the embolic device include
5 different thermomechanical properties

[0011] In general, in another aspect, embodiments of the invention feature a method for treating a vascular disorder of a patient. The method can include the step of delivering into the vascular disorder an embolic device including a coil segment and, coupled thereto, a mesh-screen segment, such that (i) the coil segment is disposed within a cavity formed by the
10 vascular disorder and (ii) the mesh-screen segment is disposed across a neck of the vascular disorder.

[0012] In various embodiments, the vascular disorder is an aneurysm. In some instances, the delivering step includes releasing the device from a distal tip of a delivery pusher. In such instances, the method can further include advancing the delivery pusher through a
15 microcatheter having a distal end disposed within the vascular disorder. The method can further include delivering a second embolic device into the vascular disorder without repositioning the microcatheter. In some instances, the initially-delivered embolic device includes an additional coil segment and the mesh-screen segment is disposed between the coil segment and the additional coil segment along a length of the embolic device. In some cases,
20 the coil segment includes a helically wound wire. The coil segment can have a greater compliance than the mesh-screen segment. The mesh-screen segment can have a greater porosity than the coil segment. Upon delivery, the mesh-screen segment can be 60% to 80% porous.

[0013] In various embodiments, the mesh-screen segment includes two layers, which can
25 have different thicknesses. In some cases, at least a portion of each of the two layers are

disposed in different parallel planes. In some cases, at least a portion of each of the two layers are disposed in the same plane. In some instances, the two layers are fixed to each other. In other instances, the two layers are free to move with respect to each other. The two layers can be spaced apart from each other by a predetermined distance. The mesh-screen segment can include through-thickness perforations. In some cases, different portions of the embolic device include different thermomechanical properties

[0014] In general, in yet another aspect, embodiments of the invention feature a method of manufacturing an embolic device. The method can include the steps of forming a first coil segment and a second coil segment, forming a mesh-screen segment, and coupling the mesh-screen segment between the first coil segment and the second coil segment along a length of the embolic device.

[0015] In various embodiments, the step of forming the first and second coil segments includes helically winding at least one wire. In some instances, the step of forming the mesh-screen segment includes using a subtractive manufacturing technique, e.g., a laser technique, a mechanical technique, a wet chemical technique, an electrochemical masking technique, a maskless electrochemical technique, etching, milling, photochemical machining, and/or photoelectrochemical machining. In some instances, the step of coupling the mesh-screen segment between the first coil segment and the second coil segment includes inserting a first extension portion and a second extension portion of the mesh-screen segment into a lumen formed by the first coil segment and the second coil segment, respectively. In some cases, the step of forming the first and second coil segments and/or the step of forming the mesh-screen segment includes forming different portions of the embolic device to have different thermomechanical properties.

[0016] These and other objects, along with advantages and features of the embodiments of the present invention herein disclosed, will become more apparent through reference to the

following description, the accompanying drawings, and the claims. Furthermore, it is to be understood that the features of the various embodiments described herein are not mutually exclusive and can exist in various combinations and permutations.

5

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention. In the following description, various embodiments of the present invention are described with
10 reference to the following drawings, in which:

[0018] FIG. 1 is an image of an exemplary conventional embolic device formed from a braided wire;

[0019] FIG. 2 is a top schematic view of an embolic device in a straightened out configuration, according to one embodiment of the invention;

15 [0020] FIG. 3 is a side cross-sectional schematic view of a portion of an embolic device formed from multiple layers, according to one embodiment of the invention;

[0021] FIGS. 4A-4B are different schematic views of a portion of an embolic device formed from multiple layers, according to one embodiment of the invention;

[0022] FIGS. 5A-5D illustrate various layer configurations of a portion of an embolic
20 device, according to various embodiments of the invention;

[0023] FIG. 6 is a top schematic view of an extension portion used to attach portions of an embolic device, according to one embodiment of the invention;

[0024] FIG. 7 is an image of an exemplary embolic device being inserted into a microcatheter, according to one embodiment of the invention;

[0025] FIGS. 8A-8M are images of an exemplary embolic device in a deployed configuration and in various stages of deployment, according to various embodiments of the invention; and

[0026] FIG. 9 is an image of an exemplary attachment of an extension portion and a delivery pusher, according to one embodiment of the invention.

DESCRIPTION

[0027] Embodiments of the present invention are directed toward an improved design for an embolic device and methods of using and manufacturing the improved device. As mentioned above, porosity is a critical parameter for embolic devices because it determines how much fluid can pass through the embolic device into the aneurysm, which can directly impact how effective the embolic device is in treating the aneurysm. As shown in FIG. 1, in many conventional devices the desired porosity is achieved with a braid or mesh structure of overlapping wires that form pores 101 of a desired size. While this technique can be effective in generating desired porosity, the overlapping wires stiffen the device and reduce its compliance. Most conventional devices achieve the desired porosity over their entire length, which results in unnecessary and excessively high material density that significantly reduces the device's compliance.

[0028] The inventors developed a solution to this problem by recognizing and appreciating that the desired porosity is only necessary at limited discrete portions along the length of the device. In particular, the desired porosity need only be achieved at the portions of the device that interact with (and therefore affect) the blood flowing into the aneurysm. Typically, these portions are the portions of the device that, when the device is deployed, are located across the opening between the blood vessel and the cavity of the aneurysm (sometimes call the "neck" of the aneurysm). The inventors recognized that the remaining portions of the device, i.e., those that do not interact with or affect the blood flowing into the

aneurysm, need not have the desired porosity. Examples of portions that do not interact with or affect the blood flowing into the aneurysm include portions of the device that, when the device is deployed, are located in the middle of the cavity or along the interior wall of the cavity. The inventors recognized and appreciated that the portions of the device that need not have the desired porosity can be configured differently than the porosity sections; for example, they can be configured to be significantly more compliant than the porosity sections, which can increase the overall compliance of the entire device.

[0029] A portion of an exemplary embodiment of the improved embolic device 100 of the present invention is shown in FIG. 2. The device 100 includes a porosity section 102 and compliance sections 104. Although FIG. 2 depicts one porosity section 102 and two compliance sections 104, in general the device 100 can include any number of porosity sections 102 (e.g., 1, 2, 3, etc.) and any number of compliance sections 104 (e.g., 1, 2, 3, etc.) as may be desirable for various applications. For example, in some embodiments the device 100 includes one porosity section 102 and one compliance section 104. As another example, the device 100 can include three porosity sections 102 and two compliance section 104. Many other examples are possible.

[0030] In various embodiments, the porosity section(s) 102 and the compliance section(s) 104 are arranged in a serially alternating fashion along the length of the device 100. As an example (and as shown in FIG. 2) the device 100 can include a compliance section 104, followed by a porosity section 102, followed by another compliance section 104, and optionally followed by another porosity section 102, etc. In other embodiments, the porosity section(s) 102 and compliance section(s) 104 can be arranged using any other arrangement. For example, multiple porosity sections 102 can be arranged adjacent to each other and/or multiple compliance sections 104 can be arranged adjacent to each other. In some cases, the arrangement of the porosity section(s) 102 and the compliance sections(s) 104 is constant

(e.g., repetitive) along the entire length of the device 100. In other cases, the arrangement of the porosity section(s) 102 and the compliance section(s) 104 differs along the length of the device 100. For example, at certain locations the sections 102, 104 can be arranged in a serially alternating fashion, while at other locations the sections can be arranged with
5 multiple porosity sections 102 and/or multiple compliance sections 104 adjacent to one another.

[0031] In various embodiments, the spacing between the segments of the device 100 is controlled to optimize the shape of the device 100 once it is delivered into the aneurysm. For example, in some cases the spacing between each porosity and/or compliance section can be
10 uniform. In other cases, the spacing between each porosity and/or compliance section may vary along the length of the device 100. In general, the size and/or shape of the device 100 can be controlled and take any form to optimize the shape/size of the device 100 once it is delivered into the aneurysm.

[0032] In various embodiments, as shown in FIG. 2, the compliance sections 104 can be
15 coil segments. Because the coil segment is an exemplary type of compliance section, both the coil segment and the compliance section are referred to in this application with the reference numeral 104. In some cases, the coil segment 104 is formed from a wound wire (e.g., a helically wound wire). A coiled structure is generally much more compliant than a braided structure and inclusion of these structures along the length of the device 100 can
20 increase the overall compliance of the entire device 100. Although this specification often describes and depicts the compliance sections 104 as coiled structures, the compliance sections 104 can take other forms. In general, the compliance sections 104 can take any form that results in the sections 104 being more compliant than the porosity section 102. As one of many examples, the compliance sections 104 can be formed from braided wire and/or mesh

segments, but with less material or otherwise configured such that they have greater compliance than the porosity section 102.

[0033] In various embodiments, the compliance sections 104 and the porosity section 102 can differ in properties other than or in addition to compliance. In general, the compliance section 104 and porosity section 102 can differ from each other with respect to any property and by any desirable amount. As one example, the compliance sections 104 and the porosity section 102 can have different thermomechanical properties from each other. An example material whose thermomechanical properties can be set to advantageous values is nitinol, but this can be done with other materials (e.g., most metals) as well. A non-exhaustive list of example thermomechanical properties that can differ between the compliance sections 104 and the porosity section 102 includes (i) strength, ductility, and/or toughness as a function of prior hot and/or cold working heat treatment, (ii) austenitic phase transformation temperature, and (iii) super-elasticity and shape memory properties (e.g., stress-strain behavior as a function of temperature and/or prior hot and/or cold working heat treatment). Many other examples of thermomechanical properties are also possible.

[0034] In other instances in which there are multiple compliance sections 104 and/or multiple porosity sections 102, different sections of the same type (e.g., different compliance sections 104 and/or different porosity sections 102) can have different properties from each other (e.g., thermomechanical properties). In still other instances, a single compliance section 104 and/or porosity section 102 can have different properties at different locations. As one example, a porosity section 102 can have a thermomechanical property having a first value near its center and a different value near its perimeter. One advantage of varying thermomechanical (or other) properties within the device 100 is that it can allow the device to be tuned to achieve desired deployment (or other performance) characteristics, e.g., by adjusting the phase transformation temperatures and/or expansion force characteristics at

various locations of the device 100. In various embodiments, any two components (or locations thereof) of the device 100 can also have the same property as each other.

[0035] In various embodiments, the porosity section 102 itself has a novel and unique design that improves the function of the embolic device 100. In some cases, the improved porosity section 102 can be used with the compliance sections 104 (as described above), such that multiple features enhance the function of the device 100. In other cases, the entire device 100 can be formed from the improved porosity section 102, which can independently enhance the function of the device 100. In particular, in various embodiments, the porosity section 102 is formed from a novel and unique structure that features improved properties and characteristics over conventional braided/mesh wires, while still achieving the desired porosity. In various embodiments, the desired porosity can be in a range from about 50% to about 90% porous, in a range from about 60% to about 80% porous, in a range from about 60% to about 70% porous, and in a range from about 70% to about 80% porous.

[0036] For example, the porosity section 102 can be a mesh-screen segment that is formed from at least one flat surface (e.g., a layer), as opposed to a cylindrical surface of a wire. Because the mesh-screen segment is an exemplary type of porosity section, both the mesh-screen segment and the porosity section are referred to in this application with the reference numeral 102. A structure formed from flat surface layers can be more flexible, crimp-resistant, and expandable than a structure formed from overlapping wires, while still achieving a desired porosity. In general, the mesh-screen segment 102 can be formed from any number of layers arranged/laminated in any desirable manner. For example, in the simplest case, the mesh-screen segment 102 is formed from a single layer. In other examples, the mesh-screen segment 102 is formed from multiple layers. In some cases, the various layers have different thicknesses and exist in different and/or overlapping parallel planes.

[0037] FIG. 3 is a side cross-sectional view of an exemplary, relatively complicated, layered structure. Each of elements 1 through 7 in FIG. 3 represents a different layer of a mesh-screen segment 102. As illustrated by layer 1 and layer 2, the layers can have different thicknesses (dimension along the y-axis). As illustrated by layer 3 and layer 4, at least a portion of different layers can exist in different parallel planes (e.g. the bottom portion of layer 3 and the top portion of layer 4 are in different parallel layers). Also illustrated by layer 3 and layer 4, at least a portion of different layers can exist in overlapping planes (e.g., the middle portion of both layer 3 and layer 4 overlap). As illustrated by layer 5 and layer 6, in some instances, certain layers do not overlap at all. Conversely, as illustrated by layer 4 and layer 7, certain layers can completely overlap (e.g., exist in the same plane over the entire thickness of one and/or both layers).

[0038] As illustrated by layer 5 and layer 6, the layers can have different widths (dimension along the x-axis). As illustrated by layer 1 and layer 4, the layers can have the same width. As illustrated by layer 5 and layer 6, in some instances, there can be a gap between layers. The gap can exist in either the y-axis direction (shown in FIG. 3) or the x-axis direction. For example, gaps in the x-axis direction can be formed by through-thickness perforations formed in the mesh-screen segment 102. Exemplary through-thickness perforations 108 are shown in FIG. 2. When the device 100 is deployed within the aneurysm, fluid flows through the through-thickness perforations 108 to enter the aneurysm. Thus, the perforations 108 perform a similar function to the pores 101 formed in a conventional braided structure. For example, the size of the perforations 108 can determine the porosity of the mesh-screen segment 102, which in turn affects the amount of fluid that can traverse the mesh-screen segment 102 to enter the aneurysm. However, the perforations 108 are generally superior to the pores 101 of a braided structure because they can be configured to have a constant size (or a size with controlled variability, e.g., in embodiments in which the

layers can move with respect to each other), which allows for a more consistent and predictable porosity to be achieved. In the conventional braided structure, the wires often move with respect to each other, which changes the pore size, making it harder to achieve a predictable porosity.

5 **[0039]** In general, the through-thickness perforations 108 can be formed in any shape or size so as to achieve a desired porosity. In some cases, the through-thickness perforations have a constant shape and size across the surface of the mesh-screen section 102. In other cases, the through-thickness perforations have different shapes and/or sizes at different locations across the surface of the mesh-screen section 102. In some instances, the through-
10 thickness perforations affect other properties of the mesh-screen section 102, e.g., flexibility, expandability, crimp-resistance, etc.

[0040] As illustrated by all the layers in FIG. 3, the width of a layer can be less than the width of the entire mesh-screen section 102. In other instances, one or all of the layers can have a width that extends across the entire width of the mesh-screen section 102 (not shown
15 in FIG. 3). In various embodiments, the relationships described above can exist between either adjacent or non-adjacent layers, in either the x-axis direction or the y-axis direction. Many other examples of relationships between layers are possible.

[0041] In various embodiments, the layers are joined at junctions 304 formed along the x-axis using any known technique. For example, the layers can be formed separately and
20 joined using known attachment techniques (e.g., adhesives, welding, etc.). As another example, the layers can be formed from a single piece of material using subtractive manufacturing techniques (e.g., a laser technique, a mechanical technique, a wet chemical technique, an electrochemical masking technique, a maskless electrochemical technique, etching, milling, photochemical machining, and/or photoelectrochemical machining). In
25 addition to junctions 304 formed between layers along the x-axis, junctions 306 can also be

formed along the y-axis. In some cases, the layers are fixed at the junctions 306, e.g., using known joining techniques such as those described above. In some cases, the layers are free to move with respect to each other at the junctions 306. In certain instances, a single mesh-screen segment 102 can have some layers that are fixed to each other and other layers that are free to move with respect to each other.

[0042] FIGS. 4A and 4B illustrate an exemplary configuration of a mesh-screen segment 102. FIG. 4A is a top view of the mesh-screen segment 102 showing layers 402, 404, and 406. FIG. 4B is a perspective view of the mesh-screen segment 102 showing that layers 402 and 404 have different thicknesses and that at least a portion of each of the layers 402, 404, and 406 exist in different planes.

[0043] FIGS. 5A-5D provide further examples of various mesh-screen segment configurations. FIG. 5A indicates the point of view (i.e., the X-VIEW) from which each of FIGS. 5B-5D is depicted. FIG. 5B depicts a layered structure in which the leftmost edge of two surfaces (surface #1 and surface #2) are offset by a particular depth. FIG. 5C depicts a layered structure in which the leftmost edge of surface #1 and surface #2 are offset by a depth that is less than the offset depth shown in FIG. 5B. FIG. 5D depicts a layered structure in which the leftmost edge of surface #1 and surface #2 are not offset and exist in the same plane.

[0044] In general, the mesh-screen segment 102 can attach to adjacent sections using any technique that ensures proper attachment between the sections. For example, as shown in FIG. 2, in some embodiments the mesh-screen segment 102 includes at least one mesh-screen extension 602 that can be used to attach to adjacent sections. When the adjacent sections are coil segments 104, the mesh-screen extension 602 can extend into a lumen formed by the coil segment 104. The mesh-screen extension 602 can attach to the coil segment 104 using any suitable attachment or bonding scheme, e.g., mechanical mates, adhesive, welding,

corresponding mating profiles, interlocking tabs, notch and grove arrangements, etc. In some cases, the mesh-screen extension 602 does not attach to the coil segment 104 directly, but rather, the coil segment 104 is held between two other structures that are attached by the mesh-screen extension 602 (e.g., two mesh-screen segments 102, a mesh-screen segment 102 and a delivery pusher, etc.) In some cases, the coil segment 104 can be held between two structures and attached directly to the mesh-screen extension 602. Similarly, the mesh-screen extension 602 can attach to a delivery pusher using any suitable attachment scheme. As one example shown in FIG. 9, the mesh-screen extension 602 forms a loop 902 that engages a wire 904 of a delivery pusher assembly. In some cases, the wire can be severed to release the mesh-screen extension 602 (and the device 100) from the delivery pusher. In other instances, the mesh-screen extension 602 attaches to a delivery pusher using corresponding mating profiles, interlocking tabs, notch and grove arrangements, adhesives, welding, etc.

[0045] In some embodiments, the mesh-screen extension 602 extends all the way through the coil segment 104 until it reaches another segment (e.g., another mesh-screen segment 102, a structure for attaching to a delivery pusher, etc.). In some instances, the mesh-screen extensions 602 extend over substantially the entire length of the device 100 (except for the mesh-screen segments 102 themselves) and form a core member of the device 100. In some cases, the mesh-screen extensions 602 ensure that the insertion forces applied from a delivery pusher are translated throughout the entire length of the device 100. This may be necessary, for example, if the coil segments 104 do not adequately translate the insertion force. In some cases, the mesh-screen extensions 602 can constrain the coil segments 104 and prevent undesirable stretching (or an undesirable amount of stretching) of the coil segments 104. As shown in FIG. 2, each mesh-screen segment 102 can have multiple mesh-screen extensions 602; for example, one mesh-screen extension 602 for each adjacent coil segment 104.

[0046] FIG. 6 is a close-up view of one of the mesh-screen extensions 602 shown in FIG.

2. As shown, the mesh-screen extension 602 can include a coupling feature 604 at its terminal end that can be used to attach to other segments and/or a delivery pusher. In some instances, the mesh-screen extension 602 is symmetric. In other instances, the mesh-screen extension 602 is non-symmetric. For example, the coupling feature 604 on either end of the mesh-screen extension 602 can be different (e.g., one coupling feature can be adapted to attach to a coil segment 104 and a different coupling feature can be adapted to attach to a delivery pusher).

[0047] In operation, the embolic device 100 may be introduced, delivered, positioned, and implanted within a vascular disorder using a microcatheter. The microcatheter can be a flexible, small diameter catheter having, for example, an inside diameter between 0.016 inches and 0.021 inches. The microcatheter may be introduced by an introducer sheath/guiding catheter combination placed in the femoral artery or groin area of a patient. In some instances, the microcatheter is guided into the vascular disorder with guidewires (e.g., long, torqueable proximal wire sections with more flexible distal wire sections designed to be advanced within tortuous vessels). Such a guidewire may be visible using fluoroscopy and may be used to first access the vascular disorder, thereby allowing the microcatheter to be advanced over it into the disorder.

[0048] In some instances, once the tip of the microcatheter has accessed the vascular disorder, the guidewire is removed from the catheter lumen. The embolic device 100 may then be placed into the proximal open end of the microcatheter and advanced through the microcatheter with a delivery mechanism. While the embolic device 100 is disposed within the lumen of the microcatheter it may take a straightened out form. For example, the coil segments 104 can be straightened out to fit within the catheter lumen. In some cases, the mesh-screen section(s) 102 can be rolled, folded, or otherwise compressed so as to fit within

the lumen of the microcatheter (see FIG. 7, as an example, with the microcatheter identified with reference numeral 702). A user (e.g., a physician) may advance and/or retract the embolic device 100 several times to obtain a desirable position of the embolic device 100 within the disorder. In some cases, a mesh-screen segment 102 can be guided and pushed by the adjacent coil segments 104. Once the embolic device 100 is satisfactorily positioned, it can be released into the disorder.

[0049] Upon release, the embolic device 100 can form a secondary shape. In some instances, the formation of a secondary shape upon deployment into the vascular disorder is caused by a shape-memory nature of the material (e.g., nitinol) used to form at least a portion of the embolic device 100 (e.g., the compliance sections 104). In general, the secondary shape can be any shape desirable to treat the aneurysm. For example, the shape can include a porosity section 102 disposed across a neck of the aneurysm and the compliance sections 104 arranged in the middle of the aneurysm cavity and/or along an interior wall of the aneurysm cavity, as may be desirable for treating the aneurysm. Exemplary images of the embolic device 100 formed into a secondary shape are shown in FIGS. 8A-8M. In images 8C-8M, the images depict the embolic device 100 being deployed from a microcatheter 702. In images 8H-8M, the images depict the embolic device 100 at various stages of deployment within a glass model aneurysm sac 802, which models the environment of an aneurysm within the body.

[0050] In various embodiments, the embolic device 100 is delivered in a more effective manner than conventional devices. For example, current techniques for delivering conventional braided devices typically have detachment zones that require the microcatheter to be placed directly at the neck of the aneurysm (i.e., not within the aneurysm cavity). Once the first device is released it blocks the neck of aneurysm and inhibits re-access to the cavity of the aneurysm, e.g., for the placement of additional devices/coils. This requires that the

physician select a perfectly sized device that cannot be supplemented with additional devices, which can be challenging and often times not available.

[0051] Various embodiments of the present invention provide a solution to this problem.

In particular, because the embolic device 100 does not include the high material density
5 required to achieve the desired porosity along its entire length, the microcatheter can be placed directly within the aneurysm cavity for detaching the embolic device 100. After the first device 100 is deployed, the microcatheter can remain within the aneurysm cavity, such that additional devices/coils can be delivered without needing to remove or reposition the microcatheter. This can allow the physician to easily insert additional devices/coils which
10 may be needed to “pack” the aneurysm and/or stabilize the embolic device 100. This functionality also alleviates the requirement that the embolic device 100 be perfectly sized, which can enable it to be used more often and to treat a greater number of aneurysms/vascular disorders.

[0052] In various embodiments, inclusion of the compliance sections 104 in the embolic
15 device 100 results in the device 100 behaving more like a pure bare platinum coil than conventional braided devices. In general, the mechanical behavior and deployment of the embolic device 100 is much closer to that of a bare platinum coil than conventional braided devices. This can be advantageous because many physicians consider the feel of delivering a bare platinum coil to be familiar given traditional training and experience. Thus, the embolic
20 devices 100 described in this application may be easier for physicians to adopt than conventional braided devices. In some embodiments, the embolic device 100 includes radiopaque sections (e.g., the coil segments 104) that can increase visibility of the embolic device 100 and improve safety during delivery, e.g., when exposed to fluoroscopic imaging. It is much more difficult to include radiopaque sections in conventional braided devices.

[0053] Other aspects of the invention generally relate to methods of manufacturing an embolic device 100. In general, the method can include forming a first coil segment and a second coil segment, forming a mesh-screen segment, and coupling the mesh-screen segment between the first coil segment and the second coil segment along a length of the embolic device. The components of the device can be manufactured using proven biocompatible materials and known manufacturing processes and techniques. For example, as described above, the coil segments 104 can be formed by helically winding wires and the mesh-screen segment 102 can be formed using standard joining techniques (e.g., adhesives, welding, etc.), subtractive manufacturing techniques, and/or combinations thereof. The mesh-screen segment 102 can be attached to the coil segments 104 using the mesh-screen extensions 602 or other techniques, as described above.

[0054] Having described certain embodiments of the invention, it will be apparent to those of ordinary skill in the art that other embodiments incorporating the concepts disclosed herein may be used without departing from the spirit and scope of the invention. Accordingly, the described embodiments are to be considered in all respects as only illustrative and not restrictive.

Claims

What is claimed is:

1. An embolic device for use in treating a vascular disorder, the embolic device
5 comprising:
 - a first coil segment;
 - a second coil segment; and
 - a mesh-screen segment,wherein the mesh-screen segment is disposed between the first coil segment and the
10 second coil segment along a length of the embolic device.
2. The embolic device of claim 1, wherein the first and second coil segments each
comprise a helically wound wire.
- 15 3. The embolic device of claim 1, wherein the first and second coil segments each
comprise a greater compliance than the mesh-screen segment.
4. The embolic device of claim 1, wherein the mesh-screen segment comprises a greater
porosity than each of the first and second coil segments.
20
5. The embolic device of claim 4, wherein, when the mesh-screen segment is in a
deployed configuration, the mesh-screen segment is 60% to 80% porous.
6. The embolic device of claim 1, wherein the mesh-screen segment comprises two
25 layers.
7. The embolic device of claim 6, wherein the two layers have different thicknesses.
8. The embolic device of claim 6, wherein at least a portion of each of the two layers are
30 disposed in different parallel planes.
9. The embolic device of claim 6, wherein at least a portion of each of the two layers are
disposed in the same plane.

10. The embolic device of claim 6, wherein the two layers are fixed to each other.
11. The embolic device of claim 6, wherein the two layers are free to move with respect
5 to each other.
12. The embolic device of claim 6, wherein the two layers are spaced apart from each other by a predetermined distance.
- 10 13. The embolic device of claim 1, wherein the mesh-screen segment comprises through-thickness perforations.
14. The embolic device of claim 1, wherein the mesh-screen segment further comprises a first extension portion and a second extension portion adapted to be inserted into a lumen
15 formed by the first coil segment and the second coil segment, respectively, to couple the mesh-screen segment to the first coil segment and the second coil segment.
15. The embolic device of claim 1, wherein different portions of the embolic device comprise different thermomechanical properties.
- 20 16. A method for treating a vascular disorder of a patient, the method comprising:
delivering into the vascular disorder an embolic device comprising a coil segment
and, coupled thereto, a mesh-screen segment, such that:
the coil segment is disposed within a cavity formed by the vascular disorder,
25 and
the mesh-screen segment is disposed across a neck of the vascular disorder.
17. The method of claim 16, wherein the vascular disorder comprises an aneurysm.
- 30 18. The method of claim 16, wherein the delivering step comprises releasing the device from a distal tip of a delivery pusher.
19. The method of claim 18, further comprising advancing the delivery pusher through a microcatheter having a distal end disposed within the vascular disorder.

20. The method of claim 19, further comprising delivering a second embolic device into the vascular disorder without repositioning the microcatheter.
- 5 21. The method of claim 16, wherein the embolic device further comprises an additional coil segment, and further wherein the mesh-screen segment is disposed between the coil segment and the additional coil segment along a length of the embolic device.
22. The method of claim 16, wherein the coil segment comprises a helically wound wire.
- 10 23. The method of claim 16, wherein the coil segment comprises a greater compliance than the mesh-screen segment.
24. The method of claim 16, wherein the mesh-screen segment comprises a greater
15 porosity than the coil segment.
25. The method of claim 16, wherein, upon delivery, the mesh-screen segment is 60% to 80% porous.
- 20 26. The method of claim 16, wherein the mesh-screen segment comprises two layers.
27. The method of claim 26, wherein the two layers have different thicknesses.
28. The method of claim 26, wherein at least a portion of each of the two layers are
25 disposed in different parallel planes.
29. The method of claim 26, wherein at least a portion of each of the two layers are disposed in the same plane.
- 30 30. The method of claim 26, wherein the two layers are fixed to each other.
31. The method of claim 26, wherein the two layers are free to move with respect to each other.

32. The method of claim 26, wherein the two layers are spaced apart from each other by a predetermined distance.
33. The method of claim 16, wherein the mesh-screen segment comprises through-
5 thickness perforations.
34. The method of claim 16, wherein different portions of the embolic device comprise different thermomechanical properties.
- 10 35. A method of manufacturing an embolic device, the method comprising the steps of:
forming a first coil segment and a second coil segment;
forming a mesh-screen segment; and
coupling the mesh-screen segment between the first coil segment and the second coil
segment along a length of the embolic device.
- 15 36. The method of claim 35, wherein the step of forming the first and second coil
segments comprises helically winding at least one wire.
37. The method of claim 35, wherein the step of forming the mesh-screen segment
20 comprises using a subtractive manufacturing technique.
38. The method of claim 37, wherein the subtractive manufacturing technique is selected
from the group consisting of a laser technique, a mechanical technique, a wet chemical
technique, an electrochemical masking technique, a maskless electrochemical technique,
25 etching, milling, photochemical machining, and photoelectrochemical machining.
39. The method of claim 35, wherein the step of coupling the mesh-screen segment
between the first coil segment and the second coil segment comprises inserting a first
extension portion and a second extension portion of the mesh-screen segment into a lumen
30 formed by the first coil segment and the second coil segment, respectively.
40. The method of claim 35, wherein at least one of the step of forming the first and
second coil segments and the step of forming the mesh-screen segment comprises forming
different portions of the embolic device to have different thermomechanical properties.

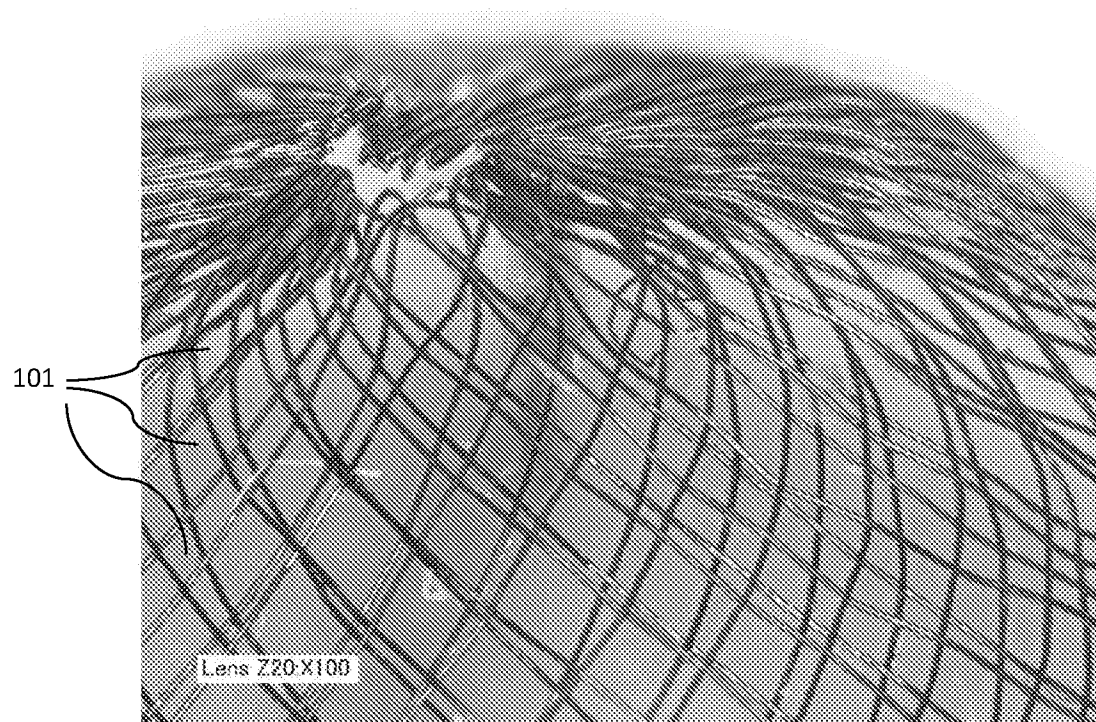


FIG. 1

PRIOR ART

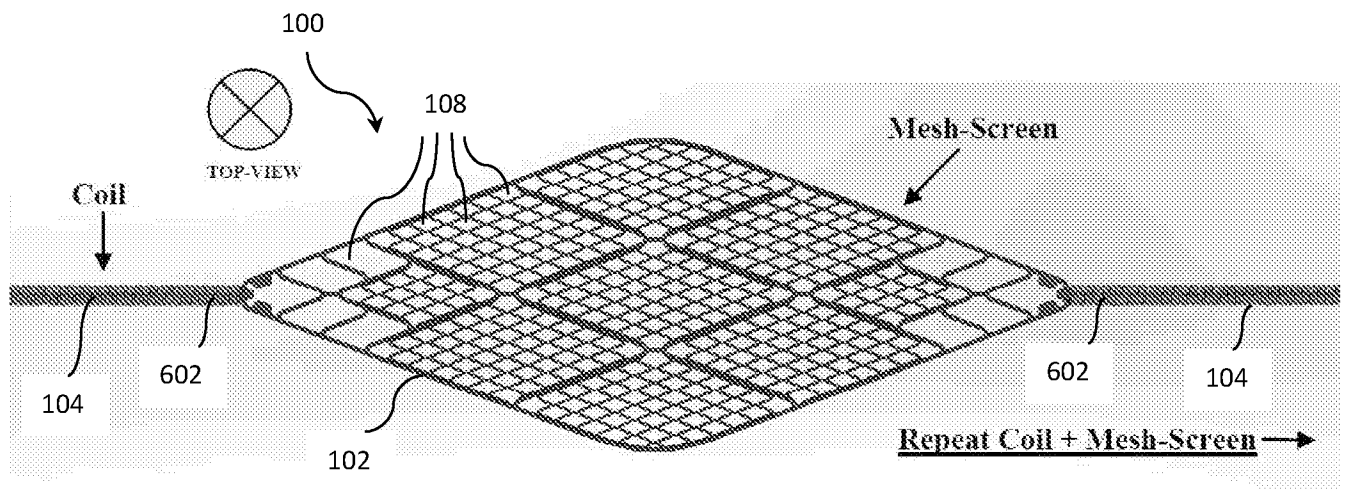


FIG. 2

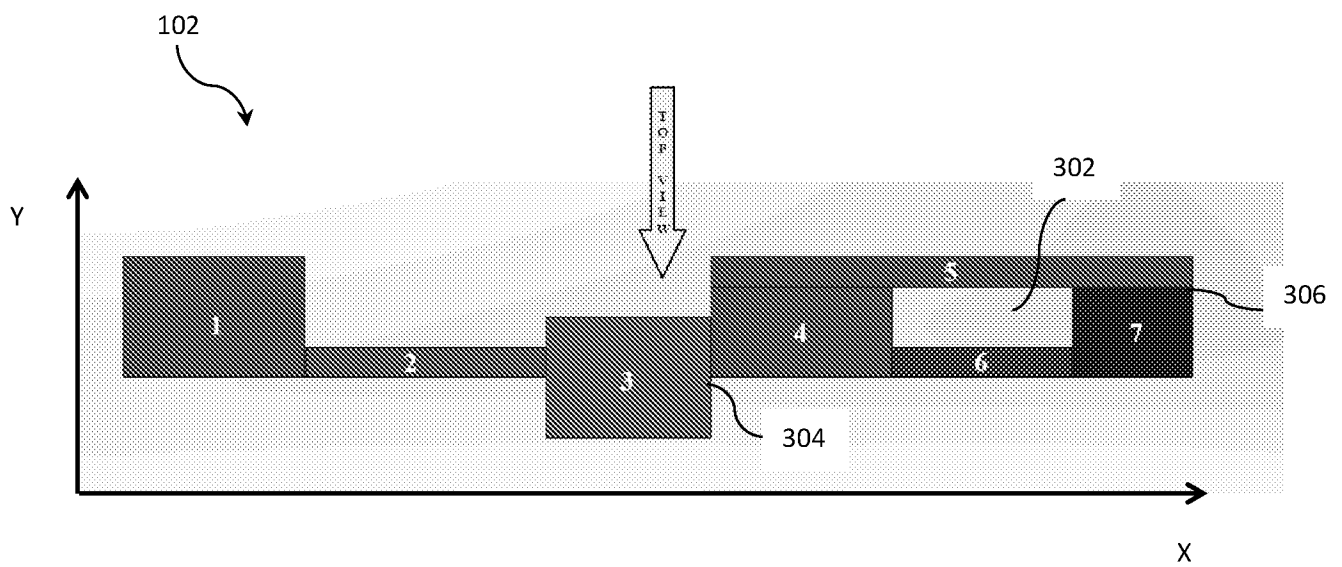


FIG. 3

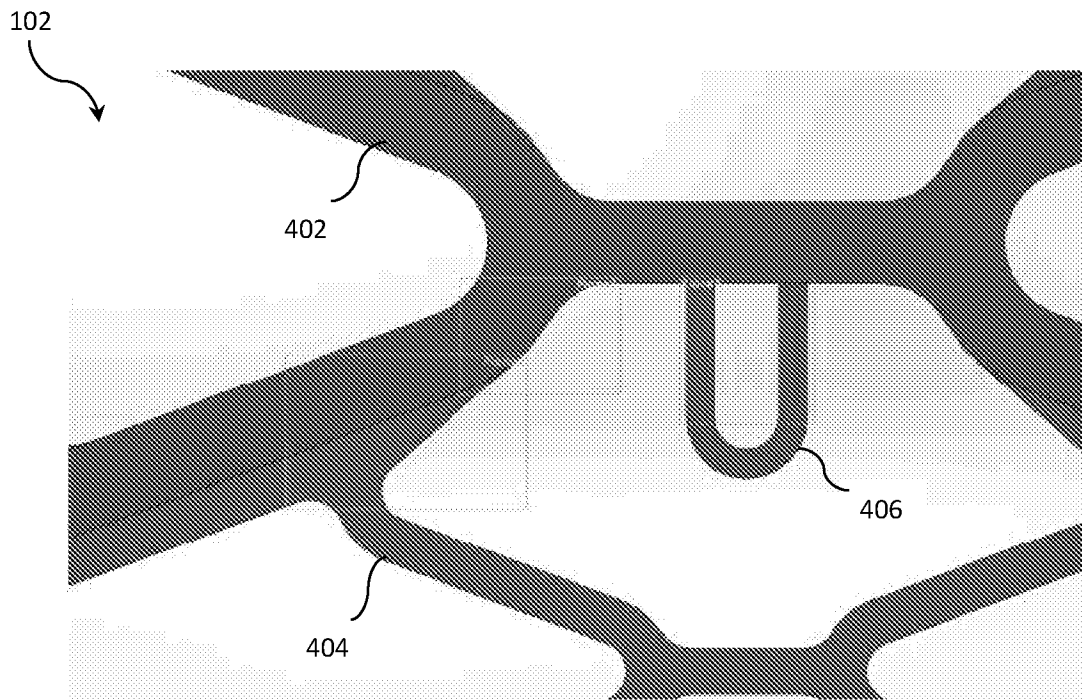


FIG. 4A

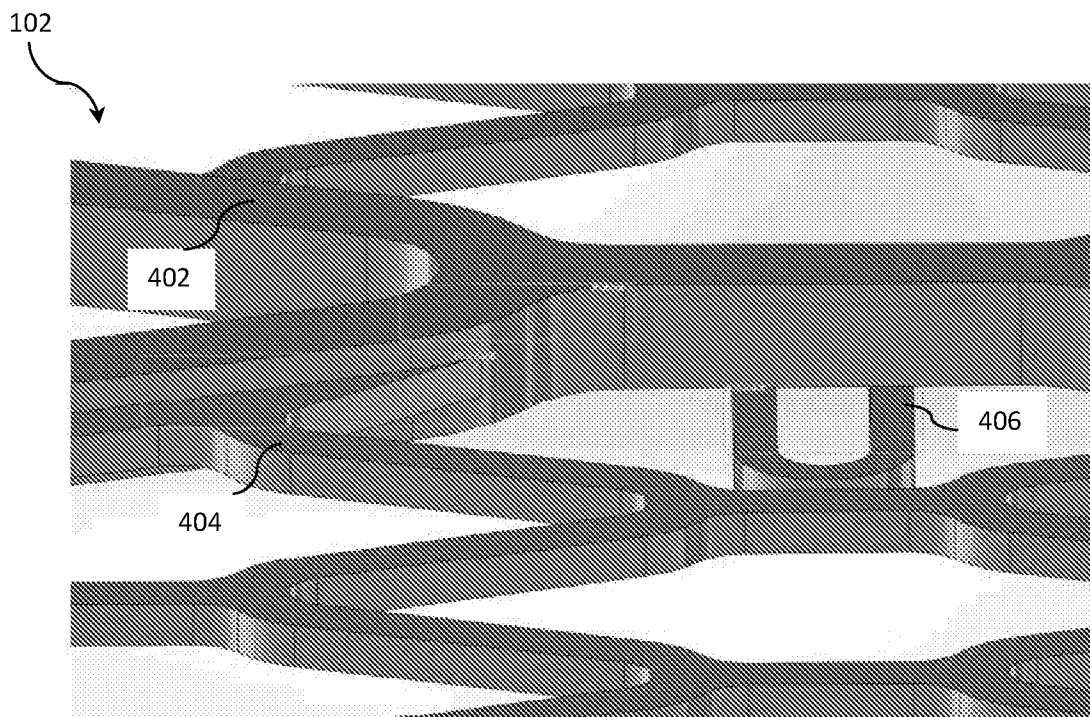


FIG. 4B

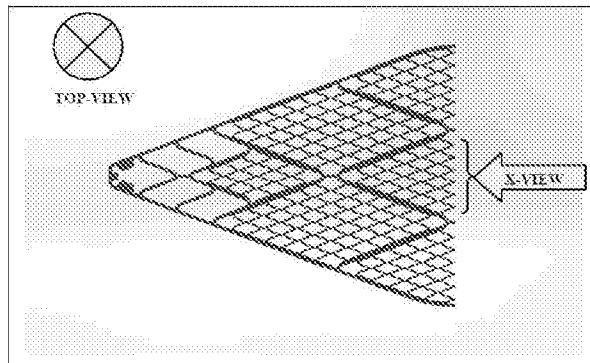


FIG. 5A

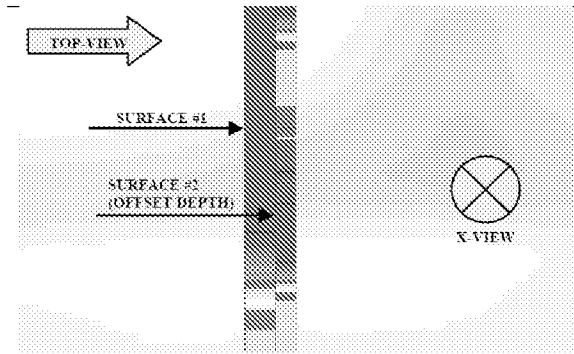


FIG. 5B

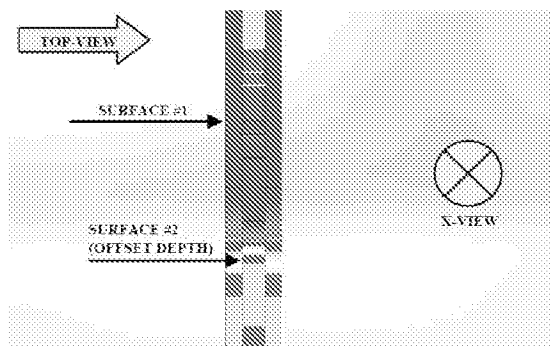


FIG. 5C

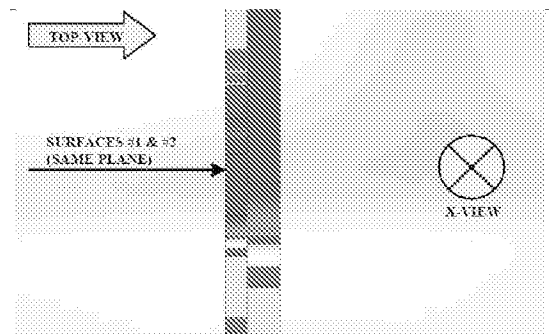


FIG. 5D

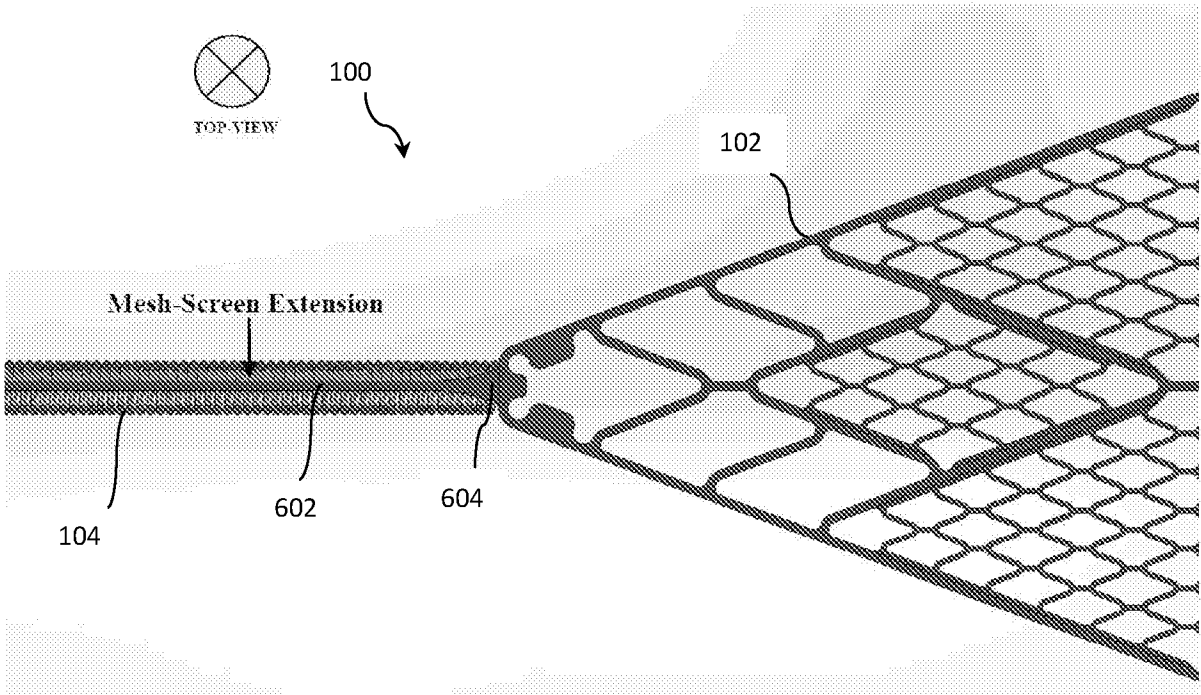


FIG. 6

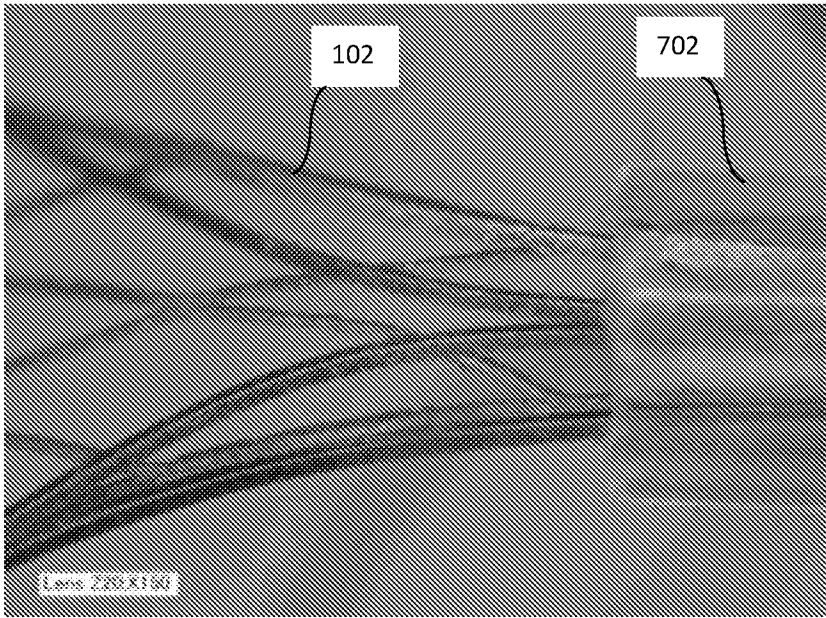


FIG. 7

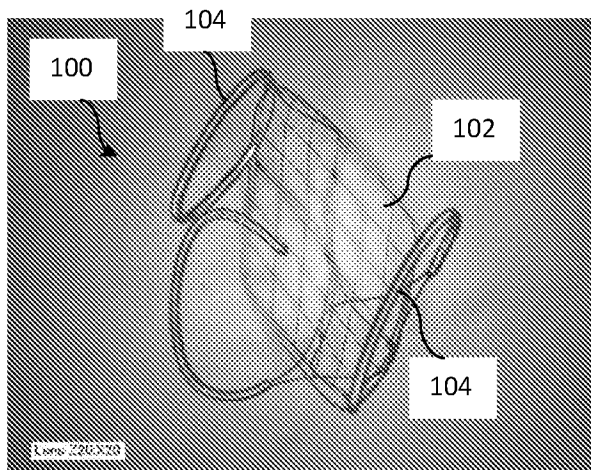


FIG. 8A

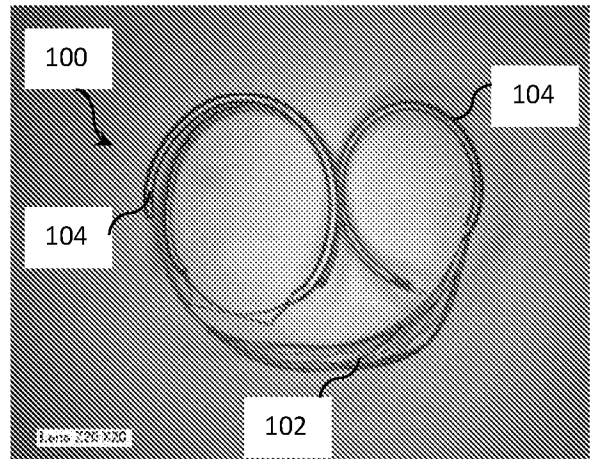


FIG. 8B

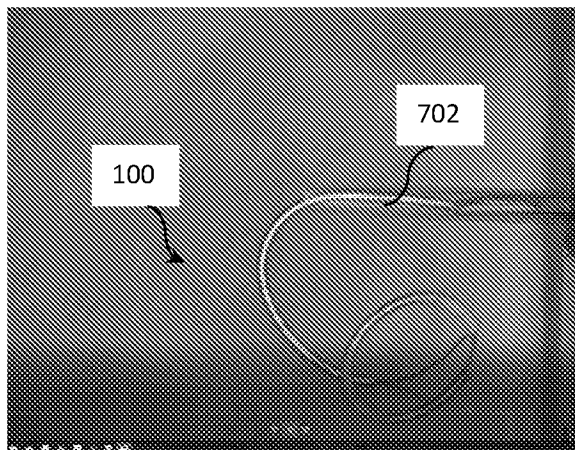


FIG. 8C

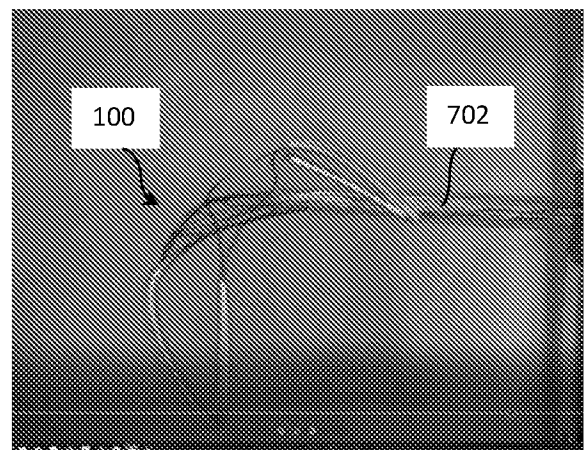


FIG. 8D

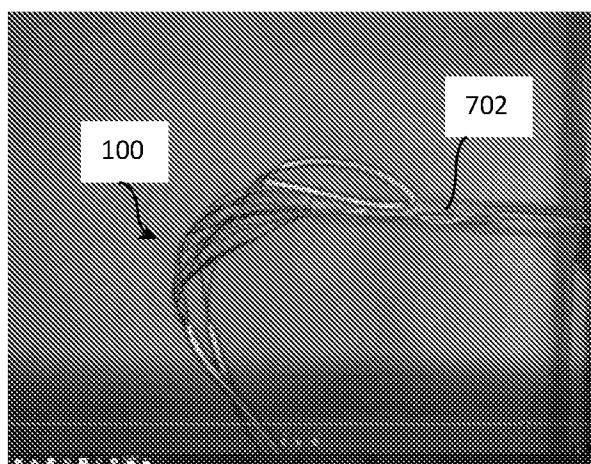


FIG. 8E

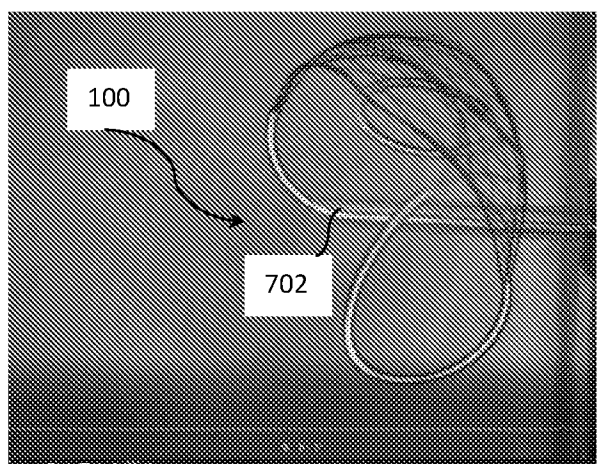


FIG. 8F

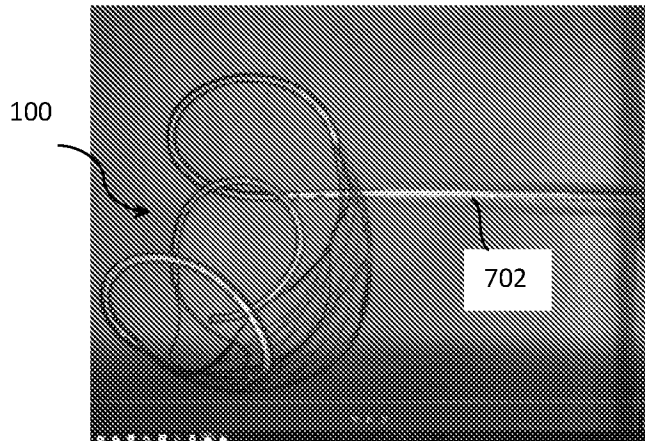


FIG. 8G

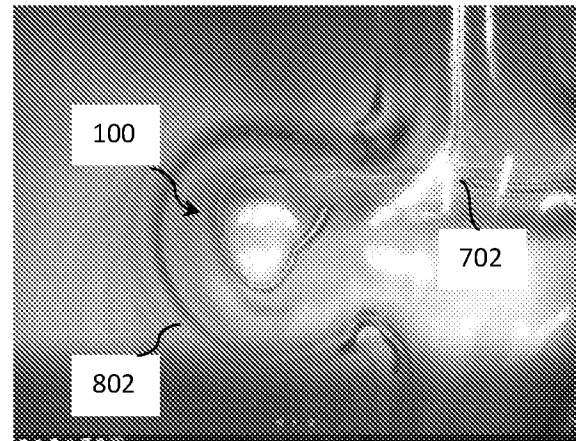


FIG. 8H

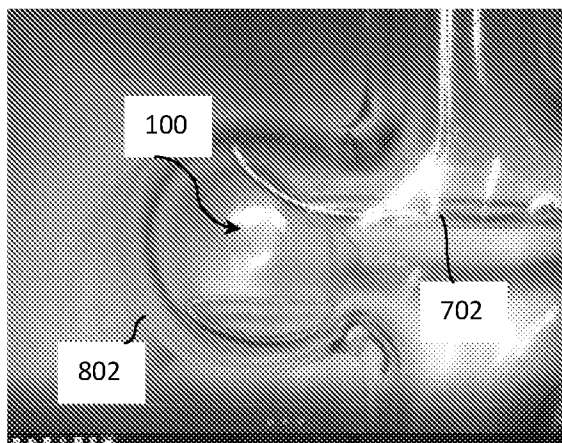


FIG. 8I

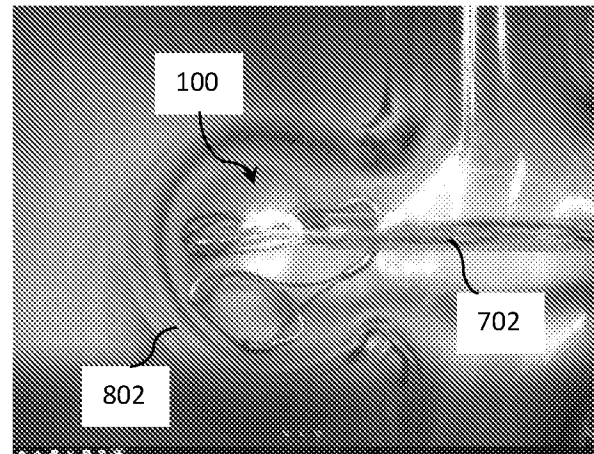


FIG. 8J

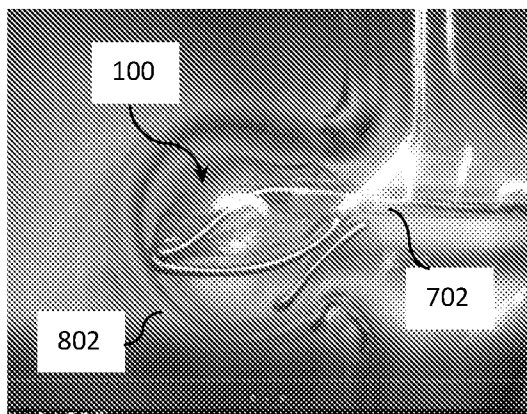


FIG. 8K

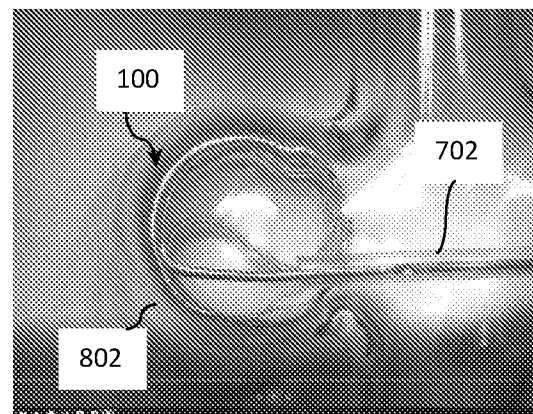


FIG. 8L

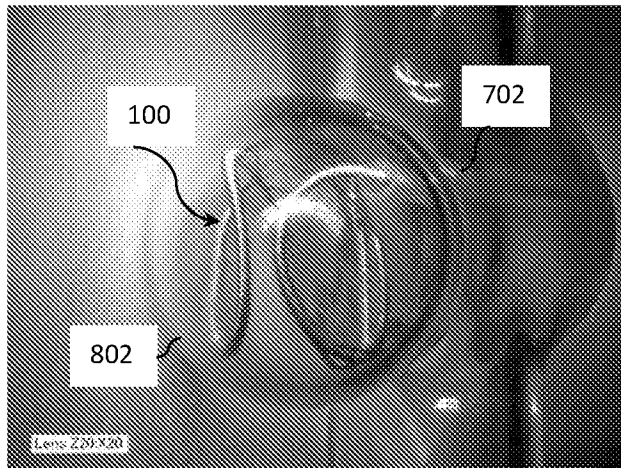


FIG. 8M

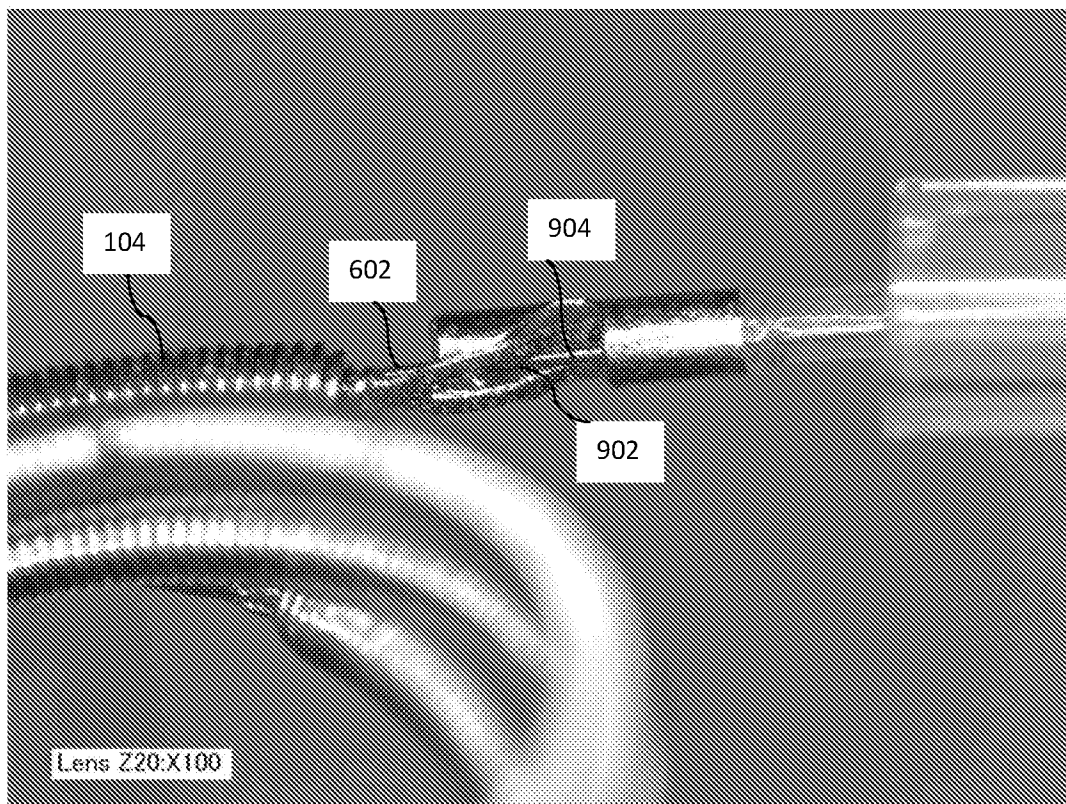


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/046263

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/12 A61B90/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 3 087 934 A1 (DEPUY SYNTHES PRODUCTS INC [US]) 2 November 2016 (2016-11-02)	1-3,15
A	figure 12A page 19	6-14
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X	----- WO 2016/014985 A1 (INCUMEDX INC [US]) 28 January 2016 (2016-01-28)	1
X	----- US 2009/270974 A1 (BEREZ AARON LEE [US] ET AL) 29 October 2009 (2009-10-29)	1-3,6,7, 10,12,15
	figure 11A paragraph [0221] ----- -/-	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

24 October 2018

Date of mailing of the international search report

31/10/2018

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Erbel, Stephan

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/046263

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 494 820 A (REVERSE MEDICAL CORP [US]) 20 March 2013 (2013-03-20) figure 21 -----	1,15
X	US 2002/169473 A1 (SEPETKA IVAN [US] ET AL) 14 November 2002 (2002-11-14) paragraph [0164]; figure 64 -----	1,2
X	WO 2017/035275 A1 (NEURVANA MEDICAL LLC [US]) 2 March 2017 (2017-03-02) figure 5 -----	1,13,15
X	US 2014/128901 A1 (KANG KEVIN [US] ET AL) 8 May 2014 (2014-05-08) figure 17B -----	1,13,15
X	US 2013/261730 A1 (BOSE ARANI [US] ET AL) 3 October 2013 (2013-10-03) figures 7,7A,7C -----	1,13,15
A	WO 2011/072053 A1 (NEUROVASX INC [US]; LEE JEFFREY A [US]) 16 June 2011 (2011-06-16) the whole document -----	1-3,6-15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/046263

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 16-40
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery. Claims 16-40 relate to a method for treating the human body by surgery. According to Rule 39.1 (iv) PCT the international search authority is not required to search subject matter falling under this category.
2. ☒ Claims Nos.: 4, 5
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 16-40

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery Claims 16-40 relate to a method for treating the human body by surgery. According to Rule 39.1 (iv) PCT the international search authority is not required to search subject matter falling under this category.

Continuation of Box II.2

Claims Nos.: 4, 5

The subject matter of claim 4 and thus also of its sub-dependent claim 5 is not clear. It is not clear how a coil could have a "porosity" as it is not specified that any pores or holes are provided in the coil. This lack of clarity renders a meaningful search for the subject matter of claims 4 and 5 impossible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2018/046263

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2018/046263

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