(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau





(10) International Publication Number WO 2014/123659 A1

(43) International Publication Date 14 August 2014 (14.08.2014)

(51) International Patent Classification: A61B 17/12 (2006.01) A61F 2/90 (2013.01) A61F 2/856 (2013.01)

(21) International Application Number:

PCT/US2014/011198

(22) International Filing Date:

13 January 2014 (13.01.2014)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/760,907 5 February 2013 (05.02.2013) US 13/826,147 14 March 2013 (14.03.2013) US

(71) Applicant: COVIDIEN LP [US/US]; 15 Hampshire Street, Mansfield, MA 02048 (US).

(72) Inventor: KUSLEIKA, Richard; 161 West Lake Street, Excelsior, MN 55331 (US).

(74) Agents: JOHNSTON, Thomas, M. et al.; Covidien Lp, 15 Hampshire Street, Mansfield, MA 02048 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

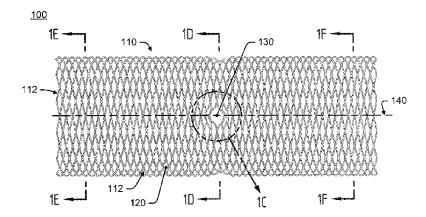
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

with international search report (Art. 21(3))

 $(\mathbf{54})$ Title: VASCULAR DEVICE ANEURYSM TREATMENT AND PROVIDING BLOOD FLOW INTO A PERFORATOR VESSEL



(57) Abstract: A vascular device (100) includes a body (110) having a first, collapsed configuration and a second, expanded configuration. The body includes a plurality of heat-set strands (112) that are braided such that when the body is in the second configuration, the strands form a plurality of pores (120) and one or more apertures (130) between the strands. The apertures are generally disposed at a longitudinal center region of the body. When the body is in the second configuration, the pores at proximal and distal portions of the body are generally uniform in size and smaller in size than the apertures. The pores and the apertures are substantially the same size when the body is in the first configuration.



2014/123659 A1

VASCULAR DEVICE FOR ANEURYSM TREATMENT AND PROVIDING BLOOD FLOW INTO A PERFORATOR VESSEL

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Patent Application No. 13/826,147, filed on March 14, 2013, titled "Vascular Device for Aneurysm Treatment and Providing Blood Flow into a Perforator Vessel"; and to U.S. Provisional Patent Application No. 61/760,907, filed on February 5, 2013, titled "Vascular Device for Aneurysm Treatment and Providing Blood Flow into a Perforator Vessel." The entire contents of the above-noted applications are incorporated by reference herein and made a part of this specification.

BACKGROUND

Lumens in a patient's body can change in size, shape, and/or patency, and such changes can present complications or affect associated bodily functions. For example, the walls of the vasculature, particularly arterial walls, may develop a pathological dilatation, commonly called an aneurysm. Aneurysms are observed as a ballooning-out of the wall of an artery. This is a result of the vessel wall being weakened by disease, injury, or a congenital abnormality. Aneurysms have thin, weak walls and have a tendency to rupture and are often caused or made worse by high blood pressure. Aneurysms can be found in different parts of the body; the most common being abdominal aortic aneurysms (AAA) and the brain or cerebral aneurysms. The mere presence of an aneurysm is not always life-threatening, but an aneurysm can have serious health consequences such as a stroke if one should rupture in the brain. Additionally, a ruptured aneurysm can also result in death.

SUMMARY

[0003] The subject technology is illustrated, for example, according to various aspects described below. Various examples of aspects of the subject technology are described as numbered clauses (1, 2, 3, etc.) for convenience. These are provided as examples, and do not limit the subject technology. It is noted that any of the dependent clauses may be combined in any combination, and placed into a respective independent clause, e.g., clause 1, 18 and 27. The other clauses can be presented in a similar manner.

1. A vascular device, comprising:

a body having a first, collapsed configuration and a second, expanded configuration, the body comprised of a plurality of heat-set strands;

wherein the strands are braided such that when the body is in the second configuration, the strands form a plurality of pores and a plurality of apertures between the strands;

wherein the apertures are disposed at a longitudinal center region of the body;

wherein, when the body is in the second configuration, the pores at proximal and distal portions of the body are generally uniform in size and smaller in size than the apertures; and

wherein the pores and the apertures are substantially the same size when the body is in the first configuration.

- 2. The vascular device of clause 1, wherein the apertures are formed by displacement of adjacent strands.
- 3. The vascular device of clause 1, wherein the plurality of apertures comprises two apertures.
- 4. The vascular device of clause 2, wherein the apertures are equally spaced and radially arranged around a longitudinal axis of the body.
- 5. The vascular device of clause 2, wherein a center region of each of the apertures is disposed along a single radial cross section of the body.
- 6. The vascular device of clause 1, wherein the plurality of apertures comprises three apertures.
- 7. The vascular device of clause 6, wherein the apertures are equally spaced and radially arranged around a longitudinal axis of the body.
- 8. The vascular device of clause 6, wherein a center region of each of the apertures is disposed along a single radial cross section of the body.
- 9. The vascular device of clause 1, wherein the plurality of apertures comprises four apertures.

10. The vascular device of clause 9, wherein the apertures are equally spaced and radially arranged around a longitudinal axis of the body.

- 11. The vascular device of clause 9, wherein a center region of each of the apertures is disposed along a single radial cross section of the body.
- 12. The vascular device of clause 1, wherein a number of strands in each of a proximal, center, and distal radial cross sections of the body is the same.
- 13. The vascular device of clause 1, wherein the body has a hoop strength that is generally uniform along the body's longitudinal length.
- 14. The vascular device of clause 1, wherein an area of at least one of the apertures is about 0.005 square millimeters or larger.
- 15. The vascular device of clause 1, wherein an area of at least one of the pores is about 0.01 square millimeters or smaller.
 - 16. The vascular device of clause 1, wherein the apertures are larger than the pores.
- 17. The vascular device of clause 1, wherein a thickness of each strand is about 0.0010 to 0.0014 inches.
 - 18. A method, for creating a plurality of apertures in a vascular device, comprising:

braiding a plurality of shape-memory strands to form the vascular device, wherein the strands are braided to form a plurality of pores between the strands, wherein the pores at proximal and distal portions of the device are generally uniform in size;

forming each of the apertures by displacing strands disposed at a longitudinal center region of the device with a tapered mandrel, wherein each aperture is larger than a pore; and

applying heat to the displaced strands to thereby set a shape of the displaced strands.

19. The method of clause 18, wherein the plurality of apertures comprises two apertures.

20. The method of clause 18, wherein the plurality of apertures comprises three apertures.

- 21. The method of clause 18, wherein the plurality of apertures comprises four apertures.
- 22. The method of clause 18, wherein the apertures are equally spaced and radially arranged around a longitudinal axis of the vascular device.
- 23. The method of clause 18, wherein a center region of each of the apertures is disposed along a single radial cross section of the vascular device.
- 24. The method of clause 18, wherein a number of strands in each of a proximal, center, and distal radial cross sections of the vascular device is the same.
- 25. The method of clause 18, wherein the vascular device has a hoop strength that is generally uniform along the device's longitudinal length.
 - 26. The method of clause 18, wherein the apertures are larger than the pores.
- 27. A method for providing blood flow into a perforator vessel extending from a sac of an aneurysm, the method comprising:

positioning a vascular device in a vessel at an opening into the aneurysm, wherein the device has a first, collapsed configuration and a second, expanded configuration, the device comprising:

a plurality of heat-set strands, wherein the strands are braided such that when the device is in the second configuration, the strands form a plurality of pores and a plurality of apertures between the strands;

wherein the apertures are disposed at a longitudinal center region of the device;

wherein, when the device is in the second configuration, the pores at proximal and distal portions of the device are generally uniform in size and smaller in size than the apertures; and

wherein the pores and the apertures are substantially the same size when the device is in the first configuration; and

aligning the longitudinal center region of the device with the aneurysm to thereby provide blood flow into the perforator through one of the apertures.

- 28. The method of clause 27, wherein the plurality of apertures comprises two apertures.
- 29. The method of clause 27, wherein the plurality of apertures comprises three apertures.
- 30. The method of clause 27, wherein the plurality of apertures comprises four apertures.
- 31. The method of clause 27, wherein the apertures are equally spaced and radially arranged around a longitudinal axis of the vascular device.
- 32. The method of clause 27, wherein a center region of each of the apertures is disposed along a single radial cross section of the vascular device.
- 33. The method of clause 27, wherein a number of strands in each of a proximal, center, and distal radial cross sections of the vascular device are the same.
- 34. The method of clause 27, wherein the vascular device has a hoop strength that is generally uniform along the device's longitudinal length.
 - 35. The method of clause 27, wherein the apertures are larger than the pores.

[0004] It is understood that other configurations of the subject technology will become readily apparent to those skilled in the art from the following detailed description, wherein various configurations of the subject technology are shown and described by way of illustration. As will be realized, the subject technology is capable of other and different configurations and its several details are capable of modification in various other respects, all without departing from the scope of the subject technology. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] A detailed description will be made with reference to the accompanying drawings:

[0006] FIG. 1A depicts a vascular device in a collapsed configuration, according to some embodiments of the subject technology.

[0007] FIG. 1B depicts a vascular device in an expanded configuration, according to some embodiments of the subject technology.

[0008] FIG. 1C depicts a detail view of an aperture, according to some embodiments of the subject technology.

[0009] FIG. 1D depicts a cross section taken at a longitudinal center of a vascular device, according to some embodiments of the subject technology.

[0010] FIG. 1E depicts a cross section taken at a proximal region of a vascular device, according to some embodiments of the subject technology.

[0011] FIG. 1F depicts a cross section taken at a distal region of a vascular device, according to some embodiments of the subject technology.

[0012] FIG. 2 depicts a cross section view of a vessel and delivery of a vascular device, according to some embodiments of the subject technology.

[0013] FIG. 3 depicts a cross section view of a vessel and delivery of a vascular device, according to some embodiments of the subject technology.

[0014] FIG. 4 depicts a cross section view of a vessel and delivery of a vascular device, according to some embodiments of the subject technology.

[0015] FIG. 5 depicts a cross section view of a vessel and delivery of a vascular device, according to some embodiments of the subject technology.

[0016] FIG. 6 depicts a cross section view of a vessel and deployed vascular device, according to some embodiments of the subject technology.

DETAILED DESCRIPTION

[0017] Aneurysms may be located, for example, along vessel side walls. A neck of an aneurysm typically defines an opening of between about 2 to 25 mm, though other sizes and ranges are also possible. The neck connects an anatomical vessel lumen to a fundus of the aneurysm. In some instances, "vessel" may refer to blood vessels (including arteries and veins) or other suitable body organs having a lumen, such as the gastrointestinal tract (e.g., esophagus, stomach, small intestine, colon, rectum), bile ducts, urinary bladder, ureter, urethra, trachea, bronchi, and the like. Blood flow within the anatomical lumen is channeled through the neck and into the fundus. In response to the constant blood flow into the fundus of the aneurysm, the wall of the aneurysm continues to distend and presents a significant risk of rupturing. When the

blood within the aneurysm causes pressure against the wall of the aneurysm that exceeds the wall strength, the aneurysm ruptures.

[0018] Reduction of blood flow to or within the aneurysm results in a reduction in force against the wall of the aneurysm and a corresponding reduction in the risk of rupturing. Conventionally, a reduction of the force and volume of blood entering the aneurysm may be accomplished by an occluding device. The conventional occluding device restricts blood flow to the aneurysm. The aneurysm, however, may have small perforator vessels or arteries extending from the aneurysm. Because the conventional occluding device isolates the aneurysm from the blood flow in the vessel, any small perforator arteries or vessel branches (both inlet and outlet branches) extending from the aneurysm are also occluded, thereby preventing blood from flowing into the perforator vessels.

The vascular devices of the subject technology solve some or all of the foregoing problems by sufficiently restricting the blood flow into the aneurysm to prevent rupture while providing sufficient blood flow to perforator vessels or arteries extending from the aneurysm, or extending from the parent vessel sidewall near the aneurysm neck (and/or from a location on the sidewall between the proximal and distal ends of the vascular device when deployed). The vascular device includes an expandable vascular device having one or more enlarged apertures disposed near the neck of the aneurysm. The vascular device is configured to reduce the laminar flow into the aneurysm to prevent rupture, while providing sufficient blood flow to the perforator vessel through one or more of the enlarged apertures. Accordingly, the vascular device exhibits a porosity configured to reduce haemodynamic flow into the aneurysm, but simultaneously allow perfusion to perforator vessels.

[0020] FIGS. 1A-1F depict a vascular device 100, according to some embodiments of the subject technology. The vascular device 100 comprises a body 110 having a first, collapsed configuration and a second, expanded configuration. The body is comprised of a plurality of heat-set strands 112 that are braided such that when the body 110 is in the expanded configuration, the strands 112 form a plurality of pores 120 and a plurality of apertures 130 between the strands 112, as shown in FIG. 1B. When the body 110 is in the expanded configuration, the pores 120 at proximal and distal portions of the body 110 are generally uniform in size and smaller in size than the apertures 130. Referring to FIG. 1A, when the body 110 is in the collapsed configuration, the pores 120 and the apertures 130 are substantially the same size.

The body 110 may be a self-expanding stent made of two or more round or ovoid wire strands or filaments 112. In one aspect, the filaments may all be of the same thickness. For example, the thickness of each strand 112 may be about 0.0001 to 0.0020 inches. The filaments may be formed of known flexible and shape memory materials, such as nitinol, platinum and stainless steel. The body 110 may be fabricated from platinum/8% tungsten and 35N LT (cobalt nickel alloy, which is a low titanium version of MP35N alloy) alloy wires. In other embodiments, one or more of the filaments can be formed of a biocompatible metal material or a biocompatible polymer, so long as the filaments are flexible and have shape memory properties. The filaments may be braided into a resulting lattice-like structure. In at least one embodiment, during braiding or winding of the body 110, the filaments may be loosely braided using a 1-over-2-under-2 system. In other embodiments, however, other methods of braiding may be followed, without departing from the scope of the disclosure.

[0022] The ends of the body 110 may be cut to length and therefore remain free for radial expansion and contraction. The body 110 may exhibit a high degree of flexibility due to the materials used, the porosity of the body 110, and the fact that the ends of the filaments are not secured to each other.

[0023] The pores 120 at the proximal and distal portions of the body 110 are sized to reduce haemodynamic flow into an aneurysm and the apertures 130 are sized to provide sufficient blood flow to any perforator vessels extending from the aneurysm. For example, an area of at least one of the pores 120 may be about 0.01 square millimeters or less and an area of at least one of the apertures 130 may be about 0.005 square millimeters or more. In some aspects, the apertures 130 are larger than the pores 120. In some embodiments, the apertures 130 are sized to be range from about two to about ten times the size of the pores 120, while in some embodiments, the apertures 130 are sized to be range from about two to about three to about seven times the size of the pores 120.

[0024] The apertures 130 may be disposed at a longitudinal center region of the body 110 and be formed by displacement of adjacent strands, as shown in FIG. 1C. In one aspect, the vascular device 100 may have two apertures 130 disposed at the longitudinal center region of the body 110. In another example, the vascular device 100 may have three apertures 130 disposed at the longitudinal center region of the body 110. In yet another example, the vascular device 100 may have four apertures 130 disposed at the longitudinal center region of the body 110.

Although FIGS. 1A-D depict four apertures 130, it is understood that a number of apertures greater than four may be suitable for many applications. The apertures 130 may be equally spaced and radially arranged around a longitudinal axis 140 of the body. In some aspects, a center region 132 of each of the apertures 130 is disposed along a single radial cross section of the body 110, as shown in FIG. 1D.

[0025] In some aspects, because the pores 120 and the apertures 130 generally comprise gaps, voids, or areas that are formed between adjacent strands 112, the number of strands 112 in each of a proximal, center, and distal radial cross sections of the body 110 is the same. For example, referring to FIGS. 1D-1F, the number of strands 112 shown at the proximal cross section of the body 110, shown in FIG. 1E, is the same as the number of strands 112 shown at the center cross section of the body 110, shown in FIG. 1D, and the distal cross section of the body 110, shown in FIG. 1F. Because the number of strands 112 at each of the proximal, center, and distal radial cross sections of the body 110 is the same, the body 110 has a hoop strength that is generally uniform along the body's 110 longitudinal length.

[0026] In one aspect, the apertures 130 may be formed on the vascular device 100 by first placing the vascular device 100 in the expanded configuration on a fixture and then inserting one or more tapered mandrels, depending on the number of apertures 130, through the body 110 to displace the strands 112 and thereby form the apertures 130. The displaced strands 112 are then heated to their shape memory temperature to "set" the displaced strands in their displaced configuration. Thereafter, the one or more mandrels are removed from the body 110 and the apertures 130 remain formed on the body 110.

[0027] When the vascular device 100 is in the collapsed configuration, the displaced strands 112 forming the apertures 130 are collapsed, along with all the strands 112 comprising the body 110, and the apertures 130 and the pores 120 are substantially the same size, as shown in FIG. 1A.

[0028] In one aspect, the vascular device may be coated with an endothelial progenitor cell coating to promote endothelium growth on an inner surface of the vascular device 100. Typically, the endothelium will grow from the proximal and/or distal ends of the vascular device 100 and traverse toward the longitudinal center of the vascular device 100. The strands 112 of the vascular device 100 serve as a substrate for the cells to attach thereto. As the inner surface of the vascular device becomes endothelialized, the pores 120 are occluded. Because the apertures 130 are larger than the pores 120, the endothelium grows around the apertures 130 but does not

occlude the apertures 130. Accordingly, the apertures 130 remain unobstructed and permit blood to flow therethrough to feed any perforator vessel emanating from an aneurysm fundus, or emanating from the parent vessel sidewall near the aneurysm neck (and/or from a location on the sidewall between the proximal and distal ends of the vascular device when deployed).

[0029] Radiopaque markers may be located adjacent the proximal or distal portions of the vascular device 100, and may be located at any position along the length of the vascular device 100 between a proximal and distal end of the vascular device 100. The markers may be attached to the vascular device 100 by techniques such as adhesives, heat fusion, interference fit, fasteners, intermediate members, coatings, or by other techniques.

[0030] In some embodiments, the markers are comprised of ultrasonic markers, MRI-safe markers, or other markers. In some embodiments ultrasonic markers permit a physician to accurately determine the position of the vascular device 100 within a patient under ultrasonic visualization. Materials for an ultrasonic marker have an acoustical density sufficiently different from the vascular device 100 to provide suitable visualization via ultrasonic techniques. Exemplary materials comprise polymers, metals such as tantalum, platinum, gold, tungsten and alloys of such metals, hollow glass spheres or microspheres, and other materials.

[0031] In some embodiments, MRI-safe markers permit a physician to accurately determine the position of the vascular device 100 within a patient under magnetic resonance imaging. Exemplary materials for making MRI-safe marker have a magnetic signature sufficiently different from the vascular device 100 to provide suitable visualization via MRI techniques. Exemplary materials comprise polymers, metals such as tantalum, platinum, gold, tungsten and alloys of such metals, non-ferrous materials, and other materials.

[0032] A technique for treating an aneurysm and providing blood flow into a perforator vessel extending from a sac of the aneurysm will now be discussed with reference to FIGS. 2-5. The vascular device 100 may be delivered to a treatment site using a delivery system 200. The delivery system 200 may include a catheter, which may for example, be an over the wire (OTW) catheter, a rapid exchange (multiple lumen) catheter, or a fixed wire catheter.

[0033] Prior to delivery, an outer sheath 210 is disposed over the vascular device 100 to confine the vascular device 100 in the first, collapsed configuration. The vascular device 100 is cooperatively movable within the outer sheath 210 in order to deliver the vascular device 100 to a treatment site, such as an aneurysm 310, within the vasculature 300 of a patient.

[0034] The outer sheath 210 may be configured to be introduced and advanced through the vasculature of the patient. The outer sheath 210 may be made from various thermoplastics, e.g., PTFE, FEP, HDPE, PEEK, etc., which may optionally be lined on the inner surface of the outer sheath 140 or an adjacent surface with a hydrophilic material such as PVP or some other plastic coating. Additionally, either surface may be coated with various combinations of different materials, depending upon the desired results.

[0035] The delivery system 200 also includes a shaft 220 and a guide wire 230. The shaft 220 has a guide wire lumen for allowing the guide wire 230 to extend therethrough. The shaft 220 may also include a reduced diameter at a distal region to provide sufficient annular space in which the vascular device 100 may be stowed.

[0036] Radiopaque markers may be provided at various locations along the length of the delivery system 200. For example, an enlarged distal tip 240 of the shaft 220 may be radiopaque. In another example, radiopaque markers may be provided on the reduced diameter distal region of the shaft 220, beneath the distal and proximal end of the vascular device 100. In yet another example, a radiopaque marker 250 may be disposed on the shaft 220 adjacent to a longitudinal center of the vascular device 100, corresponding to the location of the apertures 130.

In one aspect, the vascular device 100 may be configured with differently sized apertures 130 and/or number of apertures 130. A physician may therefore select the appropriate vascular device 100 based on a size of the aneurysm and/or a number of perforators extending from the aneurysm and the diameter of each aperture 130 and/or number of apertures 130 per vascular device 100. For example, based on the diameter of each aperture 130 and the number of perforators extending from the aneurysm sac and/or from the parent vessel 300, the vascular device 100 may be selected such that the apertures 130 in fluid communication with the sac (and/or with other relevant vessel location(s)) are sufficiently large to provide sufficient blood flow to each of the perforators when the vascular device 100 is in the second, expanded configuration. The blood flow permitted by the apertures 130 to the perforators is sufficient to provide blood to downstream tissues without inducing ischemia.

[0038] In another example, based on the number of apertures 130 in the vascular device 100 and the number of perforators extending from the aneurysm sac and/or from the parent vessel 300, the vascular device 100 may be selected such that there are a sufficient number of apertures 130 in fluid communication with the sac (and/or with other relevant vessel location(s)) to provide sufficient blood flow to each of the perforators when the vascular device 100 is in the

second, expanded configuration. In these applications, sufficient blood flow is provided for the perforators extending from the aneurysm sac and/or parent vessel 300 to avoid or limit ischemia to downstream tissue, but the blood flow within the aneurysm is disrupted sufficiently to permit healing of the aneurysm.

[0039] Referring to FIG. 2, the delivery system 200 is advanced percutaneously over the guide wire 230, in this example, to the site of the aneurysm 310 having a perforator vessel 320 extending therefrom.

[0040] Referring to FIG. 3, after navigating the system 200 to the treatment site within the patient, the outer sheath 210 is withdrawn proximally while maintaining the position of the shaft 220 to thereby expose a distal portion of the shaft 220 and the vascular device 100. The outer sheath 210 is withdrawn until a distal end of the outer sheath 210 is proximal of the vascular device 100. As the outer sheath 210 is withdrawn, the vascular device 100 expands. During expansion, the apertures 130 may begin to take form due to the shape memory properties of the strands 112.

[0041] Referring to FIGS. 4 and 5, the delivery system 200 may be adjusted or withdrawn proximally during deployment, until the radiopaque marker 250 and hence the apertures 130 are centered along the length of the ostium or neck of the aneurysm 310 and/or located on either side of the ostium, as appropriate. In other words, the longitudinal center region of the vascular device 100, the region having the apertures 130, is aligned with the aneurysm 310 to thereby provide blood flow into the perforator 320 through one of the apertures 130. In one aspect, the longitudinal center region of the vascular device 100 is centered along the length of the ostium so that at least one aperture 130 provides blood flow to the perforator 320 when the vascular device 110 is in the second, expanded configuration.

[0042] In one aspect, during deployment, the position of the vascular device 100 within the vessel 300 may be further modified, if after initial partial deployment of the vascular device 100, the vascular device is positioned incorrectly or otherwise has to be relocated to properly cover the treatment site. For example, the outer sheath 210 may be advanced distally, thereby encapsulating or compressing the vascular device 100 within the outer sheath 210 and allowing the system 200 to be repositioned. Accordingly, the vascular device 100 may be partially deployed, resheathed, and relocated multiple times in order to ensure that the vascular device is properly deployed in the correct location.

[0043] In another aspect, because of the woven or braided structure of the vascular device 100, the strands of the vascular device 100 can also move relative to each other, further allowing the vascular device 100 to flex and thereby permit advancement or rotation of the unexpanded portion of the vascular device 100 against an expanded portion of the vascular device 100 that is deployed within the vessel 300. Accordingly, through rotation or positioning of the unexpanded portion relative to the expanded portion of the vascular device 100, the apertures 130 of the vascular device 100 may be properly aligned and positioned at the treatment site.

[0044] Referring to FIG. 6, once the entire vascular device 100 is fully expanded, the catheter, along with the outer sheath 210, shaft 220, and guide wire 230 may be withdrawn from the patient.

[0045] Initially, blood may flow to the perforator vessel 320 from the plurality of pores 120 and apertures 130. As the inner surface of the vascular device 100 becomes endothelialized, the pores 120 will become occluded thereby preventing blood from flowing therethrough. The blood, however, will continue to flow through the apertures 130, thereby providing sufficient blood flow to the perforator 320.

[0046] In one arrangement, the vascular device 100 may be comprised of metal, polymer, ceramic, permanent enduring materials, and may comprise either or both of non-bioabsorbable and bioabsorbable materials. Exemplary materials include, but are not limited to, NITINOL®, stainless steel, cobalt chromium alloys, Elgiloy, magnesium alloys, polylactic acid, poly glycolic acid, poly ester amide (PEA), poly ester urethane (PEU), amino acid based bioanalogous polymers, tungsten, tantalum, platinum, polymers, bio-polymers, ceramics, bio-ceramics, or metallic glasses. Part or all of the medical device may elute over time substances such as drugs, biologics, therapies, antithrombotics, coagulants, anti-inflammatory gene drugs, anti-proliferatives, migration inhibitors, extracellular matrix immunomodulator modulators, healing promoters, re-endothelialization promoters, or other materials. In some embodiments, the vascular device 100 may be formed from materials having shape memory properties. In some embodiments, the vascular device 100 may be finished by processes to remove slag. In some embodiments, the vascular device 100 may be subjected to a tempering treatment at temperatures customarily applied to the material so that the impressed structure is permanently established.

[0047] The vascular device 100 may have various lengths and diameters. For example, the vascular device 100 may have specific cross-sectional diameters, the diameters being measured

when the vascular device 110 is fully free to expand, ranging from about 2 mm to about 6 mm. If the vascular device 110 has a diameter between about 3 mm and about 4 mm, it may be used in a size 18 microcatheters (i.e., microcatheters with an inner diameter of approximately 0.21 inch). If the vascular device 100 has a diameter between about 5 mm and about 6 mm, it may be used in a size 27 microcatheters (i.e., microcatheters with an inner diameter of approximately 0.027 inch). However, other suitable cross-sectional diameters may be used without deviating from the scope of the subject technology. In some embodiments, the vascular device 100 may have lengths, measured proximally to distally along the longitudinal axis of the vascular device 100, ranging from about 15 mm to about 40 mm, though other ranges and sizes are also possible.

[0048] The detailed description set forth above is intended as a description of various configurations of the subject technology and is not intended to represent the only configurations in which the subject technology may be practiced. The appended drawings are incorporated herein and constitute a part of the detailed description. The detailed description includes specific details for the purpose of providing a thorough understanding of the subject technology. However, it will be apparent to those skilled in the art that the subject technology may be practiced without these specific details. In some instances, well-known structures and components are shown in block diagram form in order to avoid obscuring the concepts of the subject technology.

[0049] Skilled artisans may implement the described functionality in varying ways for each particular application. Various components and blocks may be arranged differently (for example, arranged in a different order, or partitioned in a different way) all without departing from the scope of the subject technology. It is understood that the specific order or hierarchy of steps in the processes disclosed is an illustration of exemplary approaches. Based upon design preferences, it is understood that the specific order or hierarchy of steps in the processes may be rearranged. Some of the steps may be performed simultaneously. The accompanying method claims present elements of the various steps in a sample order, and are not meant to be limited to the specific order or hierarchy presented.

[0050] The previous description is provided to enable any person skilled in the art to practice the various aspects described herein. The previous description provides various examples of the subject technology, and the subject technology is not limited to these examples. Various modifications to these aspects will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other aspects. Thus, the claims are not

intended to be limited to the aspects shown herein, but is to be accorded the full scope consistent with the language claims, wherein reference to an element in the singular is not intended to mean "one and only one" unless specifically so stated, but rather "one or more." Unless specifically stated otherwise, the term "some" refers to one or more. Pronouns in the masculine (for example, his) include the feminine and neuter gender (for example, her and its) and vice versa. Headings and subheadings, if any, are used for convenience only and do not limit the invention.

[0051] A phrase such as an "aspect" does not imply that such aspect is essential to the subject technology or that such aspect applies to all configurations of the subject technology. A disclosure relating to an aspect may apply to all configurations, or one or more configurations. An aspect may provide one or more examples. A phrase such as an aspect may refer to one or more aspects and vice versa. A phrase such as an "aspect" does not imply that such aspect is essential to the subject technology or that such aspect applies to all configurations of the subject technology. A disclosure relating to an aspect may apply to all aspects, or one or more aspects. An aspect may provide one or more examples. A phrase such as an "aspect" may refer to one or more aspects and vice versa. A phrase such as a "configuration" does not imply that such configuration is essential to the subject technology or that such configuration applies to all configurations of the subject technology. A disclosure relating to a configuration may apply to all configurations, or one or more configurations. A configuration may provide one or more examples. A phrase such as a "configuration" may refer to one or more configurations and vice versa.

[0052] The word "exemplary" is used herein to mean "serving as an example or illustration." Any aspect or design described herein as "exemplary" is not necessarily to be construed as preferred or advantageous over other aspects or designs.

[0053] All structural and functional equivalents to the elements of the various aspects described throughout this disclosure that are known or later come to be known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the claims. Moreover, nothing disclosed herein is intended to be dedicated to the public regardless of whether such disclosure is explicitly recited in the claims. No claim element is to be construed under the provisions of 35 U.S.C. §112, sixth paragraph, unless the element is expressly recited using the phrase "means for" or, in the case of a method claim, the element is recited using the phrase "step for." Furthermore, to the extent that the term "include," "have," or the like is used in the description or the claims, such term is intended to be inclusive

in a manner similar to the term "comprise" as "comprise" is interpreted when employed as a transitional word in a claim.

CLAIMS

WHAT IS CLAIMED IS:

1. A vascular device, comprising:

a body having a first, collapsed configuration and a second, expanded configuration, the body comprised of a plurality of heat-set strands;

wherein the strands are braided such that when the body is in the second configuration, the strands form a plurality of pores and a plurality of apertures between the strands;

wherein the apertures are disposed at a longitudinal center region of the body;

wherein, when the body is in the second configuration, the pores at proximal and distal portions of the body are generally uniform in size and smaller in size than the apertures; and

wherein the pores and the apertures are substantially the same size when the body is in the first configuration.

- 2. The vascular device of claim 1, wherein the apertures are formed by displacement of adjacent strands.
- 3. The vascular device of claim 1, wherein the plurality of apertures comprises two apertures.
- 4. The vascular device of claim 2, wherein the apertures are equally spaced and radially arranged around a longitudinal axis of the body.
- 5. The vascular device of claim 2, wherein a center region of each of the apertures is disposed along a single radial cross section of the body.
- 6. The vascular device of claim 1, wherein the plurality of apertures comprises three apertures.
- 7. The vascular device of claim 6, wherein the apertures are equally spaced and radially arranged around a longitudinal axis of the body.

8. The vascular device of claim 6, wherein a center region of each of the apertures is disposed along a single radial cross section of the body.

- 9. The vascular device of claim 1, wherein the plurality of apertures comprises four apertures.
- 10. The vascular device of claim 9, wherein the apertures are equally spaced and radially arranged around a longitudinal axis of the body.
- 11. The vascular device of claim 9, wherein a center region of each of the apertures is disposed along a single radial cross section of the body.
- 12. The vascular device of claim 1, wherein a number of strands in each of a proximal, center, and distal radial cross sections of the body is the same.
- 13. The vascular device of claim 1, wherein the body has a hoop strength that is generally uniform along the body's longitudinal length.
- 14. The vascular device of claim 1, wherein an area of at least one of the apertures is about 0.005 square millimeters or larger.
- 15. The vascular device of claim 1, wherein an area of at least one of the pores is about 0.01 square millimeters or smaller.
 - 16. The vascular device of claim 1, wherein the apertures are larger than the pores.
- 17. The vascular device of claim 1, wherein a thickness of each strand is about 0.0010 to 0.0014 inches.
 - 18. A method, for creating a plurality of apertures in a vascular device, comprising:

 braiding a plurality of shape-memory strands to form the vascular device,
 wherein the strands are braided to form a plurality of pores between the strands,
 wherein the pores at proximal and distal portions of the device are generally
 uniform in size;

forming each of the apertures by displacing strands disposed at a longitudinal center region of the device with a tapered mandrel, wherein each aperture is larger than a pore; and

applying heat to the displaced strands to thereby set a shape of the displaced strands.

- 19. The method of claim 18, wherein the plurality of apertures comprises two apertures.
- 20. The method of claim 18, wherein the plurality of apertures comprises three apertures.
- 21. The method of claim 18, wherein the plurality of apertures comprises four apertures.
- 22. The method of claim 18, wherein the apertures are equally spaced and radially arranged around a longitudinal axis of the vascular device.
- 23. The method of claim 18, wherein a center region of each of the apertures is disposed along a single radial cross section of the vascular device.
- 24. The method of claim 18, wherein a number of strands in each of a proximal, center, and distal radial cross sections of the vascular device is the same.
- 25. The method of claim 18, wherein the vascular device has a hoop strength that is generally uniform along the device's longitudinal length.
 - 26. The method of claim 18, wherein the apertures are larger than the pores.
- 27. A method for providing blood flow into a perforator vessel extending from a sac of an aneurysm, the method comprising:

positioning a vascular device in a vessel at an opening into the aneurysm, wherein the device has a first, collapsed configuration and a second, expanded configuration, the device comprising:

a plurality of heat-set strands, wherein the strands are braided such that when the device is in the second configuration, the strands form a plurality of pores and a plurality of apertures between the strands;

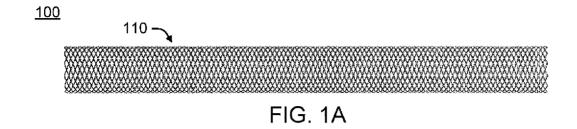
wherein the apertures are disposed at a longitudinal center region of the device;

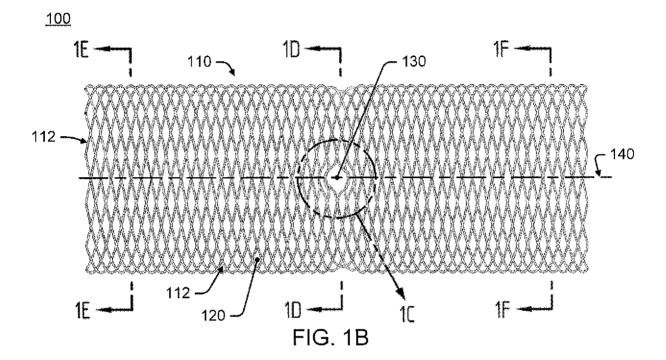
wherein, when the device is in the second configuration, the pores at proximal and distal portions of the device are generally uniform in size and smaller in size than the apertures; and

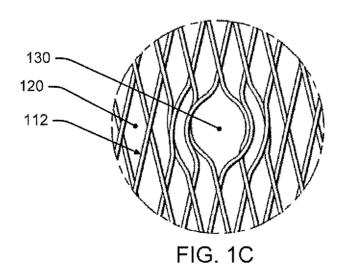
wherein the pores and the apertures are substantially the same size when the device is in the first configuration; and

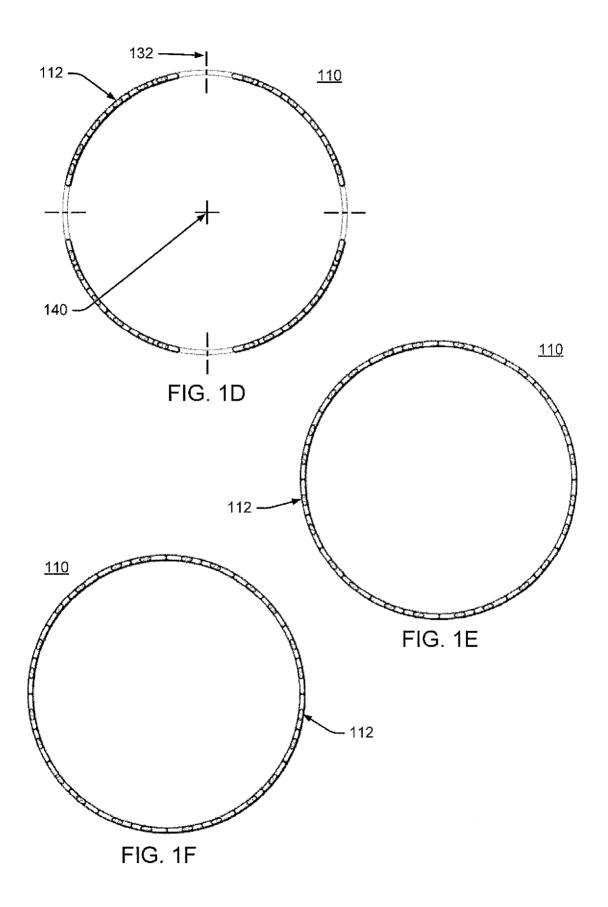
aligning the longitudinal center region of the device with the aneurysm to thereby provide blood flow into the perforator through one of the apertures.

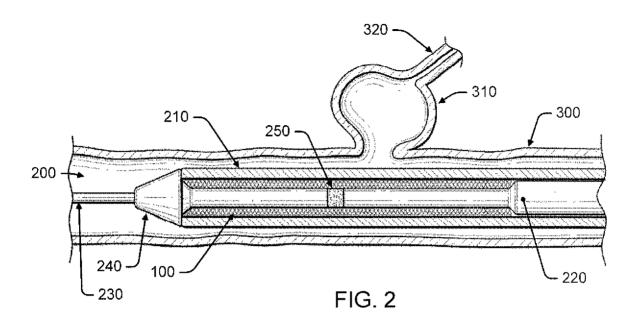
- 28. The method of claim 27, wherein the plurality of apertures comprises two apertures.
- 29. The method of claim 27, wherein the plurality of apertures comprises three apertures.
- 30. The method of claim 27, wherein the plurality of apertures comprises four apertures.
- 31. The method of claim 27, wherein the apertures are equally spaced and radially arranged around a longitudinal axis of the vascular device.
- 32. The method of claim 27, wherein a center region of each of the apertures is disposed along a single radial cross section of the vascular device.
- 33. The method of claim 27, wherein a number of strands in each of a proximal, center, and distal radial cross sections of the vascular device are the same.
- 34. The method of claim 27, wherein the vascular device has a hoop strength that is generally uniform along the device's longitudinal length.
 - 35. The method of claim 27, wherein the apertures are larger than the pores.

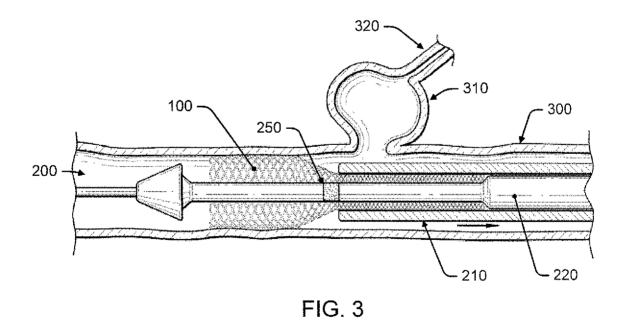












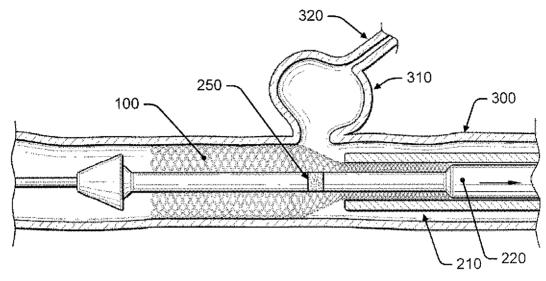
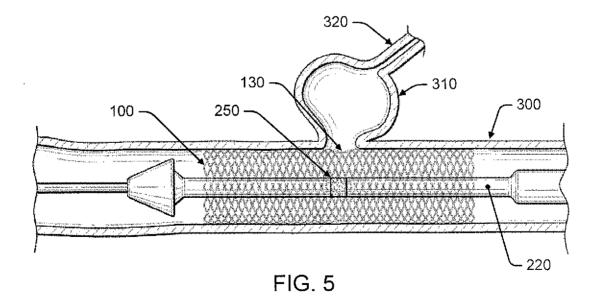


FIG. 4



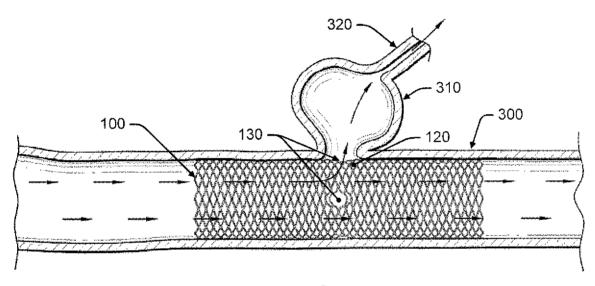


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No PCT/US2014/011198

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/12 A61F2/856 A61F2/90
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 A61F

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 rel	Relevant to claim No.	
X	US 2012/290067 A1 (CAM ANH [US] 15 November 2012 (2012-11-15) paragraph [0035] - paragraph [00 paragraph [0123] - paragraph [01 figures 2A-5	1-4,6,7, 9,10, 12-22, 24-26	
A	WO 2008/005898 A2 (EV3 ENDOVASCU [US]; KUSLEIKA RICH [US]; KRAVIK [US]) 10 January 2008 (2008-01-1 paragraph [0106]; figure 8	RICH	1-26
X Furt	her documents are listed in the continuation of Box C.	X 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	Date of mailing of the international sea	rch report
1	1 April 2014	24/04/2014	

Authorized officer

Roudaut, Tanguy

Name and mailing address of the ISA/

NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

European Patent Office, P.B. 5818 Patentlaan 2

International application No.

INTERNATIONAL SEARCH REPORT

PCT/US2014/011 198

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A vascular device (100) includes a body (110) having a first, collapsed configuration and a second, expanded configuration. The body includes a plurality of heat-set strands (112) that are braided such that when the body is in the second configuration, the strands form a plurality of pores (120) and one or more apertures (130) between the strands. The apertures are generally disposed at a longitudinal center region of the body. When the body is in the second configuration, the pores at proximal and distal portions of the body are generally uniform in size and smaller in size than the apertures. The pores and the apertures are substantially the same size when the body is in the first configuration.

International application No. PCT/US2014/011198

INTERNATIONAL SEARCH REPORT

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. X Claims Nos.: 27-35 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 Nos.: 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:				
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:				
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.				

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/011198

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT						
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.				
A	WO 2006/034140 A2 (CORDIS DEV CORP [US]; FELLER III FREDERICK [US]; JONES DONALD K [US];) 30 March 2006 (2006-03-30) paragraphs [0008], [0014], [0017] paragraph [0029] - paragraph [0040]; figures 1-4	1-26				
A	US 2010/318174 A1 (SHAOLIAN SAMUEL M [US] ET AL) 16 December 2010 (2010-12-16) paragraph [0114] - paragraph [0116]; figure 16	1-26				
A	WO 98/47447 A1 (DUBRUL WILLIAM R [US]) 29 October 1998 (1998-10-29) page 8, line 18 - page 14, line 11; figures 4A-5C	1-26				
A	US 2007/208415 A1 (GROTHEIM KEVIN [US] ET AL) 6 September 2007 (2007-09-06) paragraph [0034] - paragraph [0047]; figures 1A-4	1-26				

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/011198

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012290067 A1	15-11-2012	AU 2012253583 A1 CN 103547222 A EP 2706926 A1 US 2012290067 A1 WO 2012154782 A1	02-05-2013 29-01-2014 19-03-2014 15-11-2012 15-11-2012
WO 2008005898 A2	10-01-2008	EP 2035055 A2 EP 2460543 A1 EP 2460544 A1 US 2008125848 A1 US 2012022634 A1 WO 2008005898 A2	18-03-2009 06-06-2012 06-06-2012 29-05-2008 26-01-2012 10-01-2008
WO 2006034140 A2	30-03-2006	CA 2580612 A1 EP 1788978 A2 JP 2008513140 A US 2008195136 A1 WO 2006034140 A2	30-03-2006 30-05-2007 01-05-2008 14-08-2008 30-03-2006
US 2010318174 A1	16-12-2010	US 2010318174 A1 US 2010318181 A1	16-12-2010 16-12-2010
WO 9847447 A1	29-10-1998	EP 1011532 A1 JP 4083241 B2 JP 2002510220 A US 6258115 B1 WO 9847447 A1	28-06-2000 30-04-2008 02-04-2002 10-07-2001 29-10-1998
US 2007208415 A1	06-09-2007	CA 2640092 A1 EP 1991178 A1 JP 2009528884 A US 2007208415 A1 WO 2007102958 A1	13-09-2007 19-11-2008 13-08-2009 06-09-2007 13-09-2007