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(54) **SYSTEMS AND METHODS FOR EMBOLIZATION OF BODY STRUCTURES**

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(52) **U.S. Cl.**
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(57) **ABSTRACT**

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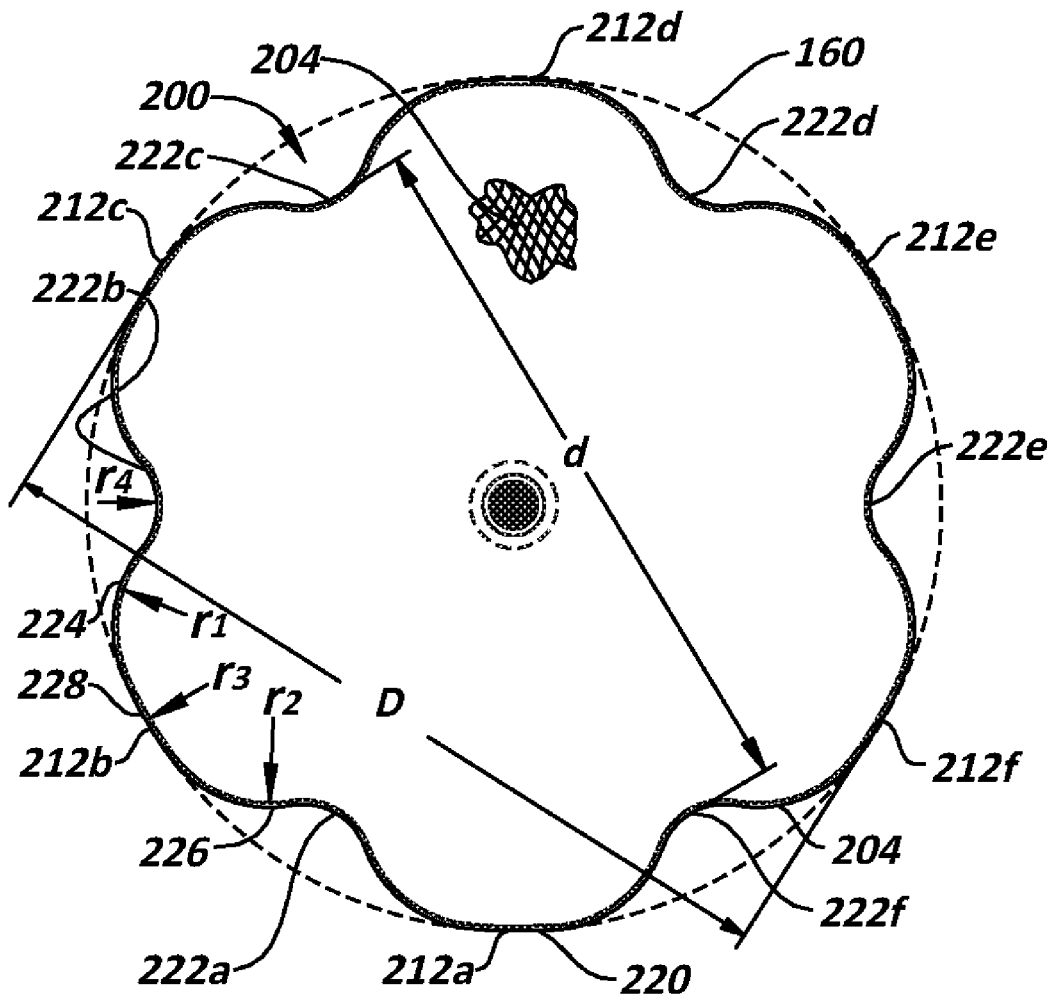
A device for treatment of a vascular defect within a patient's vasculature includes a self-expanding permeable shell having a proximal end, a distal end, and a longitudinal axis, the shell comprising a plurality of elongate resilient filaments having a braided structure, wherein the filaments are secured at at least one of the proximal end or the distal end of the permeable shell, wherein the permeable shell has a radially constrained elongated state configured for delivery within a microcatheter and has an expanded state with an axially shortened configuration relative to the radially constrained state, the permeable shell having a plurality of openings formed between the braided filaments, wherein the permeable shell in its expanded state comprises a plurality of circumferentially-arrayed lobes.

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Related U.S. Application Data

(63) Continuation of application No. 17/110,212, filed on Dec. 2, 2020, now Pat. No. 11,806,020, which is a continuation of application No. 15/923,266, filed on Mar. 16, 2018, now Pat. No. 10,881,413.

(60) Provisional application No. 62/476,104, filed on Mar. 24, 2017.



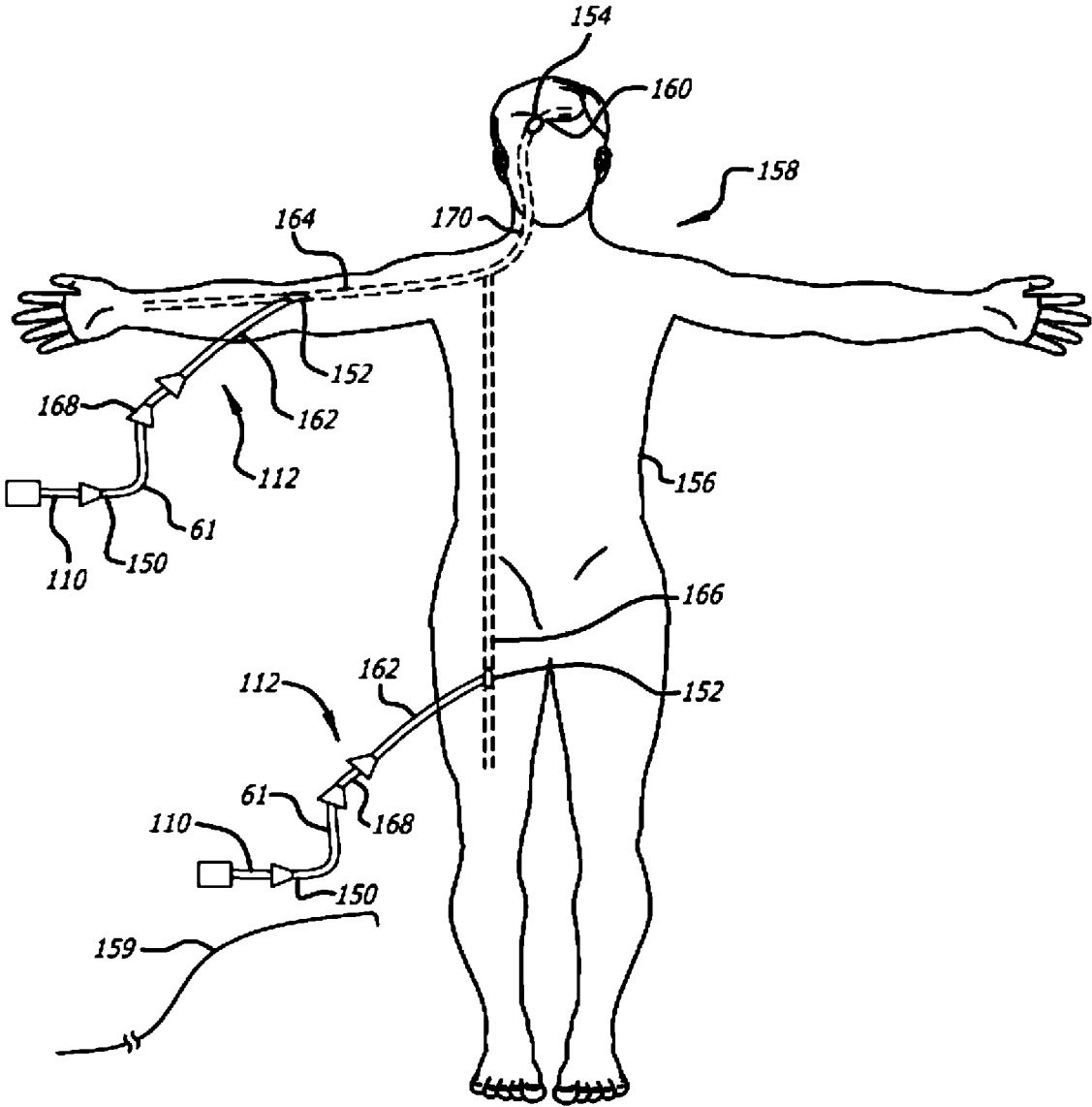


FIG. 1

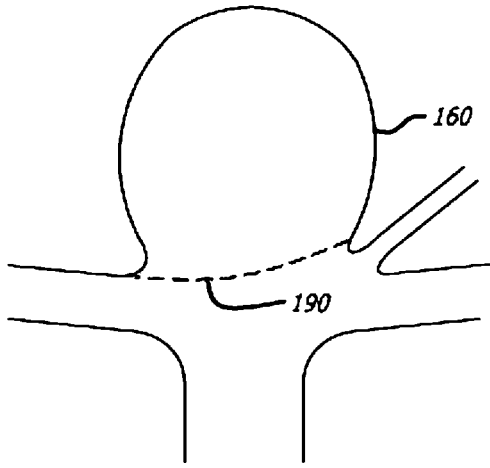


FIG. 2

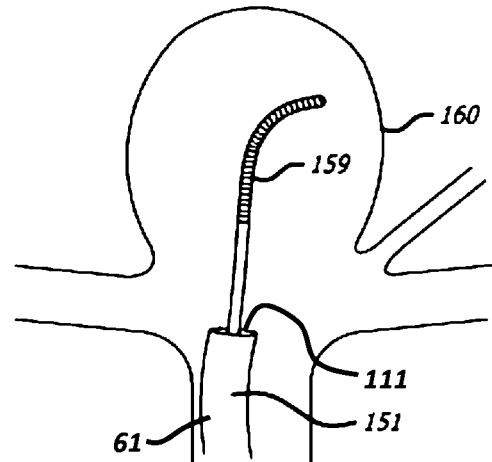


FIG. 3

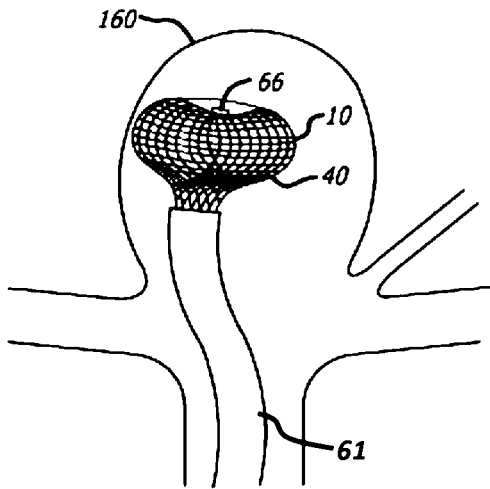


FIG. 4

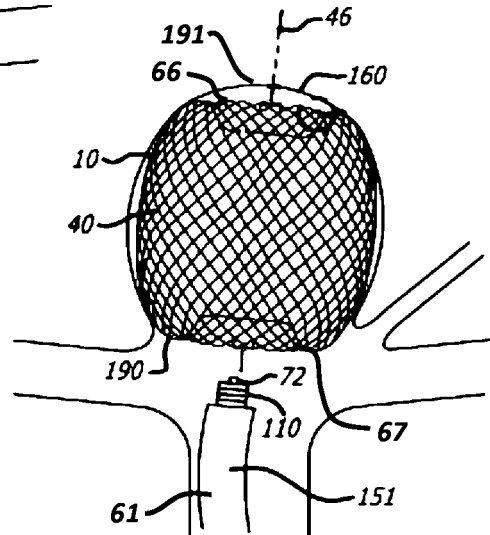


FIG. 5

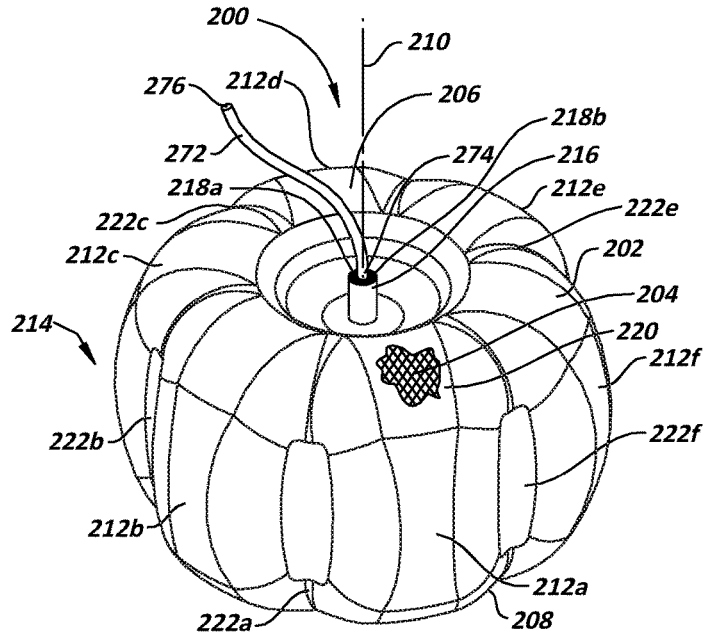


FIG. 6

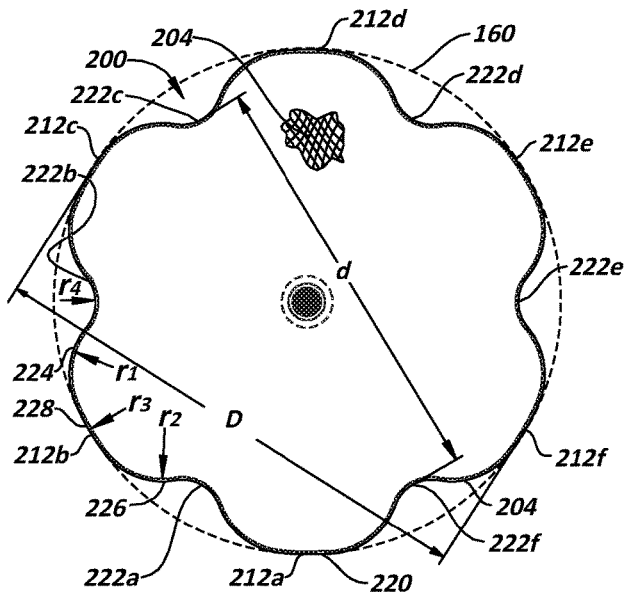


FIG. 7

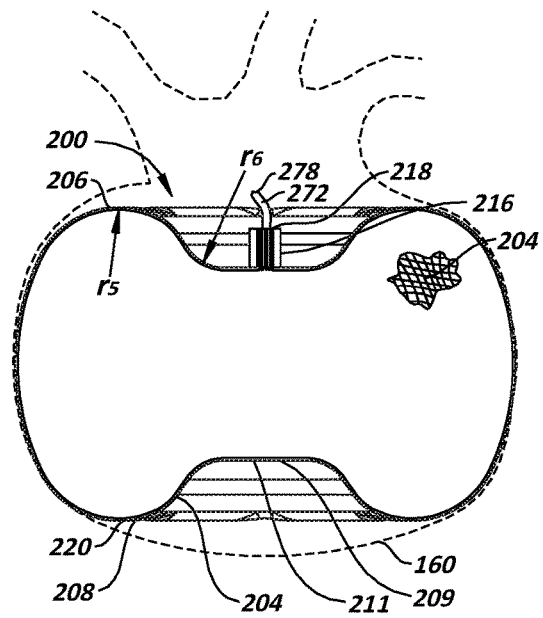


FIG. 8

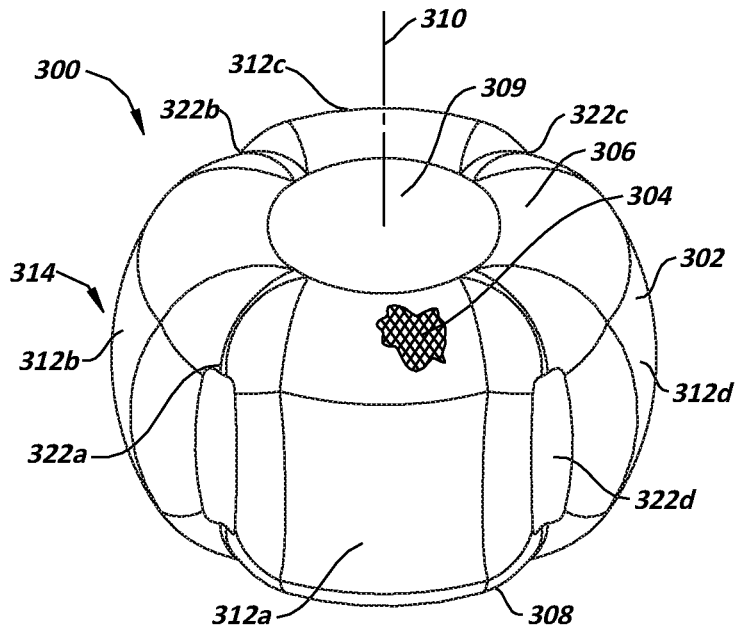


FIG. 9

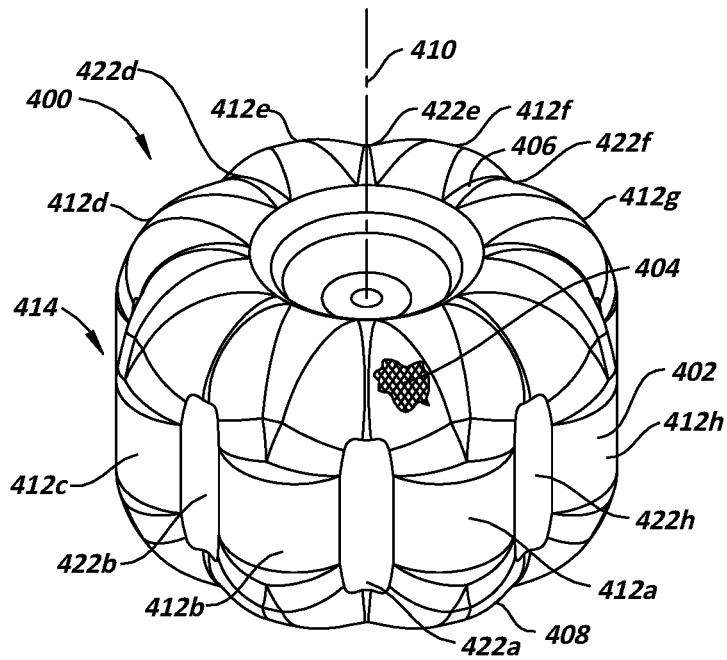


FIG. 10

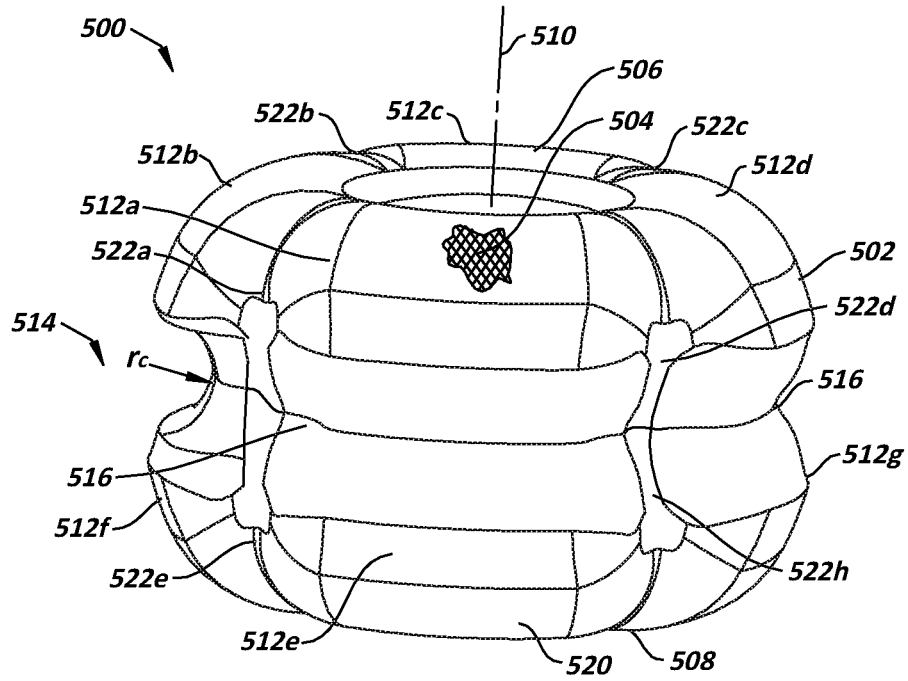


FIG. 11

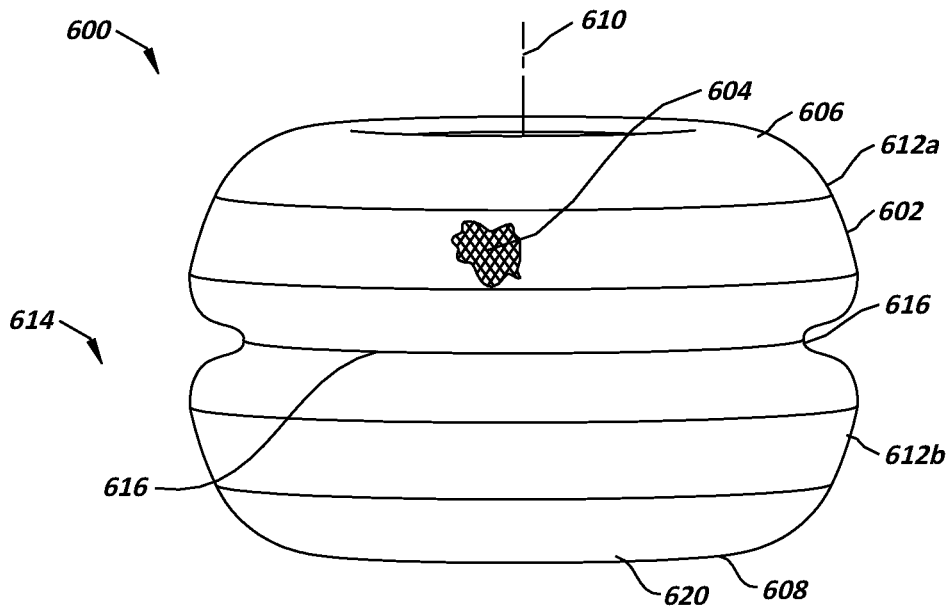


FIG. 12

SYSTEMS AND METHODS FOR EMBOLIZATION OF BODY STRUCTURES

RELATED APPLICATIONS

[0001] This application is a continuation of and claims priority to patent application Ser. No. 17/110,212 filed Dec. 2, 2020 entitled Systems And Methods For Embolization Of Body Structures, which is a continuation of and claims priority to patent application Ser. No. 15/923,266, filed Mar. 16, 2018, entitled Systems And Methods For Embolization Of Body Structures (now U.S. Pat. No. 10,881,413), which claims benefit of and priority to U.S. Provisional Application Ser. No. 62/476,104 filed Mar. 24, 2017 entitled Systems And Methods For Embolization Of Body Structures, all of which are hereby incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

[0002] Embodiments of devices and methods herein are directed to blocking a flow of fluid through a tubular vessel or into a small interior chamber of a saccular cavity or vascular defect within a mammalian body. More specifically, embodiments herein are directed to devices and methods for treatment of a vascular defect of a patient including some embodiments directed specifically to the treatment of cerebral aneurysms of patients.

BACKGROUND

[0003] The mammalian circulatory system is comprised of a heart, which acts as a pump, and a system of blood vessels that transport the blood to various points in the body. Due to the force exerted by the flowing blood on the blood vessel the blood vessels may develop a variety of vascular defects. One common vascular defect known as an aneurysm results from the abnormal widening of the blood vessel. Typically, vascular aneurysms are formed as a result of the weakening of the wall of a blood vessel and subsequent ballooning and expansion of the vessel wall. If, for example, an aneurysm is present within an artery of the brain, and the aneurysm should burst with resulting cranial hemorrhaging, death could occur.

[0004] Surgical techniques for the treatment of cerebral aneurysms typically involve a craniotomy requiring creation of an opening in the skull of the patient through which the surgeon can insert instruments to operate directly on the patient's brain. For some surgical approaches, the brain must be retracted to expose the parent blood vessel from which the aneurysm arises. Once access to the aneurysm is gained, the surgeon places a clip across the neck of the aneurysm thereby preventing arterial blood from entering the aneurysm. Upon correct placement of the clip the aneurysm will be obliterated in a matter of minutes. Surgical techniques may be effective treatment for many aneurysms. Unfortunately, surgical techniques for treating these types of conditions include major invasive surgical procedures that often require extended periods of time under anesthesia involving high risk to the patient. Such procedures thus require that the patient be in generally good physical condition in order to be a candidate for such procedures.

[0005] Various alternative and less invasive procedures have been used to treat cerebral aneurysms without resorting to major surgery. Some such procedures involve the delivery of embolic or filling materials into an aneurysm. The deliv-

ery of such vaso-occlusion devices or materials may be used to promote hemostasis or fill an aneurysm cavity entirely. Vaso-occlusion devices may be placed within the vasculature of the human body, typically via a catheter, either to block the flow of blood through a vessel with an aneurysm through the formation of an embolus or to form such an embolus within an aneurysm stemming from the vessel. A variety of implantable, coil-type vaso-occlusion devices are known. The coils of such devices may themselves be formed into a secondary coil shape, or any of a variety of more complex secondary shapes. Vaso-occlusive coils are commonly used to treat cerebral aneurysms but suffer from several limitations including poor packing density, compaction due to hydrodynamic pressure from blood flow, poor stability in wide-necked aneurysms and complexity and difficulty in the deployment thereof as most aneurysm treatments with this approach require the deployment of multiple coils.

[0006] Another approach to treating aneurysms without the need for invasive surgery involves the placement of sleeves or stents into the vessel and across the region where the aneurysm occurs. Such devices maintain blood flow through the vessel while reducing blood pressure applied to the interior of the aneurysm. Certain types of stents are expanded to the proper size by inflating a balloon catheter, referred to as balloon expandable stents, while other stents are designed to elastically expand in a self-expanding manner. Some stents are covered typically with a sleeve of polymeric material called a graft to form a stent-graft. Stents and stent-grafts are generally delivered to a preselected position adjacent a vascular defect through a delivery catheter. In the treatment of cerebral aneurysms, covered stents or stent-grafts have seen very limited use due to the likelihood of inadvertent occlusion of small perforator vessels that may be near the vascular defect being treated.

[0007] In addition, current uncovered stents are generally not sufficient as a stand-alone treatment. In order for stents to fit through the microcatheters used in small cerebral blood vessels, their density is usually reduced such that when expanded there is only a small amount of stent structure bridging the aneurysm neck. Thus, they do not block enough flow to cause clotting of the blood in the aneurysm and are thus generally used in combination with vaso-occlusive devices, such as the coils discussed above, to achieve aneurysm occlusion.

[0008] A number of aneurysm neck bridging devices with defect spanning portions or regions have been attempted; however, none of these devices has had a significant measure of clinical success or usage. A major limitation in their adoption and clinical usefulness is the inability to position the defect spanning portion to assure coverage of the neck. Existing stent delivery systems that are neurovascular compatible (i.e., deliverable through a microcatheter and highly flexible) do not have the necessary rotational positioning capability. Another limitation of many aneurysm bridging devices described in the prior art is the poor flexibility. Cerebral blood vessels are tortuous and a high degree of flexibility is required for effective delivery to most aneurysm locations in the brain.

[0009] Recently, devices and methods have been developed for delivery and use in small and tortuous blood vessels that can substantially block the flow of blood into an aneurysm, such as a cerebral aneurysm. In some cases, these devices achieve short term results, but may be prone to

compression or other changes in shape or orientation, which may result in recanalization of the aneurysm. New methods and devices are desired which are suitable for blocking blood flow in cerebral aneurysms over an extended period of time without a significant risk of deformation, compaction or dislocation.

SUMMARY OF THE INVENTION

[0010] In an embodiment of the present disclosure, a device for treatment of a vascular defect within a patient's vasculature includes a self-expanding permeable shell having a proximal end, a distal end, and a longitudinal axis, the shell comprising a plurality of elongate resilient filaments having a braided structure, wherein the filaments are secured at at least one of the proximal end or the distal end of the permeable shell, wherein the permeable shell has a radially constrained elongated state configured for delivery within a microcatheter and has an expanded state with an axially shortened configuration relative to the radially constrained state, the permeable shell having a plurality of openings formed between the braided filaments, wherein the permeable shell in its expanded state comprises a plurality of circumferentially-arrayed lobes.

[0011] In another embodiment of the present disclosure, a device for treatment of a vascular defect within a patient's vasculature includes a self-expanding permeable shell having a proximal end, a distal end, and a longitudinal axis, the shell comprising a plurality of elongate resilient filaments having a braided structure, wherein the filaments are secured at at least one of the proximal end or the distal end of the permeable shell, wherein the permeable shell has a radially constrained elongated state configured for delivery within a microcatheter and has an expanded state with an axially shortened configuration relative to the radially constrained state, the permeable shell having a plurality of openings formed between the braided filaments, wherein the permeable shell in its expanded state comprises at least one recess extending circumferentially around at least a portion of a perimeter of the permeable shell.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 is a schematic view of a patient being accessed by an introducer sheath, a microcatheter and a device for treatment of a patient's vasculature releasably secured to a distal end of a delivery device or actuator.

[0013] FIG. 2 shows a deployment sequence of a device for treatment of a patient's vasculature.

[0014] FIG. 3 shows a deployment sequence of a device for treatment of a patient's vasculature.

[0015] FIG. 4 shows a deployment sequence of a device for treatment of a patient's vasculature.

[0016] FIG. 5 shows a deployment sequence of a device for treatment of a patient's vasculature.

[0017] FIG. 6 is a perspective view of a device for treatment of vascular deformities according to an embodiment of the present disclosure.

[0018] FIG. 7 is a first cross-sectional view of the device of FIG. 6 deployed within an aneurysm.

[0019] FIG. 8 is a second cross-sectional view of the device of FIG. 6 deployed within an aneurysm.

[0020] FIG. 9 is a perspective view of a device for treatment of vascular deformities according to an embodiment of the present disclosure.

[0021] FIG. 10 is a perspective view of a device for treatment of vascular deformities according to an embodiment of the present disclosure.

[0022] FIG. 11 is a perspective view of a device for treatment of vascular deformities according to an embodiment of the present disclosure.

[0023] FIG. 12 is a perspective view of a device for treatment of vascular deformities according to an embodiment of the present disclosure.

DETAILED DESCRIPTION

[0024] Discussed herein are devices and methods for the treatment of vascular defects that are suitable for minimally invasive deployment within a patient's vasculature, and particularly, within the cerebral vasculature of a patient. For such embodiments to be safely and effectively delivered to a desired treatment site and effectively deployed, some device embodiments may be configured for collapse to a low profile constrained state with a transverse dimension suitable for delivery through an inner lumen of a microcatheter and deployment from a distal end thereof. Embodiments of these devices may also maintain a clinically effective configuration with sufficient mechanical integrity once deployed so as to withstand dynamic forces within a patient's vasculature over time that may otherwise result in compaction of a deployed device. Unless otherwise stated, one or more of the features, dimensions, or materials of the various embodiments may be used in other similar embodiments discussed herein.

[0025] Some embodiments are particularly useful for the treatment of cerebral aneurysms by reconstructing a vascular wall so as to wholly or partially isolate a vascular defect from a patient's blood flow. Some embodiments may be configured to be deployed within a vascular defect to facilitate reconstruction, bridging of a vessel wall or both in order to treat the vascular defect. For some of these embodiments, a permeable shell of the device may be configured to anchor or fix the permeable shell in a clinically beneficial position. For some embodiments, the device may be disposed in whole or in part within the vascular defect in order to anchor or fix the device with respect to the vascular structure or defect. The permeable shell may be configured to span an opening, neck or other portion of a vascular defect in order to isolate the vascular defect, or a portion thereof, from the patient's nominal vascular system in order allow the defect to heal or to otherwise minimize the risk of the defect to the patient's health.

[0026] For some or all of the embodiments of devices for treatment of a patient's vasculature discussed herein, the permeable shell may be configured to allow some initial perfusion of blood through the permeable shell. The porosity of the permeable shell may be configured to sufficiently isolate the vascular defect so as to promote healing and isolation of the defect, but allow sufficient initial flow through the permeable shell so as to reduce or otherwise minimize the mechanical force exerted on the membrane the dynamic flow of blood or other fluids within the vasculature against the device. For some embodiments of devices for treatment of a patient's vasculature, only a portion of the permeable shell that spans the opening or neck of the vascular defect, sometimes referred to as a defect spanning portion, need be permeable and/or conducive to thrombus formation in a patient's bloodstream. For such embodiments, that portion of the device that does not span an

opening or neck of the vascular defect may be substantially non-permeable or completely permeable with a pore or opening configuration that is too large to effectively promote thrombus formation.

[0027] In general, it may be desirable in some cases to use a hollow, thin walled device with a permeable shell of resilient material that may be constrained to a low profile for delivery within a patient. Such a device may also be configured to expand radially outward upon removal of the constraint such that the shell of the device assumes a larger volume and fills or otherwise occludes a vascular defect within which it is deployed. The outward radial expansion of the shell may serve to engage some or all of an inner surface of the vascular defect whereby mechanical friction between an outer surface of the permeable shell of the device and the inside surface of the vascular defect effectively anchors the device within the vascular defect. Some embodiments of such a device may also be partially or wholly mechanically captured within a cavity of a vascular defect, particularly where the defect has a narrow neck portion with a larger interior volume. In order to achieve a low profile and volume for delivery and be capable of a high ratio of expansion by volume, some device embodiments include a matrix of woven or braided filaments that are coupled together by the interwoven structure so as to form a self-expanding permeable shell having a pore or opening pattern between couplings or intersections of the filaments that is substantially regularly spaced and stable, while still allowing for conformity and volumetric constraint.

[0028] As used herein, the terms woven and braided are used interchangeably to mean any form of interlacing of filaments to form a mesh structure. In the textile and other industries, these terms may have different or more specific meanings depending on the product or application such as whether an article is made in a sheet or cylindrical form. For purposes of the present disclosure, these terms are used interchangeably.

[0029] Some embodiments for devices and methods for the treatment of vascular defects having permeable shells are described in U.S. Pat. No. 9,078,658, issued Jul. 14, 2015, and titled "Filamentary Devices for Treatment of Vascular Defects," which is incorporated herein by reference in its entirety for all purposes. Further embodiments for devices and methods for the treatment of vascular defects having permeable shells are described in co-owned U.S. Patent Application Publication No. 2016/02409934, published Sep. 1, 2016, and titled "Filamentary Devices for Treatment of Vascular Defects," which is incorporated herein by reference in its entirety for all purposes.

[0030] Embodiments for devices and methods for forming tubular braids to for creating permeable shells such as those described herein are described in U.S. Pat. No. 9,528,205, issued Dec. 27, 2016, and titled "Braiding Mechanism and Methods of Use," which is incorporated herein by reference in its entirety for all purposes. Devices for the treatment of vascular defects having permeable shells may be attached to delivery devices and delivered to vascular defects using embodiments of devices and methods such as those described in U.S. Pat. No. 8,876,855, issued Nov. 4, 2014, and titled "Delivery and Detachment Systems and Methods for Vascular Implants," which is incorporated herein by reference in its entirety for all purposes.

[0031] Embodiments of a delivery apparatus **110** may generally have a length greater than the overall length of a

microcatheter **61** to be used for a delivery system **112**. This relationship allows the delivery apparatus **110** to extend, along with an implantable device secured to the distal end thereof, from the distal port of the inner lumen **111** of the microcatheter **61** (FIG. 3) while having sufficient length extending from a proximal end **150** of the microcatheter **61**, shown in FIG. 1, to enable manipulation thereof by a physician. For some embodiments, the length of the delivery apparatus **110** may be about 170 cm to about 200 cm. A patient **158** is shown in FIG. 1 undergoing treatment of a vascular defect **160**, which may be a cerebral aneurysm. An access sheath **162** is shown disposed within either a radial artery **164** or femoral artery **166** of the body **156** of the patient **158** with the delivery system **112** that includes a microcatheter **61** and delivery apparatus **110** disposed within the access sheath **162**. The delivery system **112** is shown extending distally into the vasculature of the patient's brain adjacent a vascular defect **160** in the patient's brain.

[0032] Access to a variety of blood vessels of a patient may be established, including arteries such as the femoral artery **166**, radial artery **164**, or other blood vessels, in order to achieve percutaneous access to a vascular defect **160**. In general, the access artery may be exposed via a small surgical incision **152** and access to the lumen of the blood vessel is gained using the Seldinger technique where an introducing needle is used to place a wire over which a dilator or series of dilators dilates a vessel allowing an introducer sheath **162** to be inserted into the vessel. This would allow the device to be used percutaneously. With an introducer sheath **162** in place, a guiding catheter **168** is then used to provide a safe passageway from the entry site to a region near the target site **154** to be treated. For example, in treating a site in the human brain, a guiding catheter **168** would be chosen which would extend from the entry site **152** at the femoral artery up through the large arteries extending around the heart through the aortic arch, and downstream through one of the arteries extending from the upper side of the aorta such as the carotid artery **170**. Typically, a guidewire **159** and microcatheter **61** are then placed through the guiding catheter **168** and advanced through the patient's vasculature, until a distal end of the microcatheter **61** is disposed adjacent or within the target vascular defect **160**, such as an aneurysm.

[0033] Once a properly sized device **10** (FIGS. 2-5) has been selected, the delivery and deployment process may then proceed. It should also be noted also that the properties of the device embodiments **10** and delivery system embodiments **112** discussed herein generally allow for retraction of a device **10** after initial deployment into a defect **160**, but before detachment of the device **10**. Therefore, it may also be possible and desirable to withdraw or retrieve an initially deployed device **10** after the fit within the defect **160** has been evaluated in favor of a differently sized device **10**. An example of a terminal aneurysm **160** is shown in FIG. 2 in section. The tip **151** of a catheter, such as a microcatheter **61** may be advanced into or adjacent the vascular site or defect **160** (e.g., aneurysm) as shown in FIG. 3. For some embodiments, an embolic coil or other vaso-occlusive device or material may optionally be placed within the aneurysm **160** to provide a framework for receiving the device **10**. In addition, a stent may be placed within a parent vessel of some aneurysms substantially crossing the aneurysm neck prior to or during delivery of devices for treatment of a patient's vasculature discussed herein.

[0034] Detachment of the device 10 from the delivery apparatus 110 may be controlled by a control switch disposed at a proximal end of the delivery system 112 (FIG. 1), which may also be coupled to an energy source, which severs a tether 72 that secures the device 10 to the delivery apparatus 110. Once the device 10 is pushed out of the distal port of the microcatheter 61, or the radial constraint is otherwise removed, a distal end 66 of the device 10 may then axially move towards a proximal end 67 so as to assume the globular everted configuration within the vascular defect 160 as shown in FIGS. 4-5.

[0035] The device 10 may be inserted through the microcatheter 61 such that the catheter lumen 111 restrains radial expansion of the device 10 during delivery. Once the distal tip or deployment part of the delivery system 112 is positioned in a desirable location adjacent or within a vascular defect 160, the device 10 may be deployed out the distal end of the catheter 61 thus allowing the device to begin to radially expand as shown in FIG. 4. As the device 10 emerges from the distal end of the delivery system 112, the device 10 expands to an expanded state within the vascular defect 160, as shown in FIG. 5, but may be at least partially constrained by an interior surface of the vascular defect 160.

[0036] Upon complete deployment, radial expansion of the device 10 may serve to secure the device 10 within the vascular defect 160 and also deploy the permeable shell 40 across at least a portion of an opening 190 (e.g., aneurysm neck) so as to at least partially isolate the vascular defect 160 from flow, pressure or both of the patient's vasculature adjacent the vascular defect 160 as shown in FIG. 5. The conformability of the device 10, particularly in the neck region 190 may provide for improved sealing. For some embodiments, once deployed, the permeable shell 40 may substantially slow flow of fluids, impede flow into the vascular site, and thus reduce pressure within the vascular defect 160. For some embodiments, the device 10 may be implanted substantially within the vascular defect 160, however, in some embodiments, a portion of the device 10 may extend into the defect opening or neck 190 or into branch vessels. The longitudinal axis 46 of the permeable shell 40 is shown in FIG. 5 extending along a maximum projection of the vascular defect 160 (e.g., from the neck 190 to the dome 191). In other cases, the device 10 may be placed so that the permeable shell 40 has a different orientation in regard to the vascular defect 160, such that the longitudinal axis 46 of the permeable shell extends transversely or obliquely in relation to the neck 190 and dome 191.

[0037] FIG. 6 illustrates device for treatment of a vascular defect 200 comprising a permeable shell 202 which is woven or braided from a plurality of resilient elongate filaments 204. The resilient elongate filaments 204 are only partially shown to simplify the depiction, but in actuality make up generally the entire structure of the permeable shell 202. The permeable shell 202 has a first end 206, a second end 208, and a longitudinal axis 210. In some embodiments, the elongate resilient filaments 204 of the permeable shell 202 may have a transverse cross section that is substantially round in shape and be made from a superelastic material that may also be a shape memory metal. The filaments 204 are bonded, welded, or otherwise secured together at the first end 206. In the embodiment of FIG. 6, a collar 216 is fastened around ends 218 of the filaments 204, by crimping, welding, adhesive or epoxy bonding, or even soldering or brazing. In this particular embodiment, the first end 206 is

configured to be the proximal end, adjacent to a delivery device, however, in other embodiments, the filaments 204 may be held together at the second end 208 instead of the first end 206. In still other embodiments, the filaments 204 may be held together at both ends 206, 208. The shape memory metal of the filaments of the permeable shell 202 may be heat set in the globular configuration of the relaxed expanded state. Suitable superelastic shape memory metals may include alloys such as NiTi alloy and the like. The superelastic properties of such alloys may be useful in providing the resilient properties to the elongate filaments 204 so that they can be heat set in the form shown, fully constrained for delivery within an inner lumen of a microcatheter 61 and then released to self-expand back to substantially the original heat set shape of the globular configuration upon deployment within a patient's body. Further embodiments for devices and methods for heat setting permeable shells are described in co-owned U.S. Patent Application Publication No. 2009/0275974, published Nov. 5, 2009, and titled "Filamentary Devices for Treatment of Vascular Defects," which is incorporated herein by reference in its entirety for all purposes.

[0038] The permeable shell 202 is heat set into a secondary shape 214 that comprises six lobes 212a-f (or ribs, ears, projections, protuberances) that are circumferentially arrayed with respect to the longitudinal axis 210 of the permeable shell 202. A braided wall 220 of the permeable shell 202 has different mechanical characteristics than a wall of a permeable shell having a simple cylindrical shape (e.g., circular cross-section). Instead of a single radius of curvature being heat formed into the braided wall around the entire circumference, the braided wall 220 of the permeable shell 202 comprising the secondary shape 214 has a more complex contouring, and contains multiple radii of curvature, which can be seen in more detail in FIGS. 7 and 8.

[0039] FIGS. 7 and 8 show cross-sectional views of the device for treatment of a vascular defect 200 deployed within a vascular defect 160, which in this particular case is an aneurysm. As shown in FIG. 7, the lobes 212a-f are evenly distributed around the longitudinal axis 210, and may be separated from each other by about 60°. In alternative embodiments, an uneven distribution may be desired, and may be achieved by using a different forming fixture during the heat setting operation. As shown in both FIGS. 6 and 7, between each of the lobes 212a-f is a longitudinally-extending channel 222a-f. The lobes 212a-f are shown in FIG. 6 extending substantially between the first end 206 and the second end 208 of the permeable shell 202. The channels 222a-f may extend substantially between the first end 206 and the second end 208 of the permeable shell 202. In other embodiments, distal ends of adjacent lobes may blend into one another and/or proximal ends of adjacent lobes may blend into one another such that the channels 222a-f do not extend completely between the first end 206 and the second end 208 of the permeable shell, 202, but instead are present only in a central portion of the permeable shell 202. The channels 222a-f may be configured to provide a fold or a pleat to allow the permeable shell 202 to selectively collapse into a desired constricted or compressed shape, for placement through the lumen 111 of a microcatheter 61.

[0040] As best seen in FIG. 7, each lobe 212a-f has a first side 224 having a first radius of curvature r1 and a second side 226 having a second radius of curvature r2. In the embodiment of FIG. 7, the first radius of curvature r1 is

about equal to the second radius of curvature r_2 , but in other embodiments, they may differ. Each lobe **212a-f** may also include a central section **228**, between the first side **224** and the second side **226**, the central section **228** having a third radius of curvature r_3 . In some embodiments, the third radius r_3 , is larger than the first radius of curvature r_1 and larger than the second radius of curvature r_2 , and in other embodiments, the third radius r_3 is smaller than the first radius of curvature r_1 and smaller than the second radius of curvature r_2 . Each channel **222a-f** may have a fourth radius of curvature r_4 . By heat setting the braided wall **220** into several smaller radii of curvature, for example, radii of curvature r_1 , r_2 , and r_4 , an expanded state of the permeable shell **202** may be produced that resists compression over time, for example, radial compression by repetitive blood pressure cycling when the device for treatment of a vascular defect **200** resides within a vascular defect **160** after implantation. The adjacent and opposing radii of curvature in the braided wall **220**, for example, r_1 and r_4 , create a bolstered structure that causes the lobe **212b** (in this particular example) of the permeable shell **202** in its expanded state to resist compressive forces that would otherwise tend to crush, collapse or compress a single, larger-radiused portion of a purely circular braided wall, such as in a permeable shell having a circular cross-section of diameter D . The heat set smaller radii may increase the bending stiffness of the braided wall **220** in comparison to a purely circular cross-section braided wall having a diameter D . The permeable shell **202**, in contrast, has a major diameter D and a minor diameter d . In some embodiments, a ratio (D/d) between the major diameter D and the minor diameter d is between about 1.05 and about 1.35, or between about 1.15 and about 1.25, or about 1.20. The generally wavy outer perimeter of the radial cross-section of the braided wall **220** shown in FIG. 7 may in some cases have larger dimension than a purely circular cross-section braided wall having a diameter D , for example, 0.5% to 10% larger.

[0041] In some embodiments, the major diameter D is between about two millimeters and about fourteen millimeters, or between about three millimeters and about twelve millimeters, or between about four millimeters and about eleven millimeters. In some embodiments, the length of the permeable shell **202** (e.g., measured along the longitudinal axis **210** between the first end **206** and second end **208**) is between about two millimeters and about ten millimeters, or between about four millimeters and about eight millimeters.

[0042] In some embodiments, the third radius of curvature r_3 is about equal to one-half the major diameter D of the permeable shell **202**, thus the central sections **228** of the lobes **212a-f** would each more or less follow the contours of a circle having a diameter D .

[0043] Returning to FIG. 6, a tether **272** is connected to the device for treatment of a vascular defect **200** at a first tether end **274**. A second tether end **276** is configured to couple to a delivery or “pusher” device. In FIG. 8, the tether **272** has been cut, melted or otherwise severed during a detachment procedure, with only a small remnant **278** remaining. Also in FIG. 8, the second end **208** of the permeable shell **202** includes a closed end portion **209**. Embodiments for devices and methods for producing devices for the treatment of vascular defects having closed end portions are described in U.S. Patent Application Publication No. 2016/02409934. The filaments **204** of the permeable shell **202** each have first ends **218a** and second ends **218b** which are secured at the

first end **206** of the permeable shell **202**. The filaments **204** also each have a central section **211** between the first end **218a** and second end **218b** which passes through or is incorporated into the closed end portion **209** of the second end **208** of the permeable shell **202**.

[0044] In the longitudinal cross-section of the device for treatment of a vascular defect **200** in its expanded state in FIG. 8, other heat formed radii of curvature in the braided wall **220** serve to resist axial/longitudinal compression from factors such as repetitive blood pressure cycling. A fifth radius of curvature r_5 is adjacent a generally opposed sixth radius of curvature r_6 . In some embodiments, the fifth radius of curvature r_5 is larger than the sixth radius of curvature r_6 .

[0045] Representative ranges for the various radii of curvature, though non-limiting, are as follows. Radius of curvature r_1 may range from about 0.29 millimeters to about 2.10 millimeters, or about 0.36 millimeters to about 1.10 millimeters. Radius of curvature r_2 may range from about 0.29 millimeters to about 2.10 millimeters, or about 0.36 millimeters to about 1.10 millimeters. Radius of curvature r_3 may range from about 0.29 millimeters to about 7.28 millimeters, or about 0.89 millimeters to about 2.69 millimeters. Radius of curvature r_4 may range from about 0.16 millimeters to about 1.21 millimeters, or about 0.20 millimeters to about 0.63 millimeters. Radius of curvature r_5 may range from about 0.28 millimeters to about 2.06 millimeters, or about 0.36 millimeters to about 1.09 millimeters. Radius of curvature r_6 may range from about 0.16 millimeters to about 1.27 millimeters, or about 0.21 millimeters to about 0.65 millimeters.

[0046] Representative ranges for the ratios between different radii of curvature, though non-limiting, are as follows. The ratio r_1/r_3 may range from about 0.04 to about 2.49, or about 0.16 to about 0.48, or about 0.28 to about 0.36. The ratio r_3/r_4 may range from about 0.68 to about 44.18, or about 1.71 to about 6.42, or about 2.14 to about 6.31. The ratio r_1/r_4 may range from about 0.87 to about 12.39, or about 1.50 to about 2.61, or about 1.71 to about 1.77. The ratio r_6/r_5 may range from about 0.08 to about 4.08, or about 0.58 to about 0.90, or about 0.29 to about 0.63. The range of the ratio r_2/r_3 is expected to be similar to the range of the ratio r_1/r_3 . The range of the ratio r_2/r_4 is expected to be similar to the range of the ratio r_1/r_4 .

[0047] Though the device for treatment of a vascular defect **200** is depicted having six lobes **212a-f**, other embodiments are possible which have a different number of lobes, for example, between two lobes and sixteen lobes, or even as many as thirty-two lobes or more.

[0048] FIG. 9 illustrates a device for treatment of a vascular defect **300** comprising a permeable shell **302** which is woven or braided from a plurality of resilient elongate filaments **304**. The permeable shell **302** has a first end **306**, a second end **308**, and a longitudinal axis **310**. Any of the materials and construction techniques described in relation to the device for treatment of a vascular defect **200** of FIG. 6, may also be used in constructing the device for treatment of a vascular defect **300**. The permeable shell **302** is heat set into a secondary shape **314** that comprises four lobes **312a-d** (or ribs, ears, projections, protuberances) that are circumferentially arrayed with respect to the longitudinal axis **310** of the permeable shell **302**. Between each of the lobes **312a-d** is a longitudinally-extending channel **322a-d**. Also in FIG. 9, the first end **306** of the permeable shell **302** includes a closed end portion **309**, which may be formed in

the same manner as the closed end portion 209 of the device for treatment of a vascular defect 200 of FIG. 8.

[0049] FIG. 10 illustrates a device for treatment of a vascular defect 400 comprising a permeable shell 402 which is woven or braided from a plurality of resilient elongate filaments 404. The permeable shell 402 has a first end 406, a second end 408, and a longitudinal axis 410. Any of the materials and construction techniques described in relation to the device for treatment of a vascular defect 200 of FIG. 6 or the device for treatment of a vascular defect 300 of FIG. 9 may also be used in constructing the device for treatment of a vascular defect 400. The permeable shell 402 is heat set into a secondary shape 414 that comprises eight lobes 412a-h (or ribs, ears, projections, protuberances) that are circumferentially arrayed with respect to the longitudinal axis 410 of the permeable shell 402. Between each of the lobes 412a-h is a longitudinally-extending channel 422a-h. Each of the lobes 412a-h extends longitudinally with a generally semi-cylindrical shape arrayed around the outer periphery of the permeable shell 402. In this particular embodiment, each of the lobes 412a-h has an outer radius which is less than the one-half of the major diameter of the permeable shell 402.

[0050] It should be noted that the lobes 412a-h of the permeable shell 402 of FIG. 10, when cross-sectioned in a plane parallel to the longitudinal axis 410 in a midpoint along the longitudinal axis 410, do not have the multiple radii of curvature (e.g., where r_1 is not equal to r_3) that are displayed in the cross-section of the permeable shell 202 of FIG. 7. Instead a single radius of curvature (such that curvature r_1 , r_2 , and r_3 are all equal to each other) exists between each adjacent and generally opposite radius of curvature r_4 . Thus, the eight lobes 412a-h each have a generally cylindrical outer contour at their outer extents.

[0051] FIG. 11 illustrates a device for treatment of a vascular defect 500 comprising a permeable shell 502 which is woven or braided from a plurality of resilient elongate filaments 504. The permeable shell 502 has a first end 506, a second end 508, and a longitudinal axis 510. Any of the materials and construction techniques described in relation to the device for treatment of a vascular defect 200 of FIG. 6, the device for treatment of a vascular defect 300 of FIG. 9, or the device for treatment of a vascular defect 400 of FIG. 10 may also be used in constructing the device for treatment of a vascular defect 500. The permeable shell 502 is heat set into a secondary shape 514 that comprises eight lobes 512a-h (or ribs, ears, projections, protuberances). Lobes 512a-d are circumferentially arrayed with respect to the longitudinal axis 510 of the permeable shell 502. Lobes 512e-h are also circumferentially arrayed with respect to the longitudinal axis 510 of the permeable shell 502. Between lobes 512a-d and lobes 512e-h is a circumferentially-extending channel 516 (groove, indentation, recess). The lobes 512a-h are also separated by longitudinally-extending channels 522a-h. The circumferentially-extending channel 516 may be heat formed in the braided wall 520 and has a cross-section having a semicircular shape with a radius of curvature r_c . The radius of curvature r_c serves to resist axial and even radial compression from factors such as repetitive blood pressure cycling, as described herein. In other embodiments, the cross-section of the circumferentially-extending channel 516 may have a substantially triangular shape. In other embodiments, the cross-section of the circumferentially-extending channel 516 may comprise two or

more channels, each at a different longitudinal location along the longitudinal axis 510. For example, a first channel may be located closer to the first end 506 and a second channel may be located closer to the second end 508. Though the channel 516 is shown in FIG. 11 extending 360° around the longitudinal axis 510, in other embodiments, the channel may extend only partially around the longitudinal axis 510. In some embodiments, there may be two or more channels, each at about the same longitudinal location along the longitudinal axis 510, but each extending less than about 180° around the longitudinal axis. In one example, four different circumferentially-extending channels, each having comprising arc of about 80° are separated from each other by about 10°.

[0052] FIG. 12 illustrates a device for treatment of a vascular defect 600 comprising a permeable shell 602 which is woven or braided from a plurality of resilient elongate filaments 604. The permeable shell 602 has a first end 606, a second end 608, and a longitudinal axis 610. Any of the materials and construction techniques described in relation to the device for treatment of a vascular defect 200 of FIG. 6, the device for treatment of a vascular defect 300 of FIG. 9, the device for treatment of a vascular defect 400 of FIG. 10, or the device for treatment of a vascular defect 500 of FIG. 11 may also be used in constructing the device for treatment of a vascular defect 600. The permeable shell 602 is heat set into a secondary shape 614 that comprises two lobes 612a-b. Between lobes 612a and 612b is a circumferentially-extending channel 616 (groove, indentation, recess). The circumferentially-extending channel 616 may be heat formed in the braided wall 620 and has a cross-section having a substantially triangular shape. The channel 616 serves to resist axial and even radial compression from factors such as repetitive blood pressure cycling, as described herein. In other embodiments, the cross-section of the circumferentially-extending channel 616 may have a semi-circular shape. In other embodiments, the cross-section of the circumferentially-extending channel 616 may comprise two or more channels.

[0053] In any of the embodiments described herein, the filaments 204, 304, 404 may include filaments of different transverse dimensions. For example, one sub-group of filaments may have an outer diameter of about 0.00075 inches and another sub-group of filaments may have an outer diameter of about 0.001 inches. There may even be three or more different sub-groups of filaments, each group having a particular transverse dimension and/or material composition. In some embodiments, one or more of the filaments may contain a radiopaque material such as platinum, platinum iridium, gold, or other materials, in order to increase the radiopacity of the permeable shell 202, 302, 402. In order to provide both superelastic and/or shape memory characteristics and radiopacity within each filament, a composite filament, such as a filament comprising a drawn filled tube (DFT) may be used. Some embodiments for composite and/or DFT filaments are described in U.S. Pat. No. 9,078,658.

[0054] Embodiments are contemplated which utilize filaments having transverse dimensions of between about 0.0005 inches and about 0.002 inches, or between about 0.00075 inches and about 0.00125 inches.

[0055] It can be appreciated that the multi-lobe geometry of the permeable shell 202, 302, 402 with a heat-formed secondary shape 214, 314, 414 having multiple radii or

curvature resists in vivo compression of the permeable shell **202, 302, 402**, both radial and axial/longitudinal compression, when the permeable shell **202, 302, 402** is in its expanded state or condition. However, some elongation of the permeable shell **202, 302, 402** occurs when the permeable shell **202, 302, 402** is being compressed into its compressed, radially constrained state or condition, and is aided by some sliding which is able to occur between the filaments **204, 304, 404**. This makes the desired forced collapse on the permeable shell **202, 302, 402** for delivery through a catheter lumen simple and efficient, even though the device is able to resist compression while implanted in its expanded state over a significant length of time in a vascular defect. [0056] While embodiments have been shown and described, various modifications may be made without departing from the scope of the inventive concepts disclosed herein. In addition to cerebral aneurysms, other types of aneurysms may be treated with devices described herein, including, but not limited to aortic aneurysms. Other vascular defects which may be treated with devices described herein include structural heart deformities, including, but not limited to left atrial appendages.

What is claimed is:

1. A device for treatment of a vascular defect, comprising: a self-expanding permeable shell comprising a mesh; the self-expanding permeable shell comprising a radially compressed shape and a radially expanded shape; the radially expanded shape of the self-expanding permeable shell comprising a first plurality of longitudinally-arrayed lobes extending between a first end of the self-expanding shell and a second end of the self-expanding shell; and, wherein the mesh comprises a plurality of elongated resilient filaments and has a memorized shape which self-expands to form the first plurality of longitudinally-arrayed lobes.
2. The device of claim 1, further comprising a plurality of longitudinally-extending channels positioned between each of the first plurality of longitudinally-arrayed lobes.
3. The device of claim 2, wherein the plurality of longitudinally-extending channels only extend partially between the first end and the second end.
4. The device of claim 2, wherein the plurality of longitudinally-extending channels are folds or pleats.
5. The device of claim 1, wherein each of the first plurality of longitudinally-arrayed lobes comprise a first side having a first radius of curvature, a second side having a second radius of curvature and a central portion between the first side and the second side comprising a third radius of curvature; wherein the third radius of curvature is greater than each of the first radius of curvature and the second radius of curvature.
6. The device of claim 1, wherein the self-expanding permeable shell further comprises a circumferentially-extending channel.

7. The device of claim 1, wherein the first plurality of longitudinally-arrayed lobes are evenly distributed around a longitudinal axis of the self-expanded permeable shell.

8. The device of claim 1, wherein the plurality of elongated resilient filaments is secured together at the first end of the self-expanding shell.

9. The device of claim 1, wherein the radially expanded shape of the permeable shell comprises a major diameter D , and wherein each of the first plurality of longitudinally-arrayed lobes have a radius of curvature r , wherein $r < D/2$.

10. A device for treatment of a vascular defect, comprising:

a mesh formed of a plurality of filaments; the mesh having a radially constrained shape and a radially expanded shape;

a first plurality of lobes formed from the mesh and that are longitudinally arrayed between a first end and a second end of the radially expanded shape;

wherein the mesh has a memorized shape which self-expands to form the first plurality of lobes.

11. The device of claim 10, further comprising a continuous ring indented into the mesh and extending 360 degrees around a longitudinal axis of the radially expanded shape.

12. The device of claim 11, wherein the continuous ring has a substantially semi-circular cross-section or a substantially triangular cross-section.

13. The device of claim 10, wherein each of the first plurality of lobes comprise a first side having a first radius of curvature, a second side having a second radius of curvature and a central portion between the first side and the second side comprising a third radius of curvature; wherein the third radius of curvature is greater than each of the first radius of curvature and the second radius of curvature.

14. The device of claim 10, further comprising a plurality of longitudinal channels located between adjacent lobes of the first plurality of lobes.

15. The device of claim 14, wherein the plurality of longitudinal channels are folds or pleats.

16. The device of claim 10, wherein the mesh comprises drawn filled tubes.

17. The device of claim 10, wherein the mesh is composed of three or more groups of filaments, the filaments of each group having a different outer diameter or material composition from each other.

18. The device of claim 10, wherein the first end of the radially expanded shape of the mesh is closed and indented.

19. The device of claim 18, wherein the second end of the radially expanded shape of the mesh is closed and indented.

20. A device for treatment of a vascular defect, comprising:

a mesh means for self-expanding from a radially compressed position to a radially expanded memorized shape having a plurality of lobes formed from the mesh and that are longitudinally arrayed between a first end and a second end of the radially expanded memorized shape.

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