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(54) **VASO-OCCLUSIVE DEVICES FOR OCCLUDING BLOOD VESSELS AND METHODS FOR MAKING AND USING SAME**

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(21) Appl. No.: **19/195,670**

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Related U.S. Application Data

(63) Continuation-in-part of application No. 18/667,790, filed on May 17, 2024, which is a continuation of application No. PCT/US2022/078935, filed on Oct. 28, 2022.

(60) Provisional application No. 63/281,561, filed on Nov. 19, 2021.

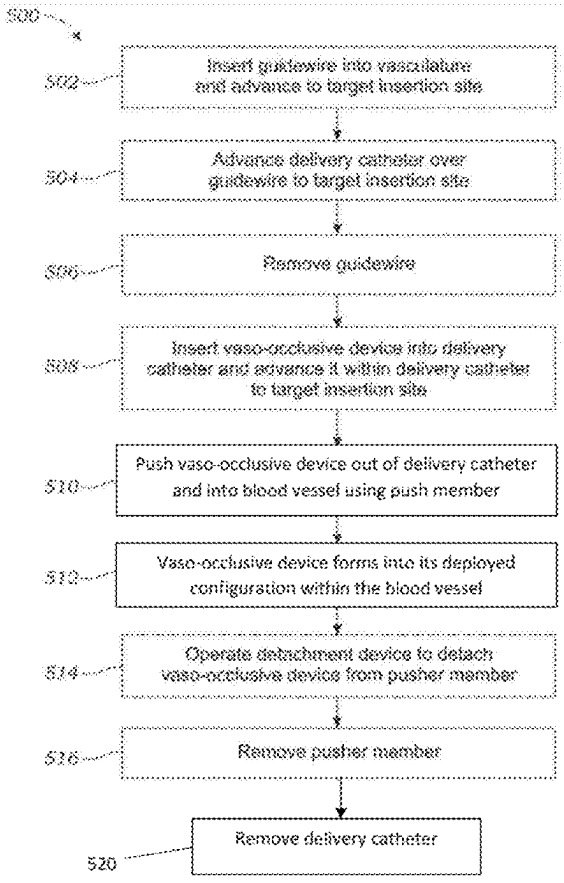
Publication Classification

(51) **Int. Cl.**
A61B 17/12 (2006.01)

(52) **U.S. Cl.**
CPC .. ***A61B 17/12113*** (2013.01); ***A61B 17/12145*** (2013.01)

(57) **ABSTRACT**

A vaso-occlusive device includes: an elongated member having a primary configuration when the vaso-occlusive device is in a constrained condition; wherein the elongated member forms a three-dimensional structure having a secondary configuration when the vaso-occlusive device is in an unconstrained condition, the three-dimensional structure comprising: a first pyramidal portion comprising a first set of at least three first loops lying within at least three different respective first planes that are non-parallel and non-perpendicular with respect to each other; and a first helical section formed from the wire and extending proximally from the first pyramidal portion.



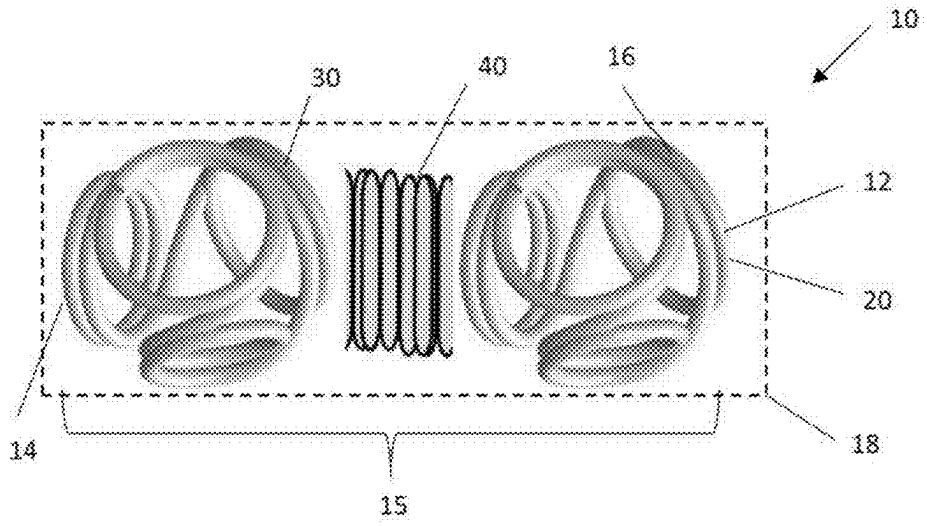


FIG. 1

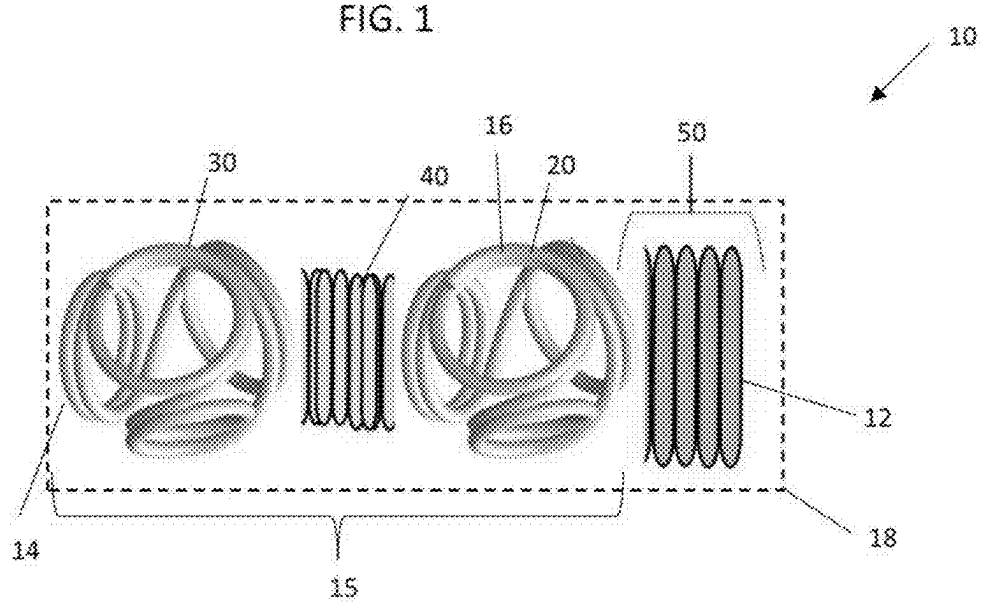


FIG. 2

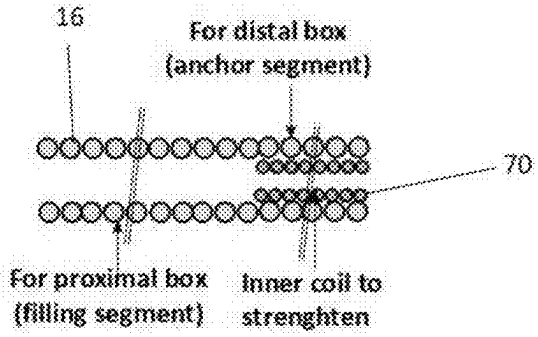


FIG. 3A

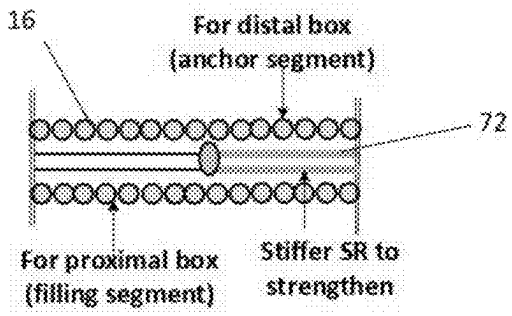


FIG. 3B

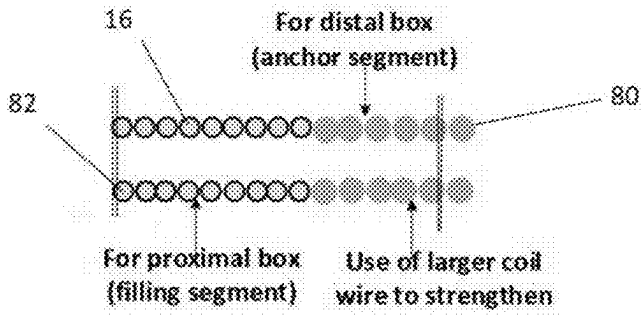


FIG. 3C

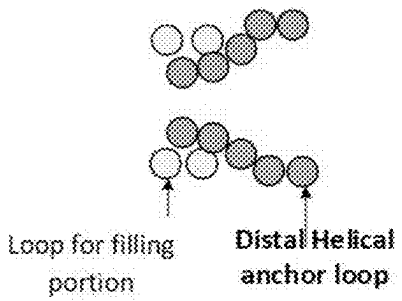


FIG. 3D

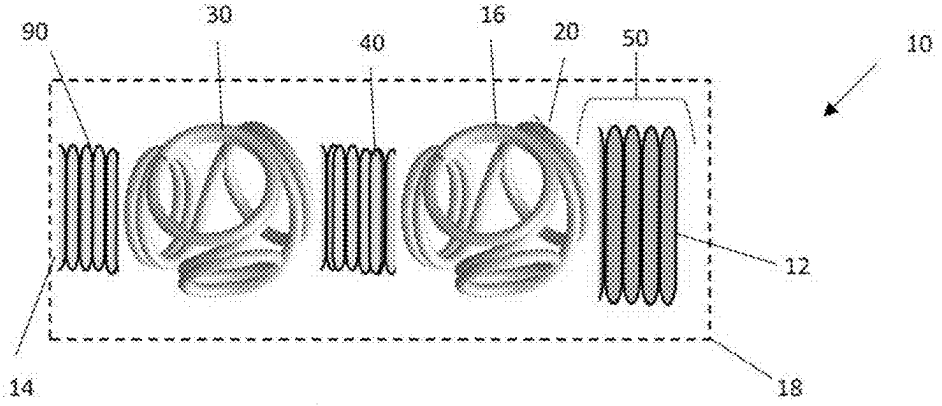


FIG. 4

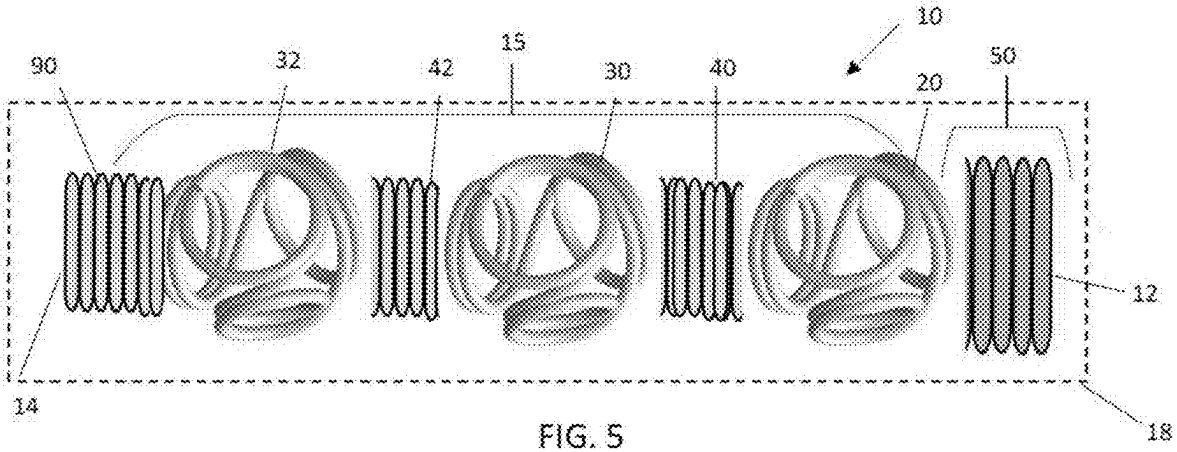


FIG. 5

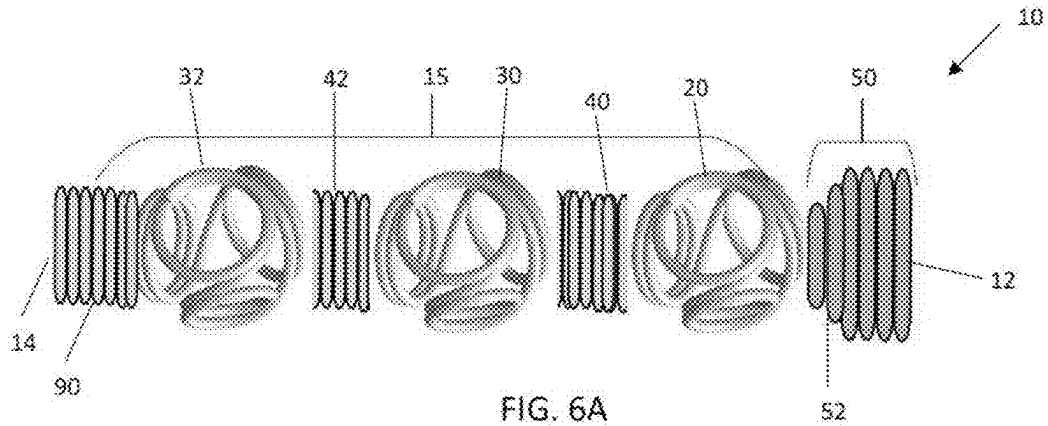


FIG. 6A

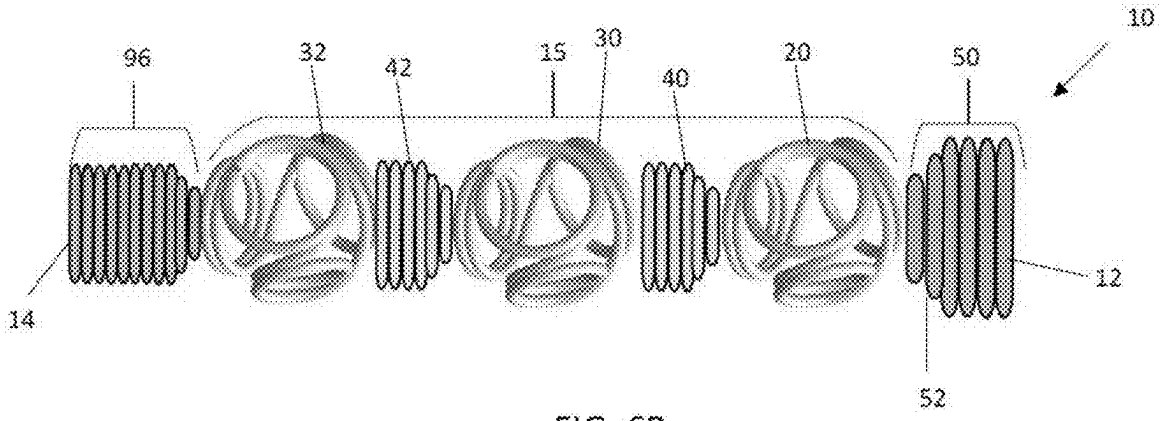


FIG. 6B

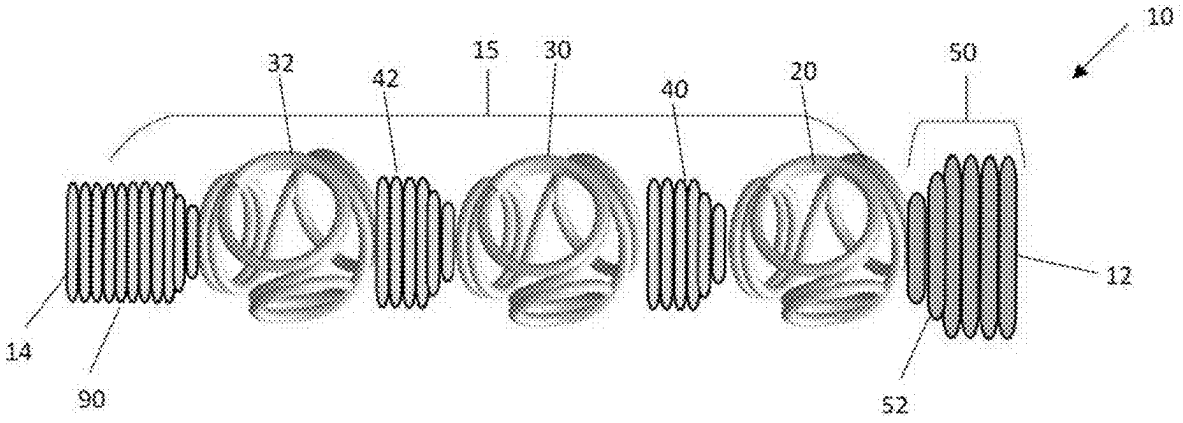


FIG. 6C

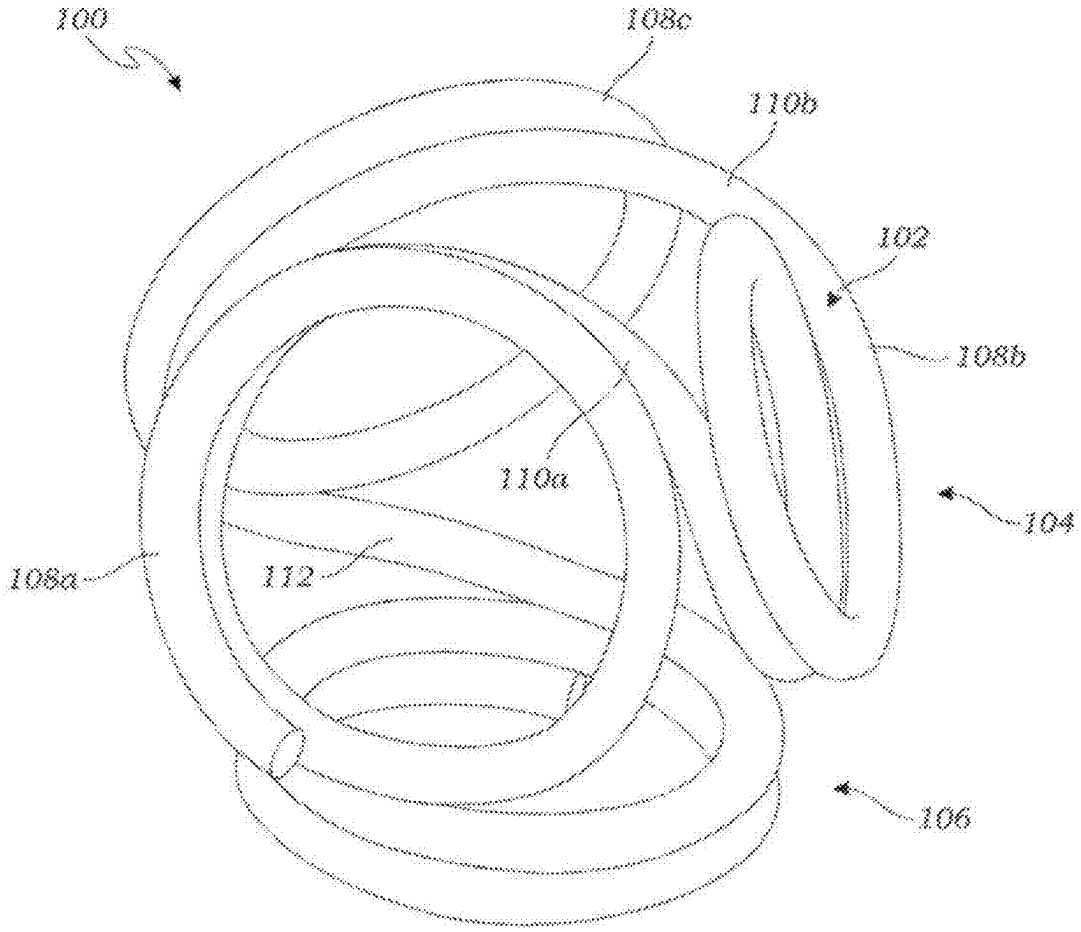


FIG. 7

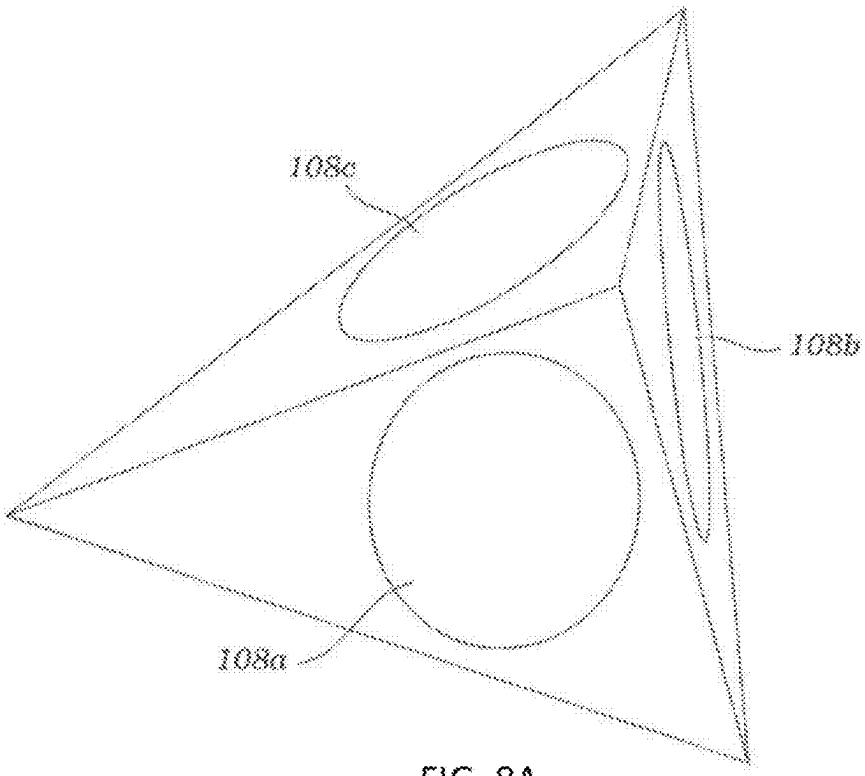


FIG. 8A

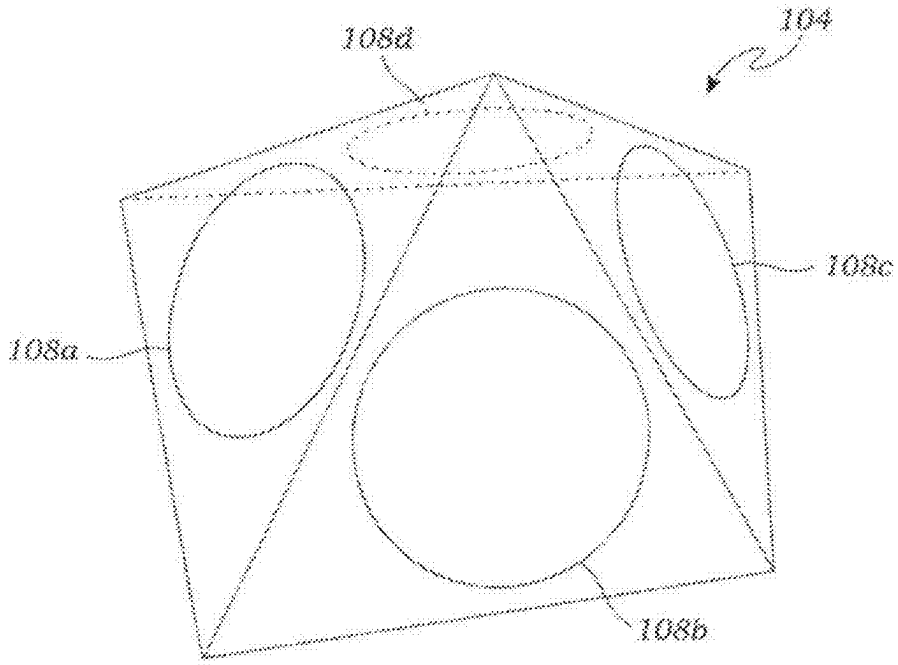


FIG. 8B

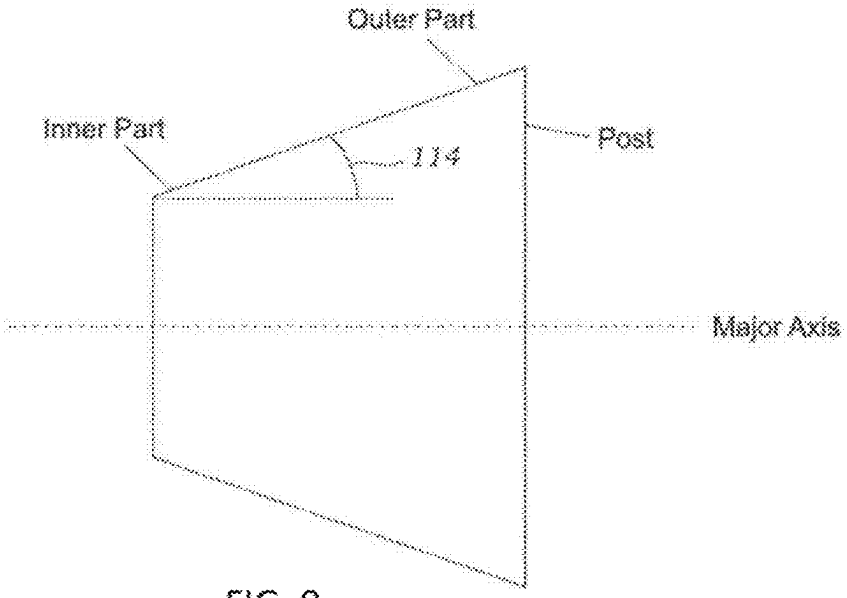

Outer Part
Inner Part
114
Post
Major Axis

FIG. 9

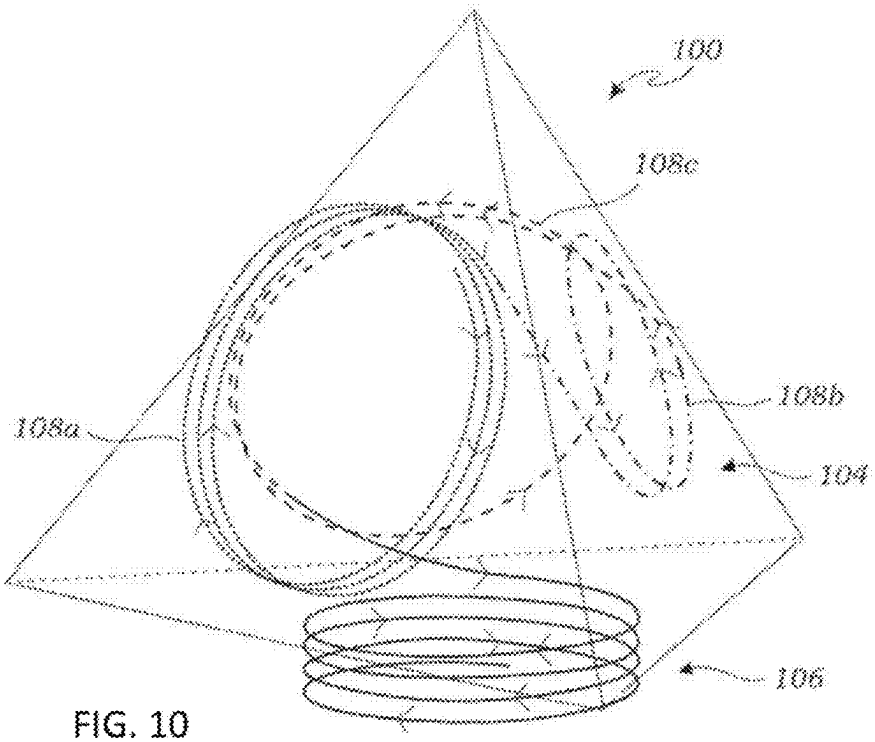

100
108c
108b
108a
104
106

FIG. 10

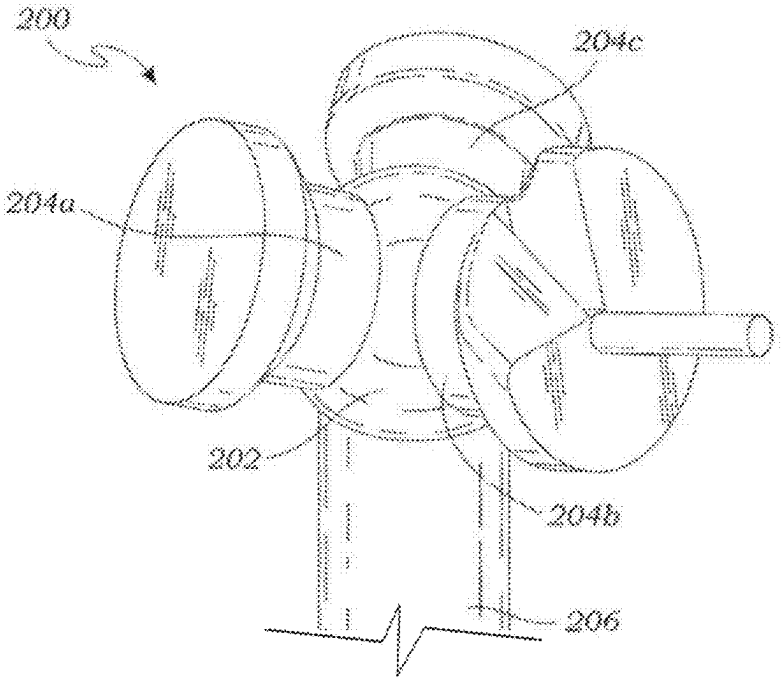


FIG. 11A

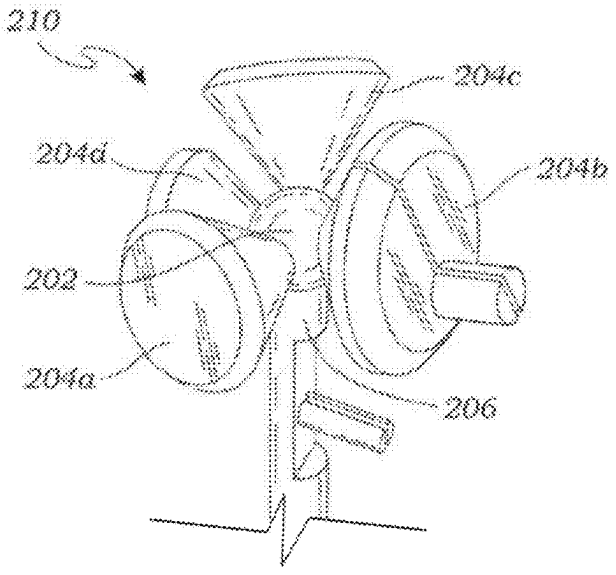


FIG. 11B

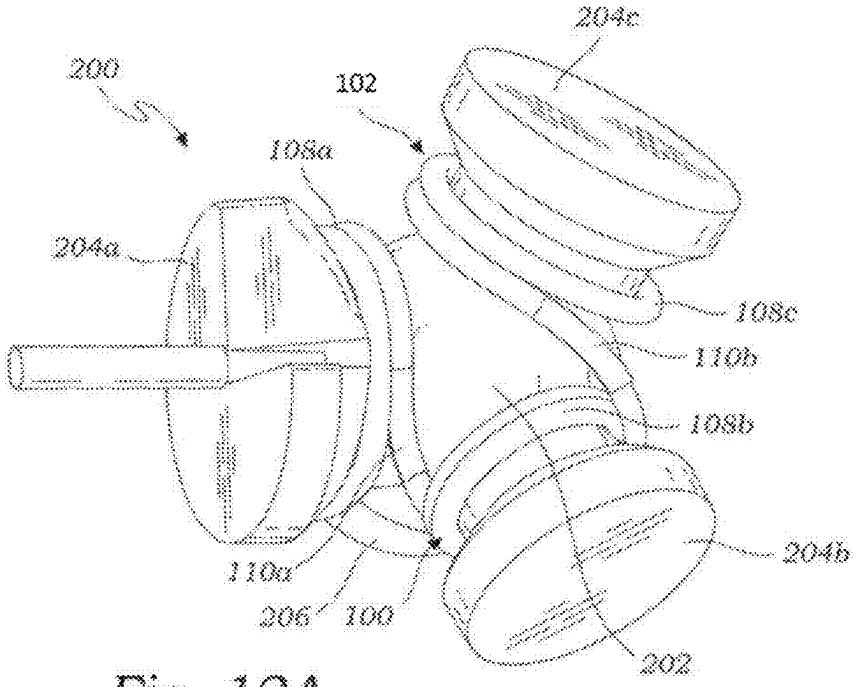


Fig. 12A

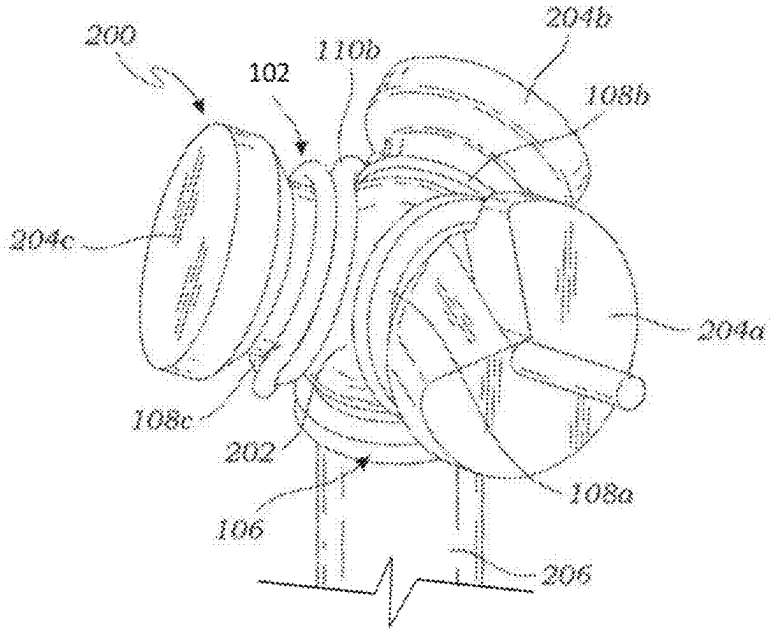


Fig. 12B

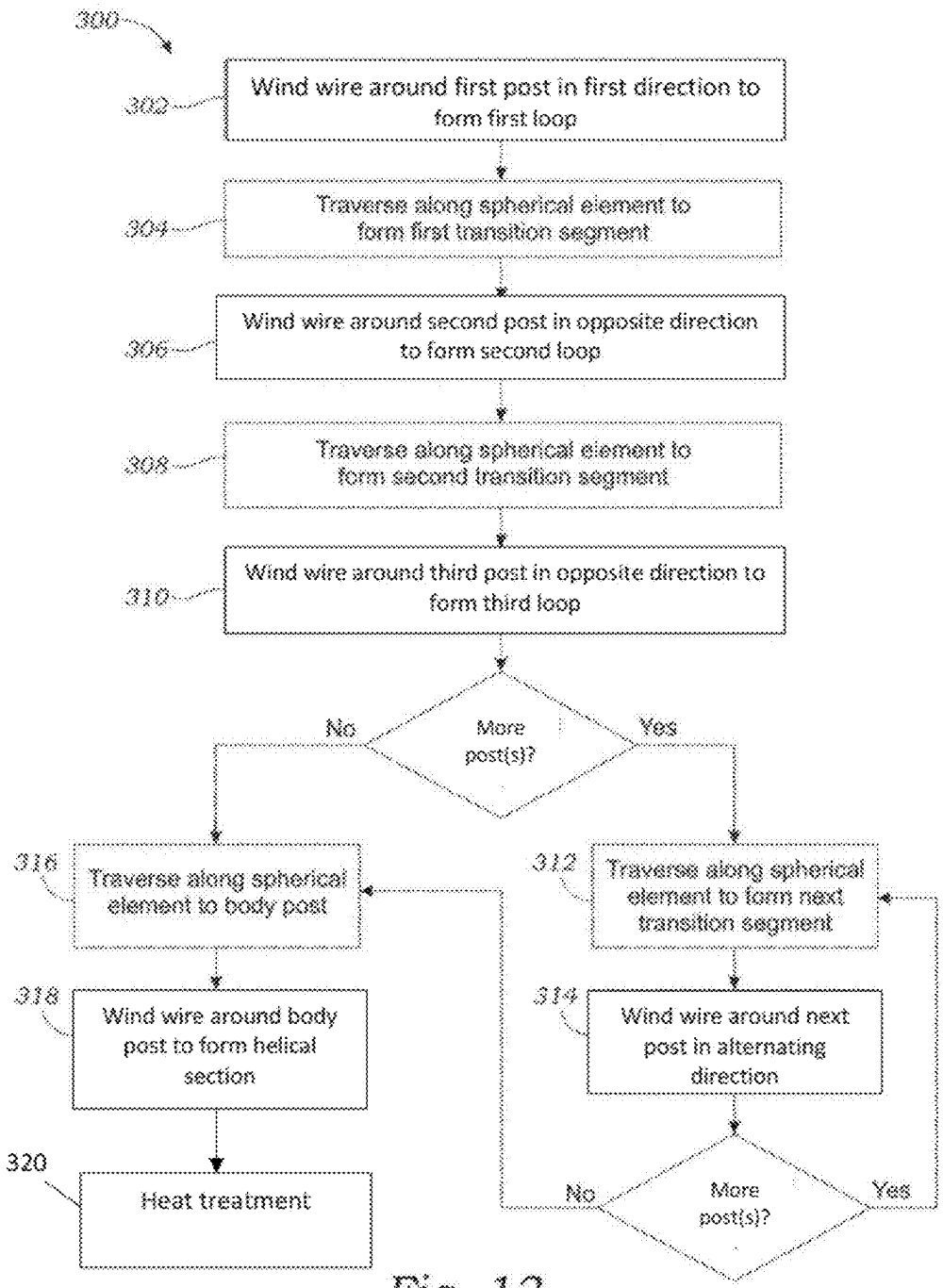

300
302
Wind wire around first post in first direction to form first loop
304
Traverse along spherical element to form first transition segment
306
Wind wire around second post in opposite direction to form second loop
308
Traverse along spherical element to form second transition segment
310
Wind wire around third post in opposite direction to form third loop
More post(s)?
No
Yes
316
Traverse along spherical element to body post
318
Wind wire around body post to form helical section
320
Heat treatment
312
Traverse along spherical element to form next transition segment
314
Wind wire around next post in alternating direction
More post(s)?
No
Yes

Fig. 13

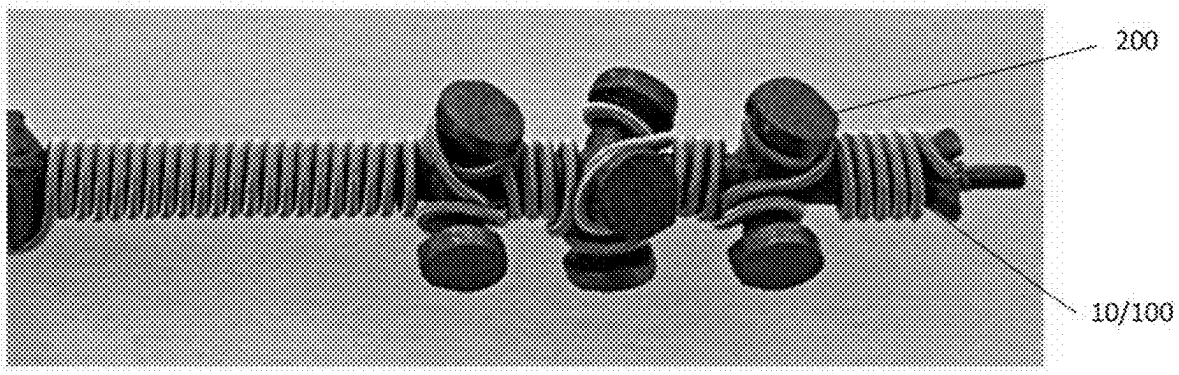


FIG. 14

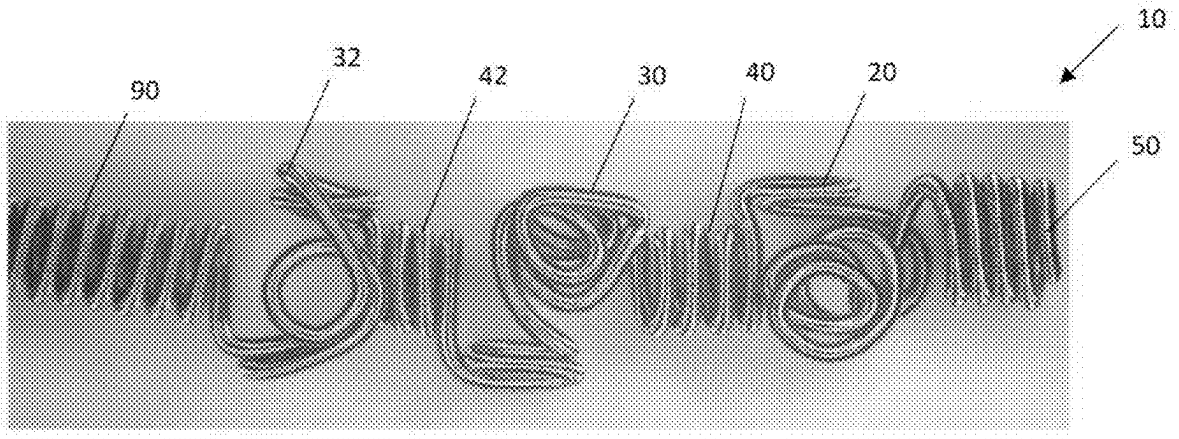


FIG. 15

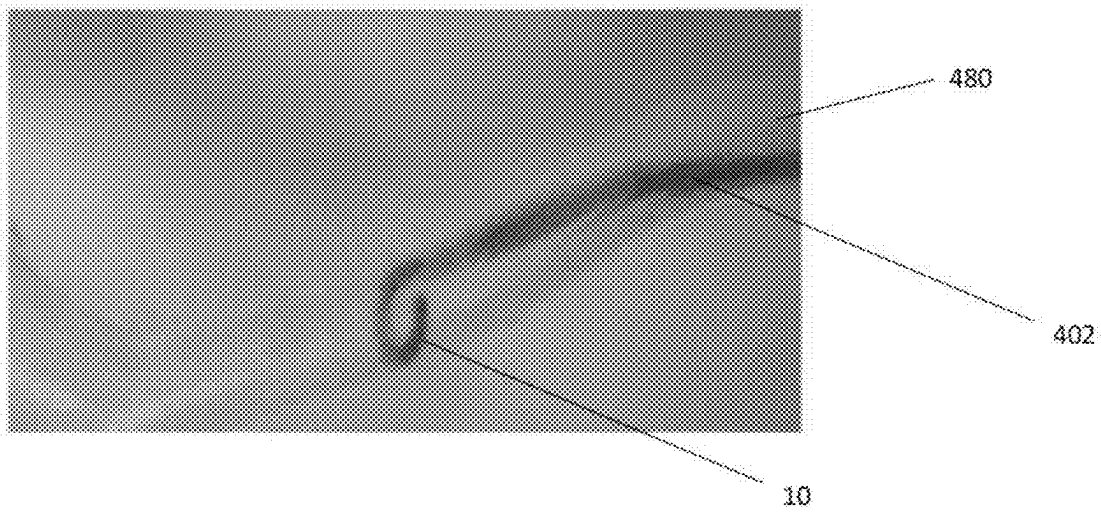


FIG. 16A

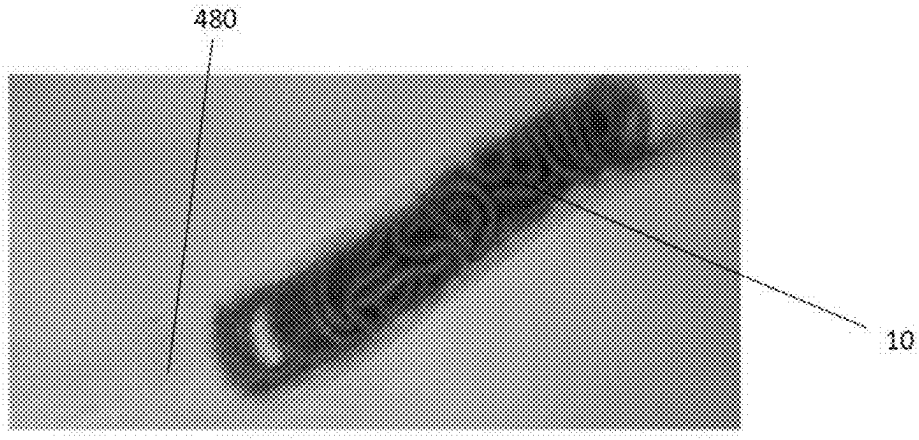


FIG. 16B

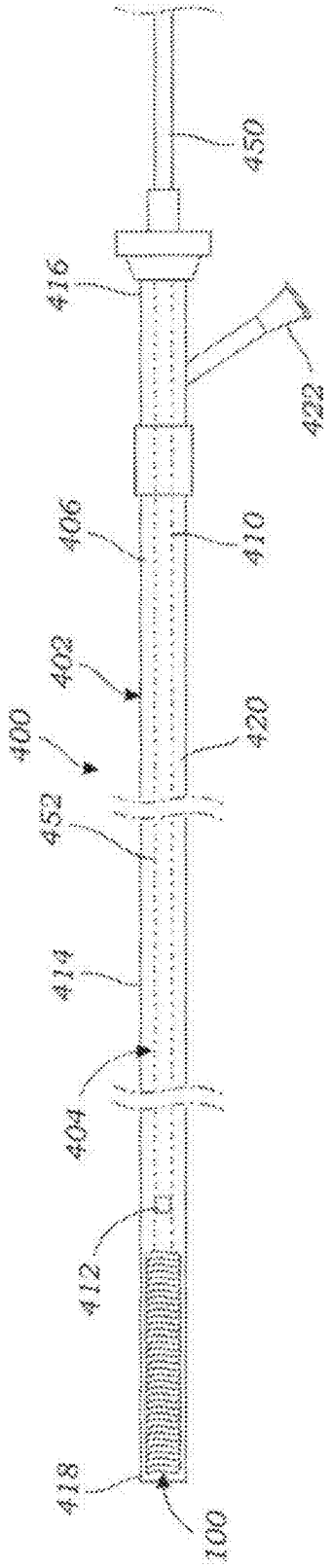


FIG. 17A

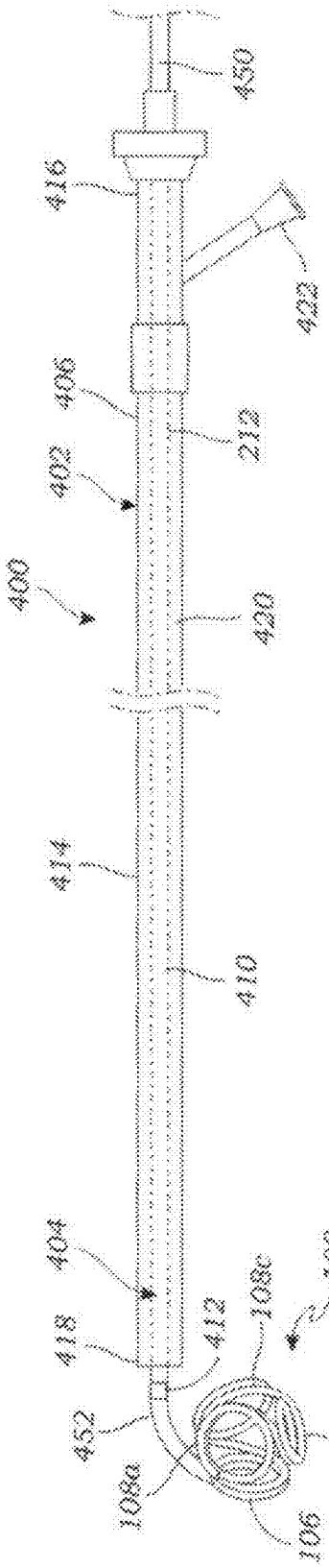


FIG. 17B

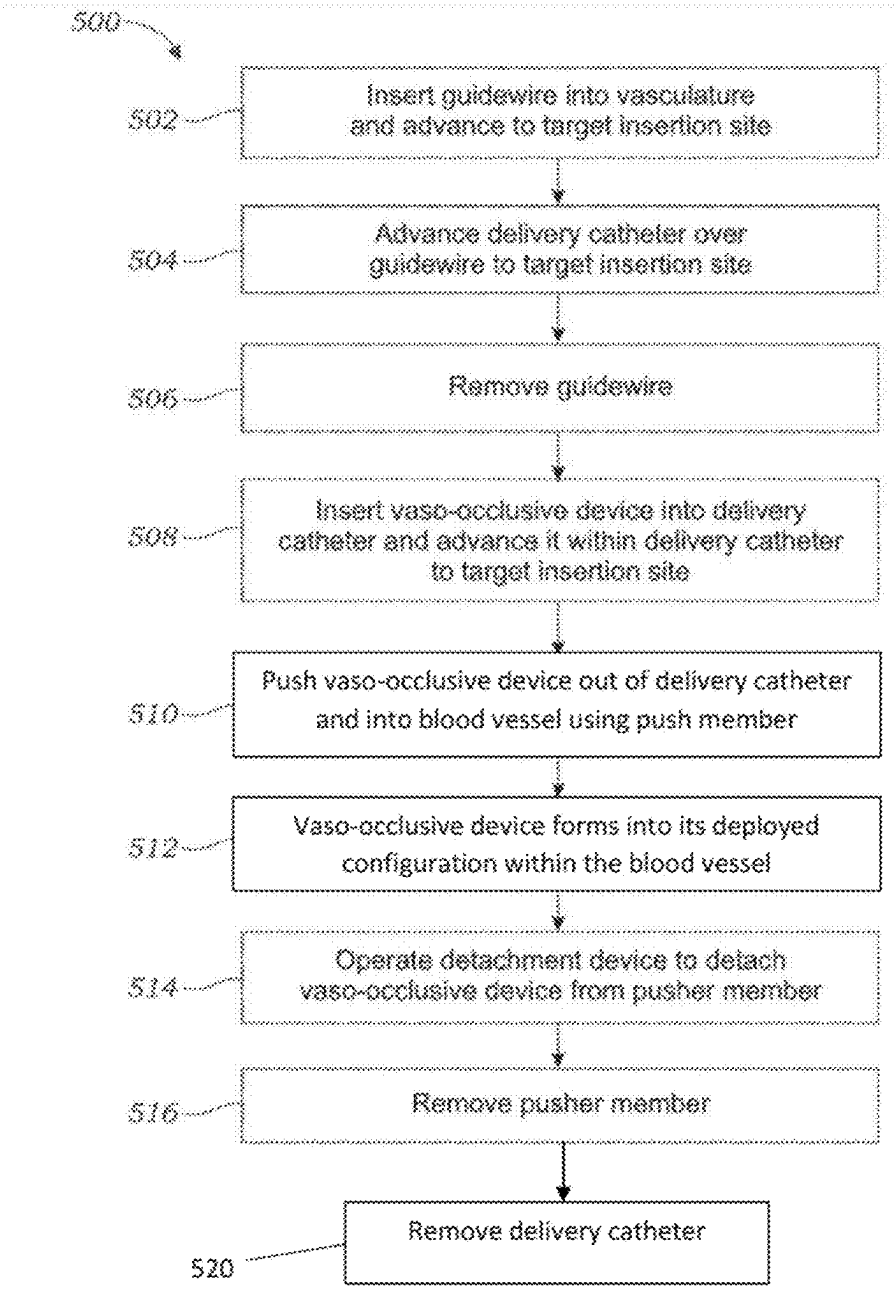

500
502
Insert guidewire into vasculature and advance to target insertion site
504
Advance delivery catheter over guidewire to target insertion site
506
Remove guidewire
508
Insert vaso-occlusive device into delivery catheter and advance it within delivery catheter to target insertion site
510
Push vaso-occlusive device out of delivery catheter and into blood vessel using push member
512
Vaso-occlusive device forms into its deployed configuration within the blood vessel
514
Operate detachment device to detach vaso-occlusive device from pusher member
516
Remove pusher member
520
Remove delivery catheter

FIG. 18

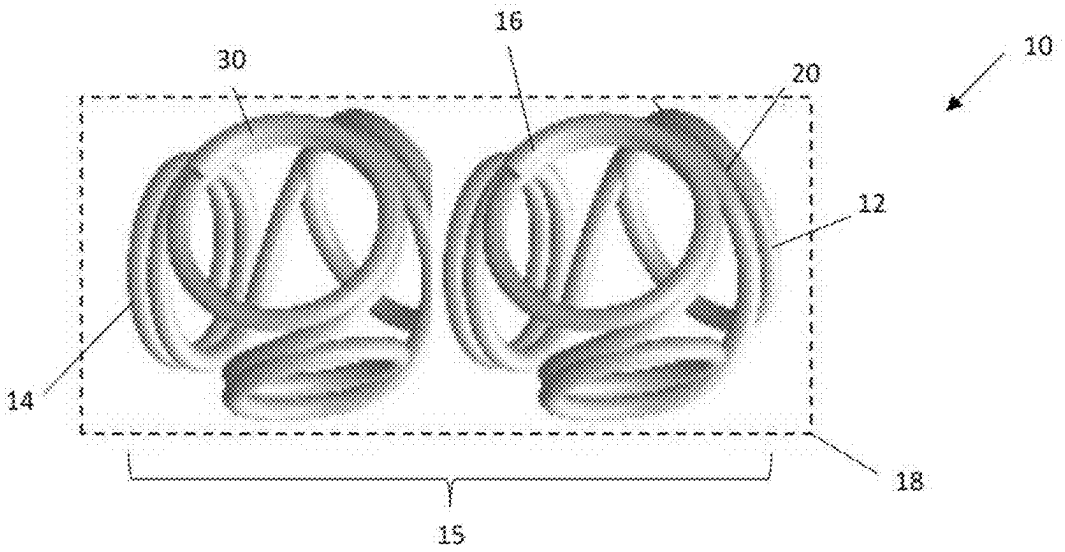


FIG. 19

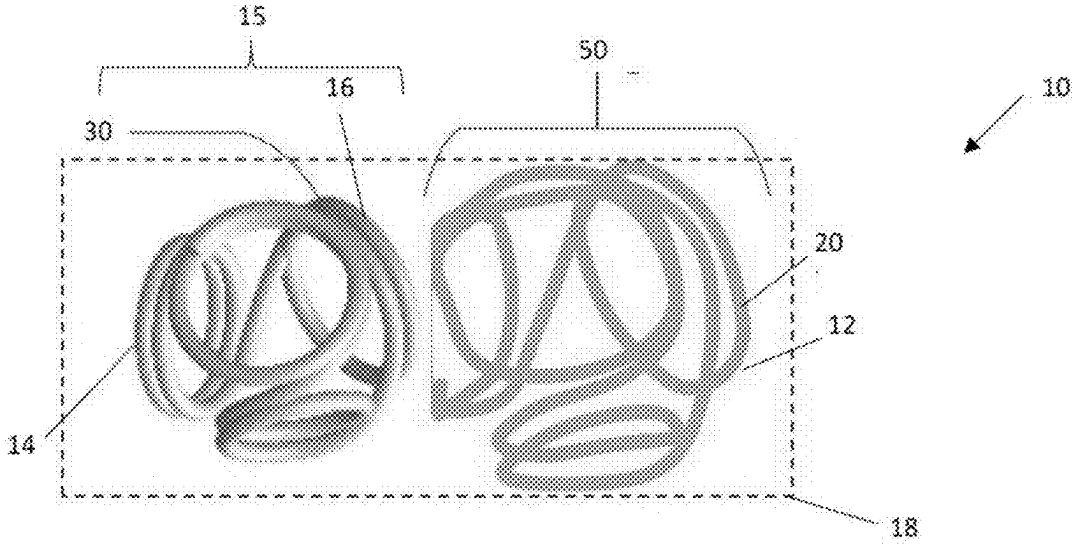


FIG. 20

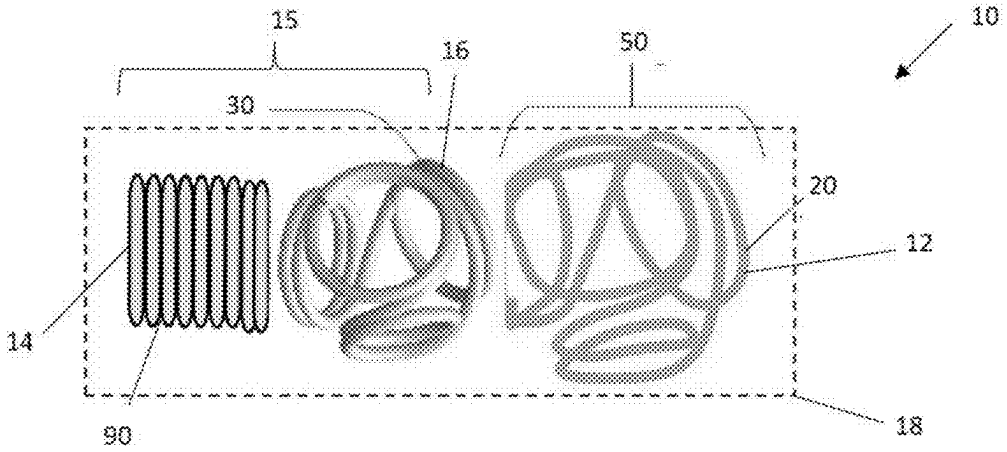


FIG. 21

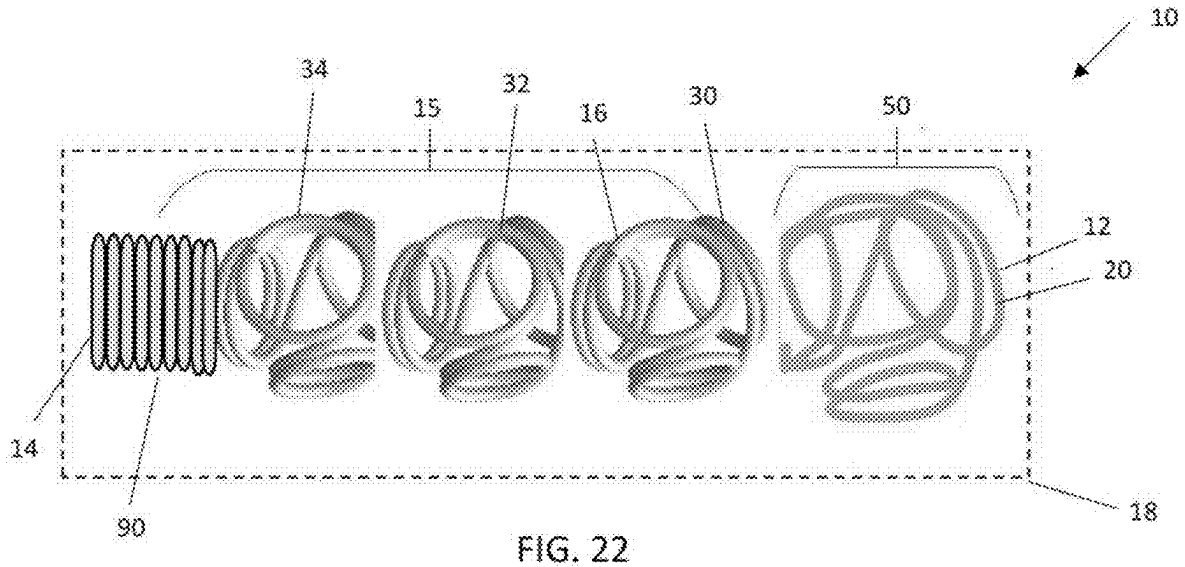


FIG. 22

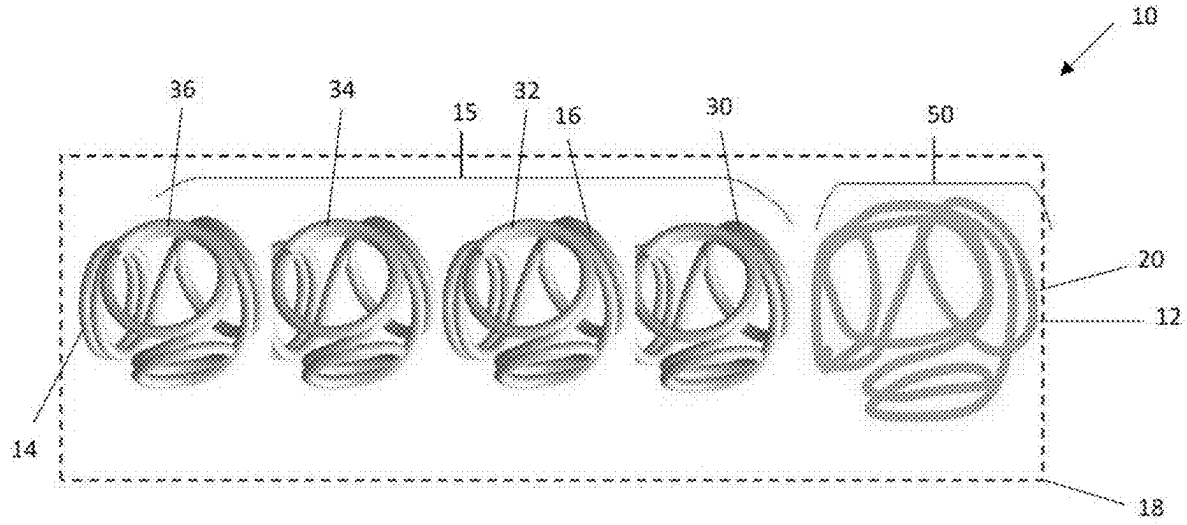


FIG. 23

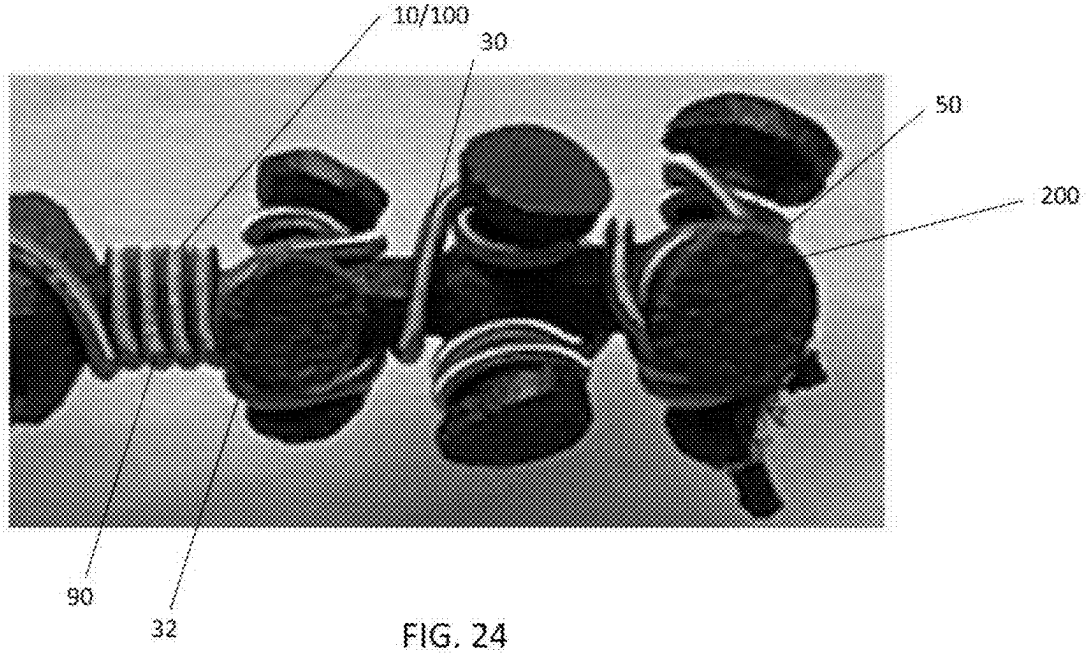


FIG. 24

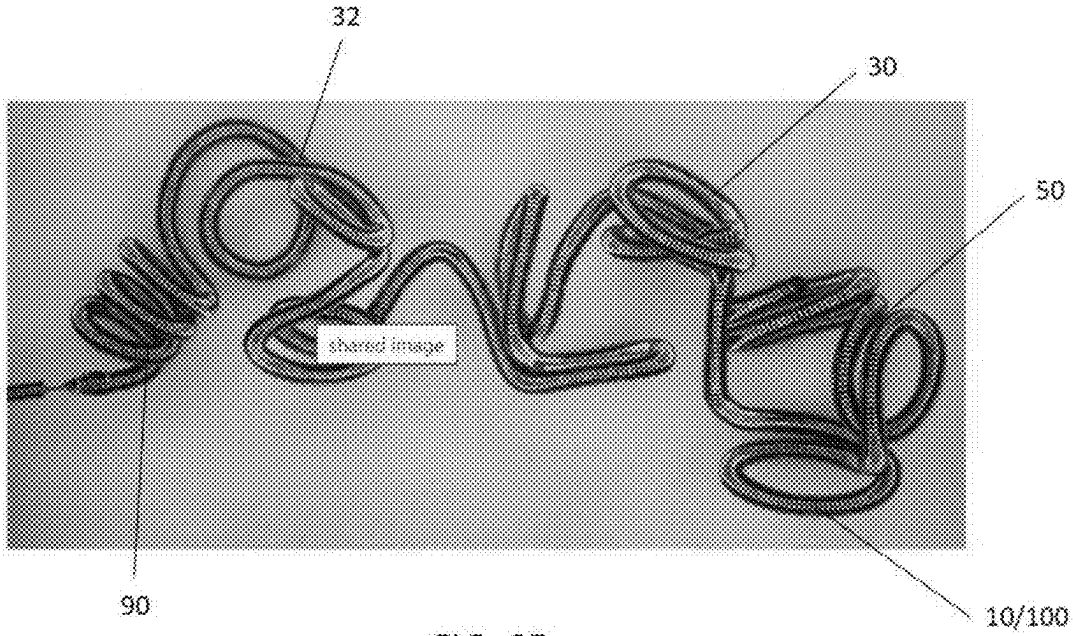


FIG. 25

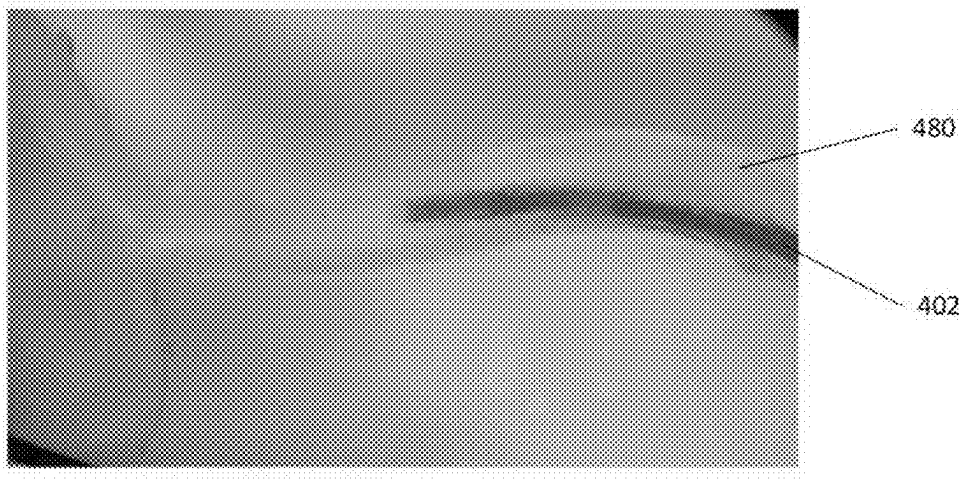


FIG. 26A

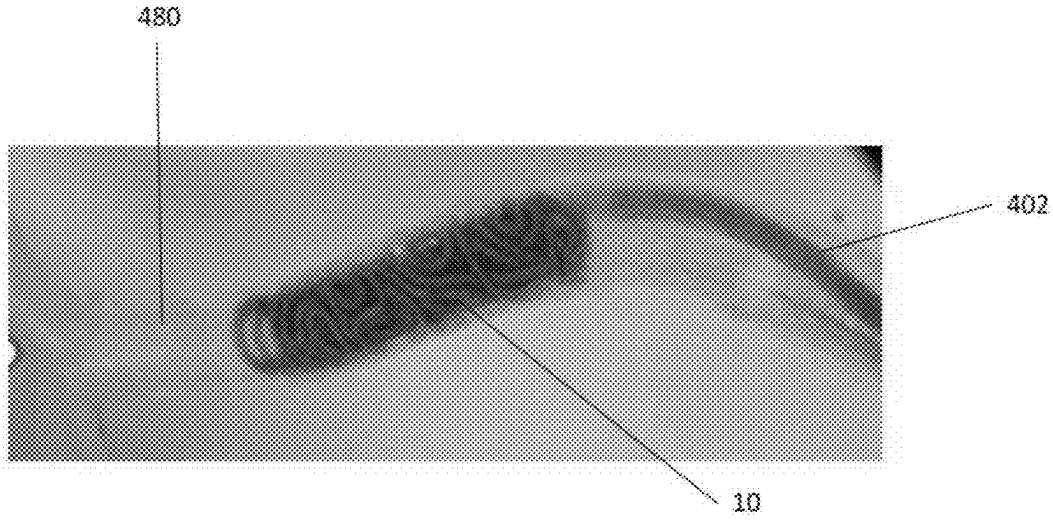


FIG. 26B

VASO-OCCLUSIVE DEVICES FOR OCCLUDING BLOOD VESSELS AND METHODS FOR MAKING AND USING SAME

RELATED APPLICATION DATA

[0001] The application is a continuation-in-part of U.S. patent application Ser. No. 18/667,790 filed on May 17, 2024, pending, which is a continuation of International Patent Application No. PCT/US2022/078935 filed on Oct. 28, 2022, which claims priority to and the benefit of U.S. Provisional Patent Application No. 63/281,561 filed on Nov. 19, 2021. The entire disclosures of the above applications are expressly incorporated by reference herein.

FIELD

[0002] The present disclosure relates generally to medical devices and intravascular medical procedures and, more particularly, to devices for occluding vasculature, such as blood vessels, and methods for making and using such devices.

BACKGROUND

[0003] Vaso-occlusive devices or implants are used for a wide variety of reasons, including treatment of intra-vascular aneurysms. An aneurysm is a dilation of a vessel, such as a blood vessel, that may pose a risk to a patient's health due to rupture, clotting, or dissection. For example, rupture of an aneurysm in a patient's brain may cause a stroke, and lead to brain damage and death. Cerebral aneurysms may be detected in a patient, e.g., following seizure or hemorrhage, and may be treated by applying vaso-occlusive devices.

[0004] Commonly used vaso-occlusive devices include soft, helically wound coils formed by winding a platinum (or platinum alloy) wire strand about a "primary" mandrel. The coil is then wrapped around a larger, "secondary" mandrel, and heat treated to impart a secondary shape. For example, U.S. Pat. No. 4,994,069, issued to Ritchart et al., which is fully incorporated herein by reference as though set forth in full, describes a vaso-occlusive device that assumes a linear, helical primary shape when stretched for placement through the lumen of a delivery catheter, and a folded, convoluted secondary shape when released from the delivery catheter and deposited in the vasculature. In order to better frame and fill aneurysms, complex three-dimensional secondary shapes can be imparted on vaso-occlusive devices and the stiffness/flexibility of vaso-occlusive devices can be modified.

[0005] In order to deliver the vaso-occlusive devices to a desired site in the vasculature, e.g., within an aneurysmal sac, it is known to first position a small profile delivery catheter or "micro-catheter" at the site using a guidewire. Typically, the distal end of the micro-catheter is provided, either by the attending physician or by the manufacturer, with a selected pre-shaped bend, e.g., 45°, 26°, "J", "S", or other bending shape, depending on the particular anatomy of the patient, so that it will stay in a desired position for releasing one or more vaso-occlusive device(s) into the aneurysmal sac once the guidewire is withdrawn. A delivery or "pusher" assembly or "wire" is then passed through the micro-catheter until a vaso-occlusive device coupled to a distal end of the delivery assembly is extended out of the distal end opening of the micro-catheter and into the aneurysmal sac. Once in the aneurysmal sac, portions of the vaso-occlusive device may deform or bend to allow more efficient and complete packing. The vaso-occlusive device is then released or "detached" from the distal end of the delivery assembly, and the delivery assembly is withdrawn back through the micro-catheter. Depending on the particular needs of the patient, one or more additional vaso-occlusive devices may be pushed through the micro-catheter and released into the same aneurysmal sac.

[0006] Fluoroscopy is typically used to visualize vaso-occlusive devices during delivery into an aneurysm, while magnetic resonance imaging (MRI) is typically used to visualize the treatment site post-procedure (e.g., a few weeks after initial treatment of the aneurysm) to ensure that the aneurysmal sac is properly occluded. As such, it is important that vaso-occlusive devices be constructed in a manner that enables their radiopacity during treatment of the aneurysm, while minimizing any visualization obscuring artifacts created during the post-procedure MRI (i.e., being MRI-compatible). It is also preferable that such vaso-occlusive devices be "soft" (i.e., be laterally flexible or conformable), and thus atraumatic, to prevent rupturing of the delicate tissues of the aneurysm.

[0007] In some cases, vaso-occlusive devices are utilized to occlude blood vessels. In such cases, physicians may use vaso-occlusive devices designed for treating aneurysms to occlude blood vessels. However, because blood vessels and aneurysms have different anatomical shapes, use of aneurysm vaso-occlusive devices for blood vessel treatment may not provide adequate treatment outcome. For example, because aneurysm vaso-occlusive devices are designed to occupy a small, isolated space inside the aneurysm, they may not have the sufficient implant length to occlude a blood vessel. As a result, the physician may use multiple aneurysm vaso-occlusive devices to occlude a blood vessel, thereby lengthening a procedure time. Because the aneurysm vaso-occlusive devices do not have a shape to sufficiently anchor the vaso-occlusive devices against the wall of the blood vessel, the delivered vaso-occlusive devices may become loose and may migrate along the blood vessel after implantation.

[0008] Thus, new vaso-occlusive devices that address the above concerns are desirable.

SUMMARY

[0009] A vaso-occlusive device includes: an elongated member having a primary configuration when the vaso-occlusive device is in a constrained condition; wherein the elongated member forms a three-dimensional structure having a secondary configuration when the vaso-occlusive device is in an unconstrained condition, the three-dimensional structure comprising: a first pyramidal portion comprising a first set of at least three first loops lying within at least three different respective first planes that are non-parallel and non-perpendicular with respect to each other; and a first helical section formed from the wire and extending proximally from the first pyramidal portion.

[0010] Optionally, the first pyramidal portion has 3 lateral faces forming a tetrahedral shape.

[0011] Optionally, the first pyramidal shape has 4 lateral faces forming a pentahedral shape.

[0012] Optionally, the three-dimensional structure further comprises a second pyramidal portion comprising a second set of at least three second loops lying within at least three

different respective second planes that are non-parallel and non-perpendicular with respect to each other.

[0013] Optionally, the three-dimensional structure comprises a second helical section extending from the second pyramidal portion.

[0014] Optionally, the second helical section has a longitudinal length that is longer than a cross-sectional width of the second pyramidal portion of the three-dimensional structure.

[0015] Optionally, the elongated member is a primary coil.

[0016] Optionally, the first helical section comprises a first secondary coil formed by a first segment of the primary coil, wherein the first pyramidal portion is formed by a second segment of the primary coil, and the second pyramidal portion is formed by a third segment of the primary coil.

[0017] Optionally, the first pyramidal portion has a cross-sectional dimension that is larger than a cross-sectional dimension of the second pyramidal portion.

[0018] Optionally, the elongated member is a primary coil, and wherein a segment of the primary coil forming the first portion comprises: a stretch-resistance member located within a lumen of the primary coil; or a stiffening coil located within the lumen of the primary coil.

[0019] Optionally, the elongated member is a primary coil, wherein a first segment of the primary coil forming the first pyramidal portion has a first coil-wire diameter, and wherein a second segment of the primary coil forming the second pyramidal portion has a second coil-wire diameter that is less than the first coil-wire diameter.

[0020] Optionally, the three-dimensional structure comprises a third pyramidal portion, and a second helical section disposed between the second pyramidal portion and the third pyramidal portion; and wherein the third pyramidal portion comprises at least three third loops lying within at least three different respective third planes that are non-parallel and non-perpendicular with respect to each other.

[0021] Optionally, the three-dimensional structure comprises a first anchor at a distal end of the vaso-occlusive device.

[0022] Optionally, the first anchor comprises a second helical section.

[0023] Optionally, the elongated member is a primary coil, and wherein a segment of the primary coil forming the first anchor comprises: a stretch-resistance member located within a lumen of the primary coil; or a stiffening coil located within the lumen of the primary coil.

[0024] Optionally, the elongated member is a primary coil, wherein a first segment of the primary coil forming the first pyramidal portion has a first coil-wire diameter, wherein a second segment of the primary coil forming the first anchor has a second coil-wire diameter that is larger than the first coil-wire diameter.

[0025] Optionally, the first anchor comprises a second pyramidal portion comprising third loops lying in different respective third planes that are non-parallel and non-perpendicular with respect to each other.

[0026] Optionally, the three-dimensional structure comprises a second anchor at a proximal end of the vaso-occlusive device.

[0027] Optionally, the secondary configuration comprises an elongated configuration configured to occlude a blood vessel.

[0028] A vaso-occlusive device includes: an elongated member having a primary configuration when constrained inside a delivery catheter; wherein the elongated member is configured to form a three-dimensional structure having a secondary configuration when deployed outside the delivery catheter; wherein the three-dimensional structure comprises a first portion having first loops, and a second portion having second loops; wherein the first loops of the first portion comprise a first set of at least three first loops lying within at least three different respective first planes that are non-parallel and non-perpendicular with respect to each other; and wherein the second loops of the second portion comprise a second set of at least three second loops lying within at least three different respective second planes that are non-parallel and non-perpendicular with respect to each other.

[0029] Optionally, the three-dimensional structure also comprises a first helical section disposed between the first portion and the second portion, wherein the first helical section comprises at least 1.0 turns.

[0030] Optionally, the first planes form a pyramidal shape.

[0031] Optionally, the pyramidal shape comprises a polyhedral shape formed of a polygonal base having n number of sides and n number of lateral faces connecting to an apex.

[0032] Optionally, the three-dimensional structure comprises a second helical section extending from the second portion.

[0033] Optionally, the second helical section has a longitudinal length that is longer than a cross-sectional width of the second portion of the three-dimensional structure.

[0034] Optionally, the elongated member is a primary coil.

[0035] Optionally, the first helical section comprises a first secondary coil formed by a first segment of the primary coil, wherein the first portion is formed by a second segment of the primary coil, and the second portion is formed by a third segment of the primary coil.

[0036] Optionally, the three-dimensional structure comprises a first anchor at a distal end of the vaso-occlusive device.

[0037] Optionally, the first anchor comprises a second helical section.

[0038] Optionally, the second helical section comprises a tapering portion.

[0039] Optionally, the first anchor comprises a second helical section, and wherein a cross-sectional dimension of the second helical section is equal to or larger than a cross-sectional dimension of the first portion of the three-dimensional structure.

[0040] Optionally, the elongated member is a primary coil, wherein a segment of the primary coil forming first anchor comprises: a stretch-resistance member located within a lumen of the primary coil; or a stiffening coil located within the lumen of the primary coil.

[0041] Optionally, the elongated member is a primary coil, wherein a first segment of the primary coil forming the first portion has a first coil-wire diameter, wherein a second segment of the primary coil forming the first anchor has a second coil-wire diameter that is larger than the first coil-wire diameter.

[0042] Optionally, the first anchor comprises a third portion comprising third loops lying in different respective third planes that are non-parallel and non-perpendicular with respect to each other.

[0043] Optionally, the three-dimensional structure comprises a second anchor at a proximal end of the vaso-occlusive device.

[0044] Optionally, the first portion has a cross-sectional dimension that is larger than a cross-sectional dimension of the second portion.

[0045] Optionally, the elongated member is a primary coil, and wherein a segment of the primary coil forming the first portion comprises: a stretch-resistance member located within a lumen of the primary coil; or a stiffening coil located within the lumen of the primary coil.

[0046] Optionally, the elongated member is a primary coil, wherein a first segment of the primary coil forming the first portion has a first coil-wire diameter, and wherein a second segment of the primary coil forming the second portion has a second coil-wire diameter that is less than the first coil-wire diameter.

[0047] Optionally, the three-dimensional structure comprises a third portion having third loops, and a second helical section disposed between the second portion and the third portion; and wherein the third loops comprise at least three third loops lying within at least three different respective third planes that are non-parallel and non-perpendicular with respect to each other.

[0048] Optionally, the secondary configuration comprises an elongated configuration configured to occlude a blood vessel.

[0049] A vaso-occlusive device includes: an elongated member having a primary configuration when constrained inside a delivery catheter; wherein the elongated member is configured to form a three-dimensional structure having a secondary configuration when deployed outside the delivery catheter; wherein the three-dimensional structure comprises a first portion having first loops, and a second portion having second loops; wherein the first loops comprise a first set of at least three first loops lying within at least three different respective first planes that are non-parallel and non-perpendicular with respect to each other; wherein the second loops comprise a second set of at least three first loops lying within at least three different respective second planes that are non-parallel and non-perpendicular with respect to each other; and wherein the secondary configuration comprises an elongated configuration configured to occlude a blood vessel.

[0050] Other and further aspects and features of embodiments of the disclosed inventions will become apparent from the ensuing detailed description in view of the accompanying figures.

BRIEF DESCRIPTION OF DRAWINGS

[0051] The drawings illustrate the design and utility of various aspects of the devices and methods disclosed herein, in which similar elements are referred to by common reference numerals. It should be noted that elements of similar structures or functions are represented by like reference numerals throughout the figures. It should also be noted that the figures are only intended to facilitate the description of the various aspects of the disclosed technology. They are not intended as an exhaustive description of the technology or as a limitation on the scope of the technology, which is defined only by the appended claims and their equivalents. In addition, an illustrated example of the disclosed technology need not have all the aspects or advantages shown or described herein. An aspect or an advantage described in conjunction with a particular example of the disclosed technology is not necessarily limited to that example and can be practiced in any other examples even if not so illustrated or explicitly described. In order to better appreciate how the above-recited and other advantages and objects of the present technology are obtained, a more particular description of the present technology briefly described above will be rendered by reference to specific examples thereof, which are illustrated in the accompanying drawings. With the understanding that these drawings and corresponding description depict only illustrative examples of the disclosed technology and are not therefore to be considered limiting of its scope, the technology will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0052] FIG. **1** illustrates a vaso-occlusive device configured to occlude a blood vessel.

[0053] FIG. **2** illustrates the vaso-occlusive device of FIG. **1**, particularly showing the vaso-occlusive device further having a distal anchor.

[0054] FIGS. **3**A-**3**D illustrate different techniques for implementing the distal anchor of FIG. **2**.

[0055] FIG. **4** illustrates the vaso-occlusive device of FIG. **2**, particularly showing the vaso-occlusive device further having a proximal helical section.

[0056] FIG. **5** illustrates the vaso-occlusive device of FIG. **4**, particularly showing the vaso-occlusive device further having additional portion and additional helical section.

[0057] FIGS. **6**A-**6**C illustrate variation of the vaso-occlusive device of FIG. **5**.

[0058] FIG. **7** is a side, perspective view of a part of the vaso-occlusive device of FIG. **1** in a relaxed, deployed configuration.

[0059] FIG. **8**A is a top perspective view of a simplification of the intersecting planes of the 3 loops forming a pyramidal portion of a vaso-occlusive device in the shape of a triangular pyramid.

[0060] FIG. **8**B is a top perspective view of a simplification of the intersecting planes of 4 loops forming a pyramidal portion of a vaso-occlusive device in the shape of a square pyramid.

[0061] FIG. **9** is a side view of post for forming a loop of a vaso-occlusive device, particularly illustrating the tapering angle for the loop.

[0062] FIG. **10** is a side, perspective view of an example of an alternative pyramidal portion of the vaso-occlusive device of FIG. **1** in which the loops have varying diameters and varying numbers of turns.

[0063] FIG. **11**A is a side, perspective view of an exemplary mandrel for making a part of the vaso-occlusive device of FIG. **1**.

[0064] FIG. **11**B is a side, perspective view of an exemplary mandrel for making a part of a vaso-occlusive device having 4 loops forming the pyramidal portion in the shape of a square pyramid.

[0065] FIG. **12**A is a top, perspective view of the mandrel of FIG. **11**A with a wire wound around the mandrel to make a part of the vaso-occlusive device of FIG. **1**.

[0066] FIG. **12**B is a side, perspective view of the mandrel of FIG. **12**A with the wire wound around the mandrel to make the vaso-occlusive device of FIG. **1**.

[0067] FIG. **13** is a flow chart showing a method of making the vaso-occlusive devices described herein using the mandrels described herein.

[0068] FIG. **14** illustrates an example of a mandrel being utilized to make the vaso-occlusive device of FIG. **5**.

[0069] FIG. **15** illustrates a prototype of the vaso-occlusive device of FIG. **5**.

[0070] FIG. **16**A illustrates a catheter being utilized to deliver a vaso-occlusive device into a model of a blood vessel

[0071] FIG. **16**B illustrates a vaso-occlusive device delivered out of a catheter into a model of a blood vessel.

[0072] FIG. **17**A is a cross-sectional side view of a vaso-occlusive system including the vaso-occlusive device of FIG. **1** in its constrained, delivery configuration within a delivery catheter.

[0073] FIG. **17**B is a cross-sectional, side view of the vaso-occlusive system of FIG. **17**A with the vaso-occlusive device deployed out of the delivery catheter and in its expanded, deployed configuration.

[0074] FIG. **18** is a flow chart of an exemplary method of using the vaso-occlusive system of FIGS. **17**A and **17**B to deploy the vaso-occlusive devices disclosed herein into a blood vessel.

[0075] FIG. **19** illustrates another vaso-occlusive device configured to occlude a blood vessel.

[0076] FIG. **20** illustrates a variation of the vaso-occlusive device of FIG. **19**, particularly showing a portion of the vaso-occlusive device being implemented as an anchor.

[0077] FIG. **21** illustrates the vaso-occlusive device of FIG. **20**, particularly showing the vaso-occlusive device having a proximal helical section.

[0078] FIG. **22** illustrates the vaso-occlusive device of FIG. **21**, particularly showing the vaso-occlusive device having additional portions.

[0079] FIG. **23** illustrates a variation of the vaso-occlusive device of FIG. **22**, particularly showing the vaso-occlusive device having no proximal helical section.

[0080] FIG. **24** illustrates an example of a mandrel being utilized to make the vaso-occlusive device of FIG. **22**.

[0081] FIG. **25** illustrates a prototype of the vaso-occlusive device of FIG. **22**.

[0082] FIG. **26**A illustrates a catheter being utilized to deliver a vaso-occlusive device into a model of a blood vessel

[0083] FIG. **26**B illustrates a vaso-occlusive device delivered out of a catheter into a model of a blood vessel.

DETAILED DESCRIPTION

[0084] Various embodiments are described hereinafter with reference to the figures. Like reference numerals refer to like elements throughout. Like elements will, thus, not be described in detail with respect to the description of each figure. It should also be noted that the figures are only intended to facilitate the description of the embodiments. They are not intended as an exhaustive description of the claimed invention or as a limitation on the scope of the claimed invention. In addition, an illustrated embodiment needs not have all the aspects or advantages shown. An aspect or an advantage described in conjunction with a particular embodiment is not necessarily limited to that embodiment and can be practiced in any other embodiments even if not so illustrated, or if not so explicitly described.

[0085] FIG. **1** illustrates a vaso-occlusive device **10** configured to occlude a blood vessel. The vaso-occlusive device **10** is configured for placement in a main lumen of the blood vessel. For example, in some cases, the vaso-occlusive device **10** may be utilized to treat tumor or cancer by blocking blood flow through the blood vessel that supplies blood to the tumor or cancer.

[0086] As shown in the figure, the vaso-occlusive device **10** includes an elongated member **16** extending between a distal end **12** and a proximal end **14** of the vaso-occlusive device **10**. The terms "distal" and "proximal" as used herein are relative to the vaso-occlusive device **10** as it is intended to be deployed, wherein the term "distal" refers to being situated toward the end of the device **10** which is inserted first, and "proximal" refers to being situated toward the end of the device **10** which is inserted last. The elongated member **16** may be bent or stretched to a primary configuration when constrained inside a delivery catheter. As shown in the figure, the elongated member **16** is configured to form a three-dimensional structure **18** having a secondary configuration when deployed outside the delivery catheter. The three-dimensional structure **18** includes a first portion **20** having first loops, a second portion **30** having second loops, and a first helical section **40** disposed between the first portion **20** and the second portion **30**. The first helical section **40** has at least 1.0 turns. In some cases, the first helical section **40** may have a number of turns that is anywhere from 1.0 turns to 20 turns (or more). The number of first loops of the first portion **20** is at least three (four first loops are shown in the example). The at least three first loops lie within at least three different respective first planes that are non-parallel and non-perpendicular with respect to each other. The number of second loops of the second portion **30** is at least three (four second loops are shown in the example). The at least three second loops lie within at least three different respective second planes that are non-parallel and non-perpendicular with respect to each other.

[0087] In the illustrated example, the loops of the first portion **20** lie in different respective planes that form a pyramidal shape. The pyramidal shape may be a polyhedral shape formed of a polygonal base having n number of sides and n number of lateral faces connecting to an apex. By means of non-limiting examples, the polyhedral shape may be a tetrahedral shape (triangular base and 3 lateral faces, also referred to as a triangular pyramid), pentahedral shape (quadrilateral base and 4 lateral faces, also referred to as a square or rectangular pyramid), hexahedral shape (pentagonal base and 5 lateral faces, also referred to as a pentagonal pyramid), etc. In the illustrated example, the pyramidal shape formed by the planes associated with the loops of the first portion **20** has a base, and three lateral sides. Alternatively, the pyramidal shape formed by the planes associated with the loops of the first portion may have a base, and four lateral sides. In further cases, the pyramidal shape of the first portion **20** may not include the base. For example, the pyramidal shape of the first portion **20** may include only first loops lying in respective planes that correspond with lateral sides of the pyramidal shape.

[0088] Similarly, the loops of the second portion **30** lie in different respective planes that form a pyramidal shape. The pyramidal shape may be a polyhedral shape formed of a polygonal base having n number of sides and n number of lateral faces connecting to an apex. By means of non-limiting examples, the polyhedral shape may be a tetrahedral shape (triangular base and 3 lateral faces, also referred to as a triangular pyramid), pentahedral shape (quadrilateral base and 4 lateral faces, also referred to as a square or rectangular pyramid), hexahedral shape (pentagonal base and 5 lateral

faces, also referred to as a pentagonal pyramid), etc. In the illustrated example, the pyramidal shape formed by the planes associated with the loops of the first portion **30** has a base, and three lateral sides. Alternatively, the pyramidal shape formed by the planes associated with the loops of the first portion may have a base, and four lateral sides. In further cases, the pyramidal shape of the second portion **30** may not include the base. For example, the pyramidal shape of the second portion **30** may include only first loops lying in respective planes that correspond with lateral sides of the pyramidal shape.

[0089] In the illustrated example, one or each of the loops in the first portion **20** and the second portion **30** is a closed loop. In other cases, one or each of the loops in the first portion **20** and the second portion **30** may be an open loop. In some cases, a loop for the first portion **20** or the second portion **30** may be created by the elongated member **16** forming one or more turns (e.g., 1 turn, 1.5 turn, 2 turns, 3 turns, etc.) for the loop. The loop diameter can be in the range of 0.5 mm to 15 mm, preferably 1 mm to 7 mm. In some cases, the loop diameter may be 90% to 160% of the target vessel diameter.

[0090] In some cases, the number of loops of the first portion **20** may be the same as the number of loops of the second portion **30**. In other cases, the number of loops of the first portion **20** may be different from the number of loops of the second portion **30**. This allows the vaso-occlusive device **10** to provide different filling characteristics (e.g., different packing densities) along a length of the blood vessel.

[0091] The first helical section **40** of the vaso-occlusive device **10** is configured to separate the first portion **20** and the second portion **30**, and to increase packing efficiency for the vaso-occlusive device **10**. In some cases, the first helical section **40** may optionally be configured to set a relative positioning (e.g., orientation) between the first portion **20** and the second portion **30**. Also, in some cases, the first helical section may be configured to provide some filing capability for the vaso-occlusive device **10**. In the illustrated example, the longitudinal length of the first helical section **40** is shorter than a cross-sectional dimension of the first portion **20** and/or the second portion **30**. In other cases, the longitudinal length of the first helical section **40** may be longer than the cross-sectional dimension of the first portion **20** and/or the second portion **30**. The first helical section **40** of the vaso-occlusive device **10** may be configured (e.g., by making it longer) to increase the packing density provided by the vaso-occlusive device **10**. The first helical section **40** can also prevent tangling between the loops of the first portion **20** with the loops of the second portion **30** when the device is pulled back into a delivery microcatheter.

[0092] As shown in the figure, the cross-sectional dimension of the first helical section **40** is less than the cross-sectional dimension of the first portion **20** and the second portion **30**. Such configuration is advantageous because it allows the first and second portions **20** and **30** to engage with the walls of the blood vessel at two different longitudinal locations along the blood vessel, while defining a space therebetween to be filled by the first helical section **40**. In some cases, if the first helical section **40** is made longer, the first helical section **40** may be folded, bent, twisted, curled up, etc., to occlude at least a part of the lumen of the blood vessel.

[0093] The total length of the entire portion **15** including the first portion **20**, the second portion **30**, the first helical portion **40**, and the proximal helical portion **90** of FIG. **4** is at least 1 cm, preferably at least 5 cm when the device is constrained in a delivery microcatheter.

[0094] In the illustrated example. The first portion **20**, the second portion **30**, and the first helical section **40** form a filling portion **15** for the vaso-occlusive device **10**. In some cases, the filling portion **15** has a bending stiffness (EI) that is less than 1.5×10^{-6} lb-in^2, and more preferably less than 1×10^{-6} lb-in^2. This is advantageous because it allows the filling portion **15** to be softer to thereby reduce the risk of rupturing the wall of the blood vessel during or after delivery of the vaso-occlusive device **10**. In other cases, the filling portion **15** has a bending stiffness (EI) that is more than 1.5×10^{-6} lb-in^2. Also, in some cases, the filling portion **15** may be soft enough to conform to a shape of the lumen of the blood vessel being occluded, and to form into a dense coil mass. The vaso-occlusive device **10** has an overall elongated configuration, which allows the vaso-occlusive device to more easily occlude a lumen of a blood vessel.

[0095] Portions **20** and **30** are configured to provide dense packing and contribute to anchoring of the occlusion plug, while the helical section **40** increases total device length for added occlusion plug density with minimal contribution to delivery friction. The helical section **40** also prevents tangling of the loops between portion **20** and portion **30**.

[0096] It should be noted that the first portion **20** is not limited to having the configurations described, and that the first portion **20** may have other configurations in other cases. For example, in other cases, the first portion **20** may have loops that form non-pyramidal shapes, such as a square shape, a random shape, etc. Similarly, the second portion **30** is not limited to having the configurations described, and that the second portion **30** may have other configurations in other cases. For example, in other cases, the second portion **30** may have loops that form non-pyramidal shapes, such as a square shape, a random shape, etc.

[0097] In the illustrated example, the elongated member **16** is a coil (e.g., a primary coil) formed by a coil wire. The primary coil can have an outside diameter from 0.005" to 0.030", preferably from 0.008" to 0.020" (e.g., 0.010", 0.014", etc.). In some cases, the primary coil may be formed by winding a coil wire with a diameter from 0.0005" to 0.005" over a mandrel with a diameter from 0.005" to 0.025". For example, the elongated member can be a coil formed by winding a wire diameter of 0.00175" over a mandrel with a diameter of 0.0102". The coil wire may have a circular cross-section, or a non-circular cross-section, such as an elliptical section, a polygonal section, etc.

[0098] The first portion **20** is formed by the primary coil bending into a number of loops. Similarly, the second portion **30** is formed by the primary coil bending into a number of loops. The first helical section **40** is also formed by the primary coil bending into a number of helical loops. Thus, the first portion **20**, the second portion **30**, and the first helical section **40** are formed by different respective segments of the elongated member **16**. Although not explicitly shown in the figure, it should be understood that there is a transition segment (a part of the elongated member **16**) extending or transitioning between first portion **20** and the first helical section **40**, and another transition segment (a part of the elongated member **16**) extending or transitioning between the first helical section **40** and the second portion **30**

of the vaso-occlusive device **10**. In other cases, the elongated member **16** may be a wire, a mesh, a braid, etc.

[0099] FIG. **2** illustrates the vaso-occlusive device **10** of FIG. **1**, particularly showing the vaso-occlusive device **10** further having an anchor **50**. The anchor **50** is at the distal end **12** of the vaso-occlusive device **10** and is configured to anchor against an interior wall of a blood vessel to be occluded by the vaso-occlusive device **10**. In the illustrated example, the anchor **50** is in a form of a helical section and may be formed by a segment of the elongated member **16**. In other cases, the anchor **50** may have other shapes, and/or may be separately connected (e.g., via adhesive, weld, solder, mechanical connector, etc.) to the first portion **20** of the vaso-occlusive device. The anchor **50** has a cross-sectional dimension that is equal to or larger than a maximum cross-sectional dimension of the filling portion **15** of the vaso-occlusive device. Alternatively, or additionally, the anchor **50** may have a compression stiffness (e.g., compression in a direction that is perpendicular to a longitudinal axis of the vaso-occlusive device **10**) that is higher than a compression stiffness of the filling portion **15** of the vaso-occlusive device **10**. In some cases, the anchor **50** may have a bending stiffness (EI) that is larger than 1.5×10^{-6} lb·in^2, and more preferably larger than 2×10^{-6} lb·in^2, and even more preferably larger than 2.5×10^{-6} lb·in^2. This is advantageous because it allows the anchor **50** to better anchor against the wall of the blood vessel. In other cases, the anchor may have a bending stiffness that is less than 1.5×10^{-6} lb·in^2.

[0100] The anchor **50** may be made of a biocompatible metallic material with recoverable strain >0.1%, and preferably >0.5%. The anchor **50** may be made from the same or different material of the portions **20**, **30** and the helical section **40** in the filling portion **15**. In some cases, the cross-sectional dimension (e.g., diameter) of the anchor **50** may be larger than a cross-sectional dimension of the target vessel to be occluded. For example, the anchor **50** may be 5% larger, or preferably 10% larger, or more preferably 10% to 60% larger than the cross-sectional dimension of the blood vessel to be occluded. This is to ensure that the anchor **50** will sufficiently anchor against the wall of the blood vessel.

[0101] FIGS. **3**A-**3**D illustrate different techniques for implementing the anchor **50** of FIG. **2**. As shown in FIG. **3**A, the elongated member **16** is a primary coil. In such cases, a segment of the primary coil **16** forming the anchor **50** has a stiffening coil **70** located within the lumen of the primary coil (the elongated member **16**). Alternatively, as shown in FIG. **3**B, a stretch-resistance member **72** may be provided within a lumen of the primary coil (the elongated member **16**) to stiffen the part of the primary coil forming the anchor **50**. As shown in FIG. **3**C, a first segment **82** of the primary coil forming the first portion **20** may have a first coil-wire diameter, and a second segment **80** of the primary coil forming the first anchor **50** may have a second coil-wire diameter that is larger than the first coil-wire diameter, to thereby provide a stiffer second segment **80** of the primary coil forming the anchor **50**. The segments **80**, **82** may be parts of the same primary coil. Alternatively, as shown in FIG. **3**D, the segments **80**, **82** may be different respective coils. In such cases, the segment **80** implementing the anchor **50** may be inserted into the lumen of the coil segment **82** forming the first portion **20**. The segments **80**, **82** may be welded together or secured to each other using other mechanisms, such as adhesive, or mechanical coupler. In further cases, a segment of the primary coil **16** forming the anchor **50** may be coated by a stiffening material to increase the stiffness of the segment. It should be noted that two or more of the above techniques may be employed together to implement the anchor **50**.

[0102] FIG. **4** illustrates the vaso-occlusive device **10** of FIG. **2**, particularly showing the vaso-occlusive device further having a proximal helical section **90**. The proximal helical section **90** is configured to enhance the occlusion capability of the vaso-occlusive device **10**. For example, the proximal helical section **90** may be configured to occlude additional part of the lumen of the blood vessel, and/or to increase the packing density for the vaso-occlusive device **10**. The proximal helical section **90** is illustrated as being shorter in the longitudinal direction than a cross-sectional dimension of the second portion **30**. In other cases, the proximal helical section **90** may be longer than the cross-sectional dimension of the second portion **30**. As shown in the figure, the cross-sectional dimension of the proximal helical section **90** is shorter than the cross-sectional dimension of the second portion **30**. This configuration allows the proximal helical section **90** to bent, fold, curl up, twist, etc. within a lumen of the blood vessel to occlude the blood vessel.

[0103] FIG. **5** illustrates the vaso-occlusive device **10** of FIG. **4**, particularly showing the vaso-occlusive device further having an additional portion **32** and an additional helical section **42**. In other cases, the vaso-occlusive device **10** may include more than one additional portion **32** (e.g., multiple additional portions **32**) and/or more than one additional helical section **42** (e.g., multiple additional helical sections **42**). Also, in other cases, the vaso-occlusive device **10** may not include the anchor **50** and/or the proximal helical section **90**.

[0104] In some cases, the vaso-occlusive device **10** may include a number of pyramidal portions (e.g., portions **20**, **30**, **32**) and a number of helical sections (e.g., helical sections **40**, **42**), wherein each helical section is disposed between two adjacent pyramidal portions. The number of pyramidal portions may be more than 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30. The number of portions may be selected to fit a particular application. For example, higher number of portions may be selected to fill a larger blood vessel, to achieve a higher occlusion, and/or to achieve a longer occluded segment along the blood vessel.

[0105] FIGS. **6**A-**6**C illustrate variations of the vaso-occlusive device **10** of FIG. **5**. As shown in FIG. **6**A, the anchor **50** of the vaso-occlusive device **10** may be implemented as a helical section having a tapering portion **52**. The tapering portion **52** is advantageous because it may prevent a part of the first portion **20** from entering into a lumen of the helical section forming the anchor **50**. In some cases, as shown in FIG. **3**D, the tapering section **52** of the anchor portion **50** may enter the lumen of the loops forming the first portion **20**. When this happens, it creates an interlock between the helical anchor segment **50** and the first portion **20** to enhance anchorability.

[0106] As shown in FIG. **6**B, instead of having the proximal helical section **90** that is configured to fill a lumen of a blood vessel, the vaso-occlusive device **10** may include an anchor **96** at a proximal end **14** of the vaso-occlusive device **10**. The anchor **96** may be implemented using any of the

techniques of FIGS. **3**A-**3**C. The anchor **96** is configured to improve an anchoring capability of the vaso-occlusive device **10**. Providing two anchors **50**, **96** at opposite ends of the vaso-occlusive device **10** is advantageous because they reduce the risk of the vaso-occlusive device **10** migrating along the blood vessel and provide two fixed anchoring positions that define a space to be occluded by the filling portion **15** of the vaso-occlusive device. As shown in FIG. **6**B, each of the anchors **50**, **96** has a tapering portion. The tapering portion is advantageous because it may prevent a part of the portion **20**/**32** from entering into a lumen of the helical section forming the anchor **50**/**96**. In some cases, as shown in FIG. **3**D, the tapering section **52** of the distal anchor portion **50** may enter the lumen of the loops forming the first portion **20**. Similarly, the tapering section of the proximal anchor portion **96** may enter the lumen of the loops forming the portion **32**. When this happens, it creates a distal interlock between the distal anchor portion **50** and the first portion **20** and a proximal interlock between the portion **32** and the proximal anchor portion **96**. Both distal and proximal interlocks enhance the anchorability of the occlusion device **10** within the vessel. Although the helical section **40**/**42** is illustrated as having a tapering portion at one end, in other cases, the helical section **40**/**42** may have tapering portions at opposite ends. In other cases, one or both of the anchors **50**, **96** may not have any tapering portion. In such cases, the anchor **50**/**96** may have a cross-sectional dimension that is uniform along a majority or an entirety of a length of the anchor. Also, as shown in FIG. **6**B, the helical sections **40**, **42** in the filler portion **15** have respective tapering portions. In other cases, each of the helical sections **40**, **42** in the filler portion **15** may have a cross-sectional dimension that is uniform along a majority or an entirety of a length of the helical section.

[0107] As shown in FIG. **6**C, in some cases, the vaso-occlusive device **10** may include a proximal helical section **90** (instead of the anchor **90**) at the proximal end **14** of the vaso-occlusive device **10**. The helical section **90** may include a tapering portion like that shown in the figure. The tapering portion may prevent a part of the portion **32** from entering into the lumen of the proximal helical section **90**. In other cases, the helical section **90** may have a cross-sectional dimension that is uniform along a majority or an entirety of a length of the helical section. The helical section **90** may have a length that is equal to, shorter or longer than, a cross-sectional dimension of the portion **20**/**30**/**32**. For example, in some cases, the helical section **90** may have a length that is 0.5, 1, 1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, etc. times the cross-sectional dimension of the portion **20**/**30**/**32**.

[0108] It should be noted that in the examples of FIGS. **2** and **4**-**6**C, the anchor **50** has a cross-sectional dimension (i.e. outside diameter) that is larger than that of the filling portion **15** (e.g., larger than the portion **20**/**30**/**32**). In some cases, the cross-sectional dimension of the anchor **50** may be 5% larger, or 10% larger, or 20% larger than the cross-sectional dimension of the portion **20**/**30**/**32**. Also, the portions **20**, **30**, **32** in the filling portion **15** may have the same size, or may have different respective sizes. In some cases, the size of the portions **20**, **30**, **32** in the vaso-occlusive device **10** of FIGS. **2** and **4**-**6**C may decrease from the distal end towards the proximal end. Thus, the cross-sectional dimension of the portion **20** may be larger than the cross-sectional dimension of the portion **30**, and the cross-sectional dimension of the portion **30** may be larger than the cross-sectional dimension of the portion **32**.

[0109] As described, the portion **20**/**30** of the vaso-occlusive device **10** may be a pyramidal portion. FIG. **7** illustrates an example of a pyramidal portion **104** of a vaso-occlusive device **100**. The vaso-occlusive device **100** may be any of the vaso-occlusive devices **10** described herein, and the pyramidal portion **104** may be an example of the portion **20**, **30**, **32**, etc. In particular, FIG. **7** depicts a portion of the vaso-occlusive device **100** in its secondary configuration in a relaxed, unconstrained condition. In other words, FIG. **7** shows the portion of the vaso-occlusive device **100** when there are no external forces exerting on the portion of the vaso-occlusive device **100**. The secondary configuration of the portion of the vaso-occlusive device **100** has a pyramidal portion **104** and a helical section **106**. The helical section **106** may be an example of the first helical section **40** described herein. In other cases, the vaso-occlusive device **100** may not include the helical section **106**.

[0110] The vaso-occlusive **100** comprises a wire **102** having a primary configuration in a constrained configuration. The wire **102** may be the elongated member **16** described herein. For instance, the constrained configuration may be an elongate, helical coil when the wire **102** is constrained within a delivery catheter (see FIG. **17**A). The primary shape may have a longitudinal length anywhere between 1 cm to 100 cm. The wire **102** is made from any suitable material, such as a radiopaque, shape memory material. By means of non-limiting examples, the material of the wire **102** may be platinum group metals, including platinum, rhodium, palladium, and rhenium, as well as tungsten, gold, silver, tantalum, and alloys of these metals. In one specific example, the wire **102** may be made from Pt-8% W. In some cases, the material of the wire **102** may have a yield strain >0.1%, and preferably >0.5%. Also, the material of the wire **102** may have a tensile strength that is larger than 150 Ksi, with elongation larger than 1% to ensure manufacturability. In other cases, the material of the wire **102** may have other mechanical properties that are different from the above examples.

[0111] The pyramidal portion **104** of the vaso-occlusive device **100** includes a plurality of loops **108** wound from the wire **102**. In the illustrated example of FIG. **7**, the pyramidal portion **104** includes three loops **108***a*, **108***b*, and **108***c* lying in respective planes corresponding to three lateral sides of a pyramidal shape. The pyramidal portion **104** does not include any loop lying in a plane corresponding with the base of the pyramidal shape. However, in other cases, the pyramidal portion **104** may include a fourth loop lying in a plane corresponding with the base of the pyramidal shape. he respective planes in which the loops **108** lie are non-parallel, non-perpendicular, and intersect with each other. As depicted in FIG. **8**A, a simplification of the intersecting planes of the loops **108** forms a tetrahedral, more specifically, a triangular pyramid. The vaso-occlusive device **100** of FIG. **7** is an example and is not limited to loops **108** forming a triangular pyramid shape, but may be other suitable pyramidal shapes, such as n number of loops **108** forming a pyramid having a polygonal base having n number of sides and n number of lateral faces connecting to an apex. For instance, the vaso-occlusive device **100** may have loops **108** in each lateral face of a pyramidal shape which may be a square pyramid having a square base and 4 lateral

faces, a quadrilateral pyramid having a quadrilateral base and 4 lateral faces, a pentagonal pyramid having a pentagonal base and 5 lateral faces, etc. As depicted in FIG. **8**B, the pyramidal portion **104** may have 4 loops **108** in each lateral face arranged to form a square pyramid having a square base and 4 lateral faces.

[0112] Turning back to FIG. **7**, each loop **108** includes a winding forming a closed loop of greater than 360°, i.e., at least a complete, closed loop. In the illustrated vaso-occlusive device **100**, each loop **108** includes a winding of 1⅔ loops (also referred to as "turns"), which is equivalent to a winding of 600°. Alternatively, each loop **108** may have at least 1⅔ turns, or between 1⅔ turns (600°) and 2 turns (720°).

[0113] The winding of each of the loops **108** also has a width which tapers outwardly from a reference point of the interior of the pyramidal portion. In the case of a helical coil as depicted in the example of FIG. **7**, the width of each loop **108** is the diameter of the turn. If the loops **108** are wound in a different shape, such as a square, pentagon, or other polygonal or curved shape, the width may be an average width, such an average of the maximum and minimum width drawn through the geometric center of the shape. Turning the example of FIG. **7**, the diameter of each loop **108** tapers such that the diameter of the outer part of the loop **108** is larger than the diameter of the inner part of the loop **108**. This may be better explained with reference to a cross-section of a cylindrical post of a mandrel upon which the wire **102** is wound to form a loop **108**, as shown in FIG. **9**. The post has a diameter which tapers outwardly from the inner part of the post to the outer part of the post, as depicted in FIG. **9**. The angle **114** of the post taper defines the angle of the taper of the loop **108** in the secondary configuration of the vaso-occlusive device **100**. Due to the outwardly tapering diameter, the turns of each of the loops **108** is inward facing. In other words, the surface of the loops faces inward toward the geometric interior of the pyramidal shape of the pyramidal portion **104**. Thus, in some embodiments, each loop has more than one turn that increases in size (e.g., hoop diameter) such that the hoop diameter of a turn closer to a periphery of the pyramidal portion is larger than the hoop diameter of a turn further away from the periphery of the pyramidal portion. In other cases, each loop may have more than one turn having a same size (e.g., hoop diameter).

[0114] Each of the loops **108** has a diameter (defined as the diameter of the inner most turn of each loop **108**) between 90 to 160 percent of a diameter of a blood vessel the vaso-occlusive device **100** is designed to occlude. Preferably, the diameter of each loop **108** may be between 100 to 130 percent of a diameter of a blood vessel the vaso-occlusive device **100** is designed to occlude.

[0115] In an alternative design of the vaso-occlusive device **100**, the loops **108** may have differing diameters and/or differing numbers of turns of the wire (e.g., the wire **102** of FIG. **7**), as illustrated in FIG. **10**. As shown in FIG. **10**, the first loop **108***a* has a larger diameter and more turns of the wire **102** (3 turns, i.e., 1080°) than the second loop **108***b* which has 1⅔ turns (600°). The third loop **108***c* also has a larger diameter than the second loop **108***b* (same diameter as the first loop **108***a* and 1⅔ turns (600°).

[0116] The pyramidal portion **104** also includes a respective transition segment **110** of the wire **102** which is between and connecting each adjacent loop **108** to each other. Each transition segment **110** extends from the ending of one loop **108** to the beginning of the subsequent loop **108**. Hence, the transition segment **110***a* extends from the ending of the first loop **108***a* to the beginning of the second loop **108***b*, and the transition segment **110***b* extends from the ending of the second loop **108***s* to the beginning of the third loop **108***c*.

[0117] There is also a transition segment **112** from the ending of the third loop **108***c* winding to the beginning of the helical section **106**, which may be an example of the first helical section **40**. The helical section **106** comprises a winding of the wire **102** which extends proximally from the pyramidal shape **104**. The helical section **106** may extend from the imaginary base of the pyramidal shape of the pyramidal portion **104**. In the illustrated example of FIG. **7**, the helical section **106** has a constant diameter. Alternatively, the helical section **106** may have a diameter which tapers outwardly or inwardly as it extends from the proximally from the pyramidal portion **104**. The helical section **106** comprises at least one full loop of the wire **102**. The helical section **106** does not have a maximum degree of winding and may include any suitable number of turns, such as between 1 and 200 turns. The helical section **106** depicted in FIG. **7** has about 2 full turns of the wire **102**. The helical section **106** depicted in FIG. **10** has about 4 full turns of the wire **102**.

[0118] In other cases, the vaso-occlusive device **100** may not include the helical section **106**. Also, in further cases, the vaso-occlusive device **100** may include an additional pyramidal portion **100**. In such cases, the transition segment **112** may extend from the third loop **108***c* (or a last loop of the first pyramidal portion **100**) to a first loop of the additional pyramidal portion **100**. Furthermore, in other cases, the pyramidal portion **100** may include a loop forming the base of the pyramidal portion **100**. In such cases, the transition segment **112** transitions to the loop forming the base of the pyramidal portion **100**.

[0119] The pyramidal shape formed by the loops **108** of the vaso-occlusive device **100** has an inherent ability to effectively dissipate forces applied to the vaso-occlusive device **100**, thereby reducing the risk of imparting excessive forces on the walls of the blood vessel which could rupture the blood vessel. Furthermore, the loops **108** are tapered to be inwardly facing and comprise full, closed loops and crossing, overlapping segments which fold more tightly than open loops when deployed in a blood vessel, thereby reducing the risk of herniation during placement. At the same time, shape stability is not compromised because of the inherent ability of the pyramidal shape to dissipate forces applied at the narrow end of the pyramidal shape (e.g., corresponding with the apex of the pyramidal shape). Furthermore, as illustrated in FIG. **7**, the pyramidal shaped vaso-occlusive device **100** is more compact than a cube shaped vaso-occlusive device having 8 coils forming the 8 sides of a cube. In other words, the volume of the pyramidal shaped vaso-occlusive device **100** has a smaller volume than a cube.

[0120] FIG. **8**A is a top perspective view of a simplification of the intersecting planes of the 3 loops of FIG. **7** forming the pyramidal portion of the vaso-occlusive device **10** in the shape of a triangular pyramid. FIG. **8**B is a top perspective view of a simplification of the intersecting planes of 4 loops forming the pyramidal portion of a vaso-occlusive device **10** in the shape of a square pyramid.

[0121] It should be noted that the loops of a portion (e.g., portion **20**, **30**, **32**, etc.) of the vaso-occlusive device **10** may

have the same size and same number of turns. In other cases, two or more of the loops of a portion (e.g., portion **20**, **30**, **32**, etc.) of the vaso-occlusive device **10** may have different respective sizes and/or different respective numbers of turns. FIG. **10** is a side, perspective view of an example of an alternative pyramidal portion of the vaso-occlusive device **10** of FIG. **1** in which the loops have varying diameters and varying numbers of turns.

[0122] Turning to FIG. **11**A, an exemplary mandrel **200** for making a portion (e.g., portion **20**, **30**, **32**, etc.) of the vaso-occlusive device **10** using a method **300** (described below) is illustrated. The mandrel **200** is used to wind the wire **102** (which may be an example of the elongated member **16**) around to form the secondary configuration of the vaso-occlusive device **10**. The mandrel **200** is configured to form a vaso-occlusive device **10** comprising a pyramidal portion having a triangular pyramid shape.

[0123] The mandrel **200** has a central, spherical element **202**. A plurality of posts **204** extend outwardly from the central spherical element **202**. The posts **204** are configured to form the loops of a portion (e.g., portion **20**, **30**, **32**, etc.) of the vaso-occlusive device **10**. The posts **204** are spaced angularly around the spherical element **202**. In the depicted mandrel **200**, the posts **204** are evenly spaced such that a respective longitudinal axis of each loop is evenly, angularly spaced around the spherical element **202**. Accordingly, in the case of three posts **204**, the posts **204** are spaced apart by 120°.

[0124] Each post **204** has a cross-sectional diameter which tapers outwardly as the post **204** extends away from the spherical element **202**, as shown in FIG. **9** which shows a side view of one of the posts **204**. The longitudinal axis of each post **204** is also canted distally such that respective planes perpendicular to each respective longitudinal axis are non-parallel and non-perpendicular and the planes have an intersection which forms a pyramidal shape having an apex distal to the posts **204**. In other cases, each post **204** may not have a taper configuration, and may instead have a constant cross-sectional dimension.

[0125] The mandrel **200** also has a body post **206** extending from the spherical element **202**. The body post **206** is configured to form a helical section (e.g., helical section **40**) of the vaso-occlusive device **100**. In the illustrated example of FIG. **11**A, the body post **206** extends proximally from the spherical element **202**. The body post **206** may be a cylinder having a constant diameter, or alternatively, the body post **206** may taper outwardly or inwardly as it extends from the spherical element **202**.

[0126] The mandrel **200** includes additional set(s) of posts **204** (not shown) for forming an additional pyramidal portion of the vaso-occlusive device **100**. In particular, the mandrel **200** may include a first set of posts **204** (like that shown in FIG. **11**A), and a second set of posts **204** that are separated from the first set of posts **204** by the body post **206**.

[0127] With the assistance of the present description, one of ordinary skill in the art would appreciate how to modify the mandrel **200** to be configured to make a vaso-occlusive device **10** comprising a pyramidal portion having the other pyramid shapes disclosed herein. For instance, FIG. **11**B shows a mandrel **210** which is configured to make a vaso-occlusive device **10** comprising a pyramidal portion having a square pyramid shape. The mandrel **210** is same or substantially similar to the mandrel **200**, except that the mandrel **210** has four posts **204** evenly, angularly spaced around the central, spherical member **202**.

[0128] Turning to the illustrations in FIGS. **12**A-**12**B and the flow chart of FIG. **13**, an exemplary method **300** of making a part (e.g., portion **20**, **30**, **32**, etc.) of a vaso-occlusive device **10** using the mandrel **200** will now be described. A wire **102** (which may be an example of the elongated member **16**) having a primary configuration is wound around the mandrel **200**. As described herein, the wire **102** may be formed of a shape memory material, and the primary configuration may be a configuration of the wire **102** in a constrained condition, such as within a sheath or delivery catheter. The primary configuration of the wire **102** may have any suitable shape, such as a helical coil—in which case, the wire **102** may be a primary coil.

[0129] At step **302**, the wire **102** is first wound around the first post **108***a* in a first direction starting on the first post **108***a* and towards the intersection of the first post **204***a*, and the spherical element **202**. Subsequent windings start at the intersection of the post **204** and spherical element **202** and wind away from the spherical element **202**. As used herein, a winding "direction" is relative to viewing inwardly along the winding axis toward the position of the attachment of a winding post to the central, spherical element or other central structure. Thus, the "first direction" as shown in the example of FIGS. **12**A and **12**B is a clockwise direction. The wire **102** is wound around the first post **204***a* to form the desired degree of winding for the first loop **108***a*, as described herein.

[0130] After winding the wire **102** around the first post **204***a*, at step **304**, the wire **102** is traversed along the spherical element **202** forming the first transition segment **110***a* to the second post **108***b* immediately adjacent to the first post **108***a*. At step **306**, the wire **102** is wound around the second post **204***b* in a second direction opposite to the first direction (counterclockwise as shown in the example of FIGS. **12**A-**12**B) starting at the intersection of the second post **204***b* and the spherical element **202**. The wire **102** is wound around the second post **204***b* to form the desired degree of winding for the second loop **108***b*, as described herein.

[0131] After winding the wire **102** around the second post **204***b*, at step **308**, the wire **102** is traversed along the spherical element **202** forming the second transition segment **110***b* to the third post **204***c* immediately adjacent to the second post **204***b*. At step **310**, the wire **102** is wound around the third post **204***c* in a third direction opposite to the second direction (clockwise as shown in the example of FIGS. **12**A-**12**B) starting at the intersection of the third post **204***c* and the spherical element **202**. The wire **102** is wound around the third post **204***c* to form the desired degree of winding for the third loop **108***c*, as described herein.

[0132] Looking at a post **204** that is being wound axially along the axis of rotation, each of the three other posts **204** can be described at ⅓ rotations as the wire **102** is being wound. Accordingly, a winding of 1⅔ loops or turns (i.e., 600°) means that as the wire **102** is wound around the post **204**, each of the other posts **204**, **206** that are passed represents a winding of ⅓ of a loop or turn. Hence, a winding of 1⅔ loops passes the three other posts **204**, **206** once, and then re-passes 2 of the 3 other posts **204**, **206** for a total of 1⅔ loops. A winding of about 2⅔ (960°) passes each of the other posts **204**, **206** twice and then passes the next 2 posts a third time. The winding of a full loop (360°),

or multiple full loops (360°×a whole number) plus another ⅔ of a loop, positions the end of a loop **108** to wind in the opposite direction on the next adjacent post **204**.

[0133] In the case of a mandrel **200** having more than 3 posts **204**, at step **312**, the wire is **102** traversed along the spherical element **202** in a next transition segment **110** to a next post **204** immediately adjacent to the preceding post **204**. At step **314**, the wire is wound around the next post **204** to form the next loop **108**, and steps **312-314** are repeated for each additional post **204**. After winding the wire around the last of the posts **204**, at step **316**, the wire **102** is transitioned along the spherical element **202** to the body post **206**.

[0134] At step **318**, the wire **102** is wound around the body post **206** to form the desired degree of winding for the helical section (e.g., helical section **40**), as described herein. In some cases, if the vaso-occlusive device **10** does not include the helical section **40**, then the mandrel **200** may not include the body post **206**, and the method **300** may not include step **318**.

[0135] In some cases, if the vaso-occlusive device **10** has another pyramidal portion, after step **314**, steps **302-314** may be repeated using an additional set of posts **204** to form the other pyramidal portion.

[0136] At step **320**, the wire **102** is heat treated to set the secondary configuration of the vaso-occlusive device **10** as wound on the mandrel **200**. The wire **102** may then be removed from the mandrel **200** after heat treatment, and the wire **102** will take on the secondary configuration having the secondary shape as wound on the mandrel in its relaxed, unconstrained condition.

[0137] FIG. **14** illustrates an example of a mandrel **200** being utilized to make the vaso-occlusive device **10** of FIG. **5**. FIG. **15** illustrates a prototype of the vaso-occlusive device **10** of FIG. **5**. In the prototype, the anchor **50** is formed from a first segment of a primary coil made from Pt-8W. The primary coil's dimensions are 0.00175"×0.0102" (i.e., the coil is formed by winding a 0.00175" wire over a 0.0102" mandrel). The anchor **50** also includes an inner coil (which is an example of the inner coil **70** described with reference to FIG. **3**A) with the dimensions 0.00225"×0.005" (i.e., the coil is formed by winding a 0.00225" wire over a 0.005" mandrel). The anchor **50** has a helical shape, with a cross-sectional dimension of 2.25 mm, and a longitudinal length of 4 cm. The first portion **20**, the second portion **30**, and the third portion **32** of the prototype are formed from a second segment, a third segment, and a fourth segment, respectively, of the primary coil. Each of the first portion **20**, the second portion **30**, and the third portion **32** has a cross-sectional dimension of 2 mm. In the illustrated example, the total longitudinal length of all portions including the first portion **20**, the second portion **30**, and the third portion **32** is 10 cm. The helical sections **40**, **42** are formed from a fifth segment and a sixth segment, respectively, of the primary coil. Each of the helical sections **40**, **42** has a cross-sectional dimension of 2 mm and a longitudinal length of 3 cm. The proximal helical section **90** is formed from a seventh segment of the primary coil. The proximal helical section **90** has a cross-sectional dimension of 2 mm, and a longitudinal length of 8 cm.

[0138] FIG. **16**A illustrates a catheter **402** being utilized to deliver the prototype of the vaso-occlusive device **10** of FIG. **15** into a model of a blood vessel **480**. FIG. **16**B illustrates the vaso-occlusive device **10** delivered out of the catheter **402** into a model of a blood vessel **480**. As shown in the figure, the vaso-occlusive device **10** forms an elongated packed structure that at least partly occludes the blood vessel. The vessel shown in the FIG. **16** has an internal diameter (ID) of 2 mm and the delivered compact coil mass (i.e. dense coil mass) is expected to be around 12 mm. It should be pointed out that the vaso-occlusive device **10** can be used to occlude the vessel with ID ranging from 1.5 mm and 2.5 mm and the resulting dense coil mass is expected to be between 5 mm and 20 mm.

[0139] FIG. **17**A is a cross-sectional side view of a vaso-occlusive system including a vaso-occlusive device **100** (which may be any of the vaso-occlusive devices **10** described herein) in its constrained, delivery configuration within a delivery catheter. FIG. **17**B is a cross-sectional, side view of the vaso-occlusive system of FIG. **17**A with the vaso-occlusive device **100** deployed out of the delivery catheter and in its expanded, deployed configuration. As shown in FIGS. **17**A-**17**B, the vaso-occlusive device **100** may be a component of a vaso-occlusive system **400** which can be used to deploy the vaso-occlusive device **100** into a body cavity, such as a main lumen of a blood vessel. The vaso-occlusive system **400** comprises a delivery assembly **402** and a vaso-occlusive assembly **404**. As shown in FIGS. **17**A and **17**B, the delivery assembly **402** may include a delivery catheter **406** and an optional guidewire (not shown). The vaso-occlusive assembly **404** comprises a vaso-occlusive device **100** and a pusher member **410** detachably coupled to the vaso-occlusive device **100** via a detachment device or junction **412**. FIG. **17**A shows the vaso-occlusive assembly **404** after it has been slidably disposed within the delivery catheter **406** such that the vaso-occlusive device **100** is in its compact, delivery configuration.

[0140] The delivery catheter **406** is an elongated, flexible tube, and can be, for example, a microcatheter or the like. The delivery catheter **406** comprises an elongate sheath body **414** having a proximal portion **416**, a distal portion **418** and a lumen **420** extending from the proximal portion **416** to the distal portion **418**. The proximal portion **416** of the delivery catheter **406** typically remains outside of the patient and accessible to the clinician when the vaso-occlusive system **400** is used, while the distal portion **418** is sized and dimensioned to reach remote locations of a patient's vasculature and is configured to deliver the vaso-occlusive device **100** to a body cavity such as a main lumen of a blood vessel. In some cases, the delivery catheter **406** may be a microcatheter having a lumen with a cross-sectional dimension that is less 0.05 inch (e.g., 0.02 inch, 0.017 inch, etc.). The delivery catheter **406** may also have one or more ports **422** in fluid communication with the lumen **420** for introducing into, or removing fluids from, the sheath body **414**. The sheath body **414** may be composed of suitable polymeric materials, metals and/or alloys, such as polyethylene, stainless steel or other suitable biocompatible materials or combinations thereof. In some instances, the proximal portion **416** may include a reinforcement layer, such as a braided layer or coiled layer to enhance the pushability of the sheath body **414**. The sheath body **414** may include a transition region between the proximal portion **416** and the distal portion **418**.

[0141] The vaso-occlusive assembly **404** also comprises a pusher member **410**. The pusher member **410** is configured to be slidably received within the lumen **420** of the delivery catheter **406**. The pusher member **410** has a proximal portion **450**, which extends proximal of the proximal portion **416** of

the delivery catheter **406**, and a distal portion **452** which is detachably coupled to the proximal end of the vaso-occlusive device **100** via the detachment device **412**. The pusher member **410** may be a coil, wire, tendon, guidewire, torquable cable tube, hypotube, or the like, having a sufficient columnar strength to permit pushing of the vaso-occlusive device **100** out through distal end **418** of the delivery catheter **406** and into a main lumen of a blood vessel. In some cases, the vaso-occlusive device **100** may be smoothly delivered through the catheter **406** via a pushing force that is <=0.1 lb, and preferably <=0.06 lb. Accordingly, the total frictional force between the vaso-occlusive device **100** and the inner wall of the catheter **406** is less than 0.1 lb, and preferably less than 0.06 lb.

[0142] The detachment device **412** provides a detachable connection between the pusher member **410** and the vaso-occlusive device **100**. The detachment device **412** may comprise an electrolytically detachment, mechanical connector, heat activated detachment, dissolving detachment, or other mechanical, thermal and hydraulic mechanism. For instance, the detachment device **412** may be an electrolytically degradable segment for electrolytically decoupling the vaso-occlusive device **100** from the pusher member **410**.

[0143] In some cases, if the system includes the optional guidewire, the optional guidewire may be positioned within the patient's vasculature with the distal end of the guidewire located at the target insertion site (e.g., a main lumen of a blood vessel), the delivery catheter **406** is advanced over the guidewire with the guidewire disposed within the lumen **420** of the delivery catheter **406**. In a "rapid-exchange" configuration of the delivery catheter **406** and guidewire, the guidewire extends through only a distal portion of the delivery catheter **406**, such as a rapid-exchange lumen. The guidewire may be used by first advancing the guidewire through the patient's vasculature to the target insertion site and then advancing the delivery catheter **406** over the guidewire to the target insertion site.

[0144] FIG. **18** is a flow chart of an exemplary method **500** of using the vaso-occlusive system of FIGS. **17**A and **17**B to deploy the vaso-occlusive device **10** disclosed herein into a blood vessel. The method **500** will be described with respect to deploying the vaso-occlusive device **10** into a blood vessel, as an example. However, the method **500** is not limited to deploying the vaso-occlusive device **10** into a blood vessel but may be used to deploy the vaso-occlusive device **10**, or other medical device as disclosed herein, into any suitable anatomical cavity which is accessible via a patient's vasculature. Referring to the flow chart of FIG. **18**, at step **502**, a guidewire is inserted into the patient's vasculature and is advanced to the target insertion site, namely a blood vessel. As described herein, the use of the guidewire is optional, and is not required in the method **500** of using the vaso-occlusive system **400** to deploy the vaso-occlusive device **10**.

[0145] At step **504**, the delivery catheter **406** of the delivery assembly **402** is advanced over the guidewire until it is positioned with the open distal end **418** proximal a target location inside a lumen of a blood vessel. At step **506**, the guidewire is pulled out of the delivery catheter **406** leaving the delivery catheter **406** in position. At step **508**, the vaso-occlusive assembly **404** is inserted into the delivery catheter **406** of the delivery assembly **402** and advanced within the delivery catheter **406** to position the distal end of the vaso-occlusive device **10** adjacent the distal portion **418** of the delivery catheter **406**. At this position, the proximal portion **450** of the pusher member **410** remains proximal and outside of the proximal portion **416** of the delivery catheter **406**. Prior to inserting the vaso-occlusive device **10** into the delivery catheter **406**, the vaso-occlusive device **10** may be pre-installed in a sheath such that the vaso-occlusive device **10** is in its constrained, delivery configuration (primary configuration). The vaso-occlusive device **10** is then inserted into the delivery catheter **406** by placing a distal end of the sheath in abutment with the proximal end **416** of the delivery catheter **406** and extruding the vaso-occlusive device **10** from the sheath into the delivery catheter **406** such that the vaso-occlusive device **10** remains in its delivery configuration within the delivery catheter **406**.

[0146] At step **510**, the vaso-occlusive device **10** is pushed through the lumen **420** of the delivery catheter **406** and distally out of the delivery catheter **406** into a blood vessel by pushing on the proximal portion **450** of the pusher member **410**. At step **512**, as the vaso-occlusive device **10** is pushed out of the open distal end **418** of the delivery catheter **406**, various parts (e.g., portions **20**, **30**, **32**, and helical sections **40**, **42**, **90**) of the vaso-occlusive device **10** are advanced into the blood vessel and formed in the blood vessel. As a result, the vaso-occlusive device **100** in its delivery configuration (primary configuration) expands into the secondary configuration (deployed configuration). In some cases, if the vaso-occlusive device **10** includes the anchor **50** at the distal end **12**, the anchor **50** is deployed first out of the delivery catheter **406**, and anchors against a wall of the blood vessel.

[0147] Once the entire vaso-occlusive device **10** is inserted into the main lumen of the blood vessel, at step **514**, the detachment device **412** is actuated, activated or otherwise operated to detach the vaso-occlusive device **10** from the pusher-member **410**. At step **516**, the pusher member **410** is removed from the patient's vasculature by withdrawing it out through the delivery catheter **406**. In some cases, a single vaso-occlusive device **10** may be sufficient to occlude the blood vessel, and the method **500** then proceeds to step **520** in which the delivery catheter **406** is removed from the patient's vasculature. In other cases, if the single vaso-occlusive device **10** is not sufficient to occlude the blood vessel, then additional vaso-occlusive device(s) **10** may be deployed. If multiple vaso-occlusive devices **10** are being implanted, then the process of steps **508**-**516** are repeated to deliver a sufficient number of vaso-occlusive devices **10** to occlude the blood vessel. After the sufficient number of vaso-occlusive devices **10** are implanted in the blood vessel, the delivery catheter **406** is removed at step **520**.

[0148] FIG. **19** illustrates another vaso-occlusive device **10** configured to occlude a blood vessel. The vaso-occlusive device **10** is the same as that described with reference to FIG. **1**, except that the vaso-occlusive device **10** does not include the first helical section **40** between the first portion **20** and the second portion **30**. In particular, as shown in the figure, the vaso-occlusive device **10** includes an elongated member **16** extending between a distal end **12** and a proximal end **14** of the vaso-occlusive device **10**. The elongated member **16** may be bent or stretched to a primary configuration when constrained inside a delivery catheter. As shown in the figure, the elongated member **16** is configured to form a three-dimensional structure **18** having a secondary configuration when deployed outside the delivery catheter. The three-dimensional structure **18** includes a first portion **20**

having first loops, and a second portion **30** having second loops. The number of first loops of the first portion **20** is at least three (four first loops are shown in the example). The at least three first loops lie within at least three different respective first planes that are non-parallel and non-perpendicular with respect to each other. The number of second loops of the second portion **30** is at least three (four second loops are shown in the example). The at least three second loops lie within at least three different respective second planes that are non-parallel and non-perpendicular with respect to each other.

[0149] In the illustrated example, the loops of the first portion **20** lie in different respective planes that form a pyramidal shape. The pyramidal shape may be a polyhedral shape formed of a polygonal base having n number of sides and n number of lateral faces connecting to an apex. By means of non-limiting examples, the polyhedral shape may be a tetrahedral shape (triangular base and 3 lateral faces, also referred to as a triangular pyramid), pentahedral shape (quadrilateral base and 4 lateral faces, also referred to as a square or rectangular pyramid), hexahedral shape (pentagonal base and 5 lateral faces, also referred to as a pentagonal pyramid), etc. In the illustrated example, the pyramidal shape formed by the planes associated with the loops of the first portion **20** has a base, and three lateral sides. Alternatively, the pyramidal shape formed by the planes associated with the loops of the first portion may have a base, and four lateral sides. In further cases, the pyramidal shape of the first portion **20** may not include the base. For example, the pyramidal shape of the first portion **20** may include only first loops lying in respective planes that correspond with lateral sides of the pyramidal shape.

[0150] Similarly, the loops of the second portion **30** lie in different respective planes that form a pyramidal shape. The pyramidal shape may be a polyhedral shape formed of a polygonal base having n number of sides and n number of lateral faces connecting to an apex. By means of non-limiting examples, the polyhedral shape may be a tetrahedral shape (triangular base and 3 lateral faces, also referred to as a triangular pyramid), pentahedral shape (quadrilateral base and 4 lateral faces, also referred to as a square or rectangular pyramid), hexahedral shape (pentagonal base and 5 lateral faces, also referred to as a pentagonal pyramid), etc. In the illustrated example, the pyramidal shape formed by the planes associated with the loops of the first portion **30** has a base, and three lateral sides. Alternatively, the pyramidal shape formed by the planes associated with the loops of the first portion may have a base, and four lateral sides. In further cases, the pyramidal shape of the second portion **30** may not include the base. For example, the pyramidal shape of the second portion **30** may include only first loops lying in respective planes that correspond with lateral sides of the pyramidal shape.

[0151] In the illustrated example, the elongated member **16** is a coil (e.g., a primary coil) formed by a coil wire. The coil wire may have a circular cross-section, or a non-circular cross-section. The first portion **20** is formed by the primary coil bending into a number of loops. Similarly, the second portion **30** is formed by the primary coil bending into a number of loops. Thus, the first portion **20** and the second portion **30** are formed by different respective segments of the elongated member **16**. Although not explicitly shown in the figure, it should be understood that there is a transition segment (a part of the elongated member **16**) extending or transitioning between first portion **20** and the second portion **30** of the vaso-occlusive device **10**. In other cases, the elongated member **16** may be a wire, a mesh, a braid, etc.

[0152] It should be noted that the first portion **20** is not limited to having the configurations described, and that the first portion **20** may have other configurations in other cases. For example, in other cases, the first portion **20** may have loops that form non-pyramidal shapes, such as a square shape, a random shape, etc. Similarly, the second portion **30** is not limited to having the configurations described, and that the second portion **30** may have other configurations in other cases. For example, in other cases, the second portion **30** may have loops that form non-pyramidal shapes, such as a square shape, a random shape, etc.

[0153] FIG. **20** illustrates a variation of the vaso-occlusive device of FIG. **19**, particularly showing the portion **20** of the vaso-occlusive device **10** being implemented as an anchor **50**. As shown in the figure, the anchor **50** is at the distal end **12** of the vaso-occlusive device **10** and is configured to anchor against an interior wall of a blood vessel to be occluded by the vaso-occlusive device **10**. In the illustrated example, the anchor **50** has a pyramidal shape, and is formed by a segment of the elongated member **16**. In other cases, the anchor **50** may have other shapes, and/or may be separately connected (e.g., via adhesive, weld, solder, mechanical connector, etc.) to the first portion **20** of the vaso-occlusive device. The anchor **50** has a cross-sectional dimension that is equal to or larger than a maximum cross-sectional dimension of the filling portion **15** of the vaso-occlusive device. Alternatively, or additionally, the anchor **50** may have a compression stiffness (e.g., compression in a direction that is perpendicular to a longitudinal axis of the vaso-occlusive device **10**) that is higher than a compression stiffness of the filling portion **15** of the vaso-occlusive device **10**. The anchor **50** may be implemented using any of the techniques, or any combination of the techniques, described with reference to FIGS. **3**A-**3**C.

[0154] The anchor **50** may be made of a biocompatible metallic material with recoverable strain >0.1%, and preferably >0.5%. The anchor **50** may be made from the same or different material for the portion **30** in the filling portion **15**. In some cases, the cross-sectional dimension (e.g., diameter) of the anchor **50** may be larger than a cross-sectional dimension of the target vessel to be occluded. For example, the anchor **50** may be 5% larger, or preferably 10% larger, or more preferably 10% to 60% larger than the cross-sectional dimension of the blood vessel to be occluded. This ensure that the anchor **50** will sufficiently anchor against the wall of the blood vessel.

[0155] FIG. **21** illustrates the vaso-occlusive device of FIG. **20**, particularly showing the vaso-occlusive device having a proximal helical section **90**. The proximal helical section **90** is configured to enhance the occlusion capability of the vaso-occlusive device **10**. For example, the proximal helical section **90** may be configured to occlude additional part of the lumen of the blood vessel, and/or to increase a packing density for the vaso-occlusive device **10**. The proximal helical section **90** is illustrated as being shorter in the longitudinal direction than a cross-sectional dimension of the second portion **30**. In other cases, the proximal helical section **90** may be longer than the cross-sectional dimension of the second portion **30**. As shown in the figure, the cross-sectional dimension of the proximal helical section **90** is shorter than the cross-sectional dimension of the second

portion **30**. This configuration allows the proximal helical section **90** to bent, fold, curl up, twist, etc. within a lumen of the blood vessel to occlude the blood vessel.

[0156] FIG. **22** illustrates the vaso-occlusive device of FIG. **21**, particularly showing the vaso-occlusive device having additional portions **32**, **34**. In other cases, the vaso-occlusive device **10** may include only one additional portion or more than two additional portions. In some cases, the vaso-occlusive device **10** may include a number of portions (e.g., portions **20**, **30**, **32**). The number of portions may be more than 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30. The number of portions may be selected to fit a particular application. For example, higher number of portions may be selected to fill a larger blood vessel, to achieve a higher occlusion, and/or to achieve a longer occluded segment along the blood vessel. Also, in some cases, the vaso-occlusive device **10** may not include the anchor **50** and/or the proximal helical section **90**.

[0157] In any of the exemplary vaso-occlusive devices **10** described herein, the proximal helical section **90** is optional, and the vaso-occlusive device **10** may not include the proximal helical section **90**. FIG. **23** illustrates a variation of the vaso-occlusive device of FIG. **22**, particularly showing the vaso-occlusive device having no proximal helical section. In such cases, the filling portion **15** of the vaso-occlusive device **10** includes the portions **30**, **32**, **34**, **36**, which are configured to occlude a main lumen of a blood vessel.

[0158] It should be noted that in the examples of FIGS. **20-23**, the anchor **50** has a cross-sectional dimension that is larger than that of the filling portion **15** (e.g., larger than the portion **30**/**32**/**34**). In some cases, the cross-sectional dimension of the anchor **50** may be 5% larger, or 10% larger, or 20% larger than the cross-sectional dimension of the portion **30**/**32**/**34**. Also, the portions **30**, **32**, **34**, **36** in the filling portion **15** may have the same size, or may have different respective sizes. In some cases, the size of the portions **30**, **32**, **34**, **36** in the vaso-occlusive device **10** of FIG. **23** may decrease from the distal end towards the proximal end. Thus, the cross-sectional dimension of the portion **30** may be larger than the cross-sectional dimension of the portion **32**, and the cross-sectional dimension of the portion **32** may be larger than the cross-sectional dimension of the portion **34**, and the cross-sectional dimension of the portion **34** may be larger than the cross-sectional dimension of the portion **36**.

[0159] FIG. **24** illustrates an example of a mandrel **200** being utilized to make a vaso-occlusive device **10** that is similar to that shown in FIG. **22**. In particular, the vaso-occlusive device **10** being made using the mandrel **200** has the same configuration as that of FIG. **22**, except that it does not include the portion **34**. FIG. **25** illustrates a prototype of the vaso-occlusive device **10** formed from the mandrel **200** of FIG. **24**. In the prototype, the anchor **50** implemented by the first portion **20** is formed from a first segment of a primary coil made from Pt-8W. The primary coil's dimensions are 0.00175"×0.0102" (i.e., the coil is formed by winding a 0.00175" wire over a 0.0102" mandrel). The anchor **50** also includes an inner coil (which is an example of the inner coil **70** described with reference to FIG. **3**A) with the dimensions 0.00225"×0.005" (i.e., the coil is formed by winding a 0.00225" wire over a 0.005" mandrel). The anchor **50** has a cross-sectional dimension (i.e., outside diameter) of 2.5 mm, and a longitudinal length (i.e., coil length) of 4 cm. The second portion **30** and the third portion **32** of the prototype are formed from a second segment and a third segment, respectively, of the primary coil. The second portion **30** has a cross-sectional dimension of 2.25 mm, and the third portion **32** has a cross-sectional dimension of 2 mm. The total length of the second portion **30** and the third portion **32** is 6.5 cm. The proximal helical section **90** is formed by a fourth segment of the primary coil, and has a cross-sectional dimension of 2 mm, and a longitudinal length of 4 cm.

[0160] FIG. **26**A illustrates a catheter **402** being utilized to deliver the prototype of the vaso-occlusive device **10** of FIG. **25** into a model of a blood vessel **480**. FIG. **26**B illustrates the vaso-occlusive device **10** delivered out of the catheter **402** into a model of a blood vessel **480**. As shown in the figure, the vaso-occlusive device **10** forms an elongated packed structure that efficiently occludes the blood vessel. The vessel shown in the FIG. **26** has an internal diameter (ID) of 2 mm and the delivered compact coil mass (i.e. dense coil mass) is expected to be around 10 mm. It should be pointed out that the vaso-occlusive device **10** can be used to occlude the vessel with ID ranging from 1.5 mm and 2.5 mm and the resulting dense coil mass is expected to be between 5 mm and 15 mm.

[0161] The vaso-occlusive devices **10** described herein are advantageous because they are specifically designed to occlude blood vessels. In some cases, the vaso-occlusive device **10** may be utilized to occlude a blood vessel in the neural vasculature and/or in the peripheral vasculature. The vaso-occlusive device **10** may also be utilized for venous vessel occlusion. In some cases, the vaso-occlusive device **10** includes one or more anchors (e.g., anchor **50** and/or anchor **96**) designed specifically to engage with the tubular wall of the blood vessel, thereby preventing the vaso-occlusive device **10** from migrating along the lumen of the blood vessel. In addition, the vaso-occlusive device **10** may have a length that is longer than those designed for aneurysm treatment. For example, in some cases, the vaso-occlusive device **10** may have a delivery length (when confined inside a catheter) that is 2 times, 3 times, 4 times, 5 times, or more, compared to that of the delivery length of a vaso-occlusive device designed for aneurysm treatment. This is advantageous because a single vaso-occlusive device **10** may establish a complete or desirable vessel occlusion. Use of a single vaso-occlusive device **10** reduces treatment time and also reduces the risk that one or more vaso-occlusive devices may migrate away from the occlusion site if multiple vaso-occlusive devices are used.

[0162] It should be noted that the vaso-occlusive device **10** described herein should not be limited to having the configurations described in the examples, and that the vaso-occlusive device **10** may have other configurations. For example, in other cases, any of the vaso-occlusive devices **10** described herein may include one or more segments with complex shapes, such as a 3D portion having six or more loops (e.g., eight loops). Such 3D portion, for example, may replace the second portion **30** in the vaso-occlusive device **10** of FIG. **1**, or may replace the proximal helical section **90** in the vaso-occlusive device of FIG. **4**, **5**, **6**A, or **6**C, or may replace the second portion **30** in the vaso-occlusive device **10** of FIG. **19** or **20**, or may replace the proximal helical section **90** in the vaso-occlusive device **10** of FIG. **21** or **22**.

[0163] In some cases, any of the vaso-occlusive devices **10** described herein may optionally further include fibers

and/or surface features to enhance thrombogenicity. The fibers may be mechanically attached to a surface of the elongated member **16** or may be weaved through the coil windings of the primary coil (elongated member **16**).

[0164] In further cases, any of the vaso-occlusive devices **10** described herein may optionally further include an accelerating agent coated on a surface of the vaso-occlusive device **10** to accelerate the formation of thrombus.

[0165] Although the vaso-occlusive devices **10** disclosed herein have been described as being configured for implantation in a lumen of a blood vessel, the vaso-occlusive devices **10** may alternatively be configured for implantation in other cavities in a patient. Thus, the examples of the vaso-occlusive device **10** described herein are not limited to being configured and used for treating blood vessel, but they are particularly well-suited for such configuration and use.

[0166] Although particular embodiments of the disclosed inventions have been shown and described herein, it will be understood by those skilled in the art that they are not intended to limit the present inventions, and it will be obvious to those skilled in the art that various changes and modifications may be made (e.g., the dimensions of various parts) without departing from the scope of the disclosed inventions, which is to be defined only by the following claims and their equivalents. The specification and drawings are, accordingly, to be regarded in an illustrative rather than restrictive sense. The various embodiments of the disclosed inventions shown and described herein are intended to cover alternatives, modifications, and equivalents of the disclosed inventions, which may be included within the scope of the appended claims.

1. A vaso-occlusive device, comprising:

an elongated member having a primary configuration when the vaso-occlusive device is in a constrained condition;

wherein the elongated member forms a three-dimensional structure having a secondary configuration when the vaso-occlusive device is in an unconstrained condition, the three-dimensional structure comprising:

a first pyramidal portion comprising a first set of at least three first loops lying within at least three different respective first planes that are non-parallel and non-perpendicular with respect to each other; and

a first helical section formed from the wire and extending proximally from the first pyramidal portion.

2. The vaso-occlusive device of claim **1**, wherein the first pyramidal portion has 3 lateral faces forming a tetrahedral shape.

3. The vaso-occlusive device of claim **1**, wherein the first pyramidal shape has 4 lateral faces forming a pentahedral shape.

4. The vaso-occlusive device of claim **1**, wherein the three-dimensional structure further comprises a second pyramidal portion comprising a second set of at least three second loops lying within at least three different respective second planes that are non-parallel and non-perpendicular with respect to each other.

5. The vaso-occlusive device of claim **1**, wherein the three-dimensional structure comprises a second helical section extending from the second pyramidal portion.

6. The vaso-occlusive device of claim **5**, wherein the second helical section has a longitudinal length that is longer than a cross-sectional width of the second pyramidal portion of the three-dimensional structure.

7. The vaso-occlusive device of claim **5**, wherein the elongated member is a primary coil.

8. The vaso-occlusive device of claim **7**, wherein the first helical section comprises a first secondary coil formed by a first segment of the primary coil, wherein the first pyramidal portion is formed by a second segment of the primary coil, and the second pyramidal portion is formed by a third segment of the primary coil.

9. The vaso-occlusive device of claim **5**, wherein the first pyramidal portion has a cross-sectional dimension that is larger than a cross-sectional dimension of the second pyramidal portion.

10. The vaso-occlusive device of claim **5**, wherein the elongated member is a primary coil, and wherein a segment of the primary coil forming the first portion comprises:

a stretch-resistance member located within a lumen of the primary coil; or

a stiffening coil located within the lumen of the primary coil.

11. The vaso-occlusive device of claim **5**, wherein the elongated member is a primary coil, wherein a first segment of the primary coil forming the first pyramidal portion has a first coil-wire diameter, and wherein a second segment of the primary coil forming the second pyramidal portion has a second coil-wire diameter that is less than the first coil-wire diameter.

12. The vaso-occlusive device of claim **5**, wherein the three-dimensional structure comprises a third pyramidal portion, and a second helical section disposed between the second pyramidal portion and the third pyramidal portion; and

wherein the third pyramidal portion comprises at least three third loops lying within at least three different respective third planes that are non-parallel and non-perpendicular with respect to each other.

13. The vaso-occlusive device of claim **1**, wherein the three-dimensional structure comprises a first anchor at a distal end of the vaso-occlusive device.

14. The vaso-occlusive device of claim **13**, wherein the first anchor comprises a second helical section.

15. The vaso-occlusive device of claim **13**, wherein the elongated member is a primary coil, and wherein a segment of the primary coil forming the first anchor comprises:

a stretch-resistance member located within a lumen of the primary coil; or

a stiffening coil located within the lumen of the primary coil.

16. The vaso-occlusive device of claim **13**, wherein the elongated member is a primary coil, wherein a first segment of the primary coil forming the first pyramidal portion has a first coil-wire diameter, wherein a second segment of the primary coil forming the first anchor has a second coil-wire diameter that is larger than the first coil-wire diameter.

17. The vaso-occlusive device of claim **13**, wherein the first anchor comprises a second pyramidal portion comprising third loops lying in different respective third planes that are non-parallel and non-perpendicular with respect to each other.

18. The vaso-occlusive device of claim **13**, wherein the three-dimensional structure comprises a second anchor at a proximal end of the vaso-occlusive device.

19. The vaso-occlusive device of claim **1**, wherein the secondary configuration comprises an elongated configuration configured to occlude a blood vessel.

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