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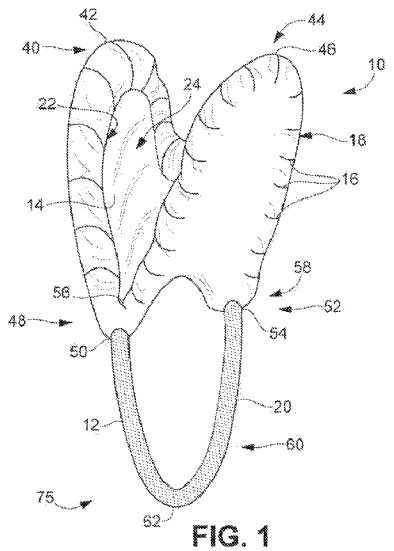

FIG. 1

(57) Abstract: An occlusion device has a covering attached to a support frame that includes a disc-shaped member and a crossbar that extends across a central opening defined by the disc-shaped member. The occlusion device has a first, or deployed, configuration in which the crossbar defines a curve that extends from the disc-shaped member, and a second, or resting, configuration in which the discshaped member and the crossbar lie substantially in a single plane. Each of the disc-shaped member and the crossbar include a core wire that extends through a lumen of a coil multiple times.

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OCCLUSION DEVICE FOR BLOCKING FLUID FLOW THROUGH BODILY PASSAGES

FIELD

[001] The disclosure relates generally to the field of intraluminal medical devices. More particularly, the disclosure relates to occlusion devices for placement in bodily passages. The devices described herein are useful in the temporary or permanent blockage of fluid flow through various types of bodily passages, such as arteries, veins, fistulas, and other passages.

BACKGROUND

[002] Intraluminal occlusion devices are used to block fluid flow through bodily passages. In certain clinical situations, such as surgical procedures during which a bloodless field is desired, a temporary blockage of fluid flow is desired. In other situations, a permanent blockage of fluid flow is desired.

[003] The art contains a variety of occlusion devices that perform the occlusion function with various degrees of efficiency and effectiveness. Several of these devices, however, have drawbacks that limit their usability. For example, some occlusion devices, such as the Amplatzer Septal Occluder (AGA Medical Corporation, Plymouth, MN), contain complex, multi-filament frame structures that contribute significant bulk to the overall profile of the occlusion device, effectively limiting its use to only relatively large bodily passages that can accommodate the bulk of the device and the catheter used to deliver and deploy the device. Also, many occlusion devices rely on thrombosis – the formation of a thrombus at the site of deployment of the occlusion device – as the mechanism for occlusion. While such devices may provide the desired blockage once a thrombus forms, the thrombus can be partially reabsorbed over time, which may reduce the effectiveness of these occlusion devices as the embolized bodily passage becomes recanalized and fluid flow is restored. Furthermore, because of their reliance on

thrombus formation to achieve occlusion, these devices may have limited effectiveness in patients with a reduced ability to form blood clots, such as patients undergoing anti-coagulant therapy and/or thrombolytic therapy with tissue plasminogen activator (tPA), streptokinase, or a similar agent.

[004] Accordingly, a need exists for improved occlusion devices for blocking fluid flow through bodily passages.

BRIEF SUMMARY OF DESCRIBED EMBODIMENTS

[005] Several occlusion devices are described and illustrated herein.

[006] A first exemplary occlusion device comprises a support frame comprising a disc-shaped member and a crossbar. The disc-shaped member defines a closed circumference and a central opening and includes a first coil defining a first passageway and a first core wire extending through the first passageway. The crossbar is attached to the disc-shaped member and extends across the central opening, and includes a second coil that defines a second passageway and a second core wire that extends through the second passageway. A covering is attached to the support frame.

[007] Additional understanding of these exemplary occlusion devices can be obtained with review of the detailed description, below, and the appended drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[008] Figure 1 is a perspective view of a first exemplary occlusion device.

[009] Figure 2 is a perspective view of the occlusion device illustrated in Figure 1. The occlusion device is illustrated in a resting configuration.

[0010] Figure 3 is a perspective view of the support frame of the occlusion device illustrated in Figures 1 and 2.

[0011] Figure 4 is a perspective view of the crossbar of the support frame illustrated in Figure 3.

[0012] Figure 5 is a sectional view of the support frame illustrated in Figure 3, taken along line 5-5.

[0013] Figure 6 is an enlarged view of the area indicated in Figure 2.

[0014] Figure 7 is a perspective view of an alternative occlusion device.

[0015] Figure 8 is a partial sectional view of a bodily passage within which the first exemplary occlusion device has been deployed.

[0016] Figure 9 is a partial section view of a bodily passage within which the first exemplary occlusion device has been deployed. A delivery and retrieval device is also positioned within the bodily passage.

[0017] Figure 10 is a perspective view of a second exemplary occlusion device.

[0018] Figure 11 is a perspective view of a third exemplary occlusion device.

[0019] Figure 12 is a perspective view of a fourth exemplary occlusion device.

[0020] Figure 13 is a perspective view of an alternative support frame for use in occlusion devices.

[0021] Figure 14 is a perspective view of a fifth exemplary occlusion device.

[0022] Figure 15 is a perspective view of an alternative occlusion device.

[0023] Figure 16 is an oblique view of a bodily passage within which an exemplary occlusion device has been implanted.

[0024] Figure 17 is a flowchart illustrating a method of making an occlusion device.

DETAILED DESCRIPTION OF DESCRIBED EMBODIMENTS

[0025] The following detailed description and the appended drawings describe and illustrate various exemplary devices and methods. The description and drawings are exemplary in nature and are provided to enable one skilled in the art to make and use one or more exemplary device and/or to practice one or more exemplary method. They are not intended to limit the scope of the claims in any manner.

[0026] Figures 1 through 9 relate to a first exemplary occlusion device. Figure 1 illustrates the occlusion device 10 in a deployed configuration and Figure 2 illustrates the occlusion device 10 in a resting configuration. Figures 3, 4, and 5 illustrate components of the occlusion device 10. Figure 6 is an enlarged view of a portion of the occlusion device 10. Figure 7 illustrates the occlusion device 10' according to an alternative construction. Figures 8 and 9 illustrate the occlusion device 10 deployed within a bodily passage 100.

[0027] The occlusion device 10 includes a support frame 12, a covering 14, and one or more attachment members 16 that attach the covering 14 to the support frame 12.

[0028] As best illustrated in Figure 3, the support frame 12 comprises a disc-shaped member 18 and a crossbar 20. The disc-shaped member 18 has a closed circumference 22 that defines a central opening 24. The crossbar 20 is connected to the disc-shaped member 18 and spans the central opening 24. The covering 14 covers the entire central opening 24, effectively closing the opening 24.

[0029] Two lengthwise axes 26a, 26b that intersect at a geometric center 28 of the closed circumference 22 divide the disc-shaped member 18 into four quadrants: a top quadrant 30, a bottom quadrant 32 diametrically opposed from

the top quadrant 30, a first lateral quadrant 34, and a second lateral quadrant 36 diametrically opposed from the first lateral quadrant 34. A first curve 40 defined by the disc-shaped member 18 in the top quadrant 30 defines a first apex 42. A second curve 44 defined by the disc-shaped member 18 in the bottom quadrant 32 defines a second apex 46. A third curve 48 defined by the disc-shaped member 18 in the first lateral quadrant 34 defines a third apex 50. A fourth curve 52 defined by the disc-shaped member 18 in the second lateral quadrant 36 defines a fourth apex 54.

[0030] Figure 1 illustrates the occlusion device 10 in a first, or deployed, configuration 75. In the first configuration 75, the disc-shaped member 18 is folded such that the first apex 42 has been moved toward the second apex 46. Each of the third apex 50 and fourth apex 54 have flexed in response to this movement to form apical bends 56, 58. In the first configuration 75, the crossbar 20 defines a curve 60 that extends from the first apical bend 56 to the second apical bend 58 and away from the disc-shaped member 18. A curve 60 defined by the crossbar 20 when the occlusion device 10 is in the first configuration 75 defines an apex 62 that is positioned opposite the first 42 and second 46 apices relative to the geometric center of the disc-shaped member 18 (not specifically referenced in Figure 1).

[0031] Figure 2 illustrates the occlusion device 10 in a second, or resting, configuration 85. In the second configuration, the disc-shaped member 18 is substantially flat such that the entire support frame 12, including the disc-shaped member 18 and the crossbar 20, lies in a single plane. In this configuration, the first 42 and second 46 apices, and the third 50 and fourth 54 apices lie opposite each other with respect to the geometric center 28 of the disc-shaped member 18. As described below, the disc-shaped member 18 is configured to have sufficient flexibility to allow it to be readily transitioned between the first 75 and second 85 configurations. In the second configuration 85, the crossbar 20 extends across the central opening 24 of the disc-shaped member 18. While the crossbar 20 is not attached to the covering 14, some contact between the crossbar 20 and the covering may occur when the occlusion device 10 is in the second configuration 85.

[0032] The disc-shaped member 18 comprises a core wire 70 disposed within and extending through a lumen 74 formed by a coil 72. The core wire 70 is passed through the lumen 74 multiple times so that it loops back on itself in the same manner as described below for the crossbar 20. Once the desired number of passes is achieved, the ends of the core wire 70, which extend outward from opposite ends of the linear coil at this stage, are brought together to form the disc shape of the disc-shaped member 18. Once the disc shape is formed, the ends of the core wire 70 are tied or otherwise secured to each other to fix the disc shape of the disc-shaped member 18. The core wire 70 can be passed through the lumen 74 of the coil 72 any suitable number of times, and a skilled artisan will be able to select an appropriate number of passes based on various considerations, including the materials used for the core wire 70 and/or coil 72, the desired radial force of the disc-shaped member 18, and other considerations. The inventors have determined that a core wire 70 passed through the lumen 74 of a coil 72 four (4) times provides a disc-shaped member 18 with suitable properties when formed of a Nitinol core wire 70 and a cold drawn cobalt chromium coil 72. Furthermore, the inventors have determined that a core wire 70 passed through the lumen 74 of a coil 72 four (4) times provides a disc-shaped member 18 with suitable properties when formed of a Nitinol core wire 70 and a stainless steel coil 72.

[0033] It is noted that an occlusion device can have different components having coils with the same or different numbers of passes of a core wire through the respective lumen. For example, the inventors have determined that an occlusion device having a core wire passed through the lumen of a coil wire of a disc-shaped member four times and a core wire passed through the lumen of a coil of an attached crossbar four times has advantageous structural properties, particularly for relatively large occlusion devices, such as 14 mm devices. Also, the inventors have determined that an occlusion device having a core wire passed through the lumen of a coil wire of a disc-shaped member four times and a core wire passed through the lumen of a coil of a crossbar three times has advantageous structural properties, particularly for relatively small occlusion devices, such as 6, 8, 10, and 12 mm devices.

[0034] While the disc-shaped member is illustrated as comprising a single coil wire, separate coil wires can be used in the disc-shaped member. For example, separate coil wires with ends spaced from each other where the crossbar is attached to the core wire 70 can be used. This structural arrangement is considered advantageous for larger sized occlusion devices, such as 14mm and larger devices. For these devices, the inclusion of two coil wires in the disc-shaped member is expected to eliminate a teardrop shape that can sometimes form in these larger-sized frames. It is noted, though, that while this structural arrangement is described as advantageous for larger sized devices, it is not considered necessary for these devices. Furthermore, this structural arrangement is considered suitable for inclusion in occlusion devices of all sizes.

[0035] The inclusion of multiple coil wires in the disc-shaped member is also considered advantageous at least because it allows for the use of a single core wire that passes through the coils of the multiple coil wires in the disc-shaped member and the coil of an attached crossbar. For example, each end of a crossbar can be positioned between ends of the separate coils of a disc-shaped member such that a core wire can be passed through the coils of the disc-shaped member and the coil of the crossbar. If desired, a second crossbar can be attached to the disc-shaped member in a similar manner or in any other suitable manner. The inventors have determined that an occlusion device having a disc-shaped member formed of two separate coils and a first crossbar attached to the disc-shaped member in this manner, e.g., via a common core wire passing through the coils forming the disc-shaped member and the coil forming the first crossbar, has advantageous structural properties, particularly for larger sized occlusion devices, such as 14 mm and larger devices. Furthermore, it is considered advantageous to have such a common core wire pass through the coils forming the disc-shaped member a total number of times that is equal to the total number of times that the common core wire passes through the coil of the first crossbar. For example, the inventors have determined that an occlusion device in which a common core wire passes through the coils forming the disc-shaped member four (4) times and through the coil of the first crossbar four (4) times has advantageous structural properties, particularly for larger sized occlusion devices, such as 14 mm and larger devices. Furthermore, if a second crossbar is attached to such an occlusion device, it can comprise a

separate core wire passed through the lumen of its coil and be attached to the disc-shaped member using the separate core wire, as described above. If such a second crossbar is included, it is considered advantageous to have the separate core wire pass through the coil forming the second crossbar a total number of times that is less than the total number of times that the common core wire passes through the coil of the first crossbar. For example, the inventors have determined that, in an occlusion device in which a common core wire passes through the coils forming the disc-shaped member four (4) times and through the coil of the first crossbar four (4) times, a second crossbar attached to the disc-shaped member and having a separate core wire that passes through the lumen of its coil three (3) times provides advantageous structural properties when attached to the disc-shaped member, particularly for larger sized occlusion devices, such as 14 mm and larger devices.

[0036] The crossbar 20 has a construction that is similar to that of the disc-shaped member 18. As best illustrated in Figure 4, the crossbar 20 comprises a core wire 80 disposed within and extending through a lumen 84 formed by a coil 82. For the crossbar 20, the core wire 80 is initially disposed within the lumen 84 such that each of the ends 86, 88 of the core wire 80 is disposed outward of the respective end 90, 92 of the coil 82. Each end 86, 88 of the core wire 80 is then passed back through the lumen 84 of the coil 82 until the end 86, 88 is disposed outward of the other end 90, 92 of the coil 82. As a result, the core wire 80 defines terminal loops 94, 96, each of which is disposed outward of an end 90, 92 of the coil 82. The construction of the crossbar 20 is similar to the construction of the anchors in United States Patent Application Publication No. 2010/0030246 to Pavcnik et al. for CLOSURE DEVICE AND METHOD FOR OCCLUDING A BODILY PASSAGEWAY, the entire contents of which is hereby incorporated into this disclosure.

[0037] As best illustrated in Figure 3, the crossbar 20 is attached to the disc-shaped member 18 by looping the terminal loops 94, 96 of the core wire 80 of the crossbar 20 around the core wire 70 of the disc-shaped member 18. This can be accomplished during assembly of the crossbar 20, as described above, by passing each of the ends 86, 88 of the core wire 80 of the crossbar 20 around the core wire

70 of the disc-shaped member 18 at the desired points of connection, such as the third 50 and fourth 54 apices of the disc-shaped member 18, before passing the ends 86, 88 back through the coil 82. The ends 86, 88 can then be drawn taught on the core wire 70 of the disc-shaped member 18 to provide secure connections between the crossbar 20 and the disc-shaped member 18. Advantageously, the ends 86, 88 of the core wire 80 are drawn sufficiently taught such that each terminal loop 94, 96 frictionally engages the respective end 90, 92 of the coil 82 of the crossbar 20.

[0038] Figure 4 illustrates the crossbar 20 independent of the disc-shaped member 18. Each of the ends 86, 88 of the core wire 80 of the crossbar 20 can extend axially beyond the respective end 90, 92 of the coil 82 by any suitable length. For example, each end 86, 88 can extend axially beyond the respective end 90, 92 of the coil 82 by a length that is less than, substantially less than, equal to, substantially equal to, greater than, or substantially greater than the axial length of the respective terminal loop 94, 96, as measured along a longitudinal axis of the crossbar 20 from the respective end 90, 92 of the coil to the apex of the respective terminal loop 94, 96. Configuring the crossbar 20 such that each of the ends 86, 88 of the core wire 80 extends axially beyond the respective end 90, 92 of the coil 82 by a length that is greater than or substantially greater than the axial length of the respective terminal loop 94, 96 is considered advantageous at least because ends 86, 88 configured in this manner can provide additional anchoring function to the occlusion device 10. Alternatively, a crossbar 20 in which each of the ends 86, 88 of the core wire 80 extends axially beyond the respective end 90, 92 of the coil 82 by a length that is less than or substantially less than the axial length of the respective terminal loop 94, 96 is considered advantageous at least because ends 86, 88 configured in this manner have limited ability to engage the covering 14. It may also be advantageous to configure the crossbar 20 such that each of the ends 86, 88 of the core wire 82 does not extend axially beyond the respective end 90, 92 of the coil 82. This configuration is believed to greatly reduce the ability of the ends 86, 88 to engage the covering 14.

[0039] The support frame 12 can be formed of any suitable material. The material selected for a support frame need only be biocompatible or able to be

made biocompatible. Examples of suitable materials include, without limitation, stainless steel, nickel titanium (NiTi) alloys, e.g., nitinol, other shape memory and/or superelastic materials, molybdenum alloys, tantalum alloys, titanium alloys, paladium alloys, precious metals such as platinum, precious metal alloys such as platinum alloys, nickel chromium alloys, cobalt chromium alloys, nickel cobalt chromium alloys, nickel cobalt chromium molybdenum alloys, nickel titanium chromium alloys, linear elastic Nitinol wires, polymers, and composite materials.

[0040] Platinum and nitinol are currently considered desirable materials for use in the support frame due at least to their biocompatibility, shapeability, imaging characteristics, and well-characterized nature. Stainless steel is considered a suitable material for use in the support frame. Also, cold drawn cobalt chromium alloys, such as ASTM F562 and ASTM F1058 (commercial examples of which include MP35NTM and ElgiloyTM, both of which are available from Fort Wayne Metals, Fort Wayne, IN; MP35N is a registered trademark of SPS Technologies, Inc. (Jenkintown, PA, USA); Elgiloy is a registered trademark of Combined Metals of Chicago LLC (Elk Grove Village, IL, USA)), are currently considered advantageous materials for use in the support frame at least because they are non-magnetic materials that provide beneficial magnetic resonance imaging (MRI) compatibility, and avoid MRI artifacts typically associated with some other materials, such as stainless steel.

[0041] Different materials can be used for the various components of the support frame 12. For example, the inventors have determined that the use of platinum for the coils 72, 82 and Nitinol for the core wires 70, 80 of the disc-shaped member 18 and the crossbar 20 provides a support frame with desirable characteristics, including desirable flexibility, manufacturability and handling characteristics. The inventors have determined that platinum coils provide desirable imaging characteristics for the support frame, including X-ray imaging characteristics, particularly when paired with a Nitinol core wire. The inventors have also determined that the use of cold drawn cobalt chromium, such as Elgiloy™ for the coils 72, 82 and nitinol for the core wires 70, 80 of the disc-shaped member 18 and the crossbar 20 provides a support frame with desirable

characteristics, including desirable flexibility, manufacturability and handling characteristics.

[0042] Any suitable dimensions can be used for the various components of the support frame. A skilled artisan will be able to select suitable dimensions for the various components based on various considerations, including the point of treatment at which a particular occlusion device is intended to be used. The inventors have determined that it is advantageous to configure the support frame 12 such that the coil 82 of the crossbar 20 has a larger outer diameter than the coil 72 for the disc-shaped member 18 at least because the additional thickness provides additional material for use in retrieval and/or repositioning of the occlusion device 10 without adding significantly to the overall bulk of the occlusion device 10 because, when the device is in the first configuration 75, such as deployed within a vessel or positioned within a delivery device, the covering 14 and disc-shaped member 18 are axially separated from the crossbar 20. The inventors have determined that a coil 82 for the crossbar 20 having an outer diameter of 18 thousandths (18/1000) of an inch is considered suitable. Also, the inventors have determined that a coil 72 for the disc-shaped member 18 having an outer diameter of 14 thousandths (14/1000) of an inch is considered suitable. Used together, the coils 82, 72 having these dimensions provide an occlusion device that can be positioned within – and delivered with – a 4 or 5 French introducer sheath. The inventors have also determined that a core wire having an outer diameter of between 2 thousandths (2/1000) of an inch and 5 thousandths (5/1000) of an inch is considered suitable. A core wire having an outer diameter of 3 thousandths (3/1000) of an inch is considered particularly suitable. Furthermore, the inventors have determined that the combination of a coil wire having an outer diameter of 14 thousandths (14/1000) of an inch with a core wire having an outer diameter of 3 thousandths (3/1000) of an inch provides a support frame with desirable radial force and overall bulk characteristics, particularly when the core wire is passed through the lumen define by the coil wire three times.

[0043] It is noted that, as used herein, the term "wire" does not refer to any particular size, diameter, or cross-sectional shape. While wire members having

substantially circular cross-sectional shapes offer particular advantages, they are not required. Examples of other suitable cross-sectional shapes include, but are not limited to, flat, square, triangular, D-shaped, trapezoidal, and delta-shaped cross-sectional shapes.

[0044] The inventors have determined that heat treating the support frame 12 can be advantageous at least because the occlusion device 10 has an improved ability to maintain its shape when a heat treatment has been applied to the support frame 12 during fabrication of the occlusion device 10. Furthermore, it is believed that heat treating the support frame 12 contributes to achieving the desired overall low profile of the occlusion device 10. If a heat treatment is applied, any suitable treatment parameters can be used. A skilled artisan will be able to determine suitable parameters for a support frame in a particular occlusion device based on various considerations, including the materials used in the core wire and coil of the support frame. The inventors have determined that subjecting a support frame to a temperature of between about 880°F and about 980°F for between about 5 minutes and about 15 minutes, prior to attachment of a covering, provides these advantages for a support frame having a nitinol core wire and a stainless steel coil. The inventors have also determined that subjecting a support frame to a temperature of about 930°F for about 5 minutes prior to attachment of a covering provides these advantages for a support frame having a nitinol core wire and a stainless steel coil.

[0045] As best illustrated in Figure 6, the covering 14 is attached to the support frame 12 by one or more attachment members 16. In the illustrated embodiment, the attachment member 16 comprises a single suture that attaches the covering 14 to the disc-shaped member 18 of the support frame 12. When sutures are used as the attachment member 16, they advantageously extend through a thickness, such as a full thickness or a partial thickness, of the covering 14 and around the core wire 70 of the disc-shaped member 18. They can be drawn taught such that portions of the suture are disposed between turns of the coil 72. Alternatively, they can be drawn taught such that they are looped around the core wire 70 and the coil 72 of the disc-shaped member.

[0046] The attachment member 16 is advantageously configured such that the covering 14 and disc-shaped member 18 of the support frame 12 are maintained in continuous contact along the closed circumference 22 defined by the disc-shaped member 18. This continuous contact between the covering 14 and the disc-shaped member 18 is considered advantageous at least because it eliminates any gaps in contact between these elements that could provide an initial passageway through which fluid could flow across the occlusion device 10.

[0047] While sutures are considered suitable attachment members 16, any suitable attachment member can be used to connect the covering 14 to the support frame 12. Other examples of suitable attachment members include clips, clamps, staples and other attachment members known in the art. Furthermore, adhesives, welds, and other compositions and processes for forming a connection between members can be used. A skilled artisan will be able to select a suitable attachment member for attaching the covering 14 to the support frame 12 based on various considerations, including the nature of the covering 14 and the support frame 12 used in a particular occlusion device.

[0048] Also, while the use of a single attachment member 16, such as the single suture illustrated in the figures, is considered advantageous, any suitable number of attachment members can be used. A skilled artisan can select a suitable number of attachment members for use in a particular occlusion device based on various considerations, including the nature of the covering 14 and the support frame 12 used and the desirable continuous contact between the covering 14 and the disc-shaped member 18.

[0049] As best illustrated in Figure 2, the covering 14 is advantageously sized and configured such that it defines an area that is substantially equal to the area defined by the closed circumference 22 of the disc-shaped member 18. This configuration minimizes the overall bulk of the occlusion device 10, enhancing its ability to be stored within and delivered by relatively small delivery catheters.

[0050] Figure 7 illustrates an alternative occlusion device 10' in which the covering 14' is oversized relative to the closed circumference 22' defined by the

disc-shaped member 18'. That is, the covering 14' is sized and configured such that it defines an area that is substantially greater than the area defined by the closed circumference 22' of the disc-shaped member 18'. The covering 14' provides a section of extra material 15' that extends radially beyond the outer edge of the disc-shaped member 18' relative to the geometric center (not specifically referenced in Figure 7) of the disc-shaped member 18' when the occlusion device 10' is in the second configuration (such as illustrated in Figure 7). The inclusion of the extra material 15' is considered advantageous at least because it provides additional material that, once the occlusion device 10' is deployed within a bodily passage, can contact and seal with the wall of the bodily passage. This structural arrangement upon deployment is expected to increase the effectiveness of the occlusion device 10' in blocking fluid flow through the bodily passage by providing additional surface area for contact with the wall of the bodily passage.

[0051] The covering 14' can be configured to have any suitable radial length 17' for the extra material 15' that extends radially beyond the outer edge of the disc-shaped member 18'. A skilled artisan can select a suitable radial length 17' for the extra material 15' based on various considerations, such as any size constraints placed on the overall bulk of the occlusion device 10' by a delivery device or intended point of treatment. The inclusion of the extra material 15' and the radial length 17' of any included extra material 15' should always be balanced against any considerations about the overall bulk of the occlusion device.

[0052] The inventors have determined that a radial length 17' that is between about 10% and about 90% of the radial length from the geometric center of the disc-shaped member 18' to the outer edge of the disc-shaped member is suitable for a variety of applications. A radial length 17' that is between about 20% and about 80% of the radial length from the geometric center of the disc-shaped member 18' to the outer edge of the disc-shaped member is suitable for a variety of applications. A radial length 17' that is between about 30% and about 70% of the radial length from the geometric center of the disc-shaped member 18' to the outer edge of the disc-shaped member is suitable for a variety of applications. A radial length 17' that is between about 40% and about 60% of the radial length

from the geometric center of the disc-shaped member 18' to the outer edge of the disc-shaped member is suitable for a variety of applications. A radial length 17' that is about 50% of the radial length from the geometric center of the disc-shaped member 18' to the outer edge of the disc-shaped member is suitable for a variety of applications. A radial length 17' that is about 40% of the radial length from the geometric center of the disc-shaped member 18' to the outer edge of the disc-shaped member is suitable for a variety of applications. A radial length 17' that is about 30% of the radial length from the geometric center of the disc-shaped member 18' to the outer edge of the disc-shaped member is suitable for a variety of applications. A radial length 17' that is about 20% of the radial length from the geometric center of the disc-shaped member 18' to the outer edge of the disc-shaped member is suitable for a variety of applications. A radial length 17' that is about 10% of the radial length from the geometric center of the disc-shaped member 18' to the outer edge of the disc-shaped member is suitable for a variety of applications. A radial length 17' that is about 5% of the radial length from the geometric center of the disc-shaped member 18' to the outer edge of the disc-shaped member is suitable for a variety of applications.

[0053] If the extra material 15' is included, the covering 14' is advantageously sized and configured such that the radial length 17' is substantially uniform around the entire closed circumference 22' of the disc-shaped member 18'.

[0054] The covering 14 can be formed of any suitable material, and need only be biocompatible or be able to be rendered biocompatible. The material can advantageously be formed of a flexible material. Examples of suitable materials for the covering 14 include natural materials, synthetic materials, and combinations of natural and synthetic materials.

[0055] Examples of suitable natural materials include extracellular matrix (ECM) materials, such as small intestine submucosa (SIS), other bioremodellable materials, and fixed natural tissues, such as fixed bovine pericardium. Other examples of ECM materials that can be used in the occlusion device include stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa, renal capsule, and dura mater. Dermis harvested from an animal,

such as porcine dermis, or from another source, such as cadaveric dermis, is also considered a suitable natural material for the covering 14. Bioremodellable materials are particularly well-suited materials for use in the covering 14 at least because of their abilities to remodel and become incorporated into adjacent tissues. These materials can provide a scaffold onto which cellular in-growth can occur, eventually allowing the material to remodel into a structure of host cells. This ability to remodel into host tissue can allow occlusion devices that include such materials as the covering to provide permanent blockage of fluid flow through a bodily passage at a point where the occlusion device is deployed.

[0056] Examples of suitable synthetic materials include polymeric materials, such as thermoplastic polyethylene materials, expanded polytetrafluoroethylene (ePTFE), and other existing and later-developed polymeric materials considered suitable for use in implantable medical devices.

[0057] Ultra high molecular weight (UHMW) polymeric materials, such as UHMW thermoplastic materials, are considered well-suited for use in the covering at least because of the ability to prepare these materials as porous structures in various forms, including films, woven sheets, and non-woven sheets. UHMW polyethylene (UHMWPE, also known as high-modulus polyethylene (HMPE) or high-performance polyethylene (HPPE)) is considered particularly advantageous at least because of the ability to prepare this material as a thin film that retains fluid-blocking properties while not contributing significantly to the overall bulk of a device. The inventors have determined that UHMWPE materials having a mircro-porous structure provide suitable materials for the covering. A micro-porous UHMWPE film having between about 40% and about 90% of the surface open, e.g., defined by pores, provides a particularly suitable material for the covering. Furthermore, the inventors have determined that a micro-porous UHMWPE film having pore sizes between about 0.05 micron and about 1.0 micron in diameter and a thickness between about 20 microns and about 120 microns provides a covering suitable for blocking fluid flow while having physical dimensions that contribute an acceptable level of bulk to the overall device. For porous materials, it is considered advantageous to use a material that provides a tortuous pore structure, such as a membrane having a fibrilar structure somewhat

similar to a nonwoven material. Woven and non-woven sheets of UHMWPE having pore sizes that render the sheets porous to air but impervious to water are also considered suitable materials for the covering. It is noted, though, that a material that is permeable to fluid can be suitable for use in the covering if a covering, as a whole, formed of such material is able to block fluid flow as described herein. Furthermore, hydrophobic forms of UHMWPE are considered advantageous at least because it is expected that such materials will more effectively block fluid flow in some applications. Hydrophilic forms of UHMWPE are, however, also considered suitable for use.

[0058] A hydrophobic UHMWPE material that is impervious to fluid is considered advantageous at least because such materials are expected to contribute to the ability of an occlusion device to provide relatively quick closure following implantation.

[0059] The covering 14 can be processed in a manner that reduces the thickness of the material of the covering 14 as compared to non-processed material. Use of such materials can allow for reduction in the overall bulk of the occlusion device 10, which can allow the occlusion device 10 to be loaded into a delivery catheter having a relatively smaller French size. This, in turn, allows the occlusion device 10 to be delivered through and deployed within bodily passages of smaller inner diameter than those through which an occlusion device 10 having a covering 14 of relatively thicker material could be delivered. For example, the inventors have determined that the use of a covering 14 formed from an ECM material, such as SIS, that has been air-dried, stretched, and rehydrated prior to being attached to the support frame is advantageous at least because it provides a covering 14 that is thinner than an ECM that has not been processed in this manner. As a result, the occlusion device 10 has less overall bulk, allowing it to be loaded into smaller delivery catheters and deployed in bodily passages of smaller inner diameter.

[0060] For ECM coverings, any suitable procedure for air-drying, stretching, and/or rehydrating the covering can be used. The inventors have determined that an SIS covering can be suitably processed by laying the covering or a sheet containing the eventual covering flat in an open area, preferably in a sterile

environment, allowing the covering to dry, gently stretching the dried covering, and rehydrating the covering with water for injection (WFI) or other suitable liquid. The rehydrated covering can then be attached to the support frame to make an occlusion device. The inventors have determined that, even after the rehydrating step, SIS processed in this manner does not swell to its original, pre-dried thickness. As a result, the processed covering has a reduced thickness that reduces the overall bulk of the finished occlusion device.

[0061] This approach – reducing the thickness or bulk of a component of the occlusion device – is contrary to a line of development taken in the art to increase effectiveness of occlusion devices. In many prior art devices, additional overall bulk has been added, such as by including a greater number of frame elements, for example, in an attempt to increase the ability of the occlusion device to occlude via thrombosis. As described more fully below, the inventors have surprisingly discovered that occlusion devices according to the disclosure demonstrate acceptable occlusion effectiveness despite efforts to reduce the overall bulk of the device, such as by using a covering that has been processed in a manner that reduces the thickness of the covering.

[0062] Figures 8 and 9 illustrate the occlusion device 10 deployed within a bodily passage 100. The occlusion device 10 has been deployed in the lumen 102 of the bodily passage 100 at a point of treatment where blockage of fluid flow, represented by arrow 106, is desired. The occlusion device 10 is in the first configuration 75 within the lumen 102. The disc-shaped member 18 has the first 42 and second 46 apices folded toward each other. As a result of tension placed on the disc-shaped member 18 by this folding, the member 18 exerts an outwardly-directed force as it seeks to return to the second, or resting, configuration (illustrated in Figure 2). The outwardly-directed force forces the covering 14 to contact the wall 104 of the bodily passage 100, creating a seal between the covering 14 and the wall 104 and that extends around the entire perimeter of the covering 14. As such, the seal extends in a zig-zag pattern around the entire inner circumference of the wall 104 of the bodily passage 100. Together, the covering 14 and seal block fluid flow 106 from passing through the occlusion device 10.

[0063] Because the occlusion device 10 is in the first configuration 75, the crossbar 20 is disposed across the lumen 102 of the bodily passage 100 and defines curve 60 with apex 62. The curve 60 and apex 62 provide a structural feature that can be used for delivery and retrieval or repositioning of the occlusion device 10 following deployment. For example, as illustrated in Figure 9, a catheter 101 with grasping arms 103, 105 can be used to engage the occlusion device 10 by grasping the curve 60 defined by the crossbar 20. The Mouse Tooth Retrieval Forceps, available from Cook Medical, is considered suitable for use in the delivery, retrieval and repositioning of the occlusion device 10.

[0064] The occlusion devices can be placed in a bodily passage using surgical, percutaneous delivery, or any other suitable placement technique. The occlusions devices are particularly well-suited, though, for placement using percutaneous delivery techniques. For example, an occlusion device can be placed in an appropriately-sized delivery catheter, navigated into a lumen of a bodily passage while in the delivery catheter, positioned at a desired point of treatment within the bodily passage, and deployed from the delivery catheter at the point of treatment. The delivery catheter can then be removed from the bodily passage, leaving the occlusion device at the point of treatment.

[0065] The occlusion devices can be placed in any suitable bodily passage, including arteries, veins, ducts, canals, and any other suitable passage where blockage of fluid flow is desired. The occlusion devices are considered particularly advantageous for placement in blood vessels, such as carotid, renal, femoral muscular branch, deep femoral, iliac, and pulmonary blood vessels, for the blockage of blood flow therein. Also, as described above, the occlusion devices include various structural and other features that enable the devices to be navigated through and placed in bodily passages of relatively small size, such as blood vessels having internal diameters as small as 2.0 mm and as large as 8.5 mm or greater. The inventors have determined that it is advantageous to size the occlusion devices with between about 50% and about 300% oversizing, comparing the outer diameter of the disc-shaped member, after any heat treatment(s), to the inner diameter of the bodily passage. The inventors have determined that it is particularly advantageous to size the occlusion devices with

between about 60% and about 150% oversizing, comparing the outer diameter of the disc-shaped member to the inner diameter of the bodily passage. The inventors have determined that it is particularly advantageous to size the occlusion devices with between about 65% and about 100% oversizing, comparing the outer diameter of the disc-shaped member to the inner diameter of the bodily passage. The inventors have determined that it is particularly advantageous to size the occlusion devices with about 66.6% oversizing, comparing the outer diameter of the disc-shaped member to the inner diameter of the bodily passage.

[0066] The occlusion device, or any portion thereof (e.g., support frame, covering, attachment members), can also comprise a bioactive. As used herein, the term "bioactive" refers to any composition that is believed to be capable of producing a biological and/or treatment effect in a host. The term includes compositions that directly produce biological effects, as well as compositions that produce, generate, or otherwise provide another composition that produces a biological effect. Further, the occlusion device can comprise two or more bioactives.

[0067] Any suitable bioactive can be used in the invention, and the specific bioactive chosen will depend on the desired effect. Examples of suitable bioactives include antithrombogenic agents, antiproliferative agents, and immunosuppressive agents. A wide range of other bioactives can be used, including heparin, covalent heparin, or another thrombin inhibitor, hirudin, hirulog, argatroban, D-phenylalanyl-L-poly-L-arginyl chloromethyl ketone, or another antithrombogenic agent, or mixtures thereof; urokinase, streptokinase, a tissue plasminogen activator, or another thrombolytic agent, or mixtures thereof; a fibrinolytic agent; a vasospasm inhibitor; a calcium channel blocker, a nitrate, nitric oxide, a nitric oxide promoter or another vasodilator; Hytrin (Hytrin is a registered trademark of Abbott Laboratories Corporation of Abbott Park, IL, USA) or other antihypertensive agents; an antimicrobial agent or antibiotic; aspirin, ticlopidine, a glycoprotein IIb/IIIa inhibitor or another inhibitor of surface glycoprotein receptors, or another antiplatelet agent; colchicine or another antimitotic, or another microtubule inhibitor, dimethyl sulfoxide (DMSO), a retinoid or another antisecretory agent; cytochalasin or another actin inhibitor; or a remodelling

inhibitor; deoxyribonucleic acid, an antisense nucleotide or another agent for molecular genetic intervention; methotrexate or another antimetabolite or antiproliferative agent; tamoxifen citrate, Taxol (Taxol is a registered trademark of Bristol-Myers Squibb Company of New York, NY, USA) or the derivatives thereof, or other anti-cancer chemotherapeutic agents; dexamethasone, dexamethasone sodium phosphate, dexamethasone acetate or another dexamethasone derivative, or another anti-inflammatory steroid or non-steroidal antiinflammatory agent; cyclosporin or another immunosuppressive agent; trapidal (a PDGF antagonist), angiopeptin (a growth hormone antagonist), angiogenin, a growth factor or an anti-growth factor antibody, or another growth factor antagonist; dopamine, bromocriptine mesylate, pergolide mesylate or another dopamine agonist; .sup.60 Co (5.3 year half life), .sup.192 Ir (73.8 days), .sup.32 P (14.3 days), .sup.111 In (68 hours), .sup.90 Y (64 hours), .sup.99m Tc (6 hours) or another radiotherapeutic agent; iodine-containing compounds, barium-containing compounds, gold, tantalum, platinum, tungsten or another heavy metal functioning as a radiopaque agent; a peptide, a protein, an enzyme, an extracellular matrix component, a cellular component or another biologic agent; captopril, enalapril or another angiotensin converting enzyme (ACE) inhibitor; ascorbic acid, alpha tocopherol, superoxide dismutase, deferoxamine, a 21-aminosteroid (lasaroid) or another free radical scavenger, iron chelator or antioxidant; a .sup.14 C-, .sup.3 H-, .sup.131 I-, .sup.32 P- or .sup.36 S-radiolabelled form or other radiolabelled form of any of the foregoing; estrogen or another sex hormone; AZT or other antipolymerases; acyclovir, famciclovir, rimantadine hydrochloride, ganciclovir sodium, Norvir, Crixivan, or other antiviral agents; 5-aminolevulinic acid, meta-tetrahydroxyphenylchlorin, hexadecafluoro zinc phthalocyanine, tetramethyl hematoporphyrin, rhodamine 123 or other photodynamic therapy agents; an IgG2 Kappa antibody against Pseudomonas aeruginosa exotoxin A and reactive with A431 epidermoid carcinoma cells, monoclonal antibody against the noradrenergic enzyme dopamine beta-hydroxylase conjugated to saporin or other antibody targeted therapy agents; gene therapy agents; and enalapril and other prodrugs; Proscar (Proscar is a registered trademark of Merck Sharp & Dohme Corporation of Whitehouse Station, NJ, USA), Hytrin (Hytrin is a registered trademark of Abbott

Laboratories Corporation of Abbott Park, IL, USA) or other agents for treating benign prostatic hyperplasia (BHP) or a mixture of any of these.

[0068] In some embodiments, the bioactive can comprise a bioactive capable of promoting healing and/or endothelialization (e.g., a peptide). A bioactive capable of promoting healing and/or endothelialization may have one or more desired treatment effects, including decreasing the propensity for recanalization.

[0069] If included, the bioactive can be associated with the occlusion device, or any portion thereof, in any suitable manner. For example, the bioactive can be coated on a surface of the occlusion device, disposed in a discrete portion of the occlusion device, and dispersed throughout a portion, or the entirety, of the occlusion device. The exact manner of associating the bioactive with the occlusion device will depend on numerous factors, which may include the nature of the bioactive and/or occlusion device, manufacturing methods, and desired treatment effect. Those skilled in the art can choose an appropriate manner of associating the bioactive with the occlusion device based on these and/or other factors.

[0070] The occlusion device may also comprise a barrier that controls release of the bioactive from the occlusion device. For example, the occlusion device can include a layer of the bioactive, either alone or with another material, and a barrier layer disposed on the bioactive layer. Also, the bioactive can be distributed in a barrier. In these embodiments, the barrier need only comprise a material that provides a controlled release of the bioactive from the occlusion device. For example, the barrier can be a polymer that controls release of the bioactive by diffusion of the bioactive through the polymer or degradation of the polymer. Furthermore, blends and layering of polymer(s) can be used to create a barrier. Examples of suitable arrangements of barriers are in United States Patent 6,299,604 to Ragheb for a COATED IMPLANTABLE MEDICAL DEVICE, which is hereby incorporated by reference in its entirety.

[0071] Figure 10 illustrates a second exemplary occlusion device 110. The occlusion device 110 is similar to the occlusion device 10 illustrated in Figure 1

and described above, except as detailed below. Reference numbers in Figure 10 refer to the same structural element or feature referenced by the same number in Figure 1, offset by 100.

[0072] The occlusion device 110 includes a support frame 112, a covering 114, and one or more attachment members 116 that attach the covering 114 to the support frame 112. The support frame 112 comprises a disc-shaped member 118 and a crossbar 120. The disc-shaped member 118 has a closed circumference 122 that defines a central opening 124. The crossbar 120 is connected to the disc-shaped member 118 and spans the central opening 124.

[0073] The covering 114 includes a first portion 117 that is attached to the disc-shaped member 118 and a second portion 119 that is attached to the crossbar 120 and extends to the second curve 144 of the disc-shaped member 118. As illustrated in the Figure 10, the second portion 119 is advantageously attached to the outside of the crossbar 120 and the outside of the second curve 144 of the disc-shaped member 118 to define a pocket 155 between the inner surfaces 121, 123 of the covering 114.

[0074] The inclusion of pocket 155 is considered advantageous at least because it is provides an additional barrier to fluid flow when the occlusion device 110 is deployed within a bodily passage. The second portion 119 of the covering 114 provides an outer surface 125 that can contact an inner surface of a wall of a bodily passage, which can provide an additional seal between the covering 114 and the wall. As illustrated in Figure 10, the second portion 119 of the covering 114 includes slack that allows the second portion 119 to fit loosely on the support frame 112. The inclusion of a degree of slack in the second portion 119 is considered advantageous at least because it is expected to allow the second portion 119 to accommodate movement of fluid in the pocket 155, which may reduce stress on the second portion 119 and prevent the damage it may produce, such as tearing.

[0075] Figure 10 illustrates the occlusion device 110 in a first, or deployed, configuration 175.

[0076] Figure 11 illustrates a third exemplary occlusion device 210. The occlusion device 210 is similar to the occlusion device 10 illustrated in Figure 1 and described above, except as detailed below. Reference numbers in Figure 11 refer to the same structural element or feature referenced by the same number in Figure 1, offset by 200.

[0077] The occlusion device 210 includes a support frame 212, a covering 214, and one or more attachment members 216 that attach the covering 214 to the support frame 212. The support frame 212 comprises a disc-shaped member 218 and a crossbar 220. The disc-shaped member 218 has a closed circumference 222 that defines a central opening 224. The crossbar 220 is connected to the disc-shaped member 218 and spans the central opening 224.

[0078] The occlusion device 210 includes a second crossbar 221 that is connected to the disc-shaped member 218 and spans the central opening 224 defined by the disc-shaped member 218. The second crossbar 221 has a similar construction to that of the crossbar 220. The second crossbar 221 is has a greater length than that of the crossbar 220, though. As illustrated in Figure 11, the second crossbar 221 is advantageously disposed orthogonally to the crossbar 220. That is, the second crossbar 221 lies in a plane that is perpendicular to or substantially perpendicular to a plane containing the crossbar 220. Also advantageously, the second crossbar 221 is attached to the disc-shaped member 218 at two points, each of which is spaced equidistant from the two attachment points where the crossbar 220 attaches to the disc-shaped member.

[0079] In the illustrated embodiment, the covering 214 extends over the second crossbar 221 so that the covering 214 is disposed radially outward of the second crossbar 221. This structural arrangement creates pocket 255 and is considered advantageous at least because it increases the surface area of the covering 214 that is exposed to fluid in the bodily passage. The increased surface area may increase the speed with which thrombus forms, which may enhance the effectiveness of the occlusion device 210 as compared to a device that lacks the pocket 255 and the additional surface area it provides for contact with the fluid in the bodily passage. The additional surface area of the covering 214 also provides additional material

for contact with the wall of the bodily passage, which may enhance the effectiveness of the occlusion device 210 by providing a more extensive and/or stronger seal between the covering 214 and the bodily passage. The covering 214 can be attached to the second crossbar 221, such as with sutures or other suitable attachment mechanisms or means for attaching, or can be left free of attachment to the second crossbar 221.

[0080] Figure 11 illustrates the occlusion device 210 in a first, or deployed, configuration 275.

[0081] Figure 12 illustrates a fourth exemplary occlusion device 310. The occlusion device 310 is similar to the occlusion device 210 illustrated in Figure 11 and described above, except as detailed below. Reference numbers in Figure 12 refer to the same structural element or feature referenced by the same number in Figure 11, offset by 100.

[0082] The occlusion device 310 includes a support frame 312, a covering 314, and one or more attachment members 316 that attach the covering 314 to the support frame 312. The support frame 312 comprises a disc-shaped member 318 and a crossbar 320. The disc-shaped member 318 has a closed circumference 322 that defines a central opening 324. The crossbar 320 is connected to the disc-shaped member 318 and spans the central opening 324.

[0083] The occlusion device 310 includes a second crossbar 321 that is connected to the disc-shaped member 318 and spans the central opening 324 defined by the disc-shaped member 318. The second crossbar 321 has a similar construction to that of the crossbar 320. The second crossbar 321 is has a greater length than that of the crossbar 320, though. As illustrated in Figure 12, the second crossbar 321 is advantageously disposed orthogonally to the crossbar 320. That is, the second crossbar 321 lies in a plane that is perpendicular to or substantially perpendicular to a plane containing the crossbar 320. Also advantageously, the second crossbar 321 is attached to the disc-shaped member 318 at two points, each of which is spaced equidistant from the two attachment points where the crossbar 320 attaches to the disc-shaped member.

[0084] In the illustrated embodiment, the covering 314 extends over the second crossbar 321 so that the covering 314 is disposed radially outward of the second crossbar 321. In this embodiment, the covering 314 does not extend along the entire length of the second crossbar 321, creating a terminal portion of the second crossbar 321 that is not covered by the covering 314. The terminal end of the covering 314 is sealed closed, such as by additional attachment members 316' that secure opposing surfaces of the covering 314 to each other.

[0085] While this structural arrangement creates a pocket 355 that has a shorter longitudinal length than the pocket 255 in the occlusion device 210 illustrated in Figure 11, this arrangement can be advantageous at least because it exposes a portion of the second crossbar 321 that can be used for engagement with a retrieval and/or repositioning device, which may avoid potential damage to the covering 314 by such devices. This arrangement can also lower the overall profile of the occlusion device 310. Furthermore, this arrangement may reduce or eliminate any stresses that may be placed on a covering that extends over the second crossbar, such as covering 214 in the embodiment illustrated in Figure 11.

[0086] In making an occlusion device according to a particular embodiment, a skilled artisan can balance the expected advantages of the embodiment illustrated in Figure 11 and described above (e.g., the depth of the pocket 255 provides additional surface area for thrombus formation and contact with the wall of the bodily passage) against the expected advantages of the embodiment illustrated in Figure 12 (e.g., the relatively low profile nature of the occlusion device 310 and the elimination of stresses on the covering 314).

[0087] Figure 13 illustrates an alternative support frame 412 for use in occlusion devices. The support frame 412 is similar to the support frames described in connection with other occlusion devices described herein, except as detailed below. Thus, the support frame 412 includes a disc-shaped member 418 formed of a core wire and a coil, and a crossbar 420 formed of a core wire and a coil. The disc-shaped member 418 defines a closed circumference 422 and a central opening 424.

[0088] An anchor 490 is attached to the disc-shaped member 418 by cannula 495. Any other suitable means for attaching can be used, but cannula 495 is considered advantageous at least because of the ease it provides in attaching the anchor 490 to the disc-shaped member 418. The anchor 490, in essence, is another crossbar. The ends of the core wire provide barb that can facilitate anchoring of an occlusion device in a bodily passage.

[0089] Figure 14 illustrates a fifth exemplary occlusion device 510. The occlusion device 510 is similar to the occlusion device 10 illustrated in Figure 1 and described above, except as detailed below. Reference numbers in Figure 14 refer to the same structural element or feature referenced by the same number in Figure 1, offset by 500.

[0090] The occlusion device 510 includes a support frame 512, a covering 514, and one or more attachment members 516 that attach the covering 514 to the support frame 512. The support frame 512 comprises a disc-shaped member 518 and a crossbar 520. The disc-shaped member 518 has a closed circumference 522 that defines a central opening 524. The crossbar 520 is connected to the disc-shaped member 518 and spans the central opening 524.

[0091] The occlusion device 510 includes a second crossbar 521 that is connected to the disc-shaped member 518 and spans the central opening 524 defined by the disc-shaped member 518. The second crossbar 521 has a similar construction to that of the crossbar 520. In this embodiment, the crossbar 520 and the second crossbar 521 have the same longitudinal length or substantially the same longitudinal length. As illustrated in Figure 14, the second crossbar 521 is advantageously disposed orthogonally or substantially orthogonally to the crossbar 520. That is, the second crossbar 521 lies in a plane that is perpendicular to or substantially perpendicular to a plane containing the crossbar 520. Also advantageously, the second crossbar 521 is attached to the disc-shaped member 518 at two points, each of which is spaced equidistant from the two attachment points where the crossbar 520 attaches to the disc-shaped member 518.

[0092] In the illustrated embodiment, the covering 514 extends over the second crossbar 521 so that the covering 514 is disposed radially outward of the second crossbar 521. This structural arrangement creates pocket 355 and is considered advantageous at least because it increases the surface area of the covering 314 that is exposed to fluid in the bodily passage.

[0093] The covering 514 can be free of attachment to second crossbar 521, as illustrated in Figure 14. Alternatively, the covering 514 can be attached to the second crossbar 521 using any suitable attachment members, such as sutures, clips, bonds, welds, and any other suitable structure, process, and/or technique for attaching a covering material to a frame. Attachment of the covering 514 to the second crossbar 521 in this manner is considered advantageous at least because it is expected to minimize movement of a free covering 514 within the body vessel following implantation, which may enhance the chronic performance of the occlusion device 510.

[0094] The covering 514 provides a section of extra material 515 that extends radially beyond the outer edge of the disc-shaped member 518 relative to the geometric center (not specifically referenced in Figure 14) of the disc-shaped member 518 when the occlusion device 510 is in the first configuration (such as illustrated in Figure 14). The inclusion of the extra material 515 is considered advantageous at least because it provides additional material that, once the occlusion device 510 is deployed within a bodily passage, can contact and seal with the wall of the bodily passage. This structural arrangement upon deployment is expected to increase the effectiveness of the occlusion device 510 in blocking fluid flow through the bodily passage by providing additional surface area for contact with the wall of the bodily passage.

[0095] Figure 14 illustrates the occlusion device 510 in a first, or deployed, configuration.

[0096] Figure 15 illustrates the fifth exemplary occlusion device 510' according to an alternative construction. The occlusion device 510' according to this alternative embodiment is similar to the occlusion device 510 illustrated in Figure

14 and described above, except as indicated below. In this alternative embodiment, the covering 514' is disposed radially inward of the second crossbar 521', i.e., closer to a geometric center of the disc-shaped member 518' than the second crossbar 521'. This structural arrangement is expected to allow a user to position the occlusion device 510' in either orientation within the bodily passage (i.e., with either the crossbar 520' or the second crossbar 521' upstream within the passage, and, as a result, with either the crossbar 520' or the second crossbar 521' downstream in the passage). This is expected to eliminate any need to confirm that the occlusion device 510' is positioned in a delivery catheter properly prior to placement within a bodily passage.

[0097] Similar to the embodiment illustrated in Figure 14 and described above, the covering 514' can be free of attachment to second crossbar 521', as illustrated in Figure 15. Alternatively, the covering 514' can be attached to the second crossbar 521' using any suitable attachment members, such as sutures, clips, bonds, welds, and any other suitable structure, process, and/or technique for attaching a covering material to a frame. Attachment of the covering 514' to the second crossbar 521' in this manner is considered advantageous at least because it is expected to minimize movement of a free covering 514' within the body vessel and, in this embodiment, within the frame, following implantation, which may enhance the chronic performance of the occlusion device 510'.

[0098] Figure 16 illustrates the occlusion device 510' implanted in an external iliac artery 575b of a human being. The disc-shaped member 518' has adopted a sinusoidal configuration as a result of the oversizing of the support frame 512' relative to the inner diameter of the artery 575b. The crossbar 520' extends away from the disc-shaped member 518' in a proximal direction, and the second crossbar 521' extends away from the disc-shaped member 518' in a substantially opposite, distal direction. The covering 514' extends distally away from the disc-shaped member 518' and defines pocket 555'. The covering also forms a circumferential seal with the internal wall of the iliac artery 575b. The occlusion device 510' is positioned to block fluid flowing distally in the external iliac artery 575b, represented by arrow 585a. Fluid flowing distally through the common iliac

artery 575a is still able to pass through the internal iliac artery 575c, represented by arrow 585b.

[0099] Figure 17 illustrates an exemplary method 600 of making an occlusion device. In an initial step 602, a sheet of ECM, such as SIS, is air dried. In another step 604, the sheet is stretched. In another step 606, the sheet is rehydrated. In another step 608, the sheet is attached to a support frame comprising a disc-shaped member and a crossbar in accordance with the disclosure to produce an occlusion device having a support frame and a covering. In another step 610, the occlusion device is placed into the lumen of a loading cartridge comprising an elongate tubular member, such as a sheath having a peel-away structure. The tubular member advantageously includes a series of holes to aid in the drying and rehydration steps below. In another step 612, the loading cartridge, containing the occlusion device, is freeze-dried. In another step 614, the loading cartridge, containing the occlusion device, is lyophilized. The inclusion of a lyophilization step is advantageous at least because it helps ensure that the covering does not adhere to itself. This is considered particularly advantageous for coverings formed of SIS and other ECMs.

[00100] Immediately prior to use, the occlusion device can be rehydrated and transferred into an appropriately-sized delivery sheath.

[00101] EXAMPLE – IN VIVO IMPLANTATION OF OCCLUSION DEVICES

[00102] Nine (9) occlusion devices were implanted in various arterial vessels of sheep (target arteries included carotid, renal, femoral muscular branch, deep femoral, iliac, and pulmonary arteries; vessel diameters ranged from 3 mm to 9 mm). Prior to implantation, each animal was fully heparanized (100 IU heparin/kg body weight). Each of the occlusion devices was constructed to be similar to the embodiment illustrated in Figure 15.

[00103] Sizing scheme

[00104] 6 mm devices (outer diameter of the disc-shaped member) were used for vessels with an inner diameter of between about 2.4 and about 3.6 mm.

[00105] 8 mm devices were used for vessels with an inner diameter of between about 3.6 and about 4.8 mm.

[00106] 10 mm devices were used for vessels with an inner diameter of between about 4.8 and about 6.0 mm.

[00107] 12 mm devices were used for vessels with an inner diameter of between about 6.0 and about 7.2 mm.

[00108] 14 mm devices were used for vessels with an inner diameter of between about 7.2 and about 8.4 mm.

[00109] Results

[00110] Eight out of nine (8/9) occlusion devices resulted in occlusion, i.e., blocked fluid flow through the vessel at the point of implantation of the occlusion device. The time between implantation and occlusion varied between immediate and about 12 minutes. The ninth occlusion device was retrieved from the animal as described above and was not allowed to remain in the vessel for thrombus formation.

[00111] Discussion

[00112] Each of the occlusion devices that were allowed to remain in the target vessel for thrombus formation produced occlusion in a relatively short period of time following implantation. Overall, occlusion times were brief despite the heparin treatment given to the animals, and are expected to be even shorter in the absence of such treatment.

[00113] The foregoing detailed description refers to exemplary occlusion devices and includes the best mode for practicing the invention. The description and the appended drawings illustrating the described devices are intended only to provide examples and not to limit the scope of the claims in any manner.

[00114] What is claimed is:

1. An occlusion device, comprising:

a support frame comprising a disc-shaped member, a first crossbar, and a second crossbar;

the disc-shaped member having an outer edge and defining a closed circumference with a central opening, the disc-shaped member including a first coil defining a first passageway and a first core wire extending through the first passageway;

the first crossbar attached to the disc-shaped member and extending across the central opening and including a second coil defining a second passageway and a second core wire extending through the second passageway;

the second crossbar attached to the disc-shaped member and extending across the central opening and including a third coil defining a third passageway and a third core wire extending through the third passageway, the second crossbar disposed substantially orthogonally to the first crossbar; and

a covering attached to the disc-shaped member and free of attachment to the second crossbar, the covering disposed radially inward of the second crossbar and extending radially beyond the outer edge of the disc-shaped member.

2. The occlusion device of claim 1, wherein the first core wire passes through the first passageway four times.

3. The occlusion device of claim 2, wherein the second core wire passes through the second passageway four times.

4. The occlusion device of claim 2, wherein the second core wire passes through the second passageway three times.

5. The occlusion device of claim 1, wherein the covering comprises a bioremodellable material.

6. The occlusion device of claim 1, wherein the covering comprises an extracellular matrix material.

7. The occlusion device of claim 1, wherein the covering comprises small intestine submucosa.

8. The occlusion device of claim 1, wherein the covering comprises an ultra high molecular weight polymeric material.

9. The occlusion device of claim 1, wherein the first coil, second coil, and third coil are formed of platinum; and

wherein the first core wire, second core wire, and third core wire are formed of nitinol.

10. The occlusion device of claim 1, wherein the first coil comprises a first outer diameter, the second coil comprises a second outer diameter, and the third coil comprises a third outer diameter; and

wherein the second and third outer diameters are larger than the first outer diameter.

11. An occlusion device, comprising:

a support frame comprising a disc-shaped member, a first crossbar, and a second crossbar;

the disc-shaped member having an outer edge and defining a closed circumference with a central opening, the disc-shaped member including a first coil defining a first passageway and a first core wire extending through the first passageway;

the first crossbar attached to the disc-shaped member and extending across the central opening and including a second coil defining a second passageway and a second core wire extending through the second passageway;

the second crossbar attached to the disc-shaped member and extending across the central opening and including a third coil defining a third passageway and a third core wire extending through the third passageway, the second crossbar disposed substantially orthogonally to the first crossbar; and

a covering attached to the disc-shaped member.

12. The occlusion device of claim 11, wherein the closed circumference of the disc-shaped member defines a first area and the covering defines a second area; and

wherein the first area and the second area are substantially equal.

13. The occlusion device of claim 11, wherein the closed circumference of the

disc-shaped member defines a first area and the covering defines a second area; and

wherein the second area is substantially greater than the first area.

14. The occlusion device of claim 11, wherein the first crossbar has a first length and the second crossbar has a second length; and

wherein the second length is greater than the first length.

15. The occlusion device of claim 11, wherein the first crossbar has a first length and the second crossbar has a second length; and

wherein the second length is substantially equal to the first length.

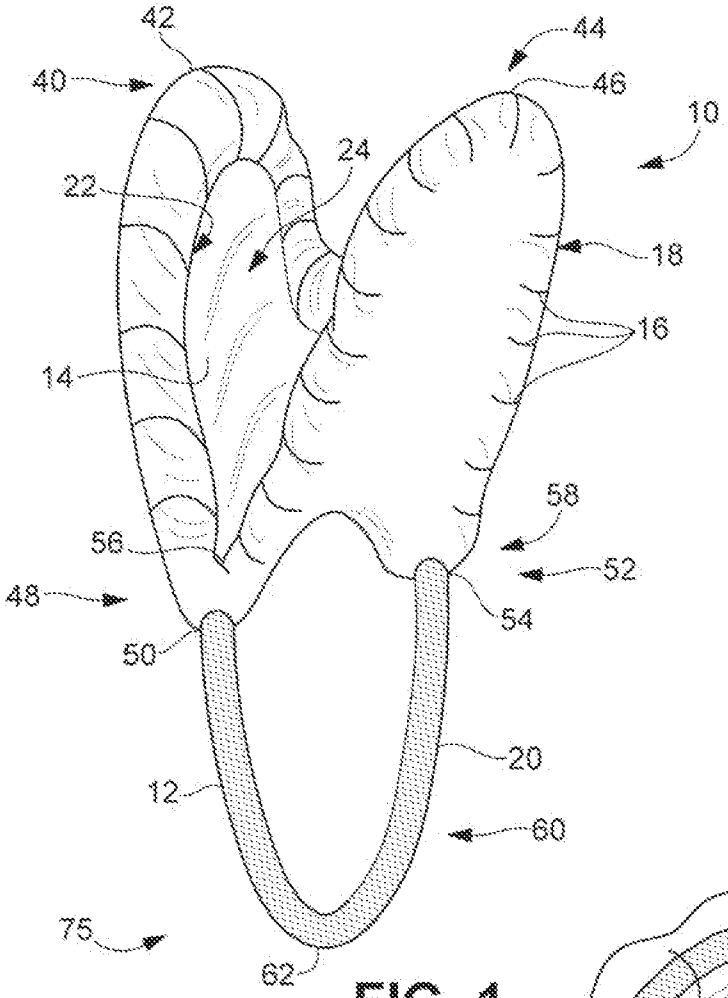
16. An occlusion device, comprising:

a support frame comprising a disc-shaped member and a crossbar;

the disc-shaped member having an outer edge and defining a closed circumference with a central opening, the disc-shaped member including a first coil defining a first passageway and a first core wire extending through the first passageway;

the crossbar attached to the disc-shaped member and extending across the central opening and including a second coil defining a second passageway and a second core wire extending through the second passageway; and

a covering attached to the support frame.


42
44
40
46
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22
18
16
14
58
56
52
48
54
50
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12
60
75
62

FIG. 1

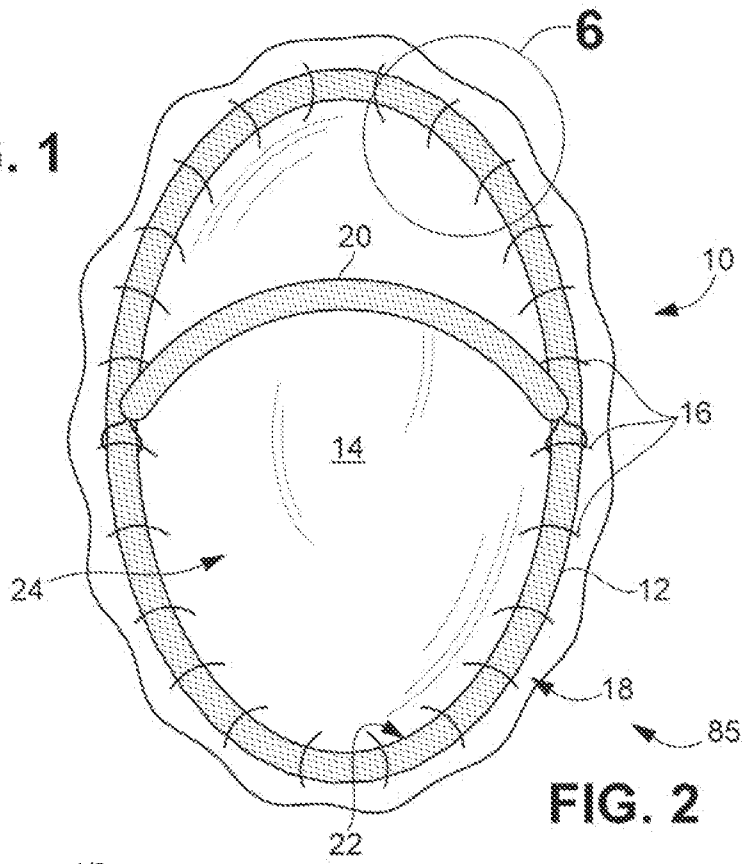
6
20
10
16
14
24
12
18
85
22

FIG. 2

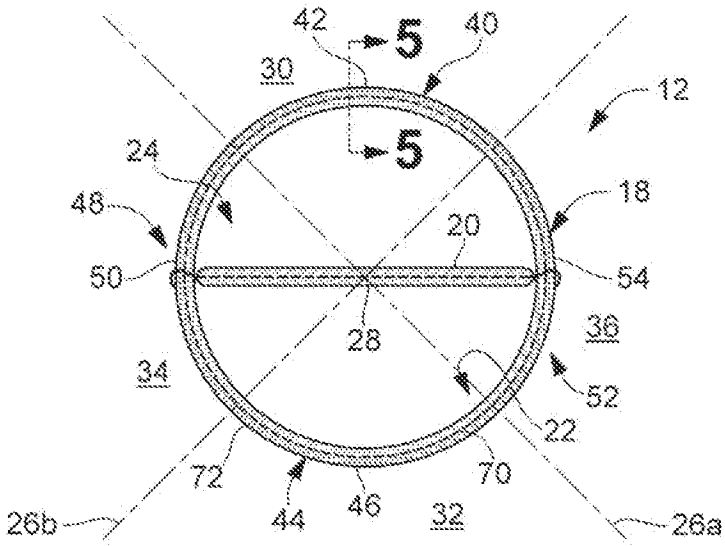

FIG. 3

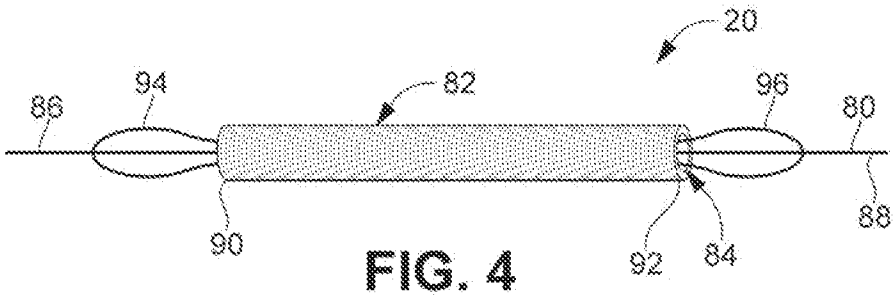

FIG. 4

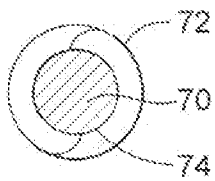

FIG. 5

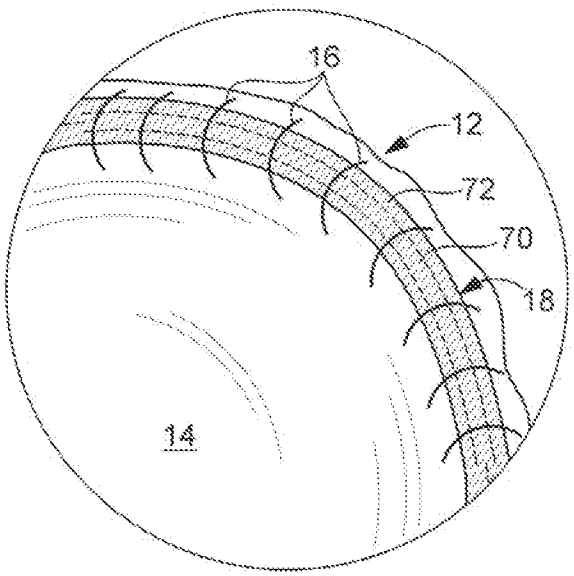

FIG. 6

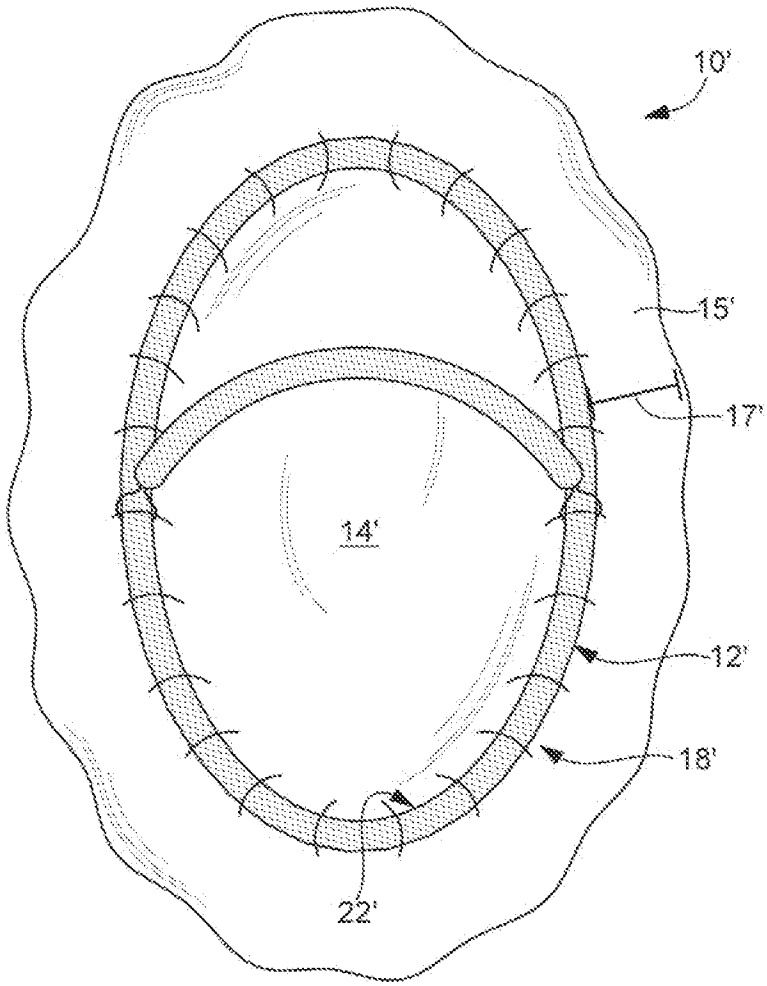

FIG. 7

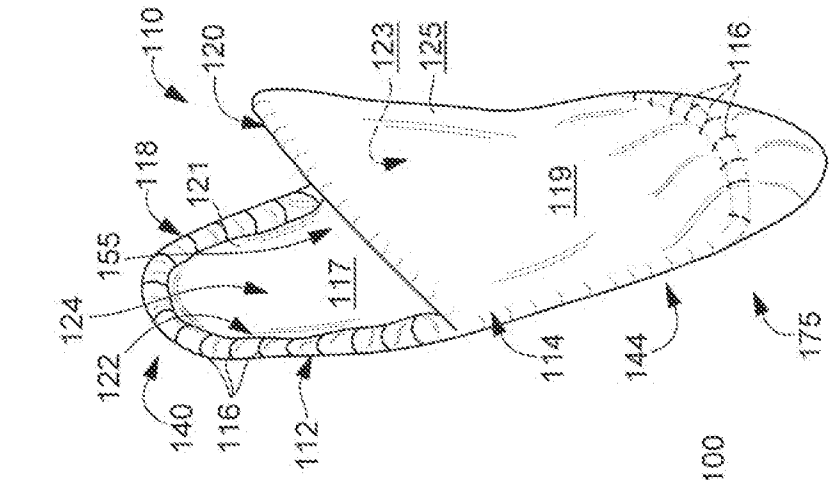

FIG. 10

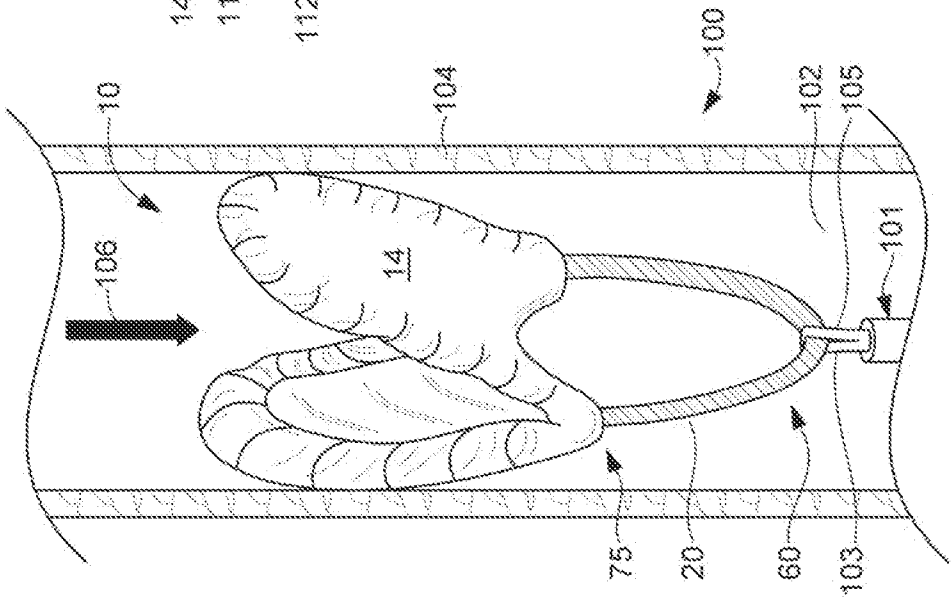

FIG. 9

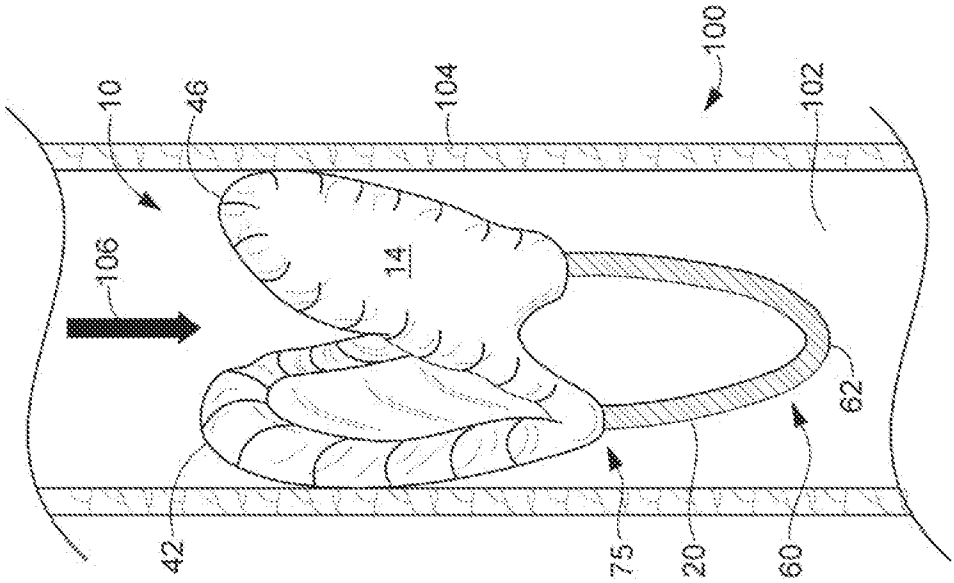

FIG. 8

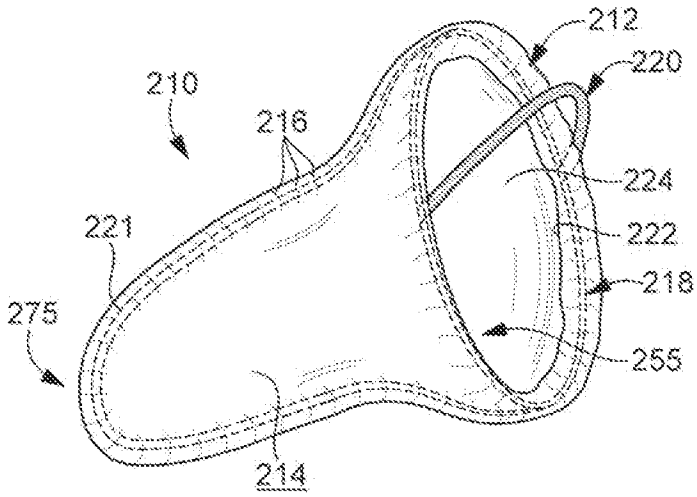

FIG. 11

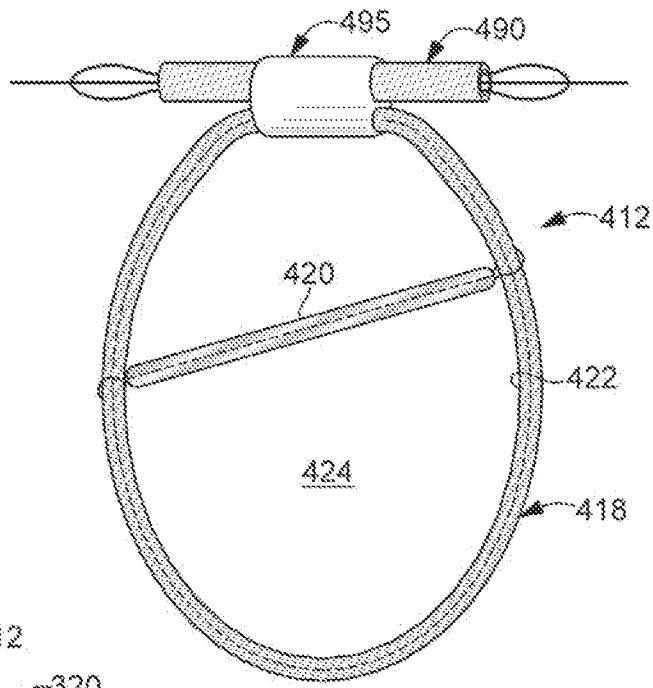

FIG. 13

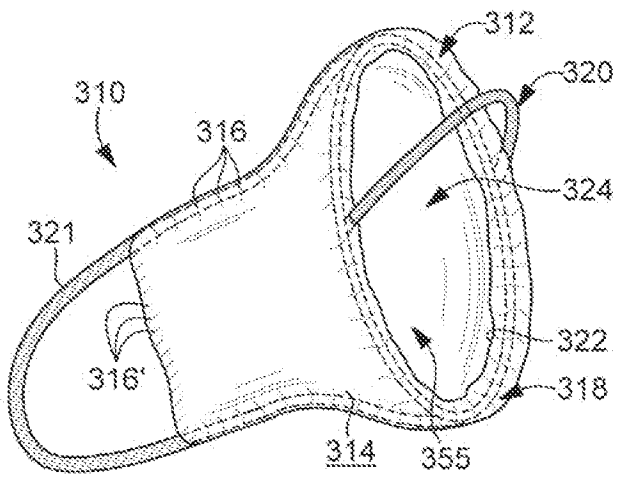

FIG. 12

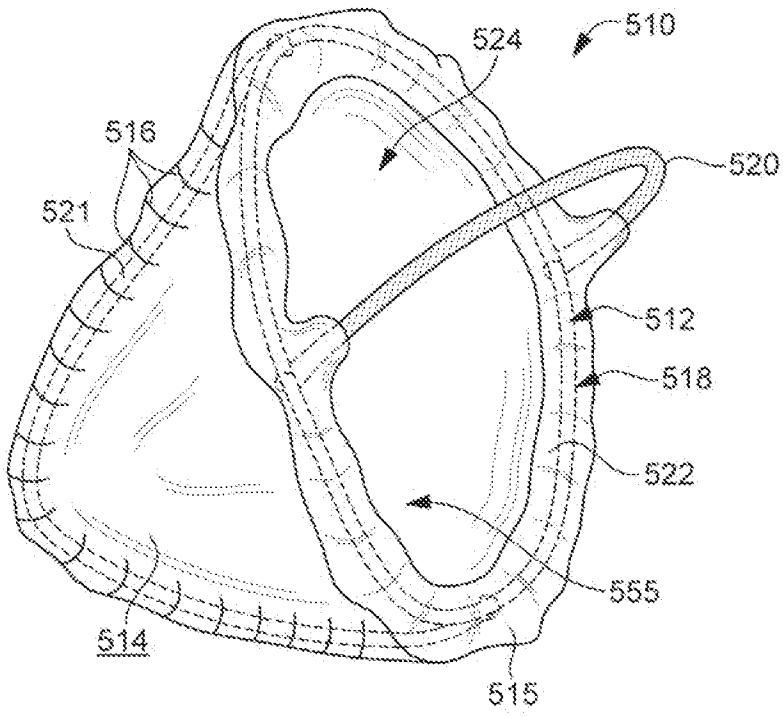

FIG. 14

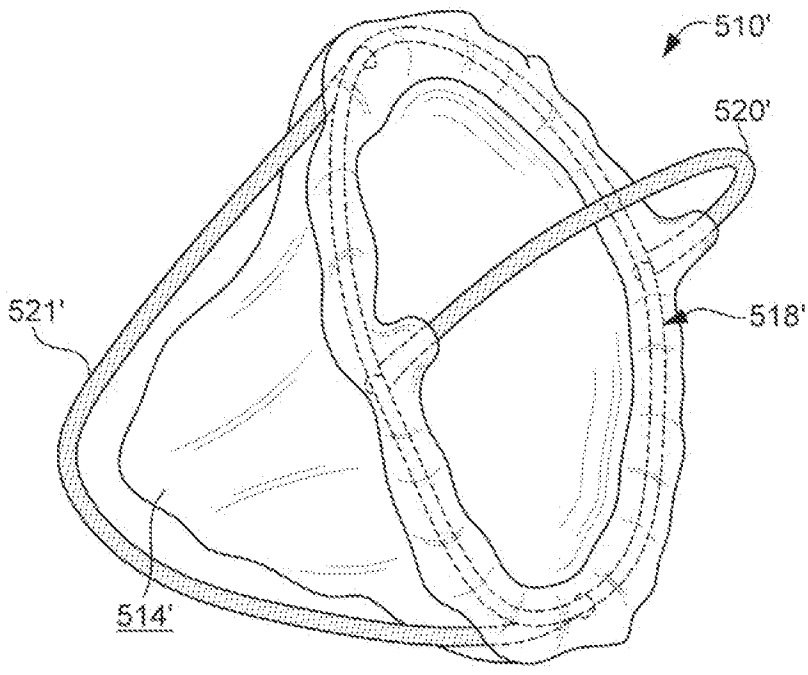

FIG. 15

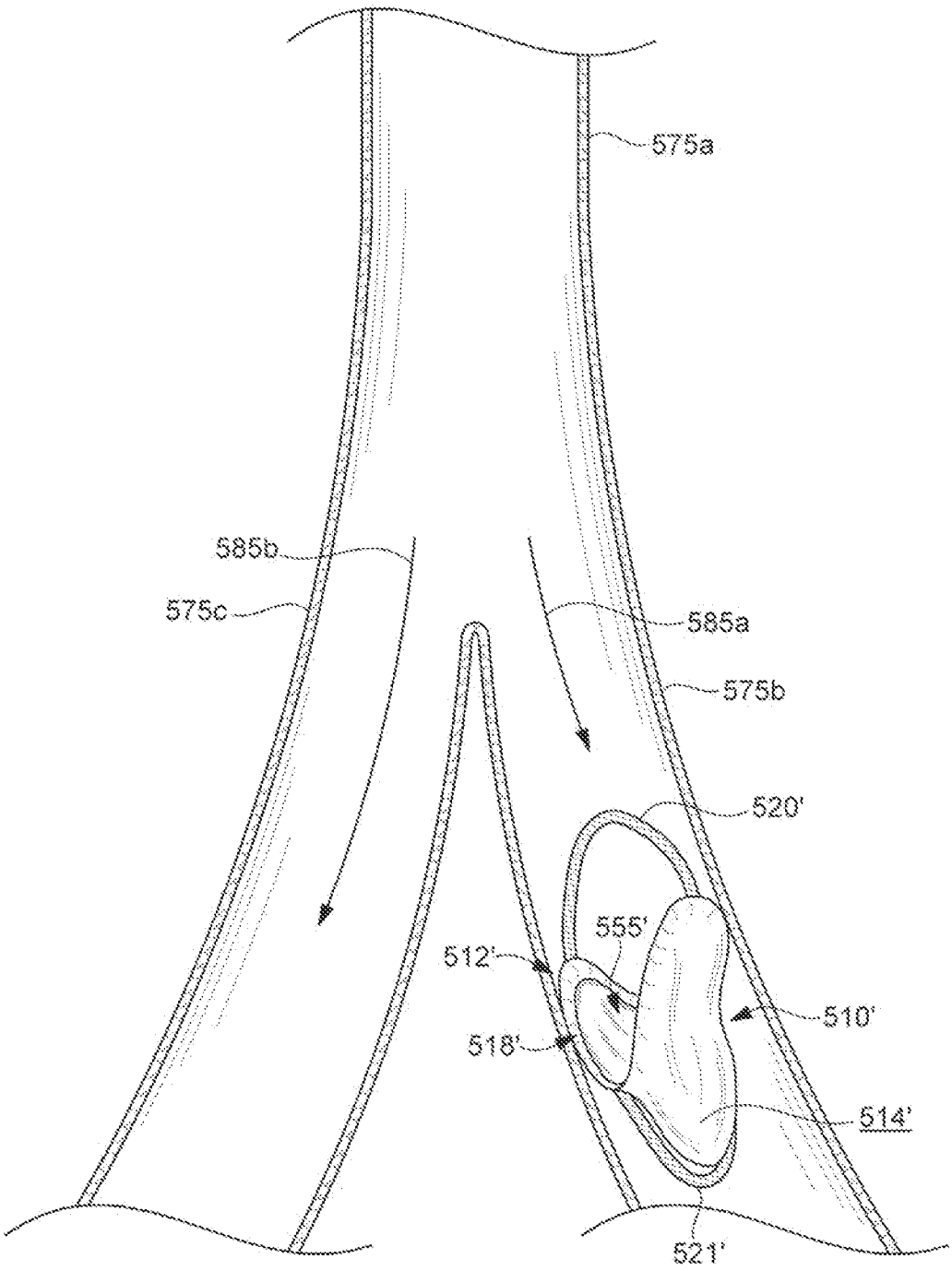

FIG. 16

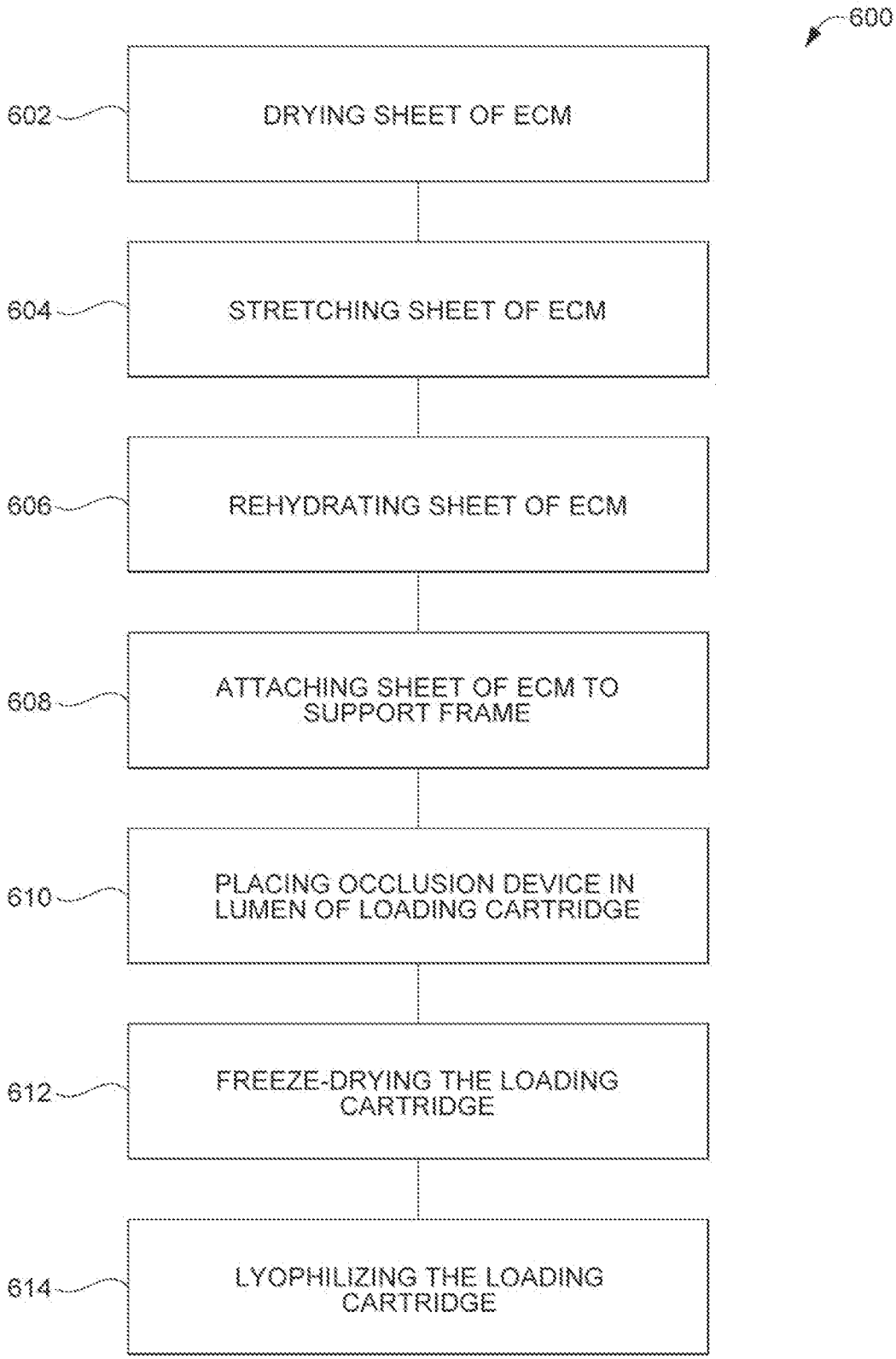
600
602
DRYING SHEET OF ECM
604
STRETCHING SHEET OF ECM
606
REHYDRATING SHEET OF ECM
608
ATTACHING SHEET OF ECM TO SUPPORT FRAME
610
PLACING OCCLUSION DEVICE IN LUMEN OF LOADING CARTRIDGE
612
FREEZE-DRYING THE LOADING CARTRIDGE
614
LYOPHILIZING THE LOADING CARTRIDGE

FIG. 17