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Inventor(s)	Walzman; Daniel Ezra

ORIENTABLE IMPLANTABLE DEVICE AND METHOD

Abstract

An intravascular system having a first catheter having a first non-circular transverse cross-sectional configuration and a first delivery device configured for insertion into the lumen of the catheter. The first delivery device includes an implantable medical device and an elongated member supporting the first medical device such that the first elongated member and the first medical device are movable through the lumen of the first catheter. The first elongated member has a second non-circular transverse cross-sectional configuration corresponding to the first non-circular transverse cross-sectional configuration to thereby inhibit rotation of the first elongated member within the catheter and control orientation of the first medical device relative to the catheter.

Inventors: **Walzman; Daniel Ezra (Teaneck, NJ)**

Applicant: **Walzman; Daniel Ezra** (Teaneck, NJ)

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION(S) [0001] This application claims priority to provisional application 63/109,387, filed on Nov. 4, 2020, and is a continuation-in-part of U.S. application Ser. No. 16/888,813, filed on May 31, 2020, which claims priority to provisional application 62/921,574, filed on Jun. 25, 2019, and is a continuation-in-part of U.S. application Ser. No. 17/246,853, filed May 3, 2021, which is a continuation of U.S. application Ser. No. 16/852,488, filed on Apr. 19, 2020, now U.S. Pat. No. 11,045,177, which claims priority to 62/921,378, filed Jun. 12, 2019. The entire contents of each of these applications are incorporated herein by reference.

FIELD OF THE INVENTION
[0002] The present disclosure relates to medical devices used to treat vascular pathologies (e.g., aneurysms, fistulas, ruptures, narrowings etc.) in intracranial or other tortuous blood vessels (vasculature). In one particular aspect, for example, the present disclosure relates to endovascular devices that are configured to deploy a stent and/or other devices (e.g., a flow-diverting stent, a covered stent, a caped stent, a fenestrated stent, a branched stent, a variable porosity stent, etc.) in a desired orientation to treat such vascular pathologies.
BACKGROUND OF THE INVENTION
Prior Art
[0003] The prior art teaches the use of a number of devices to treat vascular pathologies. One such device is a differentially porous (variable porosity) stent that includes asymmetrical braiding or coils so as to create areas of lesser or greater blood flow as may be desired. Fenestrated and branched devices have been effectively employed in the aorta and its immediate branches, and other applications having larger blood vessels with little tortuosity. Although the prior art has disclosed the theoretical application of such devices intracranially and in other tortuous and distal vasculature, no device or method has been described that can reliably deploy such devices in their

desired (rotational) orientation. This is similarly true for other vascular devices that could more ideally be customized to a particular anatomy if they were able to be positioned reliably in a desired orientation. The constraints of intracranial or other tortuous vasculature have to date precluded the use thereof in these areas.

[0004] U.S. Pat. No. 9,775,730 (Walzman) teaches a covered stent device capable of safe and effective delivery and deployment into tortuous vessels to effectively divert blood flow away from the vascular abnormality while allowing blood to flow to healthy tissue distal to the targeted treatment area and still resulting in blood stasis and thrombus formation inside the aneurysm, fistula, etc.

[0005] U.S. Pat. Publ. No. 2019/0151072 A1 (Walzman) teaches a caped stent providing a cover having a single attachment point and a free end that can be overlapped, thereby providing better conformity to target vessels than existing covered stents.

[0006] U.S. Pat. No. 8,398,701 B2 (Berez et al.) teaches a vascular occluding device deployable on a microcatheter. The occluding device includes an asymmetrical braid or differential lattice densities, as well as and corresponding/opposite variable densities of porosity to modify blood flow in a vessel while maintaining flow to surrounding tissue. Berez teaches that the flexibility of the device particularly suits it for treating aneurysms in the brain. Berez describes an embodiment including less coverage on one side at the same segment along the length of the cylinder versus the other side. For example, the area having less porosity (i.e., more coverage) should be positioned to cover an aneurysm for stagnation of flow in the aneurysm and subsequent thrombosis. The other side of the device having more porosity should be positioned on one side of a vessel or covering a branch to allow continuation of adequate flow and to prevent obstruction of flow to the branch and its distal tissue. However, Berez and others have not devised a way to consistently and reliably deploy such devices in the optimal desired radial orientation, and no such devices are available.

[0007] In the extreme, an endovascular device may provide additional porosity by including a fenestration, allowing no obstruction whatsoever of blood flow to the origin of a branch vessel. This may be combined with a full cover at or near an opposing side to cut blood flow to a target aneurysm or fistula altogether.

[0008] A common blood vessel difficulty is the persistent blood flow in the aneurysm sac extrinsic to an endograft. In fact, this is the most common complication after endovascular aneurysm repair (EVAR) with stent grafts. Such endoleaks are ameliorated by a number of means. For example, Walzman's utility application Ser. Nos. 15/732,147 and 15/732,365 teach the use of hydrogel to prevent endoleaks.

[0009] The prior art also teaches endovascular coiling as a minimally invasive technique performed to prevent blood from flowing into some saccular aneurysms. This treatment results in the coil inducing embolization (clotting) of the aneurysm, which prevents blood from flowing into the aneurysm, which in turn, prevents rupture and subsequent subarachnoid hemorrhage. Endovascular coiling however may result in procedural complications include thromboembolism, cerebral embolization, aneurysm perforation, parent artery occlusion, coil migration, arterial dissection, and others. The prior art also teaches stent-assisted coiling. The stent-assisted coiling also has some of the same short comings related to stent placement and placing a stent in the parent artery requires prolonged use of anti-platelet agents to reduce the risk of thrombosis-based stenosis within the stent.

[0010] Some aneurysms and fistulas are ideally treated with covered stents, which can most directly cover the hole of the fistula or the neck of the aneurysm and reconstruct the vessel wall, immediately redirecting blood flow into the normal path of the parent vessel. However, there is no covered neuro-stent currently available in the United States. The U.S. Food and Drug Administration (FDA) has examined and tested such covered neuro-stents but none has “FDA approval,” which means that the FDA has not decided the benefits over the existing treatment options outweigh the potential risks for the item's planned use. Additionally, there are currently no covered stents that are effective in severely tortuous anatomy in other parts of the body, including but not limited to splenic artery aneurysms and pulmonary arteriovenous fistulas.

[0011] A potentially significant use of covered neuro-stents is for the treatment of fistulas, particularly for Carotid cavernous fistula (CCF) which is an abnormal communication between the cavernous sinus and the carotid arterial system.

[0012] Other treatment of aneurysms includes surgical clipping of an intracranial aneurysm, which involves the application of a clip across the neck of the aneurysm. This treatment has several shortcomings including that it requires an open operation and physical manipulation of the brain. Sometimes surgical bypass is considered as well, but typically is associated with even higher rates of morbidity and mortality.

[0013] Additionally, prior art teaches the use of flow diversion devices to divert flow away from the aneurysm by placing a mesh stent or a structure similar to a stent, on the aneurysm neck along the parent artery. The use of these devices allows for thrombus formation inside the aneurysm. However, increased technical complications can develop following the deployment of flow diverters.

[0014] Additionally, because they do not completely block flow, they are not effective in the treatment of fistulas and ruptured vessel. Similarly, there is currently no effective vessel-sparing treatment of an iatrogenic rupture of an intracranial artery. Current treatment requires closing the ruptured artery with coils and/or liquid embolics to stop the bleeding, usually with significant resulting morbidity from ischemic injury to that arterial territory. Furthermore, when treating aneurysms with these devices, the aneurysm thromboses over time, a lag period, and is not immediately cured. This leaves the patient at risk of aneurysmal rupture during lag period. This can be especially problematic when treating ruptured aneurysms, which have high short-term re-rupture rates. Still further, when using current flow-diverting stents, many branch vessels are often crossed with the device, often resulting in narrowing's developing at the origins of these branches and sometimes resulting in occlusions and/or injury as well.

[0015] Additionally, there are devices to treat vascular outpouchings with intrasaccular, occlusive devices, including for example the W.E.B. (Terumo/Microvention) and Watchman (Boston Scientific). However, current technologies use limited sizes and shapes of these devices. More customized devices that can potentially conform better to the anatomy of a particular outpouching are difficult to orient properly utilizing current technologies. The need exists to ameliorate these difficulties and to provide accurate rotational intravascular positioning of devices including fully or partially customized intraocular devices, variable porosity stents, covered and partially covered devices, etc., via endovascular delivery and n tortuous vascular anatomies.

[0016] A need exists for an endovascular device capable of endovascular intervention for immediate cure of select intravascular aneurysm or fistula, while ameliorating the difficulties and shortcomings associated with the currently available technologies. More particularly, a need exists for a covered stent which allow said stent freedom of motion and bending without kinking around tight bends in tortuous anatomy.

[0017] Most covered stents involve producing a cylinder of a stent “skeleton” or “frame” out of semi rigid materials such as metal alloys, and then attaching an impermeable “cover” to said frame. The prior art teaches such attachments are diffuse and located throughout the covering of a stent, along fixed intervals of said covering and frame, and consequently significantly limit flexibility of the device.

[0018] All currently available flow-diverting stents have relatively uniform patterns of coverage and porosity throughout. No reliable means has been developed to successfully deploy a device that has differential porosity along different circumferentially radial segments.

[0019] For neuro-endovascular procedures (and other tortuous vascular anatomies), there is no known device or method allows for precise positioning of such a differentially porous device to achieve an ideal ratio of covering and porosity where desired, and allowing flow where desired.

Unlike larger vasculature (e.g., aortic), devices deployed through intracranial or other tortuous, circulatory anatomy are not susceptible to manual rotation at the hub end having an effect to rotate the intracranial end.
[0020] Thus, there is a need for a device that can be reproducibly positioned/landed in the appropriate orientation, such that area of dense coverage and corresponding low porosity (or complete impermeability in an extreme case, or a fenestration in another extreme case) is deployed on the desired side, while the low density of coverage and corresponding high porosity (and/or fenestration with no coverage at all in an extreme case) is deployed on the desired side. Additionally, there is a need for branched covered and flow diverting devices in distal and tortuous vasculatures. Currently such devices are not available for use in neuro-endovascular procedures, and are similarly not available in other tortuous vascular anatomies, because devices, systems, and methods to deploy such devices consistently and accurately in the desired orientation do not exist.
[0021] Similarly, in cardiac, peripheral and other vasculatures, there is a need for more effective bifurcated stent constructs to minimize the obstruction of side branches during various stenting procedures. The systems and methods described herein facilitate accurate positioning of fenestrations in a multiple stent construct to minimize the risk of obstructing branches while also facilitating more effective placement of stents across bifurcations. These constructs can effectively treat atherosclerotic narrowing's, aneurysmal diseases, dissections, fistulas, and other pathologies.
[0022] Therefore, were one to deploy such a device the ultimate orientation upon positioning would be random. For example, with the case just described, the exact opposite from ideal could occur. That is, the fenestration might end up over the aneurysm, thereby increasing flow to the lesion; while the area of high-density coverage might end up over the origin of a normal branch vessel, causing a lack of flow to said branch, and subsequent ischemic injury. The device can work easily in straight anatomy of short distances, where a catheter can easily and accurately be rotated along its entire length from its proximal hub.
[0023] Again, using the extreme example of a fenestrated device, branched devices could also be built in vivo, by deploying a fenestrated device with the fenestration over the origin of a branch, and the deploying another device from the fenestration, and into the branch. The second device can be slightly larger in diameter proximally, at the fenestration, to ensure slight overlap, without covering the primary distal branch/vessel. Similarly, a device could be built that includes multiple branches, through multiple fenestrations, provided all fenestrations are in proper relative distance and orientation to the native branches.
[0024] This concept was described elegantly by Ruiz in U.S. Pat. No. 6,261,273 B1 for an Access System for Branched Vessels [and] Methods of Use. However, Ruiz discloses the building of a directional sheath or catheter in vivo, rather than an implant. Like the Berez device, however, the Ruiz device can work easily in straight anatomy of short distances, where a catheter can easily and accurately be rotated along its entire length from its proximal hub.
[0025] Rotation is not effective with current technologies for positioning in tortuous and/or longer vascular anatomies, in which catheters do not respond in a similarly predictable fashion. This presents a difficulty when a stent device, which is usually crimped for delivery, is advanced into a delivery catheter, typically using a delivery wire and/or hypotube, in a particular arrangement. The stent will exit the delivery catheter in an unpredictable arrangement or orientation.
[0026] Furthermore, “Y” shaped stents were not heretofore practical to deploy or assemble at branches in cranial or other tortuous vascular anatomy. There exists a need for Y, bifurcated, and otherwise branched stent devices that may be effectively deployed or assembled in such anatomy. Additionally, in order to safely deploy such branches without safely and accurately, and overlapping the fenestration only slightly consistently, novel devices and methods are needed to more precisely land the proximal end of such stent devices.
[0027] Thus, a need exists for a covered or partially covered neuro stent capable of use intracranially or in other tortuous anatomy outside of the brain, which device's more porous and

less porous areas may be positioned as desired with respect to one or more branch vessels and at least one aneurysm or fistula, respectively. Additionally, there is a need for similar covered or partially covered branched devices as well. The present disclosure satisfies these unmet needs.

[0028] A need also exists for fenestrated and variable coverage and variable porosity stents, wherein the fenestrations and regions of decreased porosity along the circumference of a device can be accurately positioned, in any anatomy. This can be used in vascular applications as well as both vascular and nonvascular endoscopic applications.

SUMMARY OF THE INVENTION

[0029] Disclosed herein are methods and devices that facilitate the correct orientation of an occlusion device (e.g., in an intracranial context), such as a stent having differential porosity, with respect to desired areas of greater or lesser blood flow (e.g., branch vessels and aneurysms, respectively). For example, in certain embodiments, the devices and methods described herein may be particularly adapted for use in treating aneurysms and other vascular outpouchings and fistulas in intracranial or other tortuous vasculature, as well as vascular narrowing and other pathologies.

[0030] The methods and devices described herein may be used for treatments that require the precise orientation of a device (e.g., a stent, an intrasaccular device, etc.) within the vasculature and/or other luminal structures, which may require travel through long and twisted blood vessels prior to reaching the target area. For example, it is envisioned that the methods and devices described herein may be used in connection with the orientation of asymmetric discs in aneurysm necks or stents in GI/biliary tract (e.g., vascular, endoscopic, etc.).

[0031] Known devices and methods are difficult to properly orient due to several factors, particularly in the context of tortuous vasculature. For example, the (working) lumens of known delivery catheters (through which stents may be deployed) are typically tubular with circular (round) (transverse) cross-sectional configurations, as are the outer diameter/surface of the wires over which most balloon-mounted stents are delivered and the inner diameter/surface of known delivery balloon catheters. As a result, stents will generally be caused to rotate during deployment in an unpredictable fashion. Additionally, as catheters are advanced through tortuous anatomy, the catheters themselves can rotate (twist), and do so in an unpredictable fashion. Achieving the desired radial placement can therefore be cumbersome and can result in extending procedure times, improper placement, and other negative consequences. The methods and devices described herein address this shortcoming.

[0032] Differentially porous (variable porosity) stents (or other such braided-, mesh-, or weave-type therapeutic devices) may be oriented to a degree of desired flow or blockage. Some stents described by Walzman (Ser. No. 11/007,048-“caped stent”) optionally having a free-floating cover that is designed to optimize insertion into tortuous anatomy. Among its unique structural elements are a single circumferential attachment point at one end (as small as 1 nm), overlapping circumferential shingles and overlapping geometric shingles. Some embodiments can have fenestrations of the covering as well. Other stents are disclosed in Walzman U.S. Pat. No. 9,775,730. The entire contents of both of these Walzman patents are incorporated herein by reference.

[0033] The stent can have one or more fenestrations. In some embodiments, the stent can have a porosity of less than 28%; in other embodiments, the stent can have a porosity of greater than 28%. In some embodiments, the stent has a variable porosity in different regions along a length and/or along a circumference.

[0034] The devices described herein may optionally be deployed under flow arrest (e.g., via pharmacologic means or via delivery through a balloon guide catheter with temporary balloon inflation or other means) to minimize the possibility of blood flow affecting positioning as it is unsheathed.

[0035] In other embodiments, it is envisioned that the aforementioned covering may not fully enclose (encircle) a given segment of the stent, thus allowing for variable porosity along the circumference of the stent (e.g., the stent may include a first (covered) circumferential area with decreased porosity relative to a second (uncover) circumferential area). Varying the porosity of the stent facilitates the preservation of the origin of a branch vessel that might arise from the parent vessel along the same segment of the pathology in the parent vessel pathology (e.g., opposite to a fistula or the neck of an aneurysm). The devices and methods described herein allow for more accurate positioning (landing) of stents. For example, if a fenestration in a first stent is placed over the origin of a branch utilizing the devices and methods described herein, the devices and methods described herein can further facilitate the accurate placement of a second stent such that the second stent can be landed in a precise location so as to only overlap the first stent in a desired area (e.g., around the fenestration) and thereby reduce (if not completely eliminate) leaks between the two stents while avoiding unwanted obstruction of the primary vessel by the second stent.

[0036] The present disclosure also describes in some embodiments inner “unsheathing” hypotube or wire, which may include a reverse cone (e.g., wings) at a distal end thereof that are configured to cover a stent in the proximal direction. The stent can be mounted on the distal end of an outer hypotube. The inner hypotube goes through the outer hypotube, with its wings extending back over the distal end of the outer hypotube, and over the stent mounted thereon, and constrains the stent, which is often self-expanding in this variant. Once the stent is in the desired position, the outer hypotube can be held in place, while the inner hypotube is advanced. As the inner hypotube is advanced, its back wings are also advanced, and releases its constraint from the stent in a proximal to distal fashion. Thereby, the proximal stent is released from its constraint first, and expands for deployment. If the proximal portion position of landing is not optimal, it can be re-sheathed by pulling the inner hypotube back again. The stent can then be repositioned, and deployment can resume.

[0037] The present disclosure describes catheters and wires that include non-circular transverse cross-sectional configurations (e.g., shapes) of inner catheter lumens and/or outer diameters which facilitate mating engagement with each other. Depending on the particular device and procedure, the catheter may be deployed first, and a stent or other device may be delivered therethrough over a corresponding shaped wire; wherein the wire shape correlates with the inner diameter of the stent delivery catheter. In some configurations the wire is delivered first to the lesion site, and a stent mounted catheter is then delivered over it. It is envisioned that any such systems may be adapted for “rapid-exchange” or “over-the-wire” delivery. In other configurations, a catheter with a particular non-circular inner diameter circumferential shape can first be delivered to a lesion site over any wire. The initial wire is then removed and then a stent (or other device) mounted on a corresponding-shaped outer-diameter wire is delivered through said catheter and to the lesion site. It is envisioned that the former configuration may be more common with balloon-mounted stents and that the latter configuration is more common with self-expanding stents. It should be appreciated, however, that the former configuration may also be applied to self-expanding stents and that the latter configuration may be applied to balloon-mounted stents. Furthermore, when a wire with a non-circular outer shape is placed first, it may optionally have a stability component at or near its distal end, which would stabilize the rotational orientation of the wire and prevent its rotation during device delivery.

[0038] As elaborated upon below, the interfaces between the devices facilitated by the aforementioned non-circular transverse cross-sectional configurations (e.g., the engagement between a wire and a catheter) inhibit (if not entirely prevent) relative rotation between the devices while allowing for relative axial (longitudinal) movement (e.g., sliding), even in those embodiments in which a stent may be located between the devices (e.g., over a portion of the wire). The devices described herein thus provide for adequate freedom of movement to permit the delivery of a catheter over a wire, or the delivery of a wire through a catheter, without undo force.

[0039] In some versions (e.g., in the context of branched stenting), a wire can be placed in each of first and second branches. The wire in the first branch may then be placed through a distal end hole of the delivery catheter and the catheter may be oriented such that a side-hole in the catheter is positioned at (or adjacent to) a stent side fenestration. The wire in the second branch can then be backloaded into the side-hole (e.g., to facilitate proper positioning of the side-hole relative to the origin of the side branch while maintaining wire access to the side branch).

[0040] It is also envisioned that positioning of the initial wire or catheter can dictate the manner in which a subsequent stent or wire is delivered based upon an observed degree of rotation from the back of the wire or the hub of the catheter. For example, rotation of a “12 o'clock marker” on the back of the wire or the hub of the catheter may be observed (measured) relative to the corresponding “12 o'clock marker” on the catheter near its distal end at the lesion site. In these versions, a dual-lumen delivery catheter may optionally be employed to deploy (deliver) one or more stents. Such dual-lumen primary delivery catheters include a (first) primary lumen that extends between a proximal end hole and a distal end hole and a (second) secondary lumen that extends between the proximal end hole and a side-hole, which is positioned at (or adjacent to) a fenestration in a primary (first) stent. Via use of the delivery catheter, the primary stent, which may be mounted on a balloon on the primary catheter, can be positioned (deployed) across a lesion in one branch (e.g., a main branch) of the blood vessel (in any necessary or desired orientation) relative to a side branch of the blood vessel. A secondary wire can then be delivered through the secondary lumen and the side-hole and a corresponding hole in the balloon and first stent, into the side branch prior to deployment of the primary stent. Following deployment of the primary stent, the primary delivery catheter can be withdrawn, leaving the secondary wire in place within the side branch of the blood vessel. A secondary stent can then be delivered (e.g., using an additional delivery catheter) and deployed either in the side branch exclusively or such that the secondary stent spans the main branch and the side branch (e.g., such that a first section or portion of the secondary stent is positioned within the main branch and a second section or portion of the secondary stent is positioned in the side branch). In certain embodiments and procedures, it is envisioned that secondary stent may be positioned so as to overlap the primary stent. For example, it is envisioned that the secondary stent may be configured and positioned to overlap (overlie) a proximal portion of the primary stent. The secondary stent may also optionally have a fenestration where it crosses the primary branch. Both “over-the-wire” and “rapid exchange” devices, and combinations thereof, are envisioned within the scope of the present invention. With rapid exchange catheters, the proximal hole for the wire insertion is spaced distally from the proximalmost end of the catheter.

[0041] In one aspect of the present disclosure, an intravascular device is disclosed that includes a primary (first) wire (e.g., a guide wire), a delivery catheter, and a primary (first) stent that is loaded onto (e.g., supported by) the delivery catheter. The primary wire includes a fixed, non-circular transverse cross-sectional configuration (e.g., a non-circular outer (circumferential) contour (surface, shape)) over a majority of its length. The primary wire also includes a (first) marker (e.g., a radiopaque marker) at or adjacent to a proximal end thereof and a (second) marker (e.g., a radiopaque marker) at or adjacent to a distal end thereof. The markers can be located in identical circumferential (rotational) positions along an outer surface of the primary wire. In one particular embodiment, for example, the markers are each located in a “twelve o'clock” position.

[0042] The delivery catheter includes a proximal end, a distal end, and an inner primary lumen that defines a fixed, non-circular transverse cross-sectional configuration (e.g., a non-circular inner contour (surface, shape)) that corresponds to the transverse cross-sectional configuration defined by the primary wire. The outer diameter of the catheter may be round or any other shape. The delivery catheter optionally includes an “over-the-wire” configuration and slidably receives the primary wire such that the delivery catheter is (at least partially) positioned about the primary wire. Due to the corresponding non-circular transverse cross-sectional configurations defined by the primary wire and the inner lumen of the delivery catheter, the primary wire is insertable into the delivery catheter in a plurality of discrete (rotational) orientations, the number of which is determined by the particular configurations of the primary wire and the delivery catheter. For example, in one particular embodiment, the primary wire and the delivery catheter may include corresponding triangular transverse cross-sectional configurations, which facilitate insertion of the primary wire into the delivery catheter in three distinct (rotational) orientations that are offset from each other by (approximately) 120°. The non-circular transverse cross-sectional configurations of the primary wire and the delivery catheter allow the relative (rotational) orientations of the primary wire and the delivery catheter to be maintained during advancement of the delivery catheter through the blood vessel.

[0043] The delivery catheter may include a (third) marker (e.g., a radiopaque marker) at or adjacent to the distal end thereof. The delivery catheter is configured for insertion into and movement through a blood vessel to a target lesion, to stop at a location proximal to the target lesion, to deliver the primary stent, and for withdrawal from the blood vessel.

[0044] During use, the delivery catheter is rotated into a predetermined orientation prior to insertion of the primary wire, which results in corresponding rotation of the primary stent, when the stent is mounted on the primary catheter, such as over a balloon mounted on the primary catheter, to allow for advancement of the delivery catheter and the primary stent into the blood vessel, and deployment of the primary stent, in a predetermined (rotational) orientation.

[0045] In certain embodiments, the delivery catheter may further include at least one inflatable member, e.g., a balloon, and at least one secondary lumen that is (solely) configured to support inflation and deflation of the at least one balloon.

[0046] In certain embodiments, the primary stent may be loaded onto the at least one balloon.

[0047] In certain embodiments, the stent may include a differentially porous configuration. For example, the primary stent may include a first region including a first porosity (e.g., a covered area) and a second region including a second, different porosity (e.g., an uncovered area).

[0048] In certain embodiments, the primary stent may include at least one fenestration.

[0049] In certain embodiments, the primary stent may include at least one region that is substantially impermeable to fluid.

[0050] In certain embodiments, the intravascular device may further include at least one adhered compound (e.g., on the primary stent, and/or on other components).

[0051] In certain embodiments, the primary stent may include at least one radiopaque marker.

[0052] In certain embodiments, the at least one balloon may include at least one radiopaque marker.

[0053] In certain embodiments, the primary stent may include at least one radiopaque marker.

[0054] In certain embodiments, the primary stent may be configured (e.g., optimized) to facilitate the treatment of a narrowed lumen of the blood vessel.

[0055] In certain embodiments, the intravascular device may include a lubricious surface coating.

[0056] In certain embodiments, the delivery catheter may include a configuration supporting rapid-exchange.

[0057] In certain embodiments, the delivery catheter may include a configuration supporting over the wire insertion with a proximal end hole at the proximalmost end of the catheter.

[0058] In certain embodiments, the primary wire may include at least one anchor at or adjacent to the distal end thereof.

[0059] In certain embodiments, the at least one anchor may include a tortuous (e.g., a spring-like) configuration.

[0060] In certain embodiments, the at least one anchor may include a branched wire segment. For example, the branched wire segment may split into at least two segments such that, upon the application of a predetermined radial force or other detachment mechanism, the at least two segments are directed into walls of the blood vessel in different directions.

[0061] In certain embodiments, the at least one anchor may be configured such that the branched wire segment is moved from a first (insertion, inactive, collapsed) configuration, in which the at least two segments are positioned in generally adjacent relation, into a second (anchoring, active, expanded) configuration, in which the at least two segments are separated from each other to thereby anchor the primary wire within the blood vessel upon the application of an external stimulus.

[0062] It is envisioned that the at least one anchor may be moved from the first configuration into the second configuration upon the application of any suitable stimulus including, for example, a thermal stimulus, an electric stimulus, a mechanical stimulus, a magnetic stimulus, a hydrostatic stimulus, etc.

[0063] In certain embodiments, the at least one anchor may include a balled wire.

[0064] In certain embodiments, the at least one anchor may include a retrievable stent.

[0065] In certain embodiments, it is envisioned that the primary wire and the at least one anchor may be delivered through a secondary catheter.

[0066] In certain embodiments, the secondary catheter may be inserted over a secondary wire.

[0067] In certain embodiments, the intravascular device may include an IVUS catheter with an inner lumen that defines a fixed, non-circular transverse cross-sectional configuration (e.g., a non-circular inner contour (surface, shape)) that corresponds to the inner lumen of the primary catheter and the transverse cross-sectional configuration defined by the primary wire, whereby the IVUS catheter may be advanced over the primary wire and subsequently removed before insertion of the delivery catheter (e.g., to optimize imaging and orientation of the target lesion, side branch (branches) of the blood vessel, etc.).

[0068] In certain embodiments, the IVUS catheter may include a (fourth) marker (e.g., a radiopaque marker) that is positioned in correspondence with the (third) marker on the delivery catheter (e.g., in the “twelve o'clock” position).

[0069] In certain embodiments, the delivery catheter may include a tertiary lumen.

[0070] In certain embodiments, the tertiary lumen and/or other lumen may include a “peel-away” (side) slit up to a rapid exchange length lumen.

[0071] In certain embodiments, the tertiary lumen may be configured to receive and deliver a tertiary wire (e.g., into a side branch of the blood vessel).

[0072] In certain embodiments, the tertiary lumen may terminate in a side-hole that is located proximally of a distal end hole defined by the inner lumen such that the tertiary wire is deliverable into the blood vessel through the side-hole.

[0073] In certain embodiments, the at least one balloon may include a fenestration.

[0074] In certain embodiments, the at least one balloon may be configured such that the fenestration is generally aligned with (e.g., overlaps or overlies) the side-hole defined by the tertiary lumen.

[0075] In certain embodiments, the primary stent may include a fenestration and may be loaded onto the at least one balloon such that the fenestration of the primary stent is generally aligned with (e.g., overlaps or overlies) the fenestration of the at least one balloon and the side-hole. In certain embodiments, the tertiary wire may include a distal anchor.

[0076] In certain embodiments, the tertiary wire may include a fixed, non-circular transverse cross-sectional configuration (e.g., a non-circular outer (circumferential) contour (surface, shape)) over a majority of its length.

[0077] In certain embodiments, a secondary delivery catheter may be employed to deliver a secondary stent. In such embodiments, the secondary delivery catheter may include at least one balloon.

[0078] In certain embodiments, the secondary stent may be mounted on the at least one balloon of the secondary delivery catheter.

[0079] In certain embodiments, the secondary stent may include at least one fenestration. For example, the secondary stent may include an annular (e.g., round, circular, oval, etc.) opening (hole) that is configured to overlap an ostium (origin) of a vessel branch.

[0080] In certain embodiments, the secondary stent may include at least one secondary compound adhered thereto.

[0081] In certain embodiments, the secondary delivery may include an inner secondary lumen that defines a fixed, non-circular transverse cross-sectional configuration (e.g., a non-circular inner contour (surface, shape)) that corresponds to the transverse cross-sectional configuration defined by the tertiary wire. The secondary delivery catheter may include an "over-the-wire" configuration, which allows for slidable insertion of the tertiary wire into the secondary delivery catheter such that the secondary delivery catheter is (at least partially) positioned about the tertiary wire. Due to the non-circular transverse cross-sectional configurations defined by the tertiary wire and the secondary delivery catheter, the tertiary wire is insertable into the secondary delivery catheter in a plurality of discrete (rotational) orientations, the number of which is determined by the particular configurations of the tertiary wire and the secondary delivery catheter. For example, in one particular embodiment, the tertiary wire and the secondary delivery catheter may include corresponding triangular transverse cross-sectional configurations, which facilitate insertion of the tertiary wire into the secondary delivery catheter in three distinct (rotational) orientations that are offset from each other by (approximately) 120°. The non-circular transverse cross-sectional configurations of the tertiary wire and the secondary delivery catheter allow the relative (rotational) orientations of the tertiary wire and the secondary delivery catheter to be maintained during advancement of the secondary delivery catheter through the blood vessel.

[0082] During use, the secondary delivery catheter is rotated into a predetermined orientation prior to insertion of the tertiary wire, which results in corresponding rotation of the secondary stent to allow for advancement of the secondary delivery catheter and the secondary stent into the blood vessel, and deployment of the secondary stent, in a predetermined (rotational) orientation.

[0083] In certain embodiments, the intravascular device may include at least one energy transfer component.

[0084] In another aspect of the present disclosure, a wire is disclosed for intraluminal use. The wire includes an anchor at a distal end thereof.

[0085] In certain embodiments, the anchor may include a branched wire segment. For example, the branched wire segment may split into at least two segments such that, upon the application of a predetermined radial force, the at least two segments are directed into walls of the blood vessel in different directions.

[0086] In certain embodiments, the at least one anchor may be configured such that the branched wire segment is moved from a first (insertion, inactive, collapsed) configuration, in which the at least two segments are positioned in generally adjacent relation, into a second (anchoring, active, expanded) configuration, in which the at least two segments are separated from each other to thereby anchor the primary wire within the blood vessel upon the application of an external stimulus. It is envisioned that the at least one anchor may be moved from the first configuration into the second configuration upon the application of any suitable stimulus (e.g., to a proximal end of the wire) including, for example, a thermal stimulus, an electric stimulus, a mechanical stimulus, a magnetic stimulus, a hydrostatic stimulus, etc.

[0087] In certain embodiments, the wire may further include a central segment that continues distally beyond the at least one anchor.

[0088] In another aspect of the present disclosure, an intravascular system is disclosed for treating of a blood vessel. The intravascular system includes a first catheter defining a first lumen and a first delivery device that is configured for insertion into the first lumen of the catheter. The first lumen terminates in a distal end hole and has a first non-circular transverse cross-sectional configuration. The first delivery device includes a first stent and a first elongated member that supports the first stent such that the first elongated member and the first stent are movable through the first lumen to facilitate delivery of the first stent to a target location within the blood vessel. The first elongated member has a second non-circular transverse cross-sectional configuration that corresponds to the

first non-circular transverse cross-sectional configuration to thereby inhibit rotation of the first elongated member within the catheter and control orientation of the first stent relative to the catheter.
[0089] In certain embodiments, the delivery device may be configured as a packaging catheter. The packaging catheter can have an inner lumen that is substantially similar in dimensions to the inner lumen of the first catheter.
[0090] In certain embodiments, the packaging catheter component may further include a body and a pusher that supports the first stent. In such embodiments, the first elongated member is defined by the pusher and is configured for movement from the packaging catheter into the first lumen of the first catheter through the body, such that the pusher and the first stent are insertable into the blood vessel through the first catheter. In some embodiments, the pusher has a similar outer dimension to the corresponding inner dimension of the inner lumen of the first catheter, but slightly smaller, to allow longitudinal movement of the pusher and a mounted stent thereon, without allowing rotation.
[0091] In certain embodiments, the first stent may be configured for self-expansion such that the first stent automatically expands in the blood vessel upon exposure from the catheter.
[0092] In certain embodiments, the first delivery device may be configured as a balloon catheter including a first inflatable member. In such embodiments, the first elongated member is defined by a body of the balloon catheter such that the body of the balloon catheter is received by the first lumen of the catheter and the first stent is positioned about the first inflatable member such that the first stent is deployed upon inflation of the first inflatable member.
[0093] In certain embodiments, the first delivery device may include a second lumen that extends therethrough.
[0094] In certain embodiments, the second lumen may terminate in a side hole.
[0095] In certain embodiments, the second lumen may include a third non-circular transverse cross-sectional configuration.
[0096] In certain embodiments, the intravascular system may further include a second delivery device that is configured for insertion into the second lumen of the first delivery device.
[0097] In certain embodiments, the second delivery device may include a second stent and a second elongated member that supports the second stent such that the second elongated member and the second stent are movable through the second lumen to facilitate delivery of the second stent through the side-hole to treat a side branch of the blood vessel.
[0098] In certain embodiments, the second elongated member may have a fourth non-circular transverse cross-sectional configuration that corresponds to the third non-circular transverse cross-sectional configuration to thereby inhibit rotation of the second elongated member within the first delivery device and control orientation of the second stent relative to the catheter.
[0099] In certain embodiments, the second stent may be configured for self-expansion such that the second stent automatically expands upon exposure in the blood vessel.
[0100] In certain embodiments, the second delivery device may further include an inflatable member that is supported by the second elongated member. In such embodiments, the second stent is supported by the inflatable member such that the second stent is deployed upon inflation of the inflatable member.
[0101] In another aspect of the present disclosure, an intravascular system is disclosed for treating of a blood vessel. The intravascular system includes a first medical device and a second medical device. The first medical device includes: an elongated member; a first inflatable member that is supported by the elongated member; and a first stent that is supported by the first inflatable member such that the first stent is deployed upon inflation of the first inflatable member. The elongated member defines a first lumen that extending from a proximal end hole to a distal end hole and a second lumen that extends in generally parallel relation to the first lumen from the proximal end hole to a side-hole that is located proximally of the distal end hole. The first inflatable

member includes a first fenestration and the first stent includes a second fenestration. The second medical device is configured for insertion into the second lumen to access a side branch of the blood vessel through the side-hole, through the first fenestration in the first inflatable member, and through the second fenestration in the first stent.

[0102] In certain embodiments, the second medical device is configured as a packaging catheter.

[0103] In certain embodiments, the packaging catheter may include: a body that is configured for connection to the first medical device; a pusher that is configured for movement through the body; and a second stent that is supported on the pusher such that the pusher and the second stent are insertable into the side branch of the blood vessel through the first medical device via the second lumen and the side-hole.

[0104] In certain embodiments, the second stent may be configured for self-expansion such that the second stent automatically expands in the side branch of the blood vessel upon exposure from the side-hole.

[0105] In certain embodiments, the second lumen may define a first non-circular transverse cross-sectional configuration and the pusher defines a second non-circular transverse cross-sectional configuration corresponding to the first non-circular transverse cross-sectional configuration so as to inhibit rotation of the pusher and the second stent within the second lumen to thereby control orientation of the second stent relative to the first medical device.

[0106] In certain embodiments, the first non-circular transverse cross-sectional configuration and the second non-circular transverse cross-sectional configuration may each be defined by a plurality of linear segments.

[0107] In certain embodiments, the first non-circular transverse cross-sectional configuration and the second non-circular transverse cross-sectional configuration may be such that the pusher is insertable into the second lumen in at least three distinct (rotational) orientations.

[0108] In some embodiments, least one of the hub, first catheter, first elongated member, and medical device has at least one marker at a set circumferential rotation. In other embodiments, at least two or more of the hub, first catheter, first elongated member and medical device has one has at least one marker. In some embodiments, two or more of the markers are at a substantially same circumferential rotation. In certain embodiments, the second medical device may be configured as a guide wire.

[0109] In certain embodiments, the guide wire may be insertable into the side branch of the blood vessel through the side-hole in the first medical device.

[0110] In certain embodiments, the second medical device may be configured as a balloon catheter.

[0111] In certain embodiments, the balloon catheter may include: a body; a second inflatable member that is supported by the body; and a second stent that is supported by the second inflatable member such that the second stent is deployed upon inflation of the second inflatable member.

[0112] In certain embodiments, the body of the balloon catheter may define a lumen that is configured to receive a guide wire such that the balloon catheter is insertable into the side branch of the blood vessel over the guide wire.

[0113] In certain embodiments, the second lumen may define a first non-circular transverse cross-sectional configuration and the body of the balloon catheter may define a second non-circular transverse cross-sectional configuration that corresponds to the first non-circular transverse cross-sectional configuration to thereby inhibit rotation of the balloon catheter and the second stent within the second lumen and control orientation of the second stent relative to the first medical device.

[0114] In another aspect of the present disclosure, a system is disclosed for maintaining an orientation of a stent during delivery. The system includes a first medical device supporting the stent and a second medical device that is configured to receive the first medical device. The first medical device and the second medical device include corresponding non-circular transverse cross-sectional configurations to inhibit rotation of the first medical device within the second medical device and thereby control orientation of the stent.

[0115] In certain embodiments, the first medical device may be configured as a balloon catheter that includes an inflatable member. In such embodiments, the stent is supported by the inflatable member such that the stent is deployed upon inflation of the inflatable member.

[0116] In certain embodiments, the stent may be configured for self-expansion such that the stent automatically expands upon exposure from the second medical device.

[0117] In certain embodiments stents can be delivered sequentially as well. For example, a first catheter with a first non-circular inner lumen configuration of the system can be inserted into a vessel, beyond a branch orifice. A packaging catheter with a substantially similar inner lumen includes a first elongated member defined by a pusher, which has a similar outer dimension to the corresponding inner dimensions of the inner lumen, but slightly smaller, to allow longitudinal movement of the pusher and a mounted stent thereon, without allowing rotation. Additionally, the first catheter can have a proximal hub with a shape that corresponds to the outer shape of at least the distal segment of the packaging catheter, such that the packaging catheter can be inserted into the hub in a known orientation, and the inner lumen of the packaging catheter will then align with the orientation of the inner lumen of the proximal segment of the first catheter. A stent with a fenestration of a similar size as the orifice of the side branch can be mounted on the pusher wire, and can be delivered through the packaging catheter lumen and the first catheter lumen over the pusher, without rotating within the catheters. A stent preloaded into the packaging catheter in the correct orientation of the fenestration relative to the orifice of the side branch, with or without the aid of any rotation of the packaging catheter relative to the primary catheter and its hub, will then be delivered with the pusher from the packaging catheter and into the first catheter. The stent can then be delivered across the orifice of the side branch, and deployed with the fenestration overlying the orifice, by unsheathing the first catheter from the pusher and stent. The stent expands upon release from the constraints of the catheter. The stent can optionally be resheathable and/or detachable from the pusher, allowing the stent to be repositioned if desired before it is permanently implanted.

[0118] In some embodiments, least one of the hub, first catheter, first elongated member, and medical device has at least one marker at a set circumferential rotation. In other embodiments, at least two or more of the hub, first catheter, first elongated member and medical device has one has at least one marker. In some embodiments, the markers are at a substantially same circumferential rotation.

[0119] In some embodiments, the first delivery device comprises a packaging catheter including a second lumen, wherein the second lumen has a substantially similar shape as the first lumen, so that when the first elongate member and the first medical device are transferred from the packaging catheter to the first catheter, a cross-sectional configuration of the first catheter and first lumen, a cross-sectional configuration of the packaging catheter and the second lumen, and an outer transverse cross-sectional configuration of the first elongated member inhibit rotation of the first medical device during pushing through the packaging catheter, transfer from the packaging catheter to the first catheter, and pushing through the first catheter for subsequent delivery to a target treatment area.

[0120] In some embodiments, a hub is at a proximal end of the first catheter, wherein an inner shape of the hub and an outer shape of the distal end of the first catheter are configured in corresponding noncircular shapes so that a distal end of the delivery catheter can be inserted into the hub to thereby inhibit rotation of the packaging catheter relative to the first catheter, and thereby facilitate transfer of the first elongated member within the delivery catheter and during transfer to the first catheter and control orientation of the first medical device relative to the first catheter.

[0121] In some embodiments, a second medical device is configured as a second catheter and includes a body configured for connection to the first medical device and passage through the second lumen and a wire configured for passage through the second lumen through the first and second fenestrations and into a side branch or a side lesion, wherein the distal end-hole of the second catheter can be advanced from the second lumen, through the side hole, first and second fenestrations, and into the side branch or side lesion over the wire.

[0122] The second medical can be supported on a pusher such that the pusher and the second medical device are insertable into the side branch of the blood vessel through the second catheter, after removal or the wire, via the second lumen and the side-hole. In some embodiments, the second medical device is a stent, configured for self-expansion such that the second medical device automatically expands in the side branch of the blood vessel upon exposure from the second catheter.

[0123] In some embodiments, the second lumen defines a non-circular transverse cross-sectional configuration and an outer surface of the second medical device defines a non-circular transverse cross-sectional configuration corresponding to the non-circular transverse cross-sectional configuration of the second lumen so as to inhibit rotation of the second medical device.

[0124] In some embodiments, the inner lumen of the second catheter defines a non-circular transverse cross-sectional configuration and the outer surface of the pusher defines a non-circular transverse cross-sectional configuration corresponding to the non-circular transverse cross-sectional configuration of the second catheter so as to inhibit rotation of the pusher and the second medical device within the second lumen to thereby control orientation of the second medical device relative to the first medical device.

[0125] In some embodiments, the elongated member is removed after the first stent has been deployed.

[0126] In some embodiments, the second lumen defines a non-circular transverse cross-sectional configuration and an outer surface of a majority of the wire, including a proximal end outside the patient's body, or of a working segment, defines a non-circular transverse cross-sectional configuration corresponding to the non-circular transverse cross-sectional configuration of the second lumen to thereby inhibit rotation of the wire within the second lumen.

[0127] In some embodiments, a substantially similarly corresponding dimensioned inner diameter of a third medical device inhibits rotation of the balloon catheter and the second stent over the wire and controls orientation of the second stent relative to the vascular anatomy and/or the first medical device.

Description

DESCRIPTION OF THE DRAWINGS

[0128] Throughout the present disclosure, the term “vascular abnormality” should be understood to include aneurysms, lesions, fistulas, ruptures, and any other such malformation in a blood vessel, as well as normal vascular structures that can sometimes require closure or other coverage, including but not limited to the left atrial appendage.

[0129] Additionally, the term “medical device” should be understood to include any of the catheters, wires, or other such structures (or components of such structures) described herein and the term “elongated member” should be understood to include any elongated structure (e.g., tube, wire, catheter body, or the like) described herein.

[0130] FIG. **1**A is a perspective view of an intravascular system including a primary delivery catheter.

[0131] FIG. **1**B is a (partial) perspective view of a lumen of the primary delivery catheter seen in FIG. **1**A shown positioned within an anatomical vessel (e.g., a blood vessel).

[0132] FIG. **1**C is a (partial) transverse, cross-sectional view of a delivery device (e.g., a pusher of a packaging catheter) positioned within the lumen of the primary delivery catheter and shown in a

first (rotational) position.
[0133] FIG. **1**D is a (partial) transverse, cross-sectional view of the pusher positioned within the lumen of the primary delivery catheter and shown in a second (rotational) position.
[0134] FIG. **2**A is a perspective view of the packaging catheter and the primary delivery catheter during treatment of a vascular abnormality in a blood vessel.
[0135] FIG. **2**B is a perspective view of the primary delivery catheter shown in connection with an alternate embodiment of the delivery device, which is configured as a balloon catheter, during treatment of the vascular abnormality.
[0136] FIG. **2**C is a perspective view of a primary stent (or other such occlusion device) that is positionable within the blood vessel via the delivery device and the primary delivery catheter to treat the vascular abnormality.
[0137] FIG. **3** is a perspective view illustrating advancement of the primary stent through the blood vessel via the pusher during treatment of the vascular abnormality.
[0138] FIG. **4** is a (partial) perspective view of the primary delivery catheter.
[0139] FIG. **5** is a (partial) perspective view of the primary delivery catheter including one or more markers (e.g., radiopaque markers) to facilitate external visualization of the primary delivery catheter in the blood vessel.
[0140] FIG. **6** is a perspective view of the pusher, the primary stent, and the primary delivery catheter seen in FIG. **5** illustrating insertion of the pusher and the primary stent into the primary delivery catheter.
[0141] FIGS. **7**A-**7**D are transverse, cross-sectional views illustrating a variety of non-circular cross-sectional configurations for the lumen extending through the primary delivery catheter according to various embodiments of the present disclosure.
[0142] FIG. **7**E is a perspective view of an alternate embodiment of the primary delivery catheter, which includes a variety of markers (e.g., radiopaque markers) that are located in a variety of (rotational) positions to facilitate external visualization of the primary delivery catheter.
[0143] FIG. **8** is perspective view of the pusher.
[0144] FIG. **9** is a perspective view of the packaging catheter.
[0145] FIG. **10** is a perspective view of an alternate embodiment of the pusher, which includes a tapered distal end.
[0146] FIG. **11** illustrates an alternate embodiment of the primary delivery catheter, which includes a hub at a proximal end thereof and a series of markers (e.g., radiopaque markers).
[0147] FIG. **12** illustrates the pusher inserted into the primary delivery catheter seen in FIG. **11**.
[0148] FIG. **13** is a perspective view of an alternate embodiment of the delivery device, which includes an outer hypotube that is configured to support the primary stent.
[0149] FIG. **14** is a perspective view of an inner hypotube inserted into the outer hypotube seen in FIG. **13**.
[0150] FIG. **14**A is a perspective view of alternate embodiments of the outer hypotube and the inner hypotube.
[0151] FIG. **15** is a perspective view of a guide wire for use with the presently disclosed intravascular system.
[0152] FIG. **16** is a longitudinal, cross-sectional view illustrating deployment of the primary delivery catheter into the blood vessel via the guide wire to treat the vascular abnormality according to one aspect of the present disclosure.
[0153] FIG. **17** is a longitudinal, cross-sectional view illustrating insertion of the pusher and the primary stent through the primary delivery catheter.
[0154] FIG. **18** is a longitudinal, cross-sectional view illustrating an alternate embodiment of the intravascular system.
[0155] FIG. **19** is a transverse, cross-sectional view taken through line **19-19** in FIG. **18**.
[0156] FIG. **20** is a longitudinal, cross-sectional view illustrating deployment of a self-expanding

secondary stent into a side branch of the blood vessel through a primary delivery catheter and a first delivery device.
[0157] FIG. **21** is a transverse, cross-sectional view taken through line **21-21** in FIG. **20**.
[0158] FIG. **22** is a longitudinal, cross-sectional view illustrating deployment of a secondary guide wire through the primary delivery catheter and the first delivery device into the side branch of the blood vessel.
[0159] FIG. **23** is a longitudinal, cross-sectional view illustrating deployment of the self-expanding secondary stent into the side branch of the blood vessel through a secondary delivery catheter that is received within the primary delivery catheter and the first delivery device.
[0160] FIG. **24** is a longitudinal, cross-sectional view illustrating deployment of a balloon-expandable secondary stent into a side branch of the blood vessel through the primary delivery catheter and the first delivery device over a secondary guide wire.
[0161] FIG. **25** is a longitudinal, cross-sectional view illustrating positioning of the secondary stent within the side branch of the blood vessel such that the secondary stent overlaps (overlies) the primary stent.
[0162] Further elaborating on the brief description provided above, FIG. **1**A provides a perspective view of an intravascular system **10** for the treatment of an anatomical vessel (e.g., a blood vessel V (FIG. **2**A)). In the embodiment illustrated, the intravascular system **10** includes a delivery catheter **100** including an elongated body (member) **102** that extends along a longitudinal axis X. The body **102** includes a proximal (first) end **104** defining a proximal end hole **106**, a distal (second) end **108** defining a distal end hole **110**, and a (generally) cylindrical outer transverse cross-sectional configuration. A lumen **112** extends through the body **102** from the proximal end **104** to the distal end **108** and defines a non-circular transverse (lateral) cross-sectional configuration. More specifically, in the particular embodiment illustrated, the lumen **112** defines a (generally) triangular transverse (lateral) cross-sectional configuration. As described below, however, a variety of other non-circular transverse (lateral) cross-sectional configurations are also contemplated by the present disclosure including, for example, rectangles, pentagons, hexagons, octagons, squares, ovals, ellipse, stars, etc.
[0163] It should be appreciated that in the embodiments described herein, a stent is delivered by the catheter/system; however the catheter system can be utilized with other medical devices (the stent providing just one example).
[0164] The delivery catheter **100** is configured to deliver an occlusion device **200** (FIG. **2**C) (e.g., a stent **202**) or other medical device to a target site within the blood vessel V (or other such location within a patient's vasculature). As elaborated upon below, in certain embodiments, the occlusion device **200** may be carried (or otherwise supported) by an inflatable balloon (or other such member) that is connected to the delivery catheter **100**. Alternatively, the occlusion device **200** may be carried (or otherwise supported) by a separate delivery device.
[0165] In one embodiment, for example, it is envisioned that the delivery device may be configured as a packaging catheter **300** (FIG. **2**A) that includes an elongated pusher **302** (e.g., a wire) with a proximal end **304** and a distal end **306** that carries (or otherwise supports) the stent **202** in either a fixed or releasable (disconnectable) manner. For example, it is envisioned that the stent **202** may be pre-loaded and crimped (or otherwise secured) to the distal end **306** of the pusher **302** such that the stent **202** can be separated from the pusher **302** and deployed within the vasculature. In such embodiments, the packaging catheter **300** is pre-loaded with the pusher **302** and the stent **202** and the packaging catheter **300** is connected to the delivery catheter **100** (either directly or indirectly) such that, via axial movement of the pusher **302**, the stent **202** is deliverable from the packaging catheter **300**, into and through the delivery catheter **100**, and into the blood vessel V.
[0166] In an alternate embodiment, it is envisioned that the delivery device may be configured as a secondary catheter (e.g., a balloon catheter **400** (FIG. **2**B) or a hypotube) that is configured for insertion into the blood vessel V (FIG. **2**A) through the delivery catheter **100**. In such

embodiments, the stent **202** may be supported on an inflatable member **406** (e.g., a balloon or other such suitable structure) of the balloon catheter **400** and deployed via expansion of the inflatable member **406**. In such embodiments, it is envisioned that the balloon catheter **400** may be inserted through the delivery catheter **100** over a guide (delivery) wire **500** that extends into the blood vessel V.

[0167] Control over, and proper positioning of, the stent **202** is facilitated by inhibiting (if not entirely preventing) relative rotation between the stent **202** and the delivery catheter **100**. For example, when the delivery catheter **100** is used in connection with the packaging catheter **300**, the pusher **302** will include a non-circular (transverse) cross-sectional configuration (e.g., a cross-sectional configuration that is generally orthogonal in relation to a longitudinal axis of the pusher **302**) corresponding to that defined by the lumen **112** of the delivery catheter **100** to limit (if not entirely prevent) rotation of the pusher **302** within the delivery catheter **100**, thereby facilitating control over the (rotational) orientation of the stent **202** via manipulation of the delivery catheter **100** (and/or the pusher **302**). Similarly, when the delivery catheter **100** is used in connection with the aforementioned balloon catheter **400**, the balloon catheter **400** will include an outer (transverse) non-circular transverse cross-sectional configuration (e.g., a cross-sectional configuration that is generally orthogonal in relation to a longitudinal axis of the balloon catheter **400**) corresponding to that defined by the lumen **112** to limit (if not entirely prevent) rotation of the balloon catheter **400** within the delivery catheter **100**, thereby facilitating control over the (rotational) orientation of the stent **202** via manipulation of the balloon catheter **400** (and/or the delivery catheter **100**). Regardless of the particular method of placement and the medical devices used, it should be appreciated that the configurations of the delivery catheter **100**, the pusher **302**, and the balloon catheter **400** are such that the pusher **302** and the balloon catheter **400** are axially movable (slidable) through the delivery catheter **100** so as not to interfere with advancement of the pusher **302** and the balloon catheter **400** into the vasculature.

[0168] Thus the pusher is configured for movement from the packaging catheter into the lumen of the delivery catheter through the body, such that the pusher and the stent are insertable into the blood vessel through the delivery catheter. In some embodiments, the pusher has a similar outer dimension to the corresponding inner dimension of the inner lumen of the delivery catheter, but slightly smaller, to allow longitudinal movement of the pusher and a mounted stent thereon, without allowing rotation.

[0169] Upon positioning of the delivery catheter **100** within the vasculature (e.g., the blood vessel V), imaging can be used to confirm the orientation of the distal end **108** of the delivery catheter **100** relative to the proximal end **104** of the delivery catheter **100**. For example, it is envisioned that the respective proximal and distal ends **104**, **108** of the delivery catheter **100** may include corresponding markers **114** (e.g., radiopaque markers) that are positioned in corresponding locations (e.g., at “12 o'clock” locations), as elaborated upon below. Subsequent imaging with x-ray, 3-D x-rays, CT imaging, echocardiography, ultrasound, IVUS, or other modalities can then confirm the relative (rotational) position of the distal end **108** of the delivery catheter **100** (e.g., at, near, or adjacent to the vascular abnormality (e.g., the an aneurysm A) relative to the proximal end **104** of the delivery catheter **100** to ascertain the extent to which the distal end **108** of the delivery catheter **100** is rotationally offset from the proximal end **104** (e.g., as a result of twisting or other such deflection experienced by the delivery catheter **100** during navigation through the vasculature). When employed, the delivery device (e.g., the pusher **302**, the balloon catheter **400**, etc.) and, thus, the stent **202**, can then be rotated a corresponding amount prior to insertion into the delivery catheter **100** to account for the observed degree of (rotational) offset of the distal end **108** of the delivery catheter **100**, thereby facilitating accurate orientation and deployment of the stent **202**. Fundamentally, in somewhat tortuous anatomy, most known catheters, wires, and stents cannot be accurately rotated at the target site from the proximal end (hub) of the device. However, the present disclosure relies on a fixed degree of random rotation during initial delivery of the guide (delivery) wire **500**, the delivery catheter **300**, etc., to be recorded accurately and subsequently accounted for, allowing for accurate orientation, delivery, and placement of the stent **202**. In some cases, trial retrievable stent devices or similar devices can also be used to determine or confirm the orientation of the guide wire, the delivery catheter **300**, etc., at the target site in the vasculature.

[0170] FIG. **1**B provides a (partial) view of the delivery catheter **100** positioned within the blood vessel V such that the distal end **108** is located in proximity (e.g., at or adjacent) to the vascular abnormality (e.g., the aneurysm A) that is the subject of the medical procedure. For simplicity and clarity, only the lumen **112** of the delivery catheter **100** is illustrated.

[0171] FIG. **1**C is a (partial) cross-sectional view of the delivery catheter **100** taken transversely (e.g., orthogonally) in relation to the longitudinal axis X (FIG. **1**A) and shown with the pusher **302** of the packaging catheter **300** positioned within the lumen **112** in a first orientation.

[0172] FIG. **1**D is a (partial) cross-sectional view of the delivery catheter **100** and the pusher **302** shown positioned within the lumen **112** in second first orientation that is (rotationally) offset from the first orientation seen in FIG. **1**C by (approximately) 120°.

[0173] Although shown as a solid wire **308** (FIG. **2**A) in the illustrated embodiment, it should be appreciated that alternate configurations for the pusher **302** are also envisioned herein. For example, it is envisioned that the pusher **302** may define a lumen therethrough (e.g., to facilitate receipt of the aforementioned **114** such that the pusher **302** is advanceable into the blood vessel V in an “over-the-wire” configuration).

[0174] In the particular embodiment seen in FIG. **2**C, the stent **202** includes a self-expanding, differentially porous configuration with a first (covered) region **204** having a first porosity and a second (uncovered) region **206** having a second, different (e.g., greater) porosity. In certain embodiments, it is envisioned that the first region **204** may be completely impermeable to fluid, blood, etc., and/or that the second region **206** may be devoid of struts (threads, etc.) such that the second region **206** includes or otherwise defines one or more fenestrations **208**, holes, apertures, or other such openings in the stent **202**.

[0175] The present disclosure contemplates a variety of geometrical configurations for the stent **202** (or other medical devices) including, for example, both (generally) circular transverse cross-sectional configurations (e.g., so as to correspond to the (generally) circular transverse cross-sectional configuration of blood vessels), as seen in FIG. **2**C, for example, and non-circular transverse cross-sectional configurations (e.g., to facilitate placement and/or anchoring of the stent **202** within the vasculature).

[0176] With reference to FIG. **1**C, as mentioned above, the pusher **302** includes a non-circular transverse (lateral) cross-sectional configuration corresponding to that defined by the lumen **112** of the delivery catheter. More specifically, in the particular embodiment illustrated, the pusher **302** includes a (generally) triangular transverse (lateral) cross-sectional configuration. As discussed above (and elaborated upon below) in connection with the lumen **112**, a variety of other non-circular transverse (lateral) cross-sectional configurations for the pusher **302** are also contemplated by the present disclosure. The corresponding non-circular transverse cross-sectional configurations defined by the lumen **112** of the delivery catheter and the pusher **302** allow for receipt of the pusher **302** in a manner that allows for longitudinal (axial) movement (e.g., sliding) of the pusher **302** through the delivery catheter **100** while inhibiting (if not entirely preventing) rotation of the pusher **302** within the delivery catheter **100** to thereby facilitate control over the orientation of the pusher **302** and, thus, the stent **202**, relative to the delivery catheter **100**.

[0177] While discussed in connection with the pusher **302**, it should be appreciated that the anti-rotation principles attributable to the non-circular transverse (lateral) cross-sectional configuration are equally applicable to the balloon catheter **400**, the guide wire, or other such medical device inserted into the patient's vasculature.

[0178] The triangular cross-sectional configuration of the lumen **112** is defined by three linear segments a, b, c that intersect to define vertices vertexes AA, BB, and CC and interior angles A, B, C of (approximately) 120°. For the purposes of nomenclature, counterclockwise rotation of the delivery catheter **100** by (approximately) 120° will results in positioning of the delivery catheter **100** (and, thus, the pusher **302**) in the manner illustrated in FIG. **1**D. It should be appreciated, however, that the number of linear segments may be varied in alternate embodiment so as to define any suitable non-circular (transverse) cross-sectional configuration for the lumen **112** (e.g., four segments, five segments, six segments, etc.).

[0179] The non-circular (transverse) cross-sectional configuration of the lumen **112** allows for insertion of the pusher **302** (or the balloon catheter **400**) in a plurality of discrete (rotational) orientations. For example, in the illustrated embodiment, the triangular transverse cross-sectional configuration of the lumen **112** allows for receipt of the pusher **302** and, thus, the stent **202**, in one of three discrete (rotational) orientations that are offset from each other by (approximately) 120°. Variability in the (rotational) orientation of the pusher **302** and the stent **202** allows for and accommodates (rotational) displacement experienced by the distal end **108** of the delivery catheter **100** (relative to the proximal end **104** and the aforementioned aneurysm A) during insertion into the blood vessel V by virtue of the tortuous nature of the vasculature. For example, if no (rotational) offset is observed between the distal end **108** of the delivery catheter **100** and the proximal end **104** (and the aneurysm A) (e.g., such that the distal end **108** and the proximal end **104** each remain in an initial “12 o'clock” position), the pusher **302** (or the balloon catheter **400**) may be inserted in one (rotational) orientation (e.g., in a corresponding “12 o'clock” position). However, if a (rotational) offset is observed between the distal end **108** of the delivery catheter **100** and the proximal end **104** (and the aneurysm A), depending on the observed degree of (rotational) offset, the pusher **302** (or the balloon catheter **400**) may be inserted in one of a plurality of different (rotational) orientations, which, in the illustrated embodiment, are (rotationally) offset from each other by (approximately) 120°, such that the stent **202** may be positioned in the blood vessel V as necessary or desired to treat the aneurysm A.

[0180] To facilitate observation of the (rotational) orientations of the distal end **108** of the delivery catheter **100**, the pusher **302**, the balloon catheter **400**, the stent **202**, etc., the delivery catheter **100**, the pusher **302**, the balloon catheter **400**, the stent **202**, etc., may include one or more markers (e.g. radiopaque markers), as discussed in further detail below, which may be visualized using any suitable technique such as, for example, x-ray, 3-D x-rays, CT imaging, echocardiography, ultrasound, IVUS, etc.

[0181] FIG. **2**A illustrates the packaging catheter **300** and the delivery catheter **100** which, in the illustrated embodiment, are separated by a hub **600** having a port **602** such that the hub **600** is located between the delivery catheter **100** and the packaging catheter **300**. It is envisioned that the hub **600** may a component of the packaging catheter **300** or the delivery catheter **100**. Alternatively, it is envisioned that the hub **600** may be a discrete (free-standing) component of the intravascular system **10** that is configured to interface (connect, engage) with the packaging catheter **300** and/or the delivery catheter **100** such that the packaging catheter **300** and the delivery catheter **100** are indirectly connected via the hub **600**.

[0182] The packaging catheter **300** includes an elongated tubular body **310** having respective proximal and distal ends **312**, **314** and defining a lumen **316** that is configured to receive the pusher **302** and the stent **202**. The hub **600** is configured for releasable connection to the proximal end **104** of the delivery catheter **100** (e.g., via a corresponding hub on the delivery catheter **100**) such that the pusher **302** and the stent **202** are insertable through the port **602** in the hub **600**, into the lumen **112** of the delivery catheter **100**, and into proximity (e.g., at or adjacent) to the aneurysm A. It is envisioned that the distal end **306** of the packaging catheter **300** and the proximal end **104** of the delivery catheter **100** may be disposed within the hub **600** in (general) alignment to facilitate movement of the pusher **302** from the elongated body **310** of the packaging catheter **300** into the lumen **112** of the delivery catheter **100**.

[0183] In one method of use (seen in FIG. **2**A), the delivery catheter **100** is advanced through the blood vessel V to the target site (e.g., such that the distal end **108** of the delivery catheter **100** is located in proximity (e.g., at or adjacent) to the aneurysm A). The stent **202**, which is pre-loaded on the pusher **302**, may be then be advanced through the delivery catheter **100** into the blood vessel V (e.g., via the an elongated body **310** of the packaging catheter **300** and the hub **600**) such that the stent **202** is automatically expanded (deployed) upon exposure from the delivery catheter **100**.
[0184] FIG. **2**B illustrates insertion of the balloon catheter **400** and the stent **202** into the blood vessel V through the delivery catheter **100**. As seen in FIG. **2**B, the balloon catheter **400** includes an elongated (tubular) body (member) **402** defining a lumen **404** and an inflatable member **406** that is supported by the elongated body **402**. The stent **202** is positioned about (secured to) the inflatable member **406** (e.g., via crimping) such that the stent **202** is deployed via expansion (inflation) of the inflatable member **406**.
[0185] To facilitate proper placement of the balloon catheter **400** and the stent **202**, the guide wire **500**, which includes respective proximal and distal ends **502**, **504**, is positioned within the blood vessel **100** such that the guide wire **500** is located in proximity (e.g., at or adjacent) to the aneurysm A. The balloon catheter **400** is then advanced into the blood vessel V over the guide wire **500** (e.g., through the lumen **112** in the delivery catheter **100**) such that the guide wire **500** extends through the lumen **404** defined by the elongated body **402** of the balloon catheter **400**.
[0186] To facilitate control over, and proper positioning of, the stent **202**, as indicated above, the balloon catheter **400** includes (defines) a non-circular transverse (e.g., triangular) cross-sectional configuration corresponding to that defined by the lumen **112** of the delivery catheter **300** to inhibit (if not entirely prevent) relative rotation between the balloon catheter **400** and the delivery catheter **300**, thereby facilitating control over the (rotational) orientation of the stent **202** via manipulation of the balloon catheter **400**.
[0187] To further facilitate control over the (rotational) orientation of the stent **202**, in certain embodiments, it is envisioned that the lumen **404** of the balloon catheter **400** may include a non-circular transverse (e.g., triangular) cross-sectional configuration corresponding to that defined by the guide wire **500** to inhibit (if not entirely prevent) relative rotation between the balloon catheter **400** and the guide wire **500**.
[0188] To secure the guide wire **500** within the blood vessel V, in certain embodiments, it is envisioned that the guide wire **500** may include one or more stability components such as anchors **506** at (or adjacent to) the distal end **504** thereof. In the particular embodiment seen in FIG. **2**B, for example, the anchor **506** includes a branched wire segment **508** that defines a plurality of segments **510** (e.g., a first segment **510***i* and a second segment **510***i*). Upon the application of a predetermined radial force to the anchor **506**, the segments **510** are directed into the wall of the blood vessel V in different directions.
[0189] It is envisioned that the anchor(s) **506** may be configured such that the branched wire segment **508** is moved from a first (insertion, inactive, collapsed) configuration, in which the segments **510** are positioned in generally adjacent relation to each other and to the distal end **504** of the guide wire **500**, into a second (anchoring, active, expanded) configuration, in which the segments **510** are separated from each other to thereby anchor the guide wire **500** within the blood vessel V upon the application of an external stimulus. It is envisioned that the at least one anchor **506** may be moved from the first configuration into the second configuration upon the application of any suitable stimulus including, for example, a thermal stimulus, an electric stimulus, a mechanical stimulus, a magnetic stimulus, a hydrostatic stimulus, etc.
[0190] In various embodiments of the disclosure, it is envisioned that the configuration of the anchor(s) **506** may be varied. For example, it is envisioned that the anchor(s) **506** may include a tortuous (e.g., a spring-like) configuration. Additionally, or alternatively, it is envisioned that the anchor(s) **506** may include a balled wire, a retrievable stent, or any other structure suitable for the intended purpose of securing the guide wire **500** in relation to the blood vessel V (e.g., to maintain

the (rotational) position of the distal end **504** of the guide wire **500**).

[0191] In some embodiments, the guidewire has at least one segment that comprises at least two wires that when detached from a detachment zone (such as via the detachment methods described herein, or by other methods), the wire will splay and apply pressure to the side walls of the vessel, and thereby help anchor the wire in place. This will minimize longitudinal movement and/or rotational movement. The guidewire in some embodiments, can have a non-circular outer shape along a majority of its length, starting at its proximal end outside the patient's body, and can have at least one marker to define a circumferential position. This stability component of the wire at the distal end, preferably distal to the intended deployment site of the device, stabilizes the rotational orientation of the wire and prevents its rotation during device delivery.

[0192] It should be appreciated that the discussion above concerning the anchor(s) **506** is applicable to any of the guide wires (or embodiments thereof) described herein.

[0193] With reference to FIG. **3**, the pusher **302** and the stent **202** are illustrated and shown located within the blood vessel V following removal of the delivery catheter **100**. In certain embodiments, it is envisioned that the distal end **306** of the pusher **302** may extend distally beyond the stent **202** or, alternatively, that the distal end **306** of the pusher **302** may be coterminous with the stent **202** such that the distal end **306** of the pusher **302** does not extend distally beyond the stent **202**, as seen in FIG. **3**.

[0194] FIG. **4** provides a (partial) a view of the delivery catheter **100**. For simplicity and clarity, only the lumen **112** of the delivery catheter **100** is illustrated. As seen in FIG. **4**, the triangular transverse cross-sectional configuration of the lumen **112** defines three linear segments (sides) **116**, which are identified at the proximal end **104** of the delivery catheter **100** by the reference characters **114***i*, **114***ii*, **114***iii* and at the distal end **108** of the delivery catheter **100** by the reference characters **114***iv*, **114***v*, **114***vi*. As seen in FIG. **4**, a linear face **118***i* extends between segments **114***i*, **114***iv*, a linear face **118***ii* extends between segments **114***ii*, **114***vi*, and a linear face **118***iii* extends between segments **114***iii*, **114***vi* along the axial length of the delivery catheter **100**. Although shows as being triangular in configuration, it should be appreciated that alternative embodiments (not shown) may employ other non-circular cross-sectional configurations, such as, for example, rectangles, pentagons, hexagons, octagons, squares, ovals, ellipse, stars, etc.

[0195] FIG. **5** provides a (partial) a (partial) view of the delivery catheter **100** rotated 120° (clockwise) from the orientation seen in FIG. **4** such that the face **118***ii* is visible. In the illustrated embodiment, the markers **114** are secured to (or otherwise supported on) the face **118***ii*. The markers **114** may be present in any suitable number and may be positioned in any suitable location. As such, it is envisioned that one or more markers **114** may be located on the face **118***i* or the face **118***iii* either instead of, or in addition to, the face **118***ii*. In the particular embodiment illustrated, for example, the delivery catheter **100** includes a (first) marker **114***i* located at (or adjacent to) the proximal end **104** of the delivery catheter **100** (e.g., on a hub of the delivery catheter **100** located externally of the body so as to allow for direct visualization), a (second) marker **114***ii* located at (or adjacent to) the distal end **108** of the delivery catheter **100**, and a (third) marker **114***iii* located between the markers **114***i*, **114***ii*, wherein each of the markers **114** is oriented in a “12 o'clock” position.

[0196] FIG. **6** illustrates the stent **202** loaded onto the pusher **302** during insertion into the lumen **112** of the delivery catheter **100**. As discussed above, the lumen **112** and the pusher **302** include corresponding non-circular (e.g., triangular) transverse cross-sectional configurations that inhibit (if not entirely prevent) relative rotation between the pusher **302** (and, thus, the stent **202**) and the delivery catheter **100** while allowing for relative axial (longitudinal) movement (e.g., sliding) of the pusher **302** (and, thus, the stent **202**) through the lumen **112**.

[0197] As described below, however, a variety of other non-circular transverse (lateral) cross-sectional configurations are also contemplated by the present disclosure.

[0198] With reference to FIGS. **7**A-**7**D, as indicated above, the lumen **112** extending through the delivery catheter **100** (as well as the pusher **302**, the guide wire **500**, the lumen **404** in the balloon catheter **400**, etc.) may include a variety of non-circular transverse cross-sectional configurations such as, for example, a square-shaped configuration (FIG. **7**A), a pentagonal configuration (FIG. **7**B), an arrow-shaped configuration (FIG. **7**C), a star-shaped configuration (FIG. **7**D), or any other suitable non-circular transverse cross-sectional configuration that inhibits (if not entirely prevents) relative rotation between the pertinent structures. Note the lumens and outer diameters can correspond so they are the same configuration or can correspond so that although they are different configurations, they are non-circular and rotational movement is limited or fully inhibited.

[0199] FIG. **7**E illustrates a variation on the delivery catheter **100** in which the proximal end **104** includes the markers **114***i*, **114***ii* in the “12 o'clock” position and the “6 o'clock” position, respectively, and the distal end **108** includes the marker **114***iii* in the “12 o'clock” position.

[0200] FIG. **8** shows the pusher **302**.

[0201] FIG. **9** shows the packaging catheter **300** and the lumen **316** that extends through the elongated body **310** which, in the illustrated embodiment, includes a non-circular (e.g., triangular) transverse cross-sectional configuration.

[0202] FIG. **10** illustrates an alternate embodiment of the pusher **302**, wherein the distal end **306** includes a tapered configuration. It should be appreciated, however, that distal end **306** of the pusher **302** may include any suitable configuration in various embodiments of the present disclosure such as, for example, rounded, pointed, etc.

[0203] FIG. **11** illustrates an embodiment of the delivery catheter **100** in which the proximal end **104** includes a hub **120**. More specifically, the delivery catheter **100** is shown with the distal end **108** being (rotationally) offset from the proximal end **104** (e.g., subsequent to insertion into the blood vessel V (FIG. **2**A)), as indicated by the markers **114***i*, **114***ii* respectively included at the proximal and distal ends **104**, **108**. In the particular orientation seen in FIG. **11**, the delivery catheter **100** is deflected (twisted) such that the marker **114***ii* at the distal end **108** is in a “10 o'clock” position when compared to the “12 o'clock” position of the marker **114***i* at the proximal end **104**, which is provided on the hub **120** (e.g., such that the distal end **108** of the delivery catheter **100** is (rotationally) offset from the proximal end **104** by (approximately)) 60°.

[0204] FIG. **12** illustrates the pusher **302** inserted into the lumen **112** of the delivery catheter **100** seen in FIG. **11**.

[0205] FIGS. **13** and **14** illustrated an alternate embodiment of the disclosure in which the delivery device includes an elongated outer hypotube (member) **700** (FIG. **13**) and an inner hypotube **800** (FIG. **14**). The outer hypotube **700** supports the stent **202** (e.g., the stent **202** is secured or otherwise connected to) an outer surface **702** of the outer hypotube **700**) and defines a lumen **704** that extends therethrough. While the outer hypotube **700** is illustrated as including a (generally) annular (circular, round) transverse cross-sectional configuration (e.g., for use during procedures in which rotation is not required), it should be appreciated that the outer hypotube **700** may include a non-circular transverse cross-sectional configuration in alternate embodiments (e.g., for use during procedures in which rotation is required).

[0206] The inner hypotube **800** includes wings **802** that extend proximally (rearwardly) from a distal end **804** thereof and defines a lumen **806** that extends therethrough. The inner hypotube **800** is configured for insertion into the lumen **704** of the outer hypotube **700** (FIG. **13**) such that the wings **802** are positionable about the stent **202** to cover and constrain the stent **202** during insertion it the blood vessel V. During use of the hypotubes **700**, **800**, the stent **202** is exposed from the wings **802** by varying the relative longitudinal (axial) positions of the hypotubes **700**, **800** (e.g. by moving the inner hypotube **800** proximally within the lumen **704** of the outer hypotube **700**, by moving the outer hypotube **700** proximally in relation to the inner hypotube **800**, etc.) to thereby unsheathe (expose) the stent **202**, which allows the stent **202** to automatically expand within the blood vessel V. If necessary or desired (e.g., during movement or repositioning of the stent **202** within the blood vessel V), the stent **202** may be re-sheathed (covered) (e.g. by moving the inner hypotube **800** distally within the lumen **704** of the outer hypotube **700**, by moving the outer hypotube **700** distally in relation to the inner hypotube **800**, etc.).

[0207] It is envisioned that the lumen **806** extending through the inner hypotube **800** and/or the lumen **704** extending through the outer hypotube **700** may be configured to receive a guide wire (e.g., the aforementioned guide wire **500**) to facilitate use in an "over-the-wire" method of deployment. It is also envisioned that the inner hypotube **800** and/or the outer hypotube **700** may include a rapid exchange configuration (e.g., it is envisioned that the inner hypotube **800** may include a side hole in communication with the lumen and/or that the outer hypotube **700** may include a side hole in communication with the lumen that is configured to receive the guide wire **500**).

[0208] FIG. **14**A illustrates alternate embodiments of the outer and inner hypotubes **700**, **800** seen in FIGS. **13** and **14**, which are identified by the reference characters **700***i* and **800***i*, respectively, for use during an alternate procedure. The inner hypotube **800***i* includes a lumen **806***i* that extends therethrough and supports the stent **202**, which is loaded (connected, supported) to an outer surface **808***i* thereof. The outer hypotube **700***i* includes a lumen **704***i* that is configured to receive the inner hypotube **800***i* such that the inner hypotube **800***i* is longitudinally (axially) movable through the outer hypotube **700***i*. Upon sufficient relative longitudinal (axial) movement between the hypotubes **700***i*, **800***i*, the stent **202** is exposed from a distal end **706***i* of the outer hypotube **700***i* and is automatically deployed (expanded).

[0209] FIG. **15** illustrates the guide wire **500**. In the illustrated embodiment, the guide wire **500** includes a non-circular (e.g., triangular) transverse cross-sectional configuration that defines three linear faces (sides), which are identified by the reference characters **512***i*, **512***ii*, **512***iii*. Although shown as being (generally) triangular in configuration, it should be appreciated that alternative embodiments (not shown) may employ other non-circular cross-sectional configurations, such as, for example, rectangles, pentagons, hexagons, octagons, squares, ovals, stars, arrows, etc. In the configuration seen in FIG. **15**, the guide wire **500** is illustrated without any significant (rotational) offset between the respective proximal and distal ends **502**, **504** thereof.

DETAILED DESCRIPTION OF THE INVENTION

[0210] The embodiments of the device and variants of the device of the present disclosure are set forth with reference to the above drawings.

[0211] Referring to FIG. **1**A, the delivery catheter **100** is illustrated. As discussed above, the aforementioned lumen **112** extends through the delivery catheter **100** and includes a (first) non-circular transverse (lateral) cross-sectional configuration. Although the transverse (lateral) cross-sectional configuration of the lumen **112** is shown as being (generally) triangular in FIG. **1**A, a variety of other non-circular transverse (lateral) cross-sectional configurations are also contemplated by the present disclosure including, for example, rectangular, pentagonal, hexagonal, octagonal, square-shaped, ovate (elliptical), stars-shaped, arrow-shaped, etc., as mentioned above. The lumen **112** is configured to (slidably) receive an (elongated) medical device, such as, for example, the pusher **302** (FIG. **2**A) of the packaging catheter **300**, the balloon catheter **400** (FIG. **2**B), the hypotube **700** (FIG. **13**), the hypotube **800** (FIG. **14**), the hypotube **700***i* (FIG. **14**A), the hypotube **800***i* (FIG. **14**A), the guide wire **500**, etc. As described in further detail herein, it is envisioned that the medical device intended for insertion into the lumen **112** may include a (second) non-circular transverse (lateral) cross-sectional configuration corresponding to the (first) non-circular transverse (lateral) cross-sectional configuration defined by the lumen **112** so as to allow for longitudinal (axial) movement (e.g., sliding) of the medical device through the delivery catheter **100** while inhibiting (if not entirely preventing) rotation of the medical device within the delivery catheter **100** to thereby facilitate control over the (rotational) orientation of the medical device during deployment and placement of the stent **202**. Depending upon the particular geometry of the transverse cross-sectional configurations defined by the lumen **112** and the medical device, the medical device will be insertable into the lumen **112** in a certain number of discrete (rotational) orientations. For example, in the context of the triangular transverse cross-sectional configuration seen in FIG. **1**A, an inserted medical device will be orientable in one of three distinct (rotational) orientations that are offset from each other by (approximately) 120°. Depending upon the particular transverse cross-sectional configuration employed, however, it should be appreciated that the number of distinct (rotational) orientations, and the offset therebetween, may be varied. For example, in the context of a square-shaped transverse cross-sectional configuration, an inserted medical device will be orientable in one of four distinct (rotational) orientations that are offset from each other by (approximately) 90°. FIG. **1**B illustrates the delivery catheter **100** within the blood vessel V. For simplicity and clarity, only the lumen **112** is illustrated. The delivery catheter **100** is positioned within the blood vessel V such that the distal end hole **110** is located in proximity (e.g., at or adjacent) to the aneurysm A (or other vascular abnormality) that is the subject of the associated medical procedure. Due to the generally linear configuration and geometry of the lumen **1**, the delivery catheter **100** includes a set orientation in which one side is positioned closest to the target aneurysm A.

[0212] FIG. **1**C illustrates the pusher **302** positioned with the lumen **112** of the delivery catheter **100** in a first orientation and FIG. **1**D illustrates the pusher **302** and the delivery catheter **100** in a second, different orientation that is rotationally offset from the first orientation. More specifically, FIG. **1**D illustrates the pusher **302** and the delivery catheter **100** after 120° of counterclockwise rotation (or 240° of clockwise rotation). Rotation of the delivery catheter **100** and, thus, the pusher **302**, allows for the delivery and placement of the occlusion device **200** (e.g., the stent **202**) (FIGS. **2**A, **2**C) in a necessary or desired orientation dictated by the location of the aneurysm A, for example. A similar setup may be used to deliver other devices, such as aneurysm neck caps which may have an asymmetric shape to cover an asymmetric aneurysm neck, previously described by Walzman (U.S. Pat. No. 10,543,015). It is envisioned that one or more supplemental (additional) occlusion device(s) **200** may be used as well during the course of a particular medical procedure. As described herein, the orientation of the medical device (e.g., the pusher **302** and the stent **202**) inserted through the delivery catheter **100** may be fixed outside the patient's body by fixing the orientation of the medical device relative to the delivery catheter **100**. The orientation of the delivery catheter **100** (e.g. relative to the aneurysm A) may be established prior to insertion of the medical device into the lumen **112** such as, for example, via imaging, so as to facilitate proper insertion of the medical device to achieve proper orientation and placement of the stent **202** with respect to aneurysm A without necessitating any rotational manipulation (e.g., turning) of the pusher **302** and, thus, the stent **202**, inside the patient.

[0213] FIG. **2**A illustrates the packaging catheter **300** connected to the delivery catheter **100** via the hub **600** such that the elongated body **310** is positioned externally of the patient. In the illustrated embodiment, the lumen **316** extending through the elongated body **310** of the packaging catheter **300** includes a non-circular transverse (lateral) cross-sectional configuration corresponding to that defined by the lumen **112** of the delivery catheter **100** and that defined by the pusher **302**. Although shown as being (generally) triangular in FIG. **2**A, it should be appreciated that the transverse cross-sectional configuration defined by the lumen **316** of the elongated body **310** of the packaging catheter **300** may be varied in alternate embodiments without departing from the scope of the present disclosure (e.g., depending upon the particular transverse cross-sectional configurations defined by the lumen **112** of the delivery catheter **100** and the pusher **302**).

[0214] The distal end **306** of the pusher **302** (releasably) supports the stent **202** such that the stent **202** is positionable in proximity (e.g., at or adjacent) to the aneurysm A. Insertion of the pusher **302** and the stent **202** into the lumen **112** of the delivery catheter **100** is facilitated via positioning of the distal end **20** of the packaging catheter **300** and the proximal end **104** of the delivery catheter **100** within the hub **600**. To facilitate proper relative orientation of the packaging catheter **300** (e.g., the pusher **302** and the stent **202**) and the delivery catheter **100**, as well as proper orientation of the packaging catheter **300** within the blood vessel V, in the illustrated embodiment, the hub **600** include one or more markers (e.g., radiopaque markers) **604** and the packaging catheter **300** includes one or more markers (e.g., radiopaque markers) **318** (e.g., respective (first and second) markers **318***i*, **318***ii* that are positioned at (or adjacent to) the proximal and distal ends **304**, **306** of the elongated body **310**) which can be aligned with the marker(s) **114** FIG. **5** on the delivery catheter **100**. The marker(s) **604** on the hub **600**, the marker(s) **318** on the packaging catheter **300**, and the marker(s) **114** on the delivery catheter **100** are located in corresponding (rotational) positions, which allows the relative orientations of the packaging catheter **300**, the hub **600**, and the delivery catheter **100** to be ascertained and controlled (e.g., via rotation of the elongated body **310** of the packaging catheter **300**, the pusher **302**, and/or the delivery catheter **100**). In the illustrated embodiment, for example, the marker(s) **604** on the hub **600**, the marker(s) **318** on the packaging catheter **300**, and the marker(s) **114** on the delivery catheter **100** are each shown in the “12 o'clock” position. It should be appreciated, however, that the marker(s) **604**, **318**, and **114** may be located in any position suitable for the intended purpose of facilitating proper relative (rotational) orientation of the packaging catheter **300** (e.g., the pusher **302** and the stent **202**) and the delivery catheter **100**.

[0215] In the particular embodiment of the disclosure seen in FIG. **2**A, during use, the packaging catheter **300** is connected to the hub **600** such that the marker **604** on the hub **600** is oriented in the “12 o'clock” position. Based upon the particular configuration of the stent **202**, when so positioned, the pusher **302** and the stent **202** may be oriented in a predetermined fashion (e.g., such that the first region **204** (or the second region **206**) of the stent **202** faces (or is otherwise (rotationally) aligned with) the aneurysm A.

[0216] FIG. **3** illustrates positioning of the pusher **302** and the stent **202** within the blood vessel V following removal of the delivery catheter **100** (FIG. **2**A). Once the stent **202** is located in proximity (e.g., at or adjacent) to the aneurysm A, the stent **202** may be activated, released, or otherwise deployed such that the stent **202** expands within the blood vessel V. For example, when configured as a self-expanding stent, the stent **202** will automatically expand upon the removal of an external constraint (e.g., such as that provided by the delivery catheter **100**). Alternatively, however, it is envisioned that the stent **202** may be deployed via the balloon catheter **400** (FIG. **2**B) upon inflation of the inflatable member **406**.

[0217] In the particular embodiment illustrated, for example, the stent **202** is oriented such that the first (covered, less porous) region **204** abuts the aneurysm A while the second (uncovered, more porous) region **206** of the stent **202** promotes (or otherwise permits) blood flow to any side branches of the blood vessel V the stent **202** may cross. Although it is envisioned that the stent **202** may include a (generally) cylindrical configuration upon expansion, as seen in FIG. **2**C, for example, it is envisioned that the configuration of the stent **202** may varied in alternate embodiments of the disclosure (e.g., depending upon the particular requirements of the surgical procedure, the configuration and/or orientation of the aneurysm A (or other vascular abnormality), etc.). It is also envisioned that the stent **202** may be (temporarily) crimped (or otherwise deformed) into an alternate shape when loaded onto the pusher **302**, the inflatable member **406** of the balloon catheter **400**, or other such suitable medical device. It should be appreciated, however, that the configuration of the medical device supporting the stent **202** may be altered or varied as necessary or desired to facilitate placement of the stent **202** in the intended manner. For example, it is envisioned that the medical device supporting the stent **202** may include a cylindrical or non-cylindrical configuration in various locations along the length thereof (e.g., proximally of the stent **202**, distally of the stent **202**, and/or within the stent **202**). When being crimped on a (round, circular, tubular, toroidal) inflatable member **406**, for example, it is envisioned that inflatable member **406** may be collapsed, deflated, and mounted on an elongate member, such as, for example, the body **402** of the balloon catheter **400**, having a suitable configuration such that the inflatable member **406** (when deflated) and the stent **202** (when collapsed) may assume corresponding (e.g., similar or identical) configurations. It is envisioned that an external crimper of the same configuration may be used during the crimping process.

[0218] Now referring to FIG. **4**, the lumen **112** of the delivery catheter **100** is illustrated. More specifically, FIG. **4** illustrates the delivery catheter **100** devoid of any (rotational) offset between the distal end **108** and the proximal end **104**. It is envisioned that the (generally) triangular (transverse) cross-sectional configuration of the lumen **112** may promote (or otherwise facilitate) identification of the (rotational) orientation of the lumen **112**.

[0219] FIG. **5** illustrates the delivery catheter **100** rotated (approximately) 120° (clockwise) from the orientation seen in FIG. **4** such that the linear face **555** is visible. In the particular embodiment shown, the linear side **555** includes the marker(s) **114**, which promote visualization and proper orientation of the delivery catheter **100** during placement within the blood vessel V by allowing the clinician to ascertain the orientation of the linear face **555** relative to any suitable component of the intravascular system **10** or anatomical structure (e.g., the aneurysm A). Using that information, it is envisioned that the packaging catheter **300** may be properly oriented (e.g., relative to the hub **600**) such that, upon advancement of the pusher **302** and the stent **202** through the delivery catheter **100**, the stent **202** may be oriented as necessary or desired (e.g., such that the first (covered, less porous) region **204** of the stent **202** abuts the aneurysm A).

[0220] In certain embodiments, it is envisioned that the marker **114***ii* at the distal end **108** of the delivery catheter **100** may to (further) support visualization of the (rotational) position of the distal end **108** of the delivery catheter **100** (e.g., relative to the aneurysm A, a lesion, a side branch of the blood vessel V, or other such anatomical structures).

[0221] FIG. **6** illustrates the stent **202** supported on the pusher **302** prior to insertion of the stent **202** and the pusher **302** into the lumen **112** of the delivery catheter **100**. During introduction into the blood vessel V, by virtue of the stent **202** being crimped (or otherwise secured to the pusher **302**), the stent **202** is in a first (initial, insertion) configuration in which the stent **202** includes a transverse cross-sectional configuration corresponding to that defined by the pusher **302**. Thus, in the illustrated embodiment, the stent **202** includes a (generally) triangular transverse cross-sectional configuration prior to deployment. Upon expansion, however, the stent **202** moves into a second (subsequent, active) configuration in which the stent **202** includes a transverse cross-sectional configuration that may differ from that defined by the stent **202** in the first configuration. For example, in the particular embodiment illustrated, upon deployment (exposure) of the stent **202** from the distal end **108** of the delivery catheter **100** (within the blood vessel V) and removal of the constraint provided by the delivery catheter **100**, the stent **202** automatically expands into the (generally) cylindrical (tubular) configuration seen in FIG. **2**C.

First Method

[0222] In one method of use, the delivery catheter **100** is inserted into the blood vessel V with the proximal end **104** thereof positioned at or adjacent to the hub **600** and the markers **114***i*, **114***ii* in the "12 o'clock" position, which allows the degree of (rotational) deflection experienced by the delivery catheter **100** during insertion into the blood vessel V (if any) to be ascertained (e.g., via external visualization using any suitable technique). The packaging catheter **300**, which includes the pusher **302** and the stent **202**, is then inserted into the delivery catheter **100**. In the particular method described, the stent **202** includes the differential porosity described above, which is attributable to the disparity between the regions **204**, **206** (FIG. **2**C). After ascertaining the degree of (rotational) deflection experienced by the distal end **108** of the delivery catheter **100** (if any) (e.g., relative to the hub **600**), the packaging catheter **300** is oriented accordingly to reduce (if not entirely eliminate) any (rotational) offset between the stent **202** and the distal end **108** of the delivery catheter **100**.

[0223] As mentioned above, it is envisioned that the hub **600** and the packaging catheter **300** may include one or more markers **604**, **318**, respectively, to support more precise relative (rotational) orientation between the packaging catheter **300** and the delivery catheter **100**. The markers **604**, **318** may be disposed in any position to point to any direction. The term "12 o'clock" should be not construed as limiting in any way, but rather, as an exemplary indicator of position. For example, the clinician (user) may be instructed to rotate the hub **600** to a “3 o'clock” position, to a “6 o'clock” position, to a “9 o'clock” position, etc., which intuitively suggests a quarter-turn, a half-turn, a three-quarter turn, etc., respectively, with other “times” referring to approximate positions therebetween (e.g., a “2 o'clock” position, a “5 o'clock” position, an “11 o'clock” position, etc.). The same effect could be achieved by reference to a “North” marker, utilizing terminology such as “East,” “South,” and “West” (or interstitial positions such as “ESE” or “NW”). The delivery catheter **100** and the packaging catheter **300** may be configured for rotation through a 360° range of motion (e.g., prior association (engagement, connection) with one another) to allow for positioning of the delivery catheter **100** and the packaging catheter **300** in any manner desired or necessitated by the particular procedure being conducted (e.g., based upon the size, location, nature, etc., of the vascular abnormality being treated).

[0224] Following connection of the packaging catheter **300** and the delivery catheter **100** (e.g., via mutual connection to the hub **600**), the stent **202** is inserted into the delivery catheter **100** at a particular orientation (e.g., relative to the “12 o'clock” marker(s) **114** on the delivery catheter **100**). After insertion into the delivery catheter **100**, the final (rotational) orientation of the stent **202** will be dictated by (and will correspond to) the (rotational) orientation of the distal end **108** of the delivery catheter **100**. For example, even if it introduced in the “12 o'clock” position at the hub **600**, the stent **202** may be deployed in the “3 o'clock” position, the “6 o'clock” position, etc., depending upon the degree of (rotational) deflection experienced by the delivery catheter **100** during navigation of the blood vessel V en route to the aneurysm A (for example), if any, which is identifiable via the marker **114***ii* located at the distal end **108** thereof.

[0225] If the predicted (rotational) position of the stent **202** is not suitable (e.g., if a different (rotational) position for the stent **202** is necessary or desired), the stent **202** may be rotated accordingly (e.g., relative to the marker **114***ii* at the distal end **108** of the delivery catheter **100**) prior to insertion into the delivery catheter **100** (e.g., via rotational manipulation of the packaging catheter **300** (e.g., the pusher **302**)). Additionally, or alternatively, it is envisioned that the final the (rotational) position of the stent **202** may be varied via rotational manipulation of the delivery catheter **100** and, thus, the pusher **302** and the stent **202**, following insertion of the pusher **302** and the stent **202** into the delivery catheter (e.g., the delivery catheter, the pusher **302**, and the stent **202** may be rotated in unison via the non-rotational interface provided by the corresponding non-circular (transverse) cross-sectional configurations defined by the pusher **302** and the lumen **112** extending through the delivery catheter **100**).

[0226] In the context of triangular (transverse) cross-sectional configurations for the pusher **302** and the lumen **112**, the packaging catheter **300** may be positioned in three discrete (rotational) positions prior to insertion of the pusher **302** into the lumen **112** of the delivery catheter **100**. To facilitate additional (rotational) precision, it is envisioned that the stent **202** may be pre-loaded into the elongated body **310** of the packaging catheter **300** in a variety of (rotational) orientations (e.g., during packaging by the manufacturer), which may be identified via labeling on the device, its packaging, etc.

[0227] The process may be repeated to verify that the respective markers **114**, **318** on the delivery catheter **100** and the packaging catheter **300** are consistently aligned. Imaging may then be performed to verify the relative (rotational) positions of the markers **114**, **318** to determine the (rotational) orientation (e.g., the “hour” on the “clock”) required of the stent **202** (prior to insertion into the delivery catheter **100**) to achieve the necessary final (rotational) position within the blood vessel V.

[0228] In certain embodiments, prior to insertion of the stent **202**, the final (rotational) position of the stent **202** may be confirmed via the insertion of a test stent (or other such device), which may be temporarily advanced in the predicted orientation, visualized using any suitable imaging technique, and then removed prior to insertion and deployment of the stent **202**. To facilitate such visualization, it is envisioned that the test stent (or other such device) may include one or more suitable markers (e.g., radiopaque markers). For example, during a test insertion, in the instance where a fenestration is identified at the “7 o'clock” position (which is offset by (approximately) 90° in the clockwise direction relative to the target branch vessel), the packaging catheter **300** may be re-oriented into the “4 o'clock” position to facilitate proper orientation of the stent **202**.

[0229] Upon imaging of the distal end **108** of the delivery catheter **100**, and confirmation that the distal end **108** is positioned as necessary, the stent **202** may be loaded into the delivery catheter **100** in the appropriate (necessary) orientation and advanced to the target site.

Second Method

[0230] A second method of use will now be discussed, which uses the steps, devices, markers, etc., discussed above in connection with the First Method. As mentioned above, the lumen **112** extending through the delivery catheter **100** includes a unique (transverse), non-circular cross-sectional configuration while, in an exemplary embodiment, the delivery catheter **100** includes an outer (transverse) cross-sectional configuration that is (generally) annular (e.g., round, circular) to facilitate advancement of the delivery catheter **100** through a patient's vasculature, circulatory vessels, etc. The non-circular (transverse) cross-sectional configuration defined by the lumen **112** reduces (if not eliminates) relative rotation between the delivery catheter **100** and an inserted medical device (e.g., the pusher **302**, the hypotube **700** (FIG. **13**), the hypotube **800** (FIGS. **13**, **14**), the balloon catheter **400**, etc.) to improve precision during placement within the blood vessel V to enhance predictability in the final position of the stent **202**.

[0231] While the lumen **112** is (generally) illustrated as including a triangular (transverse) cross-sectional configuration, alternative configurations are also contemplated herein (e.g., square, hexagonal, octagonal, pentagonal, a “house” silhouette, oval, elliptical, star-shaped, etc.). In the context of a star-shaped (transverse) cross-sectional configuration, any style of star may be used including, for example, a six-pointed star, a “Star of David,” etc.

[0232] It is envisioned that the (transverse) cross-sectional configuration of the lumen **316** extending through the elongated body **310** of the packaging catheter **300** may correspond to that of the lumen **112** extending through the delivery catheter **100**, as can be appreciated through reference to FIGS. **1**A-**2**A, for example. The interface defined by the lumen **316** and the medical device positioned therein (e.g., the pusher **302**, the hypotube **700** (FIG. **13**), the hypotube **800** (FIGS. **13**, **14**), etc.) is such that the lumen **316** permits longitudinal (axial) movement (e.g., sliding) of the medical device therethrough while inhibiting (if not entirely preventing) relative rotation between the medical device within the lumen **316** and the packaging catheter **300**, which allows the (rotational) position of the medical device relative to the packaging catheter **300** (and the delivery catheter **100**) to be (substantially) maintained, thereby facilitating accurate and predicable deployment (e.g., of the stent **202**).

[0233] In another example, the aforementioned guide wire **500** may be utilized to facilitate deployment of the stent **202** via the balloon catheter **400**, as seen in FIG. **2**B. In such implementations, the guide wire **500** may be advanced into the blood vessel V via any suitable endovascular method. To inhibit (if not entirely prevent) relative rotation between the balloon catheter **400** and the guide wire **500** and thereby facilitate control over the (rotational) orientation of the balloon catheter **400** and the stent **202**, it is envisioned that the guide wire **500** and the lumen **404** extending through the elongated body **402** of the balloon catheter **400** may include corresponding non-circular (e.g., triangular) (transverse) cross-sectional configurations. In various embodiments, it is envisioned that the non-circular (transverse) cross-sectional configuration may extend continuously along an entire length of the guide wire **500**. Alternatively, it is envisioned that the non-circular (transverse) cross-sectional configuration may only extend along a portion of the length of the guide wire **500**.

[0234] To facilitate visualization of the guide wire **500** in vivo, the guide wire **500** may include one or more markers **514** (e.g., radiopaque or other such markers). For example, in the particular embodiment seen in FIG. **2**B, the guide wire **500** includes a first marker **514***i* located at (or adjacent

to) the proximal end **502** of the guide wire **500** (which may be located externally of the patient) and a second marker **514***ii* located at (or adjacent to) the distal end **504** of the guide wire **500**), each of which may be located in the “12 o'clock” position (or any other suitable reference orientation). In one particular embodiment, it is envisioned that the marker(s) **514** may be located at (or adjacent to) a transition between a first portion of the guide wire **500**, which includes the non-circular (transverse) cross-sectional configuration, and a second portion of the guide wire **500**, which includes a (generally) circular (transverse) cross-sectional configuration. It is also envisioned, however, that a variety of distinct radiopaque markers **514**, such as those of a different radio-density, shape or orientation, etc., may be utilized (e.g., to further facilitate visualization, differentiation, etc.) in connection with the guide wire **500** (or any of the components of the intravascular system **10** described herein including, for example, the delivery catheter **100**, etc.). Via visualization, the (rotational) position of the marker **514***ii* can be determined relative to the marker **514***i*, the any vascular abnormalities (e.g., the aneurysm A), the origin of a side branch, etc.
[0235] Once the (rotational) position of the marker **514***ii* at the distal end **504** of the guide wire **500** is determined, the balloon catheter **400** may be advanced into the blood vessel V over the guide wire **500** such that the guide wire **500** is received within the lumen **404**.
[0236] Following positioning of the balloon catheter **400** within the blood vessel V as desired, the inflatable member **406** can be expanded to thereby deploy (implant) the stent **202**. As indicated above, if desired, a test stent (or other such device) may be deployed and recaptured prior to placement of the stent **202** to confirm the rotational position of the guide wire **500** and, thus, the predicted final position of the stent **202**, at the target location (e.g., at or adjacent to the aneurysm A).
[0237] In various alternate embodiments, it is envisioned that the guide wire **500** and the balloon catheter **400** may be configured (adapted) for use in both “over-the-wire” configurations, as discussed above, and rapid-exchange configurations.
[0238] In another exemplary procedure, it is envisioned that the guide wire **500** may be used in combination with the packaging catheter **300** to facilitate placement and deployment of the pusher **302** and the stent **202** through the delivery catheter **100**. In such embodiments, the guide wire **500** may be utilized to facilitate the placement of the delivery catheter **100** into the blood vessel V over the guide wire **500**. In such embodiments, it is envisioned that the guide wire **500** and the lumen **112** (FIG. **1**A) extending through the delivery catheter **100** may include corresponding non-circular (transverse) cross-sectional configurations to inhibit (if not entirely prevent) relative rotation between the delivery catheter **100** and the guide wire **500**.
[0239] Following placement of the guide wire **500** and insertion of the delivery catheter **100** into the blood vessel V over the guide wire **500**, the guide wire **500** may be removed, thereby allowing for insertion of the pusher **302** and the stent **202** into to delivery catheter **100** from the elongated body **310** of the packaging catheter **300**. As indicated above, it is also envisioned that the pusher **302** and the lumen **112** extending through the delivery catheter **100** may include corresponding non-circular (transverse) cross-sectional configurations. Thus, in such embodiments, the (transverse) cross-sectional configuration defined by the lumen **112** extending through the delivery catheter **100** may be common to (shared by) both the pusher **302** and the guide wire **500**.
[0240] In such embodiments, upon sufficient advancement of the pusher **302** through the delivery catheter **100**, the stent **202** emerges from the distal end thereof, at which point, the external constraint applied to the stent **202** by the lumen **112** is removed such that the stent **202** is automatically deployed in the blood vessel V.
[0241] To facilitate the delivery of the (self-expanding) stent **202**, during the course of an “over-the-wire” procedure, it is envisioned that inner and outer hypotubes (e.g., catheters) may be utilized in place of the pusher **302**. In the embodiment of the disclosure seen in FIGS. **13** and **14**, for example, the stent **202** is loaded (mounted) on the outer hypotube **700**. The inner hypotube **800** is positioned over the guide wire **500** (e.g., such that the guide wire **500** extends through the lumen

9094) and is received by the lumen **704** of the outer hypotube **700**. It is envisioned that the lumen **9094** and the guide wire **500** may include corresponding non-circular (transverse) cross-sectional configurations, which, as discussed above, allows for relative axial movement between the guide wire **500** and the inner hypotube **800** while inhibiting (if not entirely preventing) relative rotation between the guide wire **500** and the inner hypotube **800**. The wings **802** extend from the inner hypotube **800** in the proximal direction so as to cover (sheath) the stent **202** during insertion into the blood vessel V, thereby constraining the stent **202** so as to maintain the stent **202** in a collapsed configuration during insertion into the blood vessel V. Once the stent **202** is positioned as desired within the blood vessel V (e.g., in proximity (at or adjacent) to the aneurysm A), the relative longitudinal (axial) positions of the hypotubes **9091**, **9092** can be varied to cause unsheathing of the stent **202** (e.g., exposure from the wings **802**) so as to remove the external constraint provided by the wings **802** and permit expansion (deployment) of the stent **202**.

[0242] In an alternate embodiment, which is illustrated in FIGS. **13**A and **14**A, the stent **202** is supported on an inner hypotube **800***i*, which extends into an outer hypotube **700***i* such that the outer hypotube **700***i* overlies the stent **202** to thereby constrain the stent **202** and inhibit expansion thereof during insertion into the blood vessel V. In such embodiments, the inner hypotube **800***i* is inserted over the guide wire **500** (e.g., such that the guide wire **500** is received within a lumen **9094***i* of the inner hypotube **800***i*). As discussed in connection with the hypotubes **9091**, **9092**, it is envisioned that the lumen **9094***i* and the guide wire **500** may include corresponding (transverse) cross-sectional configurations to inhibit (if not entirely prevent) relative rotation between the guide wire **500** and the inner hypotube **800***i* while allowing for relative axial movement between the guide wire **500** and the inner hypotube **800***i*. Once the stent **202** is positioned as desired within the blood vessel V (e.g., in proximity (at or adjacent) to the aneurysm A), the outer hypotube **700***i* can be retracted (moved in the proximal direction), thereby exposing the stent **202** and removing the external constraint provided by the outer hypotube **700***i* to permit expansion (deployment) of the stent **202**.

[0243] In various embodiments of the disclosure, it is envisioned that the medical devices described herein may include an energy component **900** (FIG. **2**C) that is configured to deliver ultrasound, RF energy, etc., to the target site (e.g., the aneurysm A). It can be delivered through the stent or adjacent the stent. For example, it is envisioned that the delivery of energy to the target site may soften calcifications in the walls of the blood vessel V (e.g., in the context of an intravascular lithotripsy, similar to those devices produced by Shockwave Medical).

[0244] Although shown as being associated with the stent **202** (FIG. **2**C), it should be appreciated that the energy component **900** may be associated with any of the medical devices (or components thereof) described herein and that energy may be delivered in any suitable manner using any suitable structure(s) (e.g., wire(s), etc.). For example, it is envisioned that the energy component **900** may be provided on (or otherwise in communication with) the delivery catheter **100**, the balloon catheter **400** (e.g., the inflatable member **406**), the guide wire **500**, the pusher **302**, the anchor(s) **506**, etc.

[0245] In another embodiment of the disclosure, the devices and methods described herein may be adapted for the treatment of bifurcated vessels, lesions, etc. With reference to FIGS. **16** and **17**, an alternate embodiment of the intravascular system **10** is disclosed, which is identified by the reference character **1000**. The intravascular system **1000** includes a primary delivery catheter **1100** defining a lumen **1102** and a (first) delivery device **1200** that is configured for insertion into the blood vessel V through the delivery catheter **1100** to deploy a primary stent **1300** (e.g., a first fenestrated occlusion device), which may be substantially similar or identical to the aforedescribed stent **202**.

[0246] In the embodiment seen in FIG. **17**, the (first) delivery device **1200** is configured as the aforedescribed packaging catheter **300** (FIG. **2**A). In such embodiments, the primary stent **1300** is carried (supported) on the pusher **302** and is configured for self-expansion upon exposure from the delivery catheter **1100**. To inhibit relative rotation between the delivery catheter **1100** and the primary stent **1300**, it is envisioned that the lumen **1102** of the delivery catheter **1100** and the pusher **302** may include corresponding non-circular (e.g., triangular) (transverse) cross-sectional configurations.

[0247] Alternatively, with reference to FIGS. **18-25**, it is envisioned that the (first) delivery device **1200** may be configured as a balloon catheter **1400**. The balloon catheter **1400** includes an elongated body (member) **1402** with proximal and distal ends **1404**, **1406** respectively defining end holes **1408**, **1410** and a series of lumens **1412** that extend therethrough. More specifically, the balloon catheter **1400** includes a (first) lumen **1412***i*, a (second) lumen **1412***ii* that extends in (generally) parallel relation to the lumen **1412***i*, and a (third) lumen **1412***iii* that extends in (generally) parallel relation to the lumen **1412***i* and/or the lumen **1412***ii*. The balloon catheter **1400** further includes an inflatable member (balloon) **1414** that is secured to the elongated body **1402** and supports the primary stent **1300**. In the particular embodiment illustrated, the inflatable member **406** includes a (first) fenestration (opening, aperture) **1416** and the primary stent **1300** includes a (second) fenestration (opening, aperture) **1302**.

[0248] In certain embodiments, it is envisioned that the lumen **1412***i* may extend between the respective proximal and distal end holes **1408**, **1410** of the balloon catheter **1400**. Alternatively, the lumen **1412***i* may extend along only a portion of the length of the balloon catheter **1400** (e.g., from a (first, proximal) side hole to the distal end hole **1410**) to support rapid-exchange of the balloon catheter **1400**. The lumen **1412***i* is configured to receive a primary (first) guide wire **1500**, which may be substantially similar or identical to the aforedescribed guide wire **500**. As discussed above in connection with other embodiments of the disclosure, the lumen **1412***i* and the primary guide wire **1500** may include corresponding non-circular (transverse) cross-sectional configurations so as to allow for relative axial movement between the primary guide wire **1500** and the balloon catheter **1400** while inhibiting (if not entirely preventing) relative rotation between the primary guide wire **1500** and the balloon catheter **1400** to facilitate control over the (rotational) orientation of the balloon catheter **1400** and, thus, the primary stent **1300**. In such “over-the wire” configuration, it is envisioned that there may be a third branch outside the patient's body that constitutes a proximal extension of the lumen **1412***i*.

[0249] The lumen **1412***ii* is configured to communicate fluid from a source of inflation to the inflatable member **1414**. In the particular embodiment illustrated, it is envisioned that the lumen **1412***ii* may be configured to exclusively support inflation and deflation of the inflatable member **1414**. In alternate embodiments, however, it is envisioned that the lumen **1412***ii* may be configured to receive one or more medical devices and/or support other functionality of the balloon catheter **1400**.

[0250] The lumen **1412***iii* extends to a (second, distal) side hole **1418** that is positioned in proximity (e.g. at or adjacent) to the inflatable member **1414**. For example, it is envisioned that the side hole **1418** may be positioned proximally or distally of the inflatable member **1414**. Alternatively, it is envisioned that the inflatable member **1414** may overlie the side hole **1418**, as seen in FIG. **18**, for example, such that the side hole **1418** is in communication with the fenestration **1416** in the inflatable member **406** and the fenestration **1302** in the primary stent **1300**.

[0251] In various embodiments, it is envisioned that the lumen **1412***iii* may include a “peel-away” side slit up to a rapid exchange length lumen, similar to the configuration in the Cordis Angioguard Rx. It is also envisioned that the lumen **1412***iii* may extend proximally (e.g., along the entire intravascular course of the lumen **1412***ii*) and may branch from the lumen **1412***iii* proximally (e.g., externally of the patient).

[0252] The lumen **1412***iii* is configured to receive a secondary delivery (medical) device **1600** to facilitate delivery of a secondary stent **1700** (e.g., a second fenestrated occlusion device) into a side branch S of the blood vessel V, as described in further detail below. For example, it is envisioned that the secondary delivery device **1600** may include the aforedescribed pusher **302** (FIGS. **20**, **23**), a secondary (second) guide wire **1800** (FIG. **22**), which may be substantially similar or identical to the aforedescribed guide wire **500**, or the aforedescribed balloon catheter **400** (FIG. **24**). As discussed above in connection with the lumen **1412***i* and the primary guide wire **1500**, it is envisioned that the lumen **1412***iii* and the medical device inserted therethrough may include corresponding (transverse) cross-sectional configurations so as to allows for relative axial movement between the medical device and the balloon catheter **1400** while inhibiting (if not entirely preventing) relative rotation between the medical device and the balloon catheter **1400**.

[0253] In the context of treating a bifurcation narrowing, the primary guide wire **1500** (FIG. **18**) may be introduced into a main branch M of the blood vessel V, across a limb of the narrowing (e.g., across the side branch S). The primary guide wire **1500** can then be inserted into the lumen **1412***i* in the balloon catheter **1400** such that the balloon catheter **1400** can be advanced into the blood vessel V over the primary guide wire **1500** (e.g., through the primary delivery catheter **1100**) such that the inflatable member **1414** and the primary stent **1300** and, thus, the respective fenestrations **1416**, **1302**, are positioned in proximity (e.g., at or adjacent) to the origin of the side branch S of the blood vessel V in the manner described herein. To further facilitate control over the (rotational) orientation of the balloon catheter **1400** and, thus, the primary stent **1300**, it is envisioned that the balloon catheter **1400** and the lumen **1102** of the primary delivery catheter **1100** may include corresponding non-circular (transverse) cross-sectional configurations so as to allow for relative axial movement between the balloon catheter **1400** and the delivery catheter **1100** while inhibiting (if not entirely preventing) relative rotation between the balloon catheter **1400** and the delivery catheter **1100**.

[0254] Prior to expansion of the inflatable member **1414** and deployment of the primary stent **1300**, the secondary stent **1700** may be inserted into the side branch S of the blood vessel V (via the second delivery device **1600**), which may be either self-expanding or balloon-expandable. Alternatively, the second stent can be advanced out the side hole without the second delivery device.

[0255] In the context of a self-expanding secondary stent **1700**, it is envisioned that the secondary stent **1700** may be deployed using any of the devices and methods discussed herein above. For example, it is envisioned that aforedescribed packaging catheter **300** (FIGS. **20**, **23**) may be utilized to deploy the secondary stent **1700**. In such embodiments, the secondary stent **1700** may be supported by the pusher **302** (which extends through the elongated body **310** (FIG. **2**A) of the packaging catheter **300**) such that the secondary stent **1700** automatically expands upon exposure from the balloon catheter **1400**. To facilitate such deployment, it is envisioned that the pusher **302** and the secondary stent **1700** may be advanced through the lumen **1412***iii* and the side hole **1418**, through the fenestration **1416** in the inflatable member **1414**, through the fenestration **1302** in the primary stent **1300**, and into the side branch S.

[0256] It is envisioned that the pusher **302** and the secondary stent **1700** may be advanced directly through the lumen **1412***iii* in the manner illustrated in FIG. **20**. Alternatively, it is envisioned that the secondary guide wire **1800** (FIG. **22**) may be used, which may be substantially similar or identical to the guide wire **500** and/or the primary guide wire **1500** discussed above. In such implementations, the secondary guide wire **1800** is inserted into the side branch S through the lumen **1412***iii* prior to introduction of the pusher **302** and the secondary stent **1700**. In certain embodiments, it is envisioned that the secondary guide wire **1800** may include one or more of the anchor(s) **506** (FIG. **25**) discussed above in connection with the guide wire **500**, which may be positioned in any suitable location.

[0257] To facilitate use with the secondary guide wire **1800**, it is envisioned that the pusher **302** may include a lumen that is configured to receive the secondary guide wire **1800** (e.g., such that the pusher **302** includes a “hypotube” configuration). In such embodiments, it is envisioned that the lumen extending through the pusher **302** may include a non-circular (e.g., triangular) (transverse) cross-sectional configuration corresponding to that of the secondary guide wire **1800** to facilitate control over the relative (rotational) positions of the secondary guide wire **1800** and the pusher **302** to facilitate positioning of the secondary stent **1700** within the side branch S by inhibiting (if not entirely preventing) relative rotation between the secondary guide wire **1800** and the pusher **302** in the manner discussed above.

[0258] Alternatively, with reference to FIG. **23**, it is envisioned that a secondary delivery catheter **1900** (e.g., a hypotube) may be utilized to deploy the pusher **302** and the secondary stent **1700**, which may be substantially similar or identical to the delivery catheter **100** (FIG. **1**A) discussed above. In such implementations, the secondary delivery catheter **1900** includes a lumen **1902** that is configured to receive the secondary guide wire **1800** to allow for advancement of the secondary delivery catheter **1900** over the secondary guide wire **1800** and into the side branch S through the side hole **1418**, through the fenestration **1416** in the inflatable member **1404**, through the fenestration **1302** in the primary stent **1300**, and into the side branch S. The pusher **302** and the secondary stent **1700** may then be inserted into the side branch S through the lumen **1902** of the secondary delivery catheter **1900**. During such use, it is envisioned that the secondary guide wire **1800** may be removed from the secondary delivery catheter **1900** or that the secondary guide wire **1800** may remain in place in place (e.g., within the lumen **1412***iii* and within the lumen **1902** of the secondary delivery catheter **1900**). For example, it is envisioned that the pusher **302** may be advanced through the lumen **1902** of the secondary delivery catheter **1900** in adjacent relation to the secondary guide wire **1800**.

[0259] To facilitate control over, and proper positioning of, the secondary stent **1700** within the side branch S, it is envisioned that the lumen **1902** extending through the secondary delivery catheter **1900** and the secondary guide wire **1800** may include corresponding non-circular (e.g., triangular) (transverse) cross-sectional configurations to inhibit (if not entirely prevent) relative rotation between the secondary delivery catheter **1900** and the secondary guide wire **1800**, thereby facilitating control over the (rotational) orientation of the secondary stent **1700** in the manner discussed above.

[0260] With reference to FIG. **24**, in the context of a balloon-expandable secondary stent **1700**, it is envisioned that the secondary stent **1700** may deployed using the aforedescribed balloon catheter **400** (FIG. **2**B). During such use, following insertion of the secondary guide wire **1800** into the side branch S through the lumen **1412***iii*, the balloon catheter **400** is advanced over the secondary guide wire **1800** such that the secondary guide wire **1800** extends through the lumen **404** extending through the elongated body **402** of the balloon catheter **400**. Upon sufficient advancement of the balloon catheter **400** into the side branch S over the secondary guide wire **1800**, the inflatable member **406** on the balloon catheter **400**, which carries the secondary stent **1700**, may be expanded to thereby deploy the secondary stent **1700**. To facilitate control over, and proper positioning of, the secondary stent **1700** within the side branch S, it is envisioned that the lumen **404** and the secondary guide wire **1800** may include corresponding non-circular (e.g., triangular) transverse cross-sectional configurations to inhibit (if not entirely prevent) relative rotation between the balloon catheter **400** and the secondary guide wire **1800**, thereby facilitating control over the (rotational) orientation of the secondary stent **1700** in the manner discussed above. Additionally, or alternatively, it is envisioned that the lumen **1412***iii* and the elongated body **402** of the balloon catheter **400** may include corresponding non-circular (e.g., triangular) transverse cross-sectional configurations to inhibit (if not entirely prevent) relative rotation of the balloon catheter **400** within the lumen **1412***iii*. The non-circular diameter of the wire can extend along a majority of its length, starting at the proximal end positioned outside the patient's body.

[0261] In those embodiments in which the secondary stent **1700** includes fairly large interstices (e.g., so as not to significantly (substantially) impede blood flow), it is envisioned that the secondary guide wire **1800** and the corresponding medical device supporting the secondary stent **1700** (e.g., the pusher **302**, the balloon catheter **400**, etc.) may be devoid of the non-circular (e.g., triangular) (transverse) cross-sectional configurations discussed above. Instead, in such embodiments, it is envisioned that the secondary guide wire **1800** (and the corresponding medical device supporting the secondary stent **1700**) may instead have annular (e.g., circular) transverse cross-sectional configurations to develop and deploy a “Y” configuration stent system at the bifurcation, as described in further detail below. If, however, there is a need and/or a desire to have an additional fenestration in the secondary stent **1700** overlying the origin the side branch S, then the secondary guide wire **1800** (and the corresponding medical device supporting the secondary stent **1700**) may include corresponding non-circular (transverse) cross-sectional configurations to facilitate proper alignment of the fenestration in the secondary stent **1700** in the manner discussed above.

[0262] In those embodiments employing a rapid exchange configuration (e.g., such that the primary guide wire **1500** extends through a side hole in the balloon catheter **1400** and the distal end hole **1406**), it is envisioned that the balloon catheter **1400** may be configured for use (deployment) in substantially straight (e.g., non-tortuous anatomy). In such methods of use, it is envisioned that the primary guide wire **1500** and the lumen **1412***i* may be devoid of the non-circular (e.g., triangular) (transverse) cross-sectional configurations discussed above. Instead, in such embodiments, it is envisioned that the primary guide wire **1500** and the lumen **1412***i* may instead have annular (e.g., circular) transverse cross-sectional configurations and that the secondary guide wire **1800** may be advanced into the side branch S via the side hole **1418** and the lumen **1412***iii*.

[0263] In the context of non-tortuous anatomical structures (of non-tortuous lengths of anatomical structures), it is envisioned that advancement of the secondary guide wire **1800** through the lumen **1412***iii*, through the side hole **1418**, and into the side branch S may facilitate alignment of the secondary delivery device **1600** (e.g., the balloon catheter **400**), and the components and devices inserted therethrough (e.g., the secondary stent **1700**) in the intended manner (e.g., such that any included fenestration(s) in the secondary stent **1700** are positioned at the origin of the side branch S). However, in the context of most tortuous anatomical structures, it is envisioned that the employ of corresponding non-circular (e.g., triangular) (transverse) cross-sectional configurations by the secondary guide wire **1800** and the lumen **1412***iii* may facilitate proper preloading of the secondary stent **1700** in the blood vessel V in the desired orientation (e.g., such that any fenestration(s) in the secondary stent **1700** are oriented towards the origin of the side branch S).

[0264] In various embodiments, medical devices (e.g., stents, inflatable members, etc.) including multiple fenestrations are also contemplated herein (e.g., for use in the context of multiple side branches with multiple origins).

[0265] To facilitate proper location of the primary stent **1300** and/or the secondary stent **1700**, it is envisioned that one or more markers (e.g., radiopaque markers) may be included to identify the proximal and distal ends thereof and/or the proximal and distal ends of any fenestration(s).

Common Method

[0266] Using any of the devices and methods above, the primary stent **1300** may be deployed such the fenestration **1302** (FIG. **17**) in the primary stent **1300** is positioned in proximity (e.g., at or adjacent to) the origin of the side branch S. A guide wire (e.g., the secondary guide wire **1800**) can be then advanced into the side branch S through the fenestration **1302** in the primary stent **1300** and into the side branch S to facilitate the deployment of the secondary stent **1700** using one of a variety of methods, as seen in FIGS. **20** and **22-24**, for example.

[0267] In one variation, it is envisioned that the secondary stent **1700** may be delivered over the secondary guide wire **1800** via the balloon catheter **400**, as seen in FIG. **24**, and positioned such that a proximal end **1702** of the secondary stent **1700** overlaps the fenestration **1302** in the primary stent **1300**, as seen in FIG. **25**. The devices and methods described herein facilitate precise, accurate placement of the respective primary and secondary stents **1300**, **1700** to control (e.g., reduce, minimize) the extent to which the secondary stent **1700** overlaps the primary stent **1300** and thereby reduce (if not completely eliminate) leaks between the respective primary and secondary stents **1300**, **1700** while avoiding unwanted obstruction of the blood vessel V by the secondary stent **1700** and accommodating for tapering in the side branch S (e.g., depending upon the particular patient's anatomy) that may result in a larger (transverse) cross-sectional dimension at the origin of the side branch S (when compared to more distal sections of the side branch S).

[0268] In a second variation, for example, it is envisioned that the secondary delivery catheter **1900** may be utilized to deploy the secondary stent **1700**, as discussed above, which allows for the employ of a self-expanding configuration for the secondary stent **1700** such that the secondary stent **1700** is automatically deployed in the side branch S upon exposure of the secondary stent **1700** from the secondary delivery catheter **1900**. In such procedures, it is envisioned that the secondary guide wire **1800** can be (optionally) removed. This method (and corresponding medical devices) also facilitates precise, accurate placement of the respective primary and secondary stents **1300**, **1700** to control (e.g., reduce, minimize) the extent to which the secondary stent **1700** overlaps the primary stent **1300** to realize the benefits discussed above (e.g., a reduction (if not completely elimination) of leaks between the respective primary and secondary stents **1300**, **1700**, a reduction (if not complete elimination) of unwanted obstruction of the blood vessel V by the secondary stent **1700**, and accommodation for tapering in the side branch S).

[0269] In a third variation, it is also envisioned that primary delivery catheter **1100** may be re-used instead of the secondary delivery catheter **1900**.

[0270] With respect to the second and third variations, challenges regarding landing of the secondary stent **1700** may arise, especially with "woven" or "braided" stents that may be subject to foreshortening during deployment (e.g., when compared to their length during insertion and prior to deployment).

[0271] To accommodate such challenges, it is envisioned that the secondary delivery catheter **1900** may be configured in a manner similar to that discussed above in connection with the respective hypotubes **700**, **800** (FIGS. **13**, **14**) (e.g., in correspondence with a filter-tip TAVR (transcatheter aortic valve replacement) catheter), whereby the wings **802** provide an outer constraint for the secondary stent **1700** to thereby provide control over expansion of the secondary stent **1700**. To facilitate such use, as discussed above, it is envisioned that the lumen **806** extending through the inner hypotube **800** may include a non-circular (transverse) cross-sectional configurations corresponding to that of the secondary guide wire **1800** to allow for relative axial movement between the inner hypotube **800** and the secondary guide wire **1800** while inhibiting (if not entirely preventing) relative rotation between the inner hypotube **800** and the secondary guide wire **1800** to facilitate precise control over the (rotational) orientation of the secondary stent **1700**. In such methods of use, the secondary stent **1700** is loaded onto the outer hypotube **700** and the inner hypotube **800** (and, thus, the wings **802**) are advanced distally while the outer hypotube **700** remains (relatively) longitudinally (axially) stationary. Relative longitudinal (axial) movement between the hypotubes **700**, **800** allows for exposure (and optional re-sheathing (covering)) of the secondary stent **1700**. It is envisioned that enlarging the (transverse) cross-sectional dimensions of the secondary guide wire **1800** and the lumen **806** extending through the inner hypotube **800** may further reduce (if not entirely eliminate) relative rotation between the inner hypotube **800** and the secondary guide wire **1800**, thereby further increasing precision in placement of the secondary stent **1700**.

[0272] To offset or otherwise accommodate for any unpredictability in the expansion of "woven" or "braided" embodiments of the various stents described herein (e.g., the amount of time required to realize full expansion), it is envisioned that the proximal end of such stents (and optionally other parts as well) may include one or more rings (or other such structures) to encourage more rapid expansion and/or increase apposition between the stent and the wall of the blood vessel V. In such embodiments, it is envisioned that the ring(s) (or other structures) may include (e.g., may be formed partially or entirely from) any suitable material or combination of materials such as, for example, nitinol. It is also envisioned that (optional) longitudinal wires may connected to the stents described herein to facilitate re-sheathing when desired.

[0273] It is also envisioned that the various stents described herein may be connected to one or more external members (e.g., wires, catheters, or the like). For example, it is envisioned that that external member(s) may be connected to the proximal and distal ends of the secondary stent **1700** (which may be adapted for delivery in an "over-the-wire" or rapid exchange configuration). Following placement of the secondary guide wire **1800** in the side branch S (e.g., through the fenestration **1302** in the primary stent **1300**), the secondary stent **1700** may be advanced over the secondary guide wire **1800** into the desired position and the external member(s) connected to the secondary stent **1700** may be held in place while the inner hypotube **800** (FIG. **14**) (and, thus, the wings **802**) is translated axially (e.g., relative to the outer hypotube **700**) to exposing (un-sheath) the secondary stent **1700**.
[0274] In the context of a secondary stent **1700** that is connected to one or more external members, it is envisioned that the external member(s) may expand with the secondary stent **1700**. In embodiments where the secondary stent **1700** is supported by (e.g., attached to) an outer catheter or hypotube, such as the outer hypotube **700** (FIGS. **13**, **14**), for example, the secondary stent **1700** requires unsheathing (e.g., exposure from that the wings **802**) prior to detachment (e.g., from the outer hypotube **700**). However, in embodiments in which the secondary stent **1700** is devoid of such attachment, it is envisioned that the secondary stent **1700** may automatically expand and detach (proximally to distally) in a progressive manner as a result of relative longitudinal (axial) movement between the secondary stent **1700** and the wings **802**.
[0275] Embodiments are also envisioned in which the secondary stent **1700** may be circumferentially attached to the outer device (e.g., the outer hypotube **700**) and may include at least one additional wire attached thereto (e.g., to a distal segment of the secondary stent **1700**). Additional and alternatively attachment(s) connections between the secondary stent **1700** and the outer hypotube **700** (or other such device) are also contemplated herein. For example, it is envisioned that the only a distal segment (portion) of the secondary stent **1700** may be attached (connected) to the outer hypotube **700** (or other such device). In such embodiments, it is envisioned that longitudinal (axial) advancement of the outer hypotube **700** (or other such device) may pull the attached segment of the secondary stent **1700** and push the wings **802** (and the inner hypotube **800** or other such device) in unison). Upon positioning of the secondary stent **1700** as desired, the secondary stent **1700** can be unsheathed by advancing the inner hypotube **800** (or other such device) relative to the outer hypotube **700** (or other such device) and, thus, the secondary stent **1700**, to thereby un-sheath the secondary stent **1700** (from proximal to distal). If it is determined that the location of the secondary stent **1700** requires adjustment, the inner hypotube **800** (or other such device) can be moved in the opposite direction to re-sheath the secondary stent **1700** and allow for repositioning within the vasculature.
[0276] It is further envisioned that proximal attachments between the secondary stent **1700** and the outer hypotube **700** (or other such device) may be disconnected upon unsheathing of the secondary stent **1700** to facilitate appropriate orientation and position of the secondary stent **1700** (e.g., such that the secondary stent **1700** overlaps the fenestration **1302** in the primary stent **1300**) without significant (substantial) overlapping of the main branch M of the blood vessel V). The secondary stent **1700** can then be detached once fully deployed.
[0277] In another embodiment, once the primary guide wire **1500** is inserted into the blood vessel v, a quaternary catheter may be utilized to help fix the (rotational) position of the primary guide wire **1500**. In such embodiments, it is envisioned that the quaternary catheter may include an inner lumen with a non-circular (e.g., triangular) (transverse) cross-sectional configuration (e.g., corresponding to that defined by the primary guide wire **1500**) as discussed above. It is also envisioned that the quaternary catheter may be devoid of a hub and may include a non-circular (e.g., triangular) (transverse) outer cross-sectional configuration as well as proximal and distal markers (e.g., radiopaque markers) located in any suitable position (e.g., the "12 o'clock" position) as discussed above. The primary guide wire **1500** and the quaternary catheter can be used as a

guide (rail) system to facilitate delivery of the primary delivery catheter **1100** over the quaternary catheter and guidewire (e.g., to further reduce any likelihood of undesired rotation during delivery and/or deployment of the primary stent **1300**).

[0278] With reference to FIGS. **1**A-**2**A, in one particular method, the delivery catheter **100** may be utilized in connection with the pusher **302** and the stent **202** according to the following steps:

[0279] (i) insert the delivery catheter **100** into the blood vessel V;

[0280] (ii) advance the delivery catheter **100** over the guide wire **500** (FIG. **15**) until the distal end **108** of the delivery catheter **100** is located in proximity (e.g., at or adjacent to) the vascular abnormality that is the subject of the procedure (e.g., the aneurysm A);

[0281] (iii) remove the guide wire **500**;

[0282] (iv) orient the packaging catheter **300** (e.g., the elongated body **310**, the pusher **302**, and the stent **202**) relative to the hub **600** to pre-set the orientation of the stent **202** relative to the aneurysm A;

[0283] (v) insert the packaging catheter **300** (e.g., the elongated body **310**) into the port **602** of the hub **600**;

[0284] (vi) attach the hub **600** to the proximal end **104** of the delivery catheter **100**;

[0285] (vii) advance the pusher **302** (and the stent **202**) from the elongated body **310** of the packaging catheter **300** into (and through) the delivery catheter **100** until the stent **202** is positioned in proximity (e.g., at or adjacent to) the aneurysm A;

[0286] (viii) partially withdraw the delivery catheter **100** while manipulating (e.g., holding or advancing) the pusher **302** to fully expose the stent **202** from the delivery catheter **100** to thereby deploy the stent **202**;

[0287] (ix) withdraw the pusher **302**; and

[0288] (x) withdraw the said delivery catheter **100**.

Bifurcated or Y-Shaped Stents

[0289] With reference again to FIGS. **18-25**, using any of the foregoing methodologies and devices, a "Y" shaped stent may be assembled (in vivo) from two stents (e.g., the primary stent **1300** and the secondary stent **1700**), as seen in FIG. **25**, which may be facilitated by the inclusion of a plurality of markers (e.g., radiopaque markers) on the stents **1300**, **1700**, the medical devices used during placement of the stents **1300**, **1700**, etc. For example, once the primary stent **1300** is deployed (e.g., via expansion of the inflatable member **1414**), the secondary stent **1700** can be deployed in the side branch S, which may be either self-expanding or balloon-expandable. In self-expanding embodiments, seen in FIG. **23**, for example, the secondary delivery catheter **1900** is advanced into the side branch S (e.g. over the secondary guide wire **1800** (FIG. **22**)) through the lumen **1412***iii*, through the side hole **1418** in the balloon catheter **1400**, through the fenestration **1416** in the inflatable member **1414**, through the fenestration **1302** in the primary stent **1300**, and into the side branch S such that the secondary stent **1700** is automatically deployed (expanded) upon exposure from the secondary delivery catheter **1900**.

[0290] In certain methods, the starting point of the procedure is introduction of a non-round wire which can optionally have a stabilizer/anchor and then a device is delivered over the wire. In other methods, a device, e.g., a catheter is delivered first than the non-round wire or other device is inserted through a lumen in the catheter.

[0291] In various embodiments, it is envisioned that the secondary stent **1700** may be devoid of any fenestrations and that the secondary stent **1700** may be positioned to reduce (e.g., minimize) overlap with edges of the fenestration **1302** in the primary stent **1300**. Alternatively, it is envisioned that the secondary stent **1700** can be deployed to build a "Y" shaped construct (e.g., via the methods described above used to place the primary stent **1300**) to facilitate proper overlap between the stents **1300**, **1700** (e.g., relative to the origin of the side branch S).

[0292] As mentioned above, it is envisioned that that the various medical devices (e.g., catheters, stents, hypotubes, guide wires, etc.) described herein may include one or more radiopaque markers

(or other such components) to support external visualization. It is envisioned that such markers may be positioned in any suitable location on the corresponding medical device. For example, it is envisioned that the stents described herein may include one or more marker(s) at the proximal and/or distal ends thereof. It is also envisioned that such marker(s) may be positioned to facilitate delineation between regions of varying porosity. For example, in the context of the stent **202** seen in FIG. **2**C, it is envisioned that one or more marker(s) may be positioned at the proximal and/or distal ends of the first (covered) region **204** and/or the second (uncovered) region **206**. It is also envisioned that such markers may be used to delineate or define fenestration(s) such as, for example, the fenestration **1302** in the primary stent **1300**.
[0293] It is envisioned that the various devices described herein may (optionally) include one or more steerable segments that are deflectable via one or more pull wires that extend within the wall of the device to facilitate insertion, removal, and/or increased precision in the placement of the device as disclosed in co-pending application Ser. No. 17/246,853, filed May 3, 2021, the entire contents of which are incorporated herein by reference. The various devices can include a plurality of segments and a plurality of pull wires connected to the segments. More specifically, the devices, e.g., the delivery catheter, can includes a plurality of inactive (passive) segments and a plurality of active (steerable, deflectable, articulable) segments that are connected to the plurality of pull wires and spaced along the longitudinal axis X. The inactive segments and the active segments can be arranged in a staggered pattern such the device alternates between inactive segments and active segments.
[0294] It is also envisioned that the various devices disclosed herein, e.g., the delivery catheter may include one or more (second) pull wires that are connected (secured, anchored) to the device to apply the selective application of a torsional (twisting) force to the device and, thus, rotational deflection of the device along all or a portion of the length thereof (e.g., at or adjacent to the distal end hole) to vary the angular position of the device as disclosed in co-pending application Ser. No. 17/246,853, the entire contents of which are incorporated herein by reference. The markers disclosed herein for noting the circumferential rotational position that remain outside the body can be of various forms such as a dot(s), line(s) or other mark. The markers as disclosed herein that will be inside the patient's body during a procedure can be provided to be visible with imaging used to perform that procedure (e.g., radiopaque markers, visible via ultrasound and/or other imaging modalities. Alternatively they can be similar to the variations of markers used outside the body, e.g., a dot, line, etc., if direct visualization via cameras or similar technology is used. The markers as described herein can be for example on the hub, along the lumen, etc. of the elongated member, wire catheter, pusher, medical device inserted through the catheter, etc. to provide circumferential orientation.
[0295] The non-circular transverse cross sectional configurations of the outer and inner diameters of the various components herein can be of a configuration to limit or prohibit rotation. This could be in the form of corresponding configurations which are of the same or substantially the same shape or of non-circular configurations which are not necessarily the same or substantially the same but are configured so as to achieve the same objective of limiting or prohibiting rotation.
[0296] The present disclosure contemplates branched stent elements.
[0297] It is envisioned that that the various stents described herein may be fully or partially re-sheathable.
[0298] It is envisioned that that the various stents described herein may be detachable from the medical device supporting the stents.
[0299] It is envisioned that the various medical devices (e.g., catheters, stents, hypotubes, guide wires, etc.) and procedures described herein may be applied to various endoscopic procedures.
[0300] It is envisioned that that the various stents described herein may include any suitable (transverse) cross-sectional configuration, whether circular or non-circular (e.g., depending upon the particular procedure being performed, the patient's anatomy, the particular location of the

vascular abnormality being treated, the particular nature of the vascular abnormality, etc.).
[0301] The present disclosure may also find applicability in the context of introducing other devices, such as contoured mesh sacs to cover or fill an outpouching, in a particular orientation. One of many examples of such an outpouching is a vascular aneurysm. Outpouching may also include left atrial appendage, GI outpouching, GU outpouching, heart outpouching, or any other outpouching. The implants can be temporary or permanent implants. It is envisioned that the principles of the present disclosure may support the fabrication of custom implants (e.g., to contour to the configuration of a particular lesion) and subsequent accurate placement (deployment) of such custom implants.
[0302] The various medical devices being supported by the elongate member may be non-retrievable upon deployment, retrievable upon partial deployment, and/or fully retrievable upon fully deployment. In versions where they are fully retrievable upon full deployment, or in other versions the medical device can be detachably connected to the elongate member by various mechanisms/methods such as via electrolytic, hydrostatic, mechanical, thermal etc. and can have one or more attachment sites, each with independent and/or combined detachment sites and/or mechanisms.
[0303] The various medical devices (e.g., catheters, stents, hypotubes, guide wires, etc.) and procedures described herein can also be used to deliver coated devices. Suitable examples of such coatings include (but are not limited to) lubricious compounds, sticky compounds, hydrogels, pharmaceuticals, chemotherapeutic agents, cells, proteins, etc., and combinations thereof. It is envisioned that such coatings may be located on any suitable surface of the pertinent medical device (e.g., on an inner surface, an outer surface, interstices, and combinations thereof).
[0304] The various medical devices (e.g., catheters, stents, hypotubes, guide wires, etc.) and procedures described herein may be utilized (combined) with the multiple circumferential balloon catheter previously described by Walzman (US 2020/10,543,015) to facilitate additional precision when orientating a delivery catheter in a desired (rotational) orientation within a blood vessel (e.g., at or adjacent to an aneurysm or the neck of an aneurysm).
[0305] While the medical devices and procedures described herein are generally discussed in the context of intravascular use, it should be appreciated that the medical devices and procedures described herein may find wide applicability. For example, it is envisioned that the medical devices and procedures described herein may be employed in the context of gastrointestinal and genitourinary tracts, as well as in non-biological pipes.
[0306] It will be understood by those skilled in the art that the above particular embodiments are shown and described by way of illustration only. The principles and the features of the present disclosure may be employed in various and numerous embodiments thereof without departing from the scope and spirit of the disclosure as claimed. The above-described embodiments illustrate the scope of the disclosure but do not restrict the scope of the disclosure.
[0307] While the present disclosure has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made (and equivalents may be substituted) without departing from the true spirit and scope of the present disclosure. In addition, many modifications may be made to adopt a particular situation, material, composition of matter, process, process step or steps, to the objective spirit and scope of the present disclosure. All such modifications are intended to be within the scope of the claims appended hereto.
[0308] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the present disclosure. The upper and lower limits of these smaller ranges which may independently be included in the smaller ranges is also encompassed within the present disclosure, subject to any specifically excluded limit in the stated range. Where the stated range

includes one or both of the limits, ranges excluding either both of those included limits are also included in the present disclosure.
[0309] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the present disclosure belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosure, exemplary methods and materials have been described. All publications mentioned herein are incorporated herein by reference to disclose and described the methods and/or materials in connection with which the publications are cited.
[0310] It must be noted that as used herein and in the appended claims, the singular forms “a”, “and”, and “the” include plural references unless the context clearly dictates otherwise.
[0311] Any publications discussed herein are provided solely for their disclosure prior to the filing date of the present application and each is incorporated by reference in its entirety. Nothing herein is to be construed as an admission that the present disclosure is not entitled to antedate such publication by virtue of prior disclosure. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.
[0312] Additionally, persons skilled in the art will understand that the elements and features shown or described in connection with one embodiment may be combined with those of another embodiment without departing from the scope of the present disclosure and will appreciate further features and advantages of the presently disclosed subject matter based on the description provided.
[0313] Throughout the present disclosure, terms such as “approximately,” “generally,” “substantially,” and the like should be understood to allow for variations in any numerical range or concept with which they are associated. For example, it is intended that the use of terms such as “approximately” and “generally” should be understood to encompass variations on the order of 25% (e.g., to allow for manufacturing tolerances and/or deviations in design).
[0314] Although terms such as “first,” “second,” “third,” etc., may be used herein to describe various operations, elements, components, regions, and/or sections, these operations, elements, components, regions, and/or sections should not be limited by the use of these terms in that these terms are used to distinguish one operation, element, component, region, or section from another. Thus, unless expressly stated otherwise, a first operation, element, component, region, or section could be termed a second operation, element, component, region, or section without departing from the scope of the present disclosure.
[0315] Each and every claim is incorporated as further disclosure into the specification and represents embodiments of the present disclosure. Also, the phrases “at least one of A, B, and C” and “A and/or B and/or C” should each be interpreted to include only A, only B, only C, or any combination of A, B, and C.

Claims

1-20. (canceled)
21. An intravascular system for treating a blood vessel comprising: a first medical device including: an elongated member defining: a first lumen extending from a proximal hole to a distal hole; and a second lumen extending in generally parallel relation to the first lumen at least in a distal portion of the second lumen, the second lumen extending from the proximal hole near a proximal end of the elongated member to a side-hole located proximally of the distal hole; a first inflatable member supported by the elongated member and including a first fenestration; and a first stent supported by the first inflatable member, the first stent deployed upon inflation of the first inflatable member, wherein the first stent includes a second fenestration; and a second medical device configured for insertion into the second lumen to access a side branch of the blood vessel through the side-hole, through the first fenestration in the first inflatable member, and through the second fenestration in

the first stent.
22. The intravascular system of claim 21, wherein the proximal hole is at a proximal end of the elongated member for an over-the-wire configuration.
23. The intravascular system of claim 21, wherein the proximal hole is spaced from a proximalmost end of the elongated member for a rapid-exchange configuration.
24. The intravascular system of claim 21, wherein the first lumen has a noncircular shape and at least one marker corresponding to a position of the side hole.
25. The intravascular system of claim 21, wherein the second medical device is configured as a second catheter and includes: a body configured for connection to the first medical device and passage through the second lumen of the first medical device; a wire configured for passage through the second lumen through the first and second fenestrations and into the side branch or a side lesion, wherein a distal hole of the second catheter can be advanced from the second lumen, through the side hole, first and second fenestrations, and into the side branch or side lesion over the wire.
26. The intravascular system of claim 25, wherein the second medical device is supported on a pusher such that the pusher and the second medical are insertable into the side branch of the blood vessel through the second catheter, after removal of the wire, via the second lumen and the side hole.
27. The intravascular system of claim 26, wherein the second medical device is a second stent, the second stent expandable in the side branch of the blood vessel.
28. The intravascular system of claim 21, wherein the second lumen defines a non-circular transverse cross-sectional configuration and an outer surface of the second medical device defines a non-circular transverse cross-sectional configuration so as to inhibit rotation of the second medical device.
29. The intravascular system of claim 28, wherein the cross-sectional configuration of the second medical device corresponds to the cross-sectional configuration of the second lumen.
30. The intravascular system of claim 21, wherein the first stent has a variable porosity along a length.
31. The intravascular system of claim 21, wherein the second medical device is a sac configured for placement in an outpouching.
32. The intravascular system of claim 21, wherein the second medical device is configured as a guidewire, the guidewire being insertable into the side branch of the blood vessel through the side hole in the first medical device, the guidewire having a non-circular outer shape along at least a portion of its length, and the guidewire has at least one marker to define a circumferential position.
33. The intravascular system of claim 21, wherein the second medical device is a second stent deployed after the first stent has been deployed and the elongated member removed.
34. The intravascular system of claim 32, wherein the guidewire further comprises at least one segment comprising at least two wires that when detached a detachment zone will splay and apply pressure to side walls of the vessel, and thereby help anchor the wire in place, and minimize longitudinal movements and rotation.
35. The intravascular system of claim 21, further comprising a third medical device configured as a balloon catheter, the balloon catheter including: a body; a second inflatable member supported by the body; and a second stent supported by the second inflatable member, the second stent deployed upon inflation of the second inflatable member; wherein the body of the balloon catheter defines a lumen configured to receive a guidewire such that the balloon catheter is insertable into the side branch of the blood vessel over the guidewire.
36. The intravascular system of claim 35, wherein the second lumen defines a non-circular transverse cross-sectional configuration and an outer surface of a majority of the guidewire, including a proximal end outside the patient's body, defines a non-circular transverse cross-sectional configuration to thereby inhibit rotation of the guidewire within the second lumen and at

least one marker on at least one of the non-circular lumens or outer surfaces to mark a particular circumferential rotational position.

37. The intravascular system of claim 21, further comprising a third medical device, wherein an inner diameter of the third medical device is substantially similar to the second lumen of the first medical device to thereby inhibit rotation of the second medical device and a second stent over a wire and control orientation of the second stent relative to the vascular anatomy and the first medical device, and at least one rotational marker on at least one of the lumens or outer surfaces to mark a particular circumferential rotational position.

38. An intravascular system for treating a blood vessel comprising: an elongated member defining a first lumen and a second lumen; a first stent having a fenestration; a second medical device configured for insertion into the second lumen to access a side branch of the blood vessel through the side hole and through the fenestration in the first stent; wherein the second medical device includes a pusher and an inner lumen of the second medical device defines a non-circular transverse cross-sectional configuration and an outer surface of the pusher defines a non-circular transverse cross-sectional configuration corresponding to the non-circular transverse cross-sectional configuration of the second medical device so as to inhibit rotation of the pusher and the second medical device within the second lumen to thereby control orientation of the second medical device relative to the first medical device.

39. The intravascular system of claim 38, further comprising at least one circumferential marker along at least one of the lumens of the elongated member, second medical device, or pusher to mark corresponding rotational position.

40. An intravascular system for treating a blood vessel comprising: a first medical device including: an elongated member defining: a first lumen extending from a proximal hole to a distal hole; and a second lumen extending in generally parallel relation to the first lumen at least in a distal portion of the second lumen, the second lumen extending from the proximal hole near a proximal end of the elongated member to a side hole located proximally of the distal hole; a first inflatable member supported by the elongated member and including a first fenestration; and a first device supported by the first inflatable member, the first device is deployed upon inflation of the first inflatable member, wherein the first device includes a second fenestration; and a second medical device configured for insertion into the second lumen to access a side branch of the blood vessel through the side hole, through the first fenestration in the first inflatable member, and through the second fenestration in the first device.