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(71) Applicant: **SILK ROAD MEDICAL, INC.** [US/US]; 1213 Innsbruck Drive, Sunnyvale, CA 94089 (US).

(72) Inventors: **JANSEN, Lex**; 1213 Innsbruck Drive, Sunnyvale, CA 94089 (US). **JOHNSTON, Natasha**; 1213 Innsbruck Drive, Sunnyvale, CA 94089 (US). **ARISTIZABAL, Diego**; 1213 Innsbruck Drive, Sunnyvale, CA 94089 (US). **PAGE, Mark C.**; 1213 Innsbruck Drive, Sunnyvale, CA 94089 (US).

(74) Agent: **MACEK, Monique** et al.; Mintz Levin Cohn Ferris Glovsky and Popeo, P.C., One Financial Center, Boston, MA 02111 (US).

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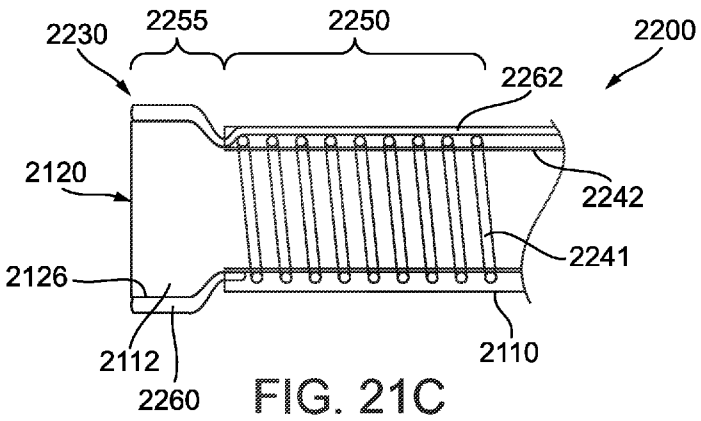


FIG. 21C

(57) Abstract: Disclosed are various embodiments and related methods of an aspiration catheter configured for removal of an occlusion from a vessel of a patient. The aspiration catheter (2200) can include an elongated body (2110) with a reinforcement element (2241) extending along a first length of the elongated body. In some embodiments, the aspiration catheter can include one or more of a deformer (2230), such as a movable deformer, a shaped distal end, and an occlusion grasper for efficiently and effectively securing and removing the occlusion to allow blood flow to be restored.

WO 2022/266195 A1

SYSTEMS AND METHODS FOR VASCULAR INTERVENTIONS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The current application claims priority under 35 U.S.C. §119(e) to U.S. Provisional patent application serial number 63/212,514, filed on June 18, 2021 and entitled "SYSTEMS AND METHODS FOR VASCULAR INTERVENTIONS," which is incorporated by reference herein in its entirety.

BACKGROUND

[0002] Blood clots can be deadly and/or threaten a loss of limbs or cognitive function. Additionally, the longer a blood clot remains in place the greater the risks to the patient. For example, blood clots can be dissolved using thrombolytic and/or anticoagulant drugs, however, use of such pharma can result in major complications for the patient, such as hemorrhage or stroke. Clots can also be removed using a device, however, at least some currently available devices for clot removal require several passes to capture and/or remove the clot.

[0003] For example, in Acute Ischemic Stroke (AIS) cases, time is imperative to patient outcomes as the longer the ischemic penumbra within the brain is allowed to grow the more deadly and damaging the ischemic penumbra can be to the patient. Therefore, the quicker a physician can remove a clot from the neurovascular anatomy, the sooner the penumbra can be limited and the better the patient outcomes can be. One of the limiting factors in this scenario, is the number of passes it can take for the physician to remove the clot completely and fully recanalize the vessel. The more recanalization passes a patient requires the more time the penumbra can grow. Devices and methods for achieving safe and effective blood clot removal as quickly as possible can provide improved outcomes for patients with occlusions.

SUMMARY

[0004] Aspects of the current subject matter can include various embodiments and related methods of an aspiration catheter configured for removal of a blood clot from a vessel of a patient. In one aspect, the aspiration catheter can include an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end. The inner lumen can be defined by an inner wall and form a distal opening at the distal body end. The aspiration catheter can further include a reinforcement element

extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, and the distal reinforcement end can be positioned a second length from the distal body end of the elongated body. The aspiration catheter can include a deformer extending along the second length of the elongated body. The deformer can be coupled to the second length such that the distal opening includes a first opening diameter when the deformer forms a first configuration and includes a second opening diameter when the deformer forms a second configuration, and the second opening diameter can be larger than the first opening diameter.

[0005] In some variations one or more of the following features can optionally be included in any feasible combination. The deformer can include an inflatable balloon. The inflatable balloon can extend helically along the second length of the elongated body. The inflatable balloon can be twisted along the second length of the elongated body. The distal opening can form a first suction area when the inflatable balloon is in the first configuration and form a second suction area when the inflatable balloon is in the second configuration. The second suction area can be larger than the first suction area. The first suction area and the second suction area can each be defined by one or more of a diameter and a cross-sectional area of the distal opening. The inflatable balloon can be deflated when in the first configuration and inflated when in the second configuration. The deformer can include a shape memory material. The shape memory material can include a nitinol material that transitions between the first configuration and the second configuration based on a temperature of the shape memory material. The shape memory material can include at least one nitinol wire that extends longitudinally along the second length. The shape memory material can include a stent retriever. The elongated body can be more flexible along the second length than along the first length. The reinforcement element can include one or more of a Teflon liner and a metal wire. The aspiration catheter can further include a plurality of LCP fibers extending along the second length of the elongated body, and a first LCP fiber of the plurality of LCP fibers can be oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers can be oriented circumferentially along the elongated body.

[0006] In another aspect, the aspiration catheter can include an elongated body formed of a flexible material and include an inner lumen extending between a proximal body end and a distal body end. The inner lumen can be defined by an inner wall and form a distal opening at the distal body end. The aspiration catheter can further include a reinforcement element

extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, and the distal reinforcement end can be positioned a second length from the distal body end of the elongated body. The aspiration catheter can include a movable deformer slidably positioned along the inner lumen of the tubular elongated body. The movable deformer can be slidable along the first length of the elongate body. The movable deformer can form a collapsed configuration along the first length thereby allowing the distal opening to form a first opening diameter. The shape memory deformer being movable to the second length for forming an expanded configuration thereby allowing the distal opening to form a second opening diameter. The second opening diameter can be larger than the first opening diameter.

[0007] In some variations one or more of the following features can optionally be included in any feasible combination. The movable deformer can include a nitinol material that transitions between the collapsed configuration and the expanded configuration based on a temperature of the movable deformer. The movable deformer can include a stent retriever. The movable deformer can include a dilator. The aspiration catheter can further include a plurality of LCP fibers extending along the second length of the elongated body, and a first LCP fiber of the plurality of LCP fibers can be oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers can be oriented circumferentially along the elongated body.

[0008] In another aspect, the aspiration catheter can include an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end. The inner lumen can be defined by an inner wall and form a distal opening at the distal body end. The distal opening can have a perimeter extending along more than one plane, and the perimeter can include a shape extending longitudinally relative to a longitudinal axis of the inner lumen. The aspiration catheter can further include a reinforcement element extending along a length of the elongated body.

[0009] In some variations one or more of the following features can optionally be included in any feasible combination. The distal opening can include a suction area defined by the perimeter of the distal opening. The shape of the perimeter can include an angled or triangular shape. The shape of the perimeter can include a rounded or sinusoidal shape. The aspiration catheter can further include a plurality of LCP fibers extending along the elongated body, and

a first LCP fiber of the plurality of LCP fibers can be oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers can be oriented circumferentially along the elongated body.

[0010] In another aspect, the aspiration catheter can include an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end, the inner lumen defined by an inner wall and forming a distal opening at the distal body end. The aspiration catheter can further include a reinforcement element extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end. The distal reinforcement end can be positioned a second length from the distal body end of the elongated body. The aspiration catheter can include an occlusion grasper extending along the inner wall of the second length of the elongated body. The occlusion grasper can include an exposed coil configured to grasp the blood clot for securing the blood clot at least partially within the inner lumen.

[0011] In some variations one or more of the following features can optionally be included in any feasible combination. The aspiration catheter can further include a plurality of LCP fibers extending along the second length of the elongated body, and a first LCP fiber of the plurality of LCP fibers can be oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers can be oriented circumferentially along the elongated body. The elongated body can be more flexible along the second length than along the first length. The reinforcement element can include one or more of a Teflon liner and a metal wire.

[0012] In another interrelated aspect of the current subject matter, a method for removing a blood clot from a vessel of a patient includes inserting a distal portion of an aspiration catheter into a vessel. The aspiration catheter can include an elongated body formed of a flexible material and include an inner lumen extending between a proximal body end and a distal body end, and the inner lumen can be defined by an inner wall and form a distal opening at the distal body end. The aspiration catheter can include a reinforcement element extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, and the distal reinforcement end can be positioned a second length from the distal body end of the elongated body. The aspiration catheter can further include a deformer extending along the second length of the elongated body, and the deformer can be coupled to the second length such that the distal opening includes a first opening diameter when the deformer forms

a first configuration and includes a second opening diameter when the deformer forms a second configuration. The second opening diameter can be larger than the first opening diameter. The method can further include causing the deformer to transition between the first configuration and the second configuration, and applying a vacuum to the elongated body for suctioning at least a part of the blood clot into the distal opening having the second opening diameter.

[0013] In some variations one or more of the following features can optionally be included in any feasible combination. The deformer can include an inflatable balloon. The inflatable balloon can extend helically along the second length of the elongated body. The inflatable balloon can be twisted along the second length of the elongated body. The distal opening can form a first suction area when the inflatable balloon is in the deflated configuration and form a second suction area when the inflatable balloon is in the inflated configuration. The second suction area can be larger than the first suction area. The first suction area and the second suction area can each be defined by one or more of a diameter and a cross-sectional area of the distal opening. The inflatable balloon can be deflated when in the first configuration and inflated when in the second configuration. The deformer can include a shape memory material. The shape memory material can include a nitinol material that transitions between the first configuration and the second configuration based on a temperature of the shape memory material. The shape memory material can include at least one nitinol wire that extends longitudinally along the second length. The reinforcement element can include one or more of a Teflon liner and a metal wire. The aspiration catheter can include a plurality of LCP fibers extending along the second length of the elongated body, and a first LCP fiber of the plurality of LCP fibers can be oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers can be oriented circumferentially along the elongated body.

[0014] In another aspect, a method for removing a blood clot from a vessel of a patient includes inserting a distal portion of an aspiration catheter into a vessel. The aspiration catheter can include an elongated body formed of a flexible material and include an inner lumen extending between a proximal body end and a distal body end. The inner lumen can be defined by an inner wall and form a distal opening at the distal body end. The aspiration catheter can further include a reinforcement element extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, and the distal reinforcement end can be positioned a second length from the distal body end of the elongated body. The aspiration catheter can include a movable deformer slidably positioned along the

inner lumen of the tubular elongated body, the movable deformer being slidable along the first length of the elongate body. The movable deformer forming a collapsed configuration along the first length thereby allowing the distal opening to form a first opening diameter. The shape memory deformer can be movable to the second length for forming an expanded configuration thereby allowing the distal opening to form a second opening diameter. The second opening diameter can be larger than the first opening diameter. The method can further include causing the deformer to transition between the first configuration and the second configuration, and applying a vacuum to the elongated body for suctioning at least a part of the blood clot into the distal opening having the second opening diameter.

[0015] In some variations one or more of the following features can optionally be included in any feasible combination. The movable deformer can include a nitinol material that transitions between the collapsed configuration and the expanded configuration based on a temperature of the movable deformer. The movable deformer can include a stent retriever. The movable deformer can include a dilator. The aspiration catheter can further include a plurality of LCP fibers extending along the second length of the elongated body, and a first LCP fiber of the plurality of LCP fibers can be oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers can be oriented circumferentially along the elongated body.

[0016] In another aspect, a method for removing a blood clot from a vessel of a patient includes inserting a distal portion of an aspiration catheter into a vessel. The aspiration catheter can include an elongated body formed of a flexible material and include an inner lumen extending between a proximal body end and a distal body end, and the inner lumen can be defined by an inner wall and form a distal opening at the distal body end. The distal opening can have a perimeter extending along more than one plane, and the perimeter can include a shape extending longitudinally relative to a longitudinal axis of the inner lumen. The aspiration catheter can include a reinforcement element extending along a length of the elongated body. The method can include applying a vacuum to the elongated body for suctioning at least a part the blood clot into the distal opening and forming a suction seal between the perimeter of the distal opening and the blood clot.

[0017] In some variations one or more of the following features can optionally be included in any feasible combination. The distal opening can include a suction area defined by the

perimeter of the distal opening. The shape of the perimeter can include an angled or triangular shape. The shape of the perimeter can include a rounded or sinusoidal shape. The aspiration catheter can include a plurality of LCP fibers extending along the elongated body, and a first LCP fiber of the plurality of LCP fibers can be oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers can be oriented circumferentially along the elongated body.

[0018] In another aspect, a method for removing a blood clot from a vessel of a patient includes inserting a distal portion of an aspiration catheter into a vessel. The aspiration catheter can be formed of a flexible material and include an inner lumen extending between a proximal body end and a distal body end. The inner lumen can be defined by an inner wall and form a distal opening at the distal body end. The aspiration catheter can include a reinforcement element extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, and the distal reinforcement end can be positioned a second length from the distal body end of the elongated body. The aspiration catheter can further include an occlusion grasper extending along the inner wall of the second length of the elongated body, and the occlusion grasper can include an exposed coil configured to grasp the blood clot for securing the blood clot at least partially within the inner lumen. The method can further include applying a vacuum to the elongated body to suction the blood clot into the distal opening, and grasping the blood clot for securing the blood clot at least partially within the inner lumen.

[0019] In some variations one or more of the following features can optionally be included in any feasible combination. The aspiration catheter can further include a plurality of LCP fibers extending along the second length of the elongated body, and a first LCP fiber of the plurality of LCP fibers can be oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers can be oriented circumferentially along the elongated body. The elongated body can be more flexible along the second length than along the first length. The reinforcement element can include one or more of a Teflon liner and a metal wire.

[0020] The details of one or more variations of the subject matter described herein are set forth in the accompanying drawings and the description below. Other features and advantages of the subject matter described herein will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] Figure 1 schematically depicts normal, antegrade cerebral or intracranial circulation with a thrombotic occlusion in the left middle cerebral artery.

[0022] Figure 2 depicts the blood flow circulation after retrograde flow has been established using the retrograde flow system described herein.

[0023] Figure 3 shows the cerebral vasculature with an interventional device such as a mechanical thrombectomy device inserted through an exemplary arterial access device.

[0024] Figure 4 shows an alternate embodiment wherein a secondary interventional device is advanced through the arterial access device and into a collateral cerebral artery.

[0025] Figure 5 shows an exemplary embodiment of a vascular access and reverse flow system that can be used to establish retrograde flow during an intervention.

[0026] Figure 6 shows another view of another exemplary embodiment of a vascular access and reverse flow system that can be used to establish retrograde flow during an intervention.

[0027] Figure 7 shows an enlarged view of the common carotid artery (CCA), internal carotid artery (ICA), and middle cerebral artery with an arterial access device and a thrombectomy device deployed.

[0028] Figures 8A-9B show embodiments of an arterial access device or system useful in the methods and systems of the present disclosure.

[0029] Figures 10A illustrates another embodiment of an arterial access device.

[0030] Figure 10B illustrates an additional arterial access device construction with a reduced diameter distal end.

[0031] Figures 11A and 11B illustrate a sheath stopper tube.

[0032] Figures 11C-11G show other embodiments of the sheath stopper tube.

[0033] Figure 12A illustrates an additional arterial access device construction with an expandable occlusion element.

[0034] Figure 12B illustrates an additional arterial access device construction with an expandable occlusion element and a reduced diameter distal end.

[0035] Figure 13 illustrates a first embodiment of a venous return device useful in the methods and systems of the present disclosure.

[0036] Figure 14A-14C illustrate alternative venous return devices useful in the methods and systems of the present disclosure.

[0037] Figure 15 shows an example of the reverse flow system with a schematic representation of the flow control assembly.

[0038] Figure 16A-16B an embodiment of a variable flow resistance component useful in the methods and systems of the present disclosure.

[0039] Figure 17 shows an arterial access device having a stepped configuration.

[0040] Figures 18A and 18B show details in cross section of an example Y-connector of the arterial access device.

[0041] Figures 19A-19D show an example arterial closure system and method.

[0042] Figure 20A illustrates a side cross-section view of an embodiment of an aspiration catheter including an elongated body with an inner lumen.

[0043] Figure 20B illustrates a distal end view of the aspiration catheter of Figure 20A.

[0044] Figure 21A illustrates a side cross-section view of an embodiment of a distal end of an aspiration catheter including an inflatable balloon extending along an expandable distal portion of the elongated body and in a deflated configuration.

[0045] Figure 21B illustrates a distal end view of the aspiration catheter of Figure 21A.

[0046] Figure 21C illustrates a side cross-section view of the aspiration catheter of Figure 21A showing the balloon in an inflated configuration.

[0047] Figure 21D illustrates a distal end view of the aspiration catheter of Figure 21C.

[0048] Figure 22A illustrates a side cross-section view of an embodiment of a distal end of an aspiration catheter including an inflatable balloon extending helically along the expandable distal portion of the elongated body and in a deflated configuration.

[0049] Figure 22B illustrates a distal end view of the aspiration catheter of Figure 22A.

[0050] Figure 22C illustrates a side cross-section view of the aspiration catheter of Figure 22A showing the balloon in an inflated configuration.

[0051] Figure 22D illustrates a distal end view of the aspiration catheter of Figure 22C.

[0052] Figure 23A illustrates a side cross-section view of an embodiment of a distal end of an aspiration catheter including an inflatable balloon that is twisted along a length of the balloon and extending helically along the expandable distal portion of the elongated body in a deflated configuration.

[0053] Figure 23B illustrates a distal end view of the aspiration catheter of Figure 23A.

[0054] Figure 23C illustrates a side cross-section view of the aspiration catheter of Figure 23A showing the balloon in an inflated configuration.

[0055] Figure 23D illustrates a distal end view of the aspiration catheter of Figure 23C.

[0056] Figure 24A illustrates a side cross-section view of an embodiment of a distal end of an aspiration catheter including a deformer extending longitudinally along the expandable distal portion of the elongated body and in an expanded configuration.

[0057] Figure 24B illustrates a distal end view of the aspiration catheter of Figure 24A.

[0058] Figure 24C illustrates a side cross-section view of the aspiration catheter of Figure 24A showing the shape memory deformer in a collapsed configuration.

[0059] Figure 24D illustrates a distal end view of the aspiration catheter of Figure 24C.

[0060] Figure 25A illustrates a side cross-section view of an embodiment of a distal end of an aspiration catheter including a shape memory deformer extending along the expandable distal portion of the elongated body and in an expanded configuration.

[0061] Figure 25B illustrates a distal end view of the aspiration catheter of Figure 24A.

[0062] Figure 25C illustrates a side cross-section view of the aspiration catheter of Figure 25A showing the shape memory deformer in a collapsed configuration.

[0063] Figure 25D illustrates a distal end view of the aspiration catheter of Figure 25C.

[0064] Figure 26A illustrates a side cross-section view of an embodiment of a distal end of an aspiration catheter including a movable deformer positioned along the expandable distal portion of the elongated body and in an expanded configuration.

[0065] Figure 26B illustrates a distal end view of the aspiration catheter of Figure 26B.

[0066] Figure 26C illustrates a side cross-section view of the aspiration catheter of Figure 26A showing the movable deformer proximal to the expandable distal portion and in a collapsed configuration.

[0067] Figure 26D illustrates a distal end view of the aspiration catheter of Figure 26C.

[0068] Figure 27A illustrates a side cross-section view of another embodiment of a distal end of an aspiration catheter including a movable deformer positioned along the expandable distal portion of the elongated body and in an expanded configuration.

[0069] Figure 27B illustrates a distal end view of the aspiration catheter of Figure 27B.

[0070] Figure 27C illustrates a side cross-section view of the aspiration catheter of Figure 27A showing the movable deformer proximal to the expandable distal portion and in a collapsed configuration.

[0071] Figure 27D illustrates a distal end view of the aspiration catheter of Figure 27C.

[0072] Figure 28A illustrates a side cross-section view of an embodiment of a distal end of an aspiration catheter including an angle-shaped perimeter of a distal opening of the elongated body.

[0073] Figure 28B illustrates a distal end view of the aspiration catheter of Figure 28A.

[0074] Figure 29A illustrates a side cross-section view of an embodiment of a distal end of an aspiration catheter including a sinusoidal-shaped perimeter of a distal opening of the elongated body;

[0075] Figure 29B illustrates a distal end view of the aspiration catheter of Figure 29A.

[0076] Figure 30A illustrates a side cross-section view of a distal end of an embodiment of a distal end of an aspiration catheter including an occlusion grasper.

[0077] Figure 30B illustrates a distal end view of the aspiration catheter of Figure 30A.

[0078] Figure 31A illustrates a side cross-section view of a distal end of an embodiment of an aspiration catheter including liquid crystal polymer (LCP) fibers.

[0079] Figure 31B illustrates a distal end view of the aspiration catheter of Figure 30A.

DETAILED DESCRIPTION

[0080] Disclosed are methods and devices that can enable safe, rapid and effective retrieval and removal of an occlusion from a blood vessel of a patient. For example, various embodiments of an aspiration catheter are disclosed that can be used at least in combination with an arterial access device for accessing an occlusion (e.g., blood clot) for removal. The disclosed systems, including the aspiration catheter, and methods are configured for use in a variety of vessels within the patient body.

[0081] In addition, disclosed herein are methods and devices that enable safe, rapid and relatively short access to at least the cerebral arteries for the introduction of interventional devices to treat a disease state or other condition in the intracranial vasculature. The disclosed systems and methods are configured for use in at least the cerebral arteries, neurovascular system, and intracranial arteries, which terms can be used herein interchangeably. In addition, the disclosed methods and devices are configured to securely close an access site to the cerebral arteries. The methods and devices include a vascular access and retrograde flow system that can be used safely and rapidly in the neurointerventional procedures.

[0082] The disclosed methods can be used pursuant to a percutaneous or surgical access to the patient's vasculature. In an implementation, the access location to the vasculature is in the region of the neck, such as in the carotid artery, which can include the common carotid artery,

the internal carotid artery, or the external carotid artery. The disclosed systems and methods use a neuroprotection system configured to generate reverse flow (also referred to as retrograde flow) through at least a portion of the carotid artery. The neuroprotection system can also comprise a stagnation of flow in at least a portion of the carotid artery. To the extent retrograde flow is generated, it can be generated in a passive manner or an active manner, as described in more detail below. The disclosed systems and methods can also utilize aspiration in an intracranial artery and/or carotid artery.

[0083] The disclosed systems and methods can be used to treat any of a variety of intracranial and neurovascular conditions including, for example, stroke, acute stroke, large vessel occlusion, intracranial atherosclerotic disease (ICAD), tandem lesion, aneurysm, arteriovenous malformation (AVM), arteriovenous fistula, acute and chronic carotid total occlusions with any of a variety of interventional devices, including some examples described herein. In addition, a variety of closure devices and methods can be used in connection with closure of the access location so as to achieve hemostasis at the access location. The disclosed methods can be used in conjunction with placement of a stent in an artery or without placement of a stent.

[0084] In an exemplary method, an access location is provided or otherwise formed at the level of the neck, such as in a region of the carotid artery, which can be inclusive of the internal carotid artery, the external carotid artery, and/or the common carotid artery. The access location in an example is in the common carotid artery. An arterial access sheath (also referred to as an arterial access device), such as the arterial access device described herein, is then inserted into the artery via the access location. The sheath is inserted into the artery and passed therethrough until a distalmost tip of the sheath is positioned at a desired location. In an embodiment, a distalmost tip of the sheath is positioned in the internal carotid artery. In another embodiment, a distalmost tip of the sheath is positioned in the external carotid artery or common carotid artery. A flow reversal state is then optionally established such as by clamping or occluding a portion of the carotid artery to achieve a pressure differential, thereby establishing a reverse flow condition. The reverse flow blood condition causes blood to flow into the sheath from an artery (such as the carotid artery), where it can be routed or shunted to a return location, such as an external container or to the vasculature (a vein or artery). In another implementation, an active flow state can be achieved such as by using a pump or a syringe, as described in more detail below. As mentioned, a flow stagnation state can also or otherwise be achieved. The reverse flow condition acts as a neuroprotection system, as described in more detail below. As

discussed below, a closure device can then be applied to the access location to establish hemostasis such as at the end of a treatment procedure. In an embodiment, the closure device is pre-deployed to the access location prior to introducing any device (such as a guidewire, sheath or interventional device) into an artery via the access location.

[0085] The arterial access device provides a passageway for insertion of an interventional tool or tools into the vasculature such that the interventional tool can be routed to a target treatment location, such as in a blood vessel of the brain. In an implantation, reverse flow is used in combination with an interventional tool comprising an aspiration catheter to aspirate a material (such as thrombotic material) into an intervention device, such as a catheter, and/or into the arterial access sheath. In this regard, the interventional device and/or the arterial access device can be inserted so that a distal-most tip of the device is positioned just proximal of the location to be aspirated or at any other location relative to the location to be aspirated. After the interventional tool is used for treatment, the reverse flow condition or stagnant flow condition is then ceased to restore antegrade flow. During the procedure, the reverse flow condition serves as a neuroprotection to limit or prevent material from flowing in an antegrade direction in the region of the intervention. As described below, a closure device can be deployed at the access location during or after the procedure without having to remove the arterial access device from the access location or having to exchange the arterial access device with another device.

[0086] Figure 1 schematically depicts normal, antegrade cerebral circulation with an example disease state (a thrombotic occlusion 10) in, for example, the left middle cerebral artery RMCA. It should be appreciated that other disease states or conditions that require intervention are within the scope of this disclosure. The left middle cerebral artery RMCA branches from the left internal carotid artery RICA. The middle cerebral arteries are large arteries that have tree-like branches that bring blood to the entire lateral aspect of each hemisphere of the brain. The thrombotic occlusion 10 occludes or limits blood flow through the left middle cerebral artery. Thus, blood supply to the brain is severely interrupted by the presence of the thrombotic occlusion 10 in the left middle cerebral artery, creating an ischemic stroke condition.

[0087] Pursuant to use of methods and systems described herein, a treatment method includes obtaining vascular access to the cerebral arteries and establishing retrograde flow in at least a

portion of the cerebral circulation and/or in the carotid artery in order to treat the thrombotic occlusion. In an example procedure, an interventional device comprising mechanical thrombectomy device is inserted into the cerebral vasculature to remove or otherwise treat the thrombotic occlusion such as under retrograde flow conditions, as described below. Figure 2 depicts the blood flow circulation after retrograde flow has been established using the retrograde flow system described herein. The system includes an arterial access device 110 that enters the left common carotid artery LCCA (or right common carotid artery) to provide access to the cerebral vasculature. The artery can be clamped or an expandable occlusion element 129 on the arterial access device 110 can be used to occlude an artery in the cerebral vasculature and establish retrograde flow, as described more fully below. Various arteries may be occluded including, for example, the common carotid artery, internal carotid artery, and/or vertebral artery. Exemplary embodiments of the system and its components are described in detail below.

[0088] Figure 3 shows the cerebral vasculature with a mechanical thrombectomy device 15 inserted through the arterial access device 110. The thrombectomy device 15 includes an elongate catheter that can be advanced through the arterial access device 110 to the location of the thrombotic occlusion 10. The thrombectomy device 15 has a distal region that includes a thrombus engaging element 68 that is adapted to interact with and remove the thrombotic occlusion 10, as described more fully below. The type of thrombectomy device can vary. In another embodiment, the interventional device is an aspiration catheter that is deployed to interact with the target location via the arterial access device 110.

[0089] Figure 4 shows another embodiment wherein a secondary interventional device, such as a balloon catheter 25, is advanced through the arterial access device 110 and into a collateral cerebral artery such as the anterior cerebral artery ACA. The balloon catheter 25 includes an expandable balloon 30 that can be expanded in the collateral cerebral artery to occlude that artery. Occlusion of the collateral cerebral artery can enhance suction and reverse flow through the cerebral vasculature.

[0090] Figure 5 shows an exemplary embodiment of a vascular access and reverse flow system 100 that can be used to establish retrograde flow during removal of the thrombotic occlusion 10. The system 100 includes the arterial access device 110, a vasculature return device, such as a venous return device 115, and a shunt 120 (which can be an extracorporeal

shunt) that provides a passageway for retrograde flow from the arterial access device 110 to the venous return device 115. A flow control assembly 125 interacts with the shunt 120. The flow control assembly 125 is adapted to regulate and/or monitor the retrograde flow through the shunt 120, as described in more detail below. The flow control assembly 125 interacts with the flow pathway through the shunt 120, either external to the flow path, inside the flow path, or both. Figure 6 shows another view of the vascular access and reverse flow system 100 coupled to a patient.

[0091] In an embodiment, the arterial access device 110 at least partially inserts into the common carotid artery CCA and the venous return device 115 at least partially inserts into a venous return site, such as for example the femoral vein or internal jugular vein, as described in more detail below. The venous return device 115 can be inserted into the femoral vein FV via a percutaneous puncture in the groin. The arterial access device 110 and the venous return device 115 couple to opposite ends of the shunt 120 at connectors.

[0092] As shown in Figure 7, the distal end of the arterial access device 110 (with an optional occlusion element 129 (if present)) may be positioned in the ICA or other portion of the carotid artery. Alternately, in some circumstances where the ICA access is extremely tortuous, it may be preferable to position the occlusion element more proximally in the common carotid artery. As mentioned, the ICA may also be clamped rather than occluded via an occlusion element. Thus, the artery may be occluded via an external location of the artery and/or via an internal location of the artery. When flow through the internal carotid artery is blocked (using the occlusion element 129 or clamp, such as umbilical tape vessel loop, etc.), a natural pressure gradient between the internal carotid artery and the venous system causes blood to flow in a retrograde or reverse direction from the cerebral vasculature through the internal carotid artery and through the shunt 120 into the venous system. The flow control assembly 125 modulates, augments, assists, monitors, and/or otherwise regulates the retrograde blood flow.

[0093] The interventional device (such as an aspiration catheter or other interventional device) is then deployed into the target location, such as the left middle cerebral artery, through the arterial access device110 and via the internal carotid artery. A distal region of the interventional device 15 is positioned in the middle cerebral artery such as in interaction with the thrombotic occlusion or other disease state. A proximal region of the interventional device protrudes from an access port in the arterial access device 110. This is described in more detail

with reference to Figure 7, which shows an enlarged view of the common carotid artery CCA, internal carotid artery ICA, and middle cerebral artery MCA with the arterial access device 110 and the interventional device 15 deployed. The arterial access device 110 accesses the common carotid artery via a transcervical approach such as via a direct cut down to the common carotid artery CCA or a percutaneous puncture of the CCA. The interventional device 15 gains access to the internal carotid artery ICA via insertion through an internal lumen of the arterial access device 110, such as by being inserted into a proximal opening that provides access into the arterial access device 110.

[0094] As discussed, the arterial access device 110 provides access to the anterior and middle cerebral arteries via the common carotid artery CCA using a transcervical approach. Transcervical access provides a short length and non-tortuous pathway from the vascular access point to the target treatment site thereby easing the time and difficulty of the procedure, compared for example to a transfemoral approach. Additionally, this access route reduces the risk of emboli generation from navigation of diseased, angulated, or tortuous aortic arch or common carotid artery anatomy. In another embodiment, the arterial access device provides access to the basilar artery BA or posterior cerebral arteries PCA via a cut down incision to in the vertebral artery or a percutaneous puncture of the vertebral artery.

[0095] In an embodiment, the arterial access device 110 accesses the common carotid artery CCA via a direct surgical transcervical approach. In the surgical approach, the common carotid artery can be clamped or occluded using a tourniquet or other device.

[0096] In another embodiment, transcervical access to the common carotid artery is achieved percutaneously via an incision or puncture in the skin through which the arterial access device 110 is inserted. If an incision is used, then the incision can be about 0.5 cm in length for example. An occlusion element 129, such as an expandable balloon, can be used to occlude the internal carotid artery ICA or the common carotid artery CCA at a location proximal of the distal tip of the arterial access device 110. The occlusion element 129 can be located on the arterial access device 110 or it can be located on a separate device

[0097] In another embodiment, the arterial access device 110 accesses the common carotid artery CCA via a transcervical approach while the venous return device 115 access a venous return site other than the femoral vein, such as the internal jugular vein.

[0098] In another embodiment, the system provides retrograde flow from the carotid artery to an external receptacle rather than to a venous return site. The arterial access device 110 connects to the receptacle via the shunt 120, which communicates with the flow control assembly 125. The retrograde flow of blood is collected in the receptacle 130. If desired, the blood is filtered and subsequently returned to the patient. The pressure of the receptacle 130 could be set at zero pressure (atmospheric pressure) or even lower, causing the blood to flow in a reverse direction from the cerebral vasculature to the receptacle 130. Optionally, to achieve or enhance reverse flow from the internal carotid artery, flow from the external carotid artery can be blocked, typically by deploying a balloon or other occlusion element in the external carotid artery just above the bifurcation with the internal carotid artery.

[0099] In another embodiment, reverse flow may be replaced or augmented by application of an aspiration source to a port (such as a stopcock) that communicates with the flow shunt 120. Examples of an aspiration source include a syringe, pump, or the like. Alternately, the system may include an active pump as part of the flow control assembly 125, with controls for pump flow rate and/or flow monitoring included in the assembly.

[0100] In yet another embodiment, the system may be used to deliver intra-arterial thrombolytic therapy, such as through a sidearm in the arterial access device 110. For example, thrombolytic therapy may be infused to the thrombotic occlusion 10 through the arterial access device 110 via a flush line 635. In another embodiment, the system may be used to deliver intra-arterial thrombolytic therapy via a micro catheter which is inserted into the arterial access device 110. The micro catheter is delivered to the site of the thrombotic occlusion 10 to infuse a thrombolytic drug. The thrombolytic therapy may be delivered either in conjunction with or as an alternative to mechanical thrombectomy such as the thrombectomy device 15.

[0101] In another embodiment, the system 100 may include a means to perfuse the cerebral vasculature and ischemic brain tissue via a perfusion catheter delivered, for example, through the arterial access device 110 to a site distal to the thrombotic occlusion 10. The perfusion catheter is adapted to deliver a perfusion solution to a desired location. Perfusion solution may include, for example, autologous arterial blood, either from the AV shunt 120 or from another artery, oxygenated solution, or other neuroprotective agents. In addition, the perfusion solution may be hypothermic to cool the brain tissue, another strategy which has been shown to minimize brain injury during periods of ischemia. The perfusion catheter may also be used to

deliver a bolus of an intra-arterial thrombolytic agent pursuant to thrombolytic therapy. Typically, thrombolytic therapy may take up to 1-2 hours or more to clear a blockage after the bolus has been delivered. Mechanical thrombectomy may also take up to 1 to 2 hours to successfully recanalize the blocked artery. Distal perfusion of the ischemic region may minimize the level of brain injury during the stroke treatment procedure.

[0102] Another embodiment of the system 100 includes a means for retroperfusion of the cerebral vasculature during the acute stroke treatment procedure. Cerebral retroperfusion as described by Frazee et al involves selective cannulation and occlusion of the transverse sinuses via the internal jugular vein, and infusion of blood via the superior sagittal sinus to the brain tissue, during treatment of ischemic stroke. The following articles, which are incorporated herein by reference in their entirety, described cerebral retroperfusion and are incorporated by reference in their entirety: Frazee, J. G. and X. Luo (1999). "Retrograde transvenous perfusion." Crit Care Clin 15(4): 777-88, vii.; and Frazee, J. G., X. Luo, et al. (1998). "Retrograde transvenous neuroperfusion: a back door treatment for stroke." Stroke 29(9): 1912-6. This perfusion, in addition to providing protection to the cerebral tissue, may also cause a retrograde flow gradient in the cerebral arteries. Used in conjunction with the reverse flow system 100, a retroperfusion component may provide oxygen to brain tissue, as well as aid in capture of embolic debris into the reverse flow shunt during recanalization of the thrombotic occlusion 10.

[0103] Any of a variety of interventional devices can be used. For example, the interventional device can be a thrombectomy device such as a stentriever device, which can be for example, a self-expanding mesh tube attached to a wire, which is guided via the arterial access device (and possibly a secondary catheter) into the vasculature such that the device can engage a clot or other disease state. A user guides the device through various blood vessels up to the treatment location such as blood clot in the brain. The stentriever then is used to grab the clot, which is pulled out when the user removes the catheter. In an example embodiment, the interventional device is any device that is configured to be delivered to a treatment site and provide treatment such as by delivering a substance to the site, removing a substance from the site, and/or interacting with the treatment site in any manner. For example, a stent, balloon, coil, glue, liquid, solid, or gel can be delivered to the treatment site. The thrombectomy device may include or be coupled to a microcatheter to assist in delivering the device into the distal vasculature.

[0104] It should be appreciated that the thrombectomy device 15 is not limited to a specific embodiment and that various embodiments of thrombectomy devices or therapeutic devices may also be used. For example, the device may be an expandable cage, basket, snare, or grasper which is used to capture and remove the thrombotic blockage. The device may also be a clot disruption device, which may be used to break up the thrombus for easier aspiration and removal. The clot disruption device may be, for example, a mechanical disrupter, sonic or ultrasonic energy source, or other energy source, or a hydraulic or vortex energy source, to break up the clot. The thrombectomy device may also comprise an aspiration means to remove the thrombotic blockage.

[0105] Other means for providing flow through a thrombotic blockage include recanalizing means, for example delivering a balloon catheter and dilating a passage through the blockage, or deploying a stent through the thrombotic blockage to create a lumen through the blockage. A stent device may be a permanent implantable stent or may be a temporary stent to open up the blocked passage for a period of time before being retrieved. The blockage may be removed by the stent or by some other thrombectomy means. Both thrombectomy and recanalization devices may be used in conjunction with thrombolytic infusion. Some exemplary stent-related devices and methods are described in the following U.S. Patents, which are incorporated herein by reference in their entirety: U.S. Patent No. 5,964,773 and U.S. Patent No. 5,456,667.

[0106] An example use of the vascular access and reverse flow system with the thrombectomy device 15 is now described. The arterial access device 110 is introduced into the common carotid artery CCA of the patient and at least partially positioned (such as a distal end of the distal sheath) in the distal common carotid artery or internal carotid artery, as shown in Figure 7. The thrombectomy device 15 is then advanced through the arterial access device 110, either with or without the microcatheter 60, into the carotid artery. Before advancing the thrombectomy device 15 further, the occlusion element 129 on the arterial access device 110 may be expanded to reduce or even stop antegrade flow through the vessel. In another embodiment, antegrade flow is stopped by externally clamping on the blood vessel. Stopping flow in the vessel may help prevent the thrombotic emboli or any parts thereof from migrating downstream due to antegrade flow during positioning of the thrombectomy device 15 or retrieval of the thrombus. The thrombectomy device 15 is then advanced, either through the microcatheter 60 or by itself within the arterial access device 110, further into the vasculature to a position proximal to, within or distal to the thrombotic occlusion 10. During any part of

the procedure, reverse flow may be initiated in the vessel via a retrograde flow system (described below) and/or via active aspiration. In an embodiment, there is a gap between an outer diameter of the device 15 and an inner diameter of the arterial access device 110 at the location where the device 15 protrudes and exits from the distal opening of the arterial access device. The gap is sized such that there is no seal between the outer diameter of the device 15 and an inner diameter of the arterial access device 110, which permits reverse-flowing blood to flow into the distal opening of the arterial access device from which the device 115 protrudes.

[0107] The thrombectomy device 15 is then placed into contact with the thrombotic occlusion 10 and possibly through the thrombotic occlusion.

[0108] The thrombectomy device 15 may be used in any suitable manner to engage the thrombotic occlusion. For example, the microcatheter 60 or sheath 65 may be advanced through the thrombotic occlusion and then retracted to expose the thrombectomy device 15. The thrombectomy device 15 is then retracted into the thrombotic occlusion to engage the thrombotic occlusion. The thrombectomy device 15 may be rotated when moved into the thrombotic occlusion. The thrombectomy device 15 may also be used to engage the thrombotic occlusion by simply retracting the microcatheter 60 or sheath 65 with the thrombectomy device 15 expanding within the thrombotic occlusion.

[0109] Another method of aiding mechanical capture of a thrombotic occlusion is to coat the device and elements of the device with a material which helps to adhere the thrombotic occlusion, and in particular thrombus, to the device or element. The material may be, for example, fibrin or may be any other suitable material.

[0110] It may be appreciated that other mechanical thrombectomy catheters may be used in a similar manner with the vascular access and reverse flow system as described above. Mechanical thrombectomy devices may include variations on the thrombus retrieval device described above, such as expandable cages, wire or filament loops, graspers, brushes, or the like. These clot retrievers may include aspiration lumens to lower the risk of embolic debris leading to ischemic complications. Alternately, thrombectomy devices may include clot disruption elements such as fluid vortices, ultrasound or laser energy elements, balloons, or the like, coupled with flushing and aspiration to remove the thrombus. Some exemplary devices and methods are described in the following U.S. Patents and Patent Publications, which are all

incorporated by reference in their entirety: U.S. Patent No. 6,663,650, U.S. Patent No. 6,730,104; U.S. Patent No. 6,428,531, U.S. Patent No. 6,379,325, U.S. Patent No. 6,481,439, U.S. Patent No. 6,929,632, U.S. Patent No. 5,938,645, U.S. Patent No. 6,824,545, U.S. Patent No. 6,679,893, U.S. Patent No. 6,685,722, U.S. Patent No. 6,436,087, U.S. Patent No. 5794629, U.S. Patent Pub. No. 20080177245, U.S. Patent Pub. No. 20090299393, U.S. Patent Pub. No. 20040133232, U.S. Patent Pub. No. 20020183783, U.S. Patent Pub. No. 20070198028, U.S. Patent Pub. No. 20060058836, U.S. Patent Pub. No. 20060058837, U.S. Patent Pub. No. 20060058838, U.S. Patent Pub. No. 20060058838, U.S. Patent Pub. No. 20030212384, and U.S. Patent Pub. No. 20020133111.

EXEMPLARY EMBODIMENT OF RETROGRADE BLOOD FLOW SYSTEM

[0111] As discussed, the system 100 includes the arterial access device 110, return device 115, and shunt 120 which provides a passageway for retrograde flow from the arterial access device 110 to the return device 115. The system also includes the flow control assembly 125, which interacts with the shunt 120 to regulate and/or monitor retrograde blood flow through the shunt 120. Exemplary embodiments of the components of the system 100 are now described. The system can include or be combined with a neurointerventional device.

Arterial Access Device

[0112] Figures 8A and 8B show an exemplary embodiment of the arterial access device 110, which comprises a distal sheath 605 (also referred to a sheath body 605), a proximal extension 610, and an adaptor or Y-connector 620 that can be fluidly attached to a flow line such as the shunt 120, such as shown in Figure 9B. The arterial access device 110 can optionally include a sheath stopper 705 (described further below) and a guidewire 611.

[0113] The distal sheath 605 is the portion of the arterial access device 110 that is sized to be inserted into the carotid artery and is actually inserted into the artery during use. The distal sheath 605 is adapted to be introduced through an incision or puncture in a wall of a common carotid artery, either an open surgical incision or a percutaneous puncture established, for example, using the Seldinger technique. The length of the distal sheath can vary. In a non-limiting example, the length is 18 cm or greater. In another embodiment, the distal sheath is in the range from 5 to 15 cm, for example being from 10 cm to 12 cm. The inner diameter can be in the range from 7 Fr (1 Fr = 0.33 mm), to 10 Fr, such 8 Fr. The distal sheath 605 can be

a 4 Fr sheath, 6 Fr sheath, 5 Fr sheath, or 8 Fr sheath in non-limiting examples. In implementations, the distal sheath has an outer diameter of 4 Fr to 8 Fr, or up to 10.5 Fr or up to 12 Fr.

[0114] When the sheath is being introduced through the transcervical approach, above the clavicle but below the carotid bifurcation, it may desirable that the sheath 605 be highly flexible while retaining hoop strength to resist kinking and buckling. Thus, the distal sheath 605 can be circumferentially reinforced, such as by braid, helical ribbon, helical wire, or the like. In an alternate embodiment, the distal sheath is adapted to be introduced through a percutaneous puncture into the femoral artery, such as in the groin, and up the aortic arch into the target common carotid artery CCA.

[0115] Figure 8A shows the components of the arterial access device 110 in an exploded state including arterial access sheath 605, sheath dilator 645, sheath stopper 705, and sheath guidewire 111. Figure 8B shows the arterial access device 110 as it would be assembled for insertion over the sheath guide wire 611 into the carotid artery. After the sheath is inserted into the artery and during the procedure, the sheath guide wire 611 and sheath dilator 705 are removed. A flush line 635 can be connected to the arterial access device 110 and can have a stopcock 640 at its proximal end. The flush-line 635 allows for the introduction of saline, contrast fluid, or the like, during the procedures. The flush line 635 can also allow pressure monitoring during the procedure. In an embodiment, the dilator 645 has a distal region that protrudes 1.5 cm distally past a distal end of a distal end of the sheath 605 when the dilator is positioned within the sheath.

[0116] The proximal extension 610 extends from a Y-adapter 620 to a proximal end of the arterial access device 110, such as at the location of the flush line 635 when present. The proximal extension 610 has an inner lumen that is fluidly contiguous with an inner lumen of the sheath body 605. The embodiment of Figure 8A includes proximal hemostasis valve 625 at a proximal-most end of the arterial access device 110. In an embodiment described below with reference to Figure 9A (or in any embodiment described herein), the arterial access device 110 does not include a hemostasis valve and can be removably coupled to a hemostasis valve. The hemostasis valve can also be eliminated from the embodiment of Figures 8A and 8B.

[0117] With reference still to Figure 8A, the Y-adaptor 620 (also referred to as a Y-connector) connects the distal portion of the sheath body 605 to the proximal extension 610. The Y-connector 620 can also include a valve 670 that can be operated to open and close fluid connection to a connector or hub 680 that can be removably connected or otherwise at least partially form a flow line such as the shunt 120. That is, the hub connects to and forms at least a portion of the retrograde shunt 120 (Figures 5 and 6).

[0118] The valve 670 (such as a stopcock) is positioned immediately adjacent to an internal lumen of the Y-adaptor 620, which communicates with the internal lumen of the sheath body 605. Figures 18A and 18A show details in cross section of an example of the Y-connector 620 with the valve 670 and the hub 680. Figure 18A shows the valve closed to the connector. This is the position that the valve would be in during prep of the arterial sheath. The valve is configured so that there is no potential for trapped air during prep of the sheath. Figure 18B shows the valve open to the connector. This position is used once the flow shunt 120 is connected to hub 680 and allows blood flow from the arterial sheath into the shunt. This configuration eliminates the need to prep both a flush line and flow line, instead allowing prep from the single flush line 635 and stopcock 640. This single-point prep is identical to prep of conventional introducer sheaths which do not have connections to shunt lines and is therefore more familiar and convenient to the user. In addition, the lack of flow line on the sheath makes handling of the arterial sheath easier during prep and insertion into the artery.

[0119] With reference again to Figure 8A, the sheath body 605 may also contain a second more distal connector 690, which is separated from the Y-adaptor 620 by a segment of tubing 665. A purpose of this second connector and the tubing 665 is to allow the valve 670 to be positioned further proximal from the distal tip of the sheath, while still limiting the length of the insertable portion of the sheath 605, and therefore allow a reduced level of exposure of the user to the radiation source as the flow shunt is connected to the arterial sheath during the procedure. In an embodiment, the distal connector 690 contains suture eyelets to aid in securement of the sheath to the patient once positioned.

[0120] In alternate implementations of any embodiment of the arterial access device 110 described herein, the arterial access device does not include a hemostasis valve on its proximal end. Rather the arterial access device has an open proximal end (such as an unimpeded or completely unblocked proximal opening) without a hemostasis valve to provide a wider access

than would otherwise be present if the hemostasis valve was located there. In an embodiment, the proximal opening is sized to receive a 0.071 inch outer diameter catheter although this can vary.

[0121] Figure 9A shows another embodiment of the arterial access device 110, which includes the sheath body 605 having one or more depth markers 3205 that are sized and spaced along the sheath body 605 to provide an indication to a user as to a depth of insertion of the sheath body 605 from a distal most edge of the sheath body to each depth marker 3205. In an embodiment, the depth markers are configured to provide an indication of depth up to at least 10 cm. In an embodiment, the sheath body 605 has a length of 18 cm, at least 18 cm, or less than 18 cm.

[0122] With reference still to Figure 9A, the proximal extension 610 extends from a Y-adapter 620 to a proximal-most end where a connector element 3210, such as a female luer connector 3210, is located. As mentioned, a hemostasis valve is not located on the proximal-most end. The connector element 3210 can be configured to removably attach to a corresponding connector on the proximal end of the arterial access dilator 645. As shown in Figure 9B, the connector element 3210 can be configured to removably attach to a rotating hemostasis valve (RHV) 3220 to achieve hemostasis. The RHV can include a Y-connector that includes a fluid line 3225 that communicates with a lumen of the arterial access device 110 when connected. The fluid line 3225 can serve as a flush line to be used for a flush fluid for example and can include an element to control flow such as a stopcock. As mentioned, the shunt 120 can be removably and fluidly coupled to the arterial access device 110 as shown in Figure 9B. One or more suture eyelets can be located at a proximal end of the distal sheath 605.

[0123] The distal tip of the sheath body 605 can be entirely or at least partially made of a different material than a proximal portion of the sheath, such as of a softer or more flexible material. The distal tip of the sheath body 605 can define a distal-most edge wherein the edge is positioned along or aligned with a plane that is normal to a longitudinal axis of the sheath body. Or the distal tip of the sheath body 605 can define a distal-most edge wherein the edge is positioned along or aligned with a plane that is angled (i.e., not normal) to a longitudinal axis of the sheath body. In an embodiment, the sheath body 605 is a 6 French or an 8 French sheath.

In an embodiment, the sheath body 605 has an inner diameter of 0.071 inch, 0.058 inch, or 0.045 inch and a length of 58 cm, although these specifications may vary.

[0124] With reference again to Figure 9A, the proximal extension 610 (when present) is removably connected to distal sheath 605 via at least one coupler or connector 3215 assembly. The connector assembly 3215 can be positioned just proximal of a distal end of the distal sheath and distal of the Y-arm 620 at a connection site. In this embodiment, an additional hemostasis valve may be included at the connection site of the proximal extension 610 to the Y-arm connector 620, so that hemostasis is maintained when the proximal extension is not attached. Thus, the proximal extension 610 and the attached Y-connector 620 can be collectively detached from the distal sheath 605 at the location connector assembly 3215.

[0125] The connector assembly 3215 can include any of a wide variety of removably attachable connector components. The arterial access device 110 can include a first connector component 3217 on a proximal end of the distal sheath 605 that removably attaches to a second connector component 3219 on the distal end of y-arm adapter 620 or at a distal end of the proximal extension 610. The first connector component 3217 and second connector component 3219 can be, for example, rotational fittings that couple to one another via a rotational-type mechanism, such as threads. In an embodiment, the connector components comprise one or more Luer connectors. At least one of the connector components can be a hemostasis valve or a hemostasis valve adaptor. For example, the first connector component 3217 can be a hemostasis valve adaptor that is configured to removably attach to the second connector 3219. The first connector component 3217 can also removably attach to a hemostasis valve in an embodiment. Thus, the second connector component 3219 can be detached from the first connector component 3217 to remove the y-arm adapter 620 and the proximal extension 610. A hemostasis valve assembly can then be attached to the first connector 3217. In an embodiment, the first connector 3217 and/or the second connector 3219 include an automatic hemostasis component that automatically achieves hemostasis upon the first connector component being detached from the second connector component. In example embodiments, the arterial access sheath has a total length of less than 20 cm or less than 16 cm. In an embodiment, the length of the arterial access sheath has a working length of 11 cm and an outer diameter of 10.5 Fr.

[0126] In an embodiment, the arterial access device 110 has an entire length of 32 cm or greater. In an example embodiment, the entire length of the distal sheath 605 is 16 cm, 20 cm, or other length less than 32 cm. The detachable proximal extension 610 (which also detaches the Y-arm connector or adapter 620, which connects to the shunt 120) permits a reduction in length of the arterial access device 110 when the proximal extension 610 is detached from the distal sheath 605. In an example method, the arterial access device is used pursuant to a treatment method with the arterial access device 110 being in a fully assembled state such that it includes both the proximal extension 110 and the attached distal sheath 605. In this state, the arterial access device 110 can be used for the introduction of one or more interventional devices into the vasculature by inserting the interventional device via a proximal opening at the proximal end of the proximal extension.

[0127] At some point during the method, such as after treatment via the interventional device is complete, the y-arm adapter 6220 and proximal extension 610 are detached from the distal sheath 605 (by uncoupling the second connector component 2319 from the first connector component 3217) while the distal sheath 605 remains inserted in the artery without the y-arm adapter 6220 and proximal extension 610. The distal sheath 605 thus provides a shorter access pathway into the artery relative to when the proximal extension 610 is attached to the distal sheath 605. The shorter access pathway may then be used to insert one or more devices for accessing and/or intervening with the artery without having to remove the entire arterial access device 110 and replace it with a shorter access device. In an embodiment, the distal sheath 605 is used as an access pathway for inserting a closure delivery system into the artery such as the closure delivery system described below relative to Figures 19A and 19B. A closure device can then be applied to achieve hemostasis at the access location. The distal sheath 605 can then be removed. Or the proximal extension may be re-attached to the distal sheath 605 prior to removal. In an embodiment, the shorter access pathway enables insertion and use of one or more devices for accessing and/or intervening with the artery than would otherwise be permissible if the longer access pathway with both the distal sheath and proximal extension were in an attached state.

[0128] Figures 10A-10B show alternate embodiment of the arterial access device 110. The distal sheath 605 can optionally have a stepped or other configuration having a reduced diameter distal region 630, as shown in Figure 10B, which shows an enlarged view of the distal region 630 of the sheath 605. The distal region 630 of the sheath can be sized for insertion into

the carotid artery, typically having an inner diameter in the range from 2.16 mm (0.085 inch) to 2.92 mm (0.115 inch) with the remaining proximal region of the sheath having larger outside and luminal diameters, with the inner diameter typically being in the range from 2.794 mm (0.110 inch) to 3.43 mm (0.135 inch). The larger luminal diameter of the proximal region minimizes the overall flow resistance through the sheath. In an embodiment, the reduced-diameter distal section 630 has a length of approximately 2 cm to 4 cm or 3 cm to 5 cm. In another embodiment, the length of the reduced-diameter distal section 630 has a length of approximately 10 cm to 15 cm. The relatively short length of the reduced-diameter distal section 630 permits this section to be positioned in the common carotid artery CCA via the transcervical approach with reduced risk that the distal end of the sheath 605 will contact the bifurcation B. Moreover, the reduced diameter section 630 also permits a reduction in size of the arteriotomy for introducing the sheath 605 into the artery while having a minimal impact in the level of flow resistance.

[0129] With reference again to Figure 10A, the proximal extension 610 has an inner lumen that is fluidly contiguous with an inner lumen of the sheath 605. The respective lumens of the proximal extension 610 and sheath body 605 are joined by the Y-connector 620 which also connects a lumen of a flow line 615 to the sheath. In the assembled system, the flow line 615 connects to and forms a first leg of the retrograde shunt 120 (Figures 5 and 6). In any embodiment, the proximal extension 610 can have a length sufficient to space a proximal hemostasis valve 625 (or proximal end of the arterial access device) well away from the Y-connector 620, which is adjacent to the percutaneous or surgical insertion site. By spacing the hemostasis valve 625 away from a percutaneous insertion site, the physician can introduce an interventional system (such as a stent delivery system or other working catheter) into the proximal extension 610 and sheath 605 while staying out of the fluoroscopic field when fluoroscopy is being performed.

[0130] The dilator 645, which may have a tapered distal end 650, can be provided to facilitate introduction of the distal sheath 605 into the common carotid artery. The dilator 645 can be introduced through the hemostasis valve 625 so that the tapered distal end 650 extends through the distal end of the sheath 605, as best seen in Figure 11A. The dilator 645 can have a central lumen to accommodate a guide wire. Typically, the guide wire is placed first into the vessel, and the dilator/sheath combination travels over the guide wire as it is being introduced into the vessel.

[0131] The dilator can vary in length. In an embodiment, the dilator has a length such that tapered distal end 650 as well as a distal region of the dilator protrudes outwardly from a distal end of the distal sheath 605 when the dilator is positioned within the internal lumen of the distal sheath 605. In example embodiments, the length of the dilator is 79 cm with a working length of 76cm although the length may vary.

Sheath Stopper

[0132] Optionally, a sheath stopper 705 such as in the form of a tube may be provided which is coaxially received over the exterior of the distal sheath 605, also as seen in Figure 11A. The sheath stopper 705 is configured to act as a mechanical device to prevent the sheath from being inserted too far into the vessel. The sheath stopper 705 is sized and shaped to be positioned over the sheath body 605 such that it covers a portion of the sheath body 605 and leaves a distal portion of the sheath body 605 exposed. The sheath stopper 705 may have a flared proximal end 710 that engages the adapter 620, and a distal end 715. Optionally, the distal end 715 may be beveled, as shown in Figure 11B.

[0133] The sheath stopper 705 may serve various purposes. For example, the length of the sheath stopper 705 limits the introduction of the sheath 605 to the exposed distal portion of the sheath 605 such that the sheath insertion length is limited to the exposed distal portion of the sheath. In an embodiment, the sheath stopper limits the exposed distal portion to a range between 2 and 3 cm. In an embodiment, the sheath stopper limited the exposed distal portion to 2.5 cm. In other words, the sheath stopper may limit insertion of the sheath into the artery to a range between about 2 and 3 cm or to 2.5 cm. In another example, the sheath stopper 705 can engage a pre-deployed puncture closure device disposed in the carotid artery wall, if present, to permit the sheath 605 to be withdrawn without dislodging the closure device.

[0134] The sheath stopper 705 may be manufactured from clear material so that the sheath body may be clearly visible underneath the sheath stopper 705. The sheath stopper 705 may also be made from flexible material, or the sheath stopper 705 include articulating or sections of increased flexibility so that it allows the sheath to bend as needed in a proper position once inserted into the artery. The sheath stopper may be plastically bendable such that it can be bent into a desired shape such that it retains the shape when released by a user. The distal portion of the sheath stopper may be made from stiffer material, and the proximal portion may be made from more flexible material. In an embodiment, the stiffer material is 85A durometer and the

more flexible section is 50A durometer. In an embodiment, the stiffer distal portion is 1 to 4 cm of the sheath stopper 705. The sheath stopper 705 may be removable from the sheath so that if the user desired a greater length of sheath insertion, the user could remove the sheath stopper 705, cut the length (of the sheath stopper) shorter, and re-assemble the sheath stopper 705 onto the sheath such that a greater length of insertable sheath length protrudes from the sheath stopper 705.

[0135] Figure 11C shows another embodiment of a sheath stopper 705 positioned adjacent a sheath 605 with a dilator 645 positioned therein. The sheath stopper 705 of Figure 11C may be deformed from a first shaped, such as a straight shape, into a second different from the first shape wherein the sheath stopper retains the second shape until a sufficient external force acts on the sheath stopper to change its shape. The second shape may be for example non-straight, curved, or an otherwise contoured or irregular shape. For example, Figure 11C shows the sheath stopper 705 having multiple bends as well as straight sections. Figure 11C shows just an example and it should be appreciated that the sheath stopper 705 may be shaped to have any quantity of bends along its longitudinal axis. Figure 11D shows the sheath stopper 705 positioned on the sheath 605. The sheath stopper 705 has a greater stiffness than the sheath 605 such that the sheath 605 takes on a shape or contour that conforms to the shape of contour of the sheath stopper 705.

[0136] The sheath stopper 705 may be shaped according to an angle of the sheath insertion into the artery and the depth of the artery or body habitus of the patient. This feature reduces the force of the sheath tip in the blood vessel wall, especially in cases where the sheath is inserted at a steep angle into the vessel. The sheath stopper may be bent or otherwise deformed into a shape that assists in orienting the sheath coaxially with the artery being entered even if the angle of the entry into the arterial incision is relatively steep. The sheath stopper may be shaped by an operator prior to sheath insertion into the patient. Or, the sheath stopper may be shaped and/or re-shaped *in situ* after the sheath has been inserted into the artery. Figures 11E and 11F show an example of the malleable sheath stopper 705 in use. Figure 11E shows the sheath stopper 705 positioned on the sheath 605 with the sheath stopper 705 in a straight shape. The sheath 605 takes on the straight shape of the sheath stopper 705 and is entering the artery A at a relatively steep angle such that the distal tip of the sheath 605 abuts or faces the wall of the artery. In Figure 11F, a user has bent the sheath stopper 705 so as to adjust the angle of entry of the sheath 605 so that the longitudinal axis of the sheath 605 is more aligned with the

axis of the artery A. In this manner, the sheath stopper 705 has been formed by a user into a shape that assists in directing the sheath 605 away from the opposing wall of the artery A and into a direction that is more coaxial with the axis of the artery A relative to the shape in Figure 11E.

[0137] In an embodiment, the sheath stopper 705 is made from malleable material, or with an integral malleable component positioned on or in the sheath stopper. In another embodiment, the sheath stopper is constructed to be articulated using an actuator such as concentric tubes, pull wires, or the like. The wall of the sheath stopper may be reinforced with a ductile wire or ribbon to assist it in holding its shape against external forces such as when the sheath stopper encounters an arterial or entryway bend. Or the sheath stopper may be constructed of a homogeneous malleable tube material, including metal and polymer. The sheath stopper body may also be at least partially constructed of a reinforced braid or coil capable of retaining its shape after deformation.

[0138] Another sheath stopper embodiment is configured to facilitate adjustment of the sheath stopper position (relative to the sheath) even after the sheath is positioned in the vessel. One embodiment of the sheath stopper includes a tube with a slit along most or all of the length, so that the sheath stopper can be peeled away from the sheath body, moved forward or backwards as desired, and then re-positioned along the length of the sheath body. The tube may have a tab or feature on the proximal end so it may be grasped and more easily to peel away.

[0139] In another embodiment, the sheath stopper is a very short tube (such as a band), or ring that resides on the distal section of the sheath body. The sheath stopper may include a feature that could be grasped easily by forceps, for example, and pulled back or forwards into a new position as desired to set the sheath insertion length to be appropriate for the procedure. The sheath stopper may be fixed to the sheath body through either friction from the tube material, or a clamp that can be opened or closed against the sheath body. The clamp may be a spring-loaded clamp that is normally clamped onto the sheath body. To move the sheath stopper, the user may open the clamp with his or her fingers or an instrument, adjust the position of the clamp, and then release the clamp. The clamp is designed not to interfere with the body of the sheath.

[0140] In another embodiment, the sheath stopper includes a feature that allows suturing the sheath stopper and sheath to the tissue of the patient, to improve securement of the sheath and reduce risk of sheath dislodgement. The feature may be suture eyelets that are attached or molded into the sheath stopper tube.

[0141] In another embodiment, as shown in Figure 8A, the sheath stopper 705 includes a distal flange 710 sized and shaped to distribute the force of the sheath stopper over a larger area on the vessel wall and thereby reduce the risk of vessel injury or accidental insertion of the sheath stopper through the arteriotomy and into the vessel. The flange 710 may have a rounded shape or other atraumatic shape that is sufficiently large to distribute the force of the sheath stopper over a large area on the vessel wall. In an embodiment, the flange is inflatable or mechanically expandable. For example, the arterial sheath and sheath stopper may be inserted through a small puncture in the skin into the surgical area, and then expanded prior to insertion of the sheath into the artery.

[0142] The sheath stopper may include one or more cutouts or indents 720 along the length of the sheath stopper which are patterned in a staggered configuration such that the indents increase the bendability of the sheath stopper while maintaining axial strength to allow forward force of the sheath stopper against the arterial wall. The indents may also be used to facilitate securement of the sheath to the patient via sutures, to mitigate against sheath dislodgement. The sheath stopper may also include a connector element 730 on the proximal end which corresponds to features on the arterial sheath such that the sheath stopper can be locked or unlocked from the arterial sheath. For example, the connector element is a hub with generally L-shaped slots 740 that correspond to pins 750 on the hub to create a bayonet mount-style connection. In this manner, the sheath stopper can be securely attached to the hub to reduce the likelihood that the sheath stopper will be inadvertently removed from the hub unless it is unlocked from the hub.

[0143] The distal sheath 605 can be configured to establish a curved transition from a generally anterior-posterior approach over the common carotid artery to a generally axial luminal direction within the common carotid artery. Arterial access through the common carotid arterial wall either from a direct surgical cut down or a percutaneous access may require an angle of access that is typically larger than other sites of arterial access. This is due to the fact that the common carotid insertion site is much closer to the treatment site (i.e., carotid

bifurcation) than from other access points. A larger access angle may be needed to increase the distance from the insertion site to the treatment site to allow the sheath to be inserted at an adequate distance without the sheath distal tip reaching the carotid bifurcation. For example, the sheath insertion angle is typically 30-45 degrees or even larger via a transcarotid access, whereas the sheath insertion angle may be 15-20 degrees for access into a femoral artery. Thus the sheath must take a greater bend than is typical with introducer sheaths, without kinking and without causing undue force on the opposing arterial wall. In addition, the sheath tip desirably does not be abut or contact the arterial wall after insertion in a manner that would restrict flow into the sheath. The sheath insertion angle is defined as the angle between the luminal axis of the artery and the longitudinal axis of the sheath.

[0144] The sheath body 605 can be formed in a variety of ways to allow for this greater bend required by the angle of access. For example, the sheath and/or the dilator may have a combined flexible bending stiffness less than typical introducer sheaths. In an embodiment, the sheath/dilator combination (i.e., the sheath with the dilator positioned inside the sheath) has a combined flexible stiffness (E*I) in the range of about 80 and 100 N-m^2 x 10^{-6},where E is the elastic modulus and I is the area moment of inertia of the device.. The sheath alone may have a bending stiffness in the range of about 30 to 40 N-m^2 x 10^{-6} and the dilator alone has a bending stiffness in the range of about 40 to 60 N-m^2 x 10^{-6}. Typical sheath/dilator bending stiffness are in the range of 150 to 250 N-m^2 x 10^{-6}. The greater flexibility may be achieved through choice of materials or design of the reinforcement. For example, the sheath may have a ribbon coil reinforcement of stainless steel with dimensions .002" to .003" thick and .005" to .015" width, and with outer jacket durometer of between 40 and 55D. In an embodiment, the coil ribbon is .003" x .010", and the outer jacket durometer is 45D. In an embodiment, the sheath 605 can be pre-shaped to have a curve or an angle some set distance from the tip, typically 0.5 to 1 cm. The pre-shaped curve or angle can typically provide for a turn in the range from 5° to 90°, preferably from 10° to 30°. For initial introduction, the sheath 605 can be straightened with an obturator or other straight or shaped instrument such as the dilator 645 placed into its lumen. After the sheath 605 has been at least partially introduced through the percutaneous or other arterial wall penetration, the obturator can be withdrawn to allow the sheath 605 to reassume its pre-shaped configuration into the arterial lumen. To retain the curved or angled shape of the sheath body after having been straightened during insertion, the sheath may be heat set in the angled or curved shape during manufacture. Alternately, the reinforcement

structure may be constructed out of nitinol and heat shaped into the curved or angled shape during manufacture. Alternately, an additional spring element may be added to the sheath body, for example a strip of spring steel or nitinol, with the correct shape, added to the reinforcement layer of the sheath.

[0145] Other sheath configurations include having a deflection mechanism such that the sheath can be placed and the catheter can be deflected *in situ* to the desired deployment angle. In still other configurations, the catheter has a non-rigid configuration when placed into the lumen of the common carotid artery. Once in place, a pull wire or other stiffening mechanism can be deployed in order to shape and stiffen the sheath into its desired configuration. One particular example of such a mechanism is commonly known as "shape-lock" mechanisms as well described in medical and patent literature.

[0146] Another sheath configuration comprises a curved dilator inserted into a straight but flexible sheath, so that the dilator and sheath are curved during insertion. The sheath is flexible enough to conform to the anatomy after dilator removal.

[0147] Another sheath embodiment is a sheath that includes one or more flexible distal sections, such that once inserted and in the angled configuration, the sheath is able to bend at a large angle without kinking and without causing undue force on the opposing arterial wall. In one embodiment, there is a distalmost section of sheath body 605 which is more flexible than the remainder of the sheath body. For example, the flexural stiffness of the distalmost section is one half to one tenth the flexural stiffness of the remainder of the sheath body 605. In an embodiment, the distalmost section has a flexural stiffness in the range 30 to 300 N-mm^2 and the remaining portion of the sheath body 605 has a flexural stiffness in the range 500 to 1500 N-mm^2, For a sheath configured for a CCA access site, the flexible, distal most section comprises a significant portion of the sheath body which may be expressed as a ratio. In an embodiment, the ratio of length of the flexible, distalmost section to the overall length of the sheath body is at least one tenth and at most one half the length of the entire sheath body. This change in flexibility may be achieved by various methods. For example, the outer jacket may change in durometer and/or material at various sections. Alternately, the reinforcement structure or the materials may change over the length of the sheath body. In an embodiment, the distal-most flexible section ranges from 1 cm to 3 cm. In an embodiment with more than one flexible section, a less flexible section (with respect to the distal-most section) may be 1

cm to 2 cm from the distal-most proximal section. In an embodiment, the distal flexible section has a bending stiffness in the range of about 30 to 50 N-m^2 x 10^{-6} and the less flexible section has a bending stiffness in the range of about 50 and 100 N-m^2 x 10^{-6}. In another embodiment, a more flexible section is located between 0.5 and 1.5 cm for a length of between 1 and 2 cm, to create an articulating section that allows the distal section of the sheath to align more easily with the vessel axis though the sheath enters the artery at an angle. These configurations with variable flexibility sections may be manufactured in several manners. For example the reinforced, less flexible section may vary such that there is stiffer reinforcement in the proximal section and more flexible reinforcement in the distal section or in the articulating section. In an embodiment, an outer-most jacket material of the sheath is 45D to 70D durometer in the proximal section and 80A to 25D in the distalmost section. In an embodiment, the flexibility of the sheath varies continuously along the length of the sheath body. Figure 11G shows such a sheath inserted in the artery, with the flexible distal section allowing the sheath body to bend and the distal tip to be in general alignment with the vessel lumen. In an embodiment, the distal section is made with a more flexible reinforcement structure, either by varying the pitch of a coil or braid or by incorporating a cut hypotube with differing cut patterns. Alternately the distal section has a different reinforcement structure than the proximal section.

[0148] In an embodiment, the distal sheath tapered tip is manufactured from harder material than the distal sheath body. A purpose of this is to facilitate ease of sheath insertion by allowing for a smooth taper on the sheath and reduce the change of sheath tip distortion or ovalizing during and after sheath insertion into the vessel. In one example the distal tapered tip material is manufactured from a higher durometer material, for example a 60-72D shore material. In another example, distal tip is manufactured from a separate material, for example HDPE, stainless steel, or other suitable polymers or metals. In an additional embodiment, the distal tip is manufactured from radiopaque material, either as an additive to the polymer material, for example tungsten or barium sulfate, or as an inherent property of the material (as is the case with most metal materials).

[0149] In another embodiment, the dilator 645 may also have variable stiffness. For example the tapered tip 650 of the dilator may be made from more flexible material than the proximal portion of the dilator, to minimize the risk of vessel injury when the sheath and dilator are inserted into the artery. In an embodiment, the distal flexible section has a bending stiffness in the range of about 45 to 55 N-m^2 x 10^{-6} and a less flexible proximal section has a bending

stiffness in the range of about 60 and 90 N-m^2 x 10^{-6}. The taper shape of the dilator may also be optimized for transcarotid access. For example, to limit the amount of sheath and dilator tip that enter the artery, the taper length and the amount of the dilator that extends past the sheath should be shorter than typical introducer sheaths. For example, the taper length may be 1 to 1.5 cm, and extend 1.5 to 2 cm from the end of the sheath body. In an embodiment, the dilator contains a radiopaque marker at the distal tip so that the tip position is easily visible under fluoroscopy.

[0150] In another embodiment, the introducer guide wire is optimally configured for transcarotid access. Typically, when inserting an introducer sheath into a vessel, an introducer guide wire is first inserted into the vessel. This may be done either with a micropuncture technique or a modified Seldinger technique. Usually there is a long length of vessel in the direction that the sheath is to be inserted into which an introducer guidewire may be inserted, for example into the femoral artery. In this instance, a user may introduce a guide wire between 10 and 15 cm or more into the vessel before inserting the sheath. The guide wire is designed to have a flexible distal section so as not to injure the vessel when being introduced into the artery. The flexible section of an introducer sheath guide wire is typically 5 to 6 cm in length, with a gradual transition to the stiffer section. Inserting the guide wire 10 to 15 cm means the stiffer section of the guide wire is positioned in the area of the puncture and allows a stable support for subsequent insertion of the sheath and dilator into the vessel. However, in the case of transcarotid sheath insertion into the common carotid artery, there is a limit on how much guide wire may be inserted into the carotid artery. In cases with carotid artery disease at the bifurcation or in the internal carotid artery, it is desirable to minimize the risk of emboli by inserting the wire into the external carotid artery (ECA), which would mean only about 5 to 7 cm of guide wire insertion, or to stop it before it reaches the bifurcation, which would be only 3 to 5 cm of guide wire insertion. Thus, a transcarotid sheath guidewire may have a distal flexible section of between 3 and 4 cm, and/or a shorter transition to a stiffer section. Alternately, a transcarotid sheath guidewire has an atraumatic tip section but have a very distal and short transition to a stiffer section. For example, the soft tip section is 1.5 to 2.5 cm, followed by a transition section with length from 3 to 5 cm, followed by a stiffer proximal segment, with the stiffer proximal section comprising the remainder of the wire.

[0151] In another embodiment, the sheath dilator is configured to be inserted over a 0.018" guide wire for transcarotid access. Standard sheath insertion using a micropuncture kit requires

first insertion of an .018" guide wire through a 22 Ga needle, then exchange of the guide wire to an .035" or .038" guide wire using a micropuncture catheter, and finally insertion of the sheath and dilator over the .035" or .038" guide wire. A 0.014 inch guidewire can also be used. There exist sheaths which are insertable over a .018" guidewire, thus eliminating the need for the wire exchange. These sheaths, usually labeled "transradial" as they are designed for insertion into the radial artery, typically have a longer dilator taper, to allow an adequate diameter increase from the .018" wire to the body of the sheath. Unfortunately for transcarotid access, the length for sheath and dilator insertion is limited and therefore these existing sheaths are not appropriate. Another disadvantage is that the .018" guide wire may not have the support needed to insert a sheath with a sharper angle into the carotid artery. In the embodiment disclosed here, a transcarotid sheath system includes a sheath body, a sheath dilator, and an inner tube with a tapered distal edge that slidably fits inside the sheath dilator and can accommodate a .018" guide wire.

[0152] To use this sheath system embodiment, the .018" guide wire is first inserted into the vessel through a 22 Ga needle. The sheath system which is coaxially assembled is inserted over the .018" wire. The inner tube is first advanced over the .018" wire which essentially transforms it into the equivalent of a .035" or .038" guide wire in both outer diameter and mechanical support. It is locked down to the .018" wire on the proximal end. The sheath and dilator are then advanced over the .018" wire and inner tube into the vessel. This configuration eliminates the wire exchange step without the need for a longer dilator taper as with current transradial sheaths and with the same guide wire support as standard introducer sheaths. As described above, this configuration of sheath system may include stopper features which prevent inadvertent advancement too far of the .018" guide wire and/or inner tube during sheath insertion. Once the sheath is inserted, the dilator, inner tube, and .018" guide wire are removed.

[0153] Figure 12A shows another embodiment of the arterial access device 110. This embodiment is substantially the same as the embodiment shown in Figure 8A, except that the distal sheath 605 includes an occlusion element 129 for occluding flow through, for example the common carotid artery. Any of the embodiments of the arterial access device can include an occlusion element. If the occluding element 129 is an inflatable structure such as a balloon or the like, the sheath 605 can include an inflation lumen that communicates with the occlusion element 129. The occlusion element 129 can be an inflatable balloon, but it can also be an inflatable cuff, a conical or other circumferential element which flares outwardly to engage the

interior wall of the common or internal carotid artery to block flow therepast, a membrane-covered braid, a slotted tube that radially enlarges when axially compressed, or similar structure which can be deployed by mechanical means, or the like. In the case of balloon occlusion, the balloon can be compliant, non-compliant, elastomeric, reinforced, or have a variety of other characteristics. In an embodiment, the balloon is an elastomeric balloon which is closely received over the exterior of the distal end of the sheath prior to inflation. When inflated, the elastomeric balloon can expand and conform to the inner wall of the common carotid artery. In an embodiment, the elastomeric balloon is able to expand to a diameter at least twice that of the non-deployed configuration, frequently being able to be deployed to a diameter at least three times that of the undeployed configuration, more preferably being at least four times that of the undeployed configuration, or larger.

[0154] As shown in Figure 12B, the distal sheath 605 with the occlusion element 129 can have a stepped or other configuration having a reduced diameter distal region 630. The distal region 630 can be sized for insertion into the carotid artery with the remaining proximal region of the sheath 605 having larger outside and luminal diameters, with the inner diameter typically being in the range from 2.794 mm (0.110 inch) to 3.43 mm (0.135 inch). The larger luminal diameter of the proximal region minimizes the overall flow resistance of the sheath. In an embodiment, the reduced-diameter distal section 630 has a length of approximately 2 cm to 4 cm or 3 cm to 5 cm. In another embodiment, the length of the reduced-diameter distal section 630 has a length of approximately 10 cm to 15 cm. The relatively short length of the reduced-diameter distal section 630 permits this section to be positioned in the common carotid artery CCA via the transcervical approach with reduced risk that the distal end of the sheath 605 will contact the bifurcation B. In an alternate embodiment, shown in Figure 28, the reduced diameter distal section 630 is tapered or stepped and has a length of approximately 10 cm to 15 cm, such that the distal tip can be positioned in the internal carotid artery ICA.

[0155] In a situation with a sharp sheath insertion angle and/or a short length of sheath inserted in the artery, such as one might see in a transcarotid access procedure, the distal tip of the sheath has a higher likelihood of being partially or totally positioned against the vessel wall, thereby restricting flow into the sheath. In an embodiment, the sheath is configured to center the tip in the lumen of the vessel. One such embodiment includes a balloon such as the occlusion element 129 described above. In another embodiment, a balloon may not be occlusive to flow but still center the tip of the sheath away from a vessel wall, like an inflatable

bumper. In another embodiment, expandable features are situated at the tip of the sheath and mechanically expanded once the sheath is in place. Examples of mechanically expandable features include braided structures or helical structures or longitudinal struts which expand radially when shortened.

[0156] In an embodiment, occlusion of the vessel proximal to the distal tip of the sheath may be done from the outside of the vessel, as in a Rummel tourniquet or vessel loop proximal to sheath insertion site. In an alternate embodiment, an occlusion device may fit externally to the vessel around the sheath tip, for example an elastic loop, inflatable cuff, or a mechanical clamp that could be tightened around the vessel and distal sheath tip. In a system of flow reversal, this method of vessel occlusion minimizes the area of static blood flow, thereby reducing risk of thrombus formation, and also ensure that the sheath tip is axially aligned with vessel and not partially or fully blocked by the vessel wall.

[0157] In an embodiment, the distal portion of the sheath body could contain side holes so that flow into the sheath is maintained even if tip of sheath is partially or fully blocked by arterial wall.

Venous Return Device

[0158] Referring now to Figure 13, the venous return device 115 can comprise a distal sheath 910 and a flow line 915, which connects to and forms a leg of the shunt 120 when the system is in use. The distal sheath 910 is adapted to be introduced through an incision or puncture into a venous return location, such as the jugular vein or femoral vein. The distal sheath 910 and flow line 915 can be permanently affixed, or can be attached using a conventional luer fitting, as shown in Figure 13. Optionally, as shown in Figure 14A, the sheath 910 can be joined to the flow line 915 by a Y-connector 1005. The Y-connector 1005 can include a hemostasis valve 1010, permitting insertion of a dilator 1015 to facilitate introduction of the venous return device into the internal jugular vein or other vein. As with the arterial access dilator 645, the venous dilator 1015 includes a central guide wire lumen so the venous sheath and dilator combination can be placed over a guide wire. Optionally, the venous sheath 910 can include a flush line 1020 with a stopcock 1025 at its proximal or remote end.

[0159] An alternate configuration is shown in Figures 14B and 14C. Figure 14B shows the components of the venous return device 115 including venous return sheath 910, sheath dilator

1015, and sheath guidewire 611. Figure 14C shows the venous return device 115 as it would be assembled for insertion over the sheath guide wire 611 into a central vein. Once the sheath is inserted into the vein, the dilator and guidewire are removed. The venous sheath can include a hemostastis valve 1010 and flow line 915. A stopcock 1025 on the end of the flow line allows the venous sheath to be flushed via the flow line prior to use. This configuration allows the sheath to be prepped from a single point, as is done with conventional introducer sheaths. Connection to the flow shunt 120 is made with a connector 1030 (such a hemostasis valve) on the stopcock 1025. The venous return device 115 can include one or more eyelets that can be used to couple to suture for securing the venous return device 115 to a patient.

[0160] In order to reduce the overall system flow resistance, the arterial access flow line 615 and Y-connector 620 (Figure 8A) and the venous return flow line 915, and Y-connectors 1005 (Figure 13 or 14), can each have a relatively large flow lumen inner diameter, typically being in the range from 2.54 mm (0.100 inch) to 5.08 mm (0.200 inch), and a relatively short length, typically being in the range from 10 cm to 20 cm. The low system flow resistance is desirable since it permits the flow to be maximized during portions of a procedure when the risk of emboli is at its greatest. The low system flow resistance also allows the use of a variable flow resistance for controlling flow in the system, as described in more detail below. The dimensions of the venous return sheath 910 can be generally the same as those described for the arterial access sheath 605 above. In the venous return sheath, an extension for the hemostasis valve 1010 is not required.

Retrograde Shunt or Flow Line

[0161] The shunt 120 can be formed of a single tube or multiple, connected tubes that provide fluid communication between the arterial access catheter 110 and the venous return catheter 115 to provide a pathway for retrograde blood flow therebetween. As shown in Figure 5 and Figure 6, the shunt 120 connects at one end to the flow line 615 of the arterial access device 110, and at an opposite end to the flow line 915 of the venous return catheter 115.

[0162] In an embodiment, the shunt 120 can be formed of at least one tube that communicates with the flow control assembly 125. The shunt 120 can be any structure that provides a fluid pathway for blood flow. The shunt 120 can have a single lumen or it can have multiple lumens. The shunt 120 can be removably attached to the flow control assembly 125, arterial access

device 110, and/or venous return device 115. Prior to use, the user can select a shunt 120 with a length that is most appropriate for use with the arterial access location and venous return location. In an embodiment, the shunt 120 can include one or more extension tubes that can be used to vary the length of the shunt 120. The extension tubes can be modularly attached to the shunt 120 to achieve a desired length. The modular aspect of the shunt 120 permits the user to lengthen the shunt 120 as needed depending on the site of venous return. For example, in some patients, the internal jugular vein IJV is small and/or tortuous. The risk of complications at this site may be higher than at some other locations, due to proximity to other anatomic structures. In addition, hematoma in the neck may lead to airway obstruction and/or cerebral vascular complications. Consequently, for such patients it may be desirable to locate the venous return site at a location other than the internal jugular vein IJV, such as the femoral vein. A femoral vein return site may be accomplished percutaneously, with lower risk of serious complication, and also offers an alternative venous access to the central vein if the internal jugular vein IJV is not available. Furthermore, the femoral venous return changes the layout of the reverse flow shunt such that the shunt controls may be located closer to the "working area" of the intervention, where the devices are being introduced and the contrast injection port is located.

[0163] In an embodiment, the shunt 120 has an internal diameter of 4.76 mm (3/16 inch) and has a length of 40-70 cm. As mentioned, the length of the shunt can be adjusted or can vary from what is described herein.

[0164] In an embodiment, the shunt may contain a port which can be connected to an aspiration source such as a syringe, suction pump, or the like.

[0165] In an additional embodiment, the shunt may contain an element that connects to an active pump, for example a peristaltic pump, a diaphragm pump, an impeller pump, or a syringe pump.

Flow Control Assembly - Regulation and Monitoring of Retrograde Flow

[0166] The flow control assembly 125 interacts with the retrograde shunt 120 to regulate and/or monitor the retrograde flow rate from the common carotid artery to the venous return site, such as the internal jugular vein, or to the external receptacle. In this regard, the flow control assembly 125 enables the user to achieve higher maximum flow rates than existing

systems and to also selectively adjust, set, or otherwise modulate the retrograde flow rate. Various mechanisms can be used to regulate the retrograde flow rate, as described more fully below. The flow control assembly 125 enables the user to configure retrograde blood flow in a manner that is suited for various treatment regimens, as described below.

[0167] In general, the ability to control the continuous retrograde flow rate allows the physician to adjust the protocol for individual patients and stages of the procedure. The retrograde blood flow rate will typically be controlled over a range from a low rate to a high rate. The high rate can be at least two fold higher than the low rate, typically being at least three fold higher than the low rate, and often being at least five fold higher than the low rate, or even higher. In an embodiment, the high rate is at least three fold higher than the low rate and in another embodiment the high rate is at least six fold higher than the low rate. While it is generally desirable to have a high retrograde blood flow rate to maximize the extraction of emboli from the carotid arteries, the ability of patients to tolerate retrograde blood flow will vary. Thus, by having a system and protocol which allows the retrograde blood flow rate to be easily modulated, the treating physician can determine when the flow rate exceeds the tolerable level for that patient and set the reverse flow rate accordingly. For patients who cannot tolerate continuous high reverse flow rates, the physician can chose to turn on high flow only for brief, critical portions of the procedure when the risk of embolic debris is highest. At short intervals, for example between 15 seconds and 1 minute, patient tolerance limitations are usually not a factor.

[0168] In specific embodiments, the continuous retrograde blood flow rate can be controlled at a base line flow rate in the range from 10 ml/min to 200 ml/min, typically from 20 ml/min to 100 ml/min. These flow rates will be tolerable to the majority of patients. Although flow rate is maintained at the base line flow rate during most of the procedure, at times when the risk of emboli release is increased, the flow rate can be increased above the base line for a short duration in order to improve the ability to capture such emboli. For example, the retrograde blood flow rate can be increased above the base line when the stent catheter is being introduced, when the stent is being deployed, pre- and post-dilatation of the stent, removal of the common carotid artery occlusion, and the like.

[0169] The flow rate control system can be cycled between a relatively low flow rate and a relatively high flow rate in order to "flush" the carotid arteries in the region of the carotid

bifurcation prior to reestablishing antegrade flow. Such cycling can be established with a high flow rate which can be approximately two to six fold greater than the low flow rate, typically being about three fold greater. The cycles can typically have a length in the range from 0.5 seconds to 10 seconds, usually from 2 seconds to 5 seconds, with the total duration of the cycling being in the range from 5 seconds to 60 seconds, usually from 10 seconds to 30 seconds.

[0170] Figure 15 shows an example of the system 100 with a schematic representation of the flow control assembly 125, which is positioned along the shunt 120 such that retrograde blood flow passes through or otherwise communicates with at least a portion of the flow control assembly 125. The flow control assembly 125 can include various controllable mechanisms for regulating and/or monitoring retrograde flow. The mechanisms can include various means of controlling the retrograde flow, including one or more pumps 1110, valves 1115, syringes 1120 and/or a variable resistance component 1125. The flow control assembly 125 can be manually controlled by a user and/or automatically controlled via a controller 1130 to vary the flow through the shunt 120. For example, varying the flow resistance, the rate of retrograde blood flow through the shunt 120 can be controlled. The controller 1130, which is described in more detail below, can be integrated into the flow control assembly 125 or it can be a separate component that communicates with the components of the flow control assembly 125.

[0171] In addition, the flow control assembly 125 can include one or more flow sensors 1135 and/or anatomical data sensors 1140 (described in detail below) for sensing one or more aspects of the retrograde flow. A filter 1145 can be positioned along the shunt 120 for removing emboli before the blood is returned to the venous return site. When the filter 1145 is positioned upstream of the controller 1130, the filter 1145 can prevent emboli from entering the controller 1145 and potentially clogging the variable flow resistance component 1125. It should be appreciated that the various components of the flow control assembly 125 (including the pump 1110, valves 1115, syringes 1120, variable resistance component 1125, sensors 1135/1140, and filter 1145) can be positioned at various locations along the shunt 120 and at various upstream or downstream locations relative to one another. The components of the flow control assembly 125 are not limited to the locations shown in Figure 15. Moreover, the flow control assembly 125 does not necessarily include all of the components but can rather include various sub-combinations of the components. For example, a syringe could optionally be used within the flow control assembly 125 for purposes of regulating flow or it could be used outside of the

assembly for purposes other than flow regulation, such as to introduce fluid such as radiopaque contrast into the artery in an antegrade direction via the shunt 120.

[0172] Both the variable resistance component 1125 and the pump 1110 can be coupled to the shunt 120 to control the retrograde flow rate. The variable resistance component 1125 controls the flow resistance, while the pump 1110 provides for positive displacement of the blood through the shunt 120. Thus, the pump can be activated to drive the retrograde flow rather than relying on the perfusion stump pressures of the ECA and ICA and the venous back pressure to drive the retrograde flow. The pump 1110 can be a peristaltic tube pump or any type of pump including a positive displacement pump. The pump 1110 can be activated and deactivated (either manually or automatically via the controller 1130) to selectively achieve blood displacement through the shunt 120 and to control the flow rate through the shunt 120. Displacement of the blood through the shunt 120 can also be achieved in other manners including using the aspiration syringe 1120, or a suction source such as a vacutainer, vaculock syringe, or wall suction may be used. The pump 1110 can communicate with the controller 1130.

[0173] One or more flow control valves 1115 can be positioned along the pathway of the shunt. The valve(s) can be manually actuated or automatically actuated (via the controller 1130). The flow control valves 1115 can be, for example one-way valves to prevent flow in the antegrade direction in the shunt 120, check valves, or high pressure valves which would close off the shunt 120, for example during high-pressure contrast injections (which are intended to enter the arterial vasculature in an antegrade direction).

[0174] The controller 1130 communicates with components of the system 100 including the flow control assembly 125 to enable manual and/or automatic regulation and/or monitoring of the retrograde flow through the components of the system 100 (including, for example, the shunt 120, the arterial access device 110, the venous return device 115 and the flow control assembly 125). For example, a user can actuate one or more actuators on the controller 1130 to manually control the components of the flow control assembly 125. Manual controls can include switches or dials or similar components located directly on the controller 1130 or components located remote from the controller 1130 such as a foot pedal or similar device. The controller 1130 can also automatically control the components of the system 100 without requiring input from the user. In an embodiment, the user can program software in the

controller 1130 to enable such automatic control. The controller 1130 can control actuation of the mechanical portions of the flow control assembly 125. The controller 1130 can include circuitry or programming that interprets signals generated by sensors 1135/1140 such that the controller 1130 can control actuation of the flow control assembly 125 in response to such signals generated by the sensors.

[0175] The flow control assembly 125 may also include an active pump actuator which interfaces with an element in the shunt to enable active retrograde pumping of blood, such as a pump head for a roller pump, a rotary motor for an impeller-style pump, or the like. The controller 1130 would provide controls for the pump rate.

[0176] The representation of the controller 1130 in Figure 15 is merely exemplary. It should be appreciated that the controller 1130 can vary in appearance and structure. The controller 1130 is shown in Figure 15 as being integrated in a single housing. This permits the user to control the flow control assembly 125 from a single location. It should be appreciated that any of the components of the controller 1130 can be separated into separate housings. Further, Figure 15 shows the controller 1130 and flow control assembly 125 as separate housings. It should be appreciated that the controller 1130 and flow control regulator 125 can be integrated into a single housing or can be divided into multiple housings or components.

Flow State Indicator(s)

[0177] The controller 1130 can include one or more indicators that provides a visual and/or audio signal to the user regarding the state of the retrograde flow. An audio indication advantageously reminds the user of a flow state without requiring the user to visually check the flow controller 1130. The indicator(s) can include a speaker 1150 and/or a light 1155 or any other means for communicating the state of retrograde flow to the user. The controller 1130 can communicate with one or more sensors of the system to control activation of the indicator. Or, activation of the indicator can be tied directly to the user actuating one of the flow control actuators 1165. The indicator need not be a speaker or a light. The indicator could simply be a button or switch that visually indicates the state of the retrograde flow. For example, the button being in a certain state (such as a pressed or down state) may be a visual indication that the retrograde flow is in a high state. Or, a switch or dial pointing toward a particular labeled flow state may be a visual indication that the retrograde flow is in the labeled state.

[0178] The indicator can provide a signal indicative of one or more states of the retrograde flow. In an embodiment, the indicator identifies only two discrete states: a state of "high" flow rate and a state of "low" flow rate. In another embodiment, the indicator identifies more than two flow rates, including a "high" flow rate, a "medium" flow rate, and a "low" rate. The indicator can be configured to identify any quantity of discrete states of the retrograde flow or it can identify a graduated signal that corresponds to the state of the retrograde flow. In this regard, the indicator can be a digital or analog meter 1160 that indicates a value of the retrograde flow rate, such as in ml/min or any other units.

[0179] In an embodiment, the indicator is configured to indicate to the user whether the retrograde flow rate is in a state of "high" flow rate or a "low" flow rate. For example, the indicator may illuminate in a first manner (e.g., level of brightness) and/or emit a first audio signal when the flow rate is high and then change to a second manner of illumination and/or emit a second audio signal when the flow rate is low. Or, the indicator may illuminate and/or emit an audio signal only when the flow rate is high, or only when the flow rate is low. Given that some patients may be intolerant of a high flow rate or intolerant of a high flow rate beyond an extended period of time, it can be desirable that the indicator provide notification to the user when the flow rate is in the high state. This would serve as a fail-safe feature.

[0180] In another embodiment, the indicator provides a signal (audio and/or visual) when the flow rate changes state, such as when the flow rate changes from high to low and/or vice-versa. In another embodiment, the indicator provides a signal when no retrograde flow is present, such as when the shunt 120 is blocked or one of the stopcocks in the shunt 120 is closed.

Flow Rate Actuators

[0181] The controller 1130 can include one or more actuators that the user can press, switch, manipulate, or otherwise actuate to regulate the retrograde flow rate and/or to monitor the flow rate. For example, the controller 1130 can include a flow control actuator 1165 (such as one or more buttons, knobs, dials, switches, etc.) that the user can actuate to cause the controller to selectively vary an aspect of the reverse flow. For example, in the illustrated embodiment, the flow control actuator 1165 is a knob that can be turned to various discrete positions each of which corresponds to the controller 1130 causing the system 100 to achieve a particular retrograde flow state. The states include, for example, (a) OFF; (b) LO-FLOW; (c) HI-FLOW; and (d) ASPIRATE. It should be appreciated that the foregoing states are merely exemplary

and that different states or combinations of states can be used. The controller 1130 achieves the various retrograde flow states by interacting with one or more components of the system, including the sensor(s), valve(s), variable resistance component, and/or pump(s). It should be appreciated that the controller 1130 can also include circuitry and software that regulates the retrograde flow rate and/or monitors the flow rate such that the user wouldn't need to actively actuate the controller 1130.

[0182] The OFF state corresponds to a state where there is no retrograde blood flow through the shunt 120. When the user sets the flow control actuator 1165 to OFF, the controller 1130 causes the retrograde flow to cease, such as by shutting off valves or closing a stop cock in the shunt 120. The LO-FLOW and HI-FLOW states correspond to a low retrograde flow rate and a high retrograde flow rate, respectively. When the user sets the flow control actuator 1165 to LO-FLOW or HI-FLOW, the controller 1130 interacts with components of the flow control regulator 125 including pump(s) 1110, valve(s) 1115 and/or variable resistance component 1125 to increase or decrease the flow rate accordingly. Finally, the ASPIRATE state corresponds to opening the circuit to a suction source, for example a vacutainer or suction unit, if active retrograde flow is desired. The suction source can be coupled to any portion of the circuit, including the shunt 120 or the arterial access device 110.

[0183] The system can be used to vary the blood flow between various states including an active state, a passive state, an aspiration state, and an off state. The active state corresponds to the system using a means that actively drives retrograde blood flow. Such active means can include, for example, a pump, syringe, vacuum source, etc. The passive state corresponds to when retrograde blood flow is driven by the perfusion stump pressures of the ECA and ICA and possibly the venous pressure. The aspiration state corresponds to the system using a suction source, for example a vacutainer or suction unit, to drive retrograde blood flow. The off state corresponds to the system having zero retrograde blood flow such as the result of closing a stopcock or valve. The low and high flow rates can be either passive or active flow states. In an embodiment, the particular value (such as in ml/min) of either the low flow rate and/or the high flow rate can be predetermined and/or pre-programmed into the controller such that the user does not actually set or input the value. Rather, the user simply selects "high flow" and/or "low flow" (such as by pressing an actuator such as a button on the controller 1130) and the controller 1130 interacts with one or more of the components of the flow control assembly 125 to cause the flow rate to achieve the predetermined high or low flow rate value. In another

embodiment, the user sets or inputs a value for low flow rate and/or high flow rate such as into the controller. In another embodiment, the low flow rate and/or high flow rate is not actually set. Rather, external data (such as data from the anatomical data sensor 1140) is used as the basis for affects the flow rate.

[0184] The flow control actuator 1165 can be multiple actuators, for example one actuator, such as a button or switch, to switch state from LO-FLOW to HI-FLOW and another to close the flow loop to OFF, for example during a contrast injection where the contrast is directed antegrade into the carotid artery. In an embodiment, the flow control actuator 1165 can include multiple actuators. For example, one actuator can be operated to switch flow rate from low to high, another actuator can be operated to temporarily stop flow, and a third actuator (such as a stopcock) can be operated for aspiration using a syringe. In another example, one actuator is operated to switch to LO-FLOW and another actuator is operated to switch to HI-FLOW. Or, the flow control actuator 1165 can include multiple actuators to switch states from LO-FLOW to HI-FLOW and additional actuators for fine-tuning flow rate within the high flow state and low flow state. Upon switching between LO-FLOW and HI-FLOW, these additional actuators can be used to fine-tune the flow rates within those states. Thus, it should be appreciated that within each state (i.e. high flow state and low flow states) a variety of flow rates can be dialed in and fine-tuned. A wide variety of actuators can be used to achieve control over the state of flow.

[0185] The controller 1130 or individual components of the controller 1130 can be located at various positions relative to the patient and/or relative to the other components of the system 100. For example, the flow control actuator 1165 can be located near the hemostasis valve where any interventional tools are introduced into the patient in order to facilitate access to the flow control actuator 1165 during introduction of the tools. The location may vary, for example, based on whether a transfemoral or a transcervical approach is used. The controller 1130 can have a wireless connection to the remainder of the system 100 and/or a wired connection of adjustable length to permit remote control of the system 100. The controller 1130 can have a wireless connection with the flow control regulator 125 and/or a wired connection of adjustable length to permit remote control of the flow control regulator 125. The controller 1130 can also be integrated in the flow control regulator 125. Where the controller 1130 is mechanically connected to the components of the flow control assembly 125, a tether with mechanical actuation capabilities can connect the controller 1130 to one or more of the

components. In an embodiment, the controller 1130 can be positioned a sufficient distance from the system 100 to permit positioning the controller 1130 outside of a radiation field when fluoroscopy is in use.

[0186] The controller 1130 and any of its components can interact with other components of the system (such as the pump(s), sensor(s), shunt, etc.) in various manners. For example, any of a variety of mechanical connections can be used to enable communication between the controller 1130 and the system components. Alternately, the controller 1130 can communicate electronically or magnetically with the system components. Electro-mechanical connections can also be used. The controller 1130 can be equipped with control software that enables the controller to implement control functions with the system components. The controller itself can be a mechanical, electrical or electro-mechanical device. The controller can be mechanically, pneumatically, or hydraulically actuated or electromechanically actuated (for example in the case of solenoid actuation of flow control state). The controller 1130 can include a computer, computer processor, and memory, as well as data storage capabilities.

Sensor(s)

[0187] As mentioned, the flow control assembly 125 can include or interact with one or more sensors, which communicate with the system 100 and/or communicate with the patient's anatomy. Each of the sensors can be adapted to respond to a physical stimulus (including, for example, heat, light, sound, pressure, magnetism, motion, etc.) and to transmit a resulting signal for measurement or display or for operating the controller 1130. In an embodiment, the flow sensor 1135 interacts with the shunt 120 to sense an aspect of the flow through the shunt 120, such as flow velocity or volumetric rate of blood flow. The flow sensor 1135 could be directly coupled to a display that directly displays the value of the volumetric flow rate or the flow velocity. Or the flow sensor 1135 could feed data to the controller 1130 for display of the volumetric flow rate or the flow velocity.

[0188] The type of flow sensor 1135 can vary. The flow sensor 1135 can be a mechanical device, such as a paddle wheel, flapper valve, rolling ball, or any mechanical component that responds to the flow through the shunt 120. Movement of the mechanical device in response to flow through the shunt 120 can serve as a visual indication of fluid flow and can also be calibrated to a scale as a visual indication of fluid flow rate. The mechanical device can be coupled to an electrical component. For example, a paddle wheel can be positioned in the shunt

120 such that fluid flow causes the paddle wheel to rotate, with greater rate of fluid flow causing a greater speed of rotation of the paddle wheel. The paddle wheel can be coupled magnetically to a Hall-effect sensor to detect the speed of rotation, which is indicative of the fluid flow rate through the shunt 120.

[0189] In an embodiment, the flow sensor 1135 is an ultrasonic or electromagnetic flow meter, which allows for blood flow measurement without contacting the blood through the wall of the shunt 120. An ultrasonic or electromagnetic flow meter can be configured such that it does not have to contact the internal lumen of the shunt 120. In an embodiment, the flow sensor 1135 at least partially includes a Doppler flow meter, such as a Transonic flow meter, that measures fluid flow through the shunt 120. It should be appreciated that any of a wide variety of sensor types can be used including an ultrasound flow meter and transducer. Moreover, the system can include multiple sensors.

[0190] The system 100 is not limited to using a flow sensor 1135 that is positioned in the shunt 120 or a sensor that interacts with the venous return device 115 or the arterial access device 110. For example, an anatomical data sensor 1140 can communicate with or otherwise interact with the patient's anatomy such as the patient's neurological anatomy. In this manner, the anatomical data sensor 1140 can sense a measurable anatomical aspect that is directly or indirectly related to the rate of retrograde flow from the carotid artery. For example, the anatomical data sensor 1140 can measure blood flow conditions in the brain, for example the flow velocity in the middle cerebral artery, and communicate such conditions to a display and/or to the controller 1130 for adjustment of the retrograde flow rate based on predetermined criteria. In an embodiment, the anatomical data sensor 1140 comprises a transcranial Doppler ultrasonography (TCD), which is an ultrasound test that uses reflected sound waves to evaluate blood as it flows through the brain. Use of TCD results in a TCD signal that can be communicated to the controller 1130 for controlling the retrograde flow rate to achieve or maintain a desired TCD profile. The anatomical data sensor 1140 can be based on any physiological measurement, including reverse flow rate, blood flow through the middle cerebral artery, TCD signals of embolic particles, or other neuromonitoring signals.

[0191] In an embodiment, the system 100 comprises a closed-loop control system. In the closed-loop control system, one or more of the sensors (such as the flow sensor 1135 or the anatomical data sensor 1140) senses or monitors a predetermined aspect of the system 100 or

the anatomy (such as, for example, reverse flow rate and/or neuromonitoring signal). The sensor(s) feed relevant data to the controller 1130, which continuously adjusts an aspect of the system as necessary to maintain a desired retrograde flow rate. The sensors communicate feedback on how the system 100 is operating to the controller 1130 so that the controller 1130 can translate that data and actuate the components of the flow control regulator 125 to dynamically compensate for disturbances to the retrograde flow rate. For example, the controller 1130 may include software that causes the controller 1130 to signal the components of the flow control assembly 125 to adjust the flow rate such that the flow rate is maintained at a constant state despite differing blood pressures from the patient. In this embodiment, the system 100 need not rely on the user to determine when, how long, and/or what value to set the reverse flow rate in either a high or low state. Rather, software in the controller 1130 can govern such factors. In the closed loop system, the controller 1130 can control the components of the flow control assembly 125 to establish the level or state of retrograde flow (either analog level or discreet state such as high, low, baseline, medium, etc.) based on the retrograde flow rate sensed by the sensor 1135.

[0192] In an embodiment, the anatomical data sensor 1140 (which measures a physiologic measurement in the patient) communicates a signal to the controller 1130, which adjusts the flow rate based on the signal. For example the physiological measurement may be based on flow velocity through the MCA, TCD signal, or some other cerebral vascular signal. In the case of the TCD signal, TCD may be used to monitor cerebral flow changes and to detect microemboli. The controller 1130 may adjust the flow rate to maintain the TCD signal within a desired profile. For example, the TCD signal may indicate the presence of microemboli ("TCD hits") and the controller 1130 can adjust the retrograde flow rate to maintain the TCD hits below a threshold value of hits.

[0193] In the case of the MCA flow, the controller 1130 can set the retrograde flow rate at the "maximum" flow rate that is tolerated by the patient, as assessed by perfusion to the brain. The controller 1130 can thus control the reverse flow rate to optimize the level of protection for the patient without relying on the user to intercede. In another embodiment, the feedback is based on a state of the devices in the system 100 or the interventional tools being used. For example, a sensor may notify the controller 1130 when the system 100 is in a high risk state, such as when an interventional catheter is positioned in the sheath 605. The controller 1130 then adjusts the flow rate to compensate for such a state.

[0194] The controller 1130 can be used to selectively augment the retrograde flow in a variety of manners. For example, it has been observed that greater reverse flow rates may cause a resultant greater drop in blood flow to the brain, most importantly the ipsilateral MCA, which may not be compensated enough with collateral flow from the Circle of Willis. Thus a higher reverse flow rate for an extended period of time may lead to conditions where the patient's brain is not getting enough blood flow, leading to patient intolerance as exhibited by neurologic symptoms. Studies show that MCA blood velocity less than 10 cm/sec is a threshold value below which patient is at risk for neurological blood deficit. There are other markers for monitoring adequate perfusion to the brains, such as EEG signals. However, a high flow rate may be tolerated even up to a complete stoppage of MCA flow for a short period, up to about 15 seconds to 1 minute.

[0195] Thus, the controller 1130 can optimize embolic debris capture by automatically increasing the reverse flow only during limited time periods which correspond to periods of heightened risk of emboli generation during a procedure. These periods of heightened risk include the period of time while an interventional device (such as the thrombectomy device 15) crosses the thrombotic occlusion 10. During lower risk periods, the controller can cause the reverse flow rate to revert to a lower, baseline level. This lower level may correspond to a low reverse flow rate in the ICA, or even slight antegrade flow in those patients with a high ECA to ICA perfusion pressure ratio.

[0196] In a flow regulation system where the user manually sets the state of flow, there is risk that the user may not pay attention to the state of retrograde flow (high or low) and accidentally keep the circuit on high flow. This may then lead to adverse patient reactions. In an embodiment, as a safety mechanism, the default flow rate is the low flow rate. This serves as a fail-safe measure for patient's that are intolerant of a high flow rate. In this regard, the controller 1130 can be biased toward the default rate such that the controller causes the system to revert to the low flow rate after passage of a predetermined period of time of high flow rate. The bias toward low flow rate can be achieved via electronics or software, or it can be achieved using mechanical components, or a combination thereof. In an embodiment, the flow control actuator 1165 of the controller 1130 and/or valve(s) 1115 and/or pump(s) 1110 of the flow control regulator 125 are spring loaded toward a state that achieves a low flow rate. The controller 1130 is configured such that the user may over-ride the controller 1130 such as to manually cause the system to revert to a state of low flow rate if desired.

[0197] In another safety mechanism, the controller 1130 includes a timer 1170 (Figure 15) that keeps time with respect to how long the flow rate has been at a high flow rate. The controller 1130 can be programmed to automatically cause the system 100 to revert to a low flow rate after a predetermined time period of high flow rate, for example after 15, 30, or 60 seconds or more of high flow rate. After the controller reverts to the low flow rate, the user can initiate another predetermined period of high flow rate as desired. Moreover, the user can override the controller 1130 to cause the system 100 to move to the low flow rate (or high flow rate) as desired.

[0198] In an exemplary procedure, embolic debris capture is optimized while not causing patient tolerance issues by initially setting the level of retrograde flow at a low rate, and then switching to a high rate for discreet periods of time during critical stages in the procedure. Alternately, the flow rate is initially set at a high rate, and then verifying patient tolerance to that level before proceeding with the rest of the procedure. If the patient shows signs of intolerance, the retrograde flow rate is lowered. Patient tolerance may be determined automatically by the controller based on feedback from the anatomical data sensor 1140 or it may be determined by a user based on patient observation. The adjustments to the retrograde flow rate may be performed automatically by the controller or manually by the user. Alternately, the user may monitor the flow velocity through the middle cerebral artery (MCA), for example using TCD, and then to set the maximum level of reverse flow which keeps the MCA flow velocity above the threshold level. In this situation, the entire procedure may be done without modifying the state of flow. Adjustments may be made as needed if the MCA flow velocity changes during the course of the procedure, or the patient exhibits neurologic symptoms.

Exemplary Mechanism to Regulate Reverse Flow

[0199] The system 100 is adapted to regulate retrograde flow in a variety of manners. Any combination of the pump 1110, valve 1115, syringe 1120, and/or variable resistance component 1125 can be manually controlled by the user or automatically controlled via the controller 1130 to adjust the retrograde flow rate. Thus, the system 100 can regulate retrograde flow in various manners, including controlling an active flow component (e.g., pump, syringe, etc.), reducing the flow restriction, switching to an aspiration source (such as a pre-set VacLock syringe, Vacutainer, suction system, or the like), or any combination thereof.

[0200] In the situation where an external receptacle or reservoir is used, the retrograde flow may be augmented in various manners. The reservoir has a head height comprised of the height of the blood inside the reservoir and the height of the reservoir with respect to the patient. Reverse flow into the reservoir may be modulated by setting the reservoir height to increase or decrease the amount of pressure gradient from the CCA to the reservoir. In an embodiment, the reservoir is raised to increase the reservoir pressure to a pressure that is greater than venous pressure. Or, the reservoir can be positioned below the patient, such as down to a level of the floor, to lower the reservoir pressure to a pressure below venous or atmospheric pressure.

[0201] The variable flow resistance in shunt 120 may be provided in a wide variety of ways. In this regard, flow resistance component 1125 can cause a change in the size or shape of the shunt to vary flow conditions and thereby vary the flow rate. Or, the flow resistance component 1125 can re-route the blood flow through one or more alternate flow pathways in the shunt to vary the flow conditions. Some exemplary embodiments of the flow resistance component 1125 are now described.

[0202] In a non-limiting embodiment, the flow resistance through shunt 120 may be changed by providing two or more alternative flow paths. As shown in Figures 16A and 16B, the flow through shunt 120 passes through a main lumen 1700 as well as secondary lumen 1705. The secondary lumen 1705 is longer and/or has a smaller diameter than the main lumen 1700. Thus, the secondary lumen 1705 has higher flow resistance than the main lumen 1700. By passing the blood through both these lumens, the flow resistance will be at a minimum. Blood is able to flow through both lumens 1700 and 1705 due to the pressure drop created in the main lumen 1700 across the inlet and outlet of the secondary lumen 1705. This has the benefit of preventing stagnant blood. As shown in Figure 20B, by blocking flow through the main lumen 1700 of shunt 120, the flow can be diverted entirely to the secondary lumen 1705, thus increasing the flow resistance and reducing the blood flow rate. It will be appreciated that additional flow lumens could also be provided in parallel to allow for a three, four, or more discrete flow resistances. The shunt 120 may be equipped with a valve 1710 that controls flow to the main lumen 1700 and the secondary lumen 1705 with the valve 1710 being controlled by the controller 1130 or being controlled manually by the user. The embodiment of Figures 16A and 16B has an advantage in that this embodiment in that it does not require as small of lumen sizes to achieve desired retrograde flow rates as some of the other embodiments of variable flow

resistance mechanisms. This is a benefit in blood flow lines in that there is less chance of clogging and causing clots in larger lumen sizes than smaller lumen sizes.

Closure

[0203] Any type of closing element, including a self-closing element, may be deployed about the penetration in the wall of the common carotid artery prior to withdrawing the sheath 605 at the end of the procedure. The closing element can be deployed at or near the beginning of the procedure, but optionally, the closing element could be deployed as the sheath is being withdrawn, often being released from a distal end of the sheath onto the wall of the artery where the penetration occurs, such as the common carotid artery. Use of a self-closing element is advantageous since it affects substantially the rapid closure of the penetration in the common carotid artery as the sheath is being withdrawn. Such rapid closure can reduce or eliminate unintended blood loss either at the end of the procedure or during accidental dislodgement of the sheath. In addition, such a self-closing element may reduce the risk of arterial wall dissection during access. Further, the self-closing element may be configured to exert a frictional or other retention force on the sheath during the procedure. Such a retention force is advantageous and can reduce the chance of accidentally dislodging the sheath during the procedure. A self-closing element eliminates the need for vascular surgical closure of the artery with suture after sheath removal, reducing the need for a large surgical field and greatly reducing the surgical skill required for the procedure.

[0204] The disclosed systems and methods may employ a wide variety of closing elements, such as mechanical elements which include an anchor portion and a closing portion such as a self-closing portion. The anchor portion may comprise hooks, pins, staples, clips, tine, suture, or the like, which are engaged in the exterior surface of the common carotid artery about the penetration to immobilize the self-closing element when the penetration is fully open. The self-closing element may also include a spring-like or other self-closing portion which, upon removal of the sheath, will close the anchor portion in order to draw the tissue in the arterial wall together to provide closure. Usually, the closure will be sufficient so that no further measures need be taken to close or seal the penetration. Optionally, however, it may be desirable to provide for supplemental sealing of the self-closing element after the sheath is withdrawn. For example, the self-closing element and/or the tissue tract in the region of the element can be treated with hemostatic materials, such as bioabsorbable polymers, collagen

plugs, glues, sealants, clotting factors, or other clot-promoting agents. Alternatively, the tissue or self-closing element could be sealed using other sealing protocols, such as electrocautery, suturing, clipping, stapling, or the like. In another method, the self-closing element will be a self-sealing membrane or gasket material which is attached to the outer wall of the vessel with clips, glue, bands, or other means. The self-sealing membrane may have an inner opening such as a slit or cross cut, which would be normally closed against blood pressure. Any of these self-closing elements could be designed to be placed in an open surgical procedure, or deployed percutaneously. The closure example described below can be modified for delivery of an expandable collagen plug that unfurls or expands once deployed at the artery so as to fill an arterial opening and achieve hemostasis.

[0205] In an embodiment, the closing element is a is a suture-based blood vessel closure device that can perform the dilation of an arteriotomy puncture, and therefore does not require previous dilation of the arteriotomy puncture by a separate device or by a procedural sheath dilator. The suture-based vessel closure device can place one or more sutures across a vessel access site such that, when the suture ends are tied off after sheath removal, the stitch or stitches provide hemostasis to the access site. The sutures can be applied either prior to insertion of a procedural sheath through the arteriotomy or after removal of the sheath from the arteriotomy. The device can maintain temporary hemostasis of the arteriotomy after placement of sutures but before and during placement of a procedural sheath and can also maintain temporary hemostasis after withdrawal of the procedural sheath but before tying off the suture. Some exemplary suture-based blood vessel disclosure devices are described in the following U.S. Patents, which are incorporated herein by reference in their entirety: U.S. Patent No. 7,001,400, and U.S. Patent No. 7,004,952.

[0206] In an embodiment described with reference to Figures 19A through 19D, there is shown a system and method for hemostasis of a puncture site in an artery such as the carotid artery using a hemostasis delivery device 1902, which can be an elongated body configured to deploy a device configured to achieve hemostasis. A user deploys an introducer sheath 1905 (which can be a separate sheath or can be the arterial access device 110) into the access location of the artery such as in the neck. The introducer sheath can be percutaneously deployed to the artery. The access location can extend through skin 1910 and an outer wall of the carotid artery CA. A distal end of the sheath 1905 is positioned in a lumen 1915 of the carotid artery CA. As shown in Figure 19B, the user then inserts the hemostasis delivery device 1902 through

the introducer sheath 1905 with a hemostasis member coupled to the hemostasis delivery device such as at a distal end or region of the hemostasis delivery device. The hemostasis member can be, for example, an expansible hemostasis member 1920. The hemostasis delivery device 1902 is deployed through the sheath 1905 such that the hemostasis member 1920 is positioned outside a distal tip of the sheath 1905 and in the lumen 1915.

[0207] With reference now to Figure 19C and 19D, the hemostasis member 1720 is then caused to be deployed. The hemostasis member 1920 can be caused to expand outward and then the hemostasis device 1902 is pulled proximally to engage the hemostasis member 1920 with the wall of the artery. The introducer sheath 1905 is then removed leaving the expansible hemostasis member 1920 seated at a location 1925 that forms the entry into the carotid artery CA to achieve hemostasis. An external tension element, such as a clip 1920, can be positioned at the skin surface to maintain tension to hold the expansible hemostasis member 1720 in position. U.S. Patent No. 7,993,366, which is incorporated by reference, describes an example closure system.

Interventional Device – Aspiration Catheters

[0208] A variety of interventional devices can be used in conjunction with the disclosed systems, such as inserting an interventional device through the arterial access device 110 to perform a treatment. For example, the interventional device can include an aspiration catheter to provide localized aspiration at a location distal the sheath 605 of the arterial access device 110, such as for capturing and removing a blood clot in a blood vessel. For example, the aspiration catheter can be sized and shaped or otherwise configured to be inserted through the hemostasis valve 625, as well as into and through the proximal extension 610 and sheath 605 for accessing a treatment site within a blood vessel. The aspiration catheter may use a previously placed guide wire or other device to facilitate placement of a distal opening of the aspiration catheter near an occlusion. Once the distal opening of the aspiration catheter is positioned at or near the treatment site, the aspiration catheter may then be used to apply aspiration to the blood clot for capturing and removing the blood clot from the patient. For example, the aspiration catheter may be connected to an aspiration source such as a pump or a syringe.

[0209] In some embodiments, the arterial access device 110 and aspiration catheter may be configured for access to any number of a variety of vessels, including the common carotid

artery CCA and/or the femoral artery. For example, the aspiration catheter can be introduced into vasculature for occlusion (e.g., blood clot) retrieval from either a carotid artery access site or a femoral artery access site. As discussed above, the access device 110 can include a control assembly 125 and a shunt 120 that can be connected to a mechanism for passive or active reverse flow. For example, reverse flow can be performed during aspiration of an occlusion using any of the aspiration catheter embodiments described herein.

[0210] Figures 20A-20B illustrate an embodiment of an aspiration catheter 2100 including an elongated body 2110 and an inner lumen 2112 extending between a distal body end 2114 and a proximal body end 2116 of the elongated body 2110. In some embodiments, the elongated body 2110 is formed of a flexible material. The proximal body end 2116 can be configured to couple to an aspiration source, such as an active or passive aspiration mechanism (e.g., pump, syringe). The inner lumen 2112 can be defined by an inner wall 2126. The distal body end 2114 can include a distal opening 2120 defined at least in part by the inner lumen 2112. The distal opening 2120 can provide localized aspiration at a location distal of a distal-most end of the arterial access device 110, such as for capturing and removing a blood clot from a blood vessel.

[0211] As shown in Figures 20A-20B, the distal opening 2120 can be in fluid communication with the aspiration source and can include a suction area 2122 for applying suction to an occlusion, such as a blood clot, for capturing and removing the occlusion. For example, the suction area 2122 can be defined as a cross-sectional area of the inner lumen 2112 at the distal body end 2114. As such, the suction area 2122 can be determined based on a diameter of the distal opening 2120 and/or a perimeter 2124 of the inner lumen 2112 at the distal body end 2114. The inner lumen 2112 can be defined by an inner wall 2126.

[0212] For example, as the perimeter 2124 defining the distal opening 2120 increases, the suction area 2122 can increase thereby increasing the amount of suction force that can be applied to a blood clot. Greater suction forces provided by the aspiration catheter 2100 can result in more efficient and effective blood clot retrieval and removal by the aspiration catheter 2100. Secure capturing and removal of a blood clot can be important for returning blood flow to the vessel and reducing negative physical effects from the occlusion. At least some current occlusion retrieval/removal devices can require at least two attempts at capturing an occlusion for removal. The unsuccessful attempts to remove the occlusion can increase the time at which

blood flow along a part of the body is stopped and thus increases the likelihood that negative physical and/or cognitive effects can result. However, although having a larger suction area 2122 can improve occlusion procedure and patient outcomes, the size and shape of the aspiration catheter 2100, including the distal body end 2114 of the aspiration catheter 2100, can be limited by the arterial access device 110 and one or more vessels the aspiration catheter 2100 travels along for treatment of the occlusion.

[0213] The following describes various embodiments of an aspiration catheter 2100 that include a variety of distal features (e.g., deformers, shaped distal opening perimeters, occlusion graspers) that provide improved suction areas 2122 and/or occlusion capture/removal for achieving more efficient and effective aspiration of blood clots and restoring blood flow along one or more affected vessels. As will be described in greater detail below, some embodiments of the aspiration catheter 2100 can include a distal portion that is expandable, such as when positioned at a treatment location. Such expansion of the distal portion can increase the suction area 2122 provided by the aspiration catheter 2100 at the treatment location for achieving greater aspiration force. This can result in efficient and effective capturing and removal of a blood clot from a patient while allowing the aspiration catheter to have a smaller diameter for insertion into and travel along one or more blood vessels. In some embodiments, the aspiration catheter 2100 includes a shaped distal end (e.g., at the distal body end 2114) having a shape that achieves a longer length of the perimeter 2124 of the distal opening 2120 thereby forming a larger suction area 2122 without changing the diameter of the distal opening 2120. Various aspiration catheters 2100 including other features and functions, such as occlusion graspers, are described herein.

[0214] In some embodiments, the aspiration catheter 2100 includes at least one reinforcement element for reducing flexibility and increasing structural strength along at least a part of the elongated body 2110, such as to assist with advancing and positioning the aspiration catheter 2100. For example, the reinforcement element can extend along a first length of the elongated body 2110 between a proximal reinforcement end and a distal reinforcement end. For example, the proximal reinforcement end can be positioned at or adjacent the proximal body end 2116 of the elongated body 2110. Additionally, the distal reinforcement end can be positioned a second length from the distal body end 2114 of the elongated body 2110. As such, in some embodiments the second length of the elongated body

2110 can remain flexible and define an expandable distal portion of the elongated body 2110, as will be described in greater detail below.

[0215] For example, the expandable distal portion can be expanded at or adjacent an occlusion in order to increase the diameter of the distal opening 2120 thereby increasing the suction area 2122 that can be applied to the occlusion for efficiently and effectively capturing and removing the occlusion. Such capturing of the occlusion can include activation of the aspiration source thereby providing a vacuum at the distal opening 2120. Capturing the occlusion by the aspiration device 2100 can include securing (e.g., with aspiration and/or an occlusion capturing feature) the occlusion at and/or within the distal opening 2120. For example, the occlusion can be captured at or within the distal opening 2120 and/or distal portion, and then the aspiration catheter 2100 can be withdrawn once the occlusion is sufficiently removed and/or captured to allow blood flow to be returned to the affected vessel.

[0216] Embodiments of the aspiration catheter 2100 described herein can be made out of one or more of a variety of materials, including various materials for achieving desired characteristics. For example, the one or more reinforcement elements can be made out of a metal wire and/or Teflon material. In some embodiments, at least the distal portion of the elongated body 2110 of the aspiration catheter 2100 can be made out of a flexible material, such as a tie layer. For example, the flexible material forming at least a part of the expandable distal portion can be elastic to allow circumferential expansion at the distal opening 2120.

[0217] In some embodiments, at least the distal portion of the elongated body 2110 can include one or more liquid crystal polymer (LCP) fibers that can promote wall strength without significantly affecting flexibility. Various embodiments of the aspiration catheter 2100 for achieving improved capture and/or removal of occlusions for efficiently and effectively restoring blood flow are described in greater detail below.

[0218] Figures 21A-21D illustrate an embodiment of the aspiration catheter 2200 including an embodiment of the elongated body 2110 having an expandable distal portion 2230. The aspiration catheter 2200 of Figures 21A-21D can include the same or similar features and functions as discussed above with respect to the aspiration catheter 2100 of Figures 20A-20B. Additionally, the expandable distal portion 2230 of the elongated body 2110 can be flexible and deformable, such as to allow the distal opening 2120 to increase in diameter and thus

increase the suction area 2122 of the distal opening 2120, as will be described in greater detail below.

[0219] As shown in Figure 21A, the aspiration catheter 2200 can include one or more reinforcement elements 2240 extending along a first length 2250 of the elongated body 2110. For example, the reinforcement element 2240 can include a metal wire 2241 that helically extends along the inner wall 2126 of the first length 2250 of the elongated body 2110. Additionally, the reinforcement element 2240 can include a Teflon liner 2242 that extends along an inner diameter of the helical metal wire 2241, as shown in Figure 21A and 21C. For example, the reinforcement elements 2240 can extend along the first length 2250 of the elongated body 2110 between a proximal reinforcement end and a distal reinforcement end. For example, the proximal reinforcement end can be positioned at or adjacent the proximal body end 2116 of the elongated body 2110. The distal reinforcement end can be positioned a second length 2255 from the distal body end 2114 of the elongated body 2110. As such, the second length 2255 can remain flexible and define at least a part of the expandable distal portion 2230 of the elongated body 2110. Furthermore, each of the one or more reinforcement elements 2240 can extend along a variety of lengths of the elongated body 2110 proximal to the second length 2255 without departing from the scope of this disclosure.

[0220] In some embodiments, one or more LCP fibers can extend along the flexible second length 2255 of the elongated body 2110 to assist with promoting wall strength therealong without significantly affecting flexibility of the elongated body 2110 along the second length.

[0221] As shown in Figures 21A-21D, the aspiration catheter 2200 can include a deformer, such as an inflatable balloon 2260 that is coupled to and extends along the second length 2255 of the elongated body 2110. For example, the inflatable balloon 2260 can extend along a longitudinal axis of the elongated body 2110 and along an outer wall of the elongated body 2110. For example, the inflatable balloon 2260 can be secured (e.g., adhered) to the elongated body 2110 at one or more locations, such as at a distal end and/or a proximal end of the second length 2255. In some embodiments, the inner diameter of the inflatable balloon 2260 can be approximately the same as an outer diameter of the elongated body 2110 (e.g. along the second length). As shown in Figure 21A, the inflatable balloon 2260 can form a deflated configuration and, as shown in Figure 21C, the inflatable balloon 2260 can form an inflated configuration. In the inflated configuration, the expandable distal portion 2230 (e.g., the second length 2255

of the elongated body 2110) can be deformed and increase in diameter in the distal direction thereby increasing the diameter of the distal opening 2120 compared to when the inflatable balloon 2260 is in the deflated configuration.

[0222] As shown in Figures 21A and 21C, the inflatable balloon 2260 can be in fluid communication with a fill line 2262 that extends from a proximal end of the elongated body 2110 and can provide fluid (e.g., saline, contrast solution) to the inflatable balloon 2260 for allowing the inflatable balloon 2260 to form the inflated configuration. The fill line 2262 can also provide a fluid passageway for the inflatable balloon 2260 to dispense fluid for forming the deflated configuration.

[0223] For example, when the inflatable balloon 2260 is in a deflated configuration, as shown in Figure 21B, the distal opening 2120 can form a first suction area 2122a and have approximately the same diameter as the diameter of the elongated body 2110 along the first length 2250. In the inflated configuration, as shown in Figure 21D, the expandable distal portion 2230 can increase in diameter such that the distal opening 2120 forms a second suction area 2122b (e.g., having a second opening diameter) that is greater than the first suction area 2122a (e.g., having a first opening diameter). For example, as the inflatable balloon 2260 enlarges due to the fill line delivering fluid to the inflatable balloon 2260, the inflatable balloon 2260 can enlarge radially thereby deforming and radially expanding the expandable distal portion 2230. The radial expansion of the expandable distal portion 2230 can result in a larger diameter distal opening 2120 (e.g., the second opening diameter being larger than the first opening diameter) and larger suction area 2122 (compared to when the balloon 2260 is in the deflated configuration), which can allow the aspiration catheter 2200 to apply a greater suction force for retrieving an occlusion. Aspiration can be activated when the balloon 2260 is in the inflated configuration for capturing the occlusion at or within the expandable distal portion 2230 for removal from the vessel.

[0224] Figures 22A-22D illustrate another embodiment of the aspiration catheter 2300 including an embodiment of the expandable distal portion 2230. The aspiration catheter of Figures 22A-22D can include the same or similar features and functions as discussed and shown above with respect to the aspiration catheter 2200 of Figures 21A-21D. Furthermore, as shown in Figures 22A and 22C, the inflatable balloon 2360 of the aspiration catheter 2300 can extend helically around and along the second length 2255. As such, the inflatable balloon

2360 in Figures 22A-22D can have a smaller diameter and longer length compared to the inflatable balloon 2260 in Figures 21A-21D.

[0225] As shown in Figure 22B, when the inflatable balloon 2360 is in a deflated configuration, the distal opening 2120 can form a first suction area 2122a and have approximately the same diameter as the diameter of the elongated body 2110 along the first length 2250. In the inflated configuration, as shown in Figures 22C and 22D, the expandable distal portion 2230 can, as a result of the inflatable balloon 2360 forming the inflated configuration, deform and increase in diameter in the distal direction such that the distal opening 2120 forms a second suction area 2122b that is greater than the first suction area 2122a.

[0226] Figures 23A-23D illustrate another embodiment of the aspiration catheter 2400 including an embodiment of the elongate body 2110 having an expandable distal portion 2230. The aspiration catheter 2400 of Figures 23A-23D can include the same or similar features and functions as discussed above with respect to the aspiration catheter 2100 of Figures 21A-21D. Furthermore, the inflatable balloon 2460 of the aspiration catheter 2400 shown in Figures 23A-23D can extend helically around and along the second length 2255 and can be twisted along at least a part of the length of the balloon 2460 that extends helically about the second length 2255. As such, the inflatable balloon 2460 in Figures 23A-23D can have a smaller diameter and longer length compared to the inflatable balloon 2260 in Figures 21A-21D. Furthermore, the twisting of the inflatable balloon 2460 can result in the inflatable balloon 2460 in Figures 23A-23D having a longer length compared to the inflatable balloon 2260 in Figures 22A-22D. For example, longer balloon lengths can contribute to greater expanding of the expandable distal portion 2230 to form larger suction areas 2122, such as when the inflatable balloon 2460 is in the expanded configuration, as shown in Figures 23C and 23D. Figures 23A and 23D illustrate the inflatable balloon 2460 twisted and helically extending around the second length 2250 in the deflated configuration.

[0227] In some embodiments, the second length 2255 can be approximately 1 millimeter (mm) to approximately 5 mm in length. In some embodiments, the second length 2255 can be approximately 0.5 times to 2 times the diameter of the elongated body 2110. In some embodiments, the inflatable balloon can helically wrap around the second length 2255 of the elongate body approximately 1 time to approximately 5 times. The inflatable balloon can be

made out of variety of materials, such as one or more of a biocompatible material and a compliant material, including a polyurethane or a silicone material.

[0228] In some embodiments of the aspiration catheter, a balloon is not used to deform (e.g., expand) the expandable distal portion 2230, as will be discussed in greater detail below. For example, the aspiration catheter can include a deformer having a shape memory deformer positioned along and/or coupled to the second length 2255. For example, the shape memory deformer can be configured to form a collapsed configuration and an expanded configuration, such as for forming larger suction areas 2122 when the shape memory deformer is in the expanded configuration. For example, when the shape memory deformer is in the collapsed configuration along the second length 2255, the distal opening 2120 can form a first suction area 2122a and have approximately the same diameter as the diameter of the elongated body 2110 along the first length 2250. In the expanded configuration, the shape memory deformer can deform the expandable distal portion 2230 to increase in diameter such that the distal opening 2120 forms a second suction area 2122b that is greater than the first suction area 2122a.

[0229] In some embodiments, the shape memory deformer can include nitinol material, such as at least one nitinol wire that extends along the second length 2255. For example, the nitinol wire can be configured to form the collapsed configuration when the nitinol wire is below a first temperature (e.g., body temperature) and form the expanded configuration when the nitinol wire reaches and/or exceeds the first temperature. Other temperatures can be predetermined for causing the nitinol wire to form the collapsed and expanded configurations. For example, some embodiments of the aspiration catheter can include a thermally and/or electrically conductive wire that can extend between the shape memory deformer and a power source. As such, in some embodiments a current can be delivered along the conductive wire for increasing the nitinol wire temperature for causing the nitinol wire to transition into the expanded configuration. Other shape memory materials and formations of the nitinol material are within the scope of this disclosure.

[0230] Figures 24A-24D illustrate another embodiment of the aspiration catheter 2500 including an embodiment of the elongated body 2110 having an expandable distal portion 2230. The aspiration catheter 2500 of Figures 24A-24D can include the same or similar features and functions as discussed above with respect to the aspiration catheter 2100 of Figures 21A-21D, however, instead of the inflatable balloon 2260 extending along the second length

2255 for deforming (e.g., expanding) the expandable distal portion 2230, the aspiration catheter 2500 of Figures 24A-24D includes a shape memory deformer 2570 that can transition between a collapsed configuration, as shown in Figures 24C-24D, and an expanded configuration, as shown in Figures 24A-24B.

[0231] For example, the shape memory deformer 2570 can include at least one nitinol wire 2572 extending longitudinally along the second length 2255 of the elongated body 2110. As shown in Figures 24A-24D, the nitinol wire 2572 can extend longitudinally in a plurality of radial positions along the second length 2255. In some embodiments, the nitinol wire 2572 can extend along the inner wall 2126 of the inner lumen 2112 of the elongated body 2110 and/or extend along an outer wall of the elongated body 2110. An additional material sheath 2574 can extend over the nitinol wire 2572, such as to position the nitinol wire 2572 between the material sheath 2574 and the second length 2255 of the elongated body 2110. As discussed above, the shape memory deformer 2570 can transition between the collapsed and expanded configurations based on a temperature of the shape memory deformer 2570. In some embodiments, the nitinol wire 2572 can bend radially outward and form the expanded configuration when the nitinol wire 2572 reaches body temperature, as shown in Figures 24A and 24B.

[0232] For example, when the shape memory deformer 2570 is in the collapsed configuration along the second length 2255, as shown in Figures 24C and 24D, the distal opening 2120 can form a first suction area 2122a and have approximately the same diameter as the diameter of the elongated body 2110 along the first length 2250. In the expanded configuration, the shape memory deformer 2570 can deform the expandable distal portion 2230 to increase in diameter such that the distal opening 2120 forms a second suction area 2122b that is greater than the first suction area 2122a.

[0233] Figures 25A-25D illustrate another embodiment of the aspiration catheter 2600 including an embodiment of the elongate body 2110 having an expandable distal portion 2230. The aspiration catheter 2600 of Figures 25A-25D can include the same or similar features and functions as any one of the aspiration catheter embodiments disclosed herein. For example, the aspiration catheter 2600 can include an embodiment of the shape memory deformer 2670 that can transition between a collapsed configuration, as shown in Figures 25C-25D, and an expanded configuration, as shown in Figures 25A-25B.

[0234] As shown in Figures 25A-25D, the shape memory deformer 2670 can include a stent retriever 2675 positioned along the second length 2255, such as embedded between an inner wall 2126 of the elongated body 2110 and a material sheath 2574. For example, the stent retriever 2675 can include at least one nitinol wire 2572 extending in more than one direction and at one or more angles relative to the longitudinal axis of the inner lumen 2112. As shown in Figures 25A and 25C, the stent retriever 2675 can include a woven or braided nitinol wire 2572. As discussed above, the shape memory deformer 2670 can transition between the collapsed and expanded configurations based on a temperature of the shape memory deformer 2670. For example, the woven nitinol wires 2572 of the stent retriever 2675 can move to align closer to parallel with the longitudinal axis of the inner lumen 2112 when moving into the condensed configuration, as shown in Figure 25C. Additionally, the nitinol wires 2572 of the stent retriever 2675 can move to be more angled relative to the longitudinal axis when moving into the expanded configuration, as shown in Figure 25A, such as when the nitinol wires 2572 reaches a predefined temperature (e.g., body temperature).

[0235] For example, when the shape memory deformer 2670 is in the collapsed configuration along the second length 2255, the distal opening 2120 can form a first suction area 2122a and have approximately the same diameter as the diameter of the elongated body 2110 along the first length 2250. In the expanded configuration, the shape memory deformer 2670 can deform the expandable distal portion 2230 to increase in diameter such that the distal opening 2120 forms a second suction area 2122b that is greater than the first suction area 2122a.

[0236] Figures 26A-26D illustrate another embodiment of the aspiration catheter 2700 including an expandable distal portion 2230 of the elongated body 2110. The aspiration catheter 2700 of Figures 26A-26D can include the same or similar features and functions as any one of the aspiration catheter embodiments disclosed herein. Additionally, the aspiration catheter 2700 of Figures 26A-26D includes a moveable deformer 2770 that can be translated relative to the elongated body 2110. For example, the moveable deformer 2770 can form a collapsed configuration, as shown in Figures 26C-26D, when positioned along the first length 2250 (including reinforcement elements 2240) of the elongated body 2110 and form an expanded configuration, as shown in Figures 26A-26B, when positioned along the flexible second length 2255 including the expandable distal portion 2230 of the elongated body 2110.

[0237] For example, the moveable deformer 2770 can include a movable stent retriever 2775 that can be positioned along the first length 2250 and/or the second length 2255, such as slidably controlled by a physician (e.g., via a connection feature 2776). For example, the movable stent retriever 2775 can include at least one nitinol wire 2572 extending in more than one direction and at one or more angles relative to the longitudinal axis of the inner lumen 2112. As shown in Figures 26A and 26C, the movable stent retriever 2775 can include a woven or braided nitinol wire 2572 (e.g., formed into an expandable basket) that can radially expand such that when the movable stent retriever 2775 is positioned along the flexible second length 2255 the movable stent retriever 2775 can expand radially thereby expanding the distal opening 2120 to form a larger suction area 2122, as shown in Figures 26A and 26B. For example, the movable stent retriever 2775 can also form the expanded configuration when the movable stent retriever 2775 reaches a predefined temperature (e.g., body temperature). Retrieval and removal of the occlusion (using aspiration) can be performed with the stent retriever positioned along the second length 2255.

[0238] Figures 27A-27D illustrate another embodiment of the aspiration catheter 2800 including an expandable distal portion 2230 of the elongated body 2110. The aspiration catheter 2800 of Figures 27A-27D can include the same or similar features and functions as any one of the aspiration catheter embodiments disclosed herein, including a moveable deformer 2870 that can be translated relative to the elongated body 2110. For example, the moveable deformer 2870 can form a collapsed configuration, as shown in Figures 27C-27D, when positioned along the first length 2250 (including reinforcement elements 2240) of the elongated body 2110 and form an expanded configuration, as shown in Figures 27A-27B, when positioned along the second length 2255 of the elongated body 2110.

[0239] For example, the moveable deformer 2870 can include a movable dilator 2877 that can be positioned along the first length 2250 and/or the second length 2255, such as slidably controlled by a physician within the inner wall 2126 of the elongated body 2110. For example, the movable dilator 2877 can include a tubular body including a plurality of lengthwise slits 2878 forming distal extensions 2879. At least the distal end of the movable dilator 2877 including the distal extensions 2879 can be formed of a shape memory material (e.g., nitinol) such that when the distal extensions 2879 are positioned along the flexible second length 2255 the slits 2879 allow the distal extensions 2879 to expand radially thereby expanding the distal opening 2120 to form a larger suction area 2122, as shown in Figures 27A and 27B. For

example, the movable dilator 2877 can also form the expanded configuration when the movable dilator 2877 reaches a predefined temperature (e.g., body temperature). Retrieval and removal of the occlusion (using aspiration) can be performed with the movable dilator 2877 positioned along the second length 2255.

[0240] For example, the moveable deformer 2870 can be restricted from deforming (e.g., expanding) when positioned along the second length 2255 (e.g., not expandable/deformable) and allowed to deform (e.g., expand) after reaching a predefined temperature and when positioned along the first length 2250 (e.g., expandable/deformable). As such a user can wait to move the moveable deformer (such as expandable deformer 2770 and/or 2870) to a position along the second length 2255 when deformation and expansion of the expandable distal portion 2230 is desired. A vacuum source can apply a vacuum along the elongated body and/or along the moveable deformer (such as expandable deformer 2770 and/or 2870) for suctioning at least a part of an occlusion into the moveable deformer in the expanded configuration.

[0241] Figures 28A-28B illustrate another embodiment of the aspiration catheter 2900 including an embodiment of the distal opening 2120 having a fixed diameter and thus does not expand. Additionally, the aspiration catheter 2900 of Figures 28A-28B can include the same or similar features and functions as any one of the aspiration catheter embodiments disclosed herein, such as include one or more reinforcement elements 2240 along at least a part of the elongated body 2110. However, instead of including an expandable distal portion that can be expanded to form a larger suction area 2122, the aspiration catheter 2900 of Figures. 28A and 28B include a shaped distal end 2980. The shaped distal end 2980 can include a perimeter 2124 that forms a suction seal between the perimeter 2124 and an occlusion, such as when a vacuum is applied to the elongated body 2110 for suctioning at least a part of the occlusion into the distal opening 2120. The perimeter 2124 can extend outside of a single plane, such as forms a plurality of angled shapes 2981 (e.g., triangular) extending longitudinally relative to the longitudinal axis of the inner lumen 2112, as shown in Figure 28A.

[0242] For example, the perimeter 2124 can include at least four angled shapes 2981 approximately evenly spaced along the perimeter 2124. Such plurality of angled shapes 2981 along the perimeter 2124 increases the length of the perimeter 2124 compared to, for example, if the perimeter 2124 were to extend along a single plane. As such, the longer length of the perimeter 2124 of the distal opening 2120 can form a three-dimensional suction area 2122 that

is larger, such as compared to a distal opening 2120 with a perimeter 2124 that extends along a single plane (e.g., a two-dimensional suction area 2122). As discussed above, by increasing the suction area 2122 of the distal opening 2120, a greater suction force can be applied to an occlusion thereby allowing for more efficient and effective retrieval and removal of the occlusion (and restoring blood flow). Various shapes can be formed along the perimeter 2124 of the distal opening 2120 to increase the perimeter 2124 length and suction area 2122.

[0243] Figures 29A-29B illustrate another embodiment of the aspiration catheter 3100 including an embodiment of the distal opening 2120 having a fixed diameter (does not expand) and a shaped distal end 2980. As discussed above, the shaped distal end 2980 can include a perimeter 2124 that forms a suction seal between the perimeter 2124 and an occlusion, such as when a vacuum is applied to the elongated body 2110 for suctioning at least a part of the occlusion into the distal opening 2120. The perimeter 2124 can extend outside of a single plane, such as forms a plurality of rounded shapes 3181 (e.g., circular, sinusoidal) extending longitudinally relative to the longitudinal axis of the inner lumen 2112, as shown in Figure 29A.

[0244] For example, the perimeter 2124 can include at least four rounded shapes 3181 approximately evenly spaced along the perimeter 2124. Such plurality of rounded shapes 3181 along the perimeter 2124 increases the length of the perimeter 2124 compared to, for example, the perimeter 2124 extending along a single plane. As such, the longer length of the perimeter 2124 of the distal opening 2120 can form a three-dimensional suction area 2122 that is larger, such as compared to a distal opening 2120 with a perimeter 2124 that extends along a single plane (e.g., a two-dimensional suction area 2122). As discussed above, by increasing the suction area 2122 of the distal opening 2120, a greater suction force can be applied to an occlusion thereby allowing for more efficient and effective retrieval and removal of the occlusion (and restoring blood flow). Other shapes and configurations can be formed along the perimeter 2124 of the distal opening 2120 to increase the perimeter 2124 length and suction area 2122 without departing from the scope of this disclosure. Furthermore, although the elongated body 2110 is shown as having a circular cross-section, the elongated body 2110 can include other shapes such as oval. As such, the perimeter 2124 and/or distal opening 2120 can form circular, oval, or other shapes without departing from the scope of this disclosure.

[0245] Figures 30A-30B illustrate another embodiment of the aspiration catheter 3200 including an embodiment of the distal opening 2120 having a fixed diameter (does not expand) and an occlusion grasper 3290. As shown in Figure 30A, a first length 2250 of the elongated body 2110 can include a reinforcement element 2240, such as a helical metal wire 2241, embedded within an inner wall 2126 of the elongated body 2110. As also shown in Figure 30A, a second length 2255 extending along a distal end of the elongated body 2110 can include the occlusion grasper 3290 including an internally exposed coil 3292 that extends along the inner wall 2126 and is configured to engage and capture a blood clot, such as by rotating the aspiration catheter 3200 for capturing and removing the blood clot. In some embodiments, the internally exposed coil 3292 can include the same or similar material and/or configuration as the reinforcement element 2240 extending along the first length 2250. For example, the internally exposed coil 3292 can be made out of one or more of a stainless steel and a nitinol. In some embodiments, the internally exposed coil 3292 extends approximately 1 centimeter (cm) to approximately 2 cm along the second length 2255. In some embodiments, LCP fibers can extend along the second length 2255 to provide additional wall strength.

[0246] For example, during use of the aspiration catheter 3200, aspiration can be applied to the elongated body 2110, which can pull an adjacent blood clot at least partially through the distal opening 2120. The aspiration catheter 3200 may then be rotated to allow the internally exposed coil 3292 of the occlusion grasper 3290 to either break up the blood clot into smaller pieces for aspiration and/or capture a part of the blood clot to enable secure removal of the blood clot from the vasculature.

[0247] Any one of the aspiration catheters described herein can include LCP fibers at least along the second length 2255, such as to promote wall strength without significantly reducing flexibility of the elongated body 2110 along the second length 2255. For example, wall strength of the aspiration catheters can be important for allowing efficient and effective travel of the aspiration catheter along one or more of a variety of blood vessels to reach the blood clot. Additionally, aspiration catheters can have thin wall thicknesses to achieve desired size and flexibility, however, such thin walls can negatively affect the ability of the aspiration catheter to withstand high pressure injections. As such, by adding one or more layers of LCP fibers at least along portions of the elongated body 2110 that does not include a reinforcement element, the LCP fibers can provide structural support while not significantly reducing flexibility or increasing wall thickness.

[0248] Furthermore, when a diameter of a catheter increases, the strength of the cross-section of the catheter wall can require additional structural support. Increasing a thickness of the catheter wall can provide additional structural support, however, this can undesirably increase stiffness of the catheter and reduce the inner lumen 2112 diameter. As such, the LCP fibers can be added at least to portions of the aspiration catheter without significantly affecting flexibility of the catheter along such portions. The LCP fibers can extend in a variety of directions and configurations, such as longitudinally and/or at an angle relative to the longitudinal axis of the inner lumen 2112.

[0249] Figures 31A-31B illustrate another embodiment of an aspiration catheter 3300 including a plurality of LCP fibers 3395 extending along a length of the elongated body 2110. For example, the LCP fibers 3395 can include at least one longitudinally oriented LCP fiber 3395a and at least one circumferentially oriented LCP fiber 3395b, as shown in Figure 31A. The LCP fibers can form at least one layer along the length of elongated body 2110. For example, a first layer can include circumferentially oriented LCP fibers 3395b and a second layer can include longitudinally oriented LCP fiber 3395a. Any number of a variety of layers of LCP fibers 3395 oriented in one or more directions is within the scope of this disclosure.

[0250] For example, the longitudinally oriented LCP fibers 3395a can provide additional tensile strength and the circumferentially oriented LCP fibers 3395b can increase burst strength. Such additional tensile strength and increased burst strength can be achieved at least along the portion of the elongated body 2110 the LCP fibers extend along. In some embodiments, the LCP fibers can extend along a length of the elongated body 2110 including one or more reinforcement elements 2240, such as a metal wire 2241, as shown in Figure 31A.

[0251] While this specification contains many specifics, these should not be construed as limitations on the scope of an invention that is claimed or of what may be claimed, but rather as descriptions of features specific to particular embodiments. Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable sub-combination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed

combination may be directed to a sub-combination or a variation of a sub-combination. Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results.

[0252] Although embodiments of various methods and devices are described herein in detail with reference to certain versions, it should be appreciated that other versions, embodiments, methods of use, and combinations thereof are also possible. Therefore the spirit and scope of the appended claims should not be limited to the description of the embodiments contained herein.

CLAIMS

1. An aspiration catheter configured for removal of a blood clot from a vessel of a patient, the aspiration catheter comprising:

an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end, the inner lumen defined by an inner wall and forming a distal opening at the distal body end;

a reinforcement element extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, the distal reinforcement end positioned a second length from the distal body end of the elongated body; and

a deformer extending along the second length of the elongated body, the deformer coupled to the second length such that the distal opening includes a first opening diameter when the deformer forms a first configuration and includes a second opening diameter when the deformer forms a second configuration, the second opening diameter being larger than the first opening diameter.

2. The aspiration catheter of claim 1, wherein the deformer includes an inflatable balloon.

3. The aspiration catheter of claim 2, wherein the inflatable balloon extends helically along the second length of the elongated body.

4. The aspiration catheter of claim 2, wherein the inflatable balloon is twisted along the second length of the elongated body.

5. The aspiration catheter of claim 2, wherein the distal opening forms a first suction area when the inflatable balloon is in the first configuration and forms a second suction area when the inflatable balloon is in the second configuration, the second suction area being larger than the first suction area.

6. The aspiration catheter of claim 5, wherein the first suction area and the second suction area are each defined by one or more of a diameter and a cross-sectional area of the distal opening.

7. The aspiration catheter of claim 5, wherein the inflatable balloon is deflated when in the first configuration and inflated when in the second configuration.

8. The aspiration catheter of claim 1, wherein the deformer includes a shape memory material.

9. The aspiration catheter of claim 8, wherein the shape memory material includes a nitinol material that transitions between the first configuration and the second configuration based on a temperature of the shape memory material.

10. The aspiration catheter of claim 8, wherein the shape memory material includes at least one nitinol wire that extends longitudinally along the second length.

11. The aspiration catheter of claim 8, wherein the shape memory material includes a stent retriever.

12. The aspiration catheter of claim 1, wherein the elongated body is more flexible along the second length than along the first length.

13. The aspiration catheter of claim 1, wherein the reinforcement element includes one or more of a Teflon liner and a metal wire.

14. The aspiration catheter of claim 1, further comprising a plurality of LCP fibers extending along the second length of the elongated body.

15. The aspiration catheter of claim 10, wherein a first LCP fiber of the plurality of LCP fibers is oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers is oriented circumferentially along the elongated body.

16. An aspiration catheter configured for removal of a blood clot from a vessel of a patient, the aspiration catheter comprising:

an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end, the inner lumen defined by an inner wall and forming a distal opening at the distal body end;

a reinforcement element extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, the distal reinforcement end positioned a second length from the distal body end of the elongated body; and

a movable deformer slidably positioned along the inner lumen of the tubular elongated body, the movable deformer being slidable along the first length of the elongate body, the movable deformer forming a collapsed configuration along the first length thereby allowing the distal opening to form a first opening diameter, the shape memory deformer being movable to the second length for forming an expanded configuration thereby allowing the distal opening to form a second opening diameter, the second opening diameter being larger than the first opening diameter.

17. The aspiration catheter of claim 16, wherein the movable deformer includes a nitinol material that transitions between the collapsed configuration and the expanded configuration based on a temperature of the movable deformer.

18. The aspiration catheter of claim 16, wherein the movable deformer includes a stent retriever.

19. The aspiration catheter of claim 16, wherein the movable deformer includes a dilator.

20. The aspiration catheter of claim 16, further comprising a plurality of LCP fibers extending along the second length of the elongated body.

21. The aspiration catheter of claim 20, wherein a first LCP fiber of the plurality of LCP fibers is oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers is oriented circumferentially along the elongated body.

22. An aspiration catheter configured for removal of a blood clot from a vessel of a patient, the aspiration catheter comprising:

an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end, the inner lumen defined by an inner wall and forming a distal opening at the distal body end, the distal opening having a shaped distal end including a perimeter extending along more than one plane, the perimeter including a shape extending longitudinally relative to a longitudinal axis of the inner lumen; and

a reinforcement element extending along a length of the elongated body.

23. The aspiration catheter of claim 22, wherein the distal opening includes a suction area defined by the perimeter of the distal opening.

24. The aspiration catheter of claim 22, wherein the shape of the perimeter includes an angled or triangular shape.

25. The aspiration catheter of claim 22, wherein the shape of the perimeter includes a rounded or sinusoidal shape.

26. The aspiration catheter of claim 22, further comprising a plurality of LCP fibers extending along the elongated body.

27. The aspiration catheter of claim 26, wherein a first LCP fiber of the plurality of LCP fibers is oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers is oriented circumferentially along the elongated body.

28. An aspiration catheter configured for removal of a blood clot from a vessel of a patient, the aspiration catheter comprising:

an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end, the inner lumen defined by an inner wall and forming a distal opening at the distal body end;

a reinforcement element extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, the distal reinforcement end positioned a second length from the distal body end of the elongated body; and

an occlusion grasper extending along the inner wall of the second length of the elongated body, the occlusion grasper including an exposed coil configured to grasp the blood clot for securing the blood clot at least partially within the inner lumen.

29. The aspiration catheter of claim 28, further comprising a plurality of LCP fibers extending along the second length of the elongated body.

30. The aspiration catheter of claim 29, wherein a first LCP fiber of the plurality of LCP fibers is oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers is oriented circumferentially along the elongated body. 3. The aspiration catheter of claim 1, wherein the elongated body is more flexible along the second length than along the first length.

31. The aspiration catheter of claim 28, wherein the reinforcement element includes one or more of a Teflon liner and a metal wire.

32. A method for removing a blood clot from a vessel of a patient, the method comprising:

inserting a distal portion of an aspiration catheter into a vessel, the aspiration catheter comprising:

an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end, the inner lumen defined by an inner wall and forming a distal opening at the distal body end;

a reinforcement element extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, the distal reinforcement end positioned a second length from the distal body end of the elongated body; and

a deformer extending along the second length of the elongated body, the deformer coupled to the second length such that the distal opening includes a first opening diameter when the deformer forms a first configuration and includes a second

opening diameter when the deformer forms a second configuration, the second opening diameter being larger than the first opening diameter;

causing the deformer to transition between the first configuration and the second configuration; and

applying a vacuum to the elongated body for suctioning at least a part of the blood clot into the distal opening having the second opening diameter.

33. The method of claim 32, wherein the deformer includes an inflatable balloon.

34. The method of claim 33, wherein the inflatable balloon extends helically along the second length of the elongated body.

35. The method of claim 33, wherein the inflatable balloon is twisted along the second length of the elongated body.

36. The method of claim 35, wherein the distal opening forms a first suction area when the inflatable balloon is in the deflated configuration and forms a second suction area when the inflatable balloon is in the inflated configuration, the second suction area being larger than the first suction area.

37. The method of claim 35, wherein the first suction area and the second suction area are each defined by one or more of a diameter and a cross-sectional area of the distal opening.

38. The method of claim 32, wherein the inflatable balloon is deflated when in the first configuration and inflated when in the second configuration.

39. The method of claim 32, wherein the deformer includes a shape memory material.

40. The method of claim 39, wherein the shape memory material includes a nitinol material that transitions between the first configuration and the second configuration based on a temperature of the shape memory material.

41. The method of claim 39, wherein the shape memory material includes at least one nitinol wire that extends longitudinally along the second length.

42. The method of claim 32, wherein the reinforcement element includes one or more of a Teflon liner and a metal wire.

43. The method of claim 32, further comprising a plurality of LCP fibers extending along the second length of the elongated body.

44. The method of claim 43, wherein a first LCP fiber of the plurality of LCP fibers is oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers is oriented circumferentially along the elongated body.

45. A method for removing a blood clot from a vessel of a patient, the method comprising:

inserting a distal portion of an aspiration catheter into a vessel, the aspiration catheter comprising:

an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end, the inner lumen defined by an inner wall and forming a distal opening at the distal body end;

a reinforcement element extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, the distal reinforcement end positioned a second length from the distal body end of the elongated body; and

a movable deformer slidably positioned along the inner lumen of the tubular elongated body, the movable deformer being slidable along the first length of the elongate body, the movable deformer forming a collapsed configuration along the first length thereby allowing the distal opening to form a first opening diameter, the shape memory deformer being movable to the second length for forming an expanded configuration thereby allowing the distal opening to form a second opening diameter, the second opening diameter being larger than the first opening diameter;

causing the deformer to transition between the first configuration and the second configuration; and

applying a vacuum to the elongated body for suctioning at least a part of the blood clot into the distal opening having the second opening diameter.

46. The method of claim 45, wherein the movable deformer includes a nitinol material that transitions between the collapsed configuration and the expanded configuration based on a temperature of the movable deformer.

47. The method of claim 45, wherein the movable deformer includes a stent retriever.

48. The method of claim 45, wherein the movable deformer includes a dilator.

49. The method of claim 45, further comprising a plurality of LCP fibers extending along the second length of the elongated body.

50. The method of claim 49, wherein a first LCP fiber of the plurality of LCP fibers is oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers is oriented circumferentially along the elongated body.

51. A method for removal of a blood clot from a vessel of a patient, the method comprising:

inserting a distal portion of an aspiration catheter into a vessel, the aspiration catheter comprising:

an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end, the inner lumen defined by an inner wall and forming a distal opening at the distal body end, the distal opening having a shaped distal end including a perimeter extending along more than one plane, the perimeter including a shape extending longitudinally relative to a longitudinal axis of the inner lumen; and

a reinforcement element extending along a length of the elongated body; and

applying a vacuum to the elongated body for suctioning at least a part the blood clot into the distal opening and forming a suction seal between the perimeter of the distal opening and the blood clot.

52. The method of claim 51, wherein the distal opening includes a suction area defined by the perimeter of the distal opening.

53. The method of claim 51, wherein the shape of the perimeter includes an angled or triangular shape.

54. The method of claim 51, wherein the shape of the perimeter includes a rounded or sinusoidal shape.

55. The method of claim 51, further comprising a plurality of LCP fibers extending along the elongated body.

56. The method of claim 55, wherein a first LCP fiber of the plurality of LCP fibers is oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers is oriented circumferentially along the elongated body.

57. A method for removal of a blood clot from a vessel of a patient, the method comprising:

inserting a distal portion of an aspiration catheter into a vessel, the aspiration catheter comprising:

an elongated body formed of a flexible material and including an inner lumen extending between a proximal body end and a distal body end, the inner lumen defined by an inner wall and forming a distal opening at the distal body end;

a reinforcement element extending along a first length of the elongated body between a proximal reinforcement end and a distal reinforcement end, the distal reinforcement end positioned a second length from the distal body end of the elongated body; and

an occlusion grasper extending along the inner wall of the second length of the elongated body, the occlusion grasper including an exposed coil configured to grasp the blood clot for securing the blood clot at least partially within the inner lumen;

applying a vacuum to the elongated body to suction the blood clot into the distal opening; and

grasping the blood clot for securing the blood clot at least partially within the inner lumen.

58. The method of claim 57, further comprising a plurality of LCP fibers extending along the second length of the elongated body.

59. The method of claim 58, wherein a first LCP fiber of the plurality of LCP fibers is oriented longitudinally along the elongated body and a second LCP fiber of the plurality of LCP fibers is oriented circumferentially along the elongated body. 3. The aspiration catheter of claim 1, wherein the elongated body is more flexible along the second length than along the first length.

60. The method of claim 57, wherein the reinforcement element includes one or more of a Teflon liner and a metal wire.

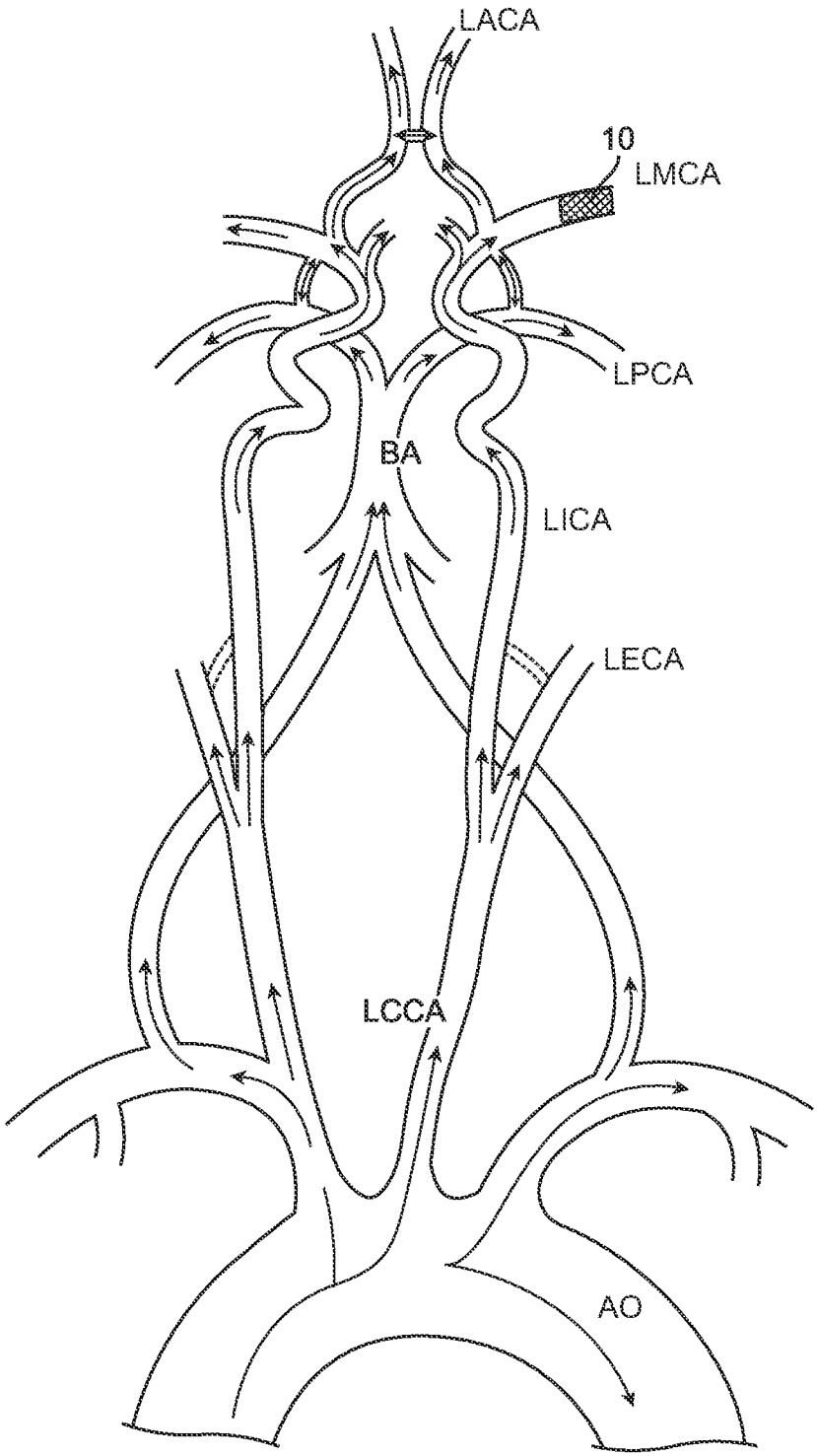


FIG. 1

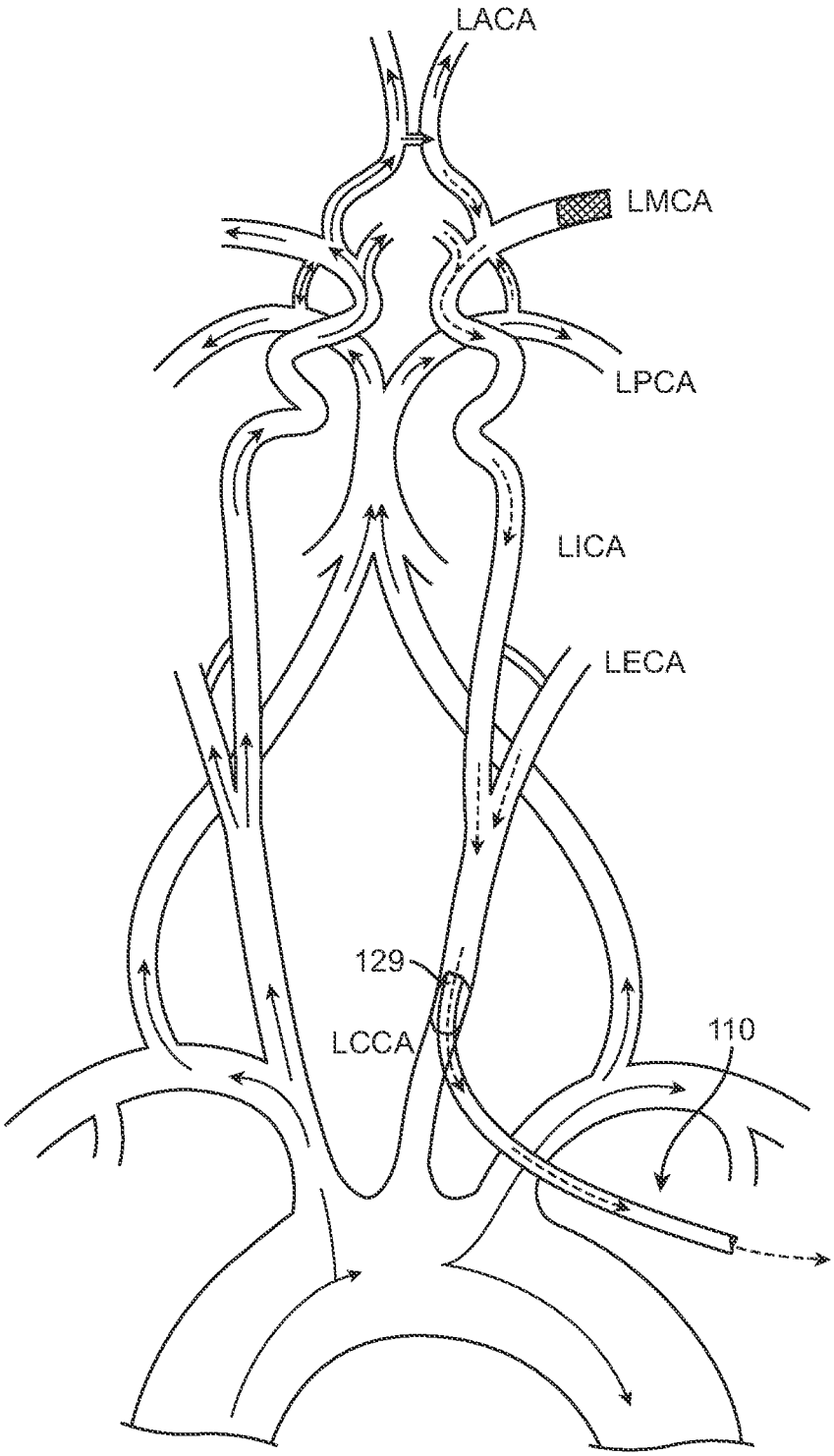


FIG. 2

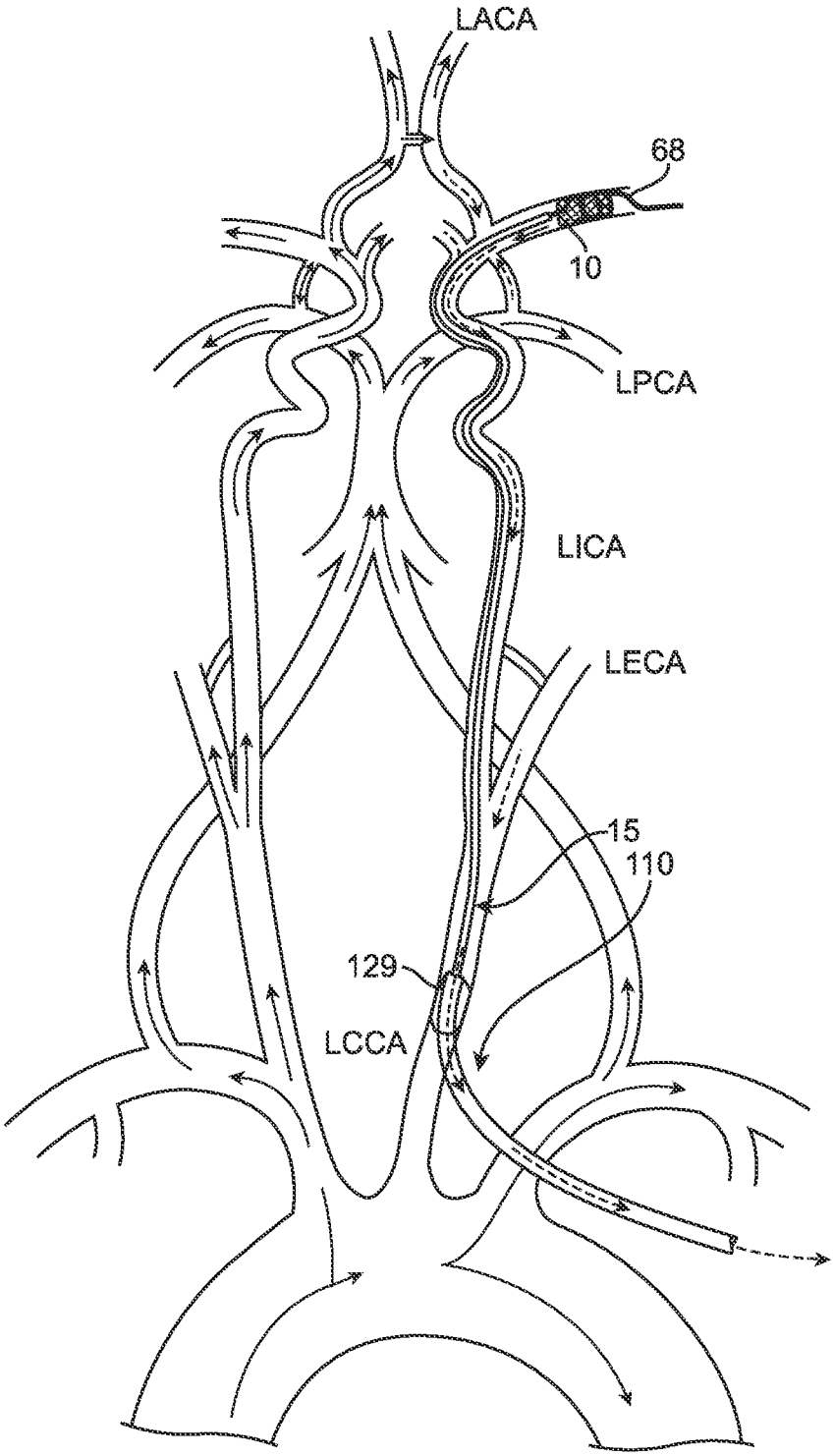


FIG. 3

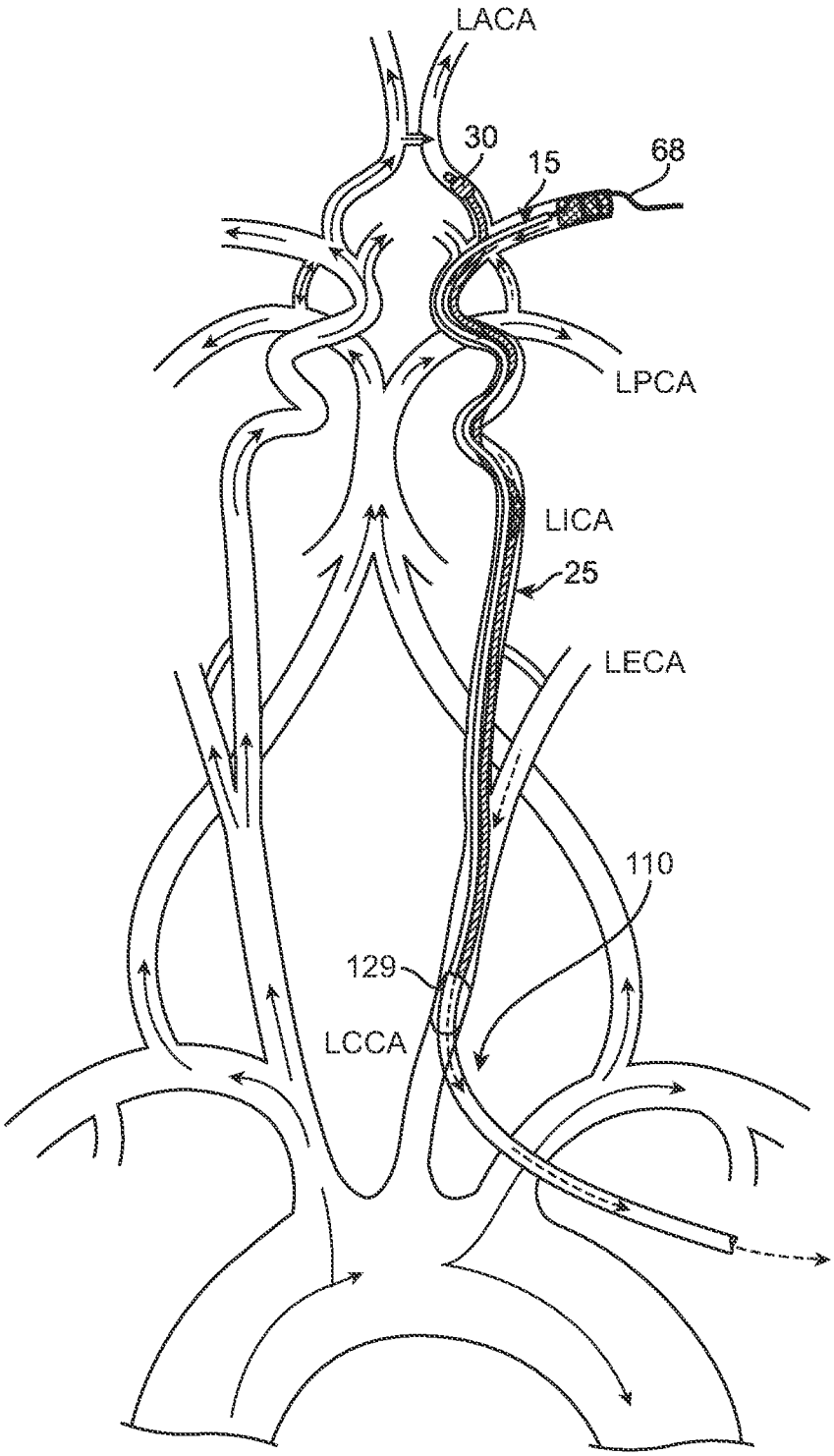


FIG. 4

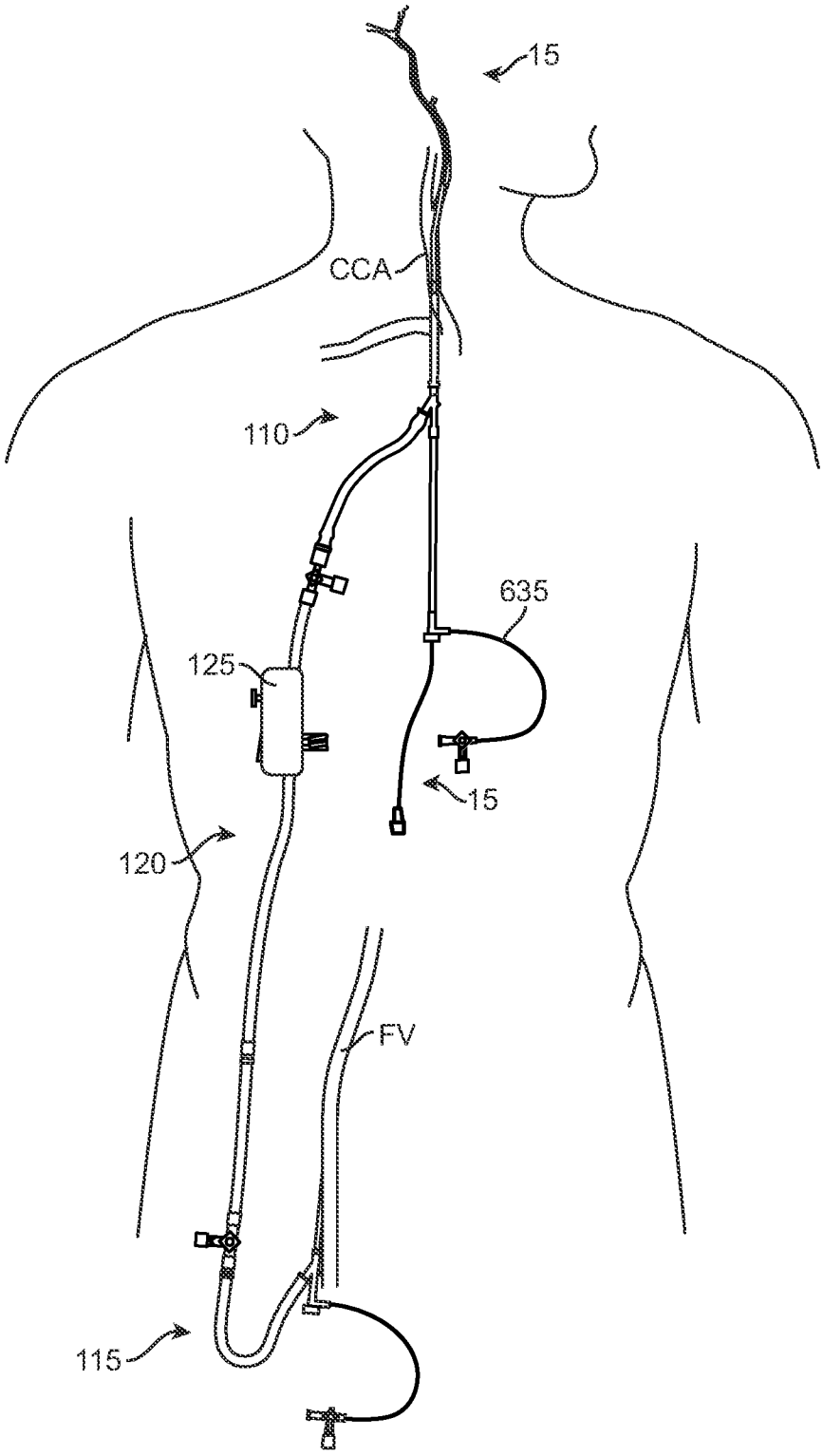


FIG. 5

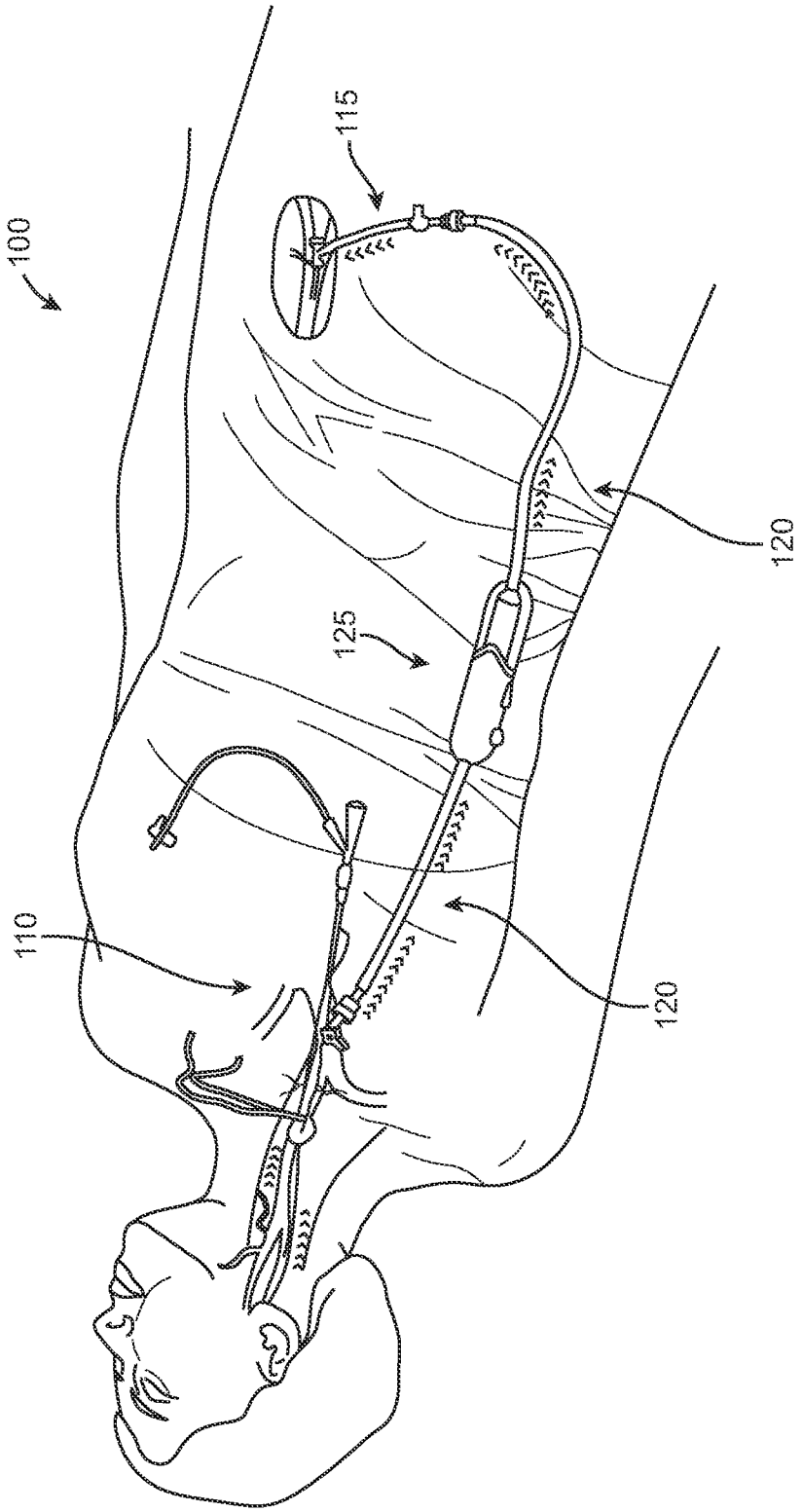


FIG. 6

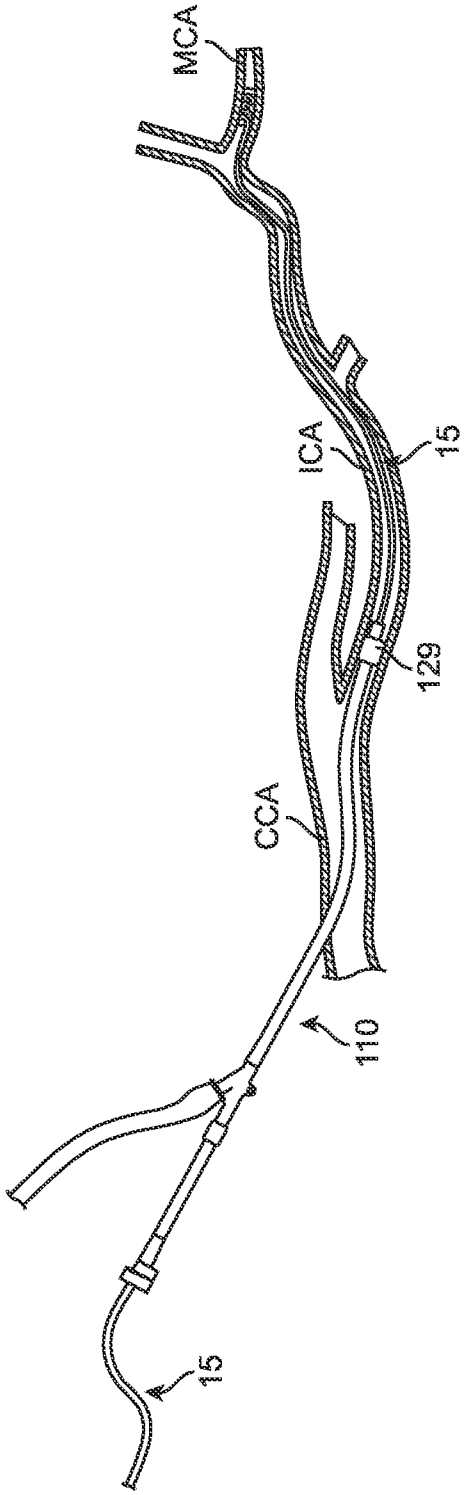


FIG. 7

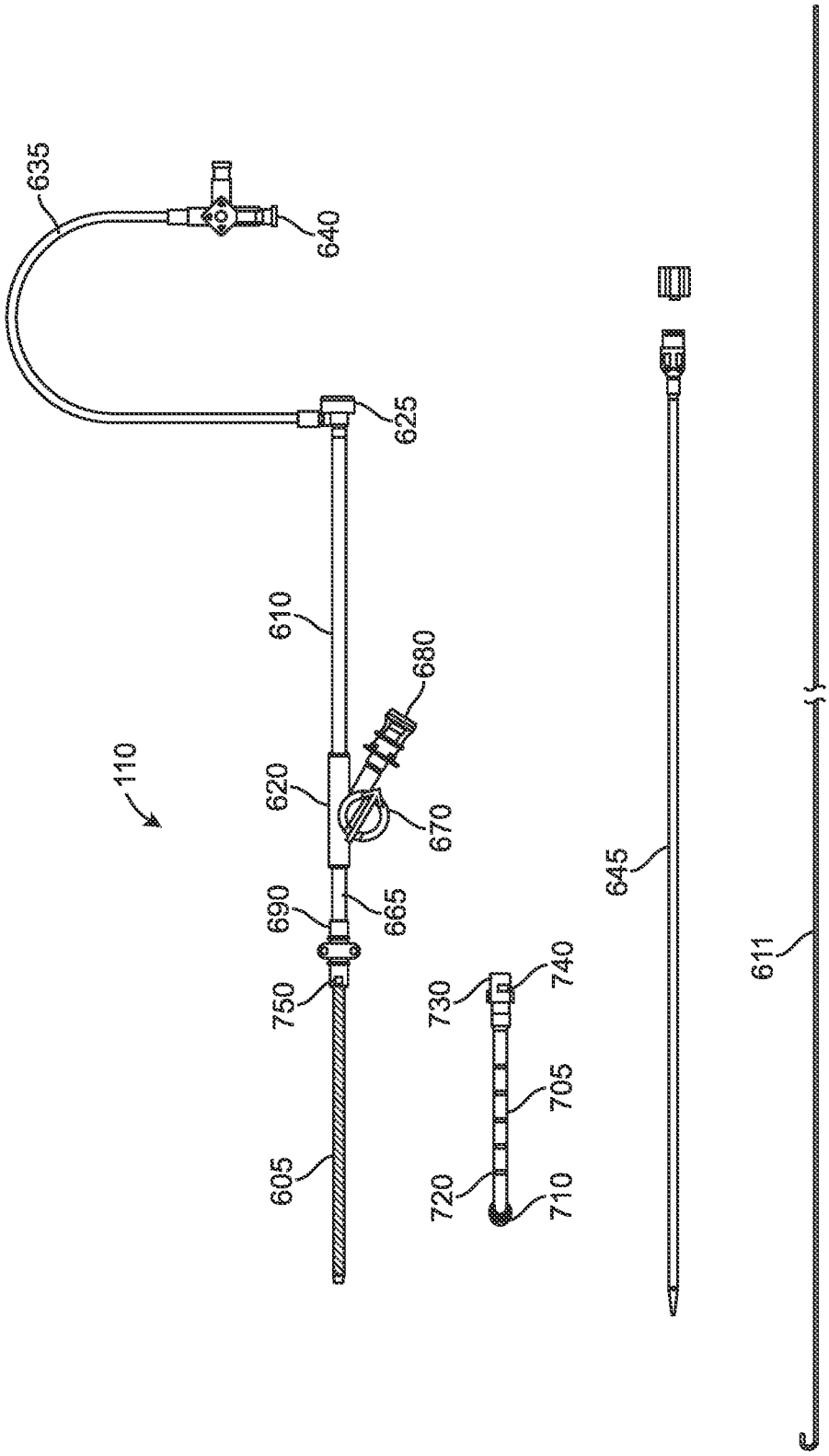

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FIG. 8A

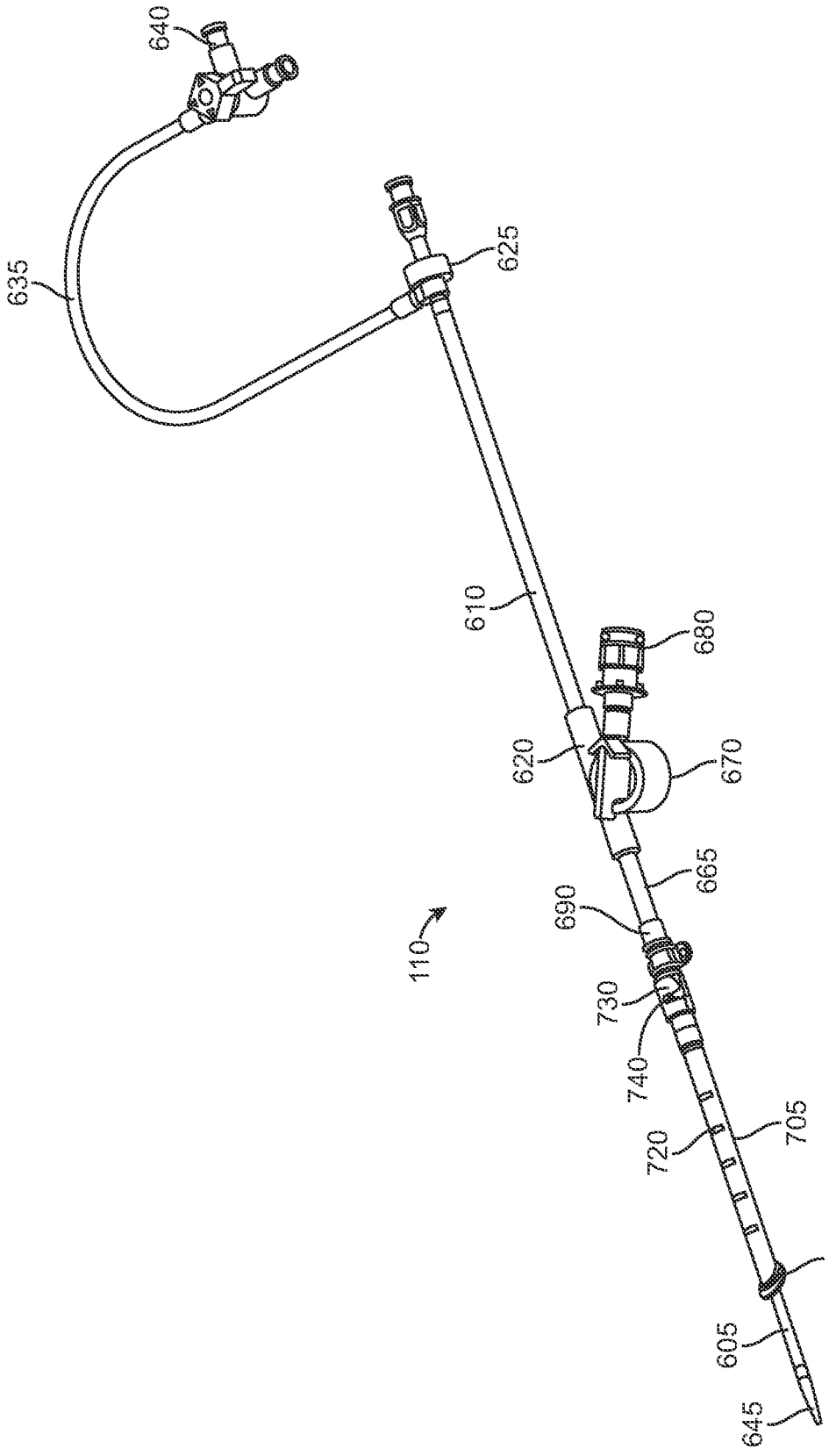

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FIG. 8B

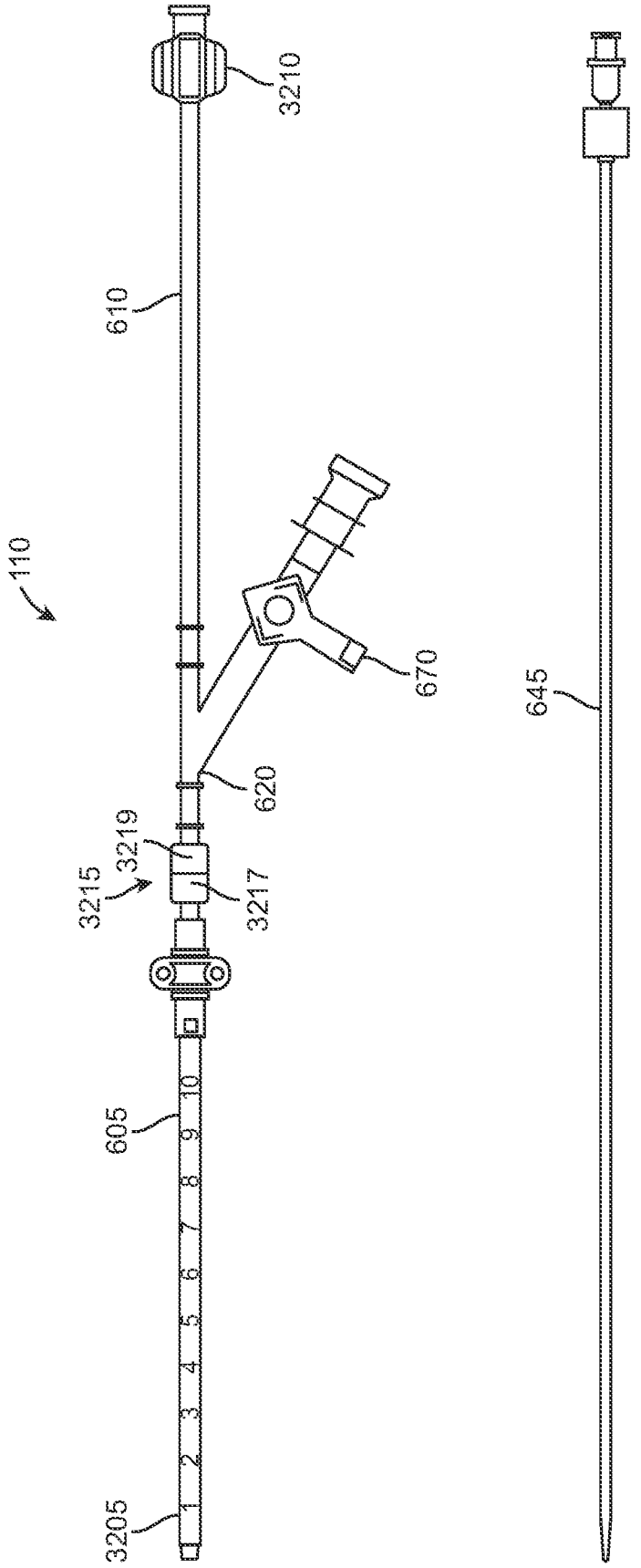


FIG. 9A

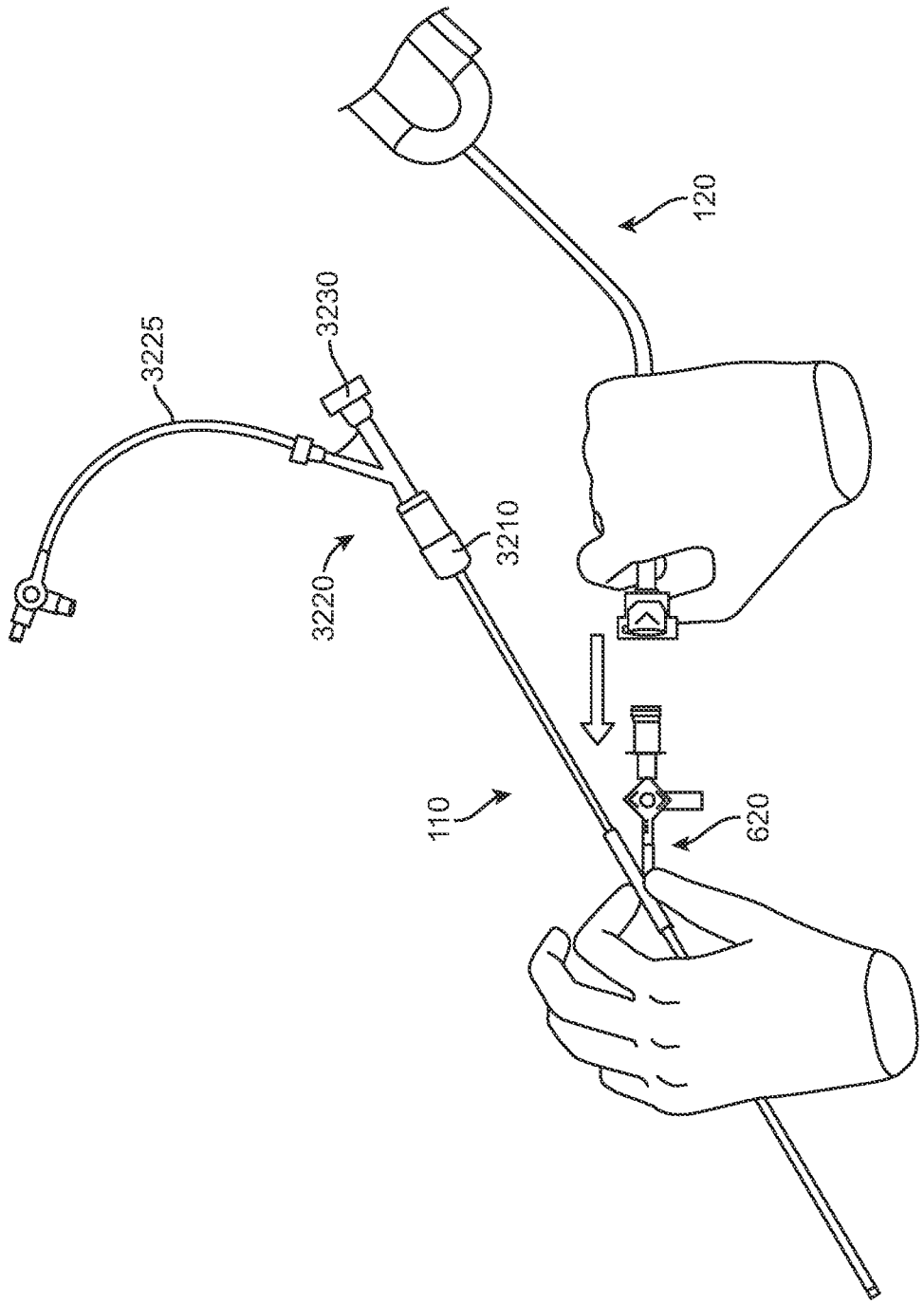


FIG. 9B

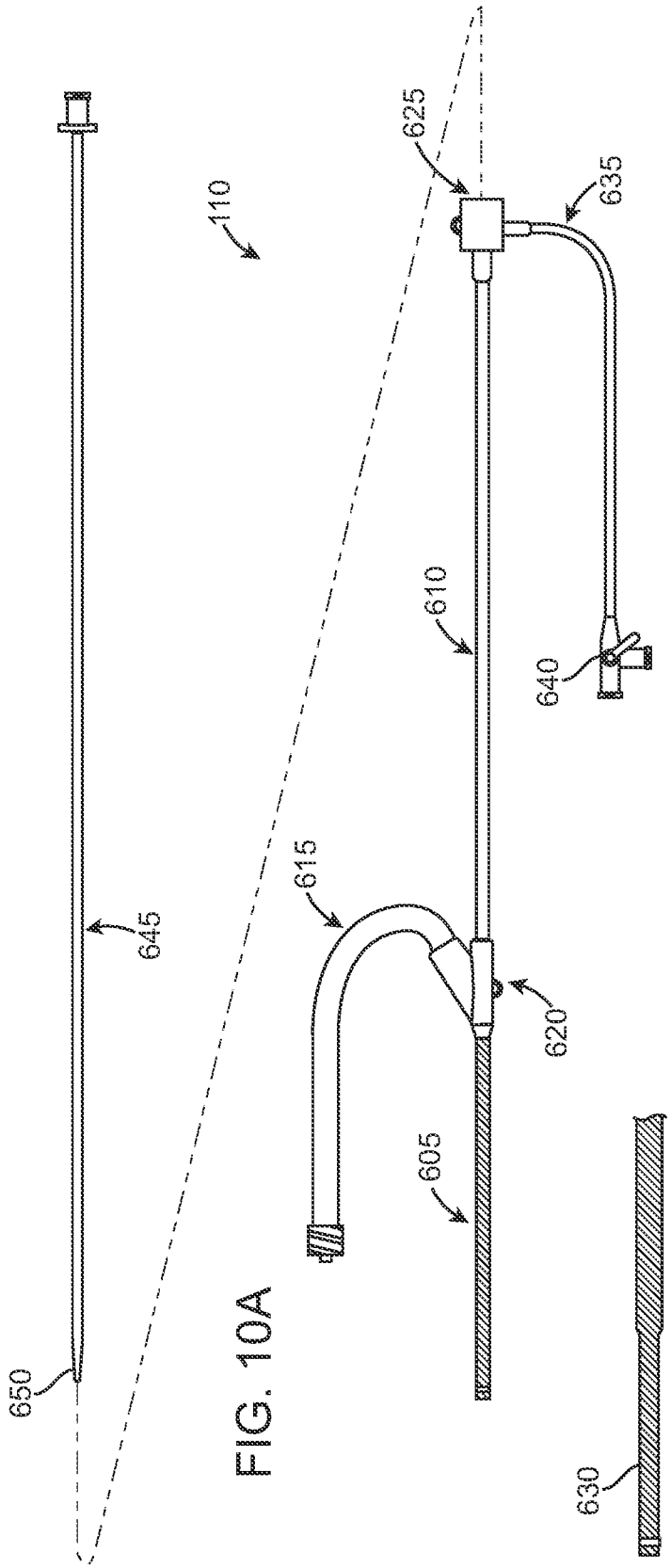


FIG. 10A

FIG. 10B



FIG. 11B

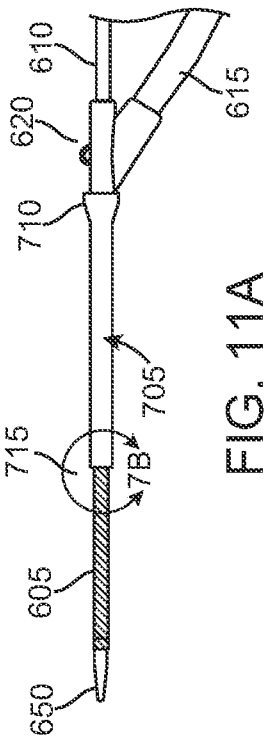


FIG. 11A

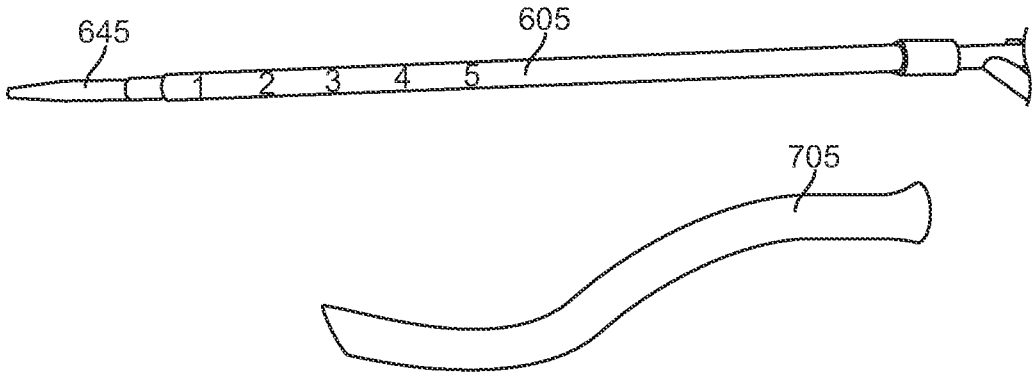


FIG. 11C

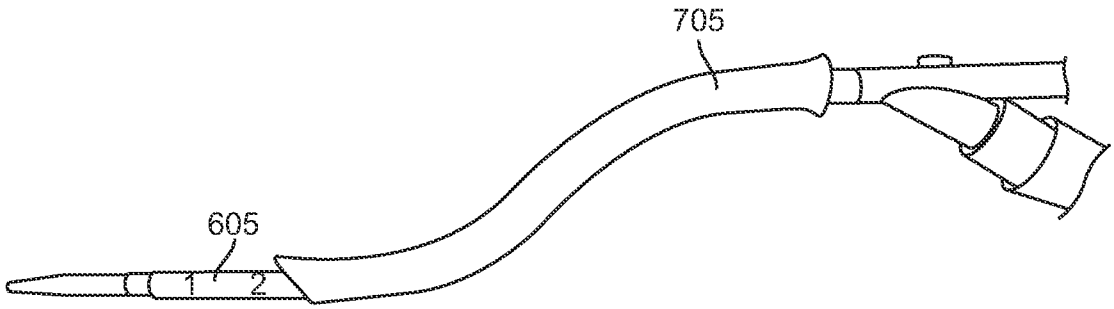


FIG. 11D

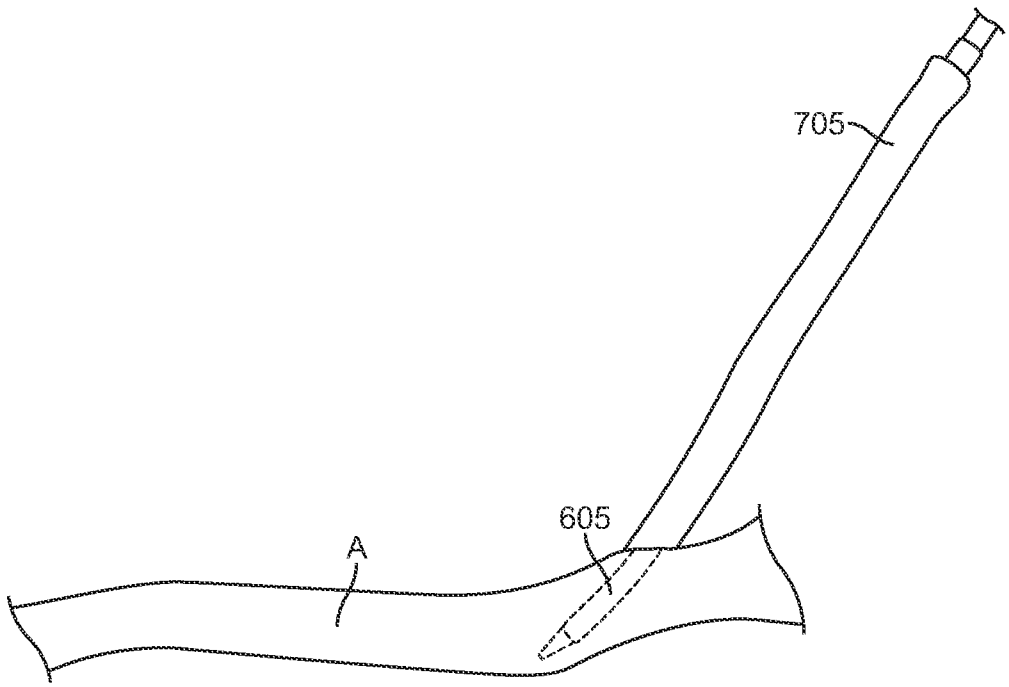


FIG. 11E

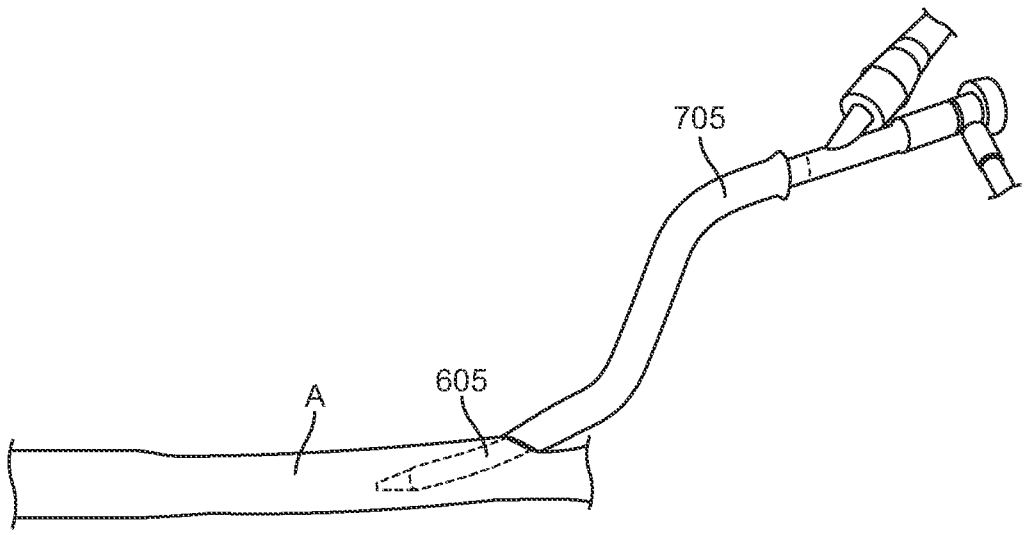


FIG. 11F

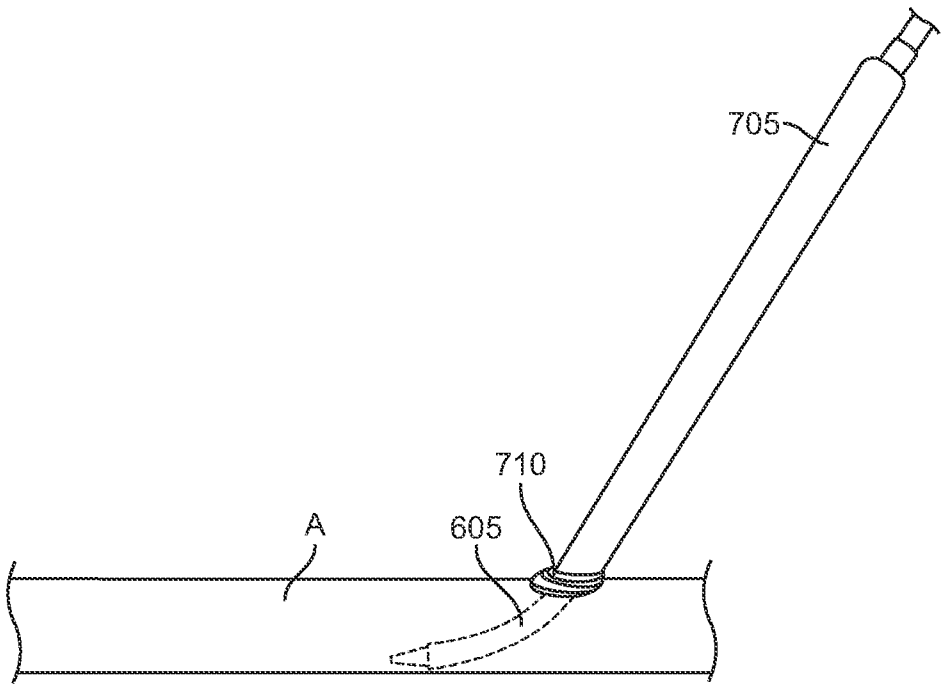


FIG. 11G

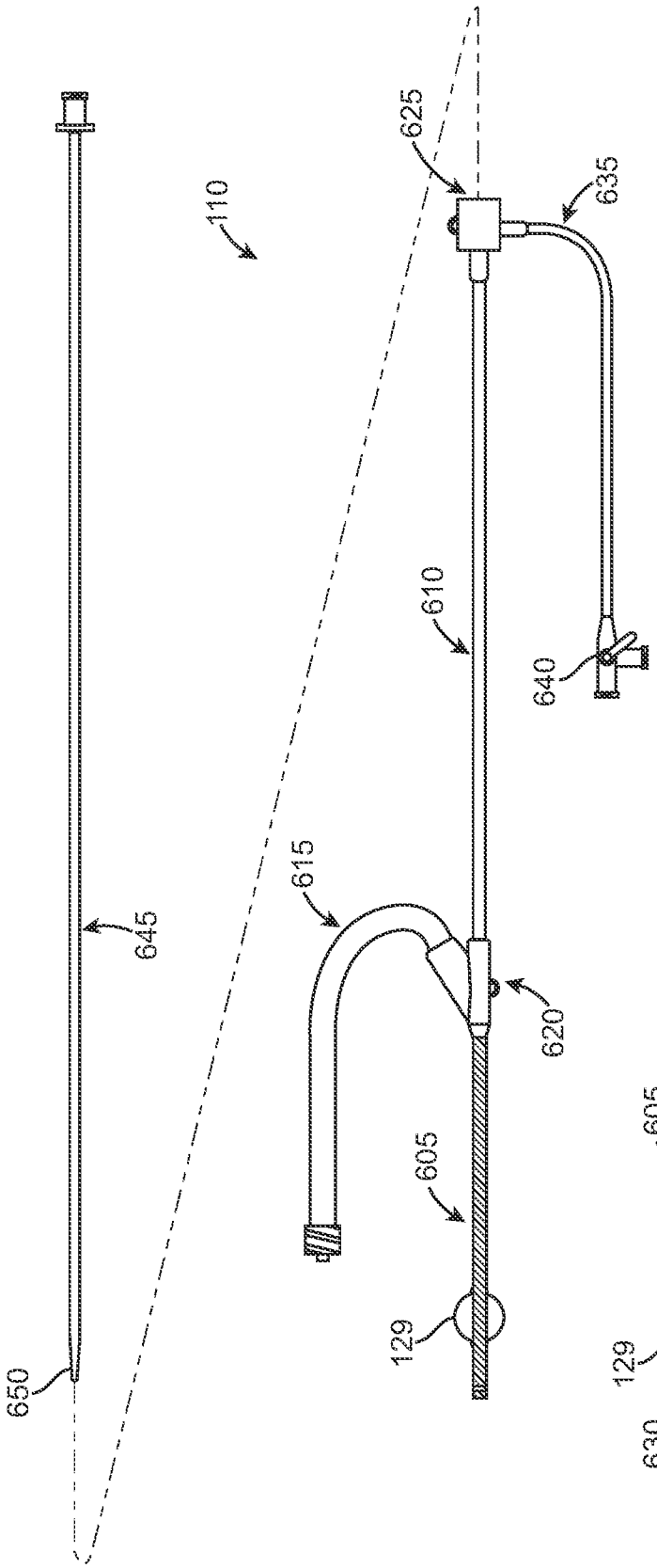


FIG. 12A

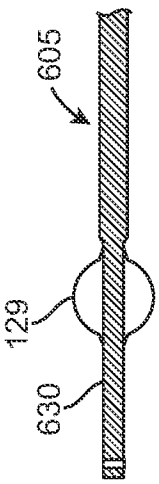


FIG. 12B

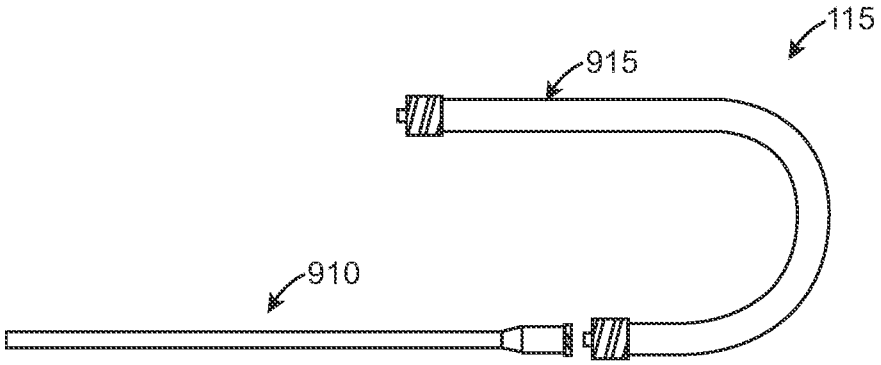


FIG. 13

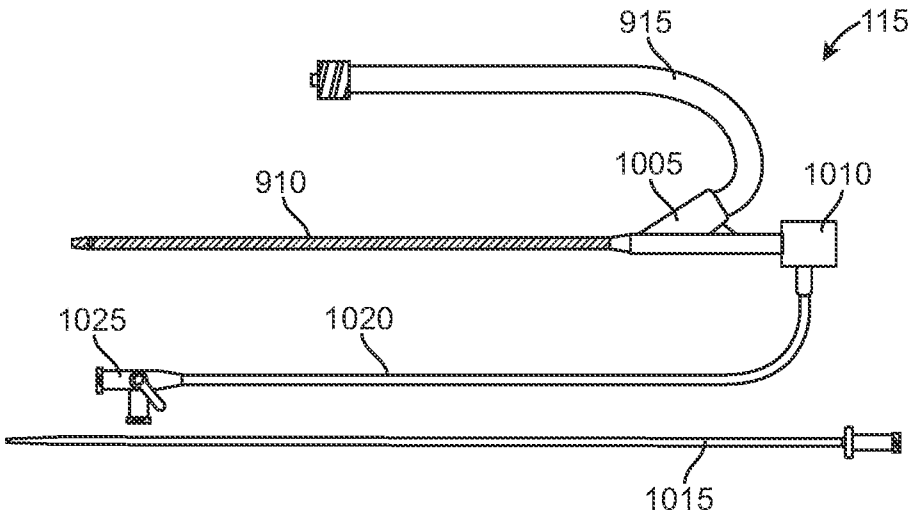


FIG. 14A

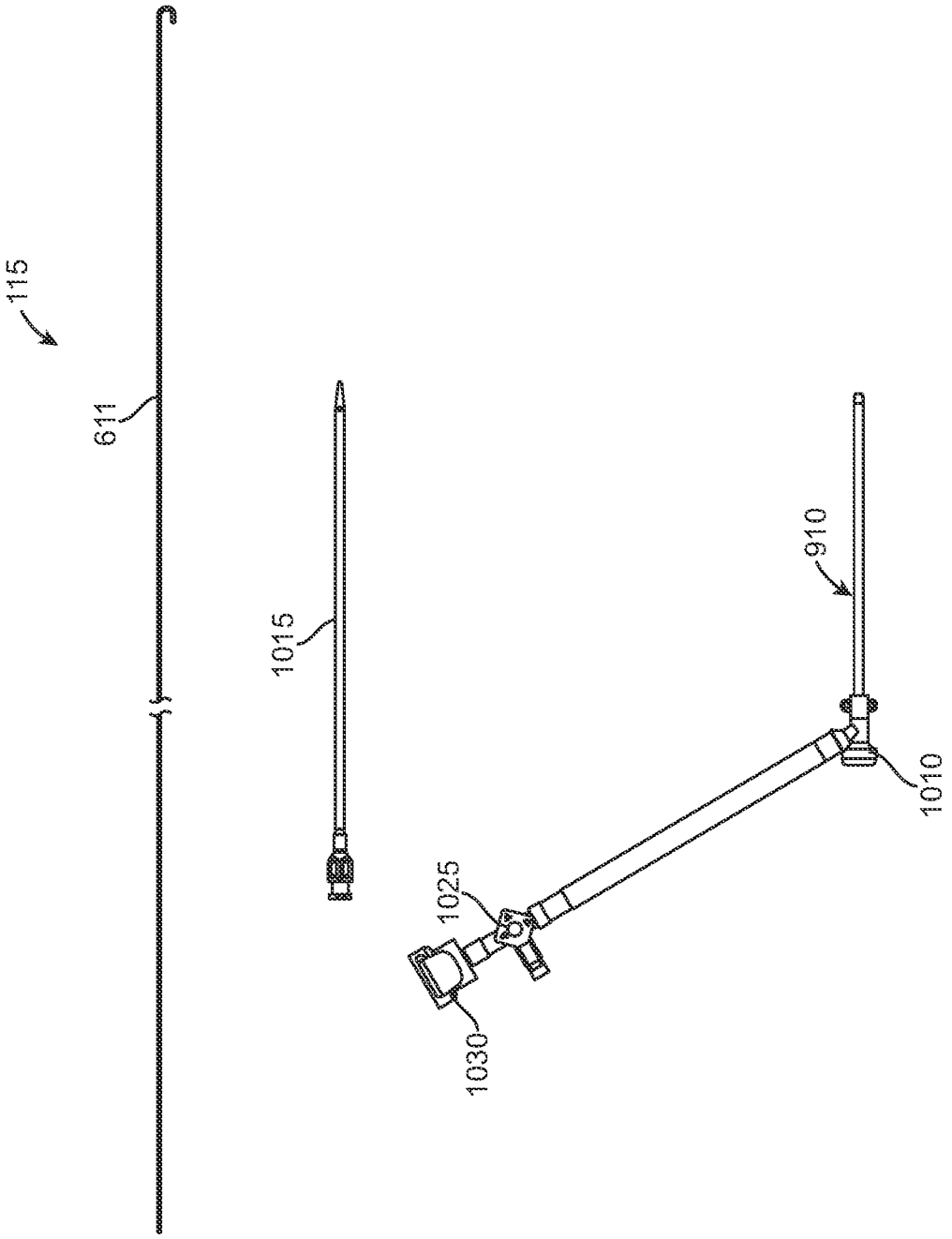


FIG. 14B

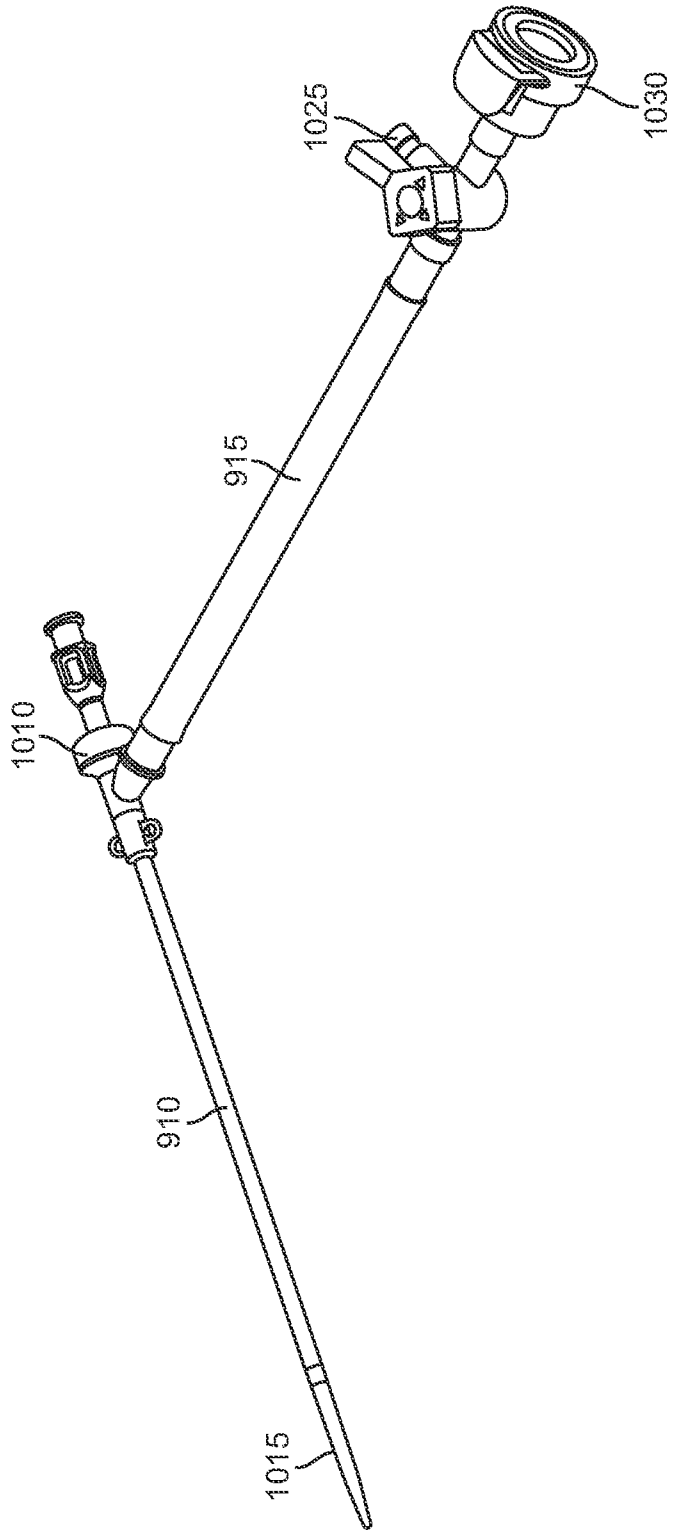


FIG. 14C

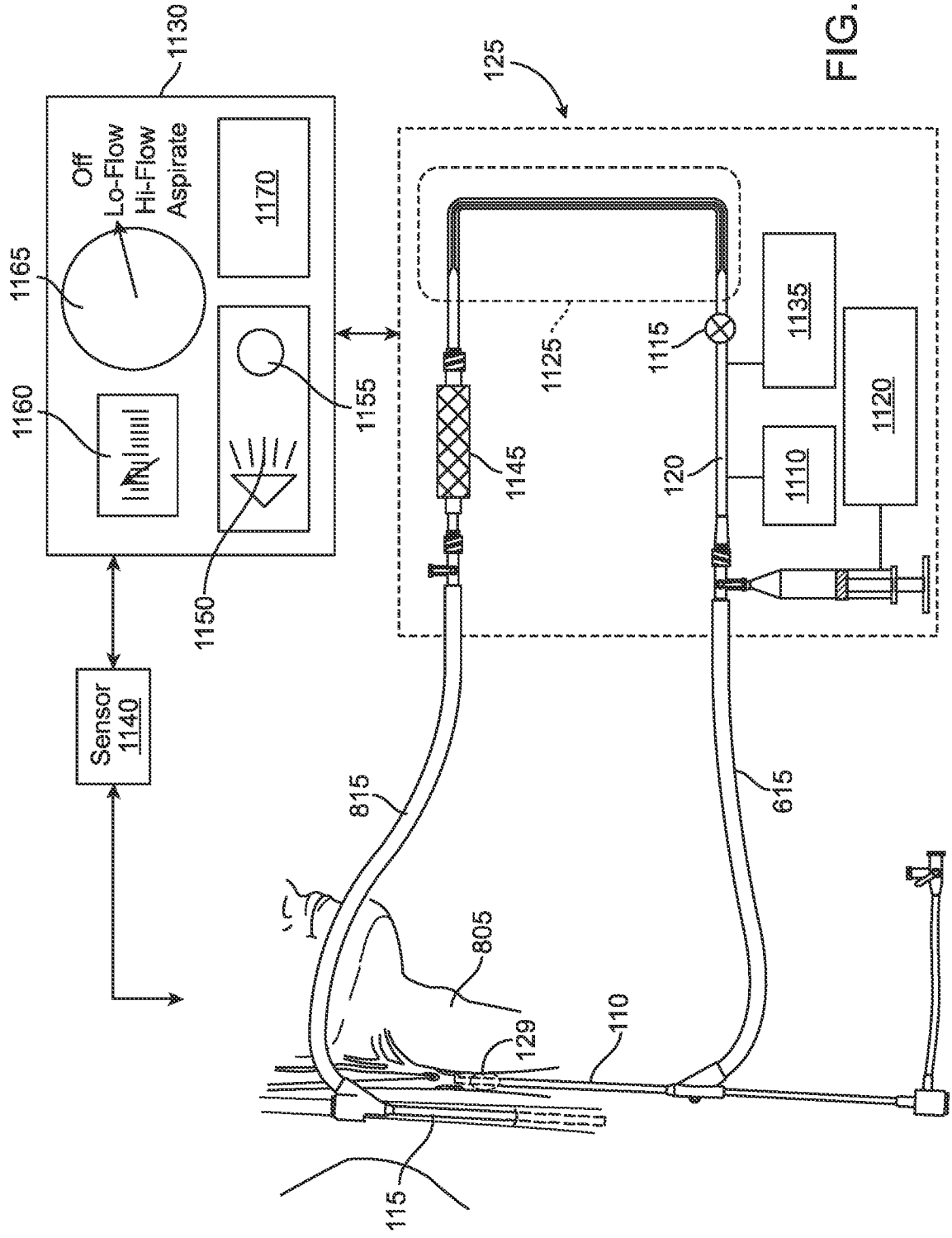

1130
Off
Lo-Flow
Hi-Flow
Aspirate
1165
1160
1170
1155
1150
Sensor
1140
125
1125
1115
1135
1120
1110
1145
120
815
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805
129
110
115

FIG. 15

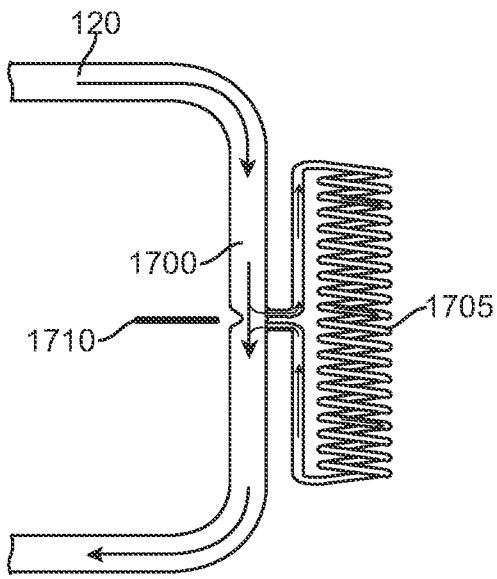


FIG. 16A

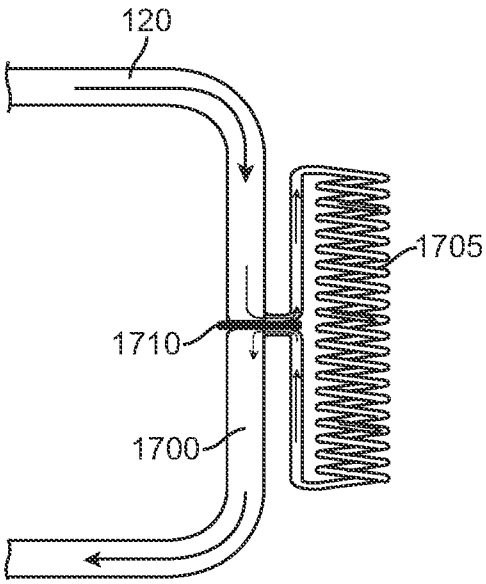


FIG. 16B

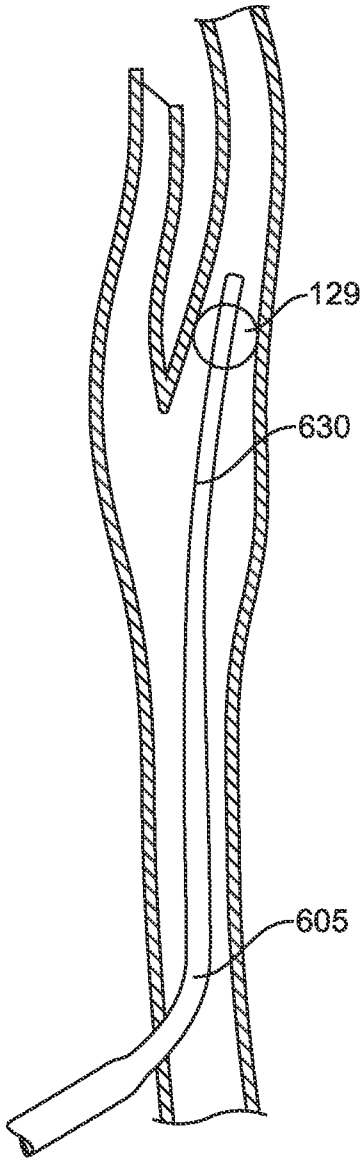


FIG. 17

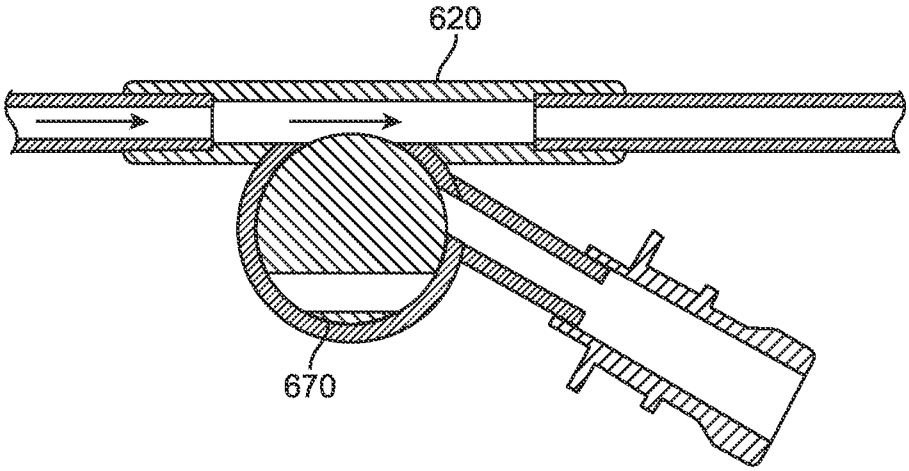


FIG. 18A

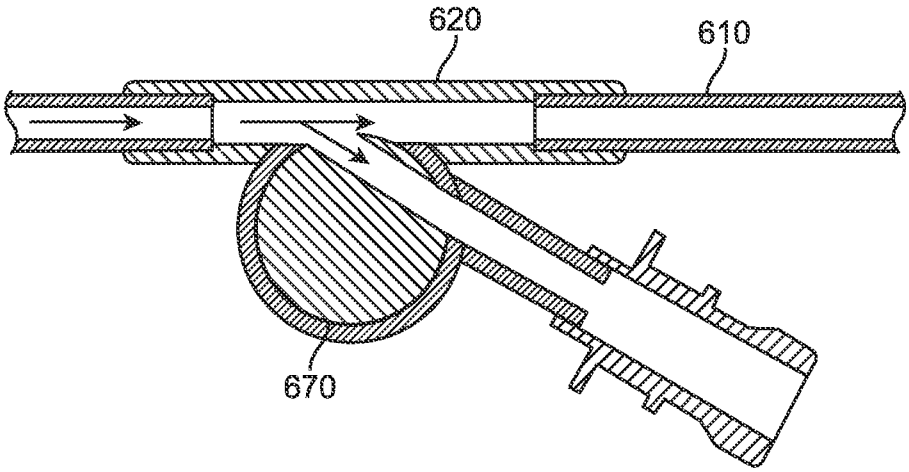


FIG. 18B

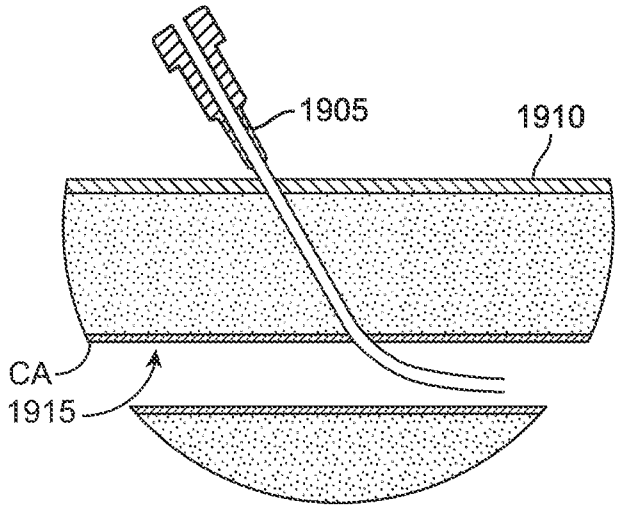


FIG. 19A

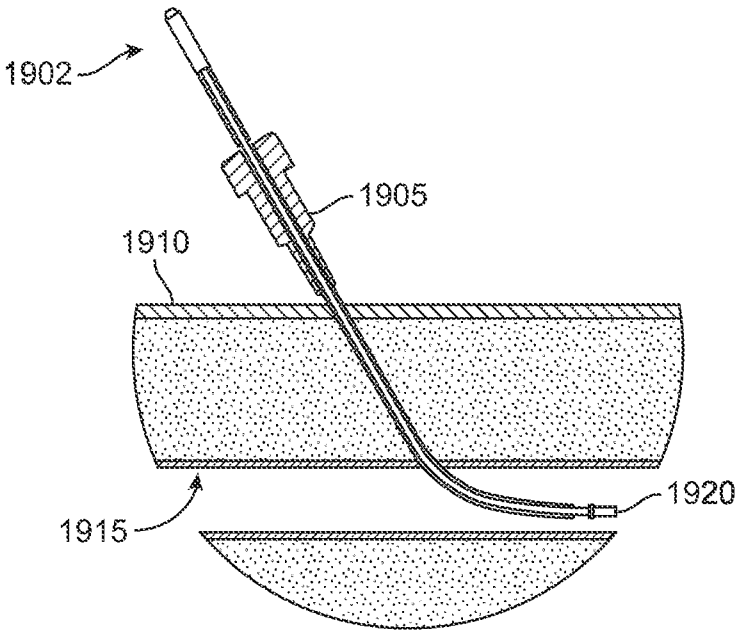


FIG. 19B

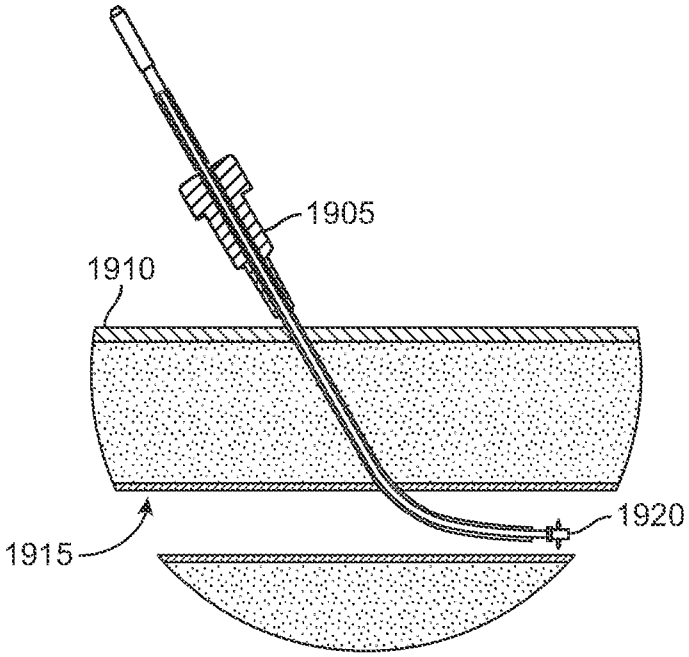


FIG. 19C

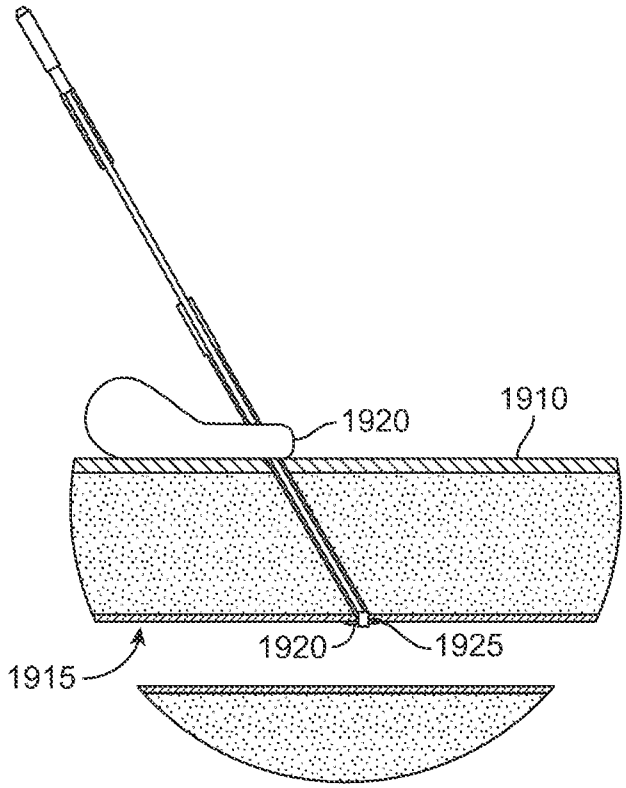


FIG. 19D

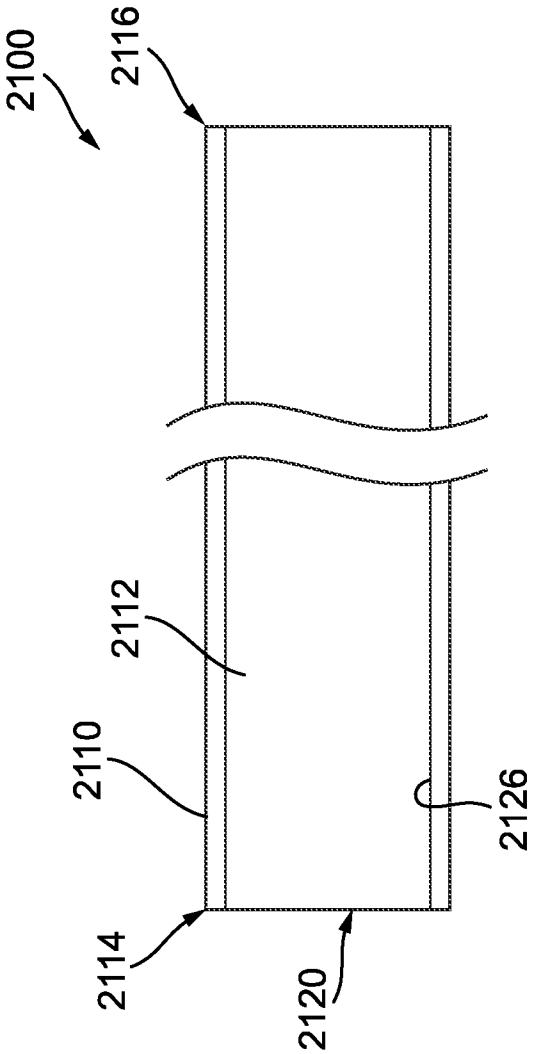


FIG. 20A

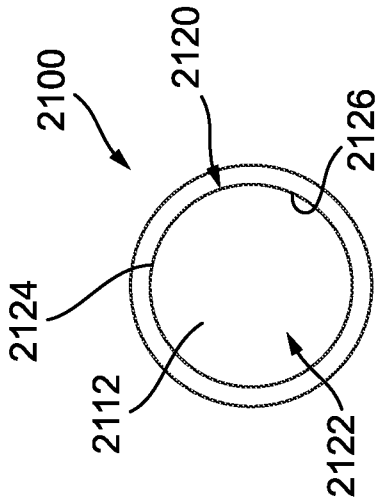


FIG. 20B

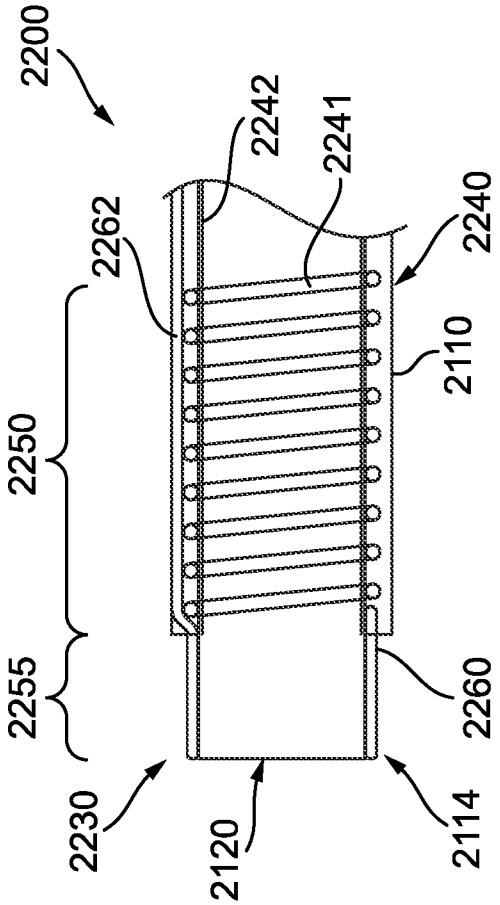


FIG. 21A

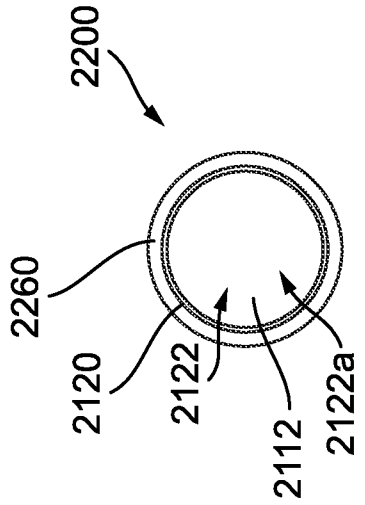


FIG. 21B

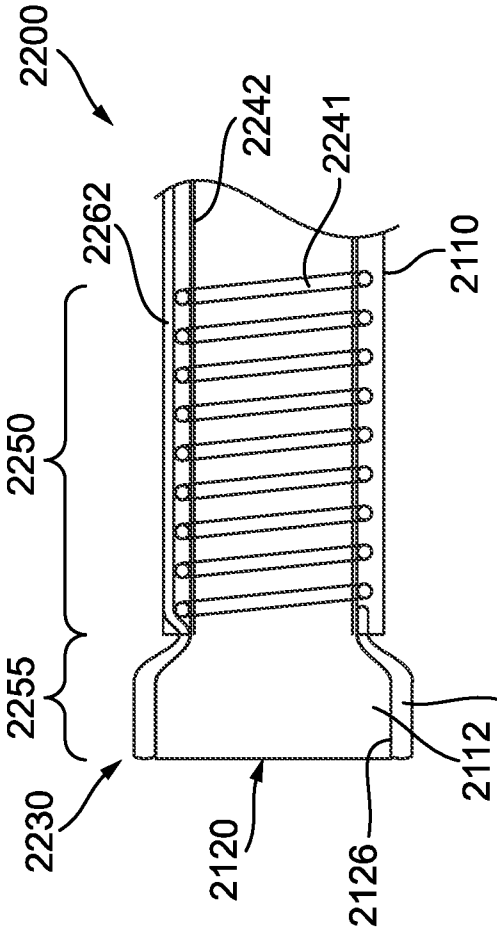


FIG. 21C

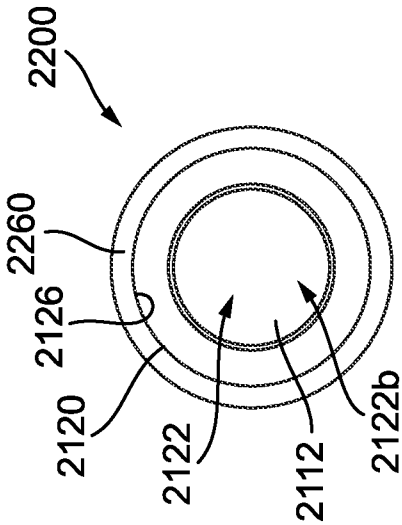


FIG. 21D

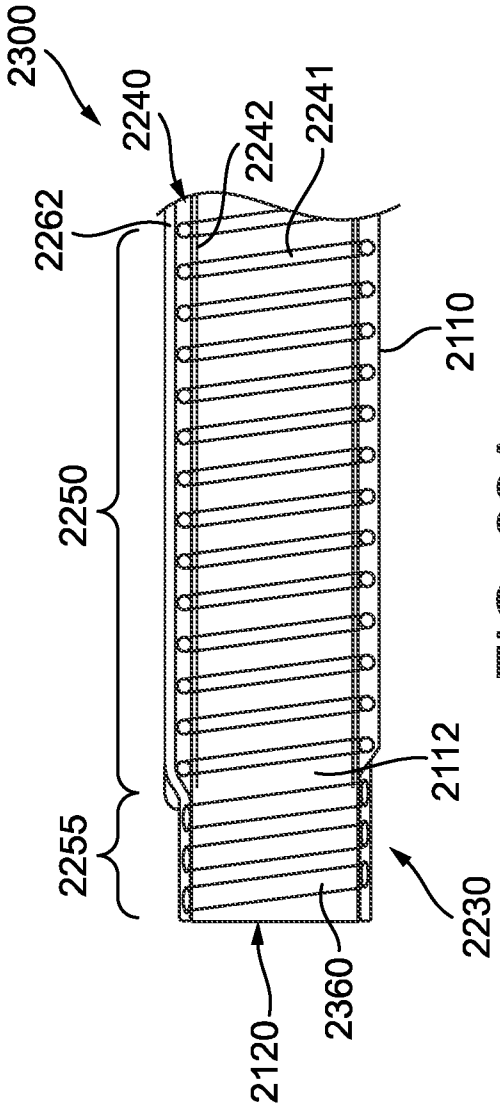


FIG. 22A

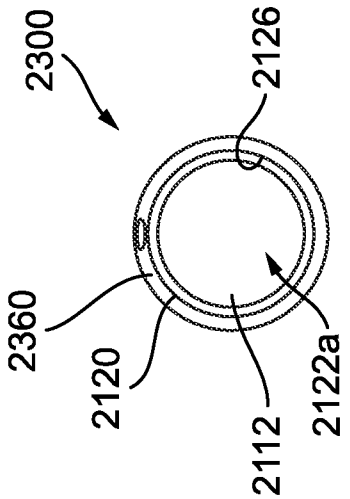


FIG. 22B

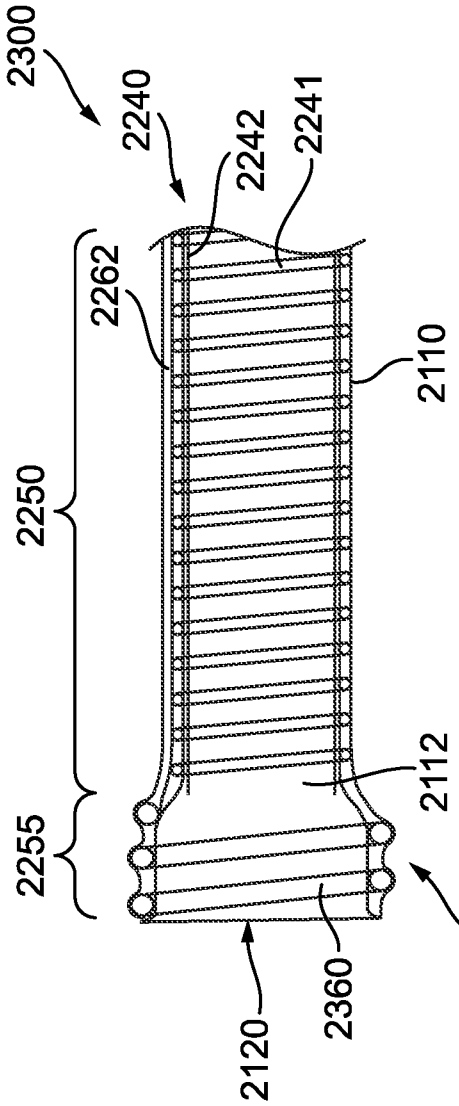


FIG. 22C

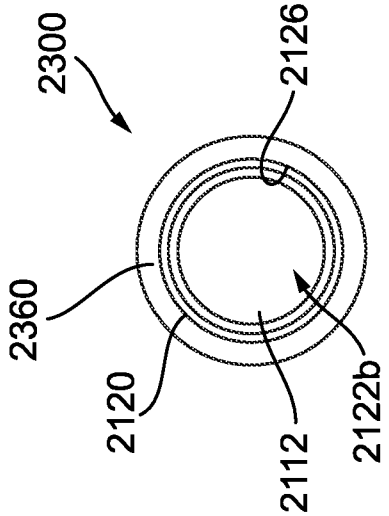


FIG. 22D

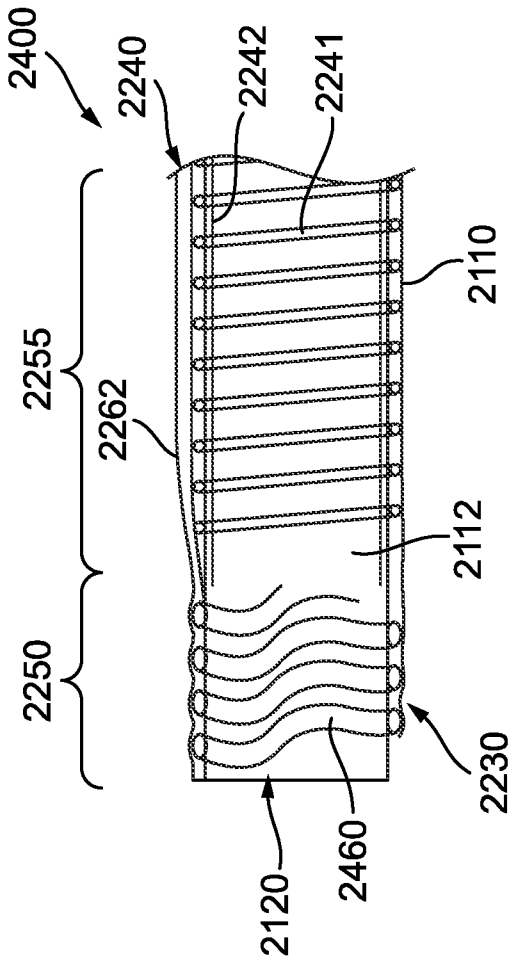


FIG. 23A

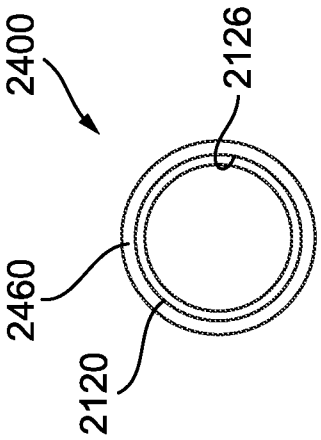


FIG. 23B

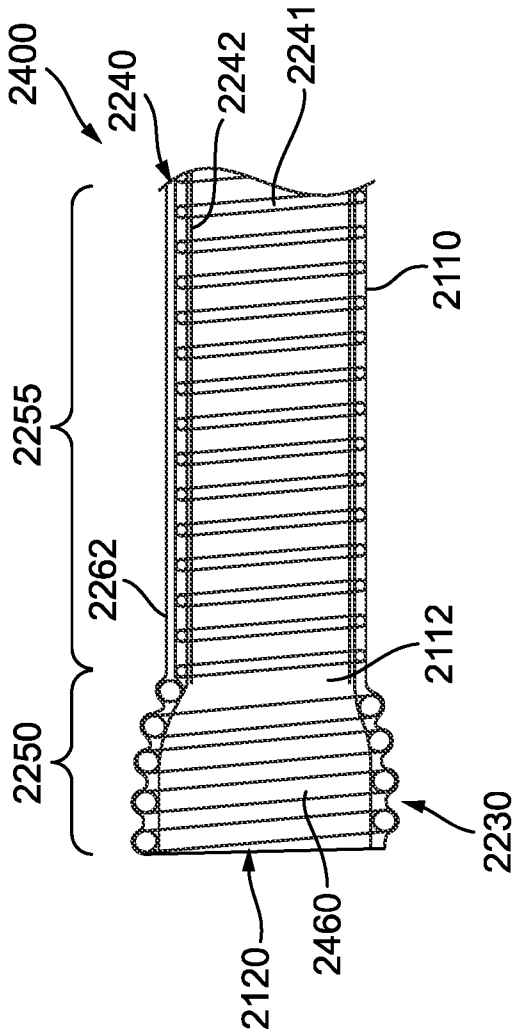


FIG. 23C

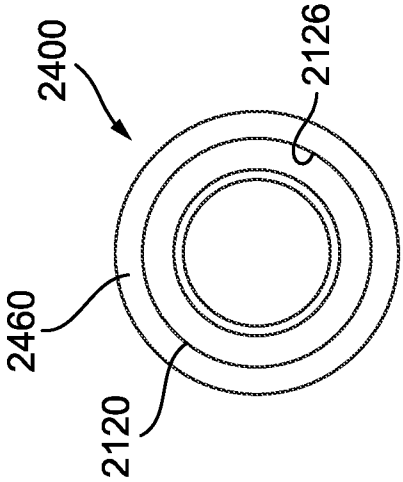


FIG. 23D

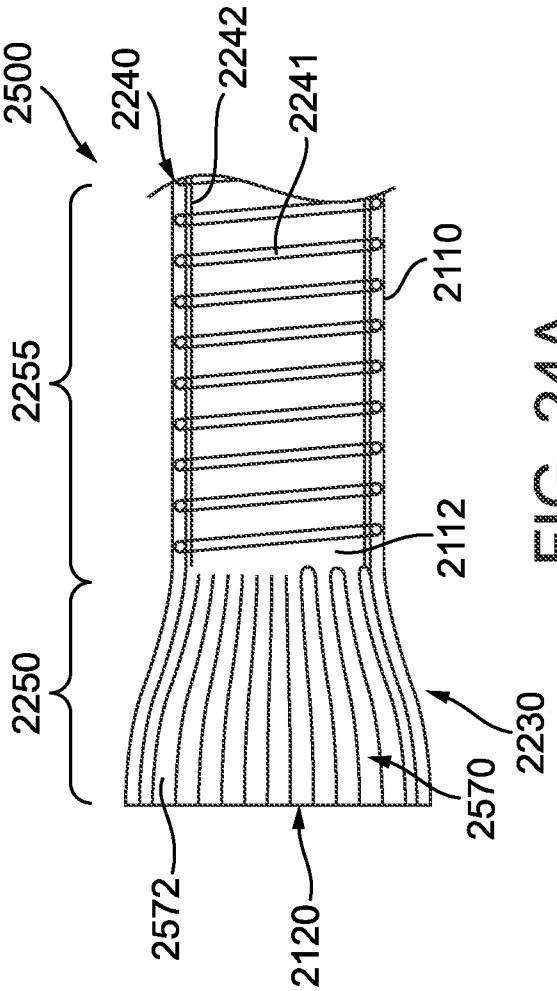


FIG. 24A

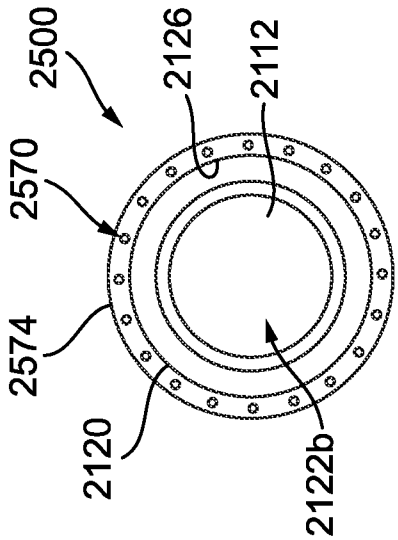


FIG. 24B

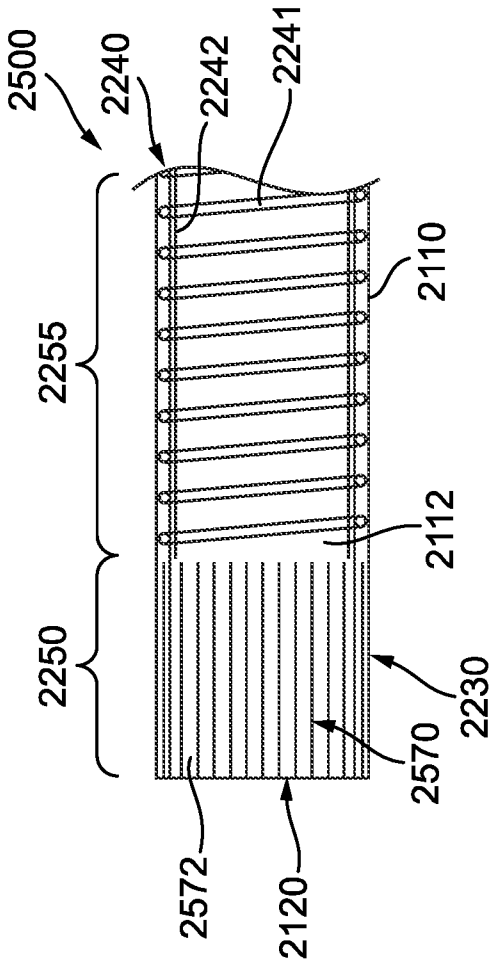


FIG. 24C

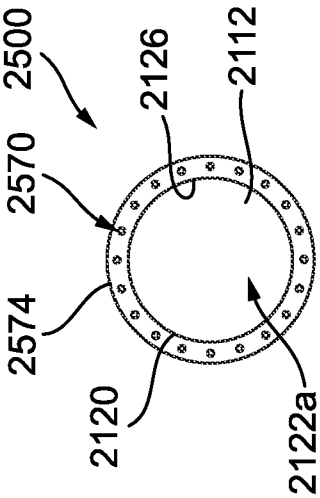


FIG. 24D

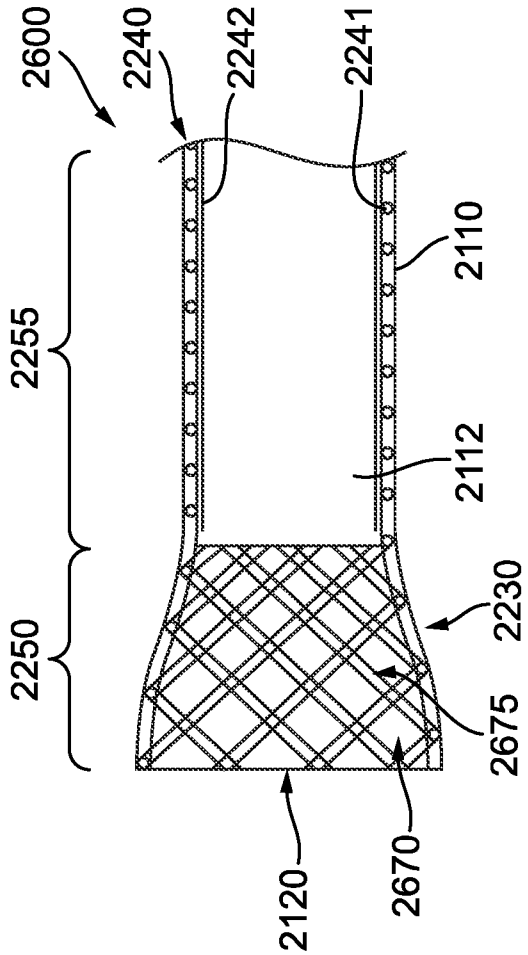


FIG. 25A

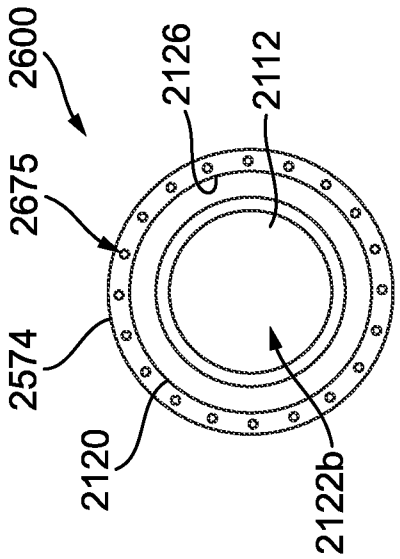


FIG. 25B

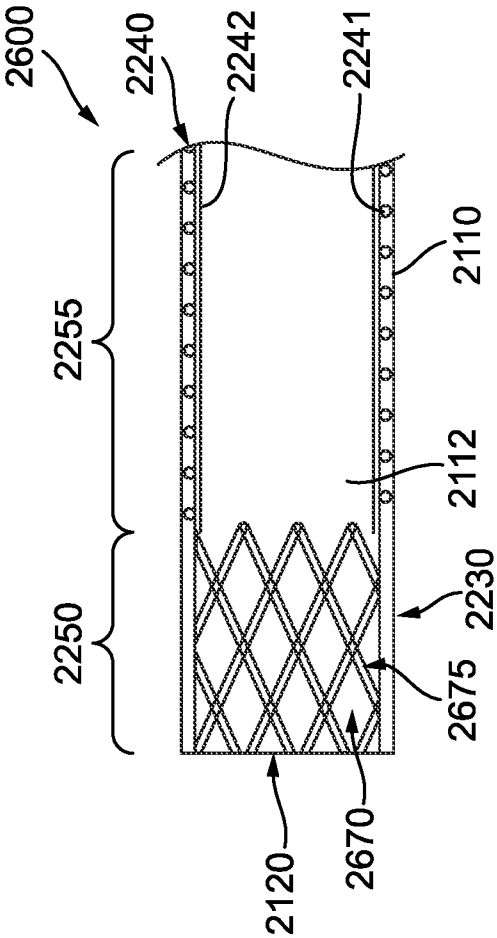


FIG. 25C

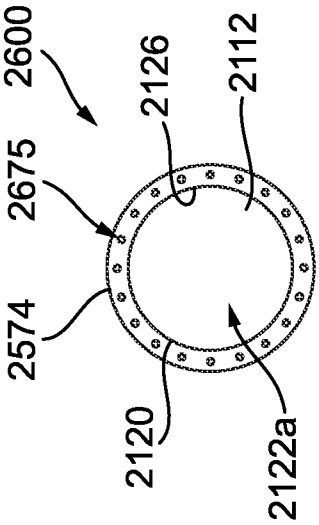


FIG. 25D

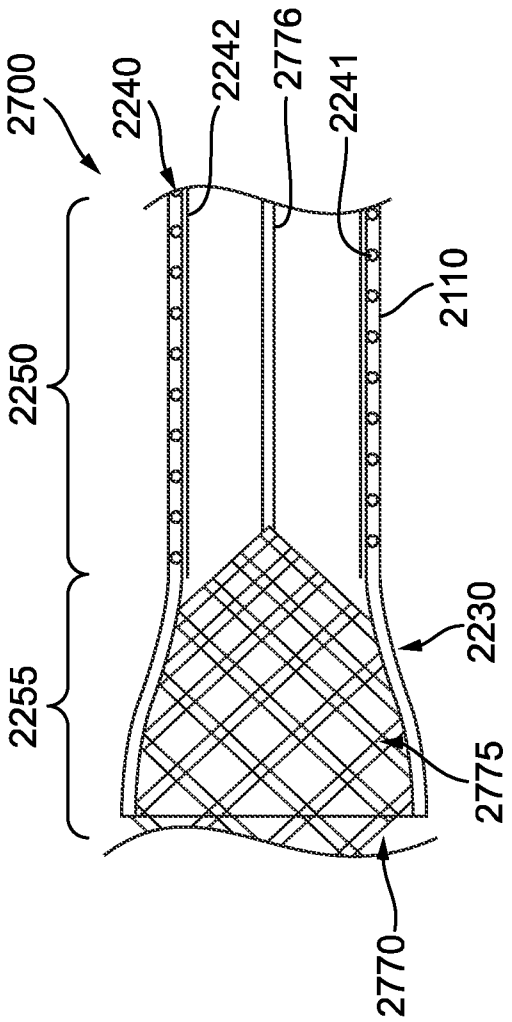


FIG. 26A

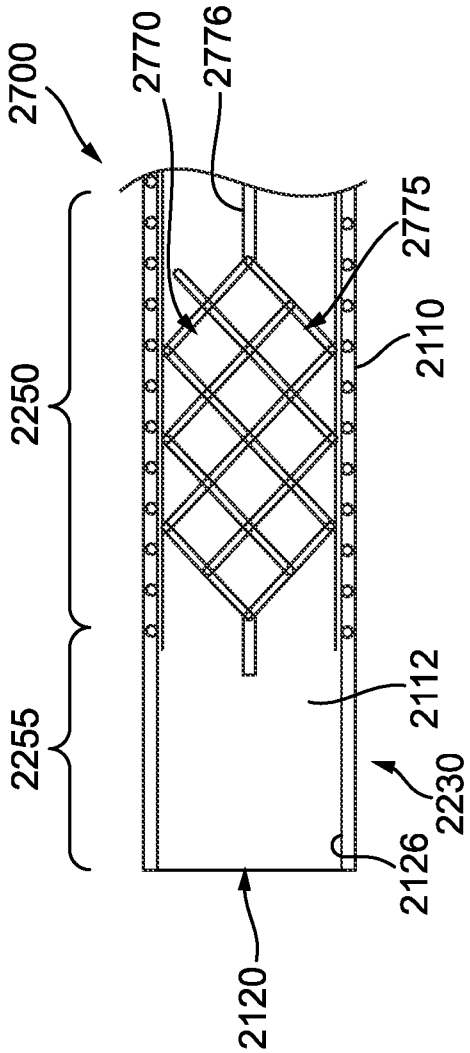


FIG. 26C

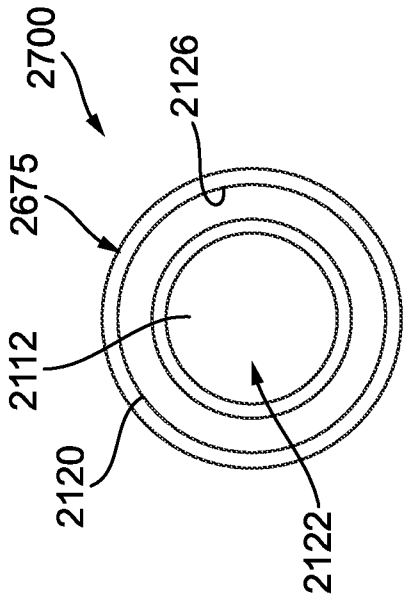


FIG. 26B

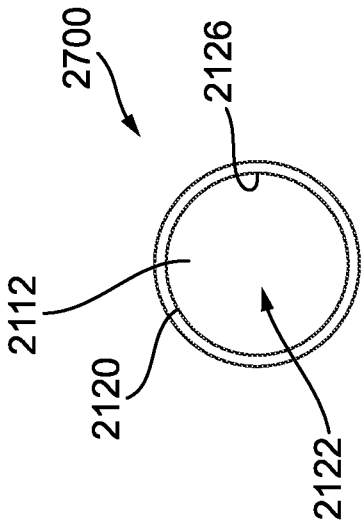


FIG. 26D

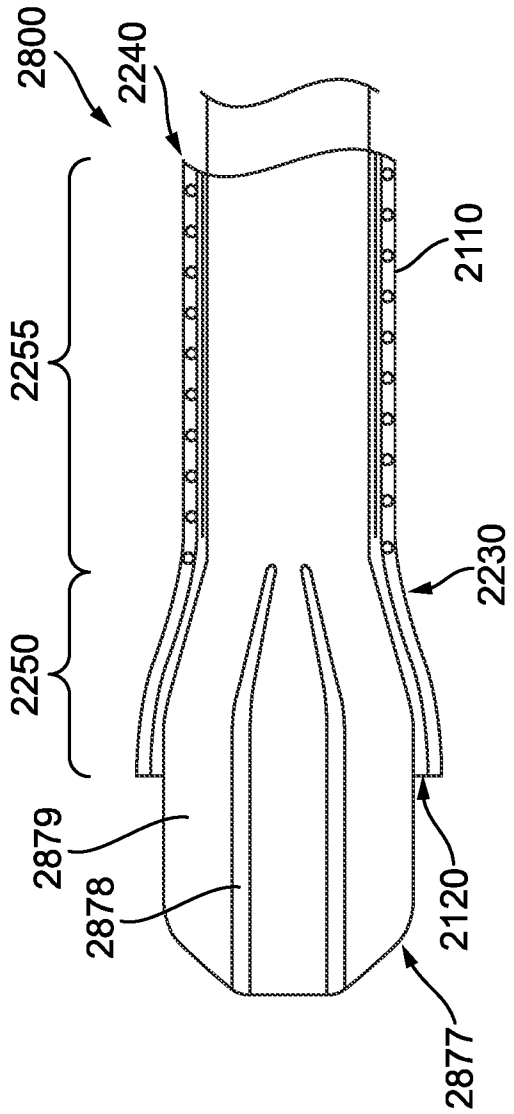


FIG. 27A

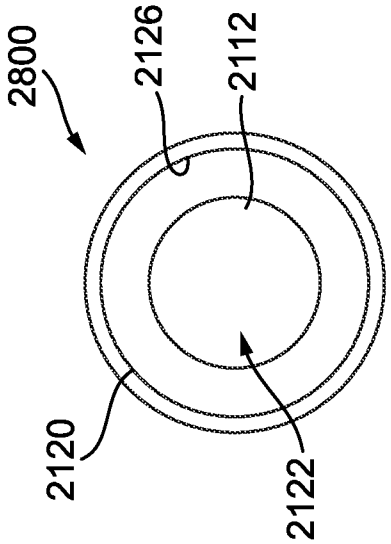


FIG. 27B

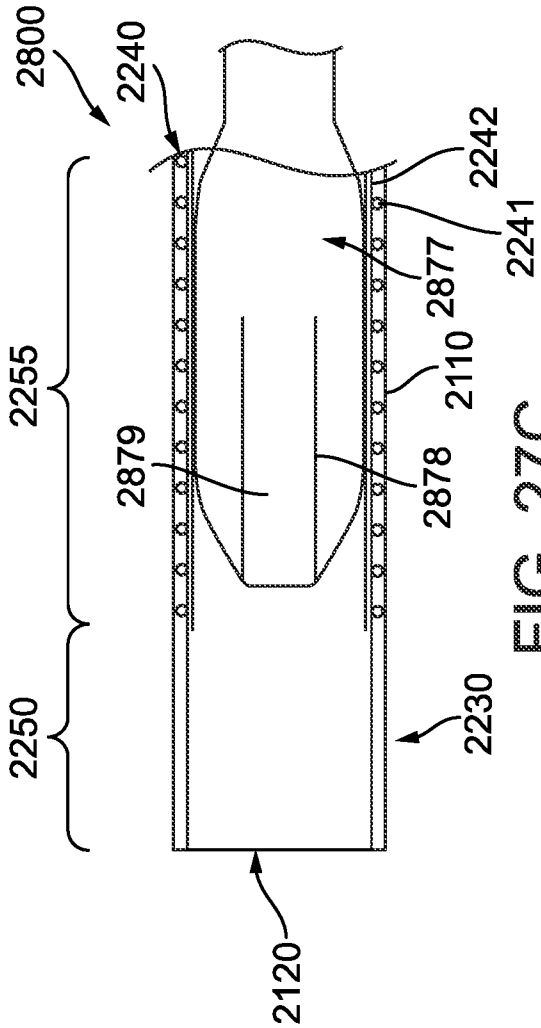


FIG. 27C

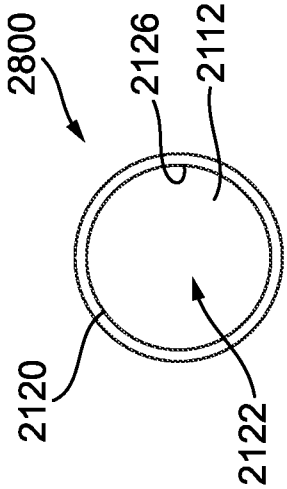


FIG. 27D

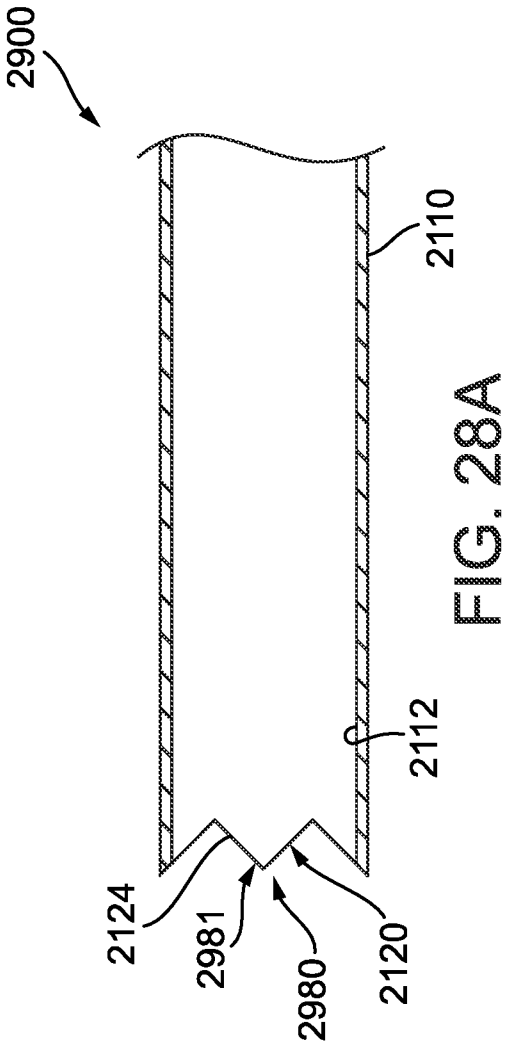


FIG. 28A

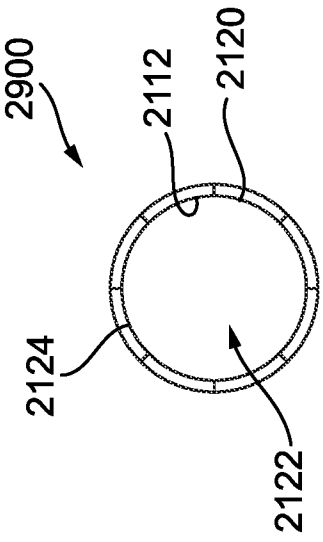


FIG. 28B

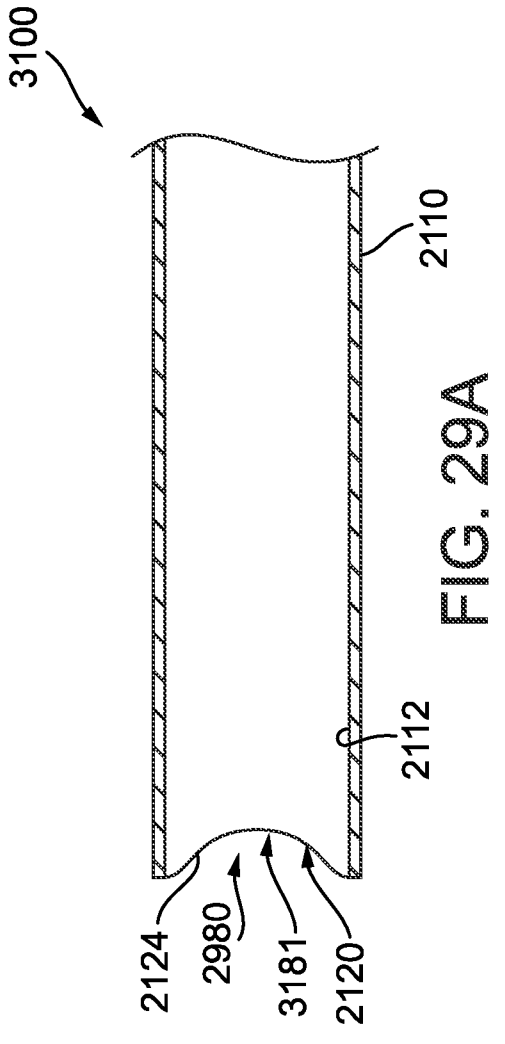


FIG. 29A

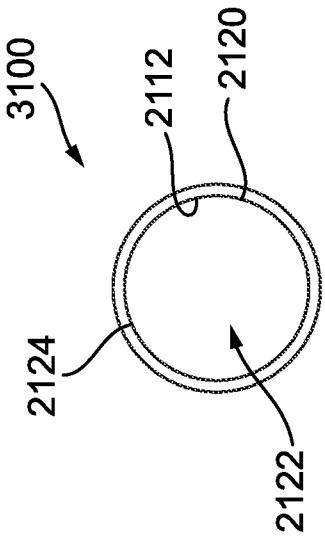


FIG. 29B

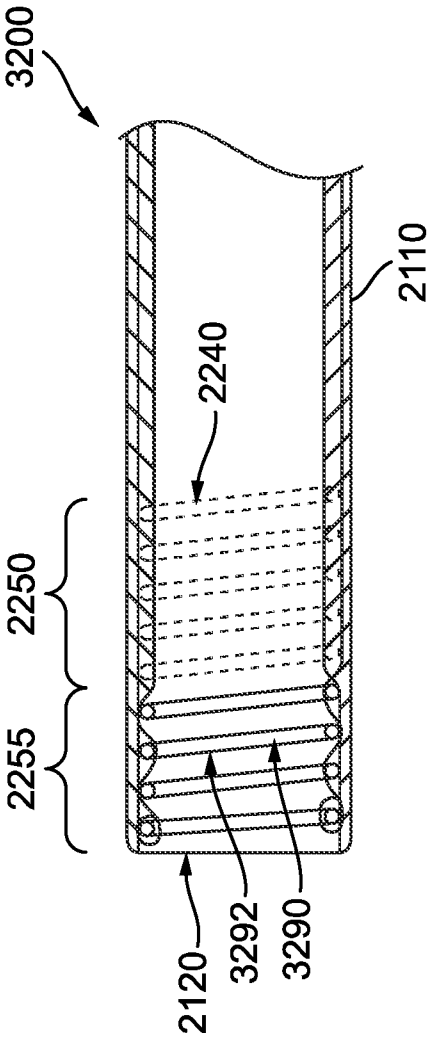


FIG. 30A

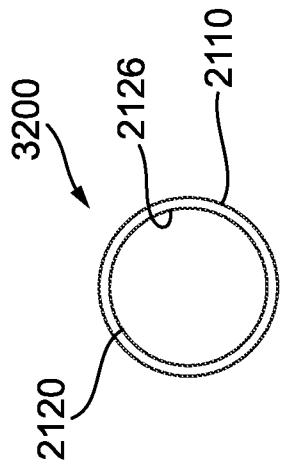


FIG. 30B

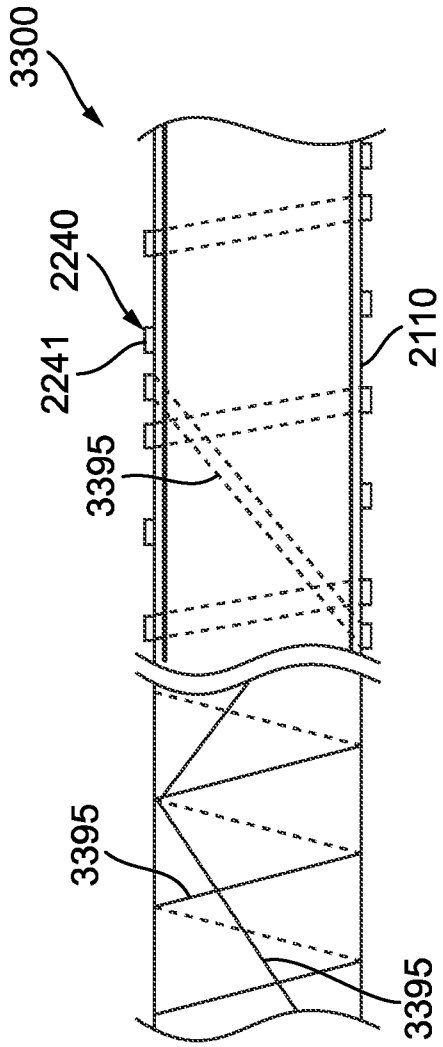


FIG. 31A

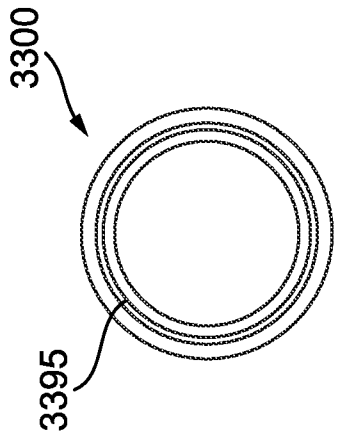


FIG. 31B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2022/033588

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/213297 A1 (AKLOG LISHAN [US] ET AL) 1 September 2011 (2011-09-01) paragraph [0038] - paragraph [0041]; figures 2A-D	1
X	US 2014/074144 A1 (SHRIVASTAVA SANJAY [US] ET AL) 13 March 2014 (2014-03-13) paragraph [0024]; figures 1-7 paragraph [0068] - paragraph [0079] paragraph [0090] - paragraph [0094]; figures 12-15	1-15
X	WO 2012/156924 A1 (CARDIOFLOW LTD [IL]; JAFFE RONEN [IL] ET AL.) 22 November 2012 (2012-11-22) paragraph [0069] - paragraph [0074]; figures 1A-C	1,8-15

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 August 2022	07/11/2022

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Moers, Roelof

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2022/033588

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017/136158 A1 (CULHANE JIM [US] ET AL) 18 May 2017 (2017-05-18) paragraph [0107] - paragraph [0122]; figures 9a-11b	1,8-15
X	US 2002/016564 A1 (COURTNEY BRIAN K [US] ET AL) 7 February 2002 (2002-02-07) paragraph [0044]; figure 4 paragraph [0049]	1-7
X	US 2019/328411 A1 (VALE DAVID [IE] ET AL) 31 October 2019 (2019-10-31) paragraph [0163] - paragraph [0166]; figures 64a-c	1,8-15
A	EP 0 934 755 A2 (MEDTRONIC INC [US]) 11 August 1999 (1999-08-11) abstract; claim 1; figure 3	14,15

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2022/033588

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 32-60
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:
1-15

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15

Aspiration catheter having reinforcement and deformer tip.

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2. claims: 16-21

Aspiration catheter having reinforcement and slidable shape memory deformer.

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3. claims: 22-31

Aspiration catheter having reinforcement and distal perimeter extending along more than one plane.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2022/033588

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