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(54) Title: RAPID ASPIRATION THROMBECTOMY SYSTEM AND METHOD

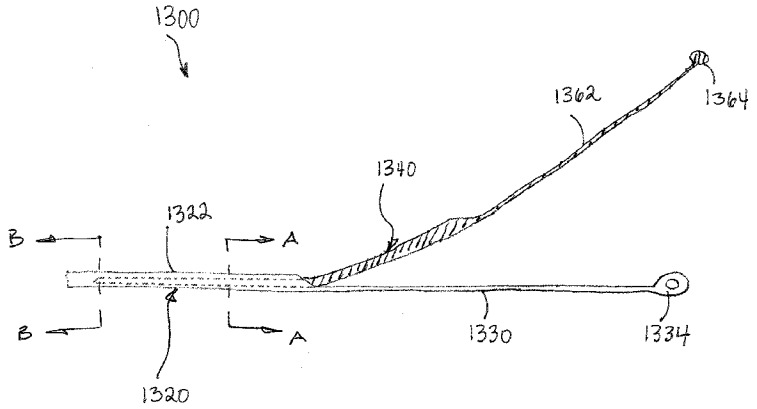

FIG. 12B

(57) Abstract: An intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature through an access sheath. The system includes an aspiration or support catheter (1320) having a flexible, distal luminal portion (1322) having an inner diameter defining a lumen (1323) extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion. The catheter has a rigid spine (1330) coupled to at least the proximal end of the luminal portion and extending proximally therefrom. The system includes a dilator (1340) having a flexible, distal dilator portion (1360) sized to be received within the lumen (1323) of the luminal portion (1322). Associated systems, devices, and methods of use are also described.

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RAPID ASPIRATION THROMBECTOMY SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Serial No. 62/111,481, filed February 4, 2015, and U.S. Provisional Application Serial No. 62/142,637, filed April 3, 2015, the disclosures of each of which are incorporated by reference herein in their entireties.

[0002] This application is also related to the following U.S. Patent Applications, which are incorporated by reference in their entirety: (1) US Patent Application Serial Number 14/576,953, filed December 19, 2014; and (2) US Patent Application Serial Number 14/569,365, filed December 12, 2014; (3) US Patent Application Serial Number 14/537,316, filed November 10, 2014; (4) US Patent Application Serial Number 14/221,917, filed March 21, 2014, which are all incorporated by reference.

BACKGROUND

[0003] The present disclosure relates generally to medical methods and devices for the treatment of acute ischemic stroke. More particularly, the present disclosure relates to methods and systems for navigating complex anatomy to perform rapid and safe aspiration and removal of cerebral occlusions.

[0004] Acute ischemic stroke is the sudden blockage of adequate blood flow to a section of the brain, usually caused by thrombus or other emboli lodging or forming in one of the blood vessels supplying the brain. If this blockage is not quickly resolved, the ischemia may lead to permanent neurologic deficit or death. The timeframe for effective treatment of stroke is within 3 hours for intravenous (IV) thrombolytic therapy and 6 hours for site-directed intra-arterial thrombolytic therapy or up to 8 hours for interventional recanalization of a blocked cerebral artery. Re-perfusing the ischemic brain after this time period has no overall benefit to the patient, and may in fact cause harm due to the increased risk of intracranial hemorrhage from fibrinolytic use. Even within this time period, there is strong evidence that the shorter the time period between onset of symptoms and treatment, the better the results. Unfortunately, the ability to recognize symptoms, deliver patients to stroke treatment sites, and finally to treat these patients within this timeframe is rare. Despite

treatment advances, stroke remains the third leading cause of death and the leading cause of serious, long-term disability in the United States.

[0005] Endovascular treatment of acute stroke is comprised of either the intra-arterial administration of thrombolytic drugs such as recombinant tissue plasminogen activator (rtPA), mechanical removal of the blockage, or a combination of the two. As mentioned above, these interventional treatments must occur within hours of the onset of symptoms. Both intra-arterial (IA) thrombolytic therapy and interventional thrombectomy involve accessing the blocked cerebral artery via endovascular techniques and devices.

[0006] Like IV thrombolytic therapy, IA thrombolytic therapy alone has the limitation in that it may take several hours of infusion to effectively dissolve the clot. Interventional thrombectomy therapies have involved capturing and removing the clot using snares, coils or temporary stents (also known as retrievable stent devices), and suctioning the clot with or without adjunct disruption of the clot. Retrievable stent devices are also utilized to restore flow quickly to the vessel during the intervention. Hybrid procedures are also utilized, combining retrievable stent devices and aspiration via the guide catheter or via intermediate catheters to aid in the removal of the clot and reduce the risk of distal emboli. Finally, balloons or stents have been used to create a patent lumen through the clot when clot removal or dissolution was not possible.

[0007] To access the cerebral anatomy, guide catheters or guide sheaths are used to guide interventional devices to the target anatomy from an arterial access site, typically the femoral artery. Balloon guide catheters are often used to enable proximal carotid artery occlusion during periods of the procedure which may potentially liberate a high level of emboli. The proximal occlusion has the effect of arresting forward flow and increasing aspiration efficiency through the lumen of the guide catheter. The length of the guide is determined by the distance between the access site and the desired location of the guide distal tip. Interventional devices such as guidewires, microcatheters, and intermediate catheters used for sub-selective guides and aspiration, are inserted through the guide and advanced to the target site. Often, devices are used in a co-axial fashion, namely, a guidewire inside a microcatheter inside an intermediate catheter is advanced as an assembly to the target site in a stepwise fashion with the inner, most atraumatic elements, advancing distally first and providing support for advancement of the outer elements. The length of each element of the coaxial assemblage takes into account the length of the guide, the length of proximal

connectors on the catheters, and the length needed to extend from the distal end. Thus, for example, the working length of an intermediate catheter is typically 20-40 cm longer than the working length of a guide, and the working length of a microcatheter is typically 10-30 cm longer than the working length of the intermediate catheter. The guidewire is typically longer than the microcatheter by another 20-50 cm.

[0008] Some exemplary issues with current technology include the time required or even the ability to access the site of the occlusion, the time required to restore flow or the inability to fully, or even partially, restore flow to the vessel, the occurrence of distal emboli during the procedure, which has potentially negative neurologic effect and procedural complications such as perforation and intracerebral hemorrhage. There is a need for a system of devices and methods that enable rapid access, optimized aspiration of the clot, distal protection throughout all stages of the procedure, which potentially liberate emboli, and safe and rapid exchange of devices as needed to fully restore flow to the blocked cerebral vessel.

SUMMARY

[0009] In one aspect, there is disclosed an intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature through an access sheath. The system includes an aspiration or support catheter having a flexible, distal luminal portion having an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion. The catheter has a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom. The system includes a dilator having a flexible, distal dilator portion sized to be received within the lumen of the luminal portion; and a rigid, dilator spine extending proximally from the dilator portion.

[0010] The dilator spine can align side-by-side with the spine of the catheter. The distal dilator portion can have a tapered distal tip. The dilator can have a length at least as long as a length of the catheter such that a distal tip of the dilator protrudes from the distal opening of the luminal portion. The dilator can be generally tubular along at least a portion of the length. A proximal end of the catheter spine can include a gripping feature configured for a user to grasp in order to move the catheter through an access sheath. A proximal end of the dilator spine can include a tab configured to be locked with the gripping feature on the catheter spine. When the catheter and the dilator are in a locked configuration they can be

advanced as a single unit through the access sheath. The gripping feature and the dilator tab can be removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature. The dilator tab can be affixed to the dilator or can be slideable on the dilator to accommodate different relative positions between the dilator and the catheter. The distal dilator portion can include one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends. The dilator spine and the catheter spine can have a similar stiffness and kink-resistance. The dilator can have a visual marker on a distal end and/or a proximal end of the distal tip. A distal end region of the dilator can be more flexible and increasingly stiffen towards a proximal end region of the dilator. The catheter spine and dilator spine can be configured to cause bi-directional sliding movement of the luminal portion through a lumen of an access sheath and navigate the luminal portion into a cerebral vessel to reach a treatment site.

[0011] In an interrelated aspect, disclosed is an intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature having an access sheath and an aspiration or support catheter. The access sheath has a sheath body having an inner diameter defining a lumen between a proximal end and a distal end of the sheath body. The sheath body has at least one opening from the lumen near a distal end region of the sheath body. The aspiration or support catheter includes a flexible, distal luminal portion having an outer diameter sized for insertion through the lumen of the access sheath, an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion, and a length between the proximal opening and the distal opening. The aspiration or support catheter includes a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom. The rigid spine is configured to cause bi-directional sliding movement of the luminal portion through the lumen of the access sheath and out the at least one opening to navigate the luminal portion into a cerebral vessel to reach a treatment site. A portion of the outer diameter of the luminal portion fluidly seals with the inner diameter of the access sheath when the distal end of the luminal portion extends into the cerebral vessel to reach the treatment site.

[0012] The luminal portion and the sheath body can be concentrically aligned and the lumen of the luminal portion and the lumen of the sheath body form a contiguous aspiration lumen from the distal end of the luminal portion to the proximal end of the sheath body. The contiguous aspiration lumen can be used to aspirate fluid and debris from the distal opening of the luminal portion. The contiguous aspiration lumen can be to deliver materials through the distal opening of the luminal portion. The contiguous aspiration lumen can form a step-up in diameter where the lumen of the luminal portion empties into the lumen of the sheath body. The lumen of the luminal portion can be shorter than the lumen of the sheath body. The luminal portion and the sheath body can form an overlap region when the luminal portion extends distally beyond the at least one opening of the sheath body. The outer diameter of the luminal portion can approach the inner diameter of the lumen of the sheath body such that a seal is formed by the overlap region. The seal can be configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg. The seal within the overlap region can be configured to enable sealing against a pressure of up to 300 mmHg or up to 600 or up to 700 mmHg. The seal can be located distal a proximal end of the luminal portion and proximal to the at least one opening of the sheath body.

[0013] The system can further include a sealing element positioned on an external surface of the luminal portion. The sealing element can include a stepped up diameter or protruding feature in the overlap region. The sealing element can include one or more external ridge features. The one or more ridge features can be compressible when the luminal portion is inserted into the lumen of the sheath body. The sealing element can include one or more inclined surfaces biased against an inner surface of the sheath body lumen. The sealing element can include one or more expandable members actuated to seal. The sheath body can have an outer diameter suitable for insertion into the carotid artery. The outer diameter of the sheath body can be between 5Fr and 7Fr.

[0014] The sheath body can have a length between the proximal end and the distal end suitable for locating the distal end of the sheath body at the petrous portion of an internal carotid artery from a transfemoral approach. The length of the sheath body can be between 80 cm and 105 cm. The length of the luminal portion can be between 10 cm and 25 cm. The length of the luminal portion can be less than a length of the sheath body such that as the catheter is retracted into the sheath body a seal remains between an overlap region of the luminal portion and the inner diameter of the sheath body.

[0015] The spine can be longer than an entire length of the sheath body. The luminal portion can include three or more layers including an inner lubricious liner, a reinforcement layer, and an outer jacket layer. The outer jacket layer can be composed of discreet sections of polymer with different durometers, compositions, and/or thicknesses to vary the flexibility along the length of the distal luminal portion. The outer diameter of the distal luminal portion can be sized for navigation into cerebral arteries. The inner diameter of the distal luminal portion can be between 0.040" and 0.088". The outer diameter of the luminal portion can approach the inner diameter of the sheath body creating a sealed area at an overlap region while still allowing the catheter to move through the sheath body. The catheter can be tapered towards the distal opening such that a distal-most end of the luminal portion has a smaller outer diameter compared to a more proximal region of the luminal portion near where the luminal portion seals with the sheath body. The distal end region of the sheath body can include an occlusion element. The distal end region of the sheath body can include an expanding distal tip. The at least one opening from the lumen can include a side opening located a distance away from a distal tip of the sheath body. The distal tip of the sheath body further can include a ramp feature configured to direct at an angulation the catheter away from a longitudinal axis of the sheath body lumen out through the at least one opening.

[0016] The spine can be longer than an entire length of the sheath body. The spine can be a wire having an outer dimension from 0.014" to 0.018". The spine can be a hypotube having a guide-wire passageway extending therethrough. The spine can be a ribbon having an outer dimension from 0.010" to 0.025" thick. The ribbon can be curved along at least a portion of an arc. The spine can be configured to rotate the luminal portion around a longitudinal axis of the access sheath. The spine can be eccentrically coupled to the luminal portion and the spine extend proximally from the luminal portion to outside the proximal end of the sheath body. The proximal end of the luminal portion can have an angled cut. The angled cut can be generally planar or curved. The sheath body can have one or more visual markers on the distal end region of the sheath body. The distal luminal portion can have one or more visual markers at a distal end region of the luminal portion, a proximal end region of the luminal portion or both. The one or more visual markers on the sheath body and the one or more visual markers on the luminal portion can be visually distinct. The spine can have one or more visual markers. The one or more visual markers of the spine can indicate overlap between the distal luminal portion and the sheath body. The one or more visual markers of

the spine can be positioned so that when the visual marker of the spine is aligned with a portion of the access sheath, the catheter is positioned at a distal-most position with minimal overlap length needed to create a seal between the catheter and the sheath body.

[0017] The system can further include a dilator having a flexible, distal dilator portion having a distal tip and sized to be received within the luminal portion of the catheter. The dilator can be a tubular element along at least a portion of its length. The dilator can be a solid rod formed of malleable material configured to be shaped by a user. The dilator can further include a rigid, dilator spine extending proximally from the dilator portion. The dilator spine can be coaxial and can have a lumen extending through it. The dilator spine can be eccentric. When in use, the dilator spine can align side-by-side with the spine of the catheter. The distal tip of the dilator can be tapered. The dilator can have a length at least as long as a length of the catheter such that the distal tip protrudes from the distal opening of the luminal portion. A proximal end of the spine can include a gripping feature configured for a user to grasp in order to move the catheter through the access sheath. A proximal end of the dilator spine can include a tab configured to be locked with the gripping feature on the catheter spine. When the catheter and dilator are in a locked configuration they can be advanced as a single unit through the sheath body. The gripping feature and the dilator tab can be removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature. The dilator tab can be affixed to the dilator and/or can be slideable on the dilator to accommodate different relative positions between the dilator and the catheter.

[0018] The distal dilator portion can include one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends. The dilator spine and the catheter spine can have a similar stiffness and kink-resistance. The dilator can have a visual marker on a distal end and/or a proximal end of the distal tip. A distal end region of the dilator can be more flexible and increasingly stiffens towards the proximal end region of the dilator.

[0019] The access sheath can further include a connector that connects the proximal end of the sheath body to a proximal hemostasis valve. The proximal hemostasis valve can have an adjustable opening sized large enough to allow removal of the catheter without dislodging any clots thereon. When in use with the access sheath, the rigid spine of

the catheter can extend proximally from the luminal portion through the access sheath lumen and out the proximal hemostasis valve of the access sheath. The connector can provide a connection of the proximal end of the sheath body to an aspiration line. The connector can have a large bore inner lumen and connects to a large-bore aspiration line. The aspiration line can connect to an aspiration source. The aspiration source can be an active aspiration source. The aspiration line can connect to a forward drip or flush line. The access sheath can further include a proximal extension portion such that when the distal luminal portion of the catheter is withdrawn from the sheath body lumen it remains within the proximal extension portion. The inner diameter of the luminal portion can be sized to permit placement of an interventional device through the luminal portion.

[0020] Other features and advantages should be apparent from the following description of various implementations, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. 1 is an exploded view of a system of devices for accessing and removing a cerebral occlusion to treat acute ischemic stroke from a femoral artery access site;

[0022] FIG. 2A shows components of the system of FIG. 1 in position in a patient from the transfemoral approach to treat the occlusion;

[0023] FIG. 2B is a detailed view of a portion of the system of FIG. 2A taken along circle BB;

[0024] FIG. 3 shows components of the system of FIG. 1 being used via a transcarotid access site;

[0025] FIG. 4 shows an implementation of an access sheath;

[0026] FIG. 5 shows an implementation of a proximal portion of the access sheath of FIG. 4 provided as a separate, removable component;

[0027] FIG. 6 shows an implementation of a connector to minimize flow resistance through the access sheath of FIG. 4 into the proximal portion;

[0028] FIG. 7 shows an implementation of an access sheath having an occlusion balloon;

[0029] FIGs. 8A-8B show implementations of sealing elements between the access sheath body and luminal portion of a catheter extending therethrough;

[0030] FIG. 9 shows an implementation of a microcatheter and retrievable stent device positioned through a spined catheter;

[0031] FIGs. 10A-10C show implementations of expandable portions on retrievable stent devices;

[0032] FIG. 11 shows an implementation of an aspiration system for use with the systems described herein;

[0033] FIG. 12A shows an implementation of a spined catheter system for use with the systems described herein;

[0034] FIG. 12B shows the spined catheter system of FIG. 12A having a spined dilator extending through a lumen of a spined catheter;

[0035] FIG. 12C shows the spined catheter system of FIG. 12A extended through a side opening of an implementation of an access sheath;

[0036] FIG. 13 is a cross-sectional view taken about line A-A of FIG. 12B;

[0037] FIG. 14 is a cross-sectional view taken about line B-B of FIG. 12B;

[0038] FIG. 15A shows an implementation of a spined aspiration catheter-dilator system having a spined catheter and a spined dilator in a locked configuration;

[0039] FIG. 15B shows the spined aspiration catheter-dilator system having the spined catheter and the spined dilator in an unlocked configuration;

[0040] FIG. 16 shows an implementation of a spined catheter system extending distally to an access sheath to treat an embolus in a cerebral vessel.

DETAILED DESCRIPTION

[0041] One of the major drawbacks to current acute stroke intervention procedures is the amount of time required to restore blood perfusion to the brain. This time includes the time it takes to access the occlusive site or sites in the cerebral artery, and the time it takes to completely remove the occlusion in the artery. Because it is often the case

that more than one attempt must be made to completely remove the occlusion, reducing the number of attempts as well as reducing the time required to exchange devices for additional attempts is an important factor in minimizing the overall time. Additionally, each attempt is associated with potential procedural risk due to device advancement in the delicate cerebral vasculature.

[0042] Disclosed herein are methods and devices that enable safe and rapid access to the complex neurovascular anatomies of the cerebral and intracranial arteries and removal of the occlusion. The methods and devices include one or more access devices, catheters, and thrombectomy devices to remove the occlusion. Methods and devices are also disclosed to provide active aspiration and/or passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli. The system offers the user a degree of flow control so as to address the specific hemodynamic requirements of the cerebral vasculature. The systems described herein provide superior ease of use in that a single operator may operate the disclosed systems using single-point continuous aspiration for rapid and safe exchange without switching. The higher efficiency of aspiration force through the systems described herein reduces distal embolic debris and increases the rate of "one-pass" thrombectomy.

[0043] It should be appreciated that while some embodiments are described with specific regard to aspirating a neurovascular anatomy, the embodiments are not so limited and may also be applicable to other uses. For example, the spined aspiration catheter and one or more components of the access systems described herein may be used to deliver working devices to a target vessel of a coronary anatomy, or other vasculature anatomy. It should be appreciated that where the phrase "aspiration catheter" is used herein that such a catheter may be used for other purposes besides or in addition to aspiration, such as the delivery of fluids to a treatment site or as a support catheter providing a conduit that facilitates and guides the delivery or exchange of other devices such as a guidewire or interventional devices. Alternatively, the access systems need not be limited only to the vasculature can be useful for access of other parts of the body outside the vasculature. It should also be appreciated that reference throughout this specification to a particular feature, structure, configuration, characteristic or implementation or embodiment may be combined in any suitable manner. The use of relative terms throughout the description may denote a relative position or direction. For example, "distal" may indicate a first direction away from

a reference point. Similarly, "proximal" may indicate a location in a second direction opposite to the first direction. However, such terms are provided to establish relative frames of reference, and are not intended to limit the use or orientation of an anchoring delivery system to a specific configuration described in the various embodiments below.

[0044] FIG. 1 shows a system of devices for accessing and removing a cerebral occlusion to treat acute ischemic stroke from a femoral artery access site. The system 100 includes an access sheath 220, sheath dilator 250, guidewire 270, one or more spined aspiration or support catheters 320, dilator 340, microcatheter 400, and a retrievable stent device 500, each of which will be described in more detail below. Further, the system 100 can include one or more arterial access sheath system 200 that includes an access sheath 220, one or more sheath dilators 250 and a sheath guidewire 270. The system 100 can include one or more spined catheter systems 300 including a spined aspiration or support catheter 320, a tapered dilator 340, and alternatively a catheter clearing tool 350. The spine catheter system 300 can incorporate nested spined catheters to provide for extended reach into distal sites. The system 100 can include an access sheath system 200, a tapered catheter system 300, a microcatheter 400, and a retrievable stent device 500.

[0045] FIG. 2A shows some elements of the system in position in the patient from the transfemoral approach to treat the occlusion. The access sheath 220 can be inserted through a femoral artery insertion site positioned with the distal tip of the access sheath 220 at or near the petrous portion of the internal carotid artery ICA. The spined aspiration catheter 320 can be positioned with the distal tip at the face of the occlusion in the artery. In some implementations, the access sheath 220 can be inserted through a direct puncture in the wall of the common carotid artery and advanced into the internal carotid artery rather than via a transfemoral approach (see FIG. 3).

[0046] As seen more clearly in detailed FIG. 2B, the access sheath 220 can have a sheath body 222 and an inner lumen 223 extending between a proximal end and a distal end region of the sheath body 222. The spined aspiration catheter 320 is sized to extend through the inner lumen 223 of the access sheath 220 such that a distal end region of the catheter 320 extends beyond a distal end region of the access sheath 220. The catheter 320 is shown in FIG. 2B exiting the lumen 223 of the sheath body 222 through a distal opening 221. It should be appreciated, however, that the sheath body 222 may have one or

more side openings near a distal end region of the body 222 through which the catheter 320 can extend (see FIG. 12C) as will be described in more detail below.

[0047] Still with respect to FIG. 2B, the spined aspiration catheter 320 can include a relatively flexible, distal luminal portion 322 coupled to a stiff and kink-resistant proximal spine 330. The distal luminal portion 322 can have an inner lumen 323 extending between a proximal end and a distal end of the luminal portion 322. The lumen 323 of the catheter 320 can have a first inner diameter and the lumen 223 of the access sheath 220 can have a second, larger inner diameter. The lumens 223, 323 are fluidly connected and contiguous such that fluid flow into and/or out of the system is possible, such as by applying suction from an aspiration source coupled to the system via a connector 226 on the access sheath 220. An overlap region 120 between the distal section of the sheath body 222 and the luminal portion 322 of the catheter 320 is sized and configured to create a seal that enables a continuous aspiration lumen from the distal tip region of the spined catheter 320 to the proximal sheath connector 226. If the sheath body 222 has a side opening through which the distal luminal portion 322 of the catheter 320 extends, the seal created at the overlap region 120 between the sheath body 222 and the luminal portion 322 is located proximal to the side opening.

[0048] Key dimensions that affect aspiration force through a tube include radius (r), pressure (P), viscosity (n) and length (L) where Flow = $Q = \pi r^4(\Delta P)/8nL$. Changes in radius increase flow to the 4^{th} power and length is inversely proportional to flow. As will be described in more detail below, the aspiration catheter has an over-the-wire portion that is a fraction of the overall distance required to reach the target site. This configuration greatly speeds up the time required to retract and re-advance the catheter. Further, the systems described herein can provide for a markedly increased radius and luminal area for aspiration of the clot and markedly shorter length, particularly compared to prior systems where the aspiration lumen runs along the entire inner diameter of the aspiration catheter. In the systems described herein, the majority of the aspiration lumen has a radius of the procedural sheath. The catheter 320 is smaller in diameter than the guide, but steps up in luminal diameter upon reaching the lumen of the access sheath 220 allowing for a greater aspiration force to be applied to a majority of the length of the luminal system. Further, the overall length of this narrow diameter region of the catheter 320 is much shorter compared to the overall length of the access sheath. The proximal spine 330 of the catheter 320 has a length

and structure that extends through the lumen 223 of the access sheath 220 to a proximal end of the system such that it can be used to advance and retract the catheter 320 through the lumen 223 of the sheath 220. The spine 330 of the aspiration catheter 320, however, takes up only a fraction of the luminal space the system resulting in increased luminal area for aspiration. Increased luminal area for aspiration increases the time it takes to aspirate the occlusion and increases the possibility of removing the occlusion in a single aspiration attempt. The stepped up luminal diameter also increases the annular area available for forward flushing of contrast, saline, or other solutions while devices such as microcatheters or tapered dilators are coaxially positioned in the spined catheter 320 and access sheath 220. This can increase the ease and ability to perform angiograms during device navigation.

[0049] Current stroke interventions pose a risk of distal emboli being released. During the effort to remove or dissolve clot blockages in the cerebral artery, for example, there is a significant risk of thrombus fragmentation creating embolic particles that can migrate downstream into either the occluded vessel or other vessels and compromise cerebral perfusion. In carotid artery stenting procedures (CAS), embolic protection devices and systems are commonly used to reduce the risk of embolic material from entering the cerebral vasculature. The types of devices include intravascular distal filters, and reverse flow or static flow systems. Unfortunately, because of the delicate anatomy and access challenges as well as the need for rapid intervention, these types of embolic protection systems are not used in interventional treatment of acute ischemic stroke. The period of a stroke intervention when flow is restored is normally considered an important time as the brain is now being perfused by blood. However, it is also a period of embolic risk. While there is blockage in the artery, there is no flow. Therefore any embolic debris created by crossing the occlusion with guidewire and/or microcatheter, or deployment of a retrievable stent device across the occlusion, remains stagnant. However, when flow is restored to the artery, the emboli can now flow antegrade to distal vascular territories.

[0050] A second period of embolic risk occurs when the retrievable stent device is being pulled back into the guide or catheter. In prior methods and devices, aspiration is applied to the intermediate catheter during retrievable stent device retraction into the catheter, or the catheter and retrievable stent device are pulled back together into the guide, while simultaneously applying aspiration to the guide catheter. Two points of aspiration, through the catheter and through the guide, may both be utilized to reduce risk of

distal emboli during the critical step of drawing the occlusion through the guide and out of the patient. Often, two people are required to enable two points of aspiration, or aspiration is performed sequentially from first the catheter and then the guide, which may lead to interruption in aspiration or sub-optimal aspiration. In the disclosed systems and methods, reverse flow may be applied to the target site during device advancement, at the critical time of flow restoration, and during the entire time that the occlusion is being removed, with a single point of aspiration.

[0051] In an aspect of the disclosure, the level of aspiration may be modified from a low level to achieve adequate protection from distal emboli, to a higher level to provide effective aspiration removal of the occlusion. This aspect allows distal protection without high levels of blood loss, yet allows a strong aspiration force as needed to remove the occlusion.

[0052] In another aspect, there are disclosed methods and devices for additionally providing active aspiration or passive retrograde flow during the procedure to remove thrombus and to minimize distal emboli. The system offers the user a degree of blood flow control so as to address the specific hemodynamic requirements of the cerebral vasculature. The system may include a flow controller, which allows the user to control the timing and mode of aspiration.

[0053] In another aspect, there are disclosed methods and devices for additionally providing flushing steps to minimize emboli entrapment in the system and increased visibility of particulates in the system during use.

[0054] The following descriptions provide detailed implementations and benefits of each aspect of the disclosed invention.

[0055] Referring again to FIG. 1 illustrating an implementation of an access sheath 220. The sheath 220 can include a sheath body 222 that is the insertable portion of the sheath 220 (i.e. the portion that inserts into the patient), a proximal connector 226, an aspiration line 230, a proximal hemostasis valve 234 and a flush line 236. The sheath 220 may also include a proximal extension portion 240, and may also include a valve on the connector 226 to fluidly isolate the sheath body 222 from the proximal portion 240 of the access sheath 220. The access sheath 220 may come in a kit with one or more dilators 250, and a sheath guidewire 270.

[0056] The diameter of the sheath body 222 is suitable for insertion into the carotid artery, with an inner lumen 223 that is suitably sized for providing a passageway for catheters to treat the occlusion. In an implementation, the sheath body 222 can have an inner diameter of about 0.074" and an outer diameter of about 0.090", corresponding to a 5 French sheath size, an inner diameter of about 0.087" and an outer diameter of about 0.104", corresponding to a 6 French sheath size, or an inner diameter of about 0.100" and an outer diameter of about 0.177", corresponding to a 7 French sheath size. The length of the sheath body 222 is configured to enable the distal tip of the sheath body 222 to be positioned as far distal as the petrous portion of the internal carotid artery. In an implementation, the sheath body 222 length is suitable for a transfemoral approach, in the range 80 to 90 cm or up to about 100 cm or up to about 105 cm. In an implementation, the sheath body 222 length is suitable for a transcarotid approach to the petrous ICA, in the range 20 to 25 cm. In an implementation, the sheath body 222 length is suitable for a transcarotid approach to the CCA or proximal ICA, in the range 10-15 cm. The sheath body 222 is configured to assume and navigate the bends of the vasculature and be subject to high aspiration forces without kinking, collapsing, or causing vascular trauma.

[0057] The sheath body 222 can be constructed in two or more layers. An inner liner can be constructed from a low friction polymer such as PTFE (polytetrafluoroethylene) or FEP (fluorinated ethylene propylene) to provide a smooth surface for the advancement of devices through the inner lumen. An outer jacket material can provide mechanical integrity to the inner liner and may be constructed from materials such as PEBAX, thermoplastic polyurethane, polyethylene, nylon, or the like. A third layer can be incorporated that can provide reinforcement between the inner liner and the outer jacket. The reinforcement layer can prevent flattening or kinking of the inner lumen of the sheath body 222 to allow unimpeded device navigation through bends in the vasculature as well as aspiration or reverse flow. The sheath body 222 can be circumferentially reinforced. The reinforcement layer can be made from metal such as stainless steel, Nitinol, Nitinol braid, helical ribbon, helical wire, cut stainless steel, or the like, or stiff polymer such as PEEK. The reinforcement layer can be a structure such as a coil or braid, or tubing that has been laser-cut or machine-cut so as to be flexible. In another implementation, the reinforcement layer can be a cut hypotube such as a Nitinol hypotube or cut rigid polymer, or the like.

[0058] The flexibility of the sheath body 222 can vary over its length, with increasing flexibility towards the distal portion of the sheath body 222. The variability in flexibility may be achieved in various ways. For example, the outer jacket may change in durometer and/or material at various sections. A lower durometer outer jacket material can be used in a distal section of the sheath compared to other sections of the sheath. Alternately, the wall thickness of the jacket material may be reduced, and/or the density of the reinforcement layer may be varied to increase the flexibility. For example, the pitch of the coil or braid may be stretched out, or the cut pattern in the tubing may be varied to be more flexible. Alternately, the reinforcement structure or the materials may change over the length of the sheath body 222. In an implementation, the distal-most section has a flexural stiffness (E*I) in the range 50 to 300 N-mm2 and the remaining portion of the sheath body 222 has a flexural stiffness in the range 500 to 1500 N-mm2 , where E is the elastic modulus and I is the area moment of inertia of the device. In another implementation, there is a transition section between the distal-most flexible section and the proximal section, with one or more sections of varying flexibilities between the distal-most section and the remainder of the sheath body 222. In this implementation, the distal-most section is about 2 cm to about 5 cm, the transition section is about 2 cm to about 10 cm and the proximal section takes up the remainder of the sheath length.

[0059] The tip of the sheath body 222 may include one or more distal radiopaque markers 224 (see FIG. 1). In an implementation, the radiopaque tip marker 224 is a metal band, for example platinum iridium alloy, embedded near the distal end of the sheath body 222. Alternately, the access sheath tip material may be a separate radiopaque material, for example a barium polymer or tungsten polymer blend. The distal region of the sheath body 222 is also the area of the overlap region 120 that allows a seal between the catheter 320 and the sheath body 222, creating a continuous aspiration lumen. Thus, the outer diameter of the luminal portion 322 of the aspiration catheter 320 approaches the inner diameter of the distal region of the sheath body 222 lumen 223 such that a seal is formed. The relative location of the seal formed may vary depending on where the aspiration catheter 320 exits the lumen 223 of the sheath body 222 and the location of the openings from the sheath body 222, as described in more detail below. For example, if the sheath body 222 has an opening at the distal tip the location of the seal may be closer to the distal end of the sheath body 222 compared to if the sheath body 222 has one or more side openings in the distal end region of the sheath body 222 through which the catheter 320 exits the lumen 223.

[0060] Referring again to FIG. 1, the access sheath 220 also can include a connector 226 that connects a proximal end of the sheath body 222 to the proximal hemostasis valve 234, and also provides a connection to the aspiration line 230. This connector 226 can have a large bore inner lumen, and connects to a large-bore aspiration line 230. In an implementation, the inner lumen of the connector 226 is at least .080". In an implementation, the inner lumen of the aspiration line 230 is at least .080". The aspiration line 230 can terminate in a stopcock, female Luer connector, or other connector 232 that allows connection to an aspiration source. In an implementation, the aspiration source is an active aspiration source such as a syringe or a pump. In another implementation, the aspiration source is a reverse flow shunt line such as that described in US Patent Number 8,157,760 and US Patent Publication Number 2010/0217276, which are both incorporated by reference. The large bore aspiration line 230 can be constructed to be resistant to collapse. For example, the aspiration line 230 can be a thick-walled polymer tubing or a reinforced polymer tubing. The aspiration line valve 232 enables the line 230 to be opened or closed. In one implementation, the valve 232 also allows connection of one or more additional fluid lines, for connecting a forward drip or a flush line for contrast or saline injections. As an example, the valve 232 may be a stopcock manifold commonly used in interventional procedures to allow multiple connections. The connector 226 may also include means to secure the access sheath 220 to the patient to reduce the risk of sheath dislodgement during the case. For example, the connector 226 may include one or more suture eyelets 233.

[0061] With reference still to FIG. 1, the proximal end of the access sheath 220 can terminate in a proximal hemostasis valve 234. This valve 234 allows the introduction of devices through the sheath 220 into the vasculature, while preventing or minimizing blood loss and preventing air introduction into the access sheath 220. The hemostasis valve 234 can include a flush line 236 or a connection to a flush line 236 so that the sheath 220 can be flushed with saline or radiopaque contrast during the procedure as desired. The flush line 236 can also be used as a second point of aspiration during portions of the procedure as described more fully below. The hemostasis valve 234 can be a static seal-type passive valve, or an adjustable-opening valve such as a Tuohy-Borst valve or rotating hemostasis valve (RHV). The hemostasis valve 234 can be integral to the access sheath 220, or the access sheath 220 can terminate on the proximal end in a female Luer adaptor to which a separate hemostasis valve 234 component, such as a passive seal valve, a Tuohy-Borst valve or rotating hemostasis valve may be attached. In an implementation, the

valve 234 has an adjustable opening that is open large enough to allow removal of devices that have adherent clot on the tip without causing the clot to dislodge at the valve 234 during removal. Alternately, the valve 234 is removable and is removed when the catheter tip is being removed from the sheath 220 to prevent clot dislodgement at the valve 234.

[0062] Referring again to FIG. 1, the arterial sheath system 200 can include one or more sheath dilators 250 and a sheath guidewire 270. The sheath guidewire 270 can be inserted first into the artery using standard vascular access techniques such as a micropuncture technique or Modified Seldinger technique. The sheath dilator 250 allows for smooth insertion of the access sheath 220 through a puncture site in the arterial wall. The dilator 250 can be inserted into the access sheath 220 and then the two components can be inserted together over the sheath guidewire 270 into the artery The distal end 256 of the dilator 250 can be generally tapered to allow the dilator 250 to dilate the needle puncture site as it is being inserted through the arterial wall into the artery. The tapered distal end 256 can be generally between 6 and 12 degrees total included angle (relative to a longitudinal axis of the dilator), with a radiused leading edge.

[0063] An inner lumen of the dilator 250 can accommodate the sheath guidewire 270, and can have an inner diameter of between .037" to .041" to correspond to a sheath guidewire 270 of between .035" to .038". Alternately, the inner lumen of the dilator 250 can be between .020" to .022" to accommodate a sheath guidewire 270 of between .014" to .018". Alternately, the dilator 250 can be a two part dilator with an inner dilator and an outer dilator. The outer dilator can have an inner diameter of between .037" to .041", and the inner dilator can have an inner diameter of between .020" to .022". In use, the sheath 220 can be inserted into the artery with the outer dilator with a sheath guidewire 270 between .035" and .038". The sheath guidewire 270 may then be removed and replaced with the inner dilator and a smaller guidewire of between .014" and .018", and the access sheath 220 can then be advanced further distally to the desired site in the carotid artery.

[0064] To insert the arterial sheath 220 initially over the sheath guidewire 270 into the artery, the dilator taper 256 can have a certain stiffness and taper angle to provide the adequate dilating force on the arterial puncture site. However, to safely reach the petrous portion of the ICA, it may be desirable to have a sheath dilator 250 with a softer and/or longer taper at a distal end than that used for initial arterial access. In an implementation, the access sheath system 200 can include two or more tapered dilators. The

first tapered dilator can be used with the arterial access device to gain entry into the artery, and is thus sized and constructed in a manner similar to standard introducer sheath dilators. Example materials that may be used for the tapered dilator include, for example, high density polyethylene, 72D PEBAX, 90D PEBAX, or equivalent stiffness and lubricity material. A second tapered dilator may be supplied with a softer distal section or a distal section that has a lower bending stiffness relative to the distal section of the first tapered dilator, and/or a longer taper length. That is, the second dilator has a distal region that is softer, more flexible, or articulates or bends more easily than a corresponding distal region of the first dilator. The distal region of the second dilator thus bends more easily than the corresponding distal region of the first dilator. In an implementation, the distal section of the first dilator has a bending stiffness in the range of 50 to 100 N-mm2 and the distal section of the second dilator has a bending stiffness in the range of 5 to 15 N-mm2. The second dilator (which has a distal section with a lower bending stiffness) may be exchanged with the initial, first dilator such that the access sheath 220 may be advanced into the internal carotid artery and around curvature in the artery without undue force or trauma on the vessel due to the softer distal section of the second dilator.

[0065] The distal section of the soft, second dilator may be, for example, 35 or 40D PEBAX, with a proximal portion made of, for example 72D PEBAX. An intermediate mid portion or portions may be included on the second dilator to provide a smooth transition between the soft distal section and the stiffer proximal section. In an implementation, both dilators have an inner diameter of between .037" to .041". In an alternate implementation, the first dilator has an inner diameter of between .037" to .041" and the second dilator has an inner diameter of between .020" to .022". In yet another implementation, the second dilator is a two part dilator with an inner dilator and an outer dilator, as described above. In an implementation, one or both dilators may have radiopaque tip markers 224 so that the dilator tip position is visible on fluoroscopy. In one variation, the radiopaque marker 224 is a section of tungsten loaded PEBAX or polyurethane that is heat welded to the distal tip of the dilator. Other radiopaque materials may similarly be used to create a radiopaque marker 224 at the distal tip.

[0066] In an implementation, the access sheath 220 includes a proximal extension 240 that extends between the connector 226 and the proximal hemostasis valve 234. In the transcarotid configuration of the system, it may be desirable to move the

proximal hemostasis valve 234 away from the distal tip of the access sheath 220, effectively elongating or lengthening the proximal portion of the access sheath that is outside the body while maintaining the length of the insertable sheath body portion 222. This allows the user to insert devices into the proximal hemostasis valve 234 of the access sheath 220 from a point further away from the target site and therefore away from the x-ray source and/or image intensifier used to image the target site fluoroscopically, thereby minimizing radiation exposure of the user's hands and also his or her entire body. In this implementation, the proximal extension 240 can be in the range between 10 and 25 cm, or between 15 and 20 cm. In either the transcarotid or transfemoral configuration, it may also be desirable to provide a section of the access sheath 220 that is fluidly connected to the access sheath aspiration line, but which may extend proximally from the aspiration line connection. This will allow users to pull devices out of the flow of blood from the sheath tip to the aspiration line, without completely removing the device from the access sheath 220.

[0067] In an alternate implementation, it may also be desirable to intermittently isolate this proximal portion 240 from the sheath body 222. In an implementation, as shown in FIG. 4, the connector 226 includes a valve 242 that can close off the fluid connection between the sheath body 222 and the proximal portion 240 of the access sheath 220, including the aspiration line 230, proximal extension 240 and proximal hemostasis valve 234. This can allow the distal portion of a catheter, retrievable stent device, or other thrombectomy device to be pulled into this proximal extension portion 240, the valve 242 closed to fluidly isolate the sheath body 222 from the proximal portion of the sheath, and then the proximal hemostasis valve 234 to be widely opened or removed, or the entire proximal extension portion 240 of the sheath 220 removed, without arterial bleeding from the sheath 220. The proximal extension 240 can be at least as long as the distal luminal portion 222 of the spined catheter 320 so that the distal luminal portion 322 may be pulled entirely into the proximal extension 240 and the valve 242 closed off before the proximal hemostasis valve 234 is widely opened to remove the catheter 320 entirely from the sheath 220.

[0068] Alternately, after the thrombectomy device or other interventional device is pulled into this proximal extension portion 240 and the sheath body 222 closed off via the valve 242, a portion of the thrombectomy device, such as the distal luminal portion 322 of the aspiration catheter 320, may remain in the proximal extension 240 and be flushed or otherwise cleared by creating flow from the flush line to the aspiration lines to dislodge

clot without fully removing the device 320 from the access sheath 220. This ability to flush and clear the thrombectomy device without fully removing the thrombectomy device may reduce bleeding, time, and risk of air emboli during the steps between thrombectomy attempts. Also, withdrawing the thrombectomy device into the proximal extension 240 without fully removing it from the sheath body 222 while flushing and clearing also minimizes operator and staff exposure to blood and debris associated with device cleansing. In any of these implementations, the proximal extension tubing is clear so that the flush solution and presence/absence of embolic debris or air is clearly visible through the tubing.

[0069] The proximal extension portion 240 of the access sheath 220 can be provided as a separate, removable component that can be attached to any sheath with a standard connection on the proximal end. As shown in FIG. 5, a proximal component 280 includes a connector 285 that can attach to a proximal hub 15 of a standard sheath 10. The coupled components can create an assembly with the configuration and features of access sheath 220. In this implementation, the user can select from any of several already available sheaths of appropriate length, shape, and mechanical characteristics for the procedure, and perform the steps of the procedure described in this disclosure. The removable proximal component 280 can include the Y-arm connector 226, aspiration line 230, proximal extension 240, proximal hemostasis valve 234 and flush line 236, along with the valve connectors 232 and 238 terminating the aspiration line 230 and flush line 236 respectively. A connector 285 can couple to the proximal connector 226 on the sheath 220. In an implementation as shown in FIG. 6, the connector 285 is configured to minimize the flow resistance through the sheath 10 and into the proximal portion 280. For example, instead of a standard male-female Luer connection, the connector 285 can include an adaptor 60 with an inner lumen and surface that matches a standard female Luer connector 62 typically found on sheaths, a seal element 64 that seals between the adaptor 60 and the sheath female Luer 62, and a rotating nut 66 that engages the thread elements of the female Luer 62 and couples the adaptor 60 and Luer 62 together such that the seal 64 is compressed and can seal against fluid and air vacuum and pressure. Again with respect to FIG.5, the proximal component 280 may also include a valve 242 on the Y-arm connector 226, so that when the proximal component 280 is attached to a sheath 10, the proximal section may be selectively open or closed to fluid connection with the sheath 10. A similar type of connection can be made for connector 232 connecting the sheath aspiration line 230 to an aspiration source.

[0070] In a preferred implementation, the proximal connection has a proximal extension length of about 22 cm, a Y-arm connector of about 7 cm, and a proximal hemostasis valve of length about 5 cm for a total length of about 34 cm.

[0071] It may be desirable to transiently occlude the carotid artery during the intervention to arrest antegrade flow of emboli during portions of the procedure. In an implementation, as shown in FIG. 7, the access sheath 220 includes an occlusion balloon 246 on the distal tip of the sheath body 222. An additional lumen in sheath body 222 can be connected to an inflation line 248 and fluidly connects the balloon 246 to the inflation line 248. An inflation device is attached to inflation line 248 to inflate the occlusion balloon 246. In this implementation, the balloon 246 is inflated when carotid artery occlusion is desired.

[0072] In some instances it is desirable to keep the sheath tip as small as possible during sheath insertion to minimize the diameter of the arterial puncture, but to expand the opening of the sheath 220 after it has been inserted into the vessel. At least one purpose of this feature is to minimize the effect or creation of distal emboli during pull back of an aspiration catheter 320 or other thrombectomy device into the sheath 220. During a thrombectomy procedure, the thrombus may be "pulled back" into a distal opening 221 of the sheath 220 on a device that has captured the thrombus. If the distal tip of the sheath 220 is enlarged relative to its initial size, or flared into a funnel shape, the chance of pieces of the thrombus breaking off and causing emboli is minimized because the larger size or funnel shape of the sheath tip is more likely to accommodate the emboli being drawn into it without being split into multiple pieces. This creates a better clinical outcome for the patient. In an implementation of the access sheath, the distal portion of the sheath body 222 is a material and/or construction such that the tip can be expanded after the sheath 220 is inserted into the artery and positioned in its desired location. In an implementation, the distal region of the sheath has an ID of about 0.087" can be enlarged to a diameter of about 0.100" to 0.120" although the size may vary and/or be flared.

[0073] Examples of expanding distal tip constructions include covered braided tips that can be shortened to expand. Another example of an expanding distal tip construction is an umbrella or similar construction that can open up with mechanical actuation or elastic spring force when unconstrained. Other mechanisms of expandable diameter tubes are well known in the art. One particular implementation is a sheath made of material that is deformable when expanded using a high pressure balloon. Co-pending U. S.

Patent Publication number 2015/0173782, filed on December 19, 2014, describes exemplary devices and is incorporated herein by reference in its entirety. Construction of such features are described in co-pending Publication number 2015/0173782.

[0074] The distal end region of the sheath body 222 also may vary in the location, size and number of openings. The sheath body 222 may incorporate one or more openings near the distal end region of the sheath 220 that allow for fluid flow between the lumen 223 of the sheath body 222 and the vasculature within which the sheath 220 is positioned. The one or more openings can be sized to allow at least the luminal portion 322 of the aspiration catheter 320 to extend therethrough. The one or more openings may be sized larger than the outer diameter of the luminal portion 322 such that the one or more openings form an elongate mouth, slot or notch in a distal end region of the sheath body 222. The one or more openings may be formed within a region of the side wall of the sheath body 222 just proximal to the distal end, such that the opening is located at least 0.25 mm, 0.5 mm, 1.0 mm, 1.5 mm, 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, or 4.0 mm or greater from the distal end of the sheath body 222. The one or more openings may be a plurality of openings forming a porous region near the distal end region of the sheath body 222 wherein at least one of the pluralities of openings is sized large enough to allow one or more components of the system to exit the lumen 223 of the sheath body 222. In some implementations, the one or more openings includes a distal opening 221 from the lumen 223 of the sheath body 222 (see FIGs. 4 and 12C). In some implementations, the one or more openings includes an elongate, distal mouth forming a side opening 1219 on a first side of the sheath body 222 located near a distal end region (see FIG. 12C). The side opening 1219 may be located at least 0.25 mm or more from the distal end of the sheath body 222. The side opening 1219 may having a diameter that is at least as large as the outer diameter of the distal luminal portion 322 of the spined catheter 320. Preferably, the side opening 1219 has a diameter that is at least 1.5x, 2x, 2.5x, or 3x as large as the outer diameter of the distal luminal portion 322. In another implementation, the sheath body 222 includes a pair of side openings 1219 on opposing and/or adjacent sides of the sheath body 222 near the distal end region. In another implementation, the sheath body 222 includes a distal opening 221 from the lumen 223 and one or more elongate side openings 1219 from the lumen 223. It should be appreciated that the sheath body 222 can be rotated around the longitudinal axis A such that the one or more side openings 1219 are positioned to allow for distal extension of the catheter 320 from the side openings 1219 in a desired direction relative to the longitudinal axis A of the sheath 220.

Inclusion of a wide-mouthed side opening 1219 can allow for a range of exit angles for the catheter 320 from a position substantially (i.e. very nearly) parallel to the sheath body 222 to a position that is at an angle to the sheath body 222, for example substantially perpendicular or at a right angle to the sheath body 222, as well as greater than 90° angle. This arrangement can be critically important in situations where there is severe angulation within the vessel being traversed or where a bifurcation is present. Often, tortuous segments in vessels and bifurcations have severe angulations to 90° or greater angle up to 180°. Classic severe angulation points in the vasculature can include the aorto-iliac junction, the left subclavian artery takeoff from the aorta, the brachiocephalic (innominate) artery takeoff from the ascending aorta as well as many other peripheral locations.

[0075] Referring again to FIG. 1, as mentioned above the catheter system 300 can include a spined aspiration catheter 320 having a flexible, distal luminal portion 322 and a rigid, proximal spine 330. The outer diameter of the distal luminal portion 322 as well as the flexibility and lubricity of the luminal portion 322 paired with the rigid spine 330 allow for the spined aspiration catheter 320 to navigate to the site of occlusions in the cerebral vasculature compared to other systems configured to navigate the cardiac vasculature. The systems described herein can reach occlusions in a region of the anatomy that has a long, tortuous access route. The route may contain stenosis plaque material in the aortic arch and carotid and brachiocephalic vessel origins, presenting a risk of embolic complications. Further, cerebral vessels are usually more delicate and prone to perforation than coronary or other peripheral vasculature. The catheter systems described herein can provide for neurovascular interventional procedures more easily due to its ability to overcome these access challenges. The catheter systems described herein are designed for navigating tortuosity rather than pushing through it. U.S. Patent Publication Number 2015/0174368, filed on December 12, 2014, and U.S. Patent Publication Number 2015/0173782, filed on December 19, 2014, which are incorporated herein by reference, describe features of catheter devices that can navigate the tortuous anatomy of the cerebral arteries.

[0076] The length of the distal luminal portion 322 can vary. In some implementations, the length of the distal luminal portion 322 extends from a region near the distal tip of the access sheath body 222 to the site of the occlusion in the carotid artery, forming a proximal overlap region 120 with the distal end of the access sheath 220 (see FIG. 2B). Taking into account the variation in occlusion sites and sites where the access sheath

distal tip may be positioned, the length of the distal luminal portion 322 may range from about 10 cm to about 25 cm. The length of the distal luminal portion 322 is less than the length of the sheath body 222 of the access sheath 220, such that as the spined aspiration catheter 320 is retracted into the sheath body 222 there remains a seal between the overlap region 328 of the spined aspiration catheter 320, and the inner diameter of the sheath body 222.

[0077] The catheter systems described herein can incorporate multiple spined catheters that are nested inside one another to allow for an extended reach into the tortuous anatomy. For example, a first spined catheter 320 having an outer diameter sized to be received within the lumen of the sheath body 222 may have a second spined catheter 320 extending through the inner lumen of the first spined catheter 320. The second spined catheter 320 can be extended using its proximal spine beyond a distal end of the first spined catheter 320 such that the smaller diameter second spined catheter 320 can reach a more distal region of the vasculature, particularly one having a narrower dimension. In this implementation, the first spined catheter 320 can act as a support catheter for the second spined catheter 320. The second spined catheter 320 can have an inner lumen that fluidly communicates with the inner lumen of the first spined catheter 320 that fluidly communicates with an inner lumen of the sheath body 222 forming a contiguous aspiration lumen.

[0078] In an implementation, the distal luminal portion 322 of the catheter 320 is constructed to be flexible and lubricious, so as to be able to be safely navigated to the target site, and kink resistant and collapse resistant when subjected to high aspiration forces, so as to be able to effectively aspirate the clot, with sections of increasing flexibility towards the distal end. In an implementation, the distal luminal portion 322 includes three or more layers, including an inner lubricious liner, a reinforcement layer, and an outer jacket layer. The outer jacket layer may be composed of discreet sections of polymer with different durometers, composition, and/or thickness to vary the flexibility along the length of the distal luminal portion 322. In an implementation the lubricious inner liner is a PTFE liner, with one or more thicknesses along variable sections of flexibility. In an implementation, the reinforcement layer is a generally tubular structure formed of, for example, a wound ribbon or wire coil or braid. The material for the reinforcement structure may be stainless steel, for example 304 stainless steel, nitinol, cobalt chromium alloy, or other metal alloy that provides the desired combination of strengths, flexibility, and resistance to crush. In an

implementation, the reinforcement structure includes multiple materials and/or designs, again to vary the flexibility along the length of the distal luminal portion 322. In an implementation, the outer surface of the catheter 320 is coated with a lubricious coating such as a hydrophilic coating. In some implementations the coating may be on an inner surface and/or an outer surface to reduce friction during tracking. The coating may include a variety of materials as is known in the art. The spine portion 330 may also be coated to improve tracking through the access sheath 220. Suitable lubricious polymers are well known in the art and may include silicone and the like, hydrophilic polymers such as high-density polyethylene (HDPE), polytetrafluoroethylene (PTFE), polyarylene oxides, polyvinylpyrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility.

[0079] The outer diameter of the distal luminal portion 322 can be sized for navigation into cerebral arteries. It is desirable to have a catheter having an inner diameter that is as large as possible that can be navigated safely to the site of the occlusion, in order to optimize the aspiration force. A suitable size for the inner diameter may range between .040" and .075" or may range between 0.040" and 0.088", depending on the patient anatomy and the clot size and composition. The outer diameter should be as small as possible while still maintaining the mechanical integrity of the catheter 320. However, at the overlap region 120, the outer diameter (OD) of the catheter 320 approaches the inner diameter (ID) of the access sheath 220, so as to create a sealed area at the overlap region 120 whilst still enabling the catheter 320 to be inserted easily through the sheath 220 and positioned at the desired site. In an implementation, the catheter 320 and access sheath 220 are sized to match at the overlap region 120 with no change in catheter 320 outer diameter (see FIG. 2B). In an implementation, the difference between the catheter OD and the access sheath ID at the overlap region is .002" or less. In another implementation, the difference is .003" or less. In an implementation, the catheter 320 is tapered towards the distal tip of the distal luminal portion 322 such that the distal-most end of the catheter has a smaller outer diameter compared to a more proximal region of the catheter near where it seals with the access sheath. In another implementation, the catheter OD steps up at an overlap portion 328 to more closely match the sheath inner diameter (see FIG. 1). This implementation is

especially useful in a system with more than one catheter suitable for use with a single access sheath size. It should be appreciated where the catheter OD of the spined catheter 320 matches the sheath inner diameter or the difference is 0.002" or less, a seal to fluid being injected or aspirated can be achieved by the overlap portion 328 such that no increase in catheter OD is necessary. A seal to fluid being injected or aspirated between the catheter and the sheath can be achieved by the overlap between their substantially similar dimensions without incorporating any separate sealing structure or seal feature.

[0080] In another implementation as shown in Figure 8A and 8B, there is a sealing element 336 positioned on the external surface of the proximal end of the distal luminal portion 322. The sealing element 336 can be one or more external ridge features, and can be compressed when the catheter 320 is inserted into the lumen of the access sheath 220. The ridge geometry can be such that the sealing element 336 behaves as an O-ring, quad ring, or other piston seal design. Figure 8B shows a similar configuration, with the sealing element 336 having a wiper seal configuration such as an inclined surface that is biased against an inner surface of access sheath body 222. Alternately, the seal element 336 may be an inflatable or expandable member such as a balloon or covered braid structure that can be inflated or expanded and provide sealing between the two devices at any time, including after the catheter 320 is positioned at the desired site. An advantage to this implementation is that there is no sealing force being exerted on the catheter 320 during catheter positioning, but rather is applied or actuated to seal after the catheter 320 is positioned.

[0081] It should be appreciated that the shape of the proximal end region of the distal luminal portion 322 may have an angled cut compared to the straight cut shown in the FIGs. 8A-8B. It should also be appreciated that the spine 330 may be coupled to a proximal end region of the catheter 320 and/or may extend along at least a portion of the distal luminal portion 322 such that the spine 330 couples to the distal luminal portion 322 a distance away from the proximal end. The spine 330 can be coupled to the portion 322 by a variety of mechanisms including bonding, welding, gluing, sandwiching, stringing, tethering, or tying one or more components making up the spine 330 and/or portion 322. In some implementations, the spine 330 and luminal portion 322 are coupled together by sandwiching the spine 330 between layers of the distal luminal portion 322. For example, the spine 330 can be a hypotube or rod having a distal end that is skived, ground or cut such that the distal end can be laminated or otherwise attached to the layers of the catheter portion 322 near a

proximal end region. The region of overlap between the distal end of the spine 330 and the portion 322 can be at least about 1 cm. This type of coupling allows for a smooth and even transition from the spine 330 to the luminal portion 322.

[0082] In an implementation, the overlap region is configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg. In an implementation, the overlap region 120 is configured to enable sealing against a pressure of up to 300 mmHg or up to 600 mmHg or up to 700 mmHg with minimal to no leakage. In addition, there may be features that prevent excessive advancement of the spined aspiration catheter 320 beyond the distal end of the access sheath 220. In any implementation that involves a stepped up diameter or protruding feature at the overlap region 328 of the spined aspiration catheter 320, the access sheath body 222 may include an undercut at the tip that prevents the proximal overlap portion of the spined aspiration catheter 320 to exit the sheath body 222.

[0083] The distal luminal portion 322 of the catheter 320 can have a radiopaque marker 324 at the distal tip to aid in navigation and proper positioning of the tip under fluoroscopy (see FIG. 1). Additionally, the proximal overlap region 328 of the catheter 320 may have one or more proximal radiopaque markers 1324 (see FIG. 12C) so that the overlap region 120 can be visualized as the relationship between the access sheath distal marker 224 and the catheter proximal marker 1324. In an implementation, the two markers (marker 324 at distal tip and a more proximal marker 1324) are distinct so as to minimize confusion of the fluoroscopic image, for example the catheter proximal marker 1324 may be a single band and the sheath tip marker 224 may be a double band.

[0084] The spine 330 of the spined aspiration catheter 320 is coupled to a proximal end region of the distal luminal portion 322. The spine 330 is configured to allow distal advancement and proximal retraction of the catheter 320 through the lumen 223 of the access sheath 220. In an implementation, the length of the spine 330 is longer than the entire length of the access sheath 220 (from distal tip to proximal valve), such as by about 5 cm to 15 cm. As shown in FIG. 1, the spine 330 can include a mark 332 to indicate the overlap between the distal luminal portion 322 of the catheter 320 and the sheath body 222. The mark 332 can be positioned so that when the mark 332 is aligned with the sheath proximal valve 234 during insertion of the catheter 320 through the sheath 220, the spined aspiration catheter 320 is positioned at the distal-most position with the minimal overlap length needed to create the seal between the spined aspiration catheter 320 and the access sheath 220. The

spine 330 can include a gripping feature such as a tab 334 on the proximal end to make the spine easy to grasp and advance or retract. The tab 334 can coupled with one or more other components of the system 300, such as a dilator configured to extend through the lumen 323 of the distal luminal portion 322 as will be described in more detail below. The proximal tab 334 can be designed to be easily identifiable amongst the other devices existing in the sheath proximal valve 234, such as guidewires 270 or retrievable stent device wires 500. In an implementation, the spine 330 is colored a bright color, or marked with a bright color, to make it easily distinguishable from guidewire, retrievable stent tethers, or the like.

[0085] The spine 330 can be configured with sufficient stiffness to allow advancement and retraction of the distal luminal portion 322 of the spined aspiration catheter 320, yet also be flexible enough to navigate through the cerebral anatomy as needed. Further, the outer diameter of the spine 330 is sized to avoid taking up too much luminal area in the lumen 223 of the access sheath 220 and sheath body 222. In an implementation, the spine 330 is a round wire, with dimensions from .014" to .018". In another implementation, the spine 330 is a ribbon with dimensions ranging from .010" to .015" thick, and .015" thick to .025" thick. The ribbon can have a variety of cross-sectional shapes such as a flat ribbon or curved ribbon forming a c-shape or other shape along an arc. In another implementation, the spine 330 is a hypotube. In an implementation, the spine 330 material is a metal such as a stainless steel or nitinol as well as a plastic such as any of a variety of polymers.

[0086] One or more components of the systems described herein may be made from a metal, metal alloy, polymer, a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable materials. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or

tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

[0087] The junction between the distal luminal portion 322 of the catheter 320 and the proximal spine 330 can be configured to allow a smooth transition of flexibility between the two portions so as not to create a kink or weak point, and also allow smooth passage of devices such as guidewires and microcatheters through the continuous inner lumen created by the lumen 223 of the access sheath 220 and the lumen 323 of the luminal portion 322 of the catheter 320. In an implementation, the distal luminal portion 322 has a transition section 326 (see FIG. 1) near where the portion 322 couples to the spine 330 that has an angled cut such that there is no abrupt step transition from the sheath 220 inner lumen 223 to the catheter 320 inner lumen 323. The angled cut can be generally planer. In an alternate implementation, the angled cut is curved or stepped to provide a more gradual transition zone. The distal luminal portion 322 and the spine 330 may be joined by a weld bond, a mechanical bond, an adhesive bond, or some combination thereof. The distal end of the spine 330 may have features that facilitate a mechanical joint during a weld, such as a textured surface, protruding features, or cut-out features. During a heat weld process, the features would facilitate a mechanical bond between the polymer distal luminal portion 322 and the spine 330. In another implementation, such as the catheter system 1300 shown in FIGs. 12A-12B having a spined catheter 1320 and a dilator 1340 extending therethrough, a smooth transition of flexibility between the two portions is formed so as not to kink or create a weak point during advancement of the system 1300. Loss of this smooth flexibility transition can occur upon removal of the dilator 1340 from the spined catheter 1320. The spine 1330 can be intended primarily to withdraw the spined catheter 1320 where risk of kink or weak spot formation is markedly lower.

[0088] Because the spined aspiration catheter 320 does not have a lumen that runs its entire length 320 due to the presence of the spine 330 on its proximal end region, traditional flushing and preparation steps, either before use or during the procedure should the lumen of the catheter become clogged, are ineffective. In a traditional single lumen catheter, a syringe is attached to the proximal adaptor of the catheter and the inner lumen may be forcefully flushed with solution. The spined catheter 320 can be supplied with an accessory catheter flushing and clearing device 350 (see FIG. 1). This device 350 may be a tube with a

rounded or tapered tip on a distal end and a female Luer connection on the proximal end. The Luer connector allows a syringe to be connected to the device 350. The blunt or tapered tip enables the device 350 to be inserted into either the distal or proximal end of the luminal portion 322 of the catheter 320, without risk of damaging the catheter 320, and the syringe actuated to flush the device. The OD of the clearing device 350 is closely matched with the ID of the luminal portion 322 of the spined catheter 320, such that the spined aspiration catheter 320 may be flushed with enough force to clear out the catheter of debris and aspirated occlusive material. The device 350 may also be used to mechanically clear out any entrapped thrombus in a plunger-type action, the working length of the device 350 can be at least as long as the distal luminal portion 322 of the catheter 320, so that it may be inserted through the entire lumen 323 of the distal luminal portion 322. Flushing may occur in conjunction with plunging the device 350, to more effectively clear the catheter 320 of entrapped thrombus or other embolic material.

[0089] In an alternate implementation, the aspiration catheter 320 is a single lumen catheter, for example, the type of catheter described in co-pending application U.S. Patent Publication Number 2015/0174368, filed December 12, 2014. In such an implementation, the catheter may be supplied with or coupled with a tapered co-axial dilator 340 that is generally tubular and has a tapered distal portion that provides a smooth transition between the catheter and a guidewire positioned within the catheter.

[0090] The spined aspiration catheter 320 can be navigated through the vasculature over an appropriately-sized microcatheter and guidewire. Alternately, the spined catheter 320 can be supplied with a co-axial dilator 340 (see FIG. 1). The dilator 340 is sized and shaped to be inserted through the internal lumen 323 of the distal luminal portion 322 of the catheter 320 in a coaxial fashion, such that a proximal end region of the dilator 340 aligns side-by-side with the spine 330 of the catheter 320 when in use. The dilator 340 can have a tapered distal tip 346. The length of the dilator 340 can be at least as long as the spined aspiration catheter 320 allowing for the distal tapered tip 346 as a minimum to protrude from the distal end of the luminal portion 322 of the spined catheter 320. The dilator 340 can have an outer diameter that forms a smooth transition to the distal tip of the catheter, and the distal tapered tip 346 that provides a smooth transition down to the guidewire that extends out the inner lumen of the dilator 340. The dilator 340 can be generally tubular along at least a portion of its length. In an implementation, the tapered dilator 340 is designed to

accommodate a guidewire that may be in the range of 0.014" and 0.018" diameter for example. In this implementation, the inner luminal diameter may be between .020" and .024". The tapered distal tip 346 may be in range from 1.5 cm to 3 cm.

[0091] It should be appreciated that the dilators described herein for use with the spined catheters can vary in their configuration. For example, as described above the dilator 340 can be a co-axial dilator 340 that is generally tubular and has a tapered distal portion that provides a smooth transition between the catheter 320 and a guidewire positioned within the catheter 320. The tubular body of the dilator 340 can extend along the entire length of the catheter 320. Alternatively, the dilator 340 can incorporate a proximal spine that aligns side-by-side with the spine of the catheter 320. The proximal spine can be positioned co-axial or eccentric to a distal end region of the dilator 340. The co-axial proximal spine of the dilator 340 can have a lumen extending through it. Alternatively, the dilator 340 can be a solid rod having no lumen. The solid rod dilator can be formed of a malleable material that skives down to have a narrow outer diameter (e.g. 0.010" – 0.014") such that the dilator can be shaped to whatever angle or shape is desired by the user, similar to how a guidewire may be used. In this configuration, the catheter system does not include a guidewire or microcatheter. Such a dilator has a benefit over a microcatheter in that it can have an outer diameter that is 0.003" - 0.010" smaller than the inner diameter of the spined catheter 320.

[0092] The dilator 340 may have a proximal female Luer adaptor 348 at a proximal end to allow the dilator 340 to be flushed with a syringe. The dilator 340 may also incorporate a clip feature at a proximal end allowing the dilator 340 to be the material of the dilator 340 can be flexible enough and the taper distal tip 346 can be long enough to create a smooth transition between the flexibility of the guidewire and the flexibility of the catheter. This configuration can facilitate advancement of the catheter 320 through the curved anatomy and into the target cerebral vasculature. In an implementation, the distal end of the dilator 340 has a radiopaque marker 344 and/or a marker 343 at the proximal end of the taper distal tip 346. The marker material may be a platinum/iridium band, a tungsten, platinum, or tantalum-impregnated polymer, or other radiopaque marker.

[0093] The dilator 340 can be constructed to have variable stiffness between the distal and proximal ends of the dilator 340. For example, the distal most section that extends beyond the distal end of the luminal portion 322 of the catheter 320 can be made

from a more flexible material, with increasingly stiffer materials towards the more proximal sections. In some implementations, the dilator 340 can be a spined dilator having a proximal spine as will be described in more detail below. The proximal end of the dilator 340 can include a tab 1364 that allows the dilator 340 to lock with the tab 334 on the proximal end of the spine 330 of the catheter 320, such that the two components (the spined catheter 320 and the dilator 340) may be advanced as a single unit over the guidewire (see FIG. 12A). In some implementations, the tab 334 of the catheter 320 can form a ring having a central opening extending therethrough. The tab 1364 of the dilator 340 can have an annular detent with a central post. The central post of the tab 1364 can be sized to insert through the central opening of the tab 334 such that the ring of the tab 334 is received within the annular detent of tab 1364 forming a singular grasping element for a user to advance and/or withdraw the catheter system through the access sheath. The tab 1364 may be affixed to the dilator 340, or may be slideable on the dilator 340 to accommodate different relative positions between the dilator 340 and the spined catheter 320.

[0094] FIGs. 12A-16 provide additional views of a spined aspiration catheter and dilator system 1300 as described elsewhere herein. FIGs. 12A-12B show the spined aspiration catheter 1320 having a dilator 1340 extending through an aspiration lumen 1323 of the distal luminal portion 1322. As described elsewhere herein, the catheter 1320 can have a proximal spine 1330 having a tab 1334 and a distal luminal portion 1322 having an aspiration lumen 1323. The spine 1330 can extend between the distal luminal portion 1322 and the tab 1334. The dilator 1340 can be received within the aspiration lumen 1323 of the spined catheter 1320. The dilator 1340 can include a distal dilator portion 1360 and a proximal spine 1362. The dilator portion 1360 can extend between a distal tip 1346 of the dilator 1340 to the start of the proximal spine 1362. When engaged with the catheter 1320, the dilator portion 1360 of the dilator 1340 may extend through an entire length of the distal luminal portion 1322 of the catheter 1320 such that the dilator tip 1346 extends a fixed distance beyond a distal end of the distal luminal portion 1322 of the catheter 1320 providing a smooth transition for improved tracking. The dilator tip 1346 can be tapered as described elsewhere herein and can be soft, atraumatic and flexible to the vessel wall to facilitate endovascular navigation to an embolus in a tortuous anatomy compared to dilators typically used for percutaneous arterial access, which are meant to bluntly dissect through tissue and artery wall.

[0095] The dilator 1340 is shown in a locked configuration with the catheter 1320 configured for improved tracking through a tortuous and often diseased vasculature in acute ischemic stroke. The dilator portion 1360 can include one or more detents on an outer surface of the dilator portion 1360. The detents can be located near a proximal end region and/or a distal end region of the dilator portion 1360. The detents are configured to lock with correspondingly-shaped surface features on the inner surface of the lumen 1323 through which the dilator portion 1360 extends. The dilator 1340 can include a dilator tab 1364 on a proximal end of the proximal spine 1362 of the dilator 1340, which as discussed above can be configured to connect and lock with a corresponding feature on the proximal end region of the catheter spine 1330, for example via one or more detents or other surface features. Thus, the dilator 1340 and the catheter 1320 can have more than a single point of locking connection between them. The proximal spine 1362 of the dilator 1340 can extend between the dilator portion 1360 and the tab 1364 of the dilator 1340. The dilator portion 1360 can be a tubular element as described elsewhere herein that forms a guidewire lumen running a length of the dilator portion 1360 (and an entire length of the distal luminal portion 1322 of the spined catheter 1320). It should be appreciated that the entire dilator 1340 can be tubular element configured to receive a guidewire through the spine 1362 as well as the dilator portion 1360. The proximal end of the dilator portion 1360, i.e., the transition section 1326 between the dilator portion 1360 and the proximal spine 1362, may include a "step up" to smooth the transition between the distal luminal portion 1322 of the catheter 1320 and the dilator portion 1360 of the dilator 1340. The transition section 1326 can incorporate an angled cut such that there is no abrupt step transition from the sheath 1220 inner lumen 1223 to the catheter 1320 inner lumen 1323. Accordingly, the spined aspiration catheter-dilator 1300 may be smooth to the vascular wall it interfaces with.

[0096] The proximal spine 1362 of the dilator 1340 may have a similar stiffness and character as the spine 1330 of catheter 1320. More particularly, one or both of the spines 1362, 1330 may be stiff and/or kink resistant. Furthermore, one or both of the spines 1362, 1330 may have a stiffness to allow pushing the distal portions, i.e., the combined distal luminal portion 1322 and dilator portion 1360, through an access sheath or a guide-sheath while producing a very low profile. In an embodiment, one or both of the spines 1362, 1330 includes a stiff wire.

[0097] The catheter tab 1334 and the dilator tab 1364 can be removably connected with one another. More particularly, the tabs 1334, 1364 may have a locked configuration and an unlocked configuration. In the locked configuration, the dilator tab 1364 can be engaged with the catheter tab 1334. In the unlocked configuration, the dilator tab 1364 may be disengaged from the catheter tab 1334. The dilator tab 1364 may attach, e.g., click or lock into, the catheter tab 1334 in a fashion as to maintain the relationships of corresponding section of the spined dilator 1340 and the spined catheter 1320 in the locked configuration. Such locking may be achieved by, e.g., using a detent on the dilator tab 1364 that snaps into place within a recess formed in the catheter tab 1334, or vice versa. In some implementations, the spine 1330 of the spined catheter 1320 can run alongside or within a specialized channel of the dilator spine 1362. The channel can be located along a length of the dilator spine 1362 and have a cross-sectional shape that matches a cross-sectional shape of the catheter spine 1330 such that the spine 1330 of the catheter 1320 can be received within the channel and slide smoothly along the channel bi-directionally. Once the spined catheter 1320 and spined dilator 1340 are fixed, the combined system, i.e., the spined aspiration catheter-dilator 1300 may be delivered to a target site, for example through the lumen 223 of the access sheath 220 described elsewhere herein.

[0098] Referring to FIG. 12B, a spined aspiration catheter-dilator 1300 having a spined catheter 1320 and a spined dilator 1340 in an unlocked configuration is illustrated in accordance with an embodiment. When the spined aspiration catheter-dilator 1300 is positioned at the target site, as discussed herein, the dilator tab 1364 can be unlocked from the catheter tab 1334. The spined dilator 1340 may be withdrawn and the spined catheter 1320 may be used, e.g., for aspiration or for wire or balloon delivery.

[0099] Referring to FIG. 13, a cross-sectional view, taken about line A-A of FIG. 12B, of a spined catheter 1320 coaxially aligned with a spined dilator 1340 is illustrated in accordance with an embodiment. The cross-section illustrates a portion of the catheter-dilator having the dilator portion 1360 received within the aspiration lumen 1323 of distal luminal portion 1322. The lumen 1323 may have an inner diameter in a range up to 0.072 inches, although a larger or smaller inner diameter is possible (larger or smaller possible). The wall of the distal luminal portion 1322 may resist kinking or ovalizing to provide maximum diameter for aspiration. The dilator portion 1360 may be received in the distal luminal portion 1322 in a slip fit. Thus, in an embodiment, an outer dimension of the

dilator portion 1360 may be less than the inner diameter of the distal luminal portion 1322. For example, the lumen 1323 may have a diameter of 0.072 inches and the dilator portion 1360 may have an outer dimension of 0.070 inches.

[00100] Referring to FIG. 14, a cross-sectional view, taken about line B-B of FIG. 12B, of a spined catheter 1320 after removal of a spined dilator 1340 is illustrated in accordance with an embodiment. The cross-section illustrates the distal luminal portion 1322 after the dilator portion 1360 has been retracted and/or removed. The distal luminal portion 1322 has an inner wall 1321 defining the lumen 1323. The lumen 1323 may be circular, as shown, or may have any other shape. In an embodiment, the effective diameter of the lumen 1323 ranges up to 0.072 inches.

[00101] Referring to FIG. 15A, a spined aspiration catheter-dilator system 1300 having a spined catheter 1320 and a spined dilator 1340 in a locked configuration is illustrated in accordance with an embodiment. In an embodiment, the spine 1330 and dilator 1340 may have an outer dimension that is substantially similar over an entire length. For example, rather than converging to a smaller dimension between the dilator portion 1360 and the dilator spine 1362, the dilator spine 1362 may have a same dimension as the dilator portion 1360. Thus, a catheter-dilator having a substantially same cross-sectional area over at least a majority of its length may be provided. As discussed above, the spine dilator 1340 and the spine catheter 1320 may have corresponding tabs 1334, 1364 that engage in a locked configuration and disengage in an unlocked configuration.

[00102] Referring to FIG. 15B, a spined aspiration catheter-dilator having a spined catheter 1320 and a spined dilator 1340 in an unlocked configuration is illustrated in accordance with an embodiment. The spined dilator 1340 may be removed from the spined catheter 1320 in a manner similar to that described above. In an embodiment, the spined aspiration catheter-dilator may have a similar cross-sectional area over a majority of its length, and thus, the shapes of the spined catheter 1320 and the spined dilator 1340 may be complimentary. For example, the spine 1330 may have a cross-sectional area along an arc, such as a quarter circle, and thus, a cross-sectional area of the dilator spine 1362 may be three quarters of a circle. As such, the spine 1330 may conform to the dilator spine 1362 to provide an overall cross-sectional area of a full circle.

[00103] Referring to FIG. 16, a schematic view of a spined catheter 1320 having a distal luminal portion 1322 having an inner lumen 1323 located in a neurovascular

anatomy is illustrated in accordance with an embodiment. Used in conjunction with an access sheath 1220 having a sheath body 1222 and an inner lumen 1232, in an embodiment where the spined catheter 1320 reaches the ICA and the distance to embolus E is consistently felt to be less than 20 cm, one would see that the distal luminal portion 1322 having a length of 25 cm would allow for an overlap region 1120 with the access sheath 1220 to create a seal. The overlap region 1120 may have a length of a few centimeters, and the may vary depending on the distance from the embolus E to the distal end of the distal luminal portion 1322, e.g., depending on how far the spined catheter 1320 is advanced relative to the access sheath 1220.

[00104] As described elsewhere herein, the luminal area available for aspiration of the embolus is greater using the spined catheter 1320 as compared to an aspiration system having a conventional large bore catheter in an access sheath. More particularly, the combined volume of the luminal area of the spined catheter 1320 and the luminal area of the access sheath 1220 proximal to the distal luminal portion 1322 is greater than the luminal area of the large bore catheter along the entire length of the system. Thus, the likelihood of removing the embolus in a single aspiration attempt may be increased. More particularly, the stepped up luminal diameter along the spine 1330 may enable a greater aspiration force to be achieved resulting in improved aspiration of the embolus. The stepped up luminal diameter may also increase the annular area available for forward flushing of contrast, saline, or other solutions while devices such as microcatheters or tapered inner members are coaxially positioned in the spined catheter and access sheath. Thus, the ease and ability to perform angiograms during device navigation may be improved.

[00105] The disclosed systems may be supplied with ancillary devices that are particularly configured to be used with the system. It should be appreciated that reference to one implementation of an access sheath system or aspiration catheter system is not intended to be limited and that the ancillary devices described herein can be used with any of the systems having any of a variety or combination of features described herein. For example, where an access sheath is described below it should be appreciated that one or more features of any of the access sheaths or access sheath systems described herein can be incorporated. Similarly, where a spined catheter is described below one or more featured of any of the spined catheters or spined catheter systems described herein can be incorporated.

[00106] In an implementation, the system includes a microcatheter 400 (see FIG. 1). The microcatheter 400 can be configured to be particularly suited for navigation in the cerebral vasculature. The microcatheter 400 may be used in place of the tapered dilator 340 to help navigate the spined catheter 320 to the desired site. As such, it may include means at the proximal end to lock the spine 330 to the microcatheter 400, so that so that the two components (the spined catheter 320 and the microcatheter 400) may be advanced as a single unit over the guidewire. In some instances the microcatheter 400 is advanced ahead of the catheter 320, to provide support as the catheter 320 is advanced, or to cross the occlusion and perform an angiogram distal to the occlusion. In this case, the length of the microcatheter 400 can be longer than the spined catheter 320 by about 10 to 20 cm. The microcatheter 400 may also be used to deliver a retrievable stent device 500 to the occlusion. In this case, the microcatheter 400 can have an inner diameter suitable for delivery of the retrievable stent device 500, for example, in the range .021" to .027" and with a PTFE inner liner. The microcatheter 400 can be at least about 5-10 cm longer or at least about 5 – 20 cm longer than the overall length of the spined catheter 320 to allow the microcatheter 400 to extend beyond the distal end of the aspiration catheter 320 during navigation.

[00107] In an implementation, the system includes a retrievable stent device 500 with a distal expandable section 510, which is sized and configured to be delivered through the microcatheter 400, as shown in FIG. 9. The retrievable stent device 500 may be used in conjunction with the other components of the system to aid in removal of the occlusion. The retrievable stent device 500 may also be used to quickly restore flow to the occluded artery during the thrombectomy procedure. Examples of retrievable stent devices include the Solitaire Revascularization Device (Medtronic) or the Trevo Stentriever (Stryker).

[00108] In a method of use, the retrievable stent device 500 is used to assist in bringing thrombus into the catheter 320 during an aspiration step, or clearing the catheter 320 that may become clogged during the aspiration step. In an implementation, the retrievable stent device 500 is configured to be particularly suited for performing these functions. For example, as shown in FIG. 10A, the distal end of the expandable portion 510 of the device 500 has multiple struts or elements 520 that come together at the distal tip to close off the distalmost end, such that the device allows blood flow across the device, but

captures the thrombus pieces as the device 500 is pulled into the catheter 320, and subsequently through the catheter 320 and out the distal end. Alternately, the distal end 520 is a filter element or a balloon element.

[00109] In another example, in FIG. 10B, the retrievable stent device 500 includes two or more segments with one or more proximal segments 510a configured to be expanded in the catheter distal inner lumen while one or more distal segments 510b are expanded across the occlusion as is done with prior retrievable stent devices. Alternately, as seen in FIG. 10C, the retrievable stent device 500 has a very long expandable portion 510, such that a proximal portion of the expandable portion may be expanded in the catheter distal inner lumen while the distal portion is expanded across the occlusion. In all these implementations, the proximal end of expandable section 510 has minimal structural elements that will allow the expandable section to be pulled easily into the lumen of the catheter 320, and out of the access sheath 320, so as minimize impediment of thrombus aspiration through the device. In these examples, the expandable portion 510 is still engaged with the clot even when the clot is aspirated into the catheter 320, and if the catheter 320 becomes corked, the device 500 is well-positioned to clear the clot when it is pulled back. Once the retrievable stent device 500 has been removed from the luminal portion 322 of the catheter 320, additional aspiration can be applied to the site through the catheter 320 if it is still partially or fully occluded. This step would not be possible if the catheter 320 remained clogged; the catheter would have to be removed and cleared outside the patient before being reinserted for additional aspiration. This configuration of retrievable stent device 500 can be used with either a conventional single lumen aspiration catheter, or a spined aspiration catheter 320.

[00110] The implementations of device 500 as shown in FIGs. 10A-10C may be used with known thrombectomy devices and methods to address the issue of catheters clogging during thrombus aspiration.

[00111] In an implementation, the system includes an aspiration source 600, as shown in FIG. 2A or FIG. 3. The aspiration source 600 can be attached to the aspiration line 230 on the access sheath 220. Examples of aspiration source 600 include a syringe or an active aspiration pump. The aspiration source 600 may be connected to a delivery location, such as a receptacle. The receptacle and source of aspiration 600 may be separate, such as a mechanical or electromechanical fluid pump whose outlet is connected to

a blood collection reservoir or may be combined into a single device such as a syringe or syringe pump. Alternately, the blood collection reservoir is connected to a source of vacuum such as a hospital vacuum line or an air vacuum pump, and is thus the receptacle as well as the source of aspiration. A filter and/or a check valve may be coupled with the aspiration source. The pump may be a positive displacement pump such as a diaphragm or piston pump, a peristaltic pump, centrifugal pump, or other fluid pump mechanism known in the art.

[00112] In an implementation, the aspiration source is a variable state or multi-state aspiration source, and includes a mechanism to control the level of aspiration, for example by modifying the vacuum level in the vacuum pump, by modifying the power to the motor of a positive displacement, peristaltic or centrifugal pump, or modifying the syringe pull back speed in the syringe or syringe pump. Alternately, the aspiration rate may be varied by providing an element with variable resistance to flow, for example parallel flow paths that can switch between a high and low flow resistance path, flow orifices or lumens that can be variably opened, or other means to vary flow resistance. In an example, the aspiration source is configured to have two levels of aspiration: a high level of aspiration to be used when the catheter is in contact with the thrombotic material, to aspirate the thrombotic occlusion, and a low level of aspiration to be used during steps in the procedure that are high risk of causing distal emboli, for example crossing the lesion or when flow is restored to the vessel when a retrievable stent device is expanded.

[00113] In another example, as shown in FIG. 11, the aspiration source 600 further includes a flow sensor 275 that senses flow in the aspiration line 230, coupled to a controller that controls the level of aspiration. The aspiration source 600 can increase in aspiration level when the flow rate is slow and decrease when the flow rate is increased. In this manner, the force is greatest when the catheter is clogged or partially clogged, but decreases to a minimal level when there is free flow to ensure protection from distal emboli but limit the volume of aspirated blood. In this manner, the system optimizes the thrombus aspiration while limiting the amount of blood aspirated. Alternately, the aspiration source 600 can include a vacuum gauge. When the flow in the catheter 320 is blocked or restricted the pump creates a higher level of vacuum. In this example the aspiration force may be configured to rise when higher vacuum is detected.

[00114] In yet another aspiration source implementation, the aspiration source 600 provides a cyclic level of aspiration force, for example, an aspiration force that

cycles between a high level of vacuum to a lower level of vacuum at a set frequency, or from a high level of vacuum to no vacuum, or from a high level of vacuum to a pressure source. A cyclic aspiration mode may provide a jack-hammer type force on the thrombus and increase the ability to aspirate the thrombus through the catheter. The cyclic aspiration force may be enabled through solenoid valves, a programmable pump motor, or the like. In an implementation, cyclic aspiration is applied only when clogged or restricted flow is detected in the aspiration line, either through low flow or high vacuum, as discussed above, and at other times, the aspiration source reverts to a low level of flow, or be turned off. This configuration may be controlled by the user, or controlled automatically via a feedback loop to the aspiration source.

[00115] In an implementation, the system includes a mechanism for passive reverse flow that is configured to be connected to the aspiration line on the access sheath. For example, the aspiration line is connected to a lower pressure site such as a central vein, or an external receptacle set to zero or negative pressure.

[00116] In an implementation as shown in FIG. 11, the flush line 236 may be connected via stopcock 238 to a syringe 286 that may hold saline fluid or radiopaque contrast. Additionally the flush line 236 may be connected to a flush source 288, for example, a pressurized bag of saline. A valve 292 can control flow from the flush source 288 to the flush line 236. When the valve 292 is opened to the flush line 236 a pressurized source of fluid is provided. In an implementation, the valve 292 is coupled via a mechanical or electromechanical coupler 295 to the aspiration source 600 such that the valve 292 is only open when the aspiration source 600 is on. Alternately, the valve 292 is coupled to a flow sensor 275 in the aspiration line 230, such that the valve 292 is only on when there is flow in the direction towards the aspiration source 600. In these implementations, the flow rate of the flush source 288 is configured to flow just enough to keep the proximal extension 240 clear of blood but not so high as to cause flow to work against the aspiration flow and limit aspiration of thrombus. An advantage of this implementation is that the proximal extension 240 remains clear of blood and any emboli or air that is in the proximal extension 240 is clearly visible. This provides a feedback to the user on when and if to flush the catheter with saline or contrast via syringe 286.

[00117] In another implementation, the valve 292 is coupled either mechanically or electromechanically to the valve 242 that connects the sheath body 222 to

the proximal portion 240 of the sheath 220. The coupling 290 can be configured such that the valve 292 can only be opened when the valve 242 is closed. This feature allows the proximal extension 240 to be cleared of blood via a flush step, without risk of flushing emboli back through the catheter into the vasculature. The coupling 290 may be configured in one of several ways For example, the coupling 290 may always open the valve 238 when the valve 242 is closed, or the coupling may prevent the valve 238 from opening unless valve 242 is closed but that does not automatically open.

[00118] In an implementation, the valve 292 is a variable state valve that allows different levels of flush flow rate. In this example, the valve 292 is configured to allow a slow flush when the aspiration source is on a low setting, a higher level of flush when the aspiration source is on a high setting. In an implementation, the valve allows yet a higher level of flush when the valve 242 is closed. These configurations allow a continuous removal of debris and/or clear visibility of the proximal portion of the access sheath and minimizes the risk of distal emboli or air entering the vasculature during the steps of the procedure. For example, during the step when the distal tip of catheter is being removed from the proximal hemostasis valve 234, any clot that was captured on the tip of the catheter may be liberated when the catheter is pulled through the valve, but with the continuous flush the liberated emboli would be flushed into the aspiration line and not remain in the sheath where it might be re-injected into the vasculature, for example during a contrast injection after the catheter is removed.

[00119] Again with respect to FIG. 1, the system 100 may include a kit of multiple devices. In an implementation, the kit includes an access sheath system 200 wherein the access sheath system includes an access sheath, one or more tapered sheath dilators, and one or more sheath guidewires. In another implementation, the system 100 includes an access sheath system 200 and one or more spined catheter systems 300 with one or more inner diameters. In an implementation, the spined catheter system 300 includes a spined aspiration catheter 320 and a tapered dilator 340. In an implementation, the spined catheter system 300 also includes a catheter clearing tool 350. In yet another implementation, the system 100 includes an access sheath system 200, a tapered catheter system 300, a microcatheter 400, and a retrievable stent device 500.

[00120] In an implementation configured for transcarotid access, the kit includes an access sheath 220, wherein the insertable sheath body 222 length is about 23 cm,

the proximal extension 240 is about 22 cm, the connector 226 is about 7 cm and the proximal hemostasis valve 234 is about 5 cm, for an overall access sheath length of about 57 cm. In an implementation, the kit also includes a spined aspiration catheter 320 wherein the catheter distal luminal portion 322 is about 20 cm, the transition section 326 is about 2-4 cm, and the spine section 330 is about 65 cm, for an overall spined catheter length of about 88 cm. In another implementation, the kit also includes a tapered dilator 340 with a working length of 93 cm. In another implementation, the kit also includes a microcatheter 400 with a working length of about 198 cm and a retrievable stent device 500 with an overall length of 128 cm.

[00121] In an implementation configured for transfemoral access, the kit includes an access sheath system 220, wherein the insertable sheath body 222 length is about 90 cm, the proximal extension 240 is about 22 cm, the connector 226 is about 7 cm and the proximal hemostasis valve 234 is about 5 cm, for an overall access sheath length of about 124 cm. The proximal portion of the access sheath may be a removable proximal portion 280. In an implementation, the kit also includes a spined aspiration catheter 320, wherein the catheter distal luminal portion 322 is about 20 cm, the transition section 326 is about 2-4 cm, the spine section 330 is about 132 cm, for an overall spined catheter length of about 155 cm. In another implementation, the kit also includes a tapered dilator 340 with a working length of 160 cm. In another implementation, the kit also includes a microcatheter 400 with a working length of about 165 cm and a retrievable stent device 500 with an overall length of 195 cm.

[00122] In another implementation, the kit includes an access sheath 220 with a removable proximal portion 280, and a single lumen aspiration catheter. In another implementation, the kit includes only the proximal portion 280 that can be attached to any introducer sheath suitable for the procedure. In this implementation, the kit may also include a spined aspiration catheter 320 or a single lumen aspiration catheter.

[00123] In any of these implementations, the kit may also include an aspiration source, for example a pump, an attachment to a vacuum pump, a syringe, a syringe that is attachable to a syringe pump, or the like. The kit may also include means for automatic flushing, for example coupling means 290 or 292.

[00124] As described elsewhere herein, it should be appreciated that reference to one implementation of an access sheath system or catheter system is not intended to be limited and that the kits described herein can incorporate any of the systems and/or

ancillary devices described herein as having any of a variety of features. For example, where an access sheath is described as being a part of a kit it should be appreciated that one or more features of any of the access sheaths or access sheath systems described herein can be incorporated. Similarly, where a spined catheter is described as being part of a kit one or more featured of any of the spined catheters or spined catheter systems described herein can be incorporated.

[00125] FIGs. 2A and 3 illustrates methods of use. As shown in FIG. 2A, an access sheath 220 is inserted using standard vascular access sheath into the femoral artery, and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal or common carotid artery. In FIG. 3, the access sheath 220 is inserted directly into the common carotid artery, and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal carotid artery. In either scenario, the sheath may be advanced initially to the common carotid artery or proximal internal carotid artery, and then the dilator and is exchanged for a softer dilator before advancing the sheath more distally into the internal carotid artery. The sheath is then secured to the patient using a suture through the eyelet on the sheath connector. The sheath aspiration line 230 is connected to an aspiration source 600 such as a syringe or aspiration pump. The sheath aspiration line may also be connected via a stopcock or stopcock manifold to a forward flush line (such as a pressurized saline bag).

[00126] Once the sheath tip is positioned at the desired location, it is secured to the patient. A spined catheter, tapered dilator, and guidewire are pre-assembled in a co-axial configuration and introduced through the sheath proximal hemostasis valve into the carotid artery. The spined aspiration catheter 320 is advanced through access sheath and positioned until the distal tip is at the treatment site. The devices are advanced using standard interventional techniques until the distal catheter tip is at the proximal face of the occlusion. A mark 332 on the spine 330 ensures that there is still an overlap region 120 between the distal luminal portion 322 of the catheter and the access sheath body 222. At this point, the tapered dilator 340 and guidewire can be removed. In an alternate implementation, a microcatheter 400 is used in place of the tapered dilator 340 to help navigate the catheter 320 to the occlusion. During the procedure, the forward flush is opened to the aspiration lumen to keep the lumen clear before or between periods of aspiration. At any point during device navigation, aspiration may be initiated from the aspiration source 600 at a level suitable for

distal embolic protection, for example when the guidewire or microcatheter 400 is crossing the occlusion.

[00127] Once the distal tip of the spined aspiration catheter 320 is at the face of the clot, aspiration is initiated at a level suitable for aspiration thrombectomy, which is a higher level than for distal embolic protection. The catheter 320 may remain in aspiration mode against the clot for some period of time, as deemed suitable by the user. Depending on the results of the aspiration thrombectomy maneuver (as observed by flow though the aspiration line and/or resistance to backwards force on the spine of the catheter), the user may determine that the clot has been completely aspirated, or if not, the user may choose to move the catheter 320 back and forth to aspirate the clot in situ, or to slowly retract the catheter 320 into the sheath 220. If flow is restored to the artery via aspiration of the clot through the catheter 320 and sheath 220, a final angiogram may be performed and the catheter 320 can be retracted. If however, thrombus occludes the catheter tip and cannot be removed, the catheter 320 is pulled back, with some or all of the occlusion attached through suction force to the tip of the catheter 320.

[00128] In the latter scenario, aspiration is maintained at the tip of the catheter 320 the entire time the catheter 320 is being pulled into the access sheath 220. Once the catheter 320 has been completely retracted into the access sheath 220, the catheter 320 can be quickly removed from the sheath body 222 while aspiration is maintained on the sheath 220. It should be appreciated that the catheter 320 may be withdrawn into the sheath body 222 after extending through the distal opening 219 at the distal tip of the sheath body 222. Alternatively, the catheter 320 may be extending through a side opening 219 near a distal end region of the sheath body 222 such that withdrawal of the catheter 320 into the sheath body 220 occurs through this side opening 219. At some time during catheter retraction, depending on if the catheter 320 is clogged with occlusive material, the aspiration level may be changed from a high level desirable for aspiration thrombectomy to a lower level desirable for distal embolic protection. By providing the ability to maintain aspiration continuously from either the catheter tip or the sheath tip or the sheath distal region, and providing the means to change aspiration levels and maintain asp, the procedure optimizes the ability to aspiration clot while minimizing distal emboli and minimizing blood loss from aspiration. If desired, aspiration may also be initiated at the flush line 236 of the proximal

valve 234, to reduce chance of distal embolization during removal of the catheter tip with possibly adhered clot through the proximal valve 234.

[00129] The spined aspiration catheter 320 may be removed completely from the proximal hemostasis valve 234 of the sheath 220. Alternately, if the access sheath 220 has a proximal extension 240, the distal luminal portion 322 may be pulled into the proximal extension portion 240. In the latter scenario, once pulled in, the catheter 320 and sheath 220 may be flushed to remove potential embolic material without removing the catheter 320 completely from the sheath 220. A vigorous flush from the proximal valve flush line 236 simultaneous with aspiration from the aspiration line 230 creates a flush environment for the catheter 320 and sheath 220. If desired, a catheter clearing tool 350 may be inserted into the sheath proximal valve 234 and used at this time to clear the inner lumen 323 of the catheter 320. If the access sheath 220 has a connector valve 242, the proximal portion 240 may be closed off from the sheath body 222 during this stage, so that there is no risk of flushing embolic material into the sheath body 222 and thence into the artery.

[00130] Alternately, the valve 242 may be closed off and aspiration paused while the proximal valve 242 is opened or removed and the catheter 320 is completely removed from the sheath 220. Closing the valve 242 limits the blood loss from the sheath 220 as the catheter 320 is removed. The catheter 320 may then be flushed onto the table or into a bowl or other receptacle, using the cleaning tool 350. The proximal extension portion 240 may also be flushed by providing a flush source 288 from the proximal valve flush line 236 simultaneous with aspiration from the aspiration line 230, or by opening a side port on the aspiration line 230 to flush to the table or into a bowl or other receptacle. If desired, an angiogram may be performed to assess flow through the treated artery. If the procedure dictates, the catheter 320 or another catheter may be re-advanced as above over a guidewire and tapered dilator 340 or microcatheter 400 to the site of the occlusion to attempt another aspiration thrombectomy step. The flushing of the catheters and proximal extension portion 240 of the access sheath 220 minimizing the risk of distal emboli during these subsequent steps.

[00131] In another exemplary method, a retrievable stent device 500 can be used in conjunction with aspiration to remove the thrombotic occlusion. FIG. 9 illustrates this method of use through either a transcarotid or transfemoral access site. In this scenario, the access sheath 220 can be positioned as above and advanced until the sheath tip is

positioned at a site as distal as safely possible in the internal carotid artery. The spined aspiration catheter 320 can be then pre-loaded onto a microcatheter 400 and guidewire, and the co-axial assembly can be introduced via the access sheath 220 into the carotid artery and advanced into the cerebral vasculature. The microcatheter 400 and guidewire can be advanced across occlusion. The tip of the spined aspiration catheter 320 can be advanced as distal as possible but proximal to the clot.

[00132] At this point, the guidewire can be removed and the retrievable stent device 500 inserted through the microcatheter 400 until it too is positioned across the occlusion. The microcatheter 400 can be pulled back to deploy the stent. At any point during device navigation, aspiration may be initiated from the aspiration source at a level suitable for distal embolic protection, for example when the guidewire or microcatheter 400 is crossing the occlusion, or prior to stent deployment. By having aspiration initiated before stent deployment, any emboli that was liberated while crossing the lesion is not carried downstream on restoration of flow in the artery, but is rather captured into the catheter tip. While the retrievable stent device 500 is deployed, aspiration may be maintained. It is typically deployed for several minutes before retraction of the stent is attempted, to maximize the engagement of the stent struts to the occlusion. Then, the retrievable stent device 500 can be pulled into the spined catheter 320 and continued to be retracted until it has been completely removed from the proximal valve of the access sheath 220.

[00133] Alternately, the stent device 500 can be pulled into the distal portion of the spined catheter 320, and the stent device 500 and spined catheter 320 can be pulled back together out of the access sheath 220. Aspiration may be increased to a higher level during stent and/or catheter retraction steps, to optimize aspiration of clot and minimize distal emboli. If the access sheath 220 has a proximal extension 240 with a valve on the connector, the device 500 can be pulled into the proximal extension 240 and the valve closed, and then the proximal hemostasis valve 234 may be opened widely and the stent device 500 or the stent device/spined catheter combination may be pulled out. The proximal extension section 240 may then be flushed via the valve flush line 236 and the aspiration line 230 before the same or alternate devices are reinserted for another thrombectomy attempt, if the procedure dictates.

[00134] Alternately after placement of an aspiration catheter 320, a long or segmented stent retriever 500 can be positioned as above with a microcatheter 400 such that

part of the expandable portion 510 is across the thrombus and part is in the distal segment 322 of the catheter 320, and then expanded. After the expandable portion 510 is expanded aspiration can be initiated so that thrombus either is suctioned completely out of the vessel and catheter 320 into the aspiration source 600, or is suctioned into the distal tip and/or distal lumen 323 of the catheter 320. At that point, the long or segmented stent retriever 500 can be carefully pulled into the catheter 320, while maintaining aspiration. During this time clot that has been clogging the catheter 320 and/or debris that is liberated during this step should be aspirated into the catheter 320. Complete removal of the stent retrieval device 500 from the working channel 323 of the catheter 320 should free up the lumen 323 from occlusive material.

[00135] In any of these scenarios, the aspiration source may be a variable or multi-state aspiration source that is configured to maximize the aspiration force on the thrombotic occlusion while minimizing blood loss during periods of free flow in the catheter.

[00136] In another exemplary method, the access sheath 220 has an occlusion balloon 246. As seen in FIG. 7, the balloon 246 may be inflated during steps of the procedure that are high risk for distal emboli, for example retraction of the stent device 500 or the spined catheter 320 with adhered clot. The balloon 246 has the effect of stopping antegrade flow and increasing the force of aspiration in the carotid artery, thus increasing the aspiration of clot and reducing the risk of distal emboli.

[00137] In another exemplary method, the access sheath 220 has an expandable distal tip. In this method, the distal tip may be expanded sometime after the access sheath tip has been positioned at the desired site, but before retraction of the spined catheter 320 into the access sheath 220. This method would reduce the chance of distal emboli caused by the release of clot that was adhered to the distal tip of the spined catheter 320, as the distal tip is pulled into the tip of the sheath 220. Instead, the access sheath tip that is expanded or flared out acts as a funnel to capture the entire clot.

[00138] In another exemplary method and as discussed briefly above, the access sheath 1220 has a side opening 1219 (best shown in FIG. 12C). In this method, the spined catheter 1320 having a spined dilator 1340 extending through lumen 1323 of the distal luminal portion 1322 of the catheter 1320 can be advanced distally through the lumen 1223 of the access sheath 1220 towards the distal end region of the sheath body 1222. The distal tip of the distal luminal portion 1322 of the spined catheter 1320 (which may having the

spined dilator extending through the distal luminal portion 1322 and forming a distal-most end to the catheter system) may exit the lumen 1223 via the side opening 1219 and then be further advanced distally beyond the distal tip of the access sheath 1220. A ramp feature 1217 or other internal feature can be incorporated at a distal end region of the lumen 1223 to provide a surface against which the tip of the dilator can be deflected to guide the catheter 1320 away from a longitudinal axis A of the lumen 1223 of the sheath body 1222 towards the side opening 1219 to achieve a smooth transition or exit from the lumen 1223. The distal tip 1346 of the dilator 1340 can abut against the ramp feature 1217 and be directed at a slight angulation away from the longitudinal axis of the sheath body 1222 towards the side opening 1219. As described elsewhere herein, the sheath body 1222 and thus the side opening 1219 can be rotated around the longitudinal axis A such that the one or more side openings 1219 are positioned to allow for distal extension of the catheter 1320 from the side openings 1219 in a desired direction relative to the longitudinal axis A of the sheath 1220. This will often be dictated by the anatomy encountered by the operator. Also as mentioned elsewhere herein, an overlap region 1120 is formed between the distal luminal portion 1322 of the catheter and the access sheath body 1222. A sealing element 1336 can be positioned on the external surface of the distal luminal portion 1322, for example, near a proximal end region of the distal luminal portion 1322 and may be located within the overlap region 1120. The seal formed can allow for full transmission of aspiration force through the contiguous lumen formed by the lumen 1323 of the luminal portion 1322 and the lumen 1223 of the access sheath body 1222 upon withdrawal of the dilator 1340 from the lumen 1323 of the luminal portion 1322.

[00139] In another exemplary method, the aspiration source 600 is connected to a blood collection reservoir that maintains the integrity of the blood in such a way that the blood can be safely returned to the patient at the conclusion of the thrombectomy portion of the procedure, either directly or through subsequent treatment of the blood such as cell washing and/or blood filtration. In another exemplary method, the aspiration source is connected to a blood shunt that is connected in turn to a device such as a venous sheath or a venous return catheter that enables blood to be returned to the patient during the procedure and not requiring a blood reservoir. In another exemplary method, the blood is collected in a reservoir and subsequently discarded at the end of the procedure.

[00140] In another exemplary method, the access sheath 1220 is delivered as described elsewhere herein from a femoral insertion site to a right or left subclavian artery

or an external carotid artery. The access sheath 1220 may be delivered to a carina of a bifurcation between a target vessel having the embolus, such as the internal carotid artery (ICA), and another vessel, such as the external carotid artery (ECA). Once the access sheath 1220 is in position a working device such as a splined aspiration catheter 1320 can be delivered through the lumen 1223 of the access sheath 1220 into the target vessel. The lumen 1223 of the access sheath 1220 and the lumen 1323 of the catheter 1320 are contiguous and form a stepped up diameter for aspiration as described elsewhere herein. An overlap region 1120 is maintained between the catheter 1320 extending distally from the lumen 1223 of the access sheath 1220. It should be appreciated that the catheter 1320 can extend distally from the lumen 1223 of the access sheath 1220 through an opening 1221 at the distal tip of the access sheath 1220 or a side opening 1119 near the distal region of the access sheath 1220. The body 1222 of the access sheath 1220 may be oriented to provide optimum placement of the side opening 1119 relative to the anatomy. The overlap region 1120 between the distal luminal portion 1322 of the catheter 1320 and the access sheath body 1222 can create a seal and allow for full transmission of aspirating force through the contiguous lumen formed by the lumen 1323 of the luminal portion 1322 and the lumen 1223 of the access sheath body 1222, as well as providing a seal for delivery of fluids to the target vessel such as angiographic contrast injection, saline, one or more drugs or other materials directly into the neurovascular anatomy. The spined aspiration catheter 1320 can create a more powerful aspiration force by allowing for the working lumen 1223 of the access sheath 1220 to provide a majority of the aspiration column. As described elsewhere herein, the dimension of the lumen 1323 of the distal luminal portion 1322 of the aspiration catheter 1320 may be less than the diameter of the lumen 1223 of the access sheath 1220, which is reduced only by a diameter of the spine 1330 extending therethrough. The increased diameter of the lumen can create a larger aspiration column than, e.g., an aspiration column of a large bore catheter having a similar overall length. The spined aspiration catheter 1320 may also be used as a supportive delivery catheter, for example, where the operator wants to reach the petrous carotid or other hard to reach landmarks within the cerebral vasculature. More particularly, after delivering the spined aspiration catheter 1320 into the target vessel through the working lumen 1223 of the access sheath 1220, a secondary working device such as a guidewire, microcatheter, stent retriever, etc. may be delivered through the lumen 1323 into a more distal anatomy to perform other procedural operations as described elsewhere herein.

[00141] 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 implementations. Certain features that are described in this specification in the context of separate implementations can also be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation can also be implemented in multiple implementations 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. Therefore the spirit and scope of the appended claims should not be limited to the description of the implementations contained herein.

CLAIMS

1. An intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature through an access sheath, the system comprising:

an aspiration or support catheter comprising:

a flexible, distal luminal portion having an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion; and

a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom; and

a dilator comprising:

a flexible, distal dilator portion sized to be received within the lumen of the luminal portion; and

a rigid, dilator spine extending proximally from the dilator portion.

2. The system of claim 1, wherein, when in use, the dilator spine aligns side-by-side with the spine of the catheter.

3. The system of claims 1 or 2, wherein the distal dilator portion has a tapered distal tip.

4. The system of any of claims 1-3, wherein the dilator has a length at least as long as a length of the catheter such that a distal tip of the dilator protrudes from the distal opening of the luminal portion.

5. The system of any of claims 1-4, wherein the dilator is generally tubular along at least a portion of the length.

6. The system of any of claims 1-5, wherein a proximal end of the catheter spine includes a gripping feature configured for a user to grasp in order to move the catheter through an access sheath.

7. The system of claim 6, wherein a proximal end of the dilator spine includes a tab configured to be locked with the gripping feature on the catheter spine.

8. The system of claim 7, wherein when the catheter and the dilator are in a locked configuration they are advanced as a single unit through the access sheath.

9. The system of claims 7 or 8, wherein the gripping feature and the dilator tab are removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature.

10. The system of any of claims 7-9, wherein the dilator tab is affixed to the dilator.

11. The system of any of claims 7-9, wherein the dilator tab is slideable on the dilator to accommodate different relative positions between the dilator and the catheter.

12. The system of any of the preceding claims, wherein the distal dilator portion comprises one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends.

13. The system of any of the preceding claims, wherein the dilator spine and the catheter spine have a similar stiffness and kink-resistance.

14. The system of any of the preceding claims, wherein the dilator has a visual marker on a distal end and/or a proximal end of the distal tip.

15. The system of any of the preceding claims, wherein a distal end region of the dilator is more flexible and increasingly stiffens towards a proximal end region of the dilator.

16. The system of any of the preceding claims, wherein the catheter spine and dilator spine are configured to cause bi-directional sliding movement of the luminal portion through a lumen of an access sheath and navigate the luminal portion into a cerebral vessel to reach a treatment site.

17. An intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature, the system comprising:

an access sheath having a sheath body comprising an inner diameter defining a lumen between a proximal end and a distal end of the sheath body, and at least one opening from the lumen near a distal end region of the sheath body; and

an aspiration or support catheter comprising:

a flexible, distal luminal portion having an outer diameter sized for insertion through the lumen of the access sheath, an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion, and a length between the proximal opening and the distal opening; and

a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom,

wherein the rigid spine is configured to cause bi-directional sliding movement of the luminal portion through the lumen of the access sheath and out the at least one opening to navigate the luminal portion into a cerebral vessel to reach a treatment site, and

wherein a portion of the outer diameter of the luminal portion fluidly seals with the inner diameter of the access sheath when the distal end of the luminal portion extends into the cerebral vessel to reach the treatment site.

18. The system of claim 17, wherein the luminal portion and the sheath body are concentrically aligned and the lumen of the luminal portion and the lumen of the sheath body form a contiguous aspiration lumen from the distal end of the luminal portion to the proximal end of the sheath body.

19. The system of claim 18, wherein the contiguous aspiration lumen is usable to aspirate fluid and debris from the distal opening of the luminal portion.

20. The system of claims 18 or 19, wherein the contiguous aspiration lumen is usable to deliver materials through the distal opening of the luminal portion.

21. The system of any of claims 17-20, wherein the contiguous aspiration lumen forms a step-up in diameter where the lumen of the luminal portion empties into the lumen of the sheath body.

22. The system of any of claims 17-21, wherein the lumen of the luminal portion is shorter than the lumen of the sheath body.

23. The system of any of claims 17-22, wherein the luminal portion and the sheath body form an overlap region when the luminal portion extends distally beyond the at least one opening of the sheath body.

24. The system of claim 23, wherein the outer diameter of the luminal portion approaches the inner diameter of the lumen of the sheath body such that a seal is formed by the overlap region.

25. The system of claim 24, wherein the seal is configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg.

26. The system of claim 24, wherein the seal within the overlap region is configured to enable sealing against a pressure of up to 300 mmHg.

27. The system of any of claims 24-26, wherein the seal is located distal a proximal end of the luminal portion and proximal to the at least one opening of the sheath body.

28. The system of any of claims 24-27, further comprising a sealing element positioned on an external surface of the luminal portion.

29. The system of claim 28, wherein the sealing element includes a stepped up diameter or protruding feature in the overlap region.

30. The system of claim 28, wherein the sealing element comprises one or more external ridge features.

31. The system of claim 30, wherein the one or more ridge features are compressible when the luminal portion is inserted into the lumen of the sheath body.

32. The system of claim 28, wherein the sealing element comprises one or more inclined surfaces biased against an inner surface of the sheath body lumen.

33. The system of claim 28, wherein the sealing element comprises one or more expandable members actuated to seal.

34. The system of any claims 17-33, wherein the sheath body has an outer diameter suitable for insertion into the carotid artery.

35. The system of claim 34, wherein the outer diameter of the sheath body is between 5Fr and 7Fr.

36. The system of any of claims 17-35, wherein the sheath body has a length between the proximal end and the distal end suitable for locating the distal end of the sheath body at the petrous portion of an internal carotid artery from a transfemoral approach.

37. The system of claim 36, wherein the length of the sheath body is between 80 cm and 105 cm.

38. The system of any of claims 17-37, wherein the length of the luminal portion is between 10 cm and 25 cm.

39. The system of any of claims 17-38, wherein the length of the luminal portion is less than a length of the sheath body such that as the catheter is retracted into the sheath body a seal remains between an overlap region of the luminal portion and the inner diameter of the sheath body.

40. The system of any of claims 17-39, wherein the spine is longer than an entire length of the sheath body.

41. The system of any of claims 17-40, wherein the luminal portion includes three or more layers including an inner lubricious liner, a reinforcement layer, and an outer jacket layer.

42. The system of claim 41, wherein the outer jacket layer is composed of discreet sections of polymer with different durometers, compositions, and/or thicknesses to vary the flexibility along the length of the distal luminal portion.

43. The system of any of claims 17-42, wherein the outer diameter of the distal luminal portion is sized for navigation into cerebral arteries.

44. The system of any of claims 17-43, wherein the inner diameter of the distal luminal portion is between 0.040" and 0.088".

45. The system of any of claims 17-44, wherein the outer diameter of the luminal portion approaches the inner diameter of the sheath body creating a sealed area at an overlap region while still allowing the catheter to move through the sheath body.

46. The system of any of claims 17-45, wherein the catheter is tapered towards the distal opening such that a distal-most end of the luminal portion has a smaller outer diameter compared to a more proximal region of the luminal portion near where the luminal portion seals with the sheath body.

47. The system of any of claims 17-46, wherein the distal end region of the sheath body comprises an occlusion element.

48. The system of any of claims 17-47, wherein the distal end region of the sheath body comprises an expanding distal tip.

49. The system of any of claims 17-48, wherein the at least one opening from the lumen comprises a side opening located a distance away from a distal tip of the sheath body.

50. The system of any of claims 17-49, wherein a distal tip of the sheath body further comprises a ramp feature configured to direct at an angulation the catheter away from a longitudinal axis of the sheath body lumen out through the at least one opening.

51. The system of any of claims 17-50, wherein the spine is longer than an entire length of the sheath body.

52. The system of any of claims 17-51, wherein the spine is a wire having an outer dimension from 0.014" to 0.018".

53. The system of any of claims 17-52, wherein the spine is a hypotube having a guide-wire passageway extending therethrough.

54. The system of any of claims 17-53, wherein the spine is a ribbon having an outer dimension from 0.010" to 0.025" thick.

55. The system of claim 54, wherein the ribbon is curved along at least a portion of an arc.

56. The system of any of claims 17-55, wherein the spine is configured to rotate the luminal portion around a longitudinal axis of the access sheath.

57. The system of any of claims 17-56, wherein the spine is eccentrically coupled to the luminal portion and the spine extends proximally from the luminal portion to outside the proximal end of the sheath body.

58. The system of any of claims 17-57, wherein the proximal end of the luminal portion has an angled cut.

59. The system of claim 58, wherein the angled cut is generally planar or is curved.

60. The system of any of claims 17-59, wherein the sheath body has one or more visual markers on the distal end region of the sheath body.

61. The system of any of claims 17-60, wherein the distal luminal portion has one or more visual markers at a distal end region of the luminal portion, a proximal end region of the luminal portion or both.

62. The system of claims 60 or 61, wherein the one or more visual markers on the sheath body and the one or more visual markers on the luminal portion are visually distinct.

63. The system of any of claims 60-62, wherein the spine has one or more visual markers.

64. The system of claim 63, wherein the one or more visual markers of the spine indicates overlap between the distal luminal portion and the sheath body.

65. The system of claims 63 or 64, wherein the one or more visual markers of the spine is positioned so that when the visual marker of the spine is aligned with a portion of the access sheath, the catheter is positioned at a distal-most position with minimal overlap length needed to create a seal between the catheter and the sheath body.

66. The system of any of claims 17-65, further comprising a dilator comprising a flexible, distal dilator portion having a distal tip and sized to be received within the luminal portion of the catheter.

67. The system of claim 66, wherein the dilator is a tubular element along at least a portion of its length.

68. The system of claim 66, wherein the dilator is a solid rod formed of malleable material configured to be shaped by a user.

69. The system of claim 66, wherein the dilator further comprises a rigid, dilator spine extending proximally from the dilator portion.

70. The system of claim 69, wherein the dilator spine is coaxial.

71. The system of claim 70, wherein the coaxial dilator spine has a lumen extending through it.

72. The system of claim 69, wherein the dilator spine is eccentric.

73. The system of any of claims 69-72, wherein when in use the dilator spine aligns side-by-side with the spine of the catheter.

74. The system of any of claims 66-73, wherein the distal tip is tapered.

75. The system of claim 74, wherein the dilator has a length at least as long as a length of the catheter such that the distal tip protrudes from the distal opening of the luminal portion.

76. The system of any of claims 69-75, wherein a proximal end of the spine includes a gripping feature configured for a user to grasp in order to move the catheter through the access sheath.

77. The system of claim 76, wherein a proximal end of the dilator spine includes a tab configured to be locked with the gripping feature on the catheter spine.

78. The system of claim 77, wherein when the catheter and dilator are in a locked configuration they are advanced as a single unit through the sheath body.

79. The system of claims 77 or 78, wherein the gripping feature and the dilator tab are removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature.

80. The system of any of claims 77-79, wherein the dilator tab is affixed to the dilator.

81. The system of any of claims 77-79, wherein the dilator tab is slideable on the dilator to accommodate different relative positions between the dilator and the catheter.

82. The system of any of claims 66-81, wherein the distal dilator portion comprises one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends.

83. The system of any of claims 69-82, wherein the dilator spine and the catheter spine have a similar stiffness and kink-resistance.

84. The system of any of claims 66-83, wherein the dilator has a visual marker on a distal end and/or a proximal end of the distal tip.

85. The system of any of claims 66-84, wherein a distal end region of the dilator is more flexible and increasingly stiffens towards the proximal end region of the dilator.

86. The system of any of claims 17-85, wherein the access sheath further comprises a connector that connects the proximal end of the sheath body to a proximal hemostasis valve.

87. The system of claim 86, wherein the proximal hemostasis valve has an adjustable opening sized large enough to allow removal of the catheter without dislodging any clots thereon.

88. The system of claim 86 or 87, wherein, when in use with the access sheath, the rigid spine of the catheter extends proximally from the luminal portion through the access sheath lumen and out the proximal hemostasis valve of the access sheath.

89. The system of any of claims 86-88, wherein the connector provides a connection of the proximal end of the sheath body to an aspiration line.

90. The system of any of claims 86-89, wherein the connector has a large bore inner lumen and connects to a large-bore aspiration line.

91. The system of claim 89 or 90, wherein the aspiration line connects to an aspiration source.

92. The system of claim 91, wherein the aspiration source is an active aspiration source.

93. The system of any of claims 89-92, wherein the aspiration line connects to a forward drip or flush line.

94. The system of any of claims 17-93, wherein the access sheath further comprises a proximal extension portion such that when the distal luminal portion of the catheter is withdrawn from the sheath body lumen it remains within the proximal extension portion.

95. The system of any of claims 17-94, wherein the inner diameter of the luminal portion is sized to permit placement of an interventional device through the luminal portion.

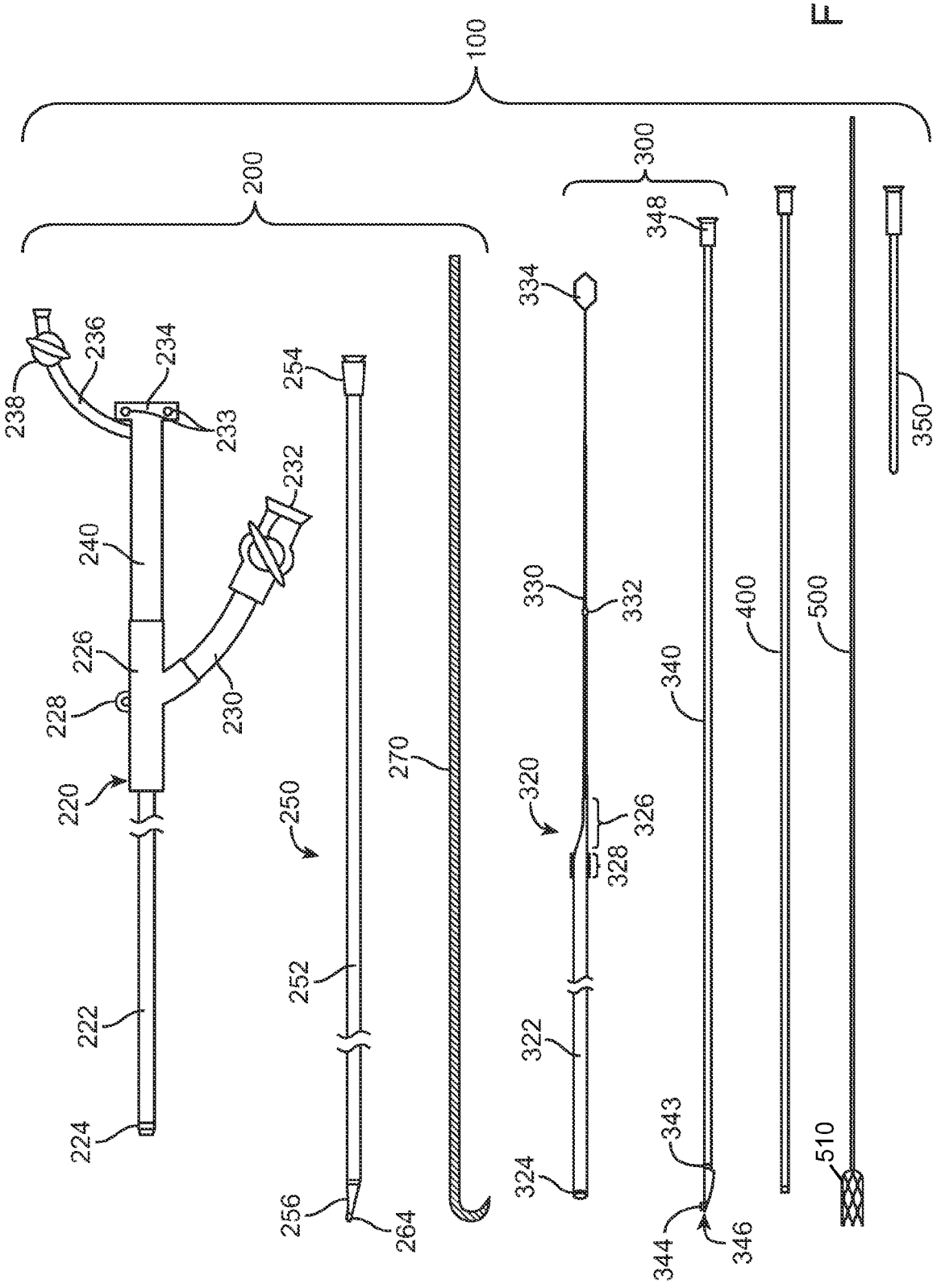
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FIG. 1

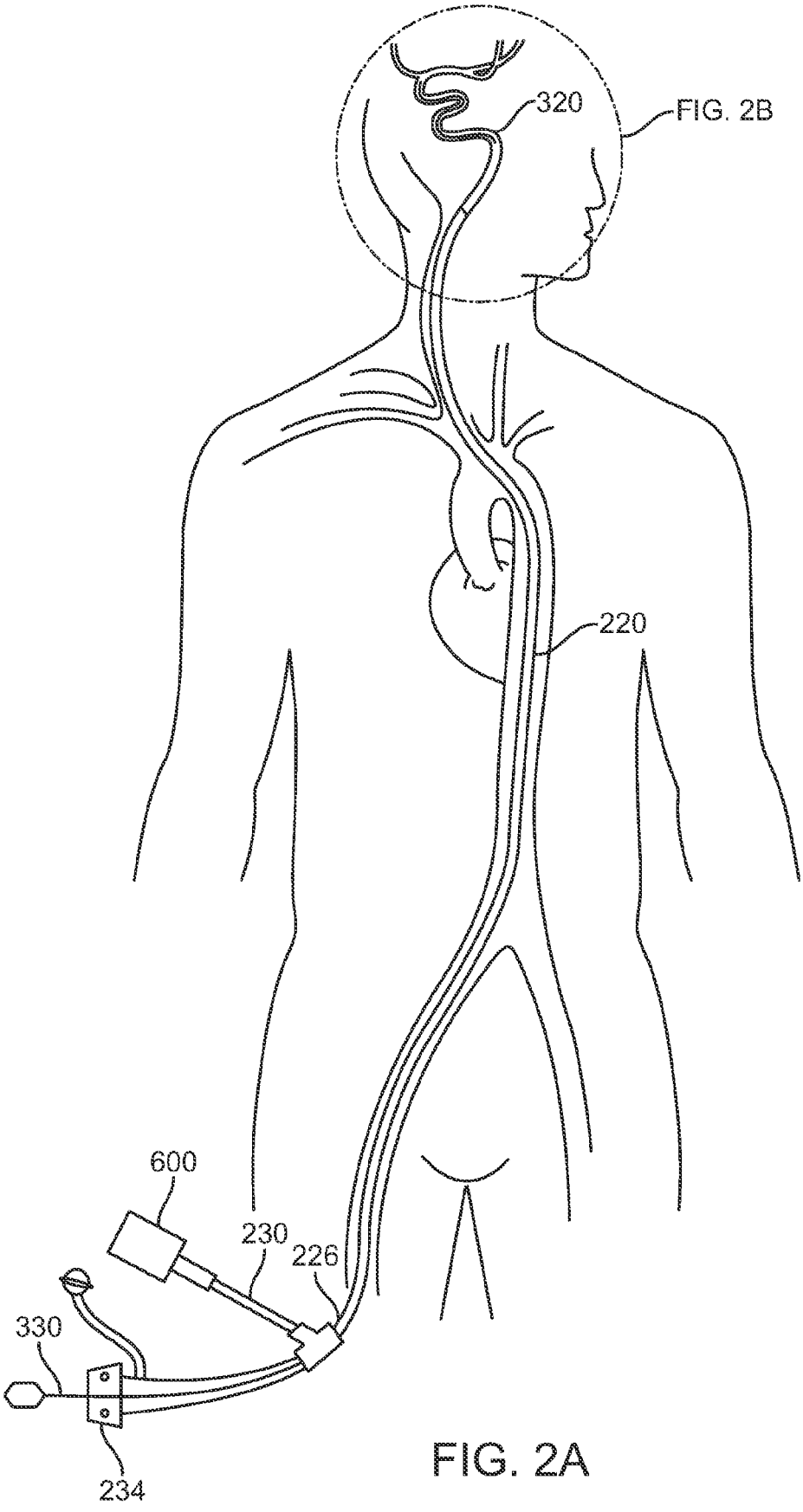

FIG. 2A

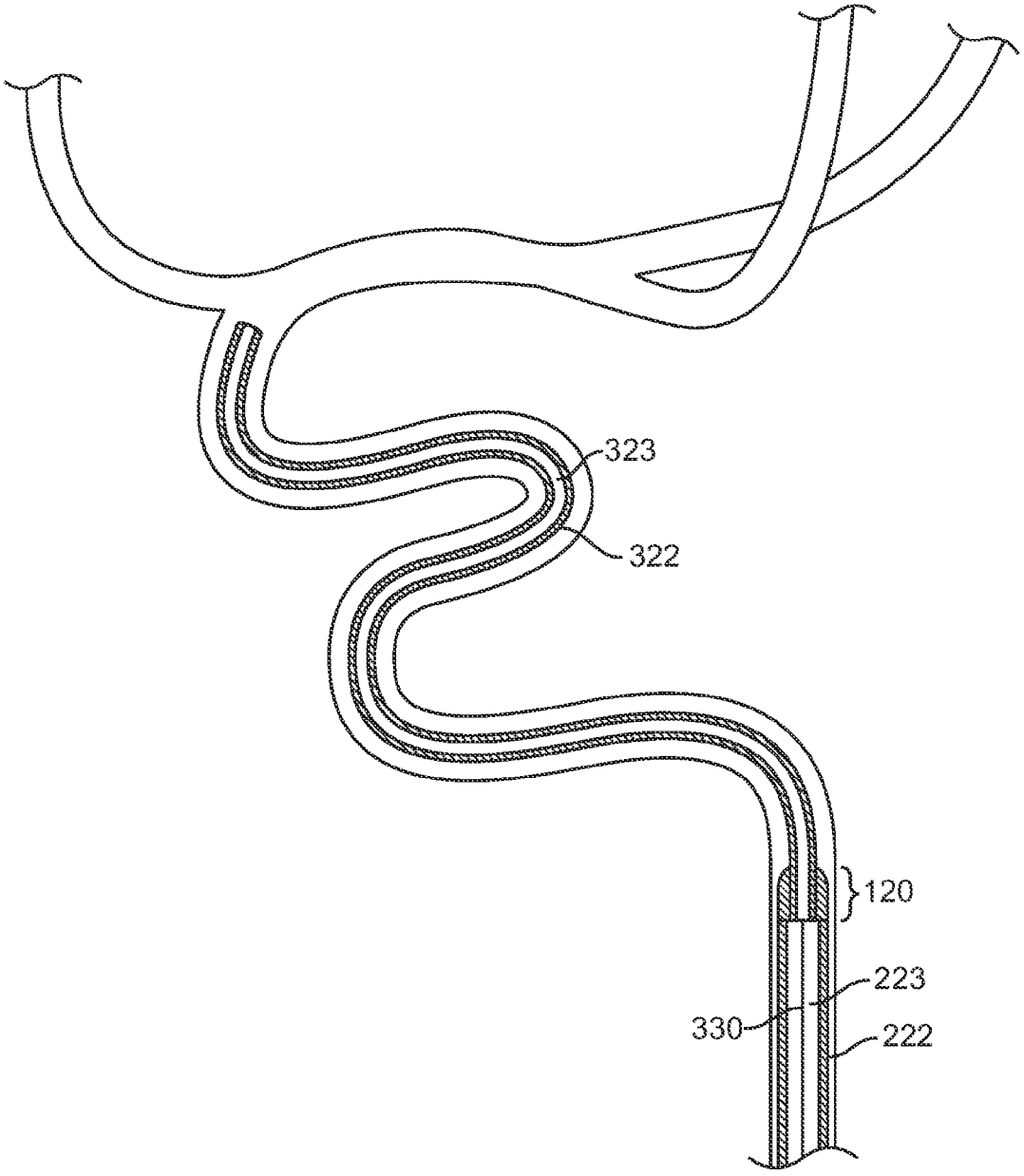

FIG. 2B

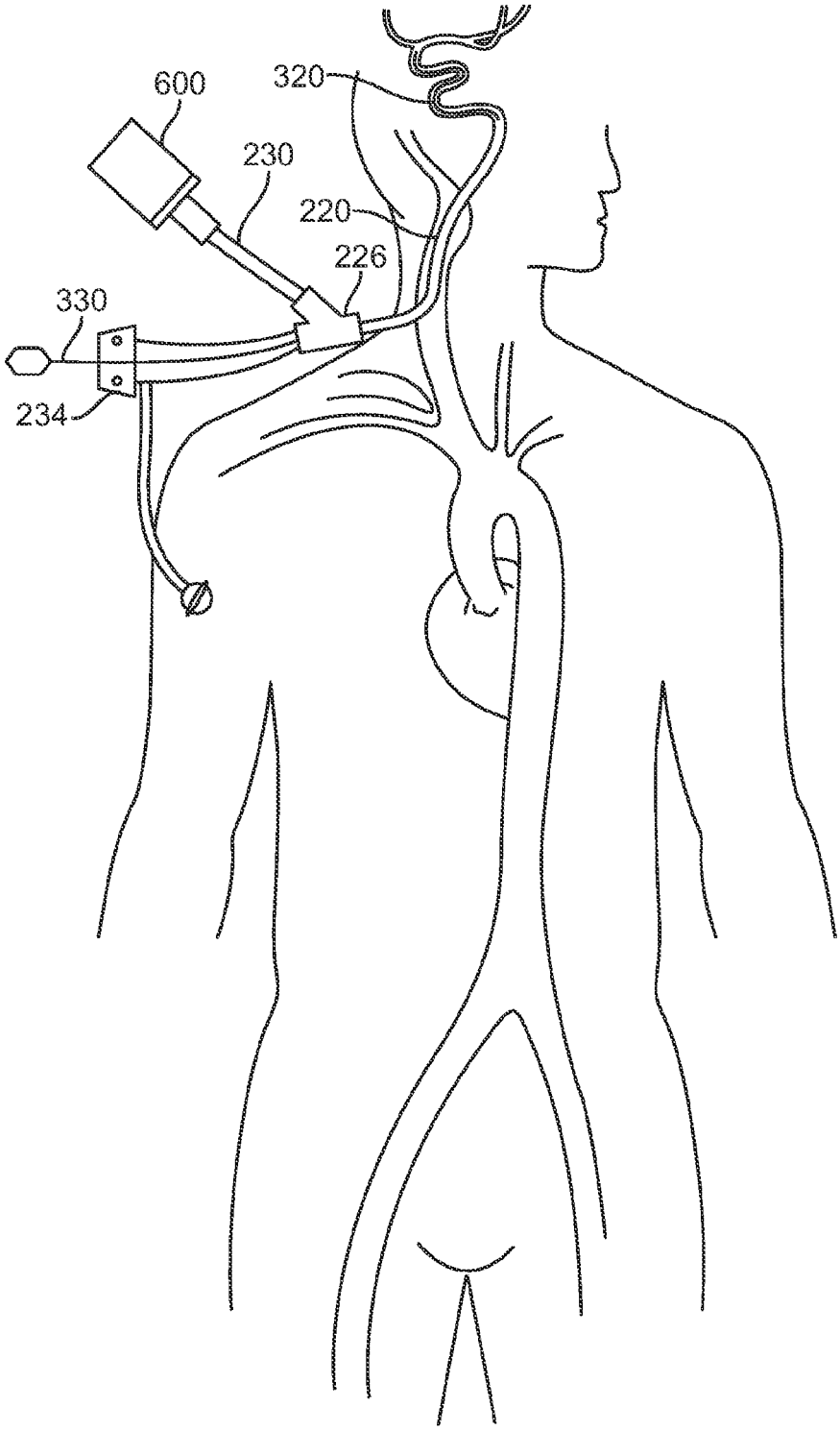

FIG. 3

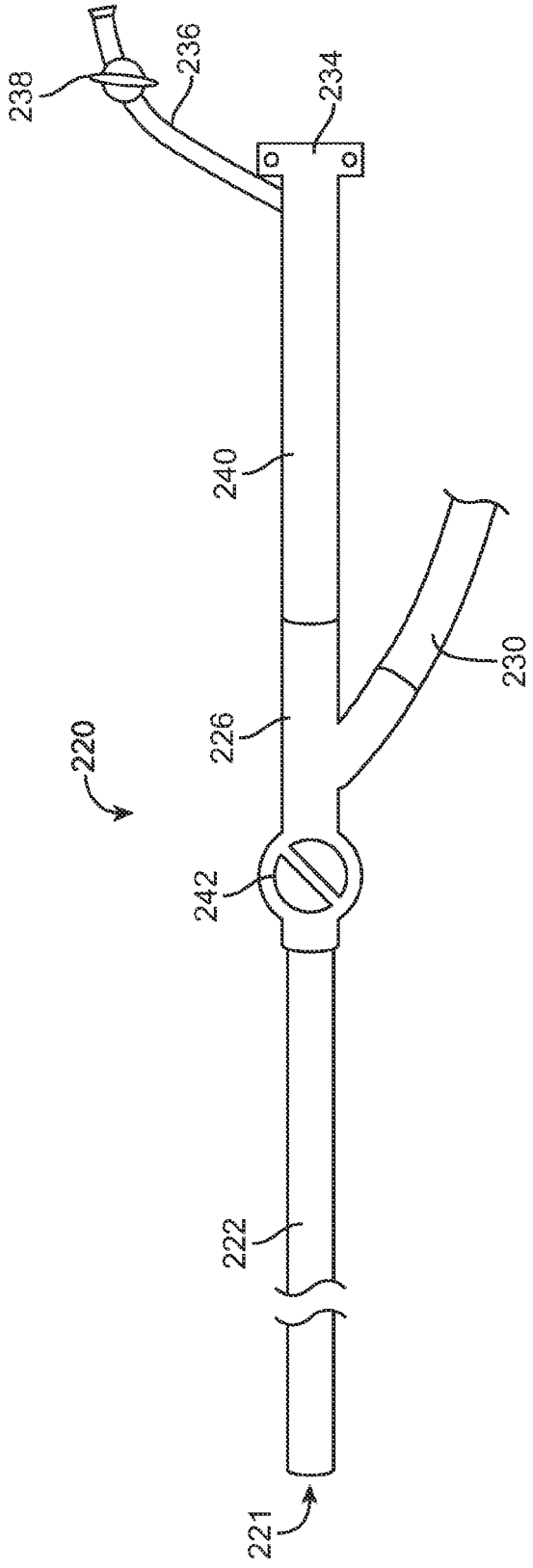

FIG. 4

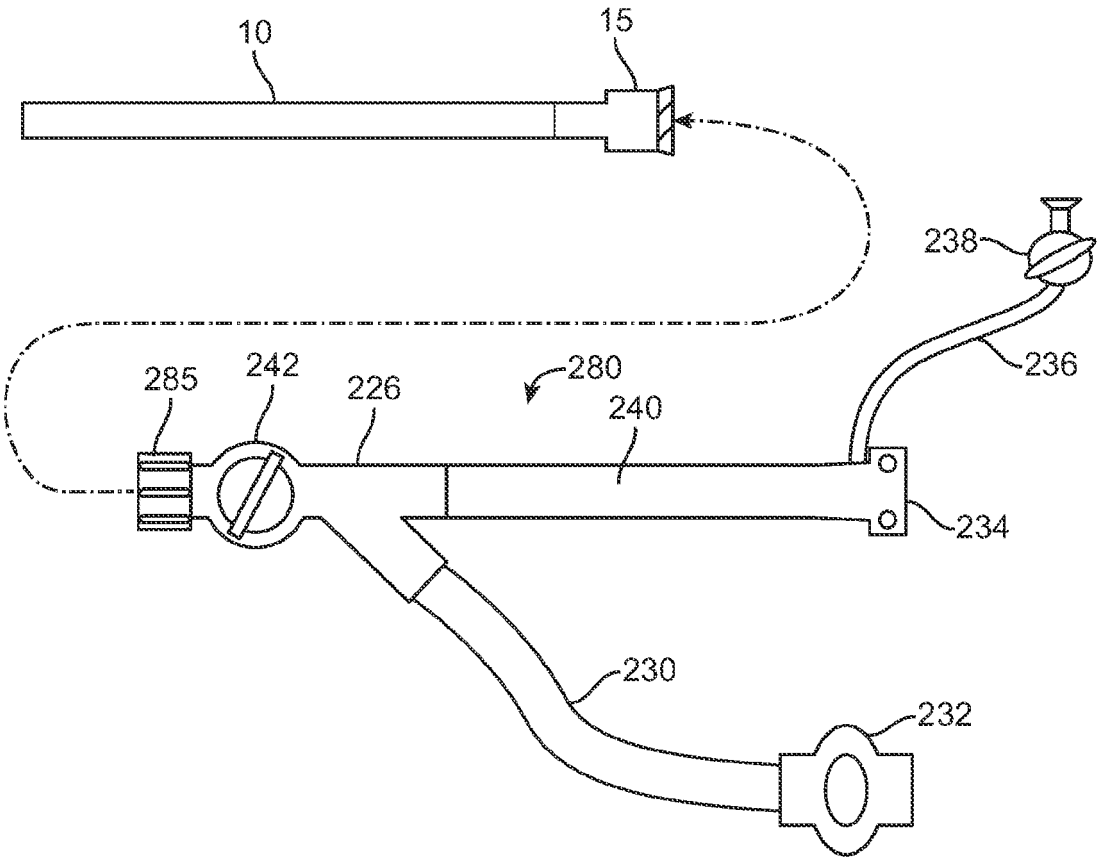

FIG. 5

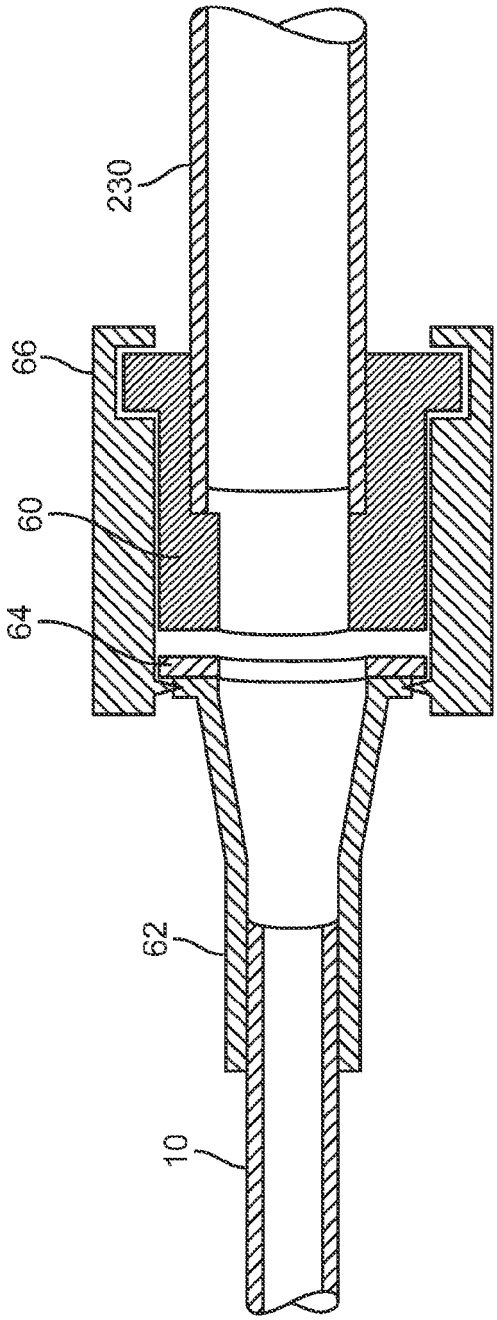

FIG. 6

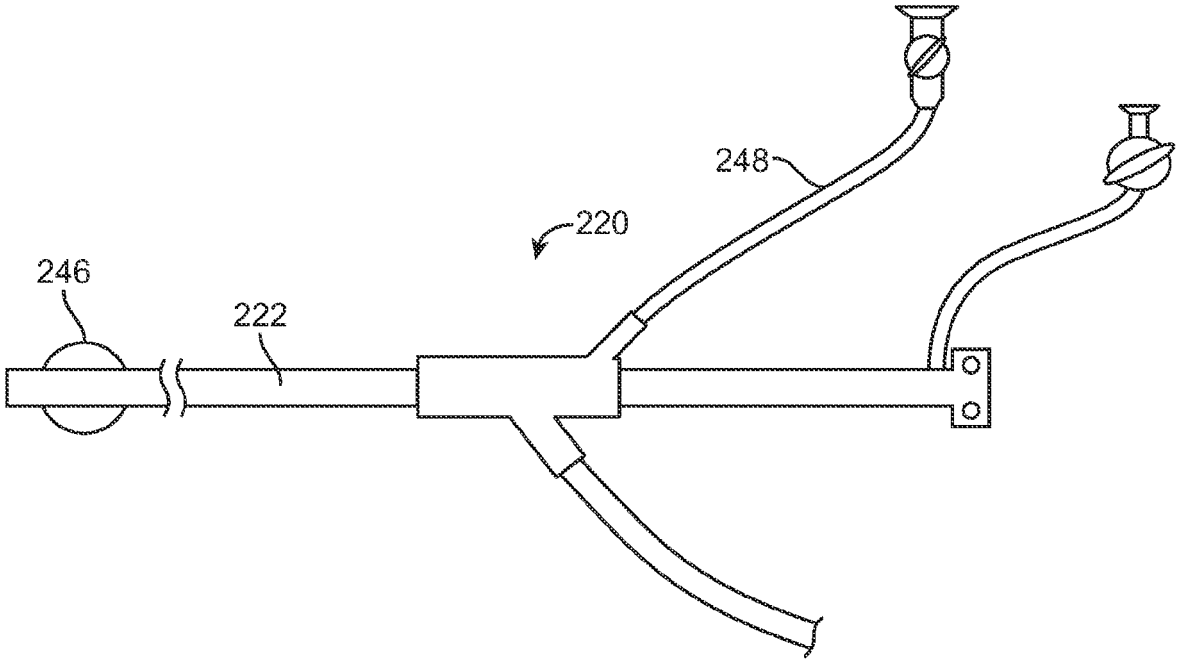

FIG. 7

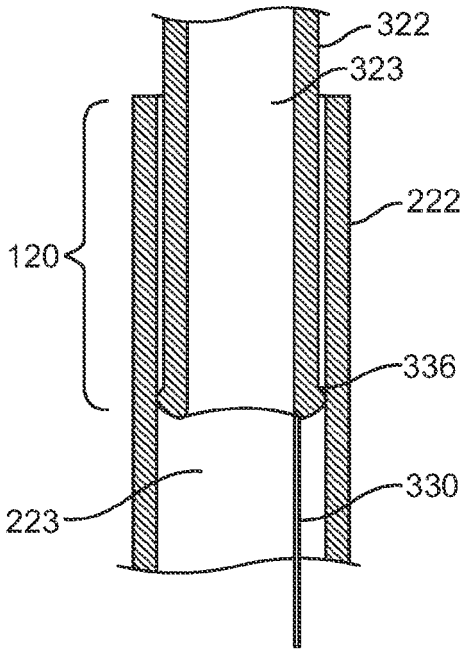

FIG. 8A

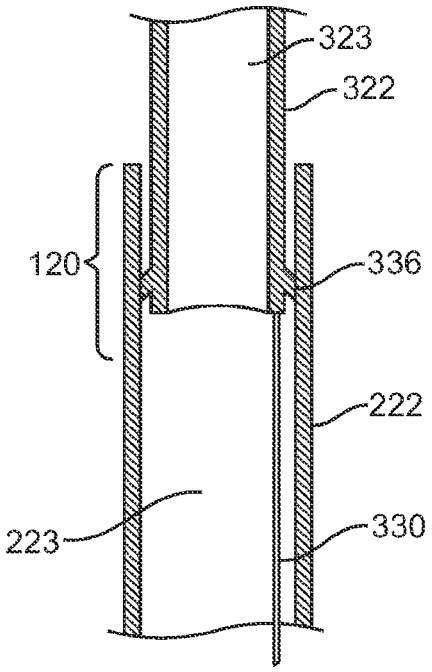

FIG. 8B

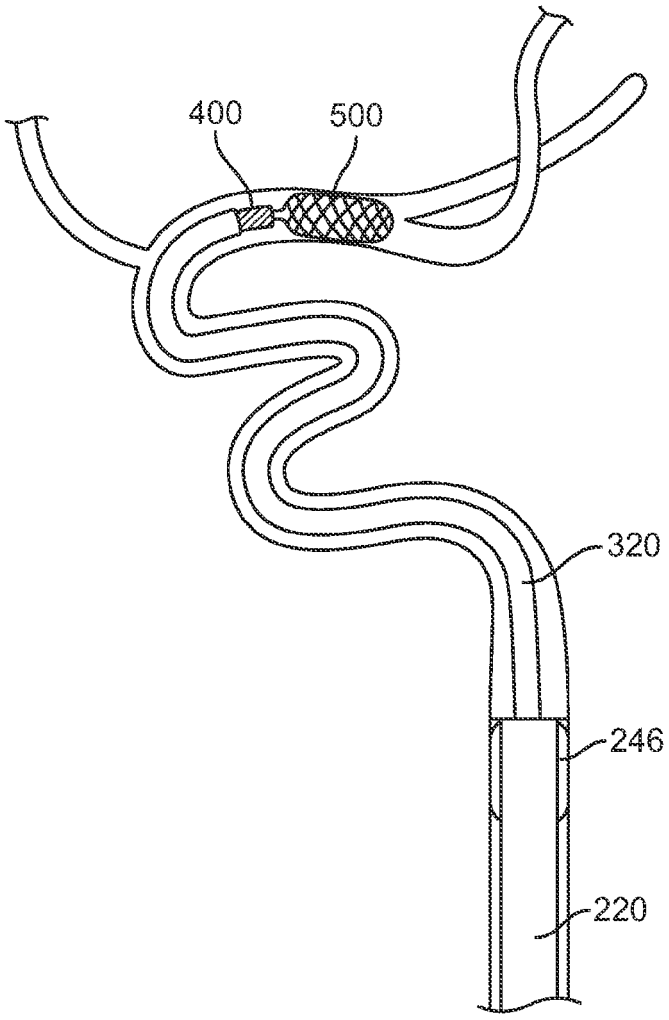

FIG. 9

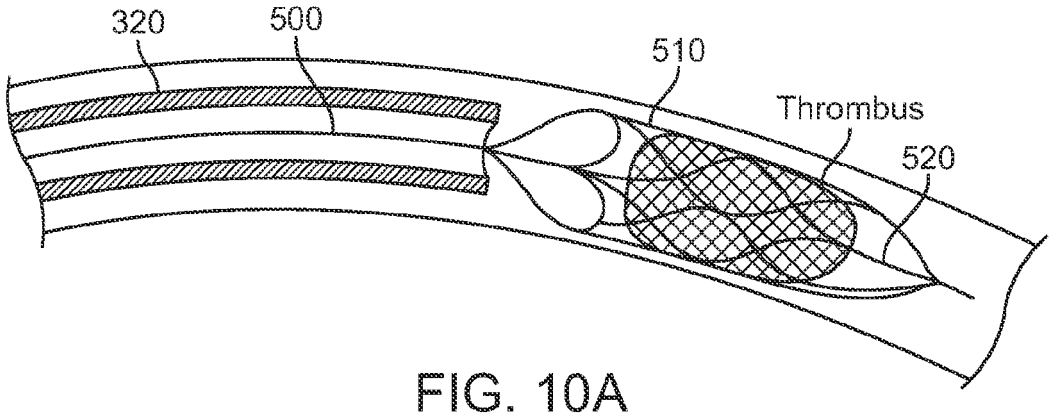

FIG. 10A

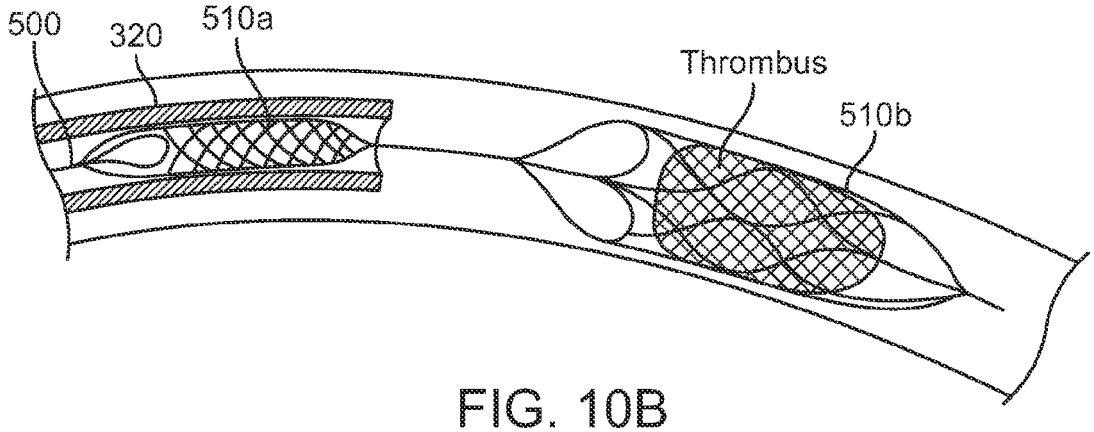

FIG. 10B

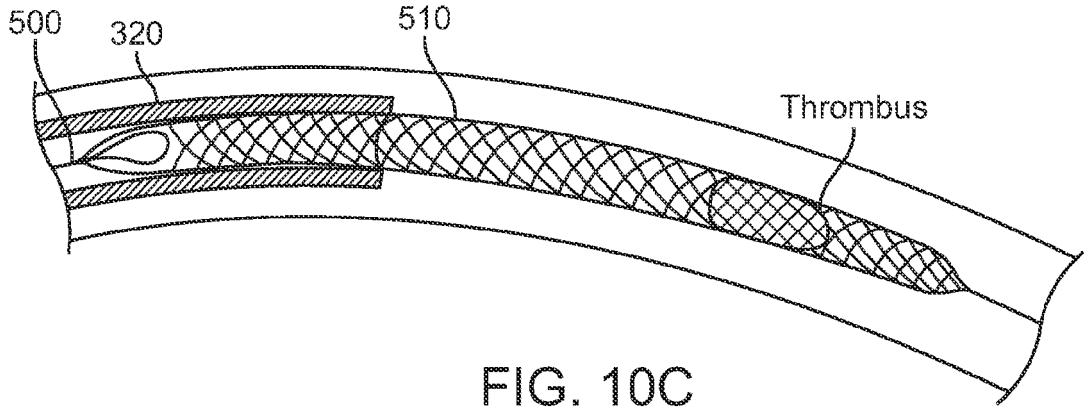

FIG. 10C

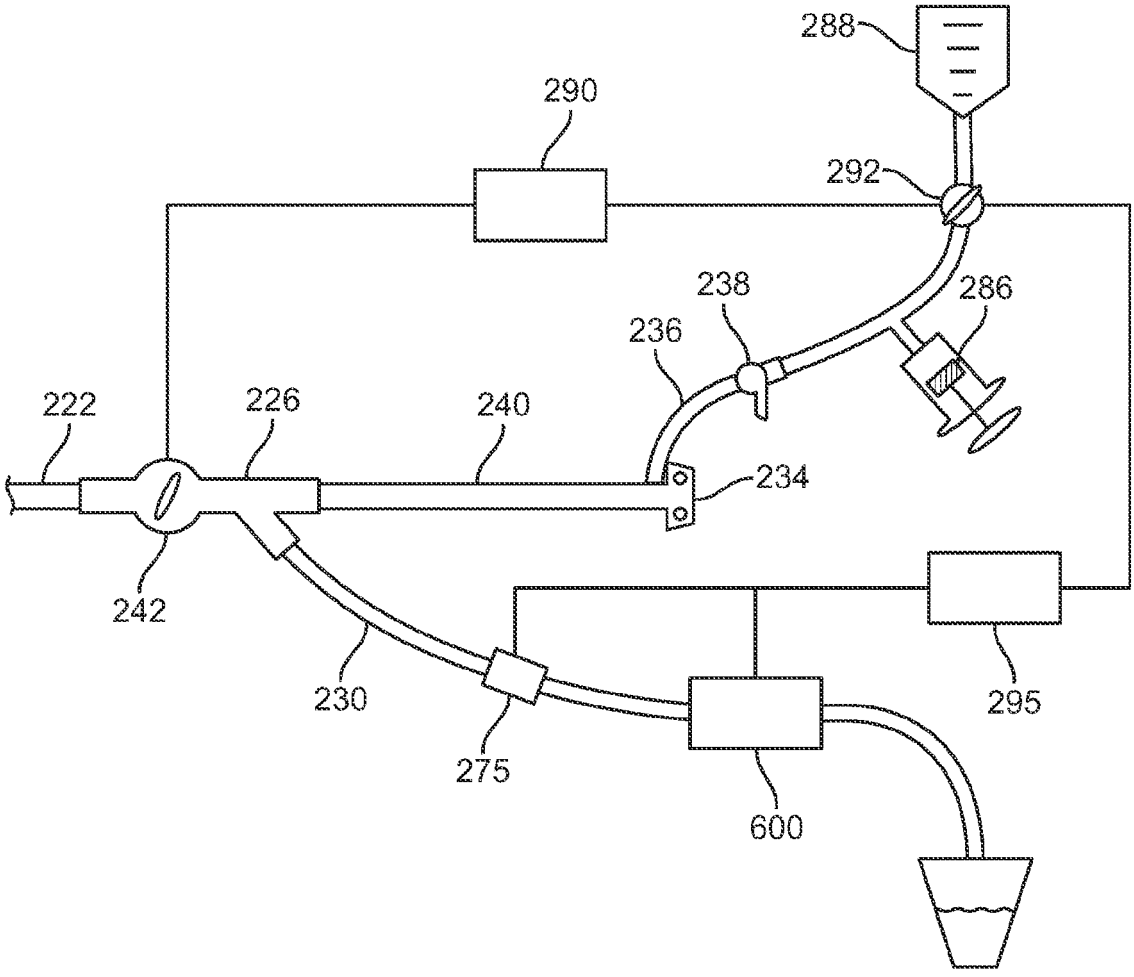

FIG. 11

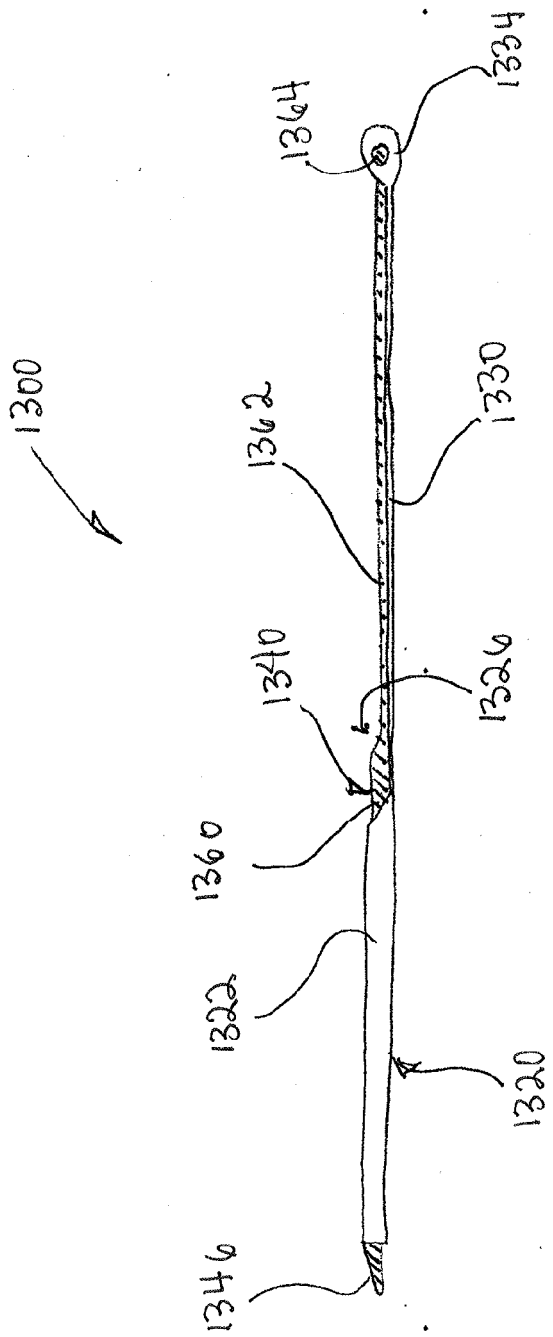

FIG. 12A

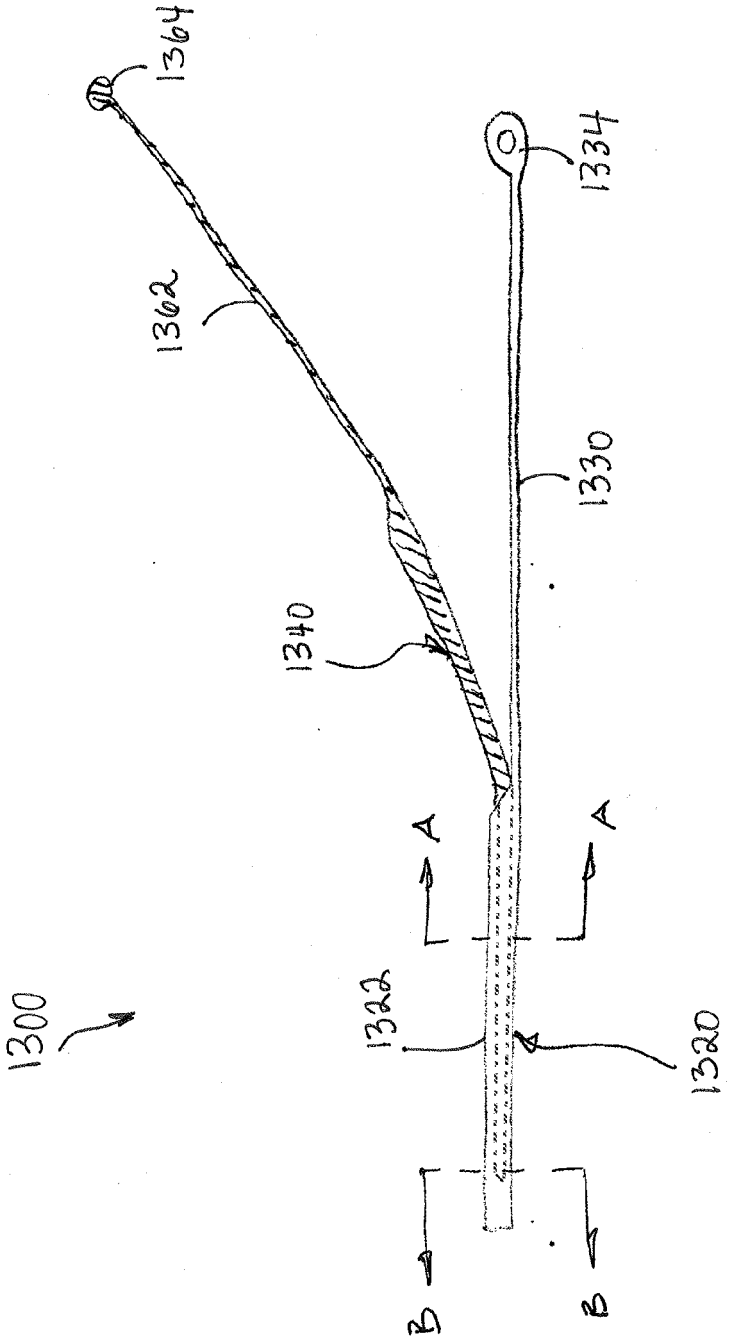

FIG. 12B

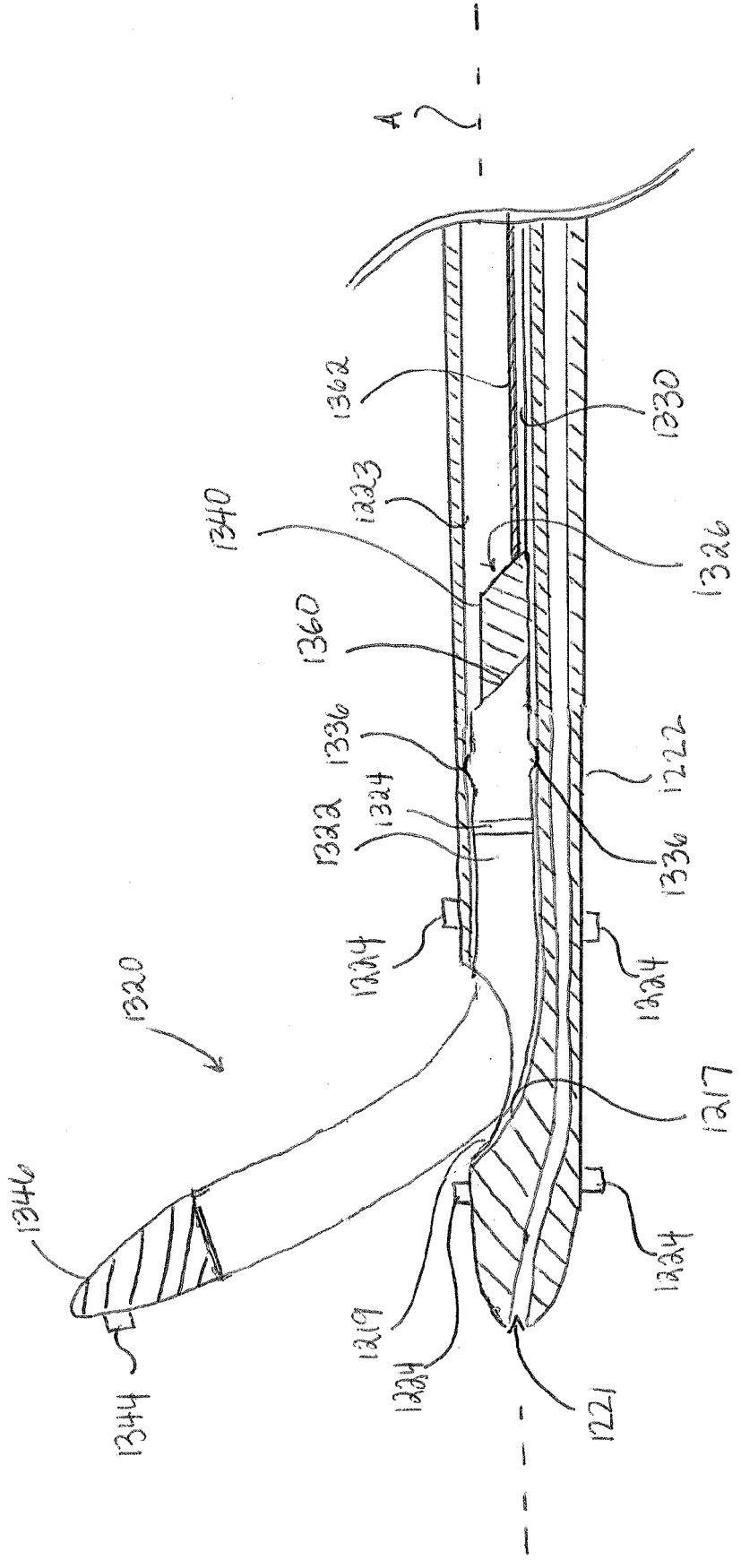
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Fig. 12C

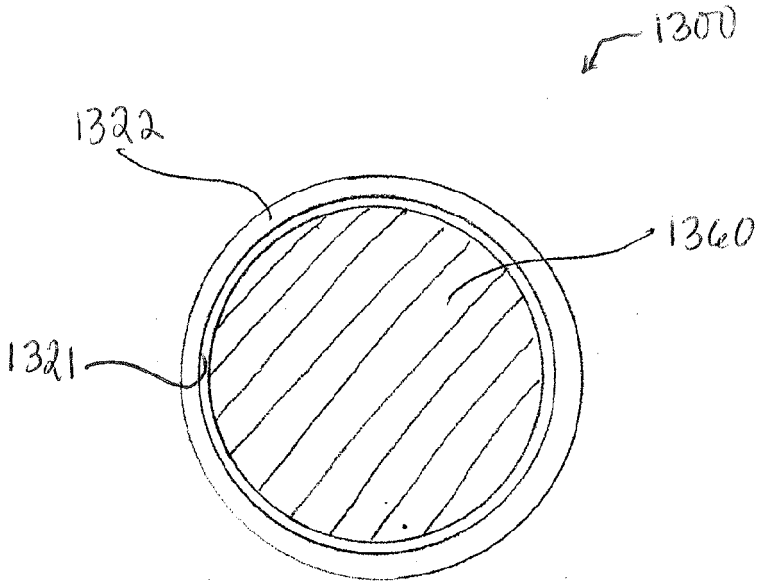

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FIG. 13

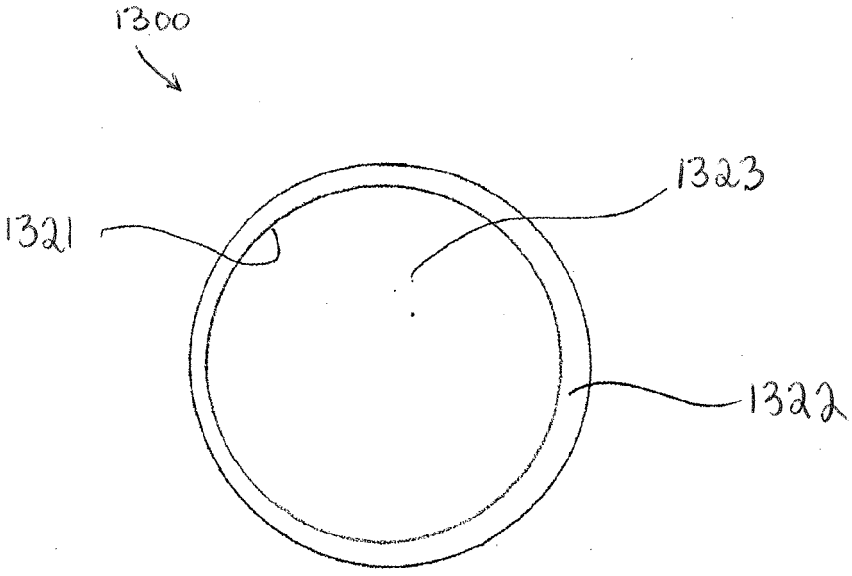

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FIG. 14

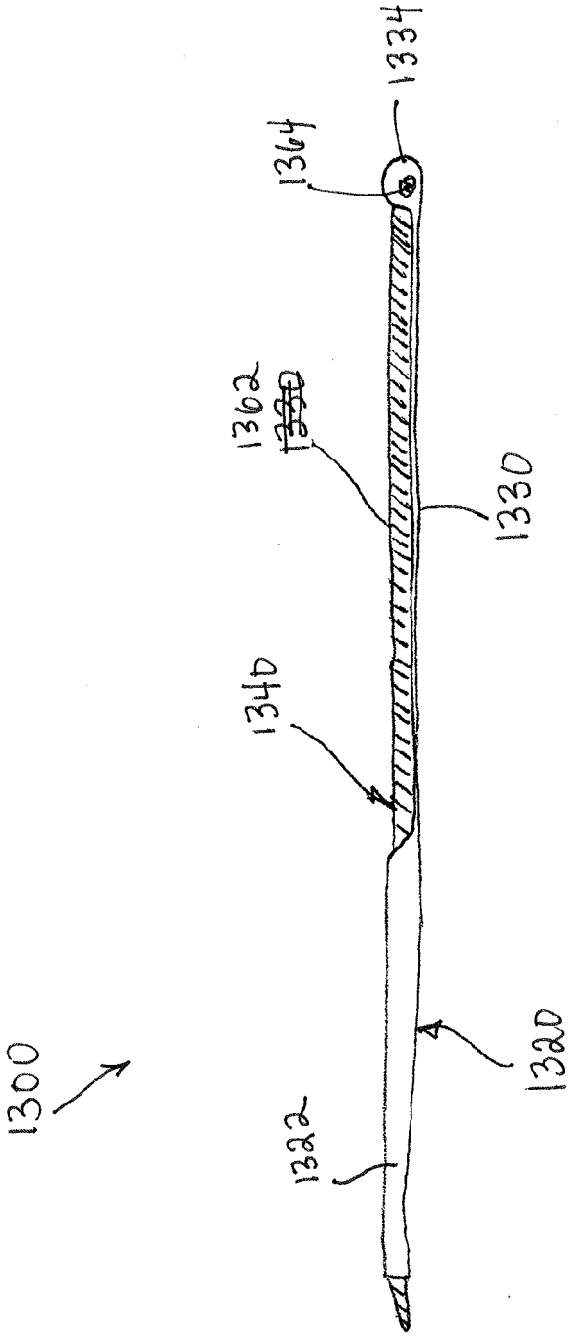

FIG. 15A

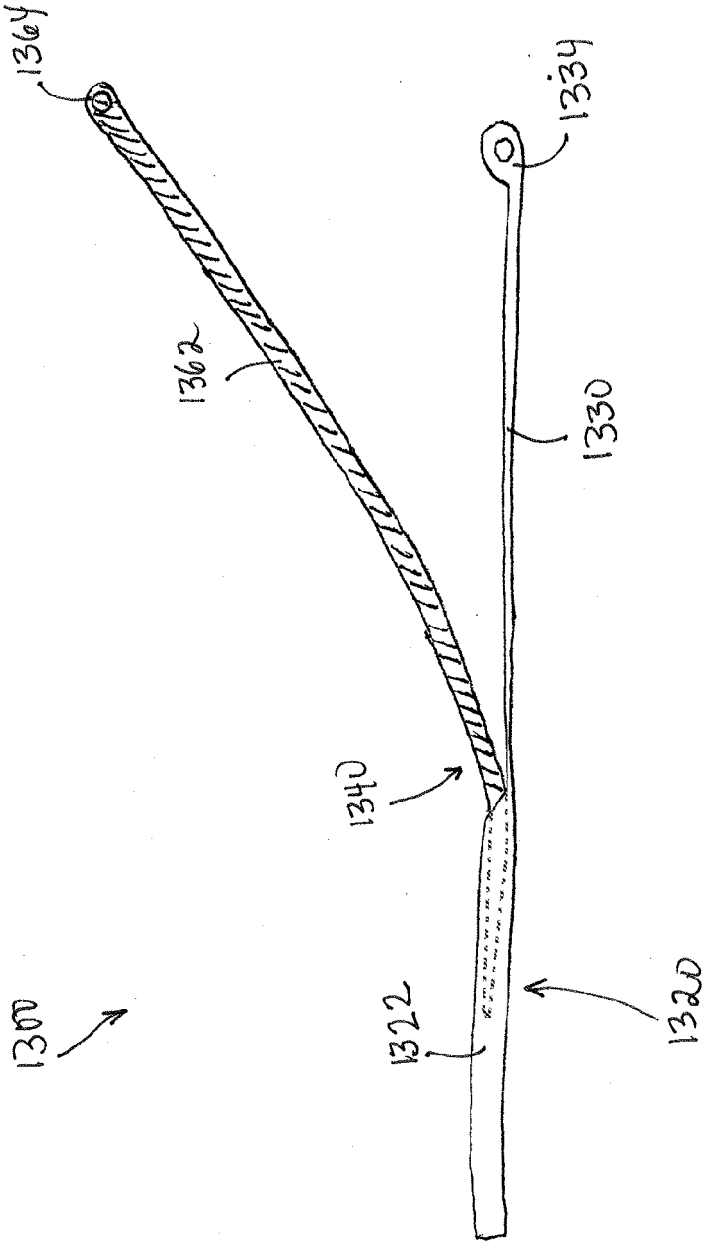

FIG. 15B

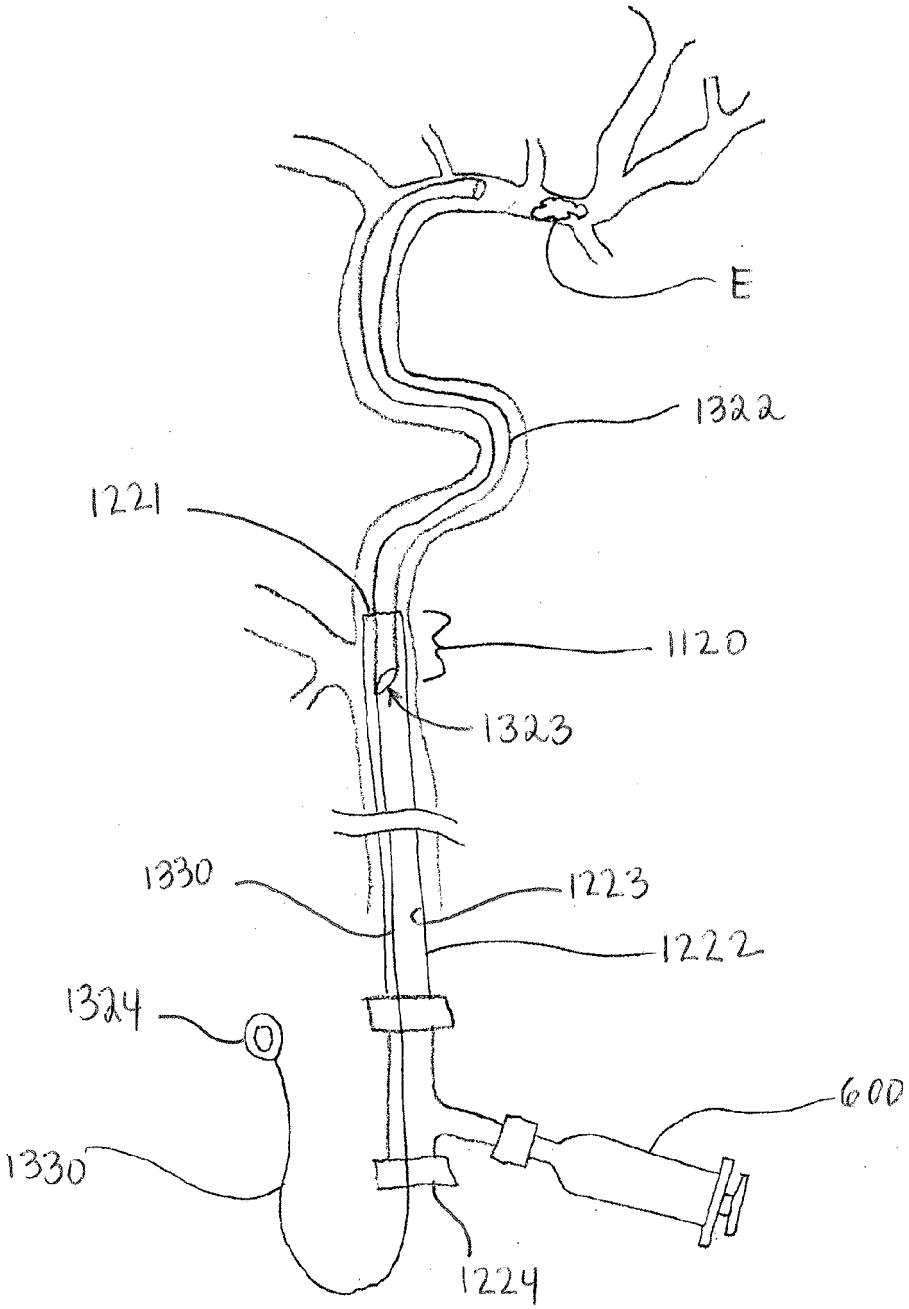

FIG. 16

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/016618

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M29/00 A61M25/01 A61B17/22
ADD. A61B17/221 A61M25/06

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)
A61M 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 2003/050600 A1 (RESSEMANN THOMAS V [US] ET AL) 13 March 2003 (2003-03-13) figures 1A, 6A-I, 11E, 11G paragraph [0086] - paragraph [0089] paragraph [0095] - paragraph [0125] paragraph [0208] - paragraph [0209] -----	1-8, 13-76, 83-95
X	EP 1 639 951 A1 (TERUMO CORP [JP]) 29 March 2006 (2006-03-29) the whole document -----	17-27, 34-46, 51,52, 56-65, 86-95

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[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
6 April 2016	18/04/2016

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	Emirdag, Eda

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/016618

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X,P	WO 2015/100178 A1 (SILK ROAD MEDICAL INC [US]) 2 July 2015 (2015-07-02) figures 31A-C paragraph [0120] - paragraph [0123] -----	17
X,P	WO 2015/157330 A1 (INCUVATE LLC [US]) 15 October 2015 (2015-10-15) figures 4, 11-24 paragraph [0076] - paragraph [0110] -----	17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2016/016618

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		WO 2015157330 A1	15-10-2015

(19)中华人民共和国国家知识产权局

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(22)申请日 2016.02.04

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62/142,637 2015.04.03 US

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2017.09.26

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WO2016/126974 EN 2016.08.11

(71)申请人 92号医疗公司
地址 美国新泽西州

(72)发明人 M·E·加里森 T·M·周
S·D·威尔逊

(74)专利代理机构 北京派特恩知识产权代理有限公司 11270
代理人 康艳青 姚开丽

(51)Int.Cl.
A61B 17/22(2006.01)
A61M 25/00(2006.01)
A61M 25/01(2006.01)
A61M 25/06(2006.01)
A61M 29/00(2006.01)

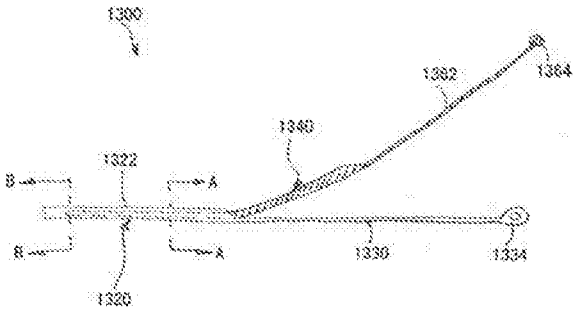
权利要求书6页 说明书27页 附图18页

(54)发明名称

快速抽吸血栓清除系统和方法

(57)摘要

一种用于促进通过通路鞘在神经血管系统内进行的管腔内医疗程序的血管内通路系统。所述系统包括抽吸或支撑导管(1320),其具有挠性远侧管腔部分(1322),所述管腔部分具有限定在所述管腔部分的近端处的近侧开口和所述管腔部分的远端处的远侧开口之间延伸的管腔(1323)的内径。所述导管具有刚性脊柱(1330),其联接到至少所述管腔部分的近端并且从其朝近侧延伸。所述系统包括扩张器(1340),其具有尺寸确定成接收在所述管腔部分(1322)的管腔(1323)内的挠性远侧扩张器部分(1360)。也描述了关联的系统、装置和使用方法。



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1.一种用于促进通过通路鞘在神经血管系统内进行的管腔内医疗程序的血管内通路系统，所述系统包括：

抽吸或支撑导管，其包括：

挠性远侧管腔部分，其具有内径，所述内径限定在所述管腔部分的近端处的近侧开口和在所述管腔部分的远端处的远侧开口之间延伸的管腔；以及

刚性脊柱，其联接到至少所述管腔部分的近端并且从其朝近侧延伸；以及

扩张器，其包括：

挠性远侧扩张器部分，其尺寸确定成接收在所述管腔部分的管腔内；以及

刚性扩张器脊柱，其从所述扩张器部分朝近侧延伸。

2.根据权利要求1所述的系统，其中，当使用时，所述扩张器脊柱与所述导管的脊柱并排对准。

3.根据权利要求1或2所述的系统，其中所述远侧扩张器部分具有锥形远侧尖端。

4.根据权利要求1-3中任一项所述的系统，其中所述扩张器具有至少与所述导管的长度一样长的长度，使得所述扩张器的远侧尖端从所述管腔部分的远侧开口突出。

5.根据权利要求1-4中任一项所述的系统，其中所述扩张器沿着所述长度的至少一部分大体上为管状。

6.根据权利要求1-5中任一项所述的系统，其中所述导管脊柱的近端包括配置成供使用者抓握以便将所述导管移动通过通路鞘的夹持特征。

7.根据权利要求6所述的系统，其中所述扩张器脊柱的近端包括配置成与所述导管脊柱上的所述夹持特征锁定的突片。

8.根据权利要求7所述的系统，其中当所述导管和所述扩张器处于锁定配置时，它们作为单个单元推进通过所述通路鞘。

9.根据权利要求7或8所述的系统，其中所述夹持特征和所述扩张器突片可去除地联接，使得在锁定配置中，所述扩张器突片接合所述夹持特征，并且在解锁配置中，所述扩张器突片从所述夹持特征脱离。

10.根据权利要求7-9中任一项所述的系统，其中所述扩张器突片固定到所述扩张器。

11.根据权利要求7-9中任一项所述的系统，其中所述扩张器突片在所述扩张器上可滑动以适应所述扩张器和所述导管之间的不同相对位置。

12.根据前述权利要求中任一项所述的系统，其中所述远侧扩张器部分包括外表面上的一个或多个棘爪，所述棘爪配置成与所述扩张器部分延伸通过的所述管腔部分的管腔的内表面上的相应形状的表面特征锁定。

13.根据前述权利要求中任一项所述的系统，其中所述扩张器脊柱和所述导管脊柱具有相似的刚度和抗扭结性。

14.根据前述权利要求中任一项所述的系统，其中所述扩张器在所述远侧尖端的远端和/或近端上具有视觉标记。

15.根据前述权利要求中任一项所述的系统，其中所述扩张器的远端区域朝着所述扩张器的近端区域挠性更大并且刚度增加。

16.根据前述权利要求中任一项所述的系统，其中所述导管脊柱和所述扩张器脊柱配置成引起所述管腔部分通过通路鞘的管腔的双向滑动运动，并且将所述管腔部分导航到脑

血管中以到达治疗部位。

17.一种用于促进神经血管系统内的管腔内医疗程序的血管内通路系统，所述系统包括：

通路鞘，其具有鞘主体，所述鞘主体具有限定所述鞘主体的近端和远端之间的管腔的内径，和靠近所述鞘主体的远端区域的来自所述管腔的至少一个开口；以及

抽吸或支撑导管，其包括：

挠性远侧管腔部分，其具有尺寸确定成用于通过所述通路鞘的管腔插入的外径，限定在所述管腔部分的近端处的近侧开口和在所述管腔部分的远端处的远侧开口之间延伸的管腔的内径，以及在所述近侧开口和所述远侧开口之间的长度；以及

刚性脊柱，其联接到至少所述管腔部分的近端并且从其朝近侧延伸，

其中所述刚性脊柱配置成引起所述管腔部分通过所述通路鞘的管腔并从所述至少一个开口出来的双向滑动运动以将所述管腔部分导航到脑血管中以到达治疗部位，并且

当所述管腔部分的远端延伸到脑血管中以到达治疗部位时，所述管腔部分的外径的一部分与所述通路鞘的内径流体密封。

18.根据权利要求17所述的系统，其中所述管腔部分和所述鞘主体同心地对准，并且所述管腔部分的管腔和所述鞘主体的管腔形成从所述管腔部分的远端到所述鞘主体的近端的连续抽吸管腔。

19.根据权利要求18所述的系统，其中所述连续抽吸管腔可用于从所述管腔部分的远侧开口抽吸流体和碎屑。

20.根据权利要求18或19所述的系统，其中所述连续抽吸管腔可用于通过所述管腔部分的远侧开口递送材料。

21.根据权利要求17-20中任一项所述的系统，其中所述连续抽吸管腔形成直径的递增部，在所述直径的递增部处所述管腔部分的管腔并入所述鞘主体的管腔中。

22.根据权利要求17-21中任一项所述的系统，其中所述管腔部分的管腔比所述鞘主体的管腔短。

23.根据权利要求17-22中任一项所述的系统，其中当所述管腔部分朝远侧延伸超过所述鞘主体的所述至少一个开口时，所述管腔部分和所述鞘主体形成重叠区域。

24.根据权利要求23所述的系统，其中所述管腔部分的外径接近所述鞘主体的管腔的内径，使得由所述重叠区域形成密封。

25.根据权利要求24所述的系统，其中所述密封配置成能够对最高达25inHg或高达28inHg的真空进行密封。

26.根据权利要求24所述的系统，其中所述重叠区域内的所述密封配置成能够对高达300mmHg的压力进行密封。

27.根据权利要求24-26中任一项所述的系统，其中所述密封位于所述管腔部分的近端的远侧和所述鞘主体的所述至少一个开口的近侧。

28.根据权利要求24-27中任一项所述的系统，其还包括定位在所述管腔部分的外表面上的密封元件。

29.根据权利要求28所述的系统，其中所述密封元件包括在所述重叠区域中的递增直径或突出特征。

30.根据权利要求28所述的系统，其中所述密封元件包括一个或多个外部脊特征。

31.根据权利要求30所述的系统，其中当所述管腔部分插入所述鞘主体的管腔中时，所述一个或多个脊特征是可压缩的。

32.根据权利要求28所述的系统，其中所述密封元件包括抵靠所述鞘主体管腔的内表面偏压的一个或多个倾斜表面。

33.根据权利要求28所述的系统，其中所述密封元件包括被致动以密封的一个或多个可膨胀构件。

34.根据权利要求17至33中任一项所述的系统，其中所述鞘主体具有适合于插入颈动脉中的外径。

35.根据权利要求34所述的系统，其中所述鞘主体的外径在5Fr到7Fr之间。

36.根据权利要求17-35中任一项所述的系统，其中所述鞘主体具有在近端和远端之间的长度，其适合于从经股进路将所述鞘主体的远端定位在颈内动脉的岩部处。

37.根据权利要求36所述的系统，其中所述鞘主体的长度在80cm到105cm之间。

38.根据权利要求17-37中任一项所述的系统，其中所述管腔部分的长度在10cm到25cm之间。

39.根据权利要求17至38中任一项所述的系统，其中所述管腔部分的长度小于所述鞘主体的长度，使得当所述导管缩回到所述鞘主体中时在所述管腔部分和所述鞘主体的内径的重叠区域之间保持密封。

40.根据权利要求17-39中任一项所述的系统，其中所述脊柱比所述鞘主体的整个长度长。

41.根据权利要求17-40中任一项所述的系统，其中所述管腔部分包括三个或更多个层，其包括内润滑衬层、加强层和外护套层。

42.根据权利要求41所述的系统，其中所述外护套层由具有不同硬度、组成和/或厚度的聚合物的不连续部分组成以沿着所述远侧管腔部分的长度改变挠性。

43.根据权利要求17-42中任一项所述的系统，其中所述远侧管腔部分的外径尺寸确定成用于导航到脑动脉中。

44.根据权利要求17-43中任一项所述的系统，其中所述远侧管腔部分的内径在0.040”到0.088”之间。

45.根据权利要求17-44中任一项所述的系统，其中所述管腔部分的外径接近所述鞘主体的内径，以在重叠区域处产生密封区域，同时仍允许所述导管移动通过所述鞘主体。

46.根据权利要求17-45中任一项所述的系统，其中所述导管朝着所述远侧开口呈锥形，使得所述管腔部分的最远端具有比所述管腔部分的更近侧区域小的外径，靠近所述更近侧区域所述管腔部分与所述鞘主体密封。

47.根据权利要求17-46中任一项所述的系统，其中所述鞘主体的远端区域包括闭塞元件。

48.根据权利要求17-47中任一项所述的系统，其中所述鞘主体的远端区域包括膨胀远侧尖端。

49.根据权利要求17-48中任一项所述的系统，其中来自所述管腔的所述至少一个开口包括位于远离所述鞘主体的远侧尖端一定距离处的侧开口。

50.根据权利要求17-49中任一项所述的系统，其中所述鞘主体的远侧尖端还包括斜面特征，所述斜面特征配置成成角度地引导所述导管远离所述鞘主体管腔的纵向轴线通过所述至少一个开口出来。

51.根据权利要求17-50中任一项所述的系统，其中所述脊柱比所述鞘主体的整个长度长。

52.根据权利要求17-51中任一项所述的系统，其中所述脊柱是具有从0.014”至0.018”的直径的丝。

53.根据权利要求17-52中任一项所述的系统，其中所述脊柱是具有延伸通过其中的导丝通道的海波管。

54.根据权利要求17-53中任一项所述的系统，其中所述脊柱是具有从0.010”至0.025”的厚度的外部尺寸的带状物。

55.根据权利要求54所述的系统，其中所述带状物沿着弧的至少一部分弯曲。

56.根据权利要求17-55中任一项所述的系统，其中所述脊柱配置成围绕所述通路鞘的纵向轴线旋转所述管腔部分。

57.根据权利要求17-56中任一项所述的系统，其中所述脊柱偏心地联接到所述管腔部分，并且所述脊柱从所述管腔部分朝近侧延伸到所述鞘主体的近端的外部。

58.根据权利要求17-57中任一项所述的系统，其中所述管腔部分的近端具有成角切口。

59.根据权利要求58所述的系统，其中所述成角切口是大致平面的或弯曲的。

60.根据权利要求17-59中任一项所述的系统，其中所述鞘主体在所述鞘主体的远端区域上具有一个或多个视觉标记。

61.根据权利要求17-60中任一项所述的系统，其中所述远侧管腔部分在所述管腔部分的远端区域、所述管腔部分的近端区域或两者处具有一个或多个视觉标记。

62.根据权利要求60或61所述的系统，其中所述鞘主体上的所述一个或多个视觉标记和所述管腔部分上的所述一个或多个视觉标记在视觉上是不同的。

63.根据权利要求60-62中任一项所述的系统，其中所述脊柱具有一个或多个视觉标记。

64.根据权利要求63所述的系统，其中所述脊柱的所述一个或多个视觉标记指示所述远侧管腔部分和所述鞘主体之间的重叠。

65.根据权利要求63或64所述的系统，其中所述脊柱的所述一个或多个视觉标记定位成使得当所述脊柱的视觉标记与所述通路鞘的一部分对准时，所述导管定位在最远侧位置处，具有产生所述导管和所述鞘主体之间的密封所需的最小重叠长度。

66.根据权利要求17-65中任一项所述的系统，其还包括具有挠性远侧扩张器部分的扩张器，所述扩张器部分具有远侧尖端并且尺寸确定成接收在所述导管的管腔部分内。

67.根据权利要求66所述的系统，其中所述扩张器沿着其长度的至少一部分是管状元件。

68.根据权利要求66所述的系统，其中所述扩张器是由配置成由使用者成形的延展性材料形成的实心杆。

69.根据权利要求66所述的系统，其中所述扩张器还包括从所述扩张器部分朝近侧延

伸的刚性扩张器脊柱。

70.根据权利要求69所述的系统，其中所述扩张器脊柱是同轴的。

71.根据权利要求70所述的系统，其中所述同轴扩张器脊柱具有延伸通过它的管腔。

72.根据权利要求69所述的系统，其中所述扩张器脊柱是偏心的。

73.根据权利要求69-72中任一项所述的系统，其中当使用时，所述扩张器脊柱与所述导管的脊柱并排对准。

74.根据权利要求66-73中任一项所述的系统，其中所述远侧尖端为锥形。

75.根据权利要求74所述的系统，其中所述扩张器具有至少与所述导管的长度一样长的长度，使得所述远侧尖端从所述管腔部分的远侧开口突出。

76.根据权利要求69-75中任一项所述的系统，其中所述脊柱的近端包括配置成供使用者抓握以便将所述导管移动通过所述通路鞘的夹持特征。

77.根据权利要求76所述的系统，其中所述扩张器脊柱的近端包括配置成与所述导管脊柱上的所述夹持特征锁定的突片。

78.根据权利要求77所述的系统，其中当所述导管和所述扩张器处于锁定配置时，它们作为单个单元推进通过所述鞘主体。

79.根据权利要求77或78所述的系统，其中所述夹持特征和所述扩张器突片可去除地联接，使得在锁定配置中，所述扩张器突片接合所述夹持特征，并且在解锁配置中，所述扩张器突片从所述夹持特征脱离。

80.根据权利要求77-79中任一项所述的系统，其中所述扩张器突片固定到所述扩张器。

81.根据权利要求77-79中任一项所述的系统，其中所述扩张器突片在所述扩张器上可滑动以适应所述扩张器和所述导管之间的不同相对位置。

82.根据权利要求66-81中任一项所述的系统，其中所述远侧扩张器部分包括外表面上的一个或多个棘爪，所述棘爪配置成与所述扩张器部分延伸通过的所述管腔部分的管腔的内表面上的相应形状的表面特征锁定。

83.根据权利要求69-82中任一项所述的系统，其中所述扩张器脊柱和所述导管脊柱具有相似的刚度和抗扭结性。

84.根据权利要求66-83中任一项所述的系统，其中所述扩张器在所述远侧尖端的远端和/或近端上具有视觉标记。

85.根据权利要求66-84中任一项所述的系统，其中所述扩张器的远端区域朝着所述扩张器的近端区域挠性更大并且刚度增加。

86.根据权利要求17-85中任一项所述的系统，其中所述通路鞘还包括将所述鞘主体的近端连接到近侧止血阀的连接器。

87.根据权利要求86所述的系统，其中所述近侧止血阀具有可调节开口，所述可调节开口尺寸确定成足够大以允许去除所述导管而不脱出其上的任何凝块。

88.根据权利要求86或87所述的系统，其中当与所述通路鞘一起使用时，所述导管的刚性脊柱从所述管腔部分朝近侧延伸通过所述通路鞘管腔并从所述通路鞘的所述近侧止血阀出来。

89.根据权利要求86-88中任一项所述的系统，其中所述连接器提供所述鞘主体的近端

到抽吸管线的连接。

90.根据权利要求86-89中任一项所述的系统，其中所述连接器具有大孔径内管腔并且连接到大孔径抽吸管线。

91.根据权利要求89或90所述的系统，其中所述抽吸管线连接到抽吸源。

92.根据权利要求91所述的系统，其中所述抽吸源是主动抽吸源。

93.根据权利要求89-92中任一项所述的系统，其中所述抽吸管线连接到前向滴注或冲洗管线。

94.根据权利要求17-93中任一项所述的系统，其中所述通路鞘还包括近侧延伸部分，使得当所述导管的远侧管腔部分从所述鞘主体管腔收回时，其保持在所述近侧延伸部分内。

95.根据权利要求17-94中任一项所述的系统，其中所述管腔部分的内径尺寸确定成允许通过所述管腔部分放置介入装置。

快速抽吸血栓清除系统和方法

[0001] 相关申请的交叉引用

[0002] 本申请要求2015年2月4日提交的美国临时申请序列号62/111,481和2015年4月3日提交的美国临时申请序列号62/142,637的优先权,上述每一个申请的公开内容通过引用完整地并入本文中。

[0003] 本申请也涉及以下美国专利申请,它们通过引用完整地并入本文中:(1)2014年12月19日提交的美国专利申请序列号14/576,953;和(2)2014年12月12日提交的美国专利申请序号14/569,365;(3)2014年11月10日提交的美国专利申请序列号14/537,316;(4)2014年3月21日提交的美国专利申请序列号14/221,917,上述申请全部通过引用并入。

背景技术

[0004] 本公开大体上涉及用于治疗急性缺血性脑卒中的医学方法和装置。更特别地,本公开涉及用于导航通过复杂的解剖结构以执行脑栓塞的快速和安全的抽吸和去除的方法和系统。

[0005] 急性缺血性脑卒中是流向大脑的一部分的充足血流的突然堵塞,其通常由在供血大脑的血管之一中留存或形成的血栓或其他栓塞导致。如果不能快速解决这种堵塞,则缺血可能导致永久性神经功能缺损或死亡。有效治疗脑卒中的时间期限是:对于静脉内(IV)溶栓疗法在3小时内,以及对于定点动脉内溶栓疗法在6小时内,或对于堵塞脑动脉的介入性再通长达8小时。在该时间段之后再灌注缺血性大脑对患者没有整体的好处,并且实际上可能导致伤害,这是由于溶解纤维蛋白的使用引起颅内出血的风险增加。即使在这段时间内,存在强有力的证据表明症状发作与治疗之间的时间段越短,疗效越好。不幸的是,识别症状、将患者送往脑卒中治疗点并且最后在该时间期限内治疗这些患者的能力是罕有的。尽管治疗进步,但脑卒中仍然是美国第三大死亡原因并且是严重、长期残疾的主要原因。

[0006] 急性脑卒中的血管内治疗包括动脉内施用溶栓药物(如重组组织纤溶酶原激活物(rtPA)),机械去除堵塞,或两者的组合。如上所述,这些介入治疗必须在症状发作的几小时内进行。动脉内(IA)溶栓疗法和介入性血栓清除术都包括经由血管内技术和装置进入堵塞的脑动脉。

[0007] 类似于IV溶栓疗法,IA溶栓疗法本身的局限性在于可能需要几个小时的输注以有效地溶解凝块。介入性血栓清除疗法包括使用圈套、线圈或临时支架(也称为可回收支架装置)捕获和去除凝块,并且在伴随或不伴随凝块破坏的情况下抽吸凝块。可回收支架装置也用于在介入期间快速恢复到血管的流动。也可以使用混合程序,其组合可回收支架装置和经由引导导管或经由中间导管的抽吸以帮助去除凝块并且减小远侧栓塞的风险。最后,当不能进行凝块去除或溶解时,已采用球囊或支架来产生通过凝块的人工腔。

[0008] 为了进入脑解剖结构,使用引导导管或引导鞘将介入装置从动脉进入部位(典型地为股动脉)引导到目标解剖结构。在可能潜在地释放高水平的栓塞的程序时段期间,常常使用球囊引导导管进行近侧颈动脉闭塞。近侧闭塞具有阻止向前流动并且增加通过引导导管的管腔的抽吸效率的作用。引导件的长度由进入部位和引导件远侧尖端的期望位置之间

的距离确定。诸如导丝、微导管和用于子选择性引导和抽吸的中间导管的介入装置插入通过引导件并且推进到目标部位。通常，以同轴方式使用装置，即，中间导管内部的微导管内部的导丝作为组件以步进的方式推进到目标部位，其中内部、最无创性的元件首先朝远侧推进并为外部元件的推进提供支撑。同轴组件的每个元件的长度考虑了引导件的长度、导管上的近侧连接器的长度以及从远端延伸所需的长度。因此，例如，中间导管的工作长度典型地比引导件的工作长度长20-40cm，而微导管的工作长度典型地比中间导管的工作长度长10-30cm。导丝典型地比微导管长另一20-50cm。

[0009] 当前技术的一些示例性问题包括进入闭塞部位所需的时间或甚至能力，恢复流动所需的时间或不能完全或甚至部分地恢复到血管的流动，程序期间远侧栓塞的发生，其具有潜在的负面神经功能影响和程序性并发症，例如穿孔和脑内出血。需要这样的装置系统和方法，其能够实现快速进入，优化凝块的抽吸，在潜在地释放栓塞的程序的所有阶段期间的远侧保护，以及根据需要安全和快速更换装置以完全恢复到堵塞的脑血管的流动。

发明内容

[0010] 在一方面，公开了一种用于促进通过通路鞘在神经血管系统内进行的管腔内医疗程序的血管内通路系统。所述系统包括抽吸或支撑导管，其具有挠性远侧管腔部分，所述管腔部分具有内径，所述内径限定在所述管腔部分的近端处的近侧开口和在所述管腔部分的远端处的远侧开口之间延伸的管腔。所述导管具有刚性脊柱，其联接到至少所述管腔部分的近端并且从其朝近侧延伸。所述系统包括扩张器和刚性扩张器脊柱，所述扩张器具有尺寸确定成接收在所述管腔部分的管腔内的挠性远侧扩张器部分；以及所述刚性扩张器脊柱从所述扩张器部分朝近侧延伸。

[0011] 所述扩张器脊柱可以与所述导管的脊柱并排对准。所述远侧扩张器部分可以具有锥形远侧尖端。所述扩张器可以具有至少与所述导管的长度一样长的长度，使得所述扩张器的远侧尖端从所述管腔部分的远侧开口突出。所述扩张器可以沿着所述长度的至少一部分大体上为管状。所述导管脊柱的近端可以包括配置成供使用者抓握以便将所述导管移动通过通路鞘的夹持特征。所述扩张器脊柱的近端可以包括配置成与所述导管脊柱上的所述夹持特征锁定的突片。当所述导管和所述扩张器处于锁定配置时，它们可以作为单个单元推进通过所述通路鞘。所述夹持特征和所述扩张器突片可以可去除地联接，使得在锁定配置中，所述扩张器突片接合所述夹持特征，并且在解锁配置中，所述扩张器突片从所述夹持特征脱离。所述扩张器突片可以固定到所述扩张器，或者可以在所述扩张器上可滑动以适应所述扩张器和所述导管之间的不同相对位置。所述远侧扩张器部分可以包括外表面上的一个或多个棘爪，所述棘爪配置成与所述扩张器部分延伸通过的所述管腔部分的管腔的内表面上的相应形状的表面特征锁定。所述扩张器脊柱和所述导管脊柱可以具有相似的刚度和抗扭结性。所述扩张器可以在所述远侧尖端的远端和/或近端上具有视觉标记。所述扩张器的远端区域可以朝着所述扩张器的近端区域挠性更大并且刚度增加。所述导管脊柱和所述扩张器脊柱可以配置成引起所述管腔部分通过通路鞘的管腔的双向滑动运动，并且将所述管腔部分导航到脑血管中以到达治疗部位。

[0012] 在相互关联的方面，公开了一种用于促进神经血管系统内的管腔内医疗程序的血管内通路系统，其具有通路鞘和抽吸或支撑导管。所述通路鞘具有鞘主体，所述鞘主体具有

限定所述鞘主体的近端和远端之间的管腔的内径。所述鞘主体具有靠近所述鞘主体的远端区域的来自所述管腔的至少一个开口。所述抽吸或支撑导管包括挠性远侧管腔部分，其具有尺寸确定成用于通过所述通路鞘的管腔插入的外径，限定在所述管腔部分的近端处的近侧开口和在所述管腔部分的远端处的远侧开口之间延伸的管腔的内径，以及在所述近侧开口和所述远侧开口之间的长度。所述抽吸或支撑导管包括刚性脊柱，其联接到至少所述管腔部分的近端并且从其朝近侧延伸。所述刚性脊柱配置成导致所述管腔部分通过所述通路鞘的管腔并从所述至少一个开口出来的双向滑动运动以将所述管腔部分导航到脑血管中以到达治疗部位。当所述管腔部分的远端延伸到脑血管中以到达治疗部位时，所述管腔部分的外径的一部分与所述通路鞘的内径流体密封。

[0013] 所述管腔部分和所述鞘主体可以同心对准，并且所述管腔部分的管腔和所述鞘主体的管腔形成从所述管腔部分的远端到所述鞘主体的近端的连续抽吸管腔。所述连续抽吸管腔可以用于从所述管腔部分的远侧开口抽吸流体和碎屑。所述连续抽吸管腔可以通过所述管腔部分的远侧开口递送材料。所述连续抽吸管腔可以形成直径的递增部，在所述直径的递增部处所述管腔部分的管腔并入所述鞘主体的管腔中。所述管腔部分的管腔可以比所述鞘主体的管腔短。当所述管腔部分朝远侧延伸超过所述鞘主体的所述至少一个开口时，所述管腔部分和所述鞘主体可以形成重叠区域。所述管腔部分的外径可以接近所述鞘主体的管腔的内径，使得由所述重叠区域形成密封。所述密封可以配置成能够对最高达25inHg或高达28inHg的真空进行密封。所述重叠区域内的所述密封可以配置成能够对高达300mmHg或高达600或高达700mmHg的压力进行密封。所述密封可以位于所述管腔部分的近端的远侧和所述鞘主体的所述至少一个开口的近侧。

[0014] 所述系统还可以包括定位在所述管腔部分的外表面上的密封元件。所述密封元件可以包括在所述重叠区域中的递增直径或突出特征。所述密封元件可以包括一个或多个外部脊特征。当所述管腔部分插入所述鞘主体的管腔中时，所述一个或多个脊特征可以是可压缩的。所述密封元件可以包括抵靠所述鞘主体管腔的内表面偏压的一个或多个倾斜表面。所述密封元件可以包括被致动以密封的一个或多个可膨胀构件。所述鞘主体可以具有适合于插入颈动脉中的外径。所述鞘主体的外径可以在5Fr到7Fr之间。

[0015] 所述鞘主体可以具有在近端和远端之间的长度，其适合于从经股进路将所述鞘主体的远端定位在颈内动脉的岩部处。所述鞘主体的长度可以在80cm到105cm之间。所述管腔部分的长度可以在10cm到25cm之间。所述管腔部分的长度可以小于所述鞘主体的长度，使得当所述导管缩回到所述鞘主体中时，在所述管腔部分的重叠区域和所述鞘主体的内径之间保持密封。

[0016] 所述脊柱可以比所述鞘主体的整个长度长。所述管腔部分可以包括三个或更多个层，其包括内润滑衬层、加强层和外护套层。所述外护套层可以由具有不同硬度、组成和/或厚度的聚合物的不连续部分组成以沿着所述远侧管腔部分的长度改变挠性。所述远侧管腔部分的外径可以尺寸确定成用于导航到脑动脉中。所述远侧管腔部分的内径可以在0.040”到0.088”之间。所述管腔部分的外径可以接近所述鞘主体的内径，以在重叠区域处产生密封区域，同时仍允许所述导管移动通过所述鞘主体。所述导管可以朝着所述远侧开口呈锥形，使得所述管腔部分的最远端具有比所述管腔部分的更近侧区域小的外径，靠近所述更近侧区域所述管腔部分与所述鞘主体密封。所述鞘主体的远端区域可以包括闭塞元件。所

述鞘主体的远端区域可以包括膨胀远侧尖端。来自所述管腔的所述至少一个开口可以包括位于远离所述鞘主体的远侧尖端一定距离处的侧开口。所述鞘主体的远侧尖端还可以包括斜面特征，所述斜面特征配置成成角度地引导所述导管远离所述鞘主体管腔的纵向轴线通过所述至少一个开口出来。

[0017] 所述脊柱可以比所述鞘主体的整个长度长。所述脊柱可以是具有从0.014”至0.018”的外径的丝。所述脊柱可以是具有延伸通过其中的导丝通道的海波管。所述脊柱可以是具有从0.010”至0.025”的厚度的外部尺寸的带状物。所述带状物可以沿着弧的至少一部分弯曲。所述脊柱可以配置成围绕所述通路鞘的纵向轴线旋转所述管腔部分。所述脊柱可以偏心地联接到所述管腔部分，并且所述脊柱从所述管腔部分朝近侧延伸到所述鞘主体的近端的外部。所述管腔部分的近端可以具有成角切口。所述成角切口可以是大致平面的或弯曲的。所述鞘主体可以在所述鞘主体的远端区域上具有一个或多个视觉标记。所述远侧管腔部分可以在所述管腔部分的远端区域、所述管腔部分的近端区域或两者处具有一个或多个视觉标记。所述鞘主体上的所述一个或多个视觉标记和所述管腔部分上的所述一个或多个视觉标记可以在视觉上是不同的。所述脊柱可以具有一个或多个视觉标记。所述脊柱的所述一个或多个视觉标记可以指示所述远侧管腔部分和所述鞘主体之间的重叠。所述脊柱的所述一个或多个视觉标记可以定位成使得当所述脊柱的视觉标记与所述通路鞘的一部分对准时，所述导管定位在最远侧位置处，具有产生所述导管和所述鞘主体之间的密封所需的最小重叠长度。

[0018] 所述系统还可以包括具有挠性远侧扩张器部分的扩张器，所述扩张器部分具有远侧尖端并且尺寸确定成接收在所述导管的管腔部分内。所述扩张器可以沿着其长度的至少一部分是管状元件。所述扩张器可以是由配置成由使用者成形的延展性材料形成的实心杆。所述扩张器还可以包括从所述扩张器部分朝近侧延伸的刚性扩张器脊柱。所述扩张器脊柱可以是同轴的并且可以具有延伸通过它的管腔。所述扩张器脊柱可以是偏心的。当使用时，所述扩张器脊柱可以与所述导管的脊柱并排对准。所述扩张器的远侧尖端可以为锥形。所述扩张器可以具有至少与所述导管的长度一样长的长度，使得所述远侧尖端从所述管腔部分的远侧开口突出。所述脊柱的近端可以包括配置成供使用者抓握以便将所述导管移动通过所述通路鞘的夹持特征。所述扩张器脊柱的近端可以包括配置成与所述导管脊柱上的所述夹持特征锁定的突片。当所述导管和所述扩张器处于锁定配置时，它们可以作为单个单元推进通过所述鞘主体。所述夹持特征和所述扩张器突片可以可去除地联接，使得在锁定配置中，所述扩张器突片接合所述夹持特征，并且在解锁配置中，所述扩张器突片从所述夹持特征脱离。所述扩张器突片可以固定到所述扩张器，和/或可以在所述扩张器上可滑动以适应所述扩张器和所述导管之间的不同相对位置。

[0019] 所述远侧扩张器部分可以包括外表面上的一个或多个棘爪，所述棘爪配置成与所述扩张器部分延伸通过的所述管腔部分的管腔的内表面上的相应形状的表面特征锁定。所述扩张器脊柱和所述导管脊柱可以具有相似的刚度和抗扭结性。所述扩张器可以在所述远侧尖端的远端和/或近端上具有视觉标记。所述扩张器的远端区域可以朝着所述扩张器的近端区域挠性更大并且刚度增加。

[0020] 所述通路鞘还可以包括将所述鞘主体的近端连接到近侧止血阀的连接器。所述近侧止血阀可以具有可调节开口，所述可调节开口尺寸确定成足够大以允许去除所述导管而

不脱出其上的任何凝块。当与所述通路鞘一起使用时，所述导管的刚性脊柱可以从所述管腔部分朝近侧延伸通过所述通路鞘管腔并从所述通路鞘的所述近侧止血阀出来。所述连接器可以提供所述鞘主体的近端到抽吸管线的连接。所述连接器可以具有大孔径内管腔并且连接到大孔径抽吸管线。所述抽吸管线可以连接到抽吸源。所述抽吸源可以是主动抽吸源。所述抽吸管线可以连接到前向滴注或冲洗管线。所述通路鞘还可以包括近侧延伸部分，使得当所述导管的远侧管腔部分从所述鞘主体管腔收回时，其保持在所述近侧延伸部分内。所述管腔部分的内径可以尺寸确定成允许通过所述管腔部分放置介入装置。

[0021] 从通过示例说明本发明的原理的各种实施例的以下描述将显而易见其他特征和优点。

附图说明

[0022] 图1是用于从股动脉进入部位进入和去除脑闭塞以治疗急性缺血性脑卒中的装置系统的分解图；

[0023] 图2A示出了图1的系统的部件从经股进路的在患者中就位以治疗闭塞；

[0024] 图2B是图2A的系统沿着圆BB截取的一部分的详细视图；

[0025] 图3示出了正经由经颈进入部位使用的图1的系统的部件；

[0026] 图4示出了通路鞘的实施例；

[0027] 图5示出了作为独立、可去除部件提供的图4的通路鞘的近侧部分的实施例；

[0028] 图6示出了最小化通过图4的通路鞘进入近侧部分的流动阻力的连接器的实施例；

[0029] 图7示出了具有闭塞球囊的通路鞘的实施例；

[0030] 图8A-8B示出了通路鞘主体和延伸通过其中的导管的管腔部分之间的密封元件的实施例；

[0031] 图9示出了通过带脊柱的导管定位的微导管和可回收支架装置的实施例；

[0032] 图10A-10C示出了可回收支架装置上的可膨胀部分的实施例；

[0033] 图11示出了用于与本文中所述的系统一起使用的抽吸系统的实施例；

[0034] 图12A示出了用于与本文中所述的系统一起使用的带脊柱的导管系统的实施例；

[0035] 图12B示出了图12A的带脊柱的导管系统，其具有延伸通过带脊柱的导管的管腔的带脊柱的扩张器；

[0036] 图12C示出了图12A的带脊柱的导管系统，其延伸通过通路鞘的实施例的侧开口；

[0037] 图13是围绕图12B的线A-A截取的横截面图；

[0038] 图14是围绕图12B的线B-B截取的横截面图；

[0039] 图15A示出了具有处于锁定配置的带脊柱的导管和带脊柱的扩张器的带脊柱的抽吸导管-扩张器系统的实施例。

[0040] 图15B示出了具有处于解锁配置的带脊柱的导管和带脊柱的扩张器的带脊柱的抽吸导管-扩张器系统；

[0041] 图16示出了带脊柱的导管系统的实施例，其朝远侧延伸到通路鞘以治疗脑血管中的栓塞。

具体实施方式

[0042] 目前的急性脑卒中介入程序的主要缺点之一是恢复对脑的血液灌注所需的时间。该时间包括进入脑动脉中的一个或多个闭塞部位所需的时间，以及完全去除动脉中的闭塞所需的时间。由于通常的情况是必须进行多于一次尝试以完全去除闭塞，因此减少尝试的次数以及减少更换装置以进行额外尝试所需的时间是最小化总时间中的重要因素。另外，每次尝试都与在脆弱的脑血管系统中的推进装置引起的潜在程序风险关联。

[0043] 本文中公开了使得能够安全和快速地进入脑和颅内动脉的复杂神经血管解剖结构并去除闭塞的方法和装置。该方法和装置包括一个或多个通路装置、导管和去除闭塞血栓清除装置。也公开了提供主动抽吸和/或被动流动逆转以便于促进闭塞去除以及远侧栓塞最小化的方法和装置。该系统为使用者提供一定程度的流动控制从而满足脑血管系统的特定血液动力学要求。本文中所述的系统提供了优异的使用便利性，这在于单个操作者可以操作所公开的系统使用单点连续抽吸来以便快速而安全地进行更换而不需要切换(switching)。通过本文中所述的系统的抽吸力的更高效率减少远侧栓塞碎片并且增加了“一次即可”的血栓清除术的比率。

[0044] 应当领会，尽管一些实施例具体关于抽吸神经血管解剖结构进行描述，但是实施例不限于此，而是也可以应用于其他用途。例如，本文中所述的通路系统的带脊柱的抽吸导管和一个或多个部件可以用于将工作装置递送到冠状动脉解剖结构或其他血管系统解剖结构的目标血管。应当领会，在本文中使用短语“抽吸导管”的情况下，这样的导管可以用于除了抽吸之外的其他目的，例如将流体递送到治疗部位或作为支撑导管提供促进和引导诸如导丝或介入装置的其他装置的递送或更换的管路。替代地，通路系统不需要仅限于血管系统，可以有用于进入血管系统的外部的身体的其他部分。也应当领会，在本说明书各处对特定特征、结构、配置、特性或实现方式或实施例的引用可以以任何合适的方式组合。在描述中各处的相对术语的使用可以表示相对位置或方向。例如，“远侧”可以指示远离参考点的第一方向。类似地，“近侧”可以指示与第一方向相反的第二方向的位置。然而，提供这样的术语以建立相对的参考系，并且不旨在将锚固递送系统的使用或取向限制到下面各种实施例中所述的具体配置。

[0045] 图1示出了用于从股动脉进入部位进入和去除脑闭塞以治疗急性缺血性脑卒中的装置系统。系统100包括通路鞘220，鞘扩张器250，导丝270，一个或多个带脊柱的抽吸或支撑导管320，扩张器340，微导管400，和可回收支架装置500，下面将更详细地描述其中的每一个。此外，系统100可以包括一个或多个动脉通路鞘系统200，其包括通路鞘220，一个或多个鞘扩张器250和鞘导丝270。系统100可以包括一个或多个带脊柱的导管系统300，其包括带脊柱的抽吸或支撑导管320，锥形扩张器340，和替代地，导管清洁工具350。带脊柱的导管系统300可以包含嵌套的带脊柱的导管以扩展延伸到远侧部位。系统100可以包括通路鞘系统200，锥形导管系统300，微导管400，和可回收支架装置500。

[0046] 图2A示出了从经股进路在患者中就位以治疗闭塞的系统的一些元件。通路鞘220可以通过股动脉插入部位插入，其定位成使得通路鞘220的远侧尖端位于颈内动脉ICA的岩部处或附近。带脊柱的抽吸导管320可以定位成使得远侧尖端位于动脉中的闭塞面处。在一些实现方式中，通路鞘220可以通过颈总动脉壁中的直接穿刺插入并且推进到颈内动脉中，而不是经由经股进路(参见图3)。

[0047] 如在详细的图2B中更清楚地看到，通路鞘220可以具有鞘主体222以及在鞘主体

222的近端和远端区域之间延伸的内管腔223。带脊柱的抽吸导管320尺寸确定成延伸通过通路鞘220的内管腔223，使得导管320的远端区域延伸超过通路鞘220的远端区域。导管320在图2B中示出为通过远侧开口221离开鞘主体222的管腔223。然而应当领会，鞘主体222可以具有靠近主体222的远端区域的一个或多个侧开口，导管320可以通过所述侧开口(参见图12C)，这将在下面将更详细地描述。

[0048] 仍然参考图2B，带脊柱的抽吸导管320可以包括联接到刚性和抗扭结的近侧脊柱330的相对挠性的远侧管腔部分322。远侧管腔部分322可以具有在管腔部分322的近端和远端之间延伸的内管腔323。导管320的管腔323可以具有第一内径，并且通路鞘220的管腔223可以具有更大的第二内径。管腔223、323流体地连接并且连续，使得流体流进和/或流出系统是可能的，例如通过从经由通路鞘220上的连接器226联接到系统的抽吸源施加抽吸。鞘主体222的远侧部分和导管320的管腔部分322之间的重叠区域120尺寸确定成并且配置成产生密封，其允许从带脊柱的导管320的远侧尖端区域到近侧鞘连接器226的连续抽吸管腔。如果鞘主体222具有导管320的远侧管腔部分322延伸通过的侧开口，则在鞘主体222和管腔部分322之间的重叠区域120处产生的密封位于侧开口的近侧。

[0049] 影响通过管的抽吸力的关键尺寸包括半径(r)，压力(P)，粘度(n)和长度(L)，其中流量＝$Q=\pi r^4(\Delta P)/8nL$的。半径的变化以4次方增加流量并且长度与流量成反比。如将在下面更详细地描述，抽吸导管具有丝上部分，其是到达目标部位所需的总距离的一部分。该配置大大加快了缩回和再推进导管所需的时间。此外，特别是与抽吸管腔沿着抽吸导管的整个内径延伸的现有系统相比，本文中所述的系统可以提供显著增加的半径和管腔面积用于抽吸凝块以及显著更短的长度。在本文所述的系统中，抽吸管腔的大部分具有程序鞘的半径。导管320在直径上小于引导件，但是在到达通路鞘220的管腔时在管腔直径上递增，允许更大的抽吸力施加到管腔系统的大部分长度。此外，导管320的该窄直径区域的总长度比通路鞘的总长度短得多。导管320的近侧脊柱330具有延伸通过通路鞘220的管腔223延伸到系统的近端的长度和结构，使得其可以用于通过鞘220的管腔223推进和缩回导管320。然而，抽吸导管320的脊柱330仅占用系统的一小部分管腔空间，导致用于抽吸的管腔面积增加。增加的用于抽吸的管腔面积增加了抽吸闭塞花费的时间，并且增加了在单次抽吸尝试中去除闭塞的可能性。当诸如微导管或锥形扩张器的装置同轴地定位在带脊柱的导管320和通路鞘220中时，递增的管腔直径也增加了可用于向前冲洗造影剂、盐水或其他溶液的环形区域。这可以增加在装置导航期间执行血管造影的容易性和能力。

[0050] 目前的脑卒中介入造成远侧栓塞被释放的风险。例如，在试图去除或溶解脑动脉中的凝块堵塞期间，存在血栓破裂产生栓塞颗粒的重大风险，该栓塞颗粒可以向下游迁移到闭塞血管或其他血管中并且损害脑灌注。在颈动脉支架手术(CAS)中，栓塞保护装置和系统通常用于降低栓塞材料进入脑血管的风险。装置的类型包括血管内远侧过滤器，以及反向流动或静态流动系统。不幸的是，由于脆弱的解剖结构和通路挑战以及快速介入的需要，这些类型的栓塞保护系统没有用于急性缺血性脑卒中的介入治疗。恢复流动时的脑卒中介入时期通常被认为是重要时间，原因是大脑现在正被血液灌注。然而，这也是栓塞风险的时期。当在动脉中存在堵塞时，没有流动。因此用导丝和/或微导管穿过闭塞或者穿过闭塞部署可回收支架装置而产生的任何栓塞碎屑仍然停滞。然而，当恢复到动脉的流动时，栓塞现在可以顺行流向远侧血管区域。

[0051] 当可回收支架装置正被拉回到引导件或导管中时，发生栓塞风险的第二时期。在现有的方法和装置中，在可回收支架装置缩回到导管中时将抽吸施加到中间导管，或者将导管和可回收支架装置一起拉回到引导件中，同时将抽吸施加到引导导管。通过导管和通过引导件的两个抽吸点都可以用于在通过引导件将闭塞从患者中吸引出来的关键步骤期间减小远侧栓塞的风险。通常，需要两个人来实现两个抽吸点，或者首先从导管并且然后从引导件顺序地执行抽吸，这可能导致抽吸的中断或次优抽吸。在公开的系统和方法中，在装置前进期间，在流动恢复的关键时间，以及在用单个抽吸点去除闭塞的整个时间期间，可以将反向流动施加到目标部位。

[0052] 在本公开的方面，抽吸水平可以从实现远侧栓塞的足够保护的低水平起改变到提供闭塞的有效抽吸去除的更高水平。该方面允许远侧保护而没有高水平的失血，但又允许所需的强抽吸力以去除闭塞。

[0053] 在另一方面，公开了用于在程序期间额外提供主动抽吸或被动逆行流动以去除血栓并最小化远侧栓塞的方法和装置。该系统为使用者提供一定程度的血流控制，从而满足脑血管系统的特定血液动力学要求。该系统可以包括流动控制器，其允许使用者控制抽吸的定时和模式。

[0054] 在另一方面，公开了用于额外提供冲洗步骤以最小化系统中的栓塞并增加使用期间系统中的颗粒的可见性的方法和装置。

[0055] 以下描述提供了所公开的发明的每个方面的详细实现方式和益处。

[0056] 再次参考示出通路鞘220的实现方式的图1。鞘220可以包括作为鞘220的可插入部分(即，插入到患者中的部分)的鞘主体222，近侧连接器226，抽吸管线230，近侧止血阀234和冲洗管线236。鞘220也可以包括近侧延伸部分240，并且也可以包括连接器226上的阀以将鞘主体222与通路鞘220的近侧部分240流体地隔离。通路鞘220可以在套件中伴随有一个或多个扩张器250，和鞘导丝270。

[0057] 鞘主体222的直径适合于插入颈动脉中，其具有的内管腔223的尺寸适合于提供用于治疗闭塞的导管的通道。在一个实施例中，鞘主体222可以具有约0.074”的内径和约0.090”的外径(对应于5Fr鞘尺寸)，约0.087”的内径和约0.104”的外径(对应于6Fr鞘尺寸)，或约0.100”的内径和约0.177”的外径(对应于7Fr鞘尺寸)。鞘主体222的长度配置成使鞘主体222的远侧尖端能够定位成与颈内动脉的岩部在一样远的远侧。在一个实施例中，鞘主体222的长度适合于经股进路，其在80到90cm或高达约100cm或高达约105cm的范围内。在一个实施例中，鞘主体222的长度适合于经颈进路到岩部ICA，其在20到25cm的范围内。在一个实施例中，鞘主体222的长度适合于经颈进路到CCA或近侧ICA，其在10-15cm的范围内。鞘主体222配置成呈现并导航通过血管系统的弯曲并且受到高吸力而不扭结、塌缩或导致血管创伤。

[0058] 鞘主体222可以以两层或更多层构造。内衬层可以由诸如PTFE(聚四氟乙烯)或FEP(氟化乙烯丙烯)的低摩擦聚合物构造以提供通过内管腔推进装置的光滑表面。外护套材料可以为内衬层提供机械完整性，并且可以由诸如PEBAX，热塑性聚氨酯，聚乙烯，尼龙等的材料构造。可以结合第三层，其可以在内衬层和外护套之间提供加强。加强层可以防止鞘主体222的内管腔的展平或扭结以允许装置无阻碍地导航通过血管系统中的弯曲部以及无阻碍的抽吸或反向流动。鞘主体222可以是周向加强的。加强层可以由诸如不锈钢，镍钛诺

(Nitinol)，镍钛诺编织物，螺旋带，螺旋丝，切割不锈钢等的金属，或诸如PEEK的刚性聚合物制成。加强层可以是诸如线圈或编织物或已被激光切割或机械切割以具有挠性的管道的结构。在另一个实施例中，加强层可以是切割海波管，例如镍钛诺海波管或切割刚性聚合物等。

[0059] 鞘主体222的挠性可以在其长度上变化，挠性朝着鞘主体222的远侧部分增加。挠性的变化可以以各种方式实现。例如，外护套可以在各个部分处改变硬度和/或材料。与鞘的其他部分相比，可以在鞘的远侧部分中使用较低硬度的外护套材料。替代地，护套材料的壁厚度可以减小，和/或加强层的密度可以变化以增加挠性。例如，线圈或编织物的节距可以被拉伸，或者管道中的切割图案可以变化以具有更大挠性。替代地，加强结构或材料可以在鞘主体222的长度上变化。在一个实施例中，最远侧部分具有在50到300N-mm^2的范围内的弯曲刚度(E*I)，而鞘主体222的剩余部分具有在500到1500N-mm^2的范围内的弯曲刚度，其中E是弹性模量并且I是装置的面积惯性矩。在另一实现方式中，在最远侧挠性部分和近侧部分之间有过渡部分，在鞘主体222的最远侧部分和剩余部分之间具有变化挠性的一个或多个部分。在该实施例中，最远侧部分为约2cm到约5cm，过渡部分为约2cm到约10cm，并且近侧部分占据鞘长度的剩余部分。

[0060] 鞘主体222的尖端可以包括一个或多个远侧不透射线标记224(参见图1)。在一个实施例中，不透射线尖端标记224是嵌入鞘主体222的远端附近的金属带，例如铂铱合金。替代地，通路鞘尖端材料可以是独立的不透射线材料，例如钡聚合物或钨聚合物共混物。鞘主体222的远侧区域也是允许导管320和鞘主体222之间密封的重叠区域120的区域，以产生连续抽吸管腔。因此，抽吸导管320的管腔部分322的外径接近鞘主体222的管腔223的远侧区域的内径，由此形成密封。形成的密封的相对位置可以根据抽吸导管320离开鞘主体222的管腔223的位置以及来自鞘主体222的开口的位置而变化，这如下面更详细地所述。例如，如果鞘主体222在远侧尖端处具有开口，则与如果鞘主体222在鞘主体222的远端区域中具有供导管320离开管腔223的一个或多个侧开口相比，密封的位置可以更靠近鞘主体222的远端。

[0061] 再次参考图1，通路鞘220也可以包括连接器226，其将鞘主体222的近端连接到近侧止血阀234，并且也提供到抽吸管线230的连接。该连接器226可以具有大孔径内管腔，并且连接到大孔径抽吸管线230。在一个实施例中，连接器226的内管腔至少为0.080”。在一个实施例中，抽吸管线230的内管腔至少为0.080”。抽吸管线230可以终止于允许连接到抽吸源的旋塞阀、阴路厄连接器或其他连接器232。在一个实施例中，抽吸源是主动抽吸源，例如注射器或泵。在另一个实施例中，抽吸源是例如在美国专利第8,157,760号和美国专利公报第2010/0217276号中描述的反向流动分路管线，上述两个专利都通过引用并入本文中。大孔径抽吸管线230可以配置成抵抗塌缩。例如，抽吸管线230可以是厚壁聚合物管道或加强聚合物管道。抽吸管线阀232使管线230能够被打开或关闭。在一个实施例中，阀232也允许连接一个或多个附加的流体管线，用于连接用于造影剂或盐水注入的前向滴注或冲洗管线。作为示例，阀232可以是通常用于介入程序中以允许多个连接的旋塞式歧管。连接器226也可以包括将通路鞘220固定到患者的装置以减少在该情况下鞘脱出的风险。例如，连接器226可以包括一个或多个缝线孔眼233。

[0062] 仍然参考图1，通路鞘220的近端可以终止于近侧止血阀234中。该阀234允许通过

鞘220将装置引入血管系统中，同时防止或最小化失血并防止将空气引入通路鞘220中。止血阀234可以包括冲洗管线236或到冲洗管线236的连接，使得在程序期间可以根据需要用盐水或不透射线的造影剂冲洗鞘220。冲洗管线236也可以在程序的部分期间用作第二抽吸点，这如下面更完整地所述。止血阀234可以是静态密封型被动阀，或可调节开口阀，如Tuohy-Borst阀或旋转止血阀(RHV)。止血阀234可以与通路鞘220成一体，或者通路鞘220可以在近端上终止于阴路厄适配器中，独立的止血阀234部件(例如被动密封阀，Tuohy-Borst阀或旋转止血阀)可以附接到所述阴路厄适配器。在一个实施例中，阀234具有可调节开口，其敞开足够大以允许去除在尖端上具有粘附凝块的装置，而不会在去除期间导致凝块在阀234处脱出。替代地，阀234是可去除的，并且当导管尖端从鞘220去除时被去除以防止阀234处的凝块脱出。

[0063] 再次参考图1，动脉鞘系统200可以包括一个或多个鞘扩张器250和鞘导丝270。鞘导丝270可以使用标准血管通路技术(例如微穿刺技术或改良塞丁格技术)首先插入动脉中。鞘扩张器250允许通路鞘220通过动脉壁中的穿刺部位平滑地插入。扩张器250可以插入通路鞘220中，并且然后两个部件可以一起在鞘导丝270上插入动脉中。扩张器250的远端256可以大体上为锥形从而当其通过动脉壁插入动脉中时允许扩张器250扩张针头穿刺部位。锥形远端256可以具有大体上在6到12度之间的总夹角(相对于扩张器的纵向轴线)，具有弧形前缘。

[0064] 扩张器250的内管腔可以容纳鞘导丝270，并且可以具有0.037”到0.041”之间的内径以对应于0.035”到0.038”之间的鞘导丝270。替代地，扩张器250的内管腔可以在0.020”到0.022”之间以容纳0.014”到0.018”之间的鞘导丝270。替代地，扩张器250可以是具有内扩张器和外扩张器的两部分扩张器。外扩张器可以具有0.037”到0.041”之间的内径，并且内扩张器可以具有0.020”到0.022”之间的内径。在使用中，鞘220可以与具有0.035”到0.038”之间的鞘导丝270的外扩张器一起插入动脉中。鞘导丝270然后可以被去除并由内扩张器和0.014”到0.018”之间的较小导丝替换，并且通路鞘220然后可以进一步朝远侧推进到颈动脉中的期望位置。

[0065] 为了将初始在鞘导丝270上的动脉鞘220插入动脉中，扩张器锥形部256可以具有一定的刚度和锥角以在动脉穿刺部位上提供足够的扩张力。然而，为了安全地到达ICA的岩部，可能期望具有这样的鞘扩张器250，其在远端处具有比用于初始动脉通路的更软和/或更长的锥形部。在一个实施方式中，通路鞘系统200可以包括两个或更多个锥形扩张器。第一锥形扩张器可以与动脉通路装置一起使用以进入动脉，并且因此以类似于标准导引器鞘扩张器的方式确定尺寸和构造。可以用于锥形扩张器的示例性材料包括例如高密度聚乙烯，72D PEBAX，90D PEBAX，或等效刚度和润滑性材料。第二锥形扩张器可提供有更软的远侧部分或相对于第一锥形扩张器的远端部分具有更低的弯曲刚度和/或更长的锥形部长度的远侧部分。也就是说，第二扩张器具有比第一扩张器的相应远侧区域更软、挠性更大或更容易分节或弯曲的远侧区域。因此第二扩张器的远侧区域比第一扩张器的相应远侧区域更容易弯曲。在一个实施例中，第一扩张器的远侧部分具有在50到100N-mm^2的范围内的弯曲刚度，并且第二扩张器的远侧部分具有在5到15N-mm^2的范围内的弯曲刚度。第二扩张器(其具有较低弯曲刚度的远侧部分)可以与初始第一扩张器交换，使得通路鞘220可以推进到颈内动脉中并且绕行动脉中的曲率，且由于第二扩张器的远侧部分更软而在血管上没有过度

力或创伤。

[0066] 软的第二扩张器的远侧部分可以是例如35或40D PEBAX，其中近侧部分由例如72D PEBAX制成。一个或多个中间中部可以包括在第二扩张器上以提供软的远侧部分和更硬的近侧部分之间的平滑过渡。在一个实施例中，两个扩张器具有0.037”到0.041”之间的内径。在替代实施例中，第一扩张器具有0.037”到0.041”之间的内径，并且第二扩张器具有0.020”到0.022”之间的内径。在又一实施例中，第二扩张器是如前所述具有内扩张器和外扩张器的两部分扩张器。在一个实施例中，一个或两个扩张器可以具有不透射线尖端标记224，使得扩张器尖端位置在荧光透视检查中可见。在一个变型中，不透射线标记224是热焊接到扩张器的远侧尖端的钨加载PEBAX或聚氨酯的一部分。类似地可以使用其他不透射线材料以在远侧尖端处产生不透射线的标记224。

[0067] 在一个实施例中，通路鞘220包括在连接器226和近侧止血阀234之间延伸的近侧延伸部240。在系统的经颈配置中，可能期望将近侧止血阀234移动远离通路鞘220的远侧尖端，在保持可插入鞘主体部分222的长度的同时有效地伸长或加长在身体外部的通路鞘的近侧部分。这允许使用者将装置从更远离目标部位并且因此远离用于荧光透视成像目标部位的x射线源和/或图像增强器的点插入通路鞘220的近侧止血阀234中，由此最小化使用者的手以及他或她的整个身体的辐射暴露。在该实施例中，近侧延伸部240可以在10到25cm之间，或15到20cm之间的范围内。在经颈或经股配置中，也可能期望提供流体地连接到通路鞘抽吸管线的通路鞘220的一部分，但是其可以从抽吸管线连接朝近侧延伸。这将允许使用者将装置从从鞘尖端到抽吸管线的血流中拉出，而不用将该装置从通路鞘220完全去除。

[0068] 在替代实施例中，也可能期望将该近侧部分240与鞘主体222间歇地隔离。在一个实施例中，如图4中所示，连接器226包括阀242，其可以关闭鞘主体222和通路鞘220的近侧部分240(包括抽吸管线230、近侧延伸部240和近侧止血阀234)之间的流体连接。这可以允许导管的远侧部分、可回收支架装置或其他血栓清除装置被拉入该近侧延伸部分240中，阀242关闭以将鞘主体222与鞘的近侧部分流体地隔离，并且然后近侧止血阀234被宽广地打开或去除，或者鞘220的整个近侧延伸部分240被去除，而没有从鞘220的动脉出血。近侧延伸部240可以至少与带脊柱的导管320的远侧管腔部分322一样长，使得远侧管腔部分322可以被完全拉入近侧延伸部240中，并且在近侧止血阀234被宽广地打开以从鞘220完全去除导管320之前关闭阀242。

[0069] 替代地，在将血栓清除装置或其他介入装置拉入该近侧延伸部分240中并且经由阀242关闭鞘主体222之后，血栓清除装置的一部分(例如抽吸导管320的远侧管腔部分322)可以保持在近侧延伸部240中，并且通过产生从冲洗管线到抽吸管线的流动而被冲洗或以其他方式清理以脱出凝块而不从通路鞘220完全去除装置320。冲洗和清理血栓清除装置而不完全去除血栓清除装置的该能力可以在血栓清除尝试之间的步骤期间减少出血、时间和气栓的风险。而且，在冲洗和清理的同时将血栓清除装置收回到近侧延伸部分240中而不用将其从鞘主体222完全去除也最小化了操作者和工作人员暴露于与装置清洁关联的血液和碎屑。在这些实施例的任何一个中，近侧延伸管道是透明的，使得冲洗溶液以及栓塞碎屑或空气的存在/缺失通过管道清楚地可见。

[0070] 通路鞘220的近侧延伸部分240可以作为独立、可去除部件被提供，其可以用近端上的标准连接附接到任何鞘。如图5中所示，近侧部件280包括可以附接到标准鞘10的近侧

接头15的连接器285。联接的部件可以产生具有通路鞘220的配置和特征的组件。在该实施例中，使用者可以从用于该程序的适当长度、形状和机械特性的若干已经可用的鞘中的任何一种选择，并且执行本公开中所述的程序的步骤。可去除的近侧部件280可以包括Y臂连接器226，抽吸管线230，近侧延伸部240，近侧止血阀234和冲洗管线236，以及相应地终止抽吸管线230和冲洗管线236的阀连接器232和238。连接器285可以联接到鞘220上的近侧连接器226。在如图6所示的实施例中，连接器285配置成最小化通过鞘10和进入近侧部分280中的流动阻力。例如，代替标准的阳-阴路厄连接，连接器285可以包括：具有内管腔和表面的适配器60，其匹配通常位于鞘上的标准阴路厄连接器62；密封元件64，其在适配器60和鞘阴路厄连接器62之间密封；以及旋转螺母66，其接合阴路厄连接器62的螺纹元件并将适配器60和路厄连接器62联接在一起使得密封件64被压缩并且可以对流体和空气真空和压力进行密封。再次参考图5，近侧部件280也可以包括在Y臂连接器226上的阀242，使得当近侧部件280附接到鞘10时，近侧部分可以选择性地打开或关闭与鞘10流体连接。对于将鞘抽吸管线230连接到抽吸源的连接器232可以进行相似类型的连接。

[0071] 在优选的实施例中，对于约34cm的总长度，近侧连接具有约22cm的近侧延伸长度，约7cm的Y臂连接器，和约5cm的长度的近侧止血阀。

[0072] 可能期望在介入期间暂时闭塞颈动脉以在程序的部分期间阻止栓塞的顺行流动。在一个实施例中，如图7中所示，通路鞘220包括在鞘主体222的远侧尖端上的闭塞球囊246。鞘主体222中的附加管腔可以连接到充胀管线248并且将球囊246流体地连接到充胀管线248。充胀装置附接到充胀管线248以充胀闭塞球囊246。在该实施例中，当期望闭塞颈动脉时充胀球囊246。

[0073] 在一些情况下，期望在鞘插入期间保持鞘尖端尽可能小以最小化动脉穿刺的直径，但是在其已插入血管中之后膨胀鞘220的开口。该特征的至少一个目的是在将抽吸导管320或其他血栓清除装置拉回到鞘220中期间最小化远端栓塞的影响或产生。在血栓清除程序期间，血栓可以被“拉回”到已捕获血栓的装置上的鞘220的远侧开口221中。如果鞘220的远侧尖端相对于其初始尺寸扩大或扩张成漏斗形状，则血栓的碎片断裂或导致栓塞的机会最小化，原因是鞘尖端的较大尺寸或漏斗形状更可能容纳吸入其中的栓塞而不被令栓塞分成多个碎片。这为患者产生更好的临床结果。在通路鞘的一个实施例中，鞘主体222的远侧部分是这样的材料和/或构造，其使得在鞘220插入动脉中并定位在其期望位置之后尖端可以膨胀。在一个实施例中，鞘的远侧区域具有约0.087”的ID，其可以扩大到约0.100”到0.120”的直径，但是尺寸可能变化和/或张开。

[0074] 膨胀远侧尖端构造的示例包括可以缩短以膨胀的覆盖编织尖端。膨胀远侧尖端构造的另一示例是伞或类似的构造，其可以在不受约束时用机械致动或弹性弹簧力打开。可膨胀直径管的其他机构是本领域中是公知的。一个特定的实施例是由当使用高压球囊膨胀时可变形的材料制成的鞘。2014年12月19日提交的共同未决的美国专利公报第2015/0173782号描述了示例性装置，并且通过引用整体并入本文中。在共同未决的公告第2015/0173782号中描述了这样的特征的构造。

[0075] 鞘主体222的远端区域也可以在开口的位置、尺寸和数量上变化。鞘主体222可以结合在鞘220的远端区域附近的一个或多个开口，其允许鞘主体222的管腔223和鞘220位于其中的血管系统之间的流体流动。一个或多个开口可以尺寸确定成允许至少抽吸导管320

的管腔部分322延伸通过其中。一个或多个开口可以尺寸确定成大于管腔部分322的外径，使得一个或多个开口在鞘主体222的远端区域中形成长形口、狭槽或槽口。一个或多个开口可以形成在鞘主体222的正好位于远端附近的侧壁区域内，使得开口位于离鞘主体222的远端至少0.25mm，0.5mm，1.0mm，1.5mm，2.0mm，2.5mm，3.0mm，3.5mm，或4.0mm或以上。一个或多个开口可以是靠近鞘主体222的远端区域形成多孔区域的多个开口，其中多个开口中的至少一个尺寸确定成足够大以允许系统的一个或多个部件离开鞘主体222的管腔223。在一些实施例中，一个或多个开口包括来自鞘主体222的管腔223的远侧开口221(参见图4和12C)。在一些实施例中，一个或多个开口包括长形远侧口，其形成靠近远端区域定位的鞘主体222的第一侧上的侧开口1219(参见图12C)。侧开口1219可以位于离鞘主体222的远端至少0.25mm或更大。侧开口1219可以具有至少与带脊柱的导管320的远侧管腔部分322的外径一样大的直径。优选地，侧开口1219具有的直径与远侧管腔部分322的外径的至少1.5倍，2倍，2.5倍或3倍一样大。在另一实施例中，鞘主体222包括靠近远端区域在鞘主体222的相对和/或相邻侧上的一对侧开口1219。在另一实施例中，鞘主体222包括来自管腔223的远侧开口221和来自管腔223的一个或多个长形侧开口1219。应当领会，鞘主体222可以围绕纵向轴线A旋转，使得一个或多个侧开口1219定位成允许导管320相对于鞘220的纵向轴线A在期望方向上从侧开口1219朝远侧延伸。包括宽口侧开口1219可以允许导管320的从大致(即非常接近)平行于鞘主体222的位置到与鞘主体222成一定角度(例如大致垂直于鞘主体222或与之成直角，以及大于90°角)的位置的出口角范围。在正穿过的血管内存在显著成角或存在分叉的情况下，该布置可以是至关重要的。通常，血管中的曲折段和分叉部具有达到90°的显著成角或高达180°的更大角。血管系统中的典型显著成角点可以包括主动脉髂动脉接合部，左锁骨下动脉从主动脉的分叉，头臂(无名)动脉从升主动脉的分叉以及许多其他周边位置。

[0076] 再次参考图1，如上所述，导管系统300可以包括具有挠性远侧管腔部分322和刚性近侧脊柱330的带脊柱的抽吸导管320。与配置成导航通过心脏血管系统的其他系统相比，远侧管腔部分322的外径以及与刚性脊柱330配对的管腔部分322的挠性和润滑性允许带脊柱的抽吸导管320导航到脑血管系统中的闭塞部位。本文中所述的系统可以在具有长的、曲折的进入路线的解剖结构的区域中到达闭塞。该路线可能包含主动脉弓和颈动脉和头臂血管起源中的狭窄斑块材料，产生栓塞并发症的风险。此外，脑血管通常比冠状动脉或其他外周血管系统更脆弱并且容易穿孔。由于其能够克服这些通路挑战，因此本文中所述的导管系统可以更容易地提供神经血管介入程序。本文中所述的导管系统设计用于导航通过曲折而不是推动通过它。2014年12月12日提交的美国专利公报第2015/0174368号和2014年12月19日提交的美国专利公报第2015/0173782号(其通过引用并入本文)描述了可以导航通过脑动脉的曲折解剖结构的导管装置的特征。

[0077] 远侧管腔部分322的长度可以变化。在一些实施例中，远侧管腔部分322的长度从靠近通路鞘主体222的远侧尖端的区域延伸到颈动脉中的闭塞部位，与通路鞘220的远端形成近侧重叠区域120(参见图2B)。考虑到闭塞部位和通路鞘远侧尖端可能定位的部位的变化，远侧管腔部分322的长度可以在约10cm至约25cm的范围内。远侧管腔部分322的长度小于通路鞘220的鞘主体222的长度，使得当带脊柱的抽吸导管320缩回到鞘主体222中时，在带脊柱的抽吸导管320的重叠区域328和鞘主体222的内径之间保持密封。

[0078] 本文中所述的导管系统可以结合彼此嵌套的多个带脊柱的导管以允许延伸到达曲折的解剖结构。例如，具有尺寸确定成接收在鞘主体222的管腔内的外径的第一带脊柱的导管320可以具有延伸通过第一带脊柱的导管320的内管腔的第二带脊柱的导管320。第二带脊柱的导管320可以使用其近侧脊柱延伸超过第一带脊柱的导管320的远端，使得较小直径的第二带脊柱的导管320可以到达血管系统的更远侧区域，特别是具有较窄尺寸的远侧区域。在该实施例中，第一带脊柱的导管320可以用作第二带脊柱的导管320的支撑导管。第二带脊柱的导管320可以具有与第一带脊柱的导管320的内管腔流体连通的内管腔，所述第一带脊柱的导管的内管腔与鞘主体222的内管腔流体连通，形成连续抽吸管腔。

[0079] 在一个实施例中，导管320的远侧管腔部分322被构造为挠性且润滑的，从而能够安全地导航到目标部位，并且当受到高抽吸力时抗扭结和抗塌缩，从而能够有效地抽吸凝块，具有朝着远端挠性增加的部分。在一个实施例中，远侧管腔部分322包括三个或更多个层，包括内润滑衬层，加强层，和外护套层。外护套层可以由具有不同硬度、组成和/或厚度的聚合物的不连续部分组成以沿着远侧管腔部分322的长度改变挠性。在一个实施例中，润滑内衬层是PTFE衬层，具有沿着挠性的可变部分的一个或更多厚度。在一个实施例中，加强层是由例如卷绕的带状物或线圈或编织物形成的大体管状结构。用于加强结构的材料可以是不锈钢，例如304不锈钢，镍钛诺，钴铬合金，或提供强度、挠性和耐挤压性的期望组合的其他金属合金。在一个实施例中，加强结构包括多种材料和/或设计，以再次沿着远侧管腔部分322的长度改变挠性。在一个实施例中，导管320的外表面涂覆有润滑涂层，例如亲水涂层。在一些实施例中，涂层可以在内表面和/或外表面上以减小跟踪(tracking)期间的摩擦。涂层可以包括本领域中已知的各种材料。脊柱部分330也可以被涂覆以改善通过通路鞘220的跟踪。合适的润滑聚合物是本领域公知的，并且可以包括硅树脂等，亲水性聚合物，如高密度聚乙烯(HDPE)，聚四氟乙烯(PTFE)，聚芳醚氧化物，聚乙烯基吡咯烷酮，聚乙烯醇，羟基烷基纤维素，藻胶，糖类，己内酯等，以及它们的混合物和组合。亲水性聚合物可以彼此之间或与配制量的不溶于水的化合物(包括一些聚合物)共混以产生具有合适润滑性、粘合性和溶解性的涂层。

[0080] 远侧管腔部分322的外径可以尺寸确定成用于导航到脑动脉中。期望的导管具有尽可能大的内径，其可以安全地导航到闭塞部位以便优化抽吸力。取决于患者的解剖结构和凝块的尺寸和组成，内径的合适尺寸可以在0.040”到0.075”之间的范围内，或者可以在0.040”到0.088”之间的范围内。外径应当尽可能小，同时仍然保持导管320的机械完整性。然而，在重叠区域120处，导管320的外径(OD)接近通路鞘220的内径(ID)，从而在重叠区域120处形成密封区域，同时仍然使导管320能够容易地通过鞘220插入并且定位在期望部位处。在一个实施例中，导管320和通路鞘220尺寸确定成在重叠区域120处匹配，而导管320的外径没有变化(参见图2B)。在一个实施例中，重叠区域的通路鞘ID与导管OD之间的差值为0.002”或更小。在另一实施例中，该差值为0.003”或更小。在一个实施例中，导管320朝着远侧管腔部分322的远侧尖端呈锥形，使得导管的最远端与导管的更近侧区域相比具有更小的外径，靠近所述更近侧区域导管与通路鞘密封。在另一实施例中，导管OD在重叠部分328处递增以更接近地匹配鞘内径(参见图1)。该实施例在具有适用于单个通路鞘尺寸的一个以上的导管的系统中特别有用。应当领会，在带脊柱的导管320的导管OD与鞘内径匹配或差值为0.002”或更小的情况下，可以通过重叠部分328实现对正被注入或抽吸的流体的密封，

使得不需要增加导管OD。在导管和鞘之间对正在被注入或抽吸的流体的密封可以通过它们的大致相似尺寸的重叠实现而不结合任何独立的密封结构或密封特征。

[0081] 在如图8A和8B所示的另一实施例中，存在位于远侧管腔部分322的近端的外表面上的密封元件336。密封元件336可以是一个或多个外部脊特征，并且当导管320插入通路鞘220的管腔中时可以被压缩。脊的几何形状可以使得密封元件336用作O形环、方形环或其他活塞密封件设计。图8B示出了类似的配置，其中密封元件336具有刮片式密封件配置，例如抵靠通路鞘主体222的内表面被偏压的倾斜表面。替代地，密封元件336可以是可充胀或可膨胀构件，如球囊或覆盖编织结构，其可以被充胀或膨胀并且在包括将导管320定位在期望部位之后的任何时间在两个装置之间提供密封。该实施例的优点是在导管定位期间没有密封力施加于导管320，而是在导管320定位之后才施加或致动密封力以密封。

[0082] 应当领会，与图8A-8B中所示的直切口相比，远侧管腔部分322的近端区域的形状可以具有成角切口。也应当领会，脊柱330可以联接到导管320的近端区域和/或可以沿着远侧管腔部分322的至少一部分延伸，使得脊柱330在离近端一定距离处联接到远侧管腔部分322。脊柱330可以通过各种机构联接到部分322，包括粘合，焊接，胶合，夹紧，串接，系拴，或绑扎构成脊柱330和/或部分322的一个或多个部件。在一些实施例中，通过将脊柱330夹紧在远侧管腔部分322的层之间将脊柱330和管腔部分322联接在一起。例如，脊柱330可以是具有远端的海波管或杆，所述远端被切削、磨削或切割使得远端可以层压或以其他方式附接到靠近近端区域的导管部分322的层。脊柱330的远端和部分322之间的重叠区域可以为至少约1cm。该类型的联接允许从脊柱330到管腔部分322的平滑和均匀过渡。

[0083] 在一个实施例中，重叠区域配置成使得能够对高达25inHg或高达28inHg的真空进行密封。在一个实施例中，重叠区域120配置成使得能够对高达300mmHg或高达600mmHg或高达700mmHg的压力进行密封而基本没有泄漏。另外，可能存在防止带脊柱的抽吸导管320过度推进超出通路鞘220的远端的特征。在涉及带脊柱的抽吸导管320的重叠区域328处的递增直径或突出特征的任何实施例中，通路鞘主体222可以包括尖端处的底切，其防止带脊柱的抽吸导管320的近侧重叠部分离开鞘主体222。

[0084] 导管320的远侧管腔部分322可以在远侧尖端具有不透射线标记324以帮助在荧光透视下导航和正确定位尖端(参见图1)。另外，导管320的近侧重叠区域328可以具有一个或多个近侧不透射线标记1324(参见图12C)，使得重叠区域120可以被可视化为通路鞘远侧标记224与导管近侧标记1324之间的关系。在一个实施例中，两个标记(远侧尖端处的标记324和更近侧标记1324)是不同的，从而使荧光透视图像的混淆最小化，例如，导管近侧标记1324可以是单带，并且鞘尖端标记224可以是双带。

[0085] 带脊柱的抽吸导管320的脊柱330联接到远侧管腔部分322的近端区域。脊柱330配置成允许导管320通过通路鞘220的管腔223的远侧推进和近侧缩回。在一个实施例中，脊柱330的长度比通路鞘220的整个长度(从远侧尖端到近侧阀)长，例如长约5cm至15cm。如图1中所示，脊柱330可以包括标记332以指示导管320的远侧管腔部分322和鞘主体222之间的重叠。标记332可以定位成使得在通过鞘220插入导管320期间当标记332与鞘近端阀234对准时，带脊柱的抽吸导管320定位在最远侧位置处，其中在带脊柱的抽吸导管320和通路鞘220之间产生密封所需的重叠长度最小。脊柱330可以包括夹持特征，例如近端上的突片334，以使脊柱易于抓握并且推进或缩回。突片334可以与系统300的一个或多个其他部件联

接，例如配置成延伸通过远侧管腔部分322的管腔323的扩张器，这将在下面更详细地描述。近侧突片334可以设计成可容易从存在于鞘近侧阀234中的其他装置(例如导丝270或可回收支架装置丝500)识别。在一个实施例中，脊柱330着色为亮色，或者用亮色标记，以使其可与导丝、可回收支架系绳等容易地区分。

[0086] 脊柱330可以配置成具有足够的刚度以允许带脊柱的抽吸导管320的远侧管腔部分322的推进和缩回，而且也具有足够的挠性以根据需要导航通过脑解剖结构。此外，脊柱330的外径尺寸确定成避免在鞘主体222和通路鞘220的管腔223中占据太多的管腔面积。在一个实施例中，脊柱330是圆形丝，具有从0.014”到0.018”的尺寸。在另一实施例中，脊柱330是具有从0.010”到0.015”厚度，和0.015”到0.025”厚度的尺寸范围的带状物。带状物可以具有各种横截面形状，例如扁平带状物或形成c形或沿着弧的其他形状的弯曲带状物。在另一实施例中，脊柱330是海波管。在一个实施例中，脊柱330的材料是诸如不锈钢或镍钛诺的金属，以及诸如各种聚合物中的任何一种的塑料。

[0087] 本文中所述的系统的一个或多个部件可以由金属，金属合金，聚合物，金属-聚合物复合材料，陶瓷，其组合等，或其他合适的材料制成。合适的金属和金属合金的一些示例包括不锈钢，如304V，304L和316LV不锈钢；软钢；镍-钛合金，如线弹性和/或超弹性镍钛诺；其他镍合金，如镍-铬-钼合金(例如，UNS：N06625，如INCONEL® 625，UNS：N06022，如HASTELLOY® C-22®，UNS：N10276．如HASTELLOY® C276®，其他HASTELLOY®合金等)，镍-铜合金(例如，UNS：N04400，如MONEL®400，NICKELVAC®400，NICORROS®400等)，镍-钴-铬-钼合金(例如，UNS：R30035，如MP35-N®等)，镍-钼合金(例如，UNS：N10665，如HASTELLOY® ALLOY B2®)，其他镍-铬合金，其他镍-钼合金，其他镍-钴合金，其他镍-铁合金，其他镍-铜合金，其他镍-钨或钨合金等；钴-铬合金；钴-铬-钼合金(例如，UNS：R30003，如ELGILOY®，PHYNOX®等)；富铂不锈钢；钛；其组合；等等；或任何其他合适的材料。

[0088] 导管320的远侧管腔部分322与近侧脊柱330之间的联结部可以配置成允许两个部分之间的挠性平滑过渡，从而不产生扭结或弱点，并且也允许诸如导丝和微导管的装置平滑地通过由通路鞘220的管腔223和导管320的管腔部分322的腔323产生的连续内管腔。在一个实施例中，远侧管腔部分322具有过渡部分326(参见图1)，在所述过渡部分附近，部分322联接到具有成角切口的脊柱330，使得从鞘220的内管腔223到导管320的内管腔323没有陡阶梯过渡。成角切口大体上可以是平面的。在替代实施例中，成角切口是弯曲的或阶梯式的以提供更渐进的过渡区域。远侧管腔部分322和脊柱330可以通过焊接结合、机械结合、粘合剂结合或其某些组合被联结。脊柱330的远端可以具有在焊接期间促进机械联结的特征，例如纹理表面、突出特征或切除特征。在热焊接过程期间，这些特征将有助于聚合物远侧管腔部分322和脊柱330之间的机械结合。在另一实施例中，例如图12A-12B中所示的具有带脊柱的导管1320和延伸通过其中的扩张器1340的导管系统1300，在两个部分之间形成挠性的平滑过渡以便在系统1300的推进期间不会扭结或产生弱点。在从带脊柱的导管1320去除扩张器1340时可发生该挠性平滑过渡的损失。脊柱1330可以主要用于收回带脊柱的导管1320，其中扭结或弱点形成的风险明显较低。

[0089] 带脊柱的抽吸导管320由于在其近端区域上存在脊柱330而不具有在其整个长度320上延伸的管腔，因此不论是在使用之前或在程序期间，如果导管的管腔变得堵塞，传统

的冲洗和准备步骤是无效的。在传统的单腔导管中，将注射器附接到导管的近侧适配器，并且内管腔可以用溶液强力冲洗。带脊柱的导管320可以提供有辅助导管冲洗和清理装置350(参见图1)。该装置350可以是在远端上具有圆形或锥形尖端和在近端上具有阴路厄连接的管。路厄连接器允许注射器连接到装置350。钝或锥形尖端使装置350能够插入导管320的管腔部分322的远端或近端中，而没有损坏导管320的风险，以及注射器被致动以冲洗该装置。清理装置350的OD与带脊柱的导管320的管腔部分322的ID紧密匹配，使得可以用足够的力冲洗带脊柱的抽吸导管320以从导管清除碎屑和抽吸的闭塞材料。装置350也可以用于以柱塞式动作机械地清除任何夹带的血栓，装置350的工作长度可以至少与导管320的远侧管腔部分322一样长，使得其可以通过远侧管腔部分322的整个管腔323插入。冲洗可以与插入装置350一起发生，从而更有效地从导管320清除夹带的血栓或其他栓塞材料。

[0090] 在替代实施例中，抽吸导管320是单腔导管，例如，在2014年12月12日提交的共同未决申请的美国专利公报第2015/0174368号中描述的类型的导管。在这样的实施例中，导管可以配备有或联接有锥形同轴扩张器340，其大体上为管状并且具有在导管和定位在导管内的导丝之间提供平滑过渡的锥形远侧部分。

[0091] 带脊柱的抽吸导管320可以在合适尺寸的微导管和导丝上导航通过血管系统。替代地，带脊柱的导管320可以配备有同轴扩张器340(参见图1)。扩张器340尺寸确定成并且成形为以同轴方式通过导管320的远侧管腔部分322的内部管腔323插入，使得在使用时扩张器340的近端区域与导管320的脊柱330并排对准。扩张器340可以具有锥形远侧尖端346。扩张器340的长度可以至少与带脊柱的抽吸导管320一样长，以允许远侧锥形尖端346至少从带脊柱的导管320的管腔部分322的远端突出。扩张器340可以具有形成到导管的远侧尖端的平滑过渡的外径，以及远侧锥形尖端346，其提供下至延伸到扩张器340的内管腔之外的导丝的平滑过渡。扩张器340可以沿其长度的至少一部分大体上为管状。在一个实施例中，锥形扩张器340设计成容纳例如可以在0.014”到0.018”的范围内的导丝。在该实施例中，内管腔直径可以在0.020”到0.024”之间。锥形远侧尖端346可以在1.5cm到3cm的范围内。

[0092] 应当领会，本文中所述的用于与带脊柱的导管一起使用的扩张器在其配置上可以变化。例如，如上所述，扩张器340可以是同轴扩张器340，其大体上为管状并且具有在导管320和定位在导管320内的导丝之间提供平滑过渡的锥形远侧部分。扩张器340的管状主体可以沿着导管320的整个长度延伸。替代地，扩张器340可以结合与导管320的脊柱并排对准的近侧脊柱。近侧脊柱可以与扩张器340的远端区域同轴或偏心地定位。扩张器340的同轴近侧脊柱可以具有延伸通过它的管腔。替代地，扩张器340可以是没有管腔的实心杆。固体棒扩张器可以由延展性材料形成，其可以削薄以具有窄外径(例如0.010”-0.014”)，使得扩张器可以成形为使用者期望的任何角度或形状，这类似于可以如何使用导丝。在该配置中，导管系统不包括导丝或微导管。这样的扩张器具有比微导管更好的优点，原因是它可以具有比带脊柱的导管320的内径小0.003”-0.010”的外径。

[0093] 扩张器340可以在近端处具有近侧阴路厄适配器348以允许用注射器冲洗扩张器340。扩张器340也可以在近端处结合夹子特征，以允许扩张器340使扩张器340的材料具有足够挠性并且锥形远侧尖端346可以足够长以在导丝的挠性和导管的挠性之间产生平滑过渡。该配置可以促进导管320通过弯曲的解剖结构推进到目标脑血管系统中。在一个实施例

中，扩张器340的远端具有在锥形远侧尖端346的近端处的不透射线标记344和/或标记343。标记材料可以是铂/铱带，钨，铂，或钽浸渍聚合物，或其他不透射线标记。

[0094] 扩张器340可以构造成在扩张器340的远端和近端之间具有可变的刚度。例如，延伸超过导管320的管腔部分322的远端的最远侧部分可以由更挠性的材料制成，朝着更近侧部分材料刚度增加。在一些实施例中，扩张器340可以是具有近侧脊柱的带脊柱的扩张器，这将在下面更详细地描述。扩张器340的近端可以包括突片1364，其允许扩张器340与导管320的脊柱330的近端上的突片334锁定，使得两个部件(带脊柱的导管320和扩张器340)可以作为单个单元在导丝上推进(参见图12A)。在一些实施例中，导管320的突片334可以形成具有延伸通过其中的中心开口的环。扩张器340的突片1364可以具有带中心柱的环形棘爪。突片1364的中心柱可以尺寸确定成通过突片334的中心开口插入，使得突片334的环接收在突片1364的环形棘爪内，形成单个抓握元件以便使用者通过通路鞘推进和/或收回导管系统。突片1364可以固定到扩张器340，或者可以在扩张器340上可滑动以适应扩张器340和带脊柱的导管320之间的不同相对位置。

[0095] 图12A-16提供了如本文中别处所述的带脊柱的抽吸导管和扩张器系统1300的附加视图。图12A-12B示出了带脊柱的抽吸导管1320具有延伸通过远侧管腔部分1322的抽吸管腔1323的扩张器1340。如本文中别处所述，导管1320可以包括具有突片1334的近侧脊柱1330和具有抽吸管腔1323的远侧管腔部分1322。脊柱1330可以在远侧管腔部分1322和突片1334之间延伸。扩张器1340可以接收在带脊柱的导管1320的抽吸管腔1323内。扩张器1340可以包括远侧扩张器部分1360和近侧脊柱1362。扩张器部分1360可以在扩张器1340的远侧尖端1346和近侧脊柱1362的起点之间延伸。当与导管1320接合时，扩张器1340的扩张器部分1360可以延伸通过导管1320的远侧管腔部分1322的整个长度，使得扩张器尖端1346延伸超过导管1320的远侧管腔部分1322的远端固定距离，以提供平滑过渡以便改善跟踪。扩张器尖端1346可以为锥形，如本文中别处所述，并且与典型地用于经皮动脉通路的扩张器(其用于钝性地切开通过组织和动脉壁)相比，可以对于血管壁是柔软、无创和挠性的以促进血管内导航到弯曲解剖结构中的栓塞。

[0096] 扩张器1340被示出为处于锁定配置，其中导管1320配置用于改善通过急性缺血性脑卒中弯曲和通常患病的血管系统的跟踪。扩张器部分1360可以包括在扩张器部分1360的外表面上的一个或多个棘爪。该棘爪可以位于扩张器部分1360的近端区域和/或远端区域附近。棘爪配置成与扩张器部分1360延伸通过的管腔1323的内表面上的相应形状的表面特征锁定。扩张器1340可以包括在扩张器1340的近侧脊柱1362的近端上的扩张器突片1364，如上所述，其可以配置成与导管脊柱1330的近端区域上的对应特征连接和锁定，例如经由一个或多个棘爪或其他表面特征。因此，扩张器1340和导管1320可以具有在它们之间的一个以上锁定连接点。扩张器1340的近侧脊柱1362可以在扩张器部分1360和扩张器1340的突片133之间延伸。扩张器部分1360可以是如本文中别处所述的管状元件，其形成在扩张器部分1360的长度(和带脊柱的导管1320的远侧管腔部分1322的整个长度)上延伸的导丝管腔。应当领会，整个扩张器1340可以是配置成接收通过脊柱1362以及扩张器部分1360的导丝的管状元件。扩张器部分1360的近端(即扩张器部分1360和近侧脊柱1362之间的过渡部分1326)可以包括“递增部”以平滑导管1320的远侧管腔部分1322和扩张器1340的扩张器部分1360之间的过渡。过渡部分1326可以结合成角切口，使得从鞘1220的内管腔1223到导管

1320的内管腔1323没有陡阶梯过渡。因此，带脊柱的抽吸导管-扩张器1300对于与其相接的血管壁可以是平滑的。

[0097] 扩张器1340的近侧脊柱1362可以具有与导管1320的脊柱1330相似的刚度和特性。更特别地，脊柱1362、1330中的一个或两者可以是刚性的和/或抗扭结的。此外，脊柱1362、1330中的一个或两者可以具有刚度以允许推动远侧部分(即组合的远侧管腔部分1322和扩张器部分1360)通过通路鞘或引导鞘，同时产生很低的轮廓。在一个实施例中，脊柱1362、1330中的一个或两者包括刚性丝。

[0098] 导管突片1334和扩张器突片1364可以可拆卸地彼此连接。更特别地，突片1334、1364可以具有锁定配置和解锁配置。在锁定配置中，扩张器突片1364可以与导管突片1334接合。在解锁配置中，扩张器突片1364可以从导管突片1334脱离。扩张器突片1364可以以这样的方式附接(例如，卡接或锁定)到导管突片1334，其将带脊柱的导管1320和带脊柱的扩张器1340的相应部分的关系保持在锁定配置。这样的锁定可以通过例如使用扩张器突片1364上的棘爪来实现，所述棘爪卡扣在形成于导管突片1334中的凹部内的适当位置，或反之亦然。在一些实施例中，带脊柱的导管1320的脊柱1330可以在扩张器脊柱1362的专用通道旁边或内部延伸。通道可以沿着扩张器脊柱1362的长度定位，并且具有与导管脊柱1330的横截面形状匹配的横截面形状，使得导管1320的脊柱1330可以接收在通道内并且沿着通道双向平滑地滑动。一旦带脊柱的导管1320和带脊柱的扩张器1340被固定，组合系统(即，带脊柱的抽吸导管-扩张器1300)可以被递送到目标部位，例如通过本文中别处所述的通路鞘220的管腔223。

[0099] 参考图12B，根据一个实施例示出了具有处于解锁配置的带脊柱的导管1320和带脊柱的扩张器1340的带脊柱的抽吸导管-扩张器1300。当带脊柱的抽吸导管-扩张器1300位于目标部位时，如本文所讨论的，扩张器突片1364可以从导管突片1334解锁。可以收回带脊柱的扩张器1340并且可以使用带脊柱的导管1320，例如用于抽吸或用于导丝或球囊递送。

[0100] 参考图13，根据一个实施例示出了与带脊柱的扩张器1340同轴对准的带脊柱的导管1320的沿着图12B的线A-A截取的横截面图。该横截面示出了扩张器部分1360接收在远侧管腔部分1322的抽吸管腔1323内的导管-扩张器的一部分。管腔1323可以具有在高达0.072英寸的范围内的内径，但是更大或更小的内径是可能的(可能更大或更小)。远侧管腔部分1322的壁可以抗扭结或椭圆化以提供用于抽吸的最大直径。扩张器部分1360可以以滑动配合接收在远侧管腔部分1322中。因此，在一个实施例中，扩张器部分1360的外部尺寸可以小于远侧管腔部分1322的内径。例如，管腔1323可以具有0.072英寸的直径，而扩张器部分1360可以具有0.070英寸的外部尺寸。

[0101] 参考图14，根据一个实施例示出了在去除带脊柱的扩张器1340之后的带脊柱的导管1320的沿着图12B的线B-B截取的横截面图。该横截面示出了在扩张器部分1360已缩回和/或去除之后的远侧管腔部分1322。远侧管腔部分1322具有限定管腔1323的内壁1321。管腔1323可以为圆形，如图所示，或者可以具有任何其他形状。在一个实施例中，管腔1323的有效直径在高达0.072英寸的范围内。

[0102] 参考图15A，根据一个实施例示出了具有处于锁定配置的带脊柱的导管1320和带脊柱的扩张器1340的带脊柱的抽吸导管-扩张器系统1300。在一个实施例中，脊柱1330和扩张器1340可以具有在整个长度上大致相似的外部尺寸。例如，不同于在扩张器部分1360和

扩张器脊柱1362之间会聚到更小的尺寸，扩张器脊柱1362可以具有与扩张器部分1360相同的尺寸。因此，可以提供在其长度的至少大部分上具有大致相同的横截面积的导管-扩张器。如上所述，带脊柱的扩张器1340和带脊柱的导管1320可以具有相应的突片1334、1364，其在锁定配置中接合并且在解锁配置中脱离。

[0103] 参考图15B，根据一个实施例示出了具有处于解锁配置的带脊柱的导管1320和带脊柱的扩张器1340的带脊柱的抽吸导管-扩张器。带脊柱的扩张器1340可以以与上述类似的方式从带脊柱的导管1320去除。在一个实施例中，带脊柱的抽吸导管-扩张器在其长度的大部分上可以具有相似的横截面，并且因此，带脊柱的导管1320和带脊柱的扩张器1340的形状可以是互补的。例如，脊柱1330可以具有沿着弧的横截面，例如四分之一圆，并且因此，扩张器脊柱1362的横截面可以是四分之三圆。因而，脊柱1330可以符合扩张器脊柱1362以提供整圆的整个横截面。

[0104] 参考图16，根据一个实施例示出了位于神经血管解剖结构中的带脊柱的导管1320的示意图，所述带脊柱的导管包括具有内管腔1323的远侧管腔部分1322。与具有鞘主体1222和内管腔1232的通路鞘1220结合使用，在带脊柱的导管1320到达ICA并且到栓塞E的距离一直感觉小于20cm的实施例中，可以看到具有25cm长度的远侧管腔部分1322将允许与通路鞘1220的重叠区域1120以产生密封。重叠区域1120可以具有几厘米的长度，并且可以取决于从栓塞E到远侧管腔部分1322的远端的距离，例如取决于带脊柱的导管1320相对于通路鞘1220推进多远而变化。

[0105] 如本文中别处所述，与在通路鞘中具有常规大孔径导管的抽吸系统相比，使用带脊柱的导管1320的可用于抽吸栓塞的管腔面积更大。更特别地，带脊柱的导管1320的管腔面积和在远侧管腔部分1322的近侧的通路鞘1220的管腔面积的组合面积大于沿着系统的整个长度的大孔径导管的管腔面积。因此，可以增加在单次抽吸尝试中去除栓塞的可能性。更特别地，沿着脊柱1330的递增管腔直径可以能够获得更大的抽吸力，导致栓塞的改善抽吸。当诸如微导管或锥形内部构件的装置同轴地定位在带脊柱的导管和通路鞘中时，递增管腔直径也可以增加可用于向前冲洗造影剂、盐水或其他溶液的环形区域。因此，可以改善在装置导航期间执行血管造影的容易性和能力。

[0106] 公开的系统可以配备有特别配置成与该系统一起使用的辅助装置。应当领会，对通路鞘系统或抽吸导管系统的一个实施例的引用并不旨在受到限制，并且本文中所述的辅助装置可以与具有本文中所述的各种特征或组合中的任何一种的任何系统一起使用。例如，在下面描述通路鞘的情况下，应当领会，可以结合本文中所述的任何通路鞘或通路鞘系统的一个或多个特征。类似地，在下面描述带脊柱的导管的情况下，可以结合本文中所述的任何带脊柱的导管或带脊柱的导管系统的一个或多个特征。

[0107] 在一个实施例中，系统包括微导管400(参见图1)。微导管400可以配置成特别适合于在脑血管中的导航。微导管400可以用于代替锥形扩张器340以帮助将带脊柱的导管320导航到期望部位。因而，它可以包括在近端处的装置以将脊柱330锁定到微导管400，使得两个部件(带脊柱的导管320和微导管400)可以作为单个单元在导丝上推进。在一些情况下，微导管400在导管320的前方被推进以在导管320被推进时提供支撑，或者穿过闭塞并且在闭塞的远侧执行血管造影。在该情况下，微导管400的长度可以比带脊柱的导管320长约10到20cm。微导管400也可以用于将可回收支架装置500递送到闭塞。在该情况下，微导管400

可以具有适合于递送可回收支架装置500的内径，例如在0.021”到0.027”的范围内并且具有PTFE内衬层。微导管400可以比带脊柱的导管320的总长度长至少约5-10cm或至少约5-20cm以允许微导管400在导航期间延伸超过抽吸导管320的远端。

[0108] 在一个实施例中，系统包括具有远侧可膨胀部分510的可回收支架装置500，其尺寸确定成并且配置成通过微导管400递送，如图9中所示。可回收支架装置500可以与系统的其他部件结合使用以帮助去除闭塞。可回收支架装置500也可以用于在血栓清除程序期间快速恢复到闭塞动脉的流动。可回收支架装置的示例包括Solitaire血管重建装置(Medtronic)或Trevo支架回收器(Stryker)。

[0109] 在使用的方法中，可回收支架装置500用于帮助在抽吸步骤期间将血栓引入导管320中，或者清理在抽吸步骤期间可能堵塞的导管320。在一个实施例中，可回收支架装置500配置成特别适于执行这些功能。例如，如图10A中所示，装置500的可膨胀部分510的远端具有多个撑杆或元件520，所述撑杆或元件在远侧尖端处聚拢在一起以封闭最远端，使得当装置500被拉入导管320中，并随后通过导管320和从远端出来时，该装置允许血流穿过该装置，但是捕获血栓碎片。替代地，远端520是过滤元件或球囊元件。

[0110] 在另一示例中，在图10B中，可回收支架装置500包括具有一个或多个近侧段510a的两个或更多个段，和现有的可回收支架装置一样，其配置成在一个或多个远侧段510b穿过闭塞膨胀时在导管远侧内管腔中膨胀。替代地，如图10C中所见，可回收支架装置500具有很长的可膨胀部分510，使得当远侧部分穿过闭塞膨胀时可膨胀部分的近侧部分可以在导管远侧内管腔中膨胀。在所有这些实施例中，可膨胀部分510的近端具有最小结构元件，其将允许可膨胀部分容易地被拉入导管320的管腔中，并且从通路鞘320出来，从而最小化抽吸血栓通过装置的阻碍。在这些示例中，即使当凝块被抽吸到导管320中时，可膨胀部分510仍然与凝块接合，并且如果导管320被阻塞，则装置500很好地定位成在其被拉回时清除凝块。一旦可回收支架装置500已从导管320的管腔部分322去除，如果部位仍然部分地或完全闭塞，则可以通过导管320将附加的抽吸施加到该部位。如果导管320仍然堵塞，则该步骤将是不可能的；导管必须在被重新插入以进行附加抽吸之前被去除并在患者外部清理。可回收支架装置500的该配置可以与传统的单腔抽吸导管或带脊柱的抽吸导管320一起使用。

[0111] 如图10A-10C中所示的装置500的实施例可以与已知的血栓清除装置和方法一起使用以解决在血栓抽吸期间导管堵塞的问题。

[0112] 在一个实施例中，系统包括抽吸源600，如图2A或图3中所示。抽吸源600可以附接到通路鞘220上的抽吸管线230。抽吸源600的示例包括注射器或主动抽吸泵。抽吸源600可以连接到递送位置，例如容器。容器和抽吸源600可以是独立的(例如机械或机电流体泵，其出口连接到血液收集储存器)或者可以组合成单个装置(如注射器或注射泵)。替代地，血液收集储存器连接到诸如医院真空管线或空气真空泵的真空源，并且因此既是容器也是抽吸源。过滤器和/或止回阀可以与抽吸源联接。泵可以是正排代泵，如隔膜或活塞泵，蠕动泵，离心泵，或本领域已知的其他流体泵机构。

[0113] 在一个实施例中，抽吸源是可变状态或多状态抽吸源，并且包括例如通过修改真空泵中的真空水平，通过修改正排代、蠕动或离心泵的马达的功率，或通过修改注射器或注射器泵中的注射器回退速度来控制抽吸水平的机构。替代地，可以通过提供具有可变流动阻力的元件来改变抽吸速率，例如可以在高和低流动阻力路径之间切换的平行流动路径，

可以可变地打开的流动孔口或管腔，或改变流动阻力的其他手段。在示例中，抽吸源配置成具有两个抽吸水平：当导管与血栓形成材料接触时使用用于抽吸血栓闭塞的高抽吸水平，以及在导致远侧栓塞的风险很高的程序步骤期间(例如当可回收支架装置膨胀恢复到血管的流动或穿过病变时)使用的低抽吸水平。

[0114] 在另一示例中，如图11中所示，抽吸源600还包括感测抽吸管线230中的流动的流动传感器275，其联接到控制抽吸水平的控制器。抽吸源600在流速缓慢时可以增加抽吸水平，并且在流速增加时可以减小抽吸水平。以该方式，力当导管堵塞或部分堵塞时是最大的，但是当有自由流动时减小到最小水平以确保远侧栓塞的保护但限制抽吸的血液的体积。以该方式，系统优化血栓抽吸，同时限制抽吸的血液量。替代地，抽吸源600可以包括真空计。当导管320中的流动被堵塞或限制时，泵产生更高真空水平。在该示例中，抽吸力可配置成当检测到更高的真空时升高。

[0115] 在又一抽吸源实施例中，抽吸源600提供循环水平的抽吸力，例如，抽吸力以设定频率在高真空水平到较低真空水平之间循环，或从高真空水平到无真空循环，或从高水平的真空到压力源循环。循环抽吸模式可以在血栓上提供气锤型力，并且增加通过导管抽吸血栓的能力。循环抽吸力可以通过电磁阀、可编程泵马达等实现。在一个实施例中，循环抽吸仅在抽吸管线中检测到堵塞或受限制的流动时通过低流动或高真空被施加，如上所述，并且在其他时间，抽吸源回到低流动水平，或被关闭。该配置可以由使用者控制，或者经由到抽吸源的反馈环自动控制。

[0116] 在一个实施例中，系统包括用于被动反向流动的机构，其配置成连接到通路鞘上的抽吸管线。例如，抽吸管线连接到诸如中央静脉的低压部位，或设置为零或负压的外部容器。

[0117] 在如图11所示的一个实施例中，冲洗管线236可以经由旋塞阀238连接到可以保持盐水流体或不透射线造影剂的注射器286。另外，冲洗管线236可以连接到冲洗源288，例如，加压盐水袋。阀292可以控制从冲洗源288到冲洗管线236的流动。当阀292对冲洗管线236打开时，提供加压流体源。在一个实施例中，阀292经由机械或机电联接件295联接到抽吸源600，使得阀292仅在抽吸源600接通时打开。替代地，阀292联接到抽吸管线230中的流动传感器275，使得阀292仅当在朝着抽吸源600的方向上有流动时打开。在这些实施例中，冲洗源288的流率配置成流动得刚刚足以保持近侧延伸部240没有血液，但不是太高以致使流动抵抗抽吸流动并限制血栓的抽吸。该实施例的优点是近侧延伸部240保持没有血液，并且在近侧延伸部240中的任何栓塞或空气清楚地可见。这为使用者提供何时以及是否经由注射器286用盐水或造影剂冲洗导管的反馈。

[0118] 在另一实施例中，阀292机械地或机电地联接到将鞘主体222连接到鞘220的近侧部分240的阀242。联接件290可以配置成使得阀292仅能够当阀242关闭时打开。该特征允许近侧延伸部240经由冲洗步骤被清除血液，而没有将栓塞通过导管反冲回血管系统中的风险。联接件290可以以几种方式中的一种配置。例如，当阀242关闭时，联接件290可以始终打开阀238，或者联接件可以阻止阀238打开，除非阀242关闭但是不自动打开。

[0119] 在一个实施例中，阀292是允许不同水平的冲洗流率的可变状态阀。在该示例中，阀292配置成当抽吸源处于低设置时允许慢冲洗，当抽吸源处于高设置时允许更高水平的冲洗。在一个实施例中，当阀242关闭时，阀允许更高水平的冲洗。这些配置允许碎屑的连续

去除和/或通路鞘的近侧部分的清楚可视性，并且使程序的步骤期间远侧栓塞或空气进入血管系统的风险最小化。例如，在从近侧止血阀234去除导管的远侧尖端的步骤期间，当导管被拉动通过阀时，捕获在导管的尖端上的任何凝块可能被释放，但是使用连续冲洗，释放的栓塞将被冲洗到抽吸管线中并且不保留在鞘中(此处它可能被再注入到血管系统中，例如在导管被去除之后的造影剂注入期间)。

[0120] 再次参考图1，系统100可以包括多个装置的套件。在实施例中，套件包括通路鞘系统200，其中通路鞘系统包括通路鞘，一个或多个锥形鞘扩张器，和一个或多个鞘导丝。在另一实施例中，系统100包括通路鞘系统200和具有一个或多个内径的一个或多个带脊柱的导管系统300。在一个实施例中，带脊柱的导管系统300包括带脊柱的抽吸导管320和锥形扩张器340。在一个实施例中，带脊柱的导管系统300也包括导管清理工具350。在又一实施例中，系统100包括通路鞘系统200，锥形导管系统300，微导管400，和可回收支架装置500。

[0121] 在配置成用于经颈进路的实施例中，套件包括通路鞘220，其中对于约57cm的通路鞘总长度，可插入鞘主体222的长度为约23cm，近侧延伸部240为约22cm，连接器226为约7cm，并且近侧止血阀234为约5cm。在一个实施例中，套件也包括带脊柱的抽吸导管320，其中对于约88cm的带脊柱的导管总长度，导管远侧管腔部分322为约20cm，过渡部分326为约2-4cm，并且脊柱部分330为约65cm。在另一实施例中，套件也包括具有93cm的工作长度的锥形扩张器340。在另一实施例中，套件也包括具有约198cm的工作长度的微导管400和具有128cm的总长度的可回收支架装置500。

[0122] 在配置成用于经股进路的实施例中，套件包括通路鞘系统220，其中对于约124cm的通路鞘总长度，可插入鞘主体222的长度为约90cm，近侧延伸部240为约22cm，连接器226为约7cm，并且近侧止血阀234为约5cm。通路鞘的近侧部分可以是可去除近侧部分280。在一个实施例中，套件也包括带脊柱的抽吸导管320，其中对于约155cm的带脊柱的导管总长度，导管远侧管腔部分322为约20cm，过渡部分326为约2-4cm，脊柱部分330为约132cm。在另一实施例中，套件也包括具有160cm的工作长度的锥形扩张器340。在另一实施例中，套件也包括具有约165cm的工作长度的微导管400和具有195cm的总长度的可回收支架装置500。

[0123] 在另一实施例中，套件包括具有可去除近侧部分280的通路鞘220，和单腔抽吸导管。在另一实施例中，套件仅包括可以附接到适合于程序的任何导引鞘的近侧部分280。在该实施例中，套件也可以包括带脊柱的抽吸导管320或单腔抽吸导管。

[0124] 在这些实施例的任何一个中，套件也可以包括抽吸源，例如泵，到真空泵的附件，注射器，可附接到注射器泵的注射器等。套件也可以包括用于自动冲洗的装置，例如联接装置290或292。

[0125] 如本文中别处所述，应当领会，对通路鞘系统或导管系统的一个实施例的引用并不旨在受到限制，并且本文中所述的套件可以结合具有本文中所述的各种特征中的任何一种的本文中所述的任何系统和/或辅助装置。例如，在通路鞘被描述为套件的一部分的情况下，应当领会，可以结合本文中所述的任何通路鞘或通路鞘系统的一个或多个特征。类似地，在带脊柱的导管被描述为套件的一部分的情况下，可以结合本文中所述的任何带脊柱的导管或带脊柱的导管系统的一个或多个特征。

[0126] 图2A和3示出了使用方法。如图2A中所示，使用标准血管通路鞘将通路鞘220插入股动脉中，并且推进直到鞘尖端定位在颈内动脉或颈总动脉中尽可能远侧的安全部位。在

图3中，通路鞘220直接插入颈总动脉中，并且推进直到鞘尖端定位在颈内动脉中尽可能远侧的安全部位。在任一种情况下，鞘可以初始推进到颈总动脉或近侧颈内动脉，并且然后在将鞘更远侧地推进到颈内动脉中之前，将扩张器更换为更软的扩张器。然后使用穿过鞘连接器上的孔眼的缝线将鞘固定到患者。鞘抽吸管线230连接到诸如注射器或抽吸泵的抽吸源600。鞘抽吸管线也可以经由旋塞阀或旋塞式歧管连接到向前冲洗管线(例如加压盐水袋)。

[0127] 一旦鞘尖端定位在期望位置，就将其固定到患者。带脊柱的导管、锥形扩张器和导丝在同轴配置中预先组装，并且通过鞘近侧止血阀引入颈动脉中。带脊柱的抽吸导管320通过通路鞘推进并且直到远侧尖端处于治疗部位地定位。装置使用标准介入技术推进直到远侧导管尖端处于闭塞的近侧面。脊柱330上的标记332确保在导管的远侧管腔部分322和通路鞘主体222之间仍然有重叠区域120。此时，可以去除锥形扩张器340和导丝。在替代的实施例中，使用微导管400代替锥形扩张器340以帮助将导管320导航到闭塞。在程序期间，在抽吸的时期之前或之间向抽吸管腔打开正向冲洗打开以保持管腔清洁。在装置导航期间的任何时候，例如当导丝或微导管400正在穿过闭塞时，抽吸可以在适合于远侧栓塞保护的水平从抽吸源600开始。

[0128] 一旦带脊柱的抽吸导管320的远侧尖端处于凝块的面处，在适合于抽吸血栓清除的水平开始抽吸，该水平是比远侧栓塞保护更高的水平。导管320可以抵靠凝块保持在抽吸模式持续使用者认为合适的一段时间。取决于抽吸血栓清除操作的结果(观察通过抽吸管线的流动和/或导管的脊柱上的向后力的阻力得到)，使用者可以确定凝块已被完全抽吸，或者如果不是，则使用者可以选择将导管320来回移动以抽吸在原位的凝块，或者将导管320缓慢地缩回到鞘220中。如果通过经导管320和鞘220抽吸凝块恢复到动脉的流动，则可以执行最后的血管造影并且可以缩回导管320。然而，如果血栓堵塞导管尖端并且不能被去除，则导管320被拉回，其中一些或全部闭塞通过抽吸力附着到导管320的尖端。

[0129] 在后一种情况下，在导管320被拉入通路鞘220的整个时间，在导管320的尖端处保持抽吸。一旦导管320已完全缩回到通路鞘220中，在鞘220上保持抽吸的同时可以将导管320从鞘主体222快速地去除。应当领会，导管320可以在延伸通过鞘主体222的远侧尖端处的远侧开口219之后收回到鞘主体222中。替代地，导管320可以延伸通过靠近鞘主体222的远端区域的侧开口219，使得通过该侧开口219发生将导管320收回到鞘主体220中。在导管缩回期间的某个时间，取决于导管320是否被闭塞材料堵塞，抽吸水平可以从期望用于抽吸血栓清除的高水平变为期望用于远侧栓塞保护的较低水平。通过提供从导管尖端或鞘尖端或鞘远侧区域连续保持抽吸的能力，并且提供改变抽吸水平并保持抽吸的手段，程序优化了抽吸凝块的能力，同时最小化远端栓塞并最小化来自抽吸的失血。如果需要，也可以在近侧阀234的冲洗管线236处开始抽吸以减少通过近侧阀234去除可能粘附凝块的导管尖端期间的远侧栓塞的机会。

[0130] 带脊柱的抽吸导管320可以从鞘220的近侧止血阀234完全去除。替代地，如果通路鞘220具有近侧延伸部240，则远侧管腔部分322可以被拉入近侧延伸部分240中。在后一种情况下，一旦被拉入，导管320和鞘220可以被冲洗以去除潜在的栓塞材料，而不从鞘220完全去除导管320。与从抽吸管线230抽吸同时从近端阀冲洗管线236强力冲洗产生用于导管320和鞘220的冲洗环境。如果需要，导管清理工具350可以插入鞘近侧阀234中，并且在此时

用于清理导管320的内管腔323。如果通路鞘220具有连接器阀242，则在该阶段期间近侧部分240可以从鞘主体222封闭，使得没有将栓塞材料冲洗到鞘主体222中并且然后进入动脉中的风险。

[0131] 替代地，阀242可以被关闭并且抽吸暂停，而近端阀242被打开或去除并且导管320从鞘220完全去除。当去除导管320时，关闭阀242限制来自鞘220的失血。然后可以使用清洁工具350将导管320冲洗到桌子上或进入碗或其他容器中。也可以通过与从抽吸管线230冲洗同时提供来自近侧阀冲洗管线236的冲洗源288，或者通过打开抽吸管线230上的侧端口以冲洗到桌子或者进入碗或其他容器中而冲洗近侧延伸部分240。如果需要，可以进行血管造影以评估经过经治疗的动脉的流动。如果程序规定，导管320或另一导管可如上所述在导丝和锥形扩张器340或微导管400上再推进到闭塞部位以尝试另一抽吸血栓清除步骤。导管和通路鞘220的近侧延伸部分240的冲洗使这些后续步骤期间的远侧栓塞的风险最小化。

[0132] 在另一示例性方法中，可回收支架装置500可以与抽吸结合使用以去除血栓闭塞。图9示出了通过经颈或经股进入部位的该使用方法。在该情况下，通路鞘220可以如上定位并且推进直到鞘尖端定位在颈内动脉中尽可能远侧的安全部位。然后可以将带脊柱的导管320预加载到微导管400和导丝上，并且可以经由通路鞘220将同轴组件引入颈动脉中并推进到脑血管中。微导管400和导丝可以推进穿过闭塞。带脊柱的抽吸导管320的尖端可以尽可能朝远侧推进，但是在凝块的近侧。

[0133] 在这时，可以去除导丝并且通过微导管400插入可回收支架装置500直到它也穿过闭塞定位。微导管400可以被拉回以部署支架。在装置导航期间的任何时候，例如当导丝或微导管400穿过闭塞时或者在支架部署之前，抽吸可以在适合于远侧栓塞保护的水平从抽吸源开始。通过在支架部署之前开始抽吸，在穿过病变时释放的任何栓塞在动脉中的流动恢复时不会被携带到下游，而是被捕获到导管尖端中。当部署可回收支架装置500时，可以保持抽吸。通常在尝试缩回支架之前将其持续部署数分钟以最大化支架撑杆与闭塞的接合。然后，可回收支架装置500可以被拉入带脊柱的导管320中，并且继续缩回直到它已从通路鞘220的近侧阀完全去除。

[0134] 替代地，支架装置500可以被拉入带脊柱的导管320的远侧部分中，并且支架装置500和带脊柱的导管320可以一起被拉回到通路鞘220之外。抽吸可以在支架和/或导管缩回步骤期间增加到更高的水平以优化凝块的抽吸并最小化远侧栓塞。如果通路鞘220具有在连接器上具有阀的近侧延伸部240，则装置500可以被拉入近侧延伸部240中并且阀关闭，并且然后近侧止血阀234可以被宽广地打开，并且支架装置500或支架装置/带脊柱的导管组合可以被拉出。然后如果程序规定，在相同或替代装置被重新插入以进行另一血栓清除尝试之前，近侧延伸部分240可以经由阀冲洗管线236和抽吸管线230被冲洗。

[0135] 替代地，在放置抽吸导管320之后，长的或分段的支架回收器500可以用微导管400如上定位，使得可膨胀部分510的一部分穿过血栓，并且一部分在导管320的远侧段322中，并且然后膨胀。在可膨胀部分510膨胀之后，可以开始抽吸使得血栓从血管和导管320完全抽出到抽吸源600中，或者被抽出到导管320的远侧尖端和/或远侧管腔323中。在这时，长的或分段的支架回收器500可以被小心地拉入导管320中，同时保持抽吸。在此期间，已堵塞导管320的凝块和/或在该步骤期间被释放的碎屑应当被抽吸到导管320中。从导管320的工作通道323完全去除支架回收装置500应当从管腔323释放闭塞材料。

[0136] 在这些情况的任何一个中，抽吸源可以是可变或多状态抽吸源，其配置成最大化血栓闭塞上的抽吸力，同时最小化导管中的自由流动时期期间的失血。

[0137] 在另一示例性方法中，通路鞘220具有闭塞球囊246。如图7中所见，在远侧栓塞的风险高的程序步骤(例如缩回具有粘附凝块的支架装置500或带脊柱的导管320)期间，可以充胀球囊246。球囊246具有停止顺行流动并增加颈动脉中抽吸力的效果，因此增加凝块的抽吸并减小远侧栓塞的风险。

[0138] 在另一示例性方法中，通路鞘220具有可膨胀远侧尖端。在该方法中，可以在通路鞘尖端已定位在期望部位处之后但是在将带脊柱的导管320缩回到通路鞘220中之前的某个时间膨胀远侧尖端。当远侧尖端被拉入鞘220的尖端中时，该方法将减少粘附到带脊柱的导管320的远侧尖端的凝块的释放所导致的远侧栓塞的机会。相反，膨胀或张开的通路鞘尖端用作漏斗以捕获整个凝块。

[0139] 在另一示例性方法中并且如上面简述，通路鞘1220具有侧开口1219(在图12C中最佳地示出)。在该方法中，具有延伸通过导管1320的远侧管腔部分1322的管腔1323的带脊柱的扩张器1340的带脊柱的导管1320可以朝着鞘主体1222的远端区域朝远侧推进通过导管鞘1220的管腔1223。带脊柱的导管1320的远侧管腔部分1322的远侧尖端(其可以具有延伸通过远侧管腔部分1322并且形成导管系统的最远端的带脊柱的扩张器)可以经由侧开口1219离开管腔1223，并且然后进一步朝远侧推进超过通路鞘1220的远侧尖端。斜面特征1217或其他内部特征可以结合在管腔1223的远端区域处以提供表面，扩张器的尖端可以抵靠所述表面偏转以朝着侧开口1219远离鞘主体1222的管腔1223的纵向轴线A引导导管1320，以实现从管腔1223的平滑过渡或离开。扩张器1340的远侧尖端1346可以抵靠斜面特征1217并且以轻微的成角朝着侧开口1219远离鞘主体1222的纵向轴线被引导。如本文中别处所述，鞘主体1222和因此侧开口1219可以围绕纵向轴线A旋转，使得一个或多个侧开口1219定位成允许导管1320在相对于鞘1220的纵向轴线A的期望方向上从侧开口1219朝远侧延伸。这通常将由操作者遇到的解剖结构决定。同样如本文中别处所述，在导管的远侧管腔部分1322和通路鞘主体1222之间形成重叠区域1120。密封元件1336可以定位在远侧管腔部分1322的外表面上，例如靠近远侧管腔部分1322的近端区域并且可以位于重叠区域1120内。当扩张器1340从管腔部分1322的管腔1323收回时，形成的密封件可以允许抽吸力通过由管腔部分1322的管腔1323和通路鞘主体1222的管腔1223形成的连续管腔的完全传递。

[0140] 在另一示例性方法中，抽吸源600连接到血液储存器，其以这样的方式保持血液的完整性，使得血液可以在程序的血栓清除部分结束时直接或通过后续血液处理(如细胞洗涤和/或血液过滤)安全地返回给患者。在另一示例性方法中，抽吸源连接到血液分流器，其又连接到诸如静脉鞘或静脉返回导管的装置，其使血液在程序期间返回到患者，并且不需要血液储存器。在另一示例性方法中，将血液收集在储存器中，并且随后在程序结束时丢弃。

[0141] 在另一示例性方法中，将通路鞘1220从股插入部位递送到右锁骨下动脉或左锁骨下动脉或颈外动脉，如本文中别处所述。通路鞘1220可以递送到具有栓塞的目标血管(例如颈内动脉(ICA))和另一血管(例如颈外动脉(ECA))之间的分叉的隆突。一旦通路鞘1220就位，诸如带脊柱的抽吸导管1320的工作装置可以通过通路鞘1220的管腔1223递送到目标血管中。通路鞘1220的管腔1223和导管1320的管腔1323是连续的并且形成用于抽吸的递增直

径，如本文中别处所述。重叠区域1120保持在从通路鞘1220的管腔1223朝远侧延伸的导管1320之间。应当领会，导管1320可以从通路鞘1220的管腔1223朝远侧延伸通过通路鞘1220的远侧尖端处的开口1221或靠近通路鞘1220的远侧区域的侧开口1119。通路鞘1220的主体1222可以定向成提供侧开口1119相对于解剖结构的最佳放置。导管1320的远侧管腔部分1322和通路鞘主体1222之间的重叠区域1120可以产生密封，并且允许抽吸力通过由管腔部分1322的管腔1323和通路鞘主体1222的管腔1223形成的连续管腔的完全传递，以及提供用于将流体递送到目标血管(例如将血管造影造影剂，盐水，一种或多种药物或其他材料直接注入神经血管解剖结构中)的密封。通过允许通路鞘1220的工作管腔1223提供抽吸柱的大部分，带脊柱的抽吸导管1320可以产生更强大的抽吸力。如本文中别处所述，抽吸导管1320的远侧管腔部分1322的管腔1323的尺寸可以小于通路鞘1220的管腔1223的直径，其仅减小延伸通过其中的脊柱1330的直径。管腔的增加直径可以产生比例如具有类似总长度的大孔径导管的抽吸柱更大的抽吸柱。在操作者想要到达颈动脉岩部或脑血管系统内的其他难以到达的地标的情况下，带脊柱的抽吸导管1320也可以用作支撑递送导管。更特别地，在通过通路鞘1220的工作管腔1223将带脊柱的抽吸导管1320递送到目标血管中之后，诸如导丝、微导管、支架回收器等的辅助工作装置可以通过管腔1323递送到更远侧解剖结构中以执行如本文中别处所述的其他程序性操作。

[0142] 尽管本说明书包含许多细节，但是这些不应被解释为对所要求保护的或可以要求保护的发明的范围的限制，而是对特定实施例特有的特征的描述。在本说明书中在独立实施例的语境中描述的某些特征也可以在单个实施例中组合实现。相反地，在单个实施例的语境中描述的各种特征也可以在多个实施例中独立地或以任何合适的子组合来实现。而且，尽管特征在上文可以描述为以某些组合起作用并且甚至最初要求如此，但是来自要求的组合的一个或多个特征在某些情况下可以从组合去除，并且所要求的组合可以涉及子组合或子组合的变型。类似地，尽管在附图中以特定顺序描绘操作，但是这不应被理解为要求以所示的特定顺序或按顺序执行这样的操作，或者执行所有所示的操作以获得期望的结果。所以，所附权利要求的实质和范围不应当被限制到本文所包含的实施例的描述。

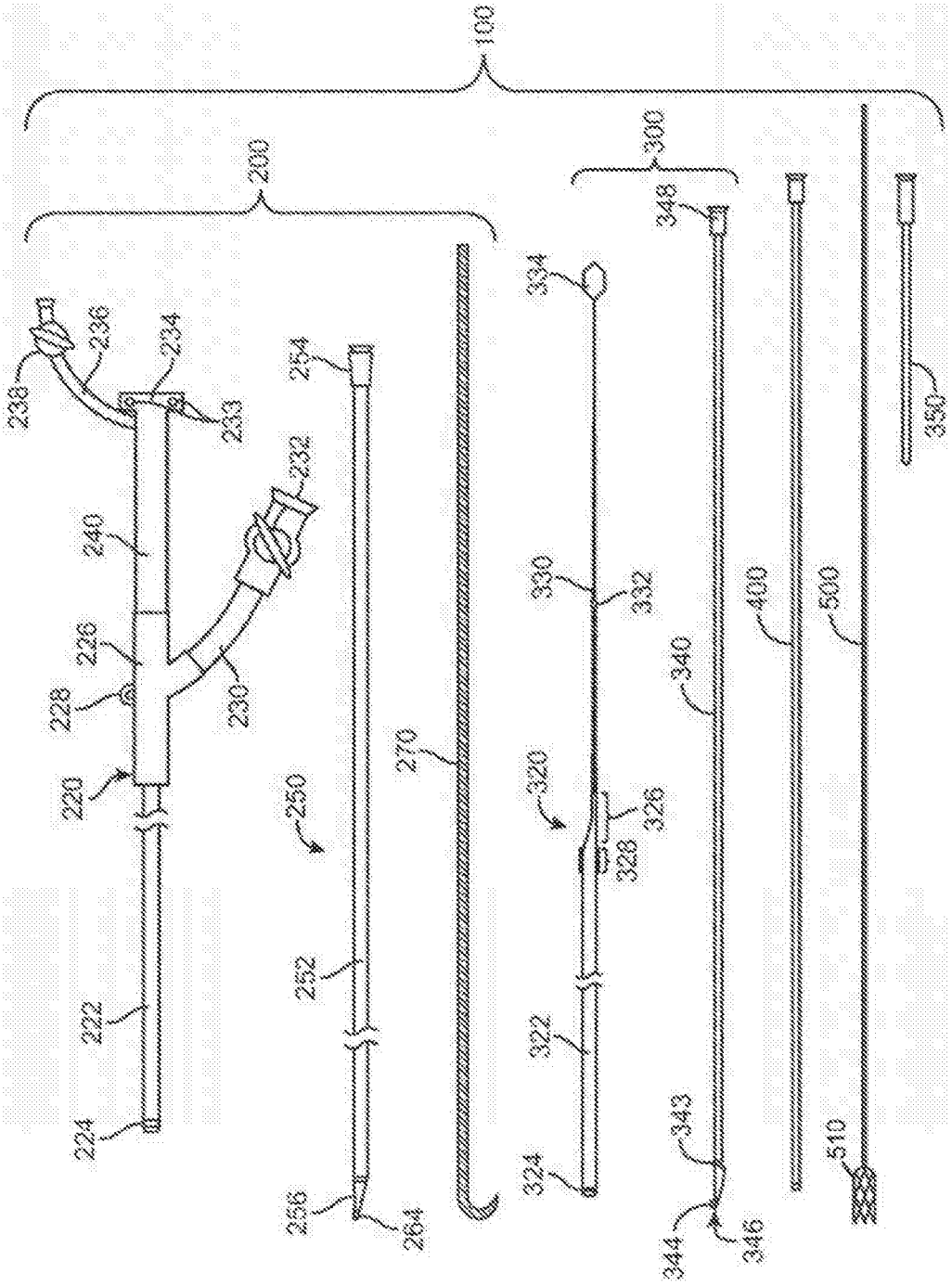
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图1

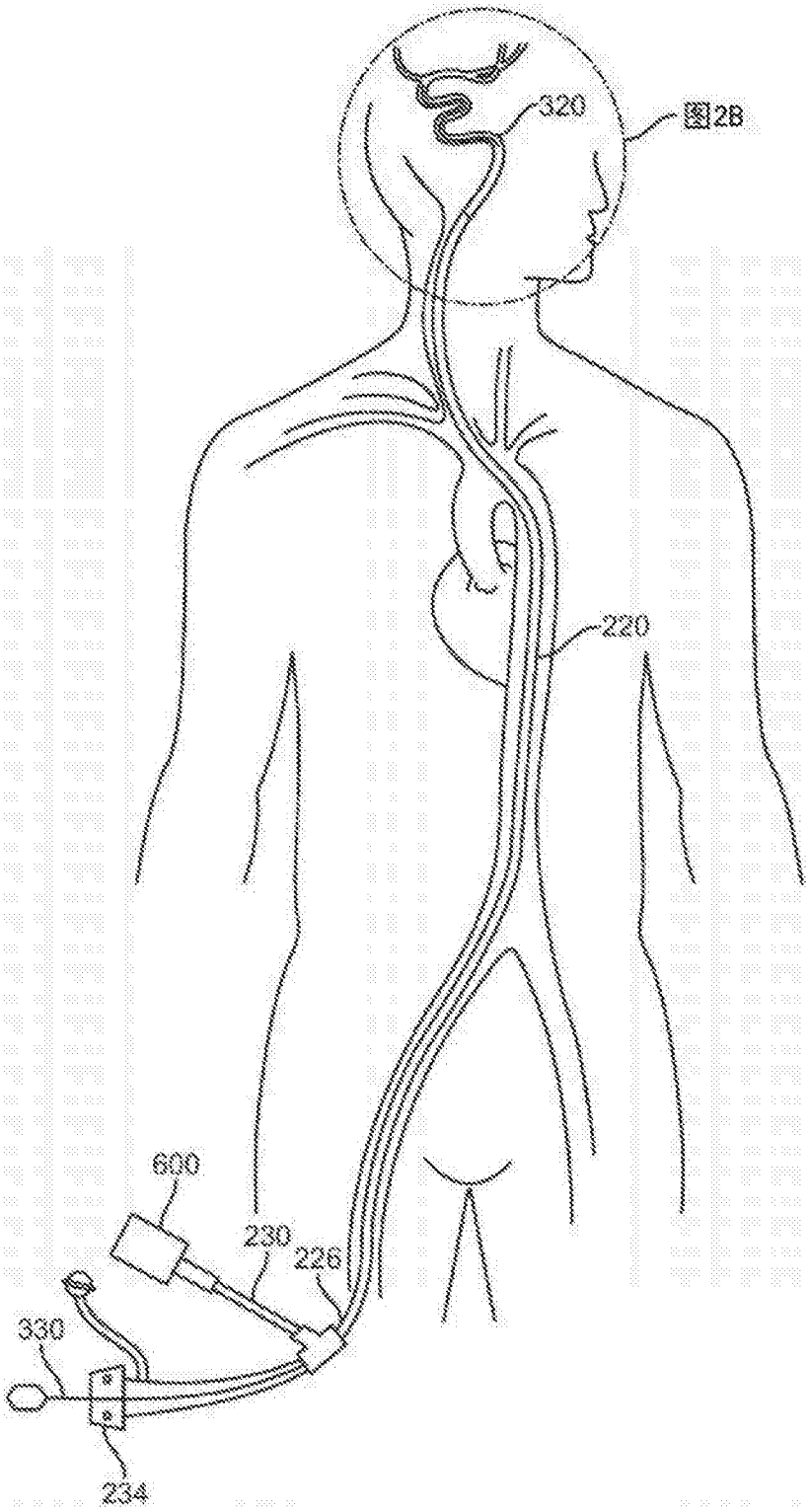

图2A

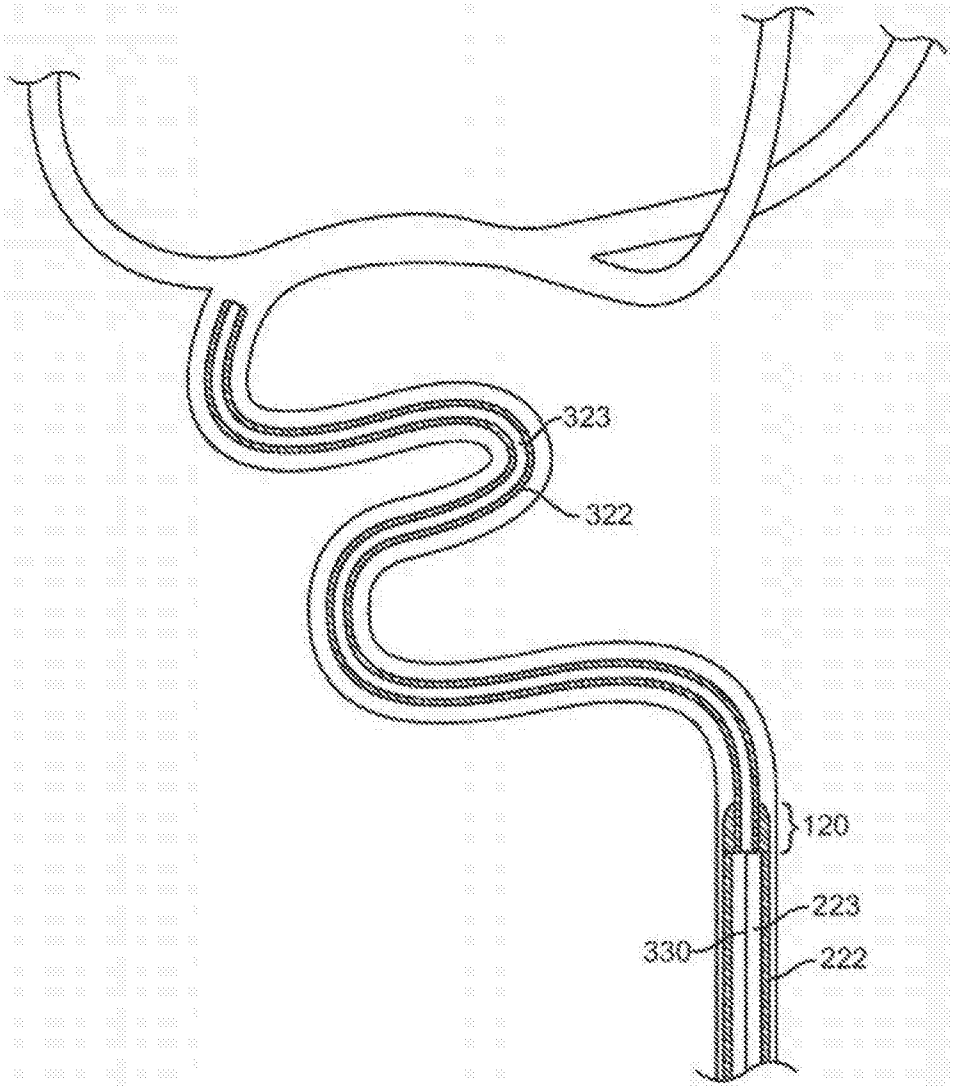

图2B

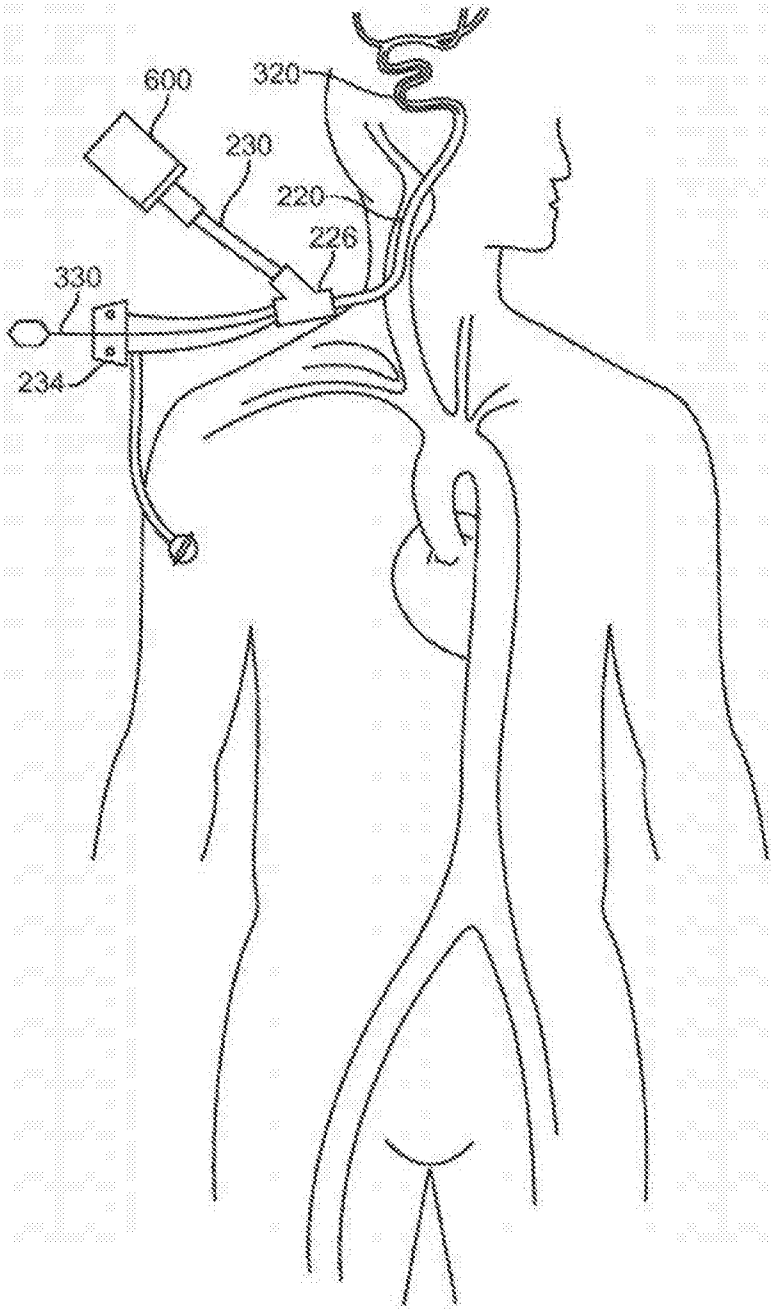

图3

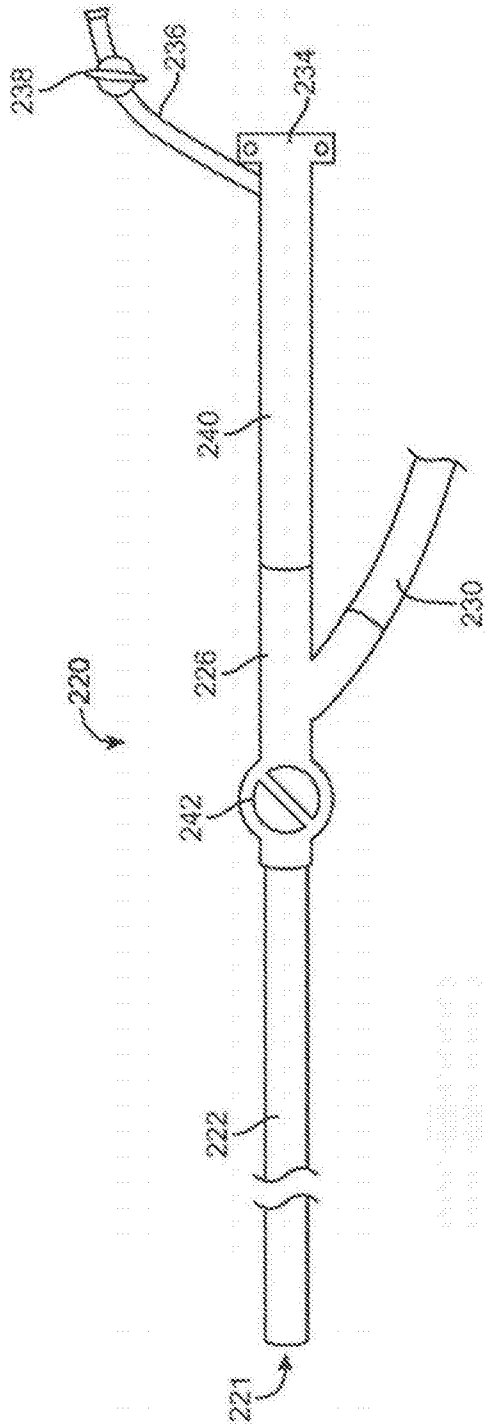

图4

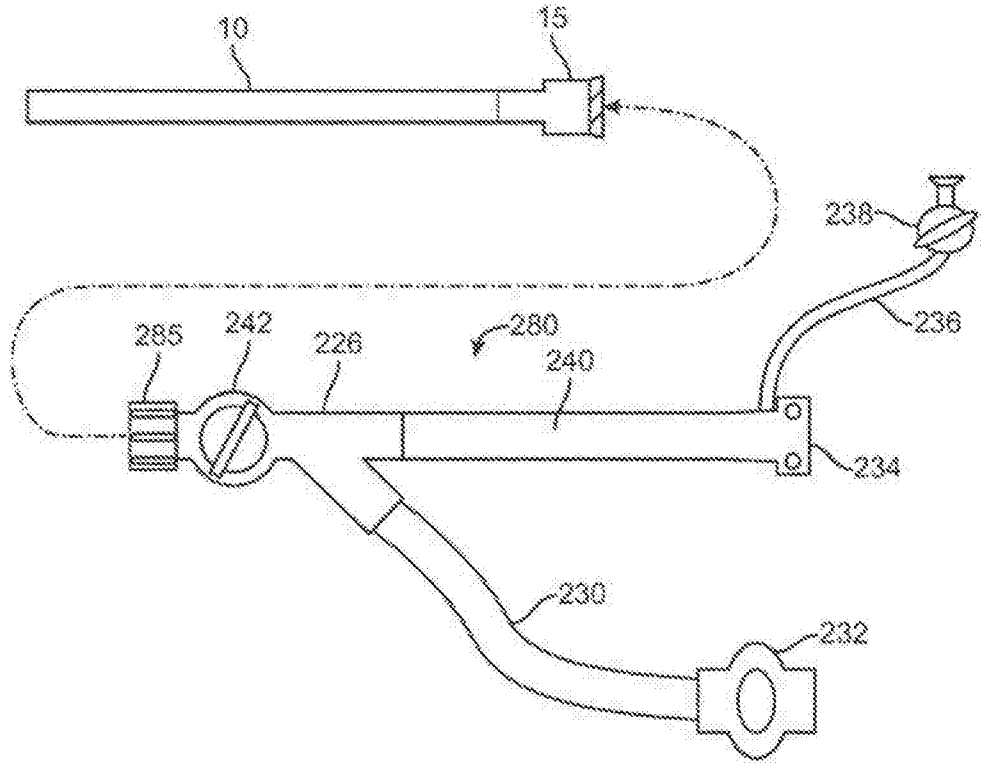

图5

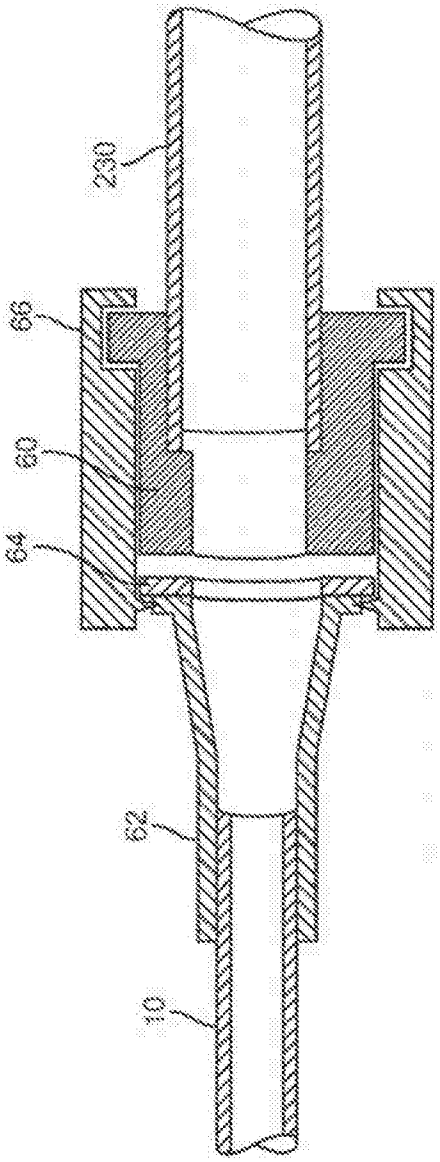

图6

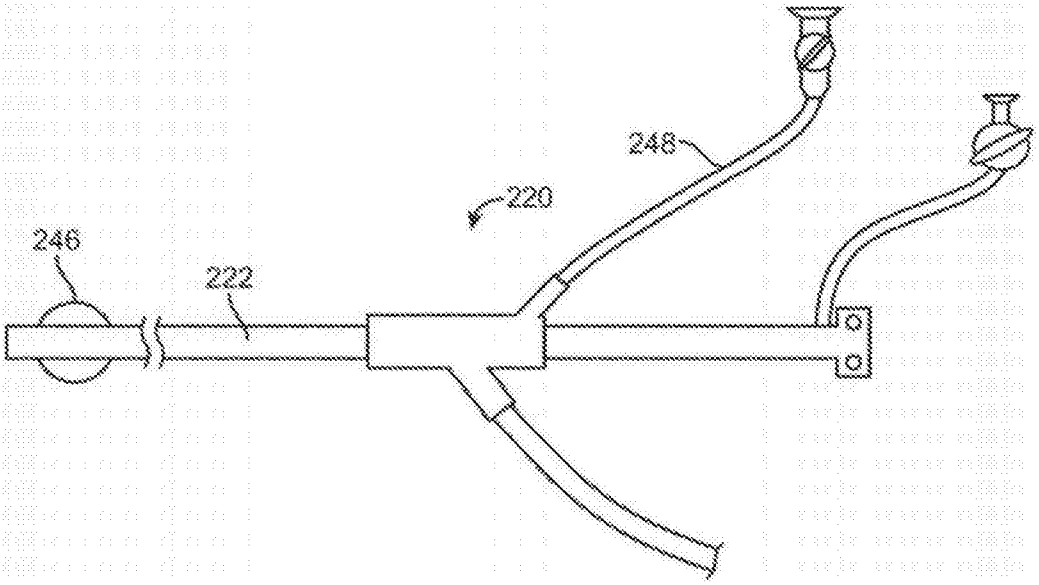

图7

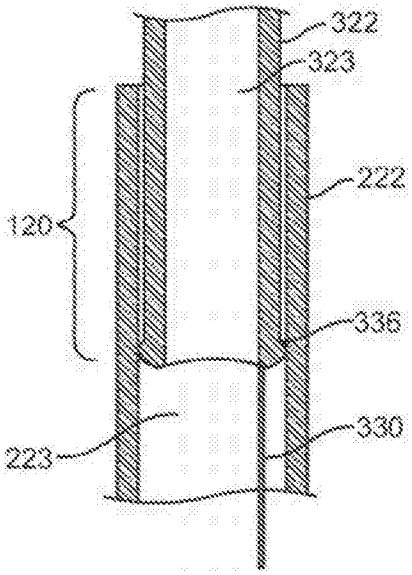

图8A

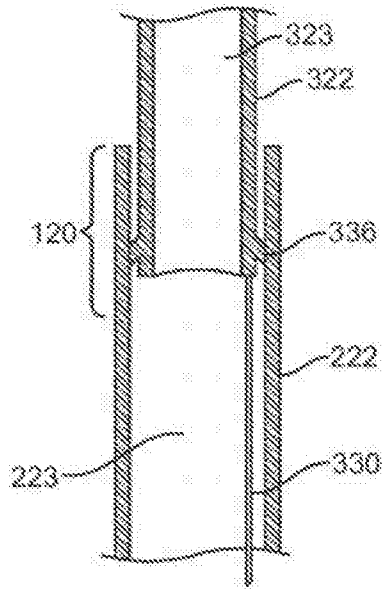

图8B

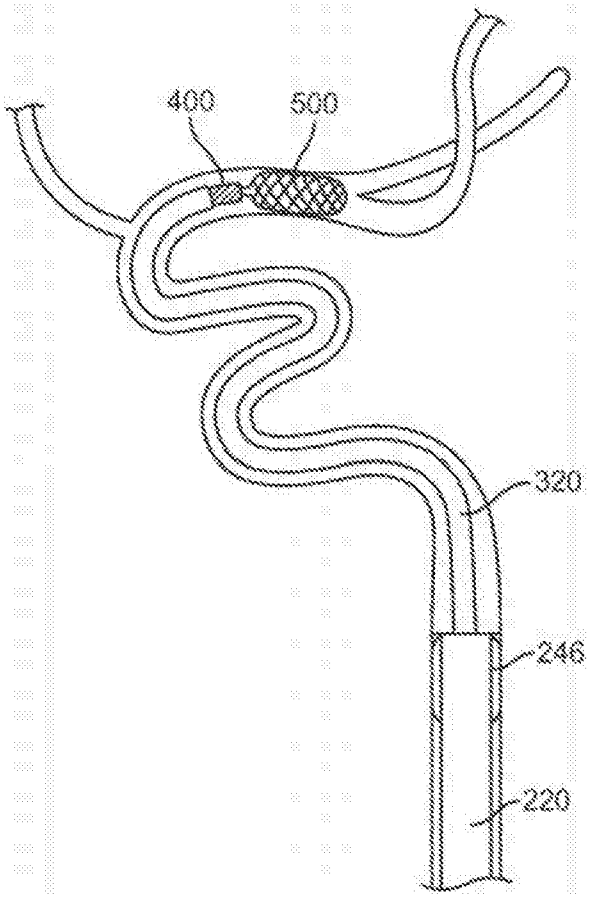

图9

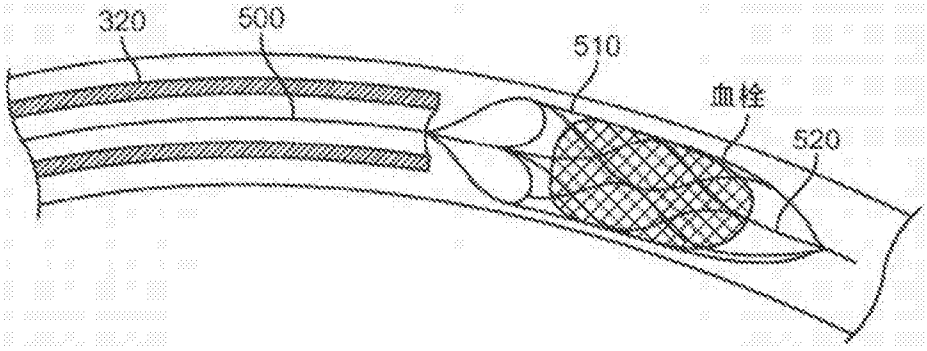

图10A

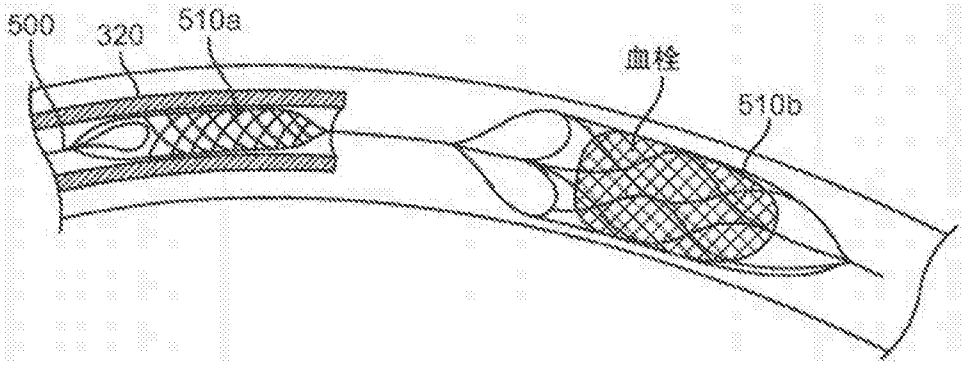

图10B

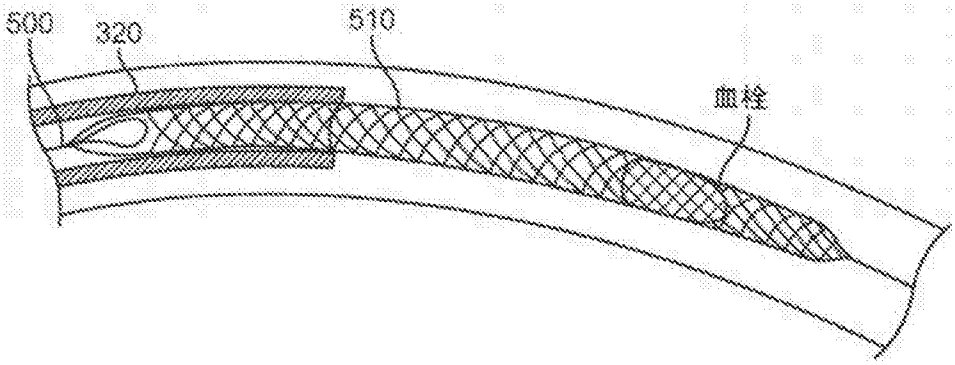

图10C

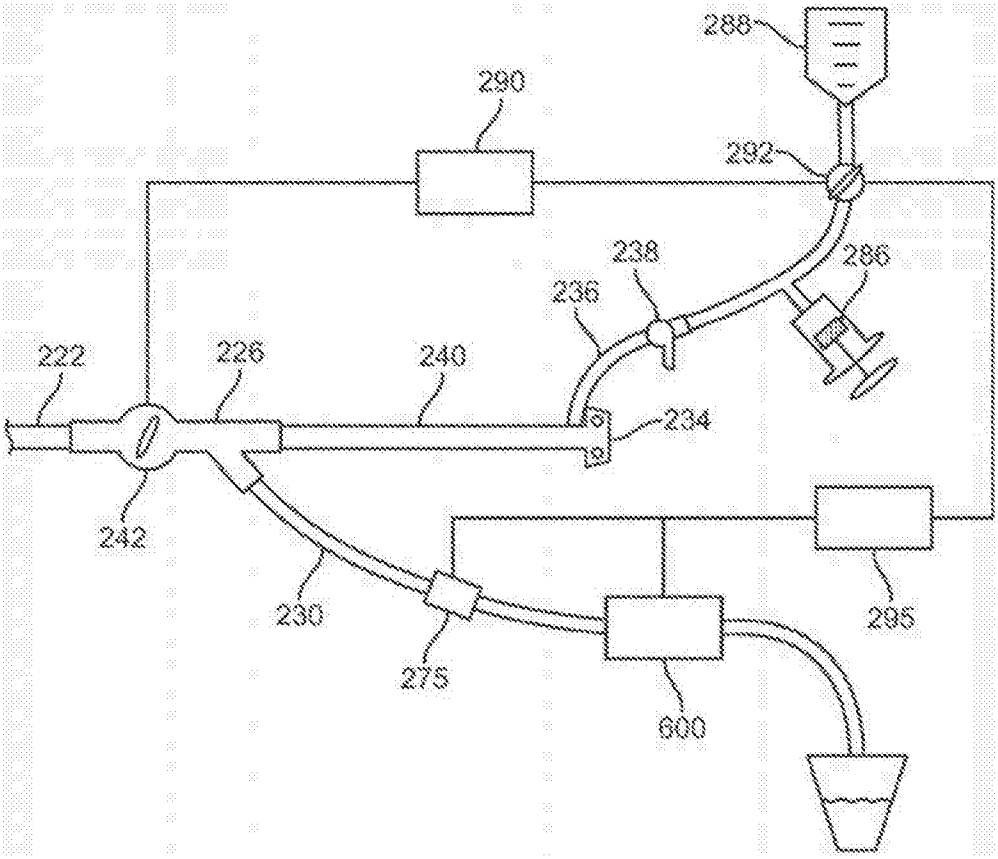

图11

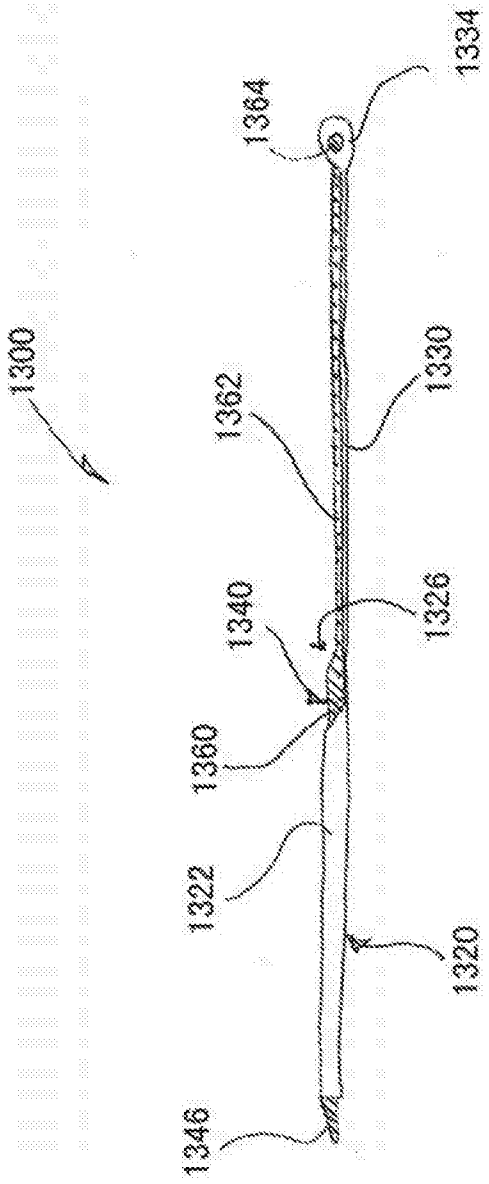

图12A

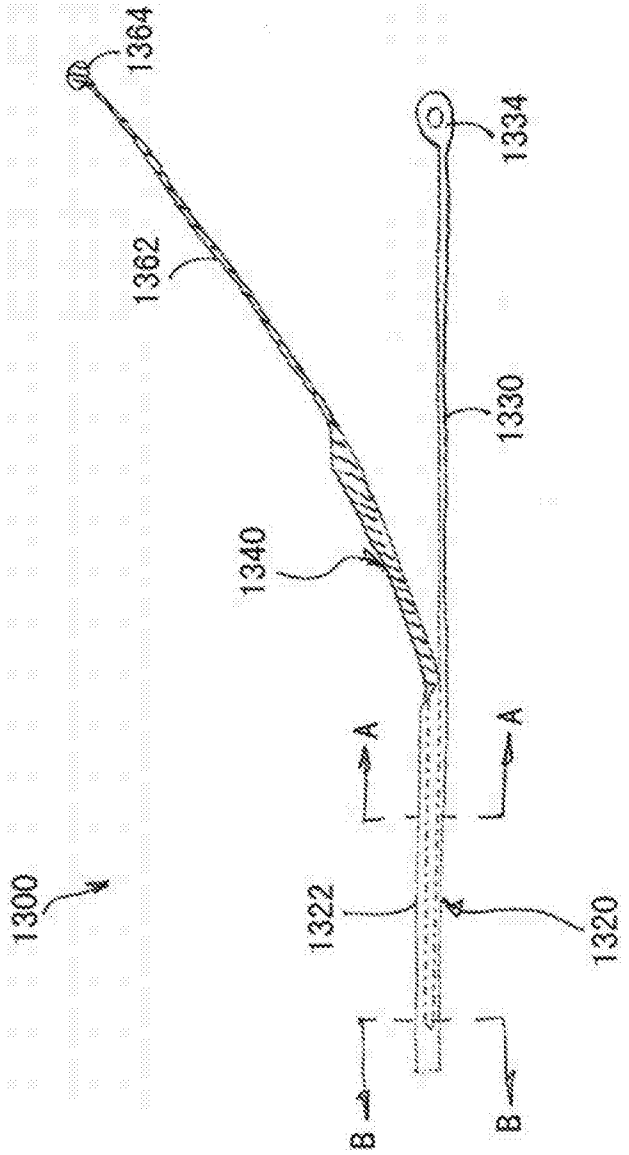

图12B

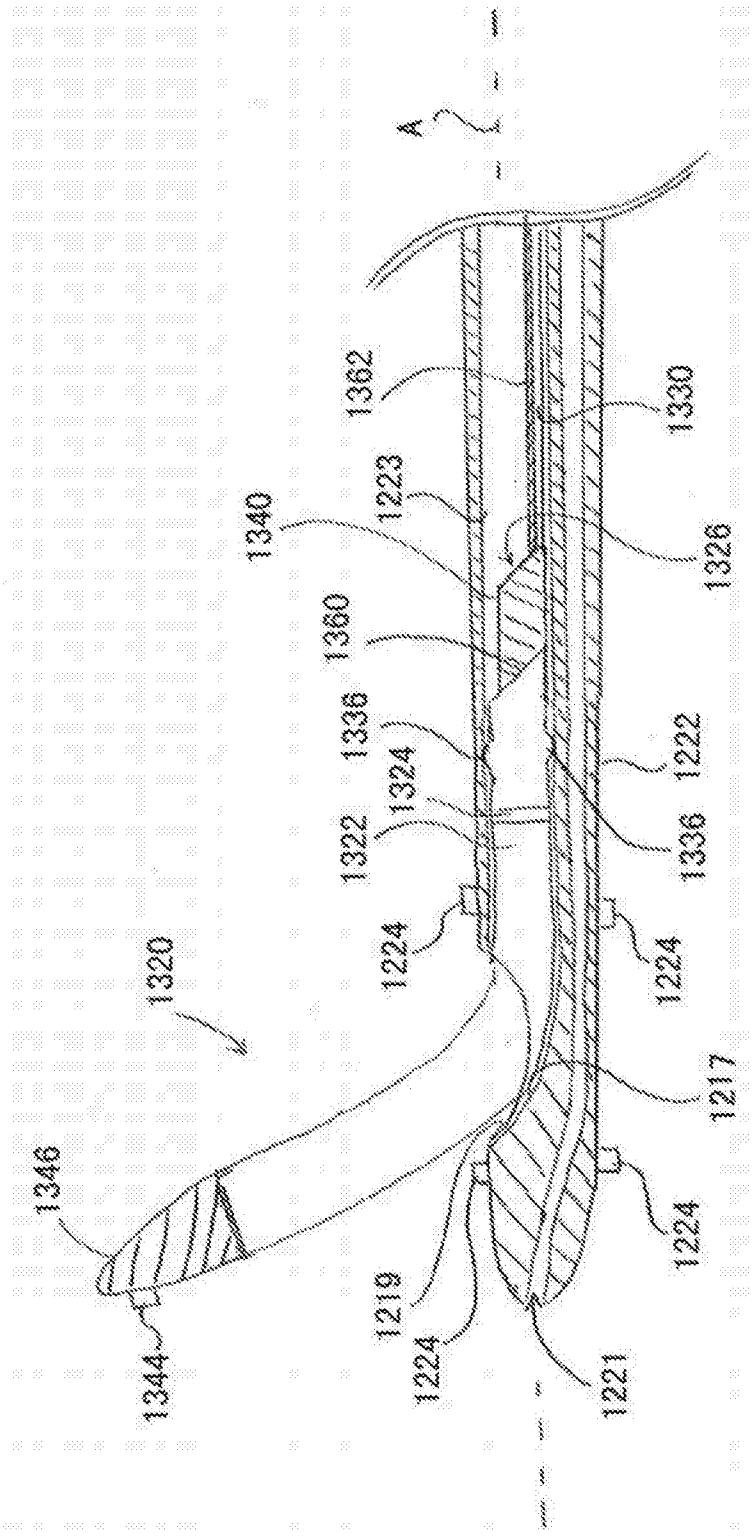
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图12C

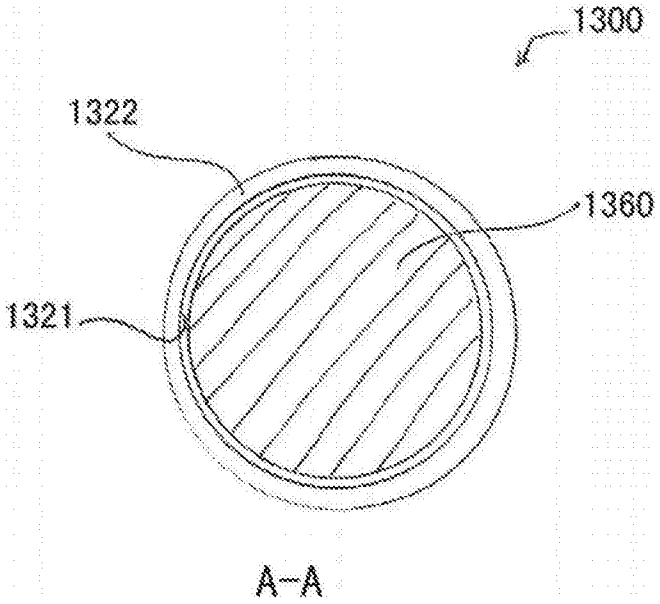

图13

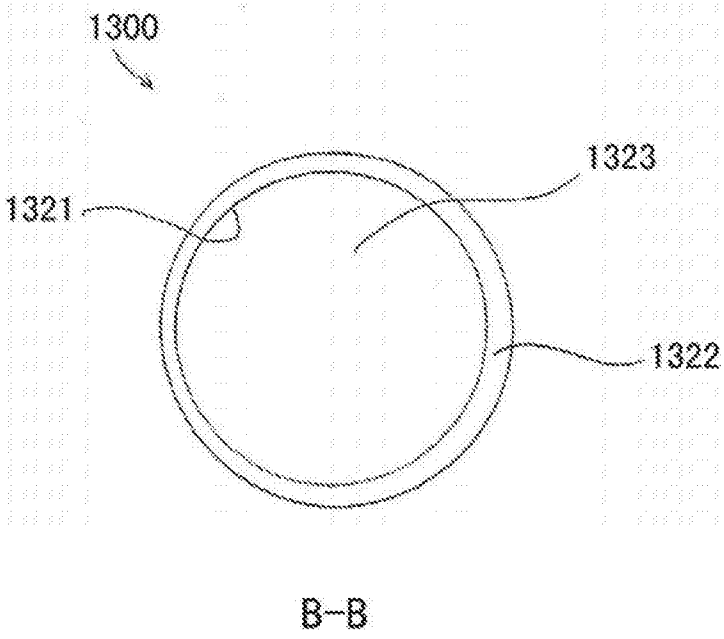

图14

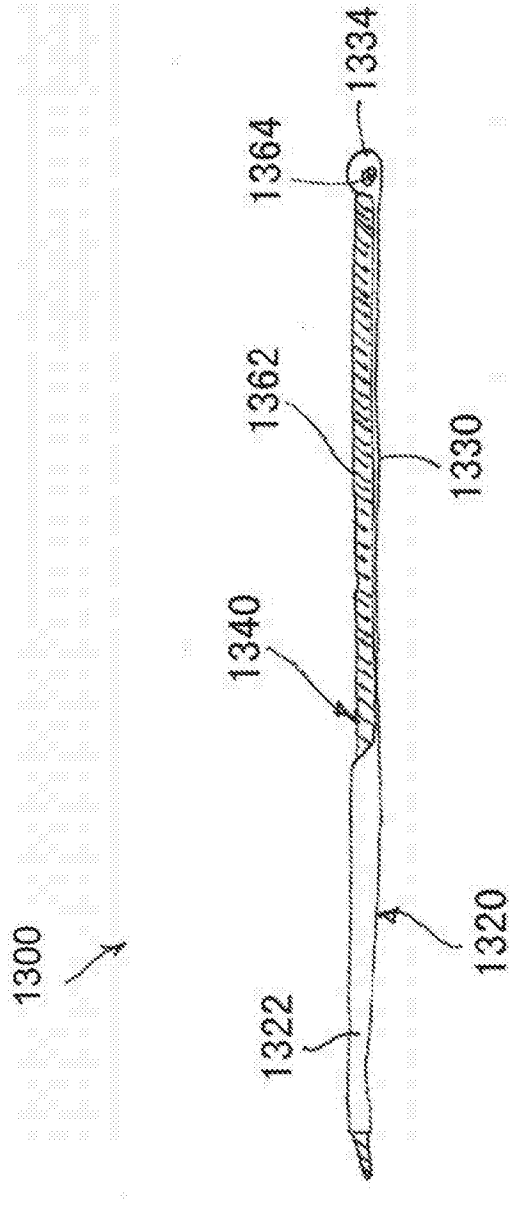

图15A

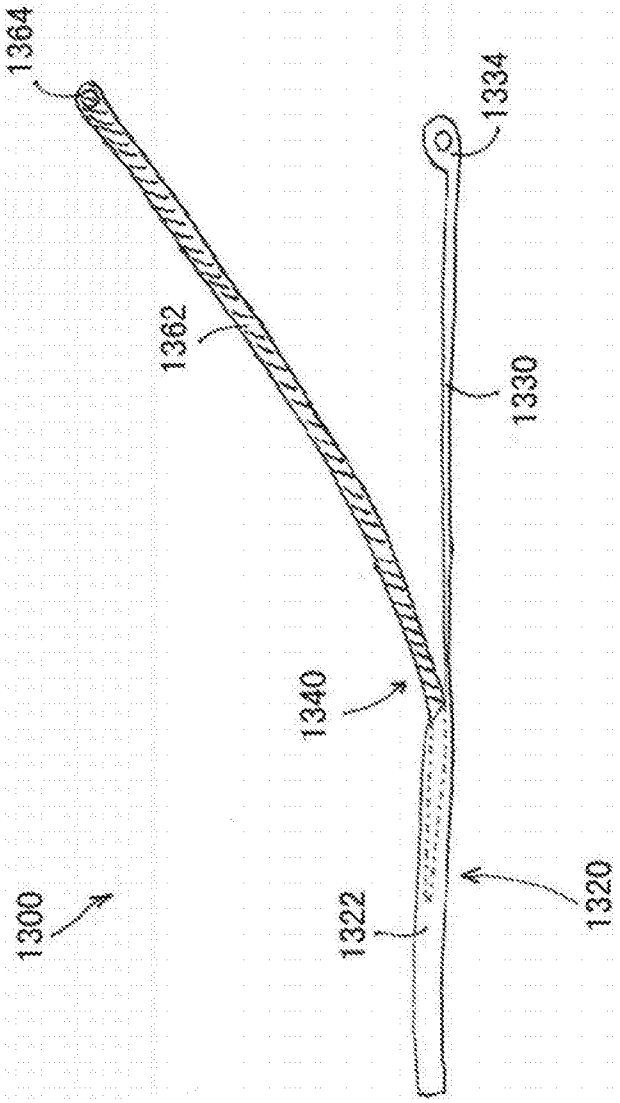

图15B

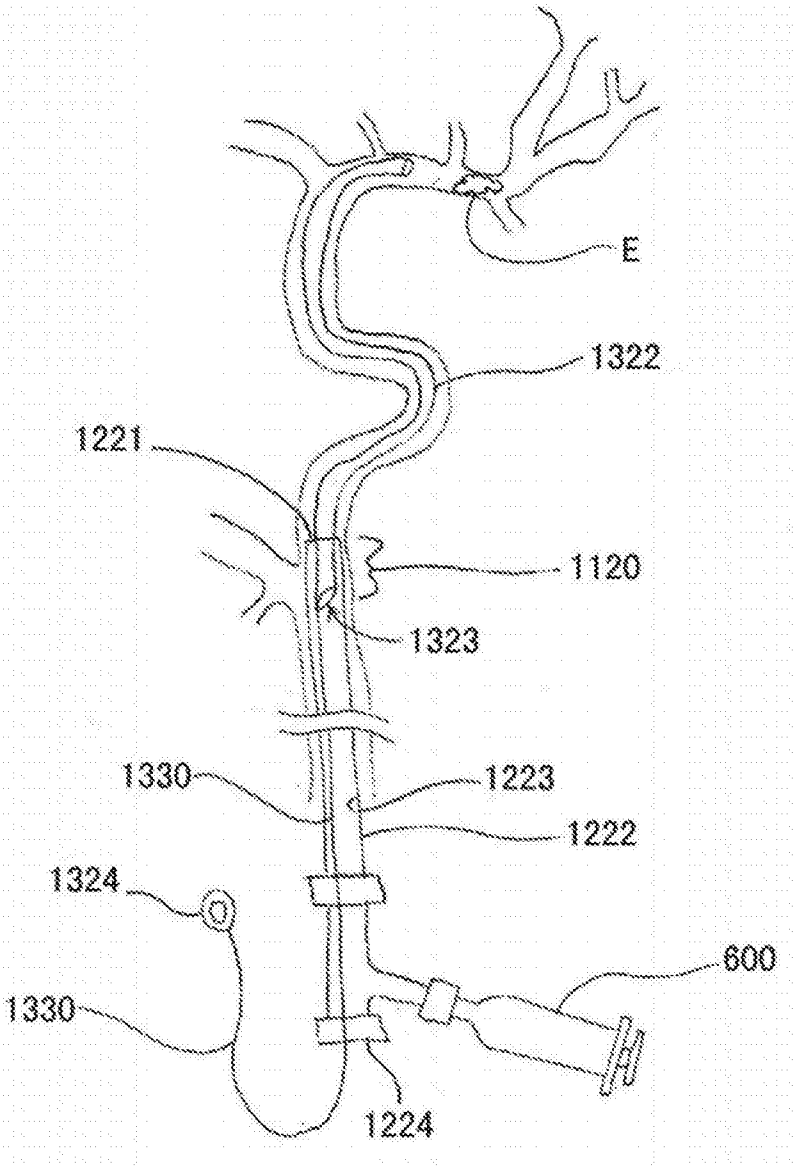

图16