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(54) **METHOD OF RESTORING BLOOD FLOW THROUGH AN OBSTRUCTED BLOOD VESSEL OF THE BRAIN**

(75) Inventors: **John Fulkerson**, Rancho Santa Margarita, CA (US); **David A. Ferrera**, Redondo Beach, CA (US); **Andrew Cragg**, Edina, MN (US)

(73) Assignee: **MINDFRAME, INC.**, Irvine, CA (US)

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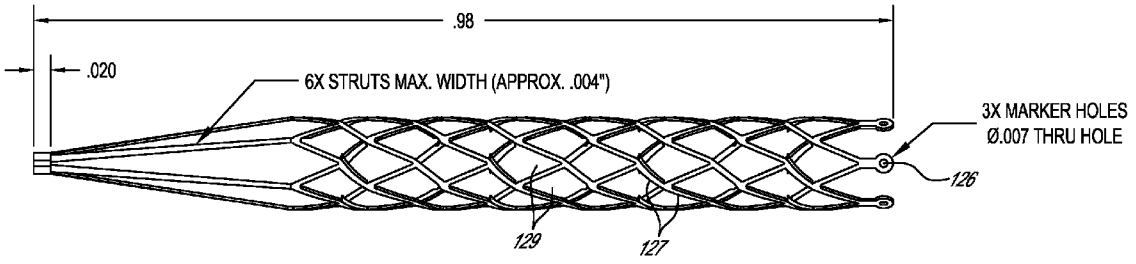
(57) **ABSTRACT**

An acute stroke recanalization system and processes include catheter-based improved reconstrainable or tethered neurological devices which are deliverable through highly constricted and tortuous vessels, crossing the zone associated with subject thrombi/emboli, where deployment impacts, addresses or bridges the embolus, compacting the same into luminal walls which enables perfusion and lysis of the embolus, while the improved neurological medical device itself remains contiguous with the delivery system acting as a filter, basket or stand alone stenting mechanism, depending on the status of the embolus and other therapeutic aspects of the treatment being offered for consideration.



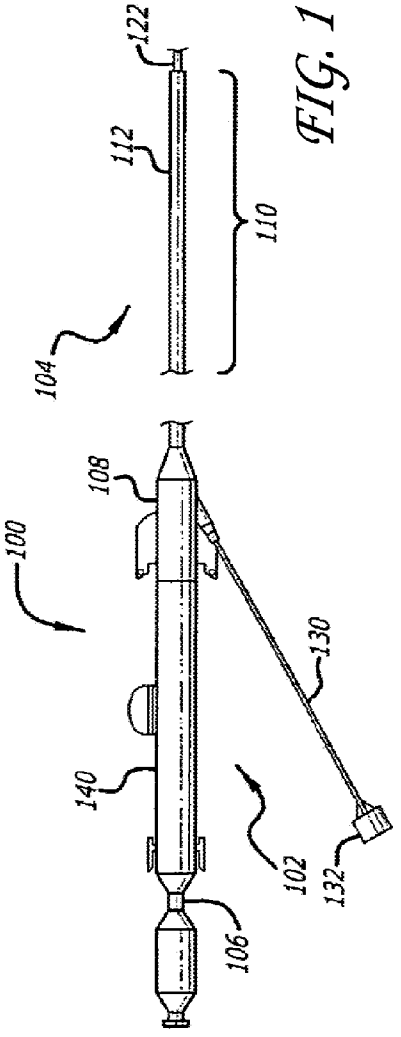

122
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FIG. 1

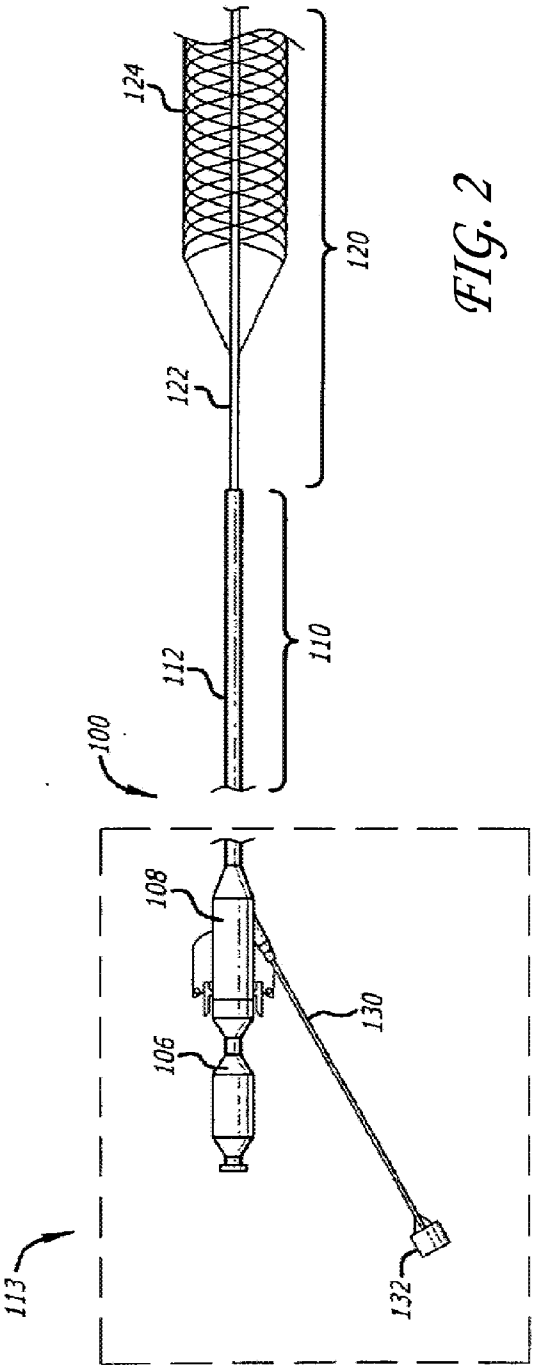
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FIG. 2

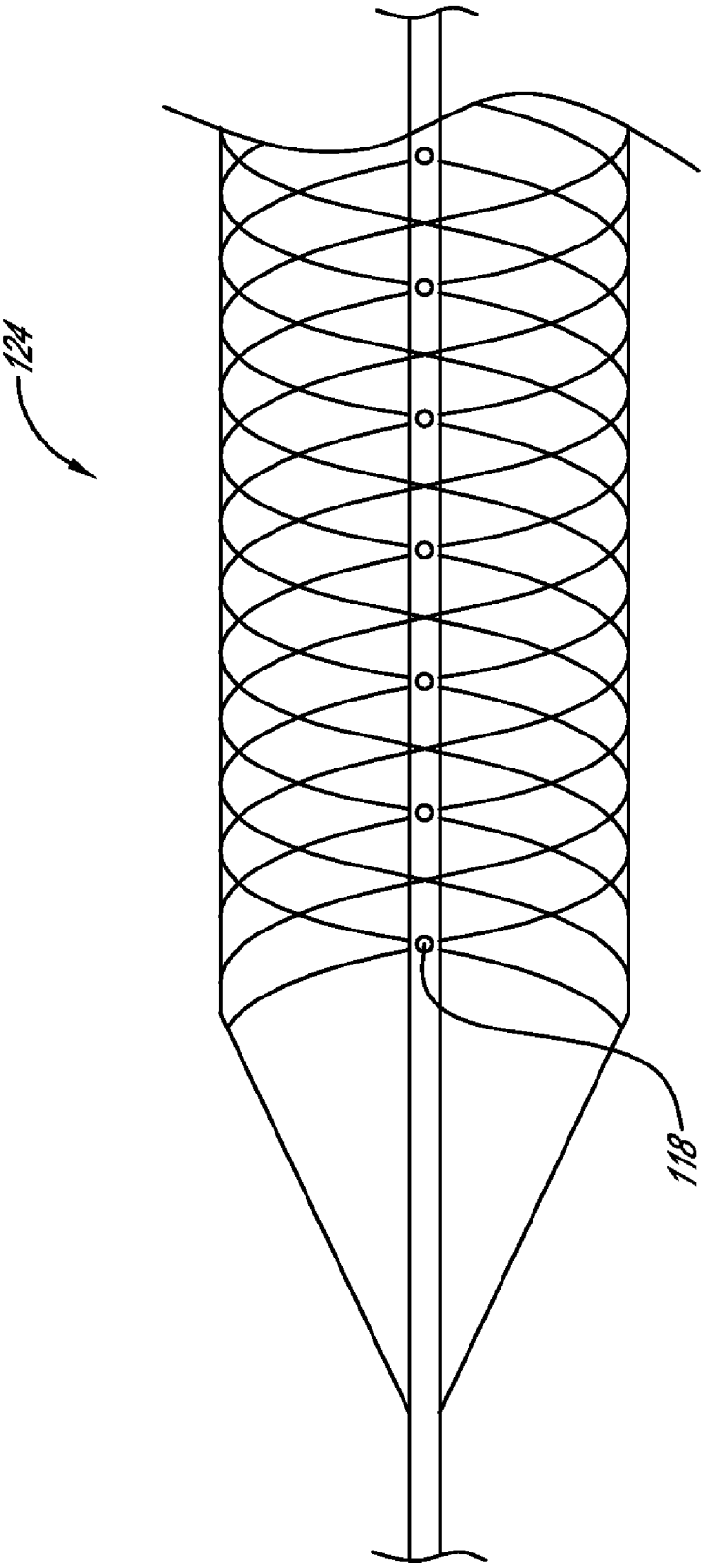

FIG. 2A

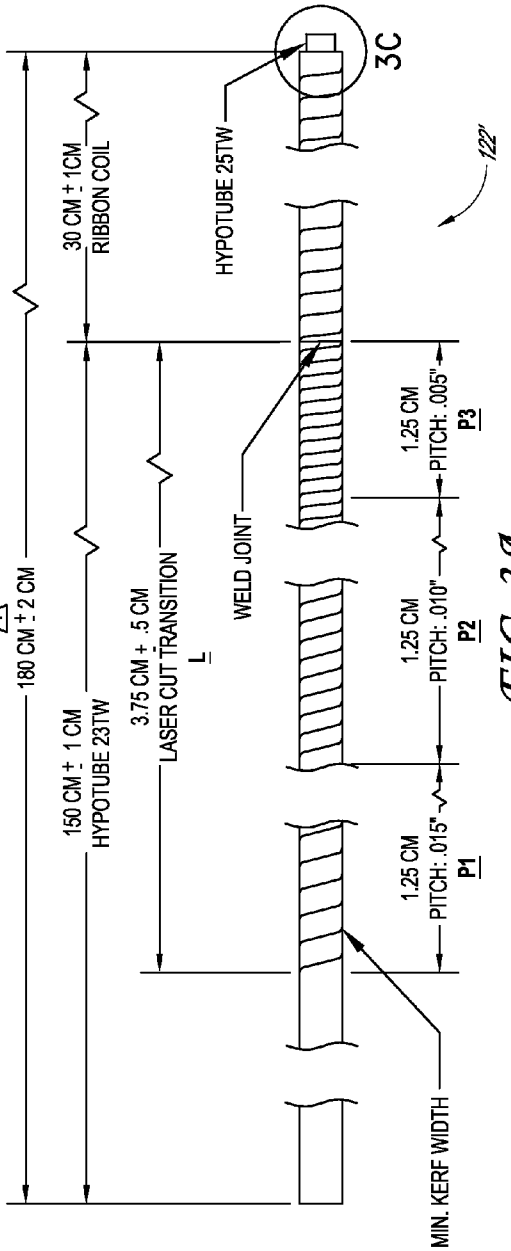

FIG. 3A

FIG. 3B

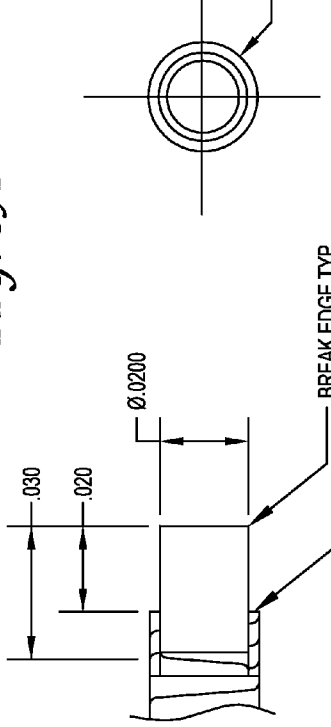

FIG. 3C

FIG. 3D

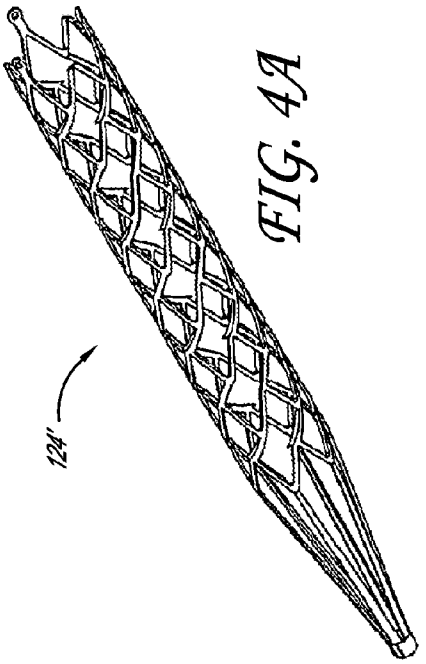

FIG. 4A

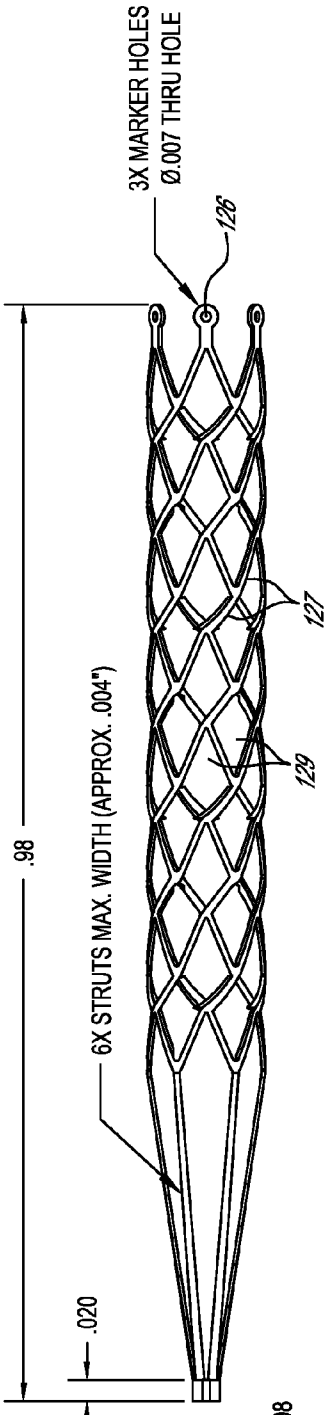

FIG. 4B

FIG. 4C

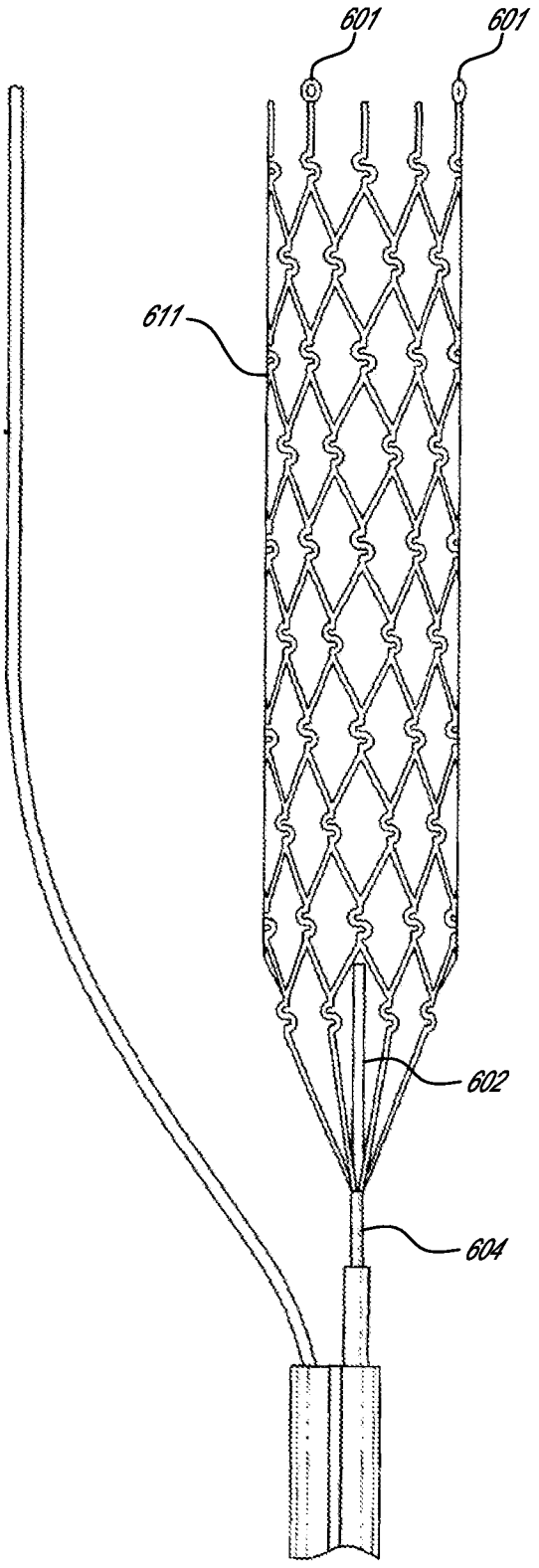

FIG. 5

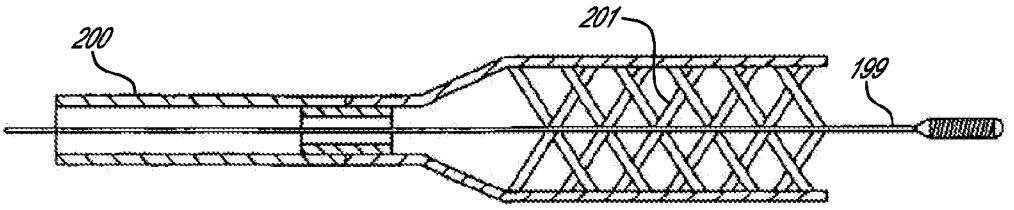

FIG. 6

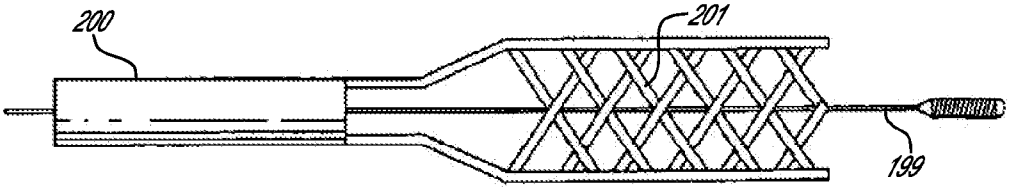

FIG. 7

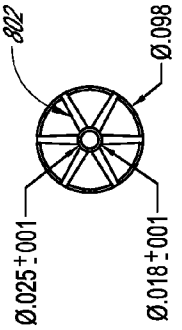

FIG. 8D

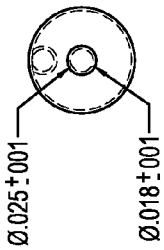

FIG. 8C

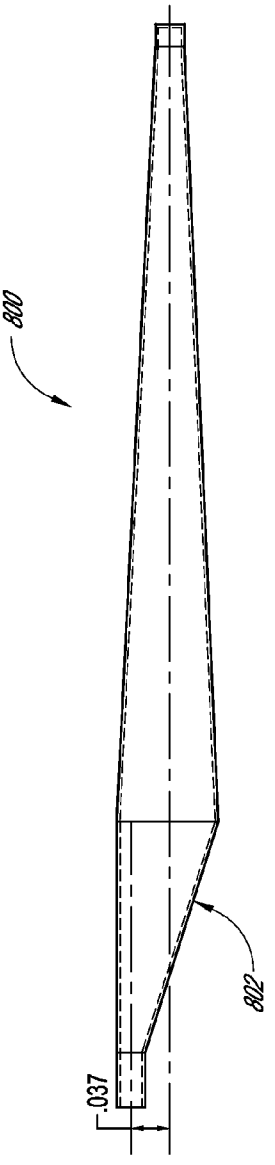

FIG. 8A

FIG. 8B

METHOD OF RESTORING BLOOD FLOW THROUGH AN OBSTRUCTED BLOOD VESSEL OF THE BRAIN

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 12/123,390, filed May 19, 2008, which claims priority to, and incorporates expressly by reference U.S. Provisional Application Ser. No. 60/980,736, filed Oct. 17, 2007; U.S. Provisional Application Ser. No. 61/044,392, filed Apr. 11, 2008; U.S. Provisional Application Ser. No. 61/015,154, filed Dec. 19, 2007; U.S. Provisional Application Ser. No. 60/989,422, filed Nov. 20, 2007; U.S. Provisional Application Ser. No. 60/987,384, filed Nov. 12, 2007; and U.S. Provisional Application Ser. No. 61/019,506, filed Jan. 7, 2008; each as if fully set forth herein.

BACKGROUND OF THE INVENTION

[0002] The present disclosure relates to minimally invasive and catheter delivered revascularization systems for use in the vasculature, especially those suited for usage above the juncture of the Subclavian Artery and Common Carotid Artery. In particular, this disclosure relates to revascularization devices for use in treatment of ischemic stroke, including improved neurological medical devices which are tethered or reconstrainable self-expanding neurological medical devices.

SUMMARY OF THE INVENTION

[0003] According to embodiments of the present invention, there are disclosed acute stroke revascularization/recanalization systems comprising, in combination; catheter systems having guidewires to access and emplace improved neurological medical devices into the cerebral vasculature, the systems including proximal stainless steel pushers with distal nitinol devices or one-piece nitinol devices. In some embodiments, the systems comprise a polymeric liner incorporated within the pusher to improve trackability of the guidewire. In some embodiments, the polymeric liner extends beyond the distal tip of the pusher for guiding the guidewire and preventing entanglement in the nitinol device.

[0004] According to embodiments, there are disclosed one-piece nitinol devices in combination with the above disclosed and/or claimed catheter systems.

[0005] Briefly stated, according to embodiments a novel enhanced tethered revascularization device is deliverable through highly constricted and tortuous vessels, entering a zone associated with subject thrombi/emboli, where deployment impacts the embolus, compacting the same into luminal walls which enables perfusion and lysis of the embolus, while the revascularization device itself remains continuous with the delivery system acting as a filter, basket or stand alone revascularization mechanism, depending on the status of the embolus and other therapeutic aspects of the treatment being offered for consideration.

[0006] According to embodiments of the system and processes of the present invention, in certain iterations, once deployed the instant system compacts the embolus against the luminal wall, creating a channel for blood flow which may act like a natural lytic agent to lyse or dissolve the embolus.

[0007] According to embodiments, there is provided an improved neurological medical device which comprises, in combination, a catheter system effective for delivering a combination radial filter/revascularization device and basket assembly into a desired location in the cerebral vascular system, a self-expanding radial filter/revascularization device and basket assembly detachably tethered to the catheter system which functions in at least three respective modes, wherein the radial filter/revascularization device and basket assembly is attached to the catheter and wherein radial filter/revascularization device and basket assembly further comprises at least two states per mode, a retracted state and an expanded state; and wherein the radial filter/revascularization device and basket assembly may retracted into the retracted state after deployment in an expanded state, in each mode.

[0008] According to embodiments, there is provided a process comprising in combination providing a revascularization device tethered to a catheter by emplacing the system into a patient for travel to a desired location in a vessel having an obstruction/lesion and deploying the revascularization device by allowing it to move from a first state to a second state across a lesion which compresses the subject embolus into a luminal wall to which it is adjacent whereby creating a channel for blood flow as a lytic agent, and removing the system which the obstruction/lesion is addressed.

[0009] It is noted that if blood flow does not lyse the blood embolus, lytic agents can be administered via the guidewire lumen, as a feature of the present invention.

[0010] According to embodiments, there is provided a process whereby the revascularization device tethered to a catheter functions as a radial filter to prevent downstream migration of emboli.

[0011] The U.S. Food and Drug Administration (FDA) has previously approved a clot retrieval device (The Merci® brand of retriever X4, X5, X6, L4, L5 & L6: Concentric Medical, Mountain View, Calif.). Unfortunately, when used alone, this clot retriever is successful in restoring blood flow in only approximately 50% of the cases, and multiple passes with this device are often required to achieve successful recanalization. IA thrombolytics administered concomitantly enhance the procedural success of this device but may increase the risk of hemorrhagic transformation of the revascularization infarction. There have been several reports of coronary and neuro-stent implantation used for mechanical thrombolysis of recalcitrant occlusions. In summary, stent placement with balloon-mounted or self-expanding coronary and neuro-types of stents has been shown to be an independent predictor for recanalization of both intracranial and extra cranial cerebro-vasculature occlusions. This provides some insight into approaches needed to overcome these longstanding issues.

[0012] By way of example, self-expanding stents designed specifically for the cerebro-vasculature can be delivered to target areas of intracranial stenosis with a success rate of >95% and an increased safety profile of deliverability because these stents are deployed at significantly lower pressures than balloon-mounted coronary stents. However, systems using this data have yet to become commercial, available or accepted by most practitioners.

[0013] The use of self-expanding stents is feasible in the setting of symptomatic medium—and large-vessel intracranial occlusions. With stent placement as a first-line mechanical treatment or as a "last-resort" maneuver, TIMI/TICI 2 or 3 revascularization can be successfully obtained, according to clinical data now available.

[0014] The literature likewise suggests that focal occlusions limited to a single medium or large vessel, particularly

solitary occlusions of the MCA or VBA, may be preferentially amenable to stent placement and thus can help clinicians to achieve improved rates of recanalization. In addition, gender may play a role in the success of self-expanding stent implementation. However, systems need to be designed to execute on this.

[0015] Despite increasing utilization of prourokinase rt-PA (recombinant tissue plasminogen activator) or other antithrombotic agents (e.g., Alteplase® and Reteplase®), recanalization rates remain approximately 60%. The major concerns with pharmacologic thrombolysis (alone) has been the rate of hemorrhage, inability to effectively dissolve fibrin\platelet-rich clots, lengthy times to recanalization, and inability to prevent abrupt reocclusions at the initial site of obstruction. In PROACTII, ICH with neurologic deterioration within 24 hours occurred in 10.9% of the prourokinase group and 3.1% of the control group (P=0.06), without differences in mortality. Abrupt reocclusions or recanalized arteries has been found to occur relatively frequently, even with the addition of angioplasty or snare manipulation for mechanical disruption of thrombus, and seems to be associated with poor clinical outcomes.

[0016] The use of other mechanical means has been reported to be effective in recanalization of acute occlusions. It makes sense that a combination of mechanical and pharmacologic approaches would yield greater benefit.

[0017] A known investigation in an animal model has shown, both the Wingspan® brand of self-expanding stent and Liberte® brand of balloon-mounted stent (Boston Scientific, Boston, Mass.) were able to re-establish flow through acutely occluded vessels. The self-expanding stents performed better than the balloon-mounted stents in terms of navigability to the target site. The self-expanding stents incurred lower rates of vasospasm and side-branch occlusions, which suggests superiority of these stents, over balloon-mounted stents, to maintain branch vessel patency during treatment of acute vessel occlusion. In a previous animal studies conducted, intimal proliferation and loss of lumen diameter were seen after the implantation of bare-metal, balloon-expandable stents. The literature further supports this set of issues.

[0018] These phenomena are believed to be attributable to intimal injury created during the high-pressure balloon angioplasty that is required for stent deployment.

[0019] Compared with coronary balloon-mounted stents, self-expanding stents designed for use in the intracranial circulation are superior because they are easier to track to the intracranial circulation and safer to deploy in vessels in which the true diameter and degree of intracranial atherosclerotic disease are unclear.

[0020] Moreover, based on previous experience, currently available self-expanding stents provide enough radial outward force at body temperature to revascularize occluded vessels, with low potential for the negative remodeling and in-stent restenosis that are associated with balloon-mounted stents in nonintracranial vascular beds.

[0021] Because self-expanding stents are not mounted on balloons, they are the most trackable of the stents currently available for the intracranial circulation. Unlike clot retrievers, which lose access to the target (occlusion site) every time they are retrieved (and often to necessitate multiple passes), self-expanding stents allow for wire access to the occlusion at all times, increasing the safety profile of the procedure by not requiring repeat maneuvers to gain access to the target site (as in the case for the Merci® brand of clot retriever).

[0022] Self-expanding stent placement of acute intracranial vessel occlusions may provide a novel means of recanalization after failure of clot retrieval, angioplasty, and/or thrombolytic therapy. The patency rates in this series are encouraging, yet issues remain to be addressed.

[0023] In the setting of acute stroke, restoring flow is of singular importance. In-stent stenosis or delayed stenosis may be treated in a delayed fashion on an elective basis, should the patient achieve a functional recovery from the stroke.

[0024] Recanalization with self-expanding stents may provide flow through the patent artery, and restore flow to the perforators, or, alternatively, they may remain occluded. Restoring flow to the main artery, however, will reduce the stroke burden. What is needed is a solution leveraging positive aspects of stent-based treatment without the negative outcomes which have been associated with traditional stenting.

DRAWINGS OF THE INVENTION

[0025] The above-mentioned features and objects of the present disclosure will become more apparent with reference to the following description taken in conjunction with the accompanying drawings wherein like reference numerals denote like elements and in which:

[0026] FIG. **1** is a perspective view of an embodiment of an acute stroke recanalization system according to embodiments of the present disclosure in a first configuration; and

[0027] FIG. **2** is a perspective view of an embodiment of an acute stroke recanalization system according to embodiments of the present disclosure tailored for use with the neurovasculature in a second configuration, further illustrating modular aspects of the system as used with tethered or reconstrainable self-expanding neurological medical devices.

[0028] FIG. **2**A illustrates a detailed view of the inner catheter of FIG. **2**.

[0029] FIGS. **3**A-**3**D illustrate an embodiment of an inner catheter of the acute stroke recanalization system of FIGS. **1** and **2**.

[0030] FIGS. **4**A-**4**C illustrate a perspective view, a side view, and a front view, respectively, of an embodiment of a self-expanding revascularization device.

[0031] FIG. **5** illustrates an embodiment of a stroke device.

[0032] FIG. **6** shows a schematic of a delivery system and exemplary iteration of a temporary tethered stent mechanism according to the present disclosure.

[0033] FIG. **7** likewise schematically depicts a delivery system with embodiments of a tethered stent for use with an over-the wire guidewire system.

[0034] FIGS. **8**A-**8**D illustrate an embodiment of a revascularization device configured for eccentric coupling to a pusher.

DETAILED DESCRIPTION OF THE INVENTION

[0035] The present inventors have realized that by leveraging a conventional self-expanding revascularization device delivery platform, a poly-modic system can be iterated which impacts, addresses and/or crosses an embolus, radially filters, and either removes the offending embolus or is optionally

emplaced to address the same. A paucity of extant systems effective for such combination therapies is noted among the art.

[0036] Using endovascular techniques self-expandable tethered or reconstrainable self-expanding neurological medical devices offer instant revascularization/recanalization of MCAs and related vessels, without any of the traditional concerns associated with stenting, according to embodiments of the present invention.

[0037] Expressly incorporated herein by reference are the following U.S. Letters patents and publications, each as if fully set forth herein: 2005/0119684; 2007/0198028; 2007/0208367; U.S. Pat. Nos. 5,449,372; 5,485,450; 5,792,157; 5,928,260; 5,972,019; 6,485,500; 7,147,655; 7,160,317; 7,172,575; 7,175,607; and 7,201,770.

[0038] The instant system allows for natural lysis, revascularization of the challenged vessels, and importantly radially filters any particulates generated, to obviate the need to be concerned with distal migration of the same, unlike prior systems or applications which include largely "off-label" usages of devices approved only for aneurysms in the brain.

[0039] The present disclosure relates to revascularization devices used to treat, among other things, ischemic stroke. Naturally, therefore, the revascularization devices of the present disclosure are designed to be used in neuro-type applications, wherein the specifications of the present catheters and revascularization devices may be deployed in the blood vessels of the cerebral vascular system. Similarly contemplated for the revascularization systems and catheters of the present disclosure is deployment in other parts of the body wherein the specifications of the present disclosure may be used in other vessels of the body in a non-invasive manner.

[0040] According to embodiments, disclosed herein is a catheter-based revascularization system. The revascularization devices of the present disclosure are for revascularization of blood vessels. When the catheter-based revascularization system of the present disclosure is deployed into a blood vessel having an embolus, the revascularization device is expanded thereby opening the vessel so that the vessel can resume proper blood flow.

[0041] According to the instant teachings, deployment of the system of the present disclosure, establishes immediate 50% of the diameter of the lumen patency of the vessel being addressed. Among the prior art, no system having adequately small profile with flexibility to promote improved access for in-site treatment is known which may be used as a temporary (not implanted) solution. Those skilled in the art readily understand that detachment methods comprising mechanical, electrical, hydraulic, chemical, or thermal, and others are within the scope of the instant teachings.

[0042] Moreover, as the embolus dissolves, either via blood flow or by infusing lytic agents than the guidewire lumen, the deployed revascularization device radially filters larger embolus particles from traveling downstream, thereby reducing the chances of further complications. Once the blood vessel is revascularized, the revascularization device is modified to be in a removable state together with filtered detritus, and the catheter-revascularization system is removed from the blood vessels of the patient.

[0043] Likewise, in the event that no resolution of the embolus is noted in the instant revascularization system the inventors contemplate detachment and employment as a stent of the cage-like membrane. Angiographic recanalization has been associated with improvement in clinical outcome in the setting of acute stroke resulting from acute intracranial thrombotic occlusion. Anatomic limitations (tortuous anatomy, length of the occlusion, or location of occlusion) or supply limitations are among the reasons precluding use of prior art systems until the advent of the instant teachings.

[0044] Stenting has been used successfully to restore flow after abrupt reocclusion occurring after recanalization with other modalities in previous cases. Stenting has also been reported in cases in which other modalities have failed to recanalize vessels. Even if an underlying stenosis is rarely the cause of stroke, stenting may play a role by morselizing the embolic clot or trapping it against the arterial wall. In several embodiments, the present invention comprises an acute stroke revascularization process that comprises providing a reconstrainable self-expanding microstent system, deploying a self-expanding microstent within a neurological vessel; achieving at least one of revascularization and recanalization of a subject vessel; and removing the self-expanding microstent. In some embodiments, at least one supplemental therapy is also provided, and comprises one or more of the following: pharmacological thrombolytic agents, intraarterial thrombolytics, and mechanical manipulation.

[0045] The use of intracranial stents as a method for arterial recanalization during cerebral ischemia caused by focal occlusion of an intracranial vessel has been demonstrated to have benefits in some cases. Despite the use of available pharmacological and mechanical therapies, angiographic recanalization of occluded vessels has not been adequately achieved before stent placement, in most cases.

[0046] When SAH and intracranial hematoma occurred in patients in whom balloon-mounted stents were used, they most likely resulted from distal wire perforation. The distal wire purchase needed to navigate a coronary stent into the intracranial circulation may explain the occurrence of these adverse events. Alternatively, multiple manipulations of the Merci® brand of retriever device or expansion of balloon-mounted stents may have induced microdissections in the vessel. Stents designed for intracranial navigation have better navigability and pliability. The Wingspan® brand of stent (Boston Scientific) was designed to have more radial force than the Neuroform® brand of stent and may further improve this technique. However, the act clearly needs to advance further in this area.

[0047] IA therapy for stroke has evolved during the past decade. Approval of the Merci® brand of retriever device represents a significant step toward achieving better outcomes in acute stroke for patients not suitable for IV tPA. However, recanalization is not always achieved using this device. Therefore, additional treatment options are required, as offered for consideration herein.

[0048] Spontaneous dissection of the internal carotid artery (ICA) is one of the main causes of ischemic stroke in young and middle-aged patients, representing 10% to 25% of such cases. Because infarct due to dissection is mainly thromboembolic, anticoagulation has been recommended to prevent new stroke in patients with acute dissection, provided they have no contraindications. In the acute phase, intravenous recombinant tissue-type plasminogen activator (IV rtPA) given within 3 hours after onset of stroke due to dissection is reportedly safe and effective. However, this often needs supplemental therapy to be effective.

[0049] Endovascular treatment with stent deployment for ICA dissection with high-grade stenosis or occlusion may be most appropriate when anticoagulation fails to prevent a new

ischemic event. In such cases, the MCA may be patent. However, to compare outcomes of patients with acute stroke consecutive to MCA occlusion due to ICA dissection treated either by stent-assisted endovascular thrombolysis/thrombectomy or by IV rtPA thrombolysis. Stent assisted endovascular thrombolysis/thrombectomy compared favorably with IV rtPA thrombolysis, underscoring the need for the instant device.

[0050] The main limitation of this procedure is the immediate need for an experienced endovascular therapist. The number of cases of MCA occlusion due to carotid artery dissection was quite small and represented <10% of patients admitted for carotid dissection. However, despite these promising preliminary results, potential drawbacks related to the procedure must be considered. Acute complications such as transient ischemic attack, ischemic stroke, femoral or carotid dissection, and death have been reported. Other potential hazards of endovascular treatment of carotid dissection could have been observed. On balance, the risk-benefit favors solutions like the present invention.

[0051] Most patients with acute cerebrovascular syndrome with MC occlusion consecutive to ICA dissection have poor outcomes when treated with conventional IV rtPA thrombolysis, whereas most patients treated with stent-assisted endovascular thrombolysis/thrombectomy show dramatic improvements. Further large randomized studies are required to confirm these data, which trends likewise are technical bases for the instant systems.

[0052] According to embodiments and as illustrated in FIG. **1**, catheter-based revascularization system **100** provides a platform for lysing emboli in occluded blood vessels. Accordingly, catheter-based revascularization system **100** generally comprises control end **102** and deployment end **104**. According to embodiments, control end **102** is a portion of the device that allows a user, such as a surgeon, to control deployment of the device through the blood vessels of a patient. Included as part of control end **102** is delivery handle **106** and winged apparatus **108**, in some embodiments. Those skilled in the art readily understand module **113** (see FIG. **2**) is detachable.

[0053] According to some examples of the instant system during shipping of catheter-revascularization system **100**, shipping lock (not shown) is installed between delivery handle **106** and winged apparatus **108** to prevent deployment and premature extension of revascularization device **124** (see FIG. **2**) while not in use. Furthermore, by preventing delivery handle **106** from being advanced towards winged apparatus **108**, coatings applied to revascularization device **124** are stored in a configuration whereby they will not rub off or be otherwise damaged while catheter-based revascularization system **100** is not in use.

[0054] According to embodiments, agent delivery device **130** provides a conduit in fluid communication with the lumen of the catheter-based revascularization system **100** enabling users of the system to deliver agents through catheter-revascularization system **100** directly to the location of the embolus. The instant revascularization system delivery device may be made from materials known to artisans, including stainless steel hypotube, stainless steel coil, polymer jackets, and/or radiopaque jackets. In one embodiment, the revascularization systems comprise a plurality of apertures **118** allowing infusable lytic agents to exit radially and distally into at least a subject embolus when transmitted through agent delivery device which is in fluid communication therewith. The revascularization systems according to several embodiments herein can comprise radiopacity for imaging purposes.

[0055] Accordingly, luer connector **132** or a functional equivalent provides sterile access to the lumen of catheter-based revascularization system **100** to effect delivery of a chosen agent. Artisans will understand that revascularization devices of the present invention include embodiments made essentially of nitinol or spring tempered stainless steel. Revascularization devices likewise may be coated or covered with therapeutic substances in pharmacologically effective amounts or lubricious materials. According to embodiments, coatings include namodopene, vasodialators, sirolamus, and paclitaxel. Additionally, at least heparin and other coating materials of pharmaceutical nature may be used.

[0056] Deployment end **104** of catheter-based revascularization system **100** comprises proximal segment **110** and distal segment **120**. Proximal segment **110**, according to embodiments, houses distal segment **120** and comprises outer catheter **112** that is of a suitable length and diameter for deployment into the blood vessel of the neck, head, and cerebral vasculature. For example in some embodiments, proximal segment **110** is from at least about 100 cm to approximately 115 cm long with an outer diameter of at least about 2.5 French to about 4 French.

[0057] Referring also to FIG. **2**, distal segment **120** comprises inner catheter **122** and revascularization device **124** (as shown here in one embodiment having uniform cells, variable cells likewise being within other embodiments of the present invention), which is connected to inner catheter **122**. Inner catheter **122**, according to embodiments, is made from stainless steel coil, stainless steel wire, or ribbon or laser cut hypotube and is of a suitable length and diameter to move through outer catheter **112** during deployment. For example, inner catheter **122** extends from outer catheter **112** 38 cm, thereby giving it a total length of between at least about 143 and 175 cm. The diameter of inner catheter **122** according to the exemplary embodiment is 2.7 French, with an inner diameter of at least about 0.012 to 0.029 inches. The inner diameter of inner catheter **122** may be any suitable diameter provided inner catheter **122** maintains the strength and flexibility to both deploy and retract revascularization device **124**. In one embodiment, an inner catheter **122'** comprises a variable-pitch hypotube, as shown in FIGS. **3**A-D. In one embodiment, the inner catheter **122'** comprises a laser-cut, variable-pitch hypotube. Region L comprises a laser cut transition region of the variable-pitch hypotube. Regions P**1**, P**2** and P**3** comprise three regions of the variable-pitch hypotube having variable pitch. In one embodiment, the pitch decreases from region P**1** to region P**2** and from region P**2** to region P**3**.

[0058] Referring to both figures, revascularization device **124** is a self-expanding, reconstrictable retractable device tethered to inner catheter **122**. Revascularization device **124** may be made from nitinol, spring tempered stainless steel, or equivalents as known and understood by artisans, according to embodiments. Revascularization device **124**, according to embodiments and depending on the particular problem being addressed, may be from at least about 3.5 mm to about 50 mm in its expanded state. In an expanded state, revascularization device **124** is designed to expand in diameter to the luminal wall of blood vessel where it is deployed.

[0059] As known to artisans, revascularization device **124** may be coated or covered with substances imparting lubricous characteristics or therapeutic substances, as desired.

Naturally, the expandable mesh design of revascularization device **124** must be a pattern whereby when revascularization device **124** is retracted, it is able to fully retract into inner catheter **122**. The nature of the cell type likewise changes with respect to the embodiment used, and is often determined based upon nature of the clot.

[0060] In one embodiment, a revascularization device **124'** comprises a plurality of struts **127** and a plurality of open cells **129**, as shown in FIGS. **4**A-**4**C. In accordance with some embodiments, recapturability, flexibility and tracking are enabled by the struts of the revascularization device **124'**, which permit flexion and extension to navigate through curved vessels. FIG. **5** illustrates a stroke device having a revascularization device **124"** coupled to a distal end of an inner catheter **122"**. In one embodiment, a revascularization device **124"** comprises one or more markers **125**. The markers **125** can comprise at least one marker material selected from the group consisting essentially of platinum and gold. With reference to FIG. **4**B, one or more markers can be pressed into pre-laser cut apertures **126** designed to matingly embrace the same.

[0061] Catheter-revascularization system **100** is deployed through a patient's blood vessels. Once the user of catheter-revascularization system **100** determines that the embolus to be addressed is crossed, as known and understood well by artisans, revascularization device **124** is deployed by first positioning outer catheter **112** in a location immediately distal to the embolus.

[0062] Then, to revascularize/reperfuse the occluded blood vessel, distal catheter **120** is deployed in a location whereby revascularization device **124** expands at the location of the embolus, as illustrated by FIG. **2**. The embolus is thereby compressed against the luminal wall of the blood vessel and blood flow is restored. Modular detachable segment **113** is known also, and may be swapped out, as needed, if an Rx system is used.

[0063] As discussed above and claimed below, creating a channel for flow ideally includes making a vessel at least about halfway-patent, or 50% of diameter of a vessel being open. According to other embodiments, the channel created may be a cerebral equivalent of thrombolysis in myocardial infarction TIMI 1, TIMI 2, or TIMI 3.

[0064] Restoration of blood flow may act as a natural lytic agent and many emboli may begin to dissolve. Revascularization device **124** is designed, according to embodiments, to radially filter larger pieces of the dissolving embolus and prevent them from traveling distal to the device and potentially causing occlusion in another location. Because the revascularization device provides continuous radial pressure at the location of the obstruction, as the embolus dissolves, the blood flow continues to increase.

[0065] After the embolus is lysed, revascularization device **124** is sheathed into outer catheter **112** and removed from the body. According to embodiments, larger pieces of the thrombus may be retracted with revascularization device **124** after being captured in the radial filtering process. According to embodiments, revascularization device **124** may be detachable whereby the revascularization device **124** may detach from catheter-based revascularization system **100** if it is determined that revascularization device **124** should remain in the patient. As discussed above, illustrated in the Figures, and claimed below according to embodiments, catheter-based revascularization system **100** reconstrainable attachment or attachment by tether may be optionally detachable. Revascularization device detachment methods comprise mechanical, electrical hydraulic, chemical, thermal, and those other uses known to artisans.

[0066] According now to FIG. **6**, delivery tube **200** deploys tethered cage-like device/temporary stent **201** prior to embolization, using standard over-the-wire (OTW) system **199**.

[0067] According to the disclosure, a temporary tethered cage-like structure/tethered stent **201** is non-detachable in some embodiments but attached either to a hypotube or guide wire **199** allowing it to be navigated into tortuous vasculature in the brain. Device **201** may be attached to guide wire **199** or tube **200**.

[0068] FIG. **7** likewise provides further details of the instant system, with tethered cage-like structure/temporary stent **201** being released from delivery tube **200** using known OTW techniques.

[0069] The delivery tube **200** is a variable stiffness tube that is able to track to and through the tortuous anatomy or the cerebral vasculature (i.e., internal carotid artery, MCA, ACA, vertebral and basilar).

[0070] The delivery tube **200** can be one or two pieces but must have greater proximal pushability (stiffness) & greater distal flexibility (softness) to allow tracking to distal cerebral arteries.

[0071] The delivery tube **200** should also have a lumen that enables tracking over a guide-wire. This feature provides a few benefits; ability to track and be delivered; ability to maintain access in the event different size devices need to be exchanged; provide support to arterial tree during device deployment and recovery. A flexible device may tend to herniate or prolapse into openings. The guide wire provides a pathway (concentric) to the artery and supports the device preventing such technical complications.

[0072] The delivery tube **200** can be mechanically attached to the tethered stent by soldering, welding or press fitting. Likewise, those skilled in the art readily understand their attachment mechanisms.

[0073] The cage-like structure/stent is made of nitinol to allow it to be compressed and loaded into an introducer for packaging. Similarly memory-based materials likewise function, in accordance with the instant systems.

[0074] By attaching it to a delivery wire, the cage-like structure/stent can be placed, retracted, repositioned and recaptured into a microcatheter.

[0075] FIGS. **8**A-**8**D illustrate an embodiment of a revascularization device **800** configured for eccentric coupling to a pusher. The revascularization device **800** can be tethered to a pusher (e.g., wire or tube) by a plurality of tether lines **802** (also shown, for example, in FIGS. **2** and **2**A). In some embodiments, the revascularization device **800** is eccentrically coupled to the pusher (e.g., tethered off-center). In various embodiments, the revascularization device comprises an open proximal end and/or an open distal end and a generally cylindrical body (see, for example, FIGS. **2** and **2**A, **4**A-**4**C, and **5**-**7**).

[0076] While the apparatus and method have been described in terms of what are presently considered to be the most practical and preferred embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the broadest interpretation so as to encompass all such modifica-

tions and similar structures. The present disclosure includes any and all embodiments of the following claims.

[0077] It should also be understood that a variety of changes may be made without departing from the essence of the invention. Such changes are also implicitly included in the description. They still fall within the scope of this invention. It should be understood that this disclosure is intended to yield a patent covering numerous aspects of the invention both independently and as an overall system and in both method and apparatus modes.

[0078] Further, each of the various elements of the invention and claims may also be achieved in a variety of manners. This disclosure should be understood to encompass each such variation, be it a variation of an embodiment of any apparatus embodiment, a method or process embodiment, or even merely a variation of any element of these.

[0079] Particularly, it should be understood that as the disclosure relates to elements of the invention, the words for each element may be expressed by equivalent apparatus terms or method terms—even if only the function or result is the same.

[0080] Such equivalent, broader, or even more generic terms should be considered to be encompassed in the description of each element or action. Such terms can be substituted where desired to make explicit the implicitly broad coverage to which this invention is entitled.

[0081] It should be understood that all actions may be expressed as a means for taking that action or as an element which causes that action.

[0082] Similarly, each physical element disclosed should be understood to encompass a disclosure of the action which that physical element facilitates.

[0083] Any patents, publications, or other references mentioned in this application for patent are hereby incorporated by reference. In addition, as to each term used it should be understood that unless its utilization in this application is inconsistent with such interpretation, common dictionary definitions should be understood as incorporated for each term and all definitions, alternative terms, and synonyms such as contained in at least one of a standard technical dictionary recognized by artisans and the Random House Webster's Unabridged Dictionary, latest edition are hereby incorporated by reference.

[0084] Finally, all referenced listed in the Information Disclosure Statement or other information statement filed with the application are hereby appended and hereby incorporated by reference; however, as to each of the above, to the extent that such information or statements incorporated by reference might be considered inconsistent with the patenting of this/these invention(s), such statements are expressly not to be considered as made by the applicant(s).

[0085] In this regard it should be understood that for practical reasons and so as to avoid adding potentially hundreds of claims, the applicant has presented claims with initial dependencies only.

[0086] Support should be understood to exist to the degree required under new matter laws—including but not limited to United States Patent Law 35 USC 132 or other such laws—to permit the addition of any of the various dependencies or other elements presented under one independent claim or concept as dependencies or elements under any other independent claim or concept.

[0087] To the extent that insubstantial substitutes are made, to the extent that the applicant did not in fact draft any claim so as to literally encompass any particular embodiment, and to the extent otherwise applicable, the applicant should not be understood to have in any way intended to or actually relinquished such coverage as the applicant simply may not have been able to anticipate all eventualities; one skilled in the art, should not be reasonably expected to have drafted a claim that would have literally encompassed such alternative embodiments.

[0088] Further, the use of the transitional phrase "comprising" is used to maintain the "open-end" claims herein, according to traditional claim interpretation. Thus, unless the context requires otherwise, it should be understood that the term "comprise" or variations such as "comprises" or "comprising", are intended to imply the inclusion of a stated element or step or group of elements or steps but not the exclusion of any other element or step or group of elements or steps.

[0089] Such terms should be interpreted in their most expansive forms so as to afford the applicant the broadest coverage legally permissible.

What is claimed is:

1. A method of restoring blood flow through an obstructed blood vessel of the cerebral vasculature, comprising:

identifying an obstructed blood vessel within the cerebral vasculature of a patient, the obstructed blood vessel having an occlusive embolus;

inserting a catheter-based revascularization system within the obstructed blood vessel;

wherein the catheter-based revascularization system comprises an outer catheter and an inner catheter longitudinally moveable with respect to each other;

wherein the inner catheter comprises a pusher and a self-expandable revascularization device eccentrically tethered to a distal end of the pusher;

wherein the self-expandable revascularization device comprises a generally cylindrical body having an open proximal end, an open distal end, and a plurality of struts that form a plurality of cells between the proximal and distal ends;

positioning the outer catheter at a location distal to the embolus;

retracting the outer catheter to deploy the self-expandable revascularization device at the location of the embolus thereby compressing the embolus against a luminal wall of the blood vessel and restoring flow through the blood vessel;

wherein the restored blood flow facilitates natural lysis of the embolus;

wherein the natural lysis and compression of the embolus cause fragmentation of at least a portion of the embolus into a plurality of embolic fragments,

wherein one or more of said embolic fragments pass through the open distal end of the self-expandable revascularization device downstream of the embolus; and

wherein the self-expandable revascularization device exerts continuous radial pressure at the location of the embolus to further facilitate blood flow through the blood vessel as the embolus lyses;

resheathing the revascularization device within the outer catheter; and

removing the revascularization system from the patient.

2. The method of claim **1**, wherein the revascularization device is permanently tethered to a distal end of the pusher.

3. The method of claim 1, wherein the revascularization device is detachably tethered to a distal end of the pusher.

4. The method of claim 1, wherein the revascularization device comprises radiopaque markers configured for tracking of the revascularization device.

5. The method of claim 4, further comprising tracking the revascularization device to confirm proper positioning with respect to the embolus.

6. The method of claim 1, wherein deploying the self-expandable revascularization device at the location of the embolus comprises creating an immediate flow channel within the blood vessel of at least about 50% of the diameter of the blood vessel of the cerebral vasculature.

7. The method of claim 1, wherein the pusher comprises a variable-pitch hypotube.

8. The method of claim 1, wherein the pusher comprises a wire.

9. The method of claim 1, wherein at least a portion of said inner catheter comprises a flexible material configured to permit flexion and extension to navigate through curved vessels of the cerebral vasculature.

10. The method of claim 1, further comprising infusing lytic agents to the location of the embolus through the revascularization system.

11. The method of claim 1, further comprising removing at least a portion of the embolus captured by the revascularization device.

12. The method of claim 1, wherein the revascularization device comprises a self-expanding microstent.

13. The method of claim 1, further comprising morselizing at least a portion of the embolus by mechanical manipulation of the revascularization device.

14. The method of claim 1, wherein inserting the catheter-based revascularization system within the obstructed blood vessel comprises advancing the revascularization system over a guidewire proximate a location of the embolus.

15. A method of restoring blood flow through an obstructed blood vessel of the brain to treat acute ischemic stroke, comprising:

identifying an obstructed blood vessel within the cerebral vasculature of a patient, the obstructed blood vessel having an embolus;

inserting a catheter-based revascularization system within the obstructed blood vessel;

wherein the catheter-based revascularization system comprises an outer catheter and an inner catheter longitudinally moveable with respect to each other;

wherein the inner catheter comprises a pusher and a self-expandable revascularization device tethered to a distal end of the pusher;

wherein the self-expandable revascularization device comprises an open proximal end, an open distal end, and a plurality of struts that form a plurality of cells between the proximal and distal ends;

positioning the outer catheter at a location distal to the embolus;

retracting the outer catheter, thereby deploying the self-expandable revascularization device at the location of the embolus, thereby compressing the embolus or lesion against a luminal wall of the obstructed blood vessel and restoring flow through the obstructed blood vessel;

wherein the restored blood flow facilitates natural lysis of the embolus;

wherein the natural lysis and compression of the embolus cause fragmentation of at least a portion of the embolus into a plurality of fragments,

wherein one or more of said fragments pass through the open distal end of the self-expandable revascularization device downstream of the embolus; and

wherein the self-expandable revascularization device exerts continuous radial pressure at the location of embolus to further facilitate blood flow through the blood vessel as the embolus lyses;

resheathing the revascularization device within the outer catheter; and

removing the revascularization system from the patient.

16. The method of claim 15, wherein the self-expandable revascularization device is generally cylindrical and eccentrically tethered to the distal end of the pusher via a plurality of tethered lines.

17. The method of claim 15, further comprising morselizing at least a portion of the embolus by mechanical manipulation of the revascularization device.

18. The method of claim 15, further comprising removing at least a portion of the embolus captured by the revascularization device.

19. The method of claim 15, wherein deploying the self-expandable revascularization device at the location of the embolus comprises creating an immediate flow channel within the blood vessel of at least about 50% of the diameter of the blood vessel of the cerebral vasculature.

20. The method of claim 15, wherein inserting a catheter-based revascularization system within the obstructed blood vessel comprises advancing the revascularization system over a guidewire proximate a location of the embolus.

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