${\bf (19)}\ World\ Intellectual\ Property\ Organization$

International Bureau





(43) International Publication Date 9 July 2009 (09.07.2009) CT (10) International Publication Number WO 2009/086154 A2

- (51) International Patent Classification:

 A61B 17/22 (2006.01) A61M 25/01 (2006.01)

 A61M 25/08 (2006.01)
- (21) International Application Number:

PCT/US2008/087759

(22) International Filing Date:

19 December 2008 (19.12.2008)

- (25) Filing Language: English
- (26) Publication Language: English

(30) Priority Data:

61/015,154	19 December 2007 (19.12.2007)	US
61/044,392	11 April 2008 (11.04.2008)	US
12/123,390	19 May 2008 (19.05.2008)	US
61/057.613	30 May 2008 (30.05.2008)	US
12/182,370	30 July 2008 (30.07.2008)	US
,	5 \	

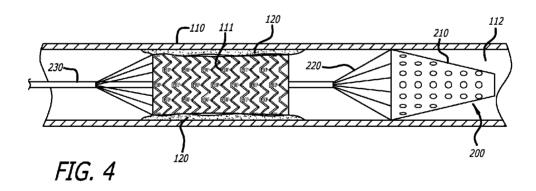
- (71) Applicant (for all designated States except US): MIND-FRAME, INC. [US/US]; 26429 Rancho Parkway South, #140, Lake Forest, CA 91630 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): FERRERA, David, A. [US/US]; 2502 Mackay Lane, Redondo Beach, CA 90278 (US). FULKERSON, John [US/US]; 10 La Sinfonia, Rancho Santa Margarita, CA 92688 (US).

- (74) Agent: GLUCK, Peter, J.; Greenbert Traurig, LLP, 2450 Colorado Avenue, Suite 400E, Santa Monica, CA 90404 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

 without international search report and to be republished upon receipt of that report

(54) Title: IMPROVED DEVICES AND METHODS FOR EMBOLUS REMOVAL DURING ACUTE ISCHEMIC STROKE



(57) Abstract: Devices, methods, and systems facilitate and enable treatment of ischemic stroke. More specifically, a tethered basket-like system operates in conjunction with a microcatheter system, to provide arterial support and capture emboli.



IMPROVED DEVICES AND METHODS FOR EMBOLUS REMOVAL DURING ACUTE ISCHEMIC STROKE

BY

DAVID A. FERRERA, REDONDO BEACH, CA

AND

JOHN FULKERSON, RANCHO SANTA MARGARITA, CA

ASSIGNED TO

MINDFRAME, INC.

RELATED APPLICATIONS

[0001] This application claims the Paris Convention Priority of and fully incorporates by reference, Application Serial No. 61/015,154, filed on December 19, 2007; Application Serial No. 61/044,392, filed on April 11, 2008; Application Serial No. 61/057,613, filed on May 30, 2008; U.S. Utility Application Serial No. 12/123,390, filed on May 19, 2008; and U.S. Utility Application Serial No. 12/182,370, filed on July 30, 2008, by the present and the instant assignee. This application fully incorporates by reference, U.S. Provisional Application Serial No. 60/980,736, filed on October 17, 2007 and Application Serial No. 60/987,384, filed on November 12, 2007 as if fully set forth herein.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to minimally invasive and catheter delivered embolic capture devices for use in the vasculature, especially those suited for usage in the brain and vessel systems perfusing the same.

[0003] Several acute stroke therapy trials were reported in 2007. Interventional Management of Stroke (IMS) II found a 9.9% rate of symptomatic intracerebral

1

hemorrhage after combination IV-intra-arterial (IA) tissue-type plasminogen activator therapy was administered within 3 hours of acute stroke onset.

[0004] Further results from the MERCI and Multi-MERCI investigators have shown that successful recanalization of acute distal ICA and proximal middle cerebral artery occlusions can be achieved in 53% to 63% of patients using the MERC1 retriever (Concentric Medical) alone or in combination with 1V/IA thrombolytics, yet symptomatic hemorrhages occurred in 6% of those patients who recanalized.

[0005] Another approach in those who fail MERCI retrieval has been to use angioplasty or self-expanding stents to compress friable clot and allow better penetration of thrombolytic agents. Recanalization rates of up to 89% with balloons and 79% with stents have been achieved in small numbers of patients.

[0006] Reports of aggressive revascularization of acute ICA and tandem ICA/middle cerebral artery occlusions using stents and intracranial thrombolysis have demonstrated the feasibility of this approach, again in small numbers of patients.

[0007] Attempts to identify prognostic factors for hemorrhagic complications and eventual clinical outcomes in patients undergoing these aggressive multimodal interventions showed that residual distal occlusions, tandem occlusions, larger initial pretreatment CT infarct size by Alberta Stroke Program Early CT Score (ASPECTS) score, hyperglycemia and use of both IA and IV thromholytics were all associated with negative results. Novel mechanical revascularization strategies used deflated microballoon catheters and the Alligator retrieval device (Chestnut Medical Technologies) to open vessels that may be refractory to IA thrombolytics or the MERCI device.

[0008] There are new stents being used to assist in the coiling of wide-necked aneurysms, such as the closed-cell design Enterprise (Cordis Neurovascular, Inc), the electrodetachable, fully retrievable Solo (eV3 Neurovascular) and the covered, balloon-expandable Willis (Microport). Development of significant focal stenosis remains a problem, seen in up to 5.8% of stent-assisted cases. A novel approach is to use a high-

coverage, endoluminal mesh to divert flow and thus induce aneurysm thrombosis. The Pipeline Neuroendovascular Device (Chestnut Medical Technologies) is a tubular, bimetallic implant with approximately 30% coverage by area. Preliminary experience in humans has bees encouraging.

[0009] It is hoped that immunohistochemical and molecular biological data can be used to develop biologically active endovascular devices in the future. A novel method for depositing viable, migration capable fibroblasts on coils and successfully passing them through microcatheters may be a promising technique for endovascular intervention.

[0010] Intra-arterial (IA) therapies for acute stroke have evolved over the past decade. Despite the promising results of 1 PROACT 11, which demonstrated a 66% recanalization rate, substantially higher recanalization rates with IA pharmacologic thrombolysis have not been achieved over the past 7 years. The Food and Drug Administration recently approved a clot retrieval device (Merci retriever X5, X6; Concentric Medical, Mountain View, CA). Unfortunately, when used alone, the clot retriever is successful in only approximately 50% of 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 reperfused infarction. There have been several reports of coronary stent implantation used for mechanical thrombolysis of recalcitrant occlusions. In a recent report, stent placement with balloon-mounted or selfexpanding coronary stents was shown to be an independent predictor for recanalization of both intracranial and extracranial cerebrovascular occlusions. In another recent report, recanalization rates of 79% were achieved using balloon-mounted stent technology.

[0011] Self-expanding stents designed specifically for the cerebrovasculature can he 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. There has been an

anecdotal report of the use of a self-expanding stent in the setting of acute symptomatic intracranial occlusion. In addition, a recent comparison of self-expanding and balloon-mounted stents in an animal model of acute embolic occlusion has shown no difference in the 2 stent groups with respect to recanalization rates.

[0012] This retrospective multicenter series demonstrates that 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 was successfully obtained in 79% of the lesions in which stents were placed. This retrospective review suggests that focal occlusions limited to a single medium or large vessel, particularly solitary occlusions of the MCA or VBS, 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 implantation: TIMI/TICI 2 or 3 flow was documented in all female patients studied, and female patients were more likely to achieve improved clinical outcomes as measured by NIHSS and mRS scores. Most importantly, our preliminary experience may lead to future pivotal studies that might aid clinicians to better stratify patients most likely to derive maximal clinical benefit from stent placement.

[0013] The use of other mechanical means has been reported to be effective in recanalization of acute occlusions. In the MERCI trial, overall recanalization rates TIMI/TICI 2 or 3 flow) of 48% were achieved with the Merci mechanical clot retriever.

[0014] Several authors have proposed endovascular treatment with stent deployment for ICA dissection with high-grade stenosis or occlusion when anticoagulation fails to prevent a new ischemic event. In these cases, the MCA was patent.

[0015] We found that stent-assisted endovascular thrombolysisithrombectomy compared favorably with IV rtPA thrombolysis.

[0016] This higher rate of MCA recanalization could be explained by carotid flow restoration, allowing direct access to the MCA thrombus.

[0017] Endovascular treatment could potentially extend the therapeutic window beyond 3 hours. Actually, in all cases in the endovascular group, MCA recanalization was obtained by 291 minutes.

[0018] 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 been observed, as they were in stenting of other cases of arteriopathy. In our series, 1 embolic stroke and 1 acute in-stent thrombosis occurred in the same patient. Despite this new infarction, we observed significant neurologic improvement in this patient, probably because the MCA remained patent. Late stent thrombosis has also been reported.

SUMMARY OF THE INVENTION

[0019] Devices, methods, and systems facilitate and enable treatment of ischemic or hemorrhagic stroke. More specifically, a tethered basket-like system operates in conjunction with a microcatheter system, to provide arterial support and capture emboli.

[0020] According to a feature of the present invention, a device for the removal of emboli is disclosed comprising a mesh capturer having at least an undeployed state and a deployed state, the mesh capturer being inserted into the neurovasculature in an undeployed state and removed from the microvasculature in its deployed state; wherein the mesh capturer is deployed into its deployed state distal to an embolus and advanced proximally until the embolus is substantially contained within the mesh capturer; and wherein the basket is deployed above the subclavian artery and common carotid artery.

[0021] According to a feature of the present invention, a method for removing an embolus is disclosed comprising inserting a microcatheter and guidewire distal to an embolus; inserting a embolus capture device over the wire through the microcatheter distal to the embolus; deploying the embolus capture device; retracting the deployed

embolus capture device until the embolus is substantially contained within the embolus capture device; and removing the embolus capture device.

BRIEF DESCRIPTION OF THE FIGURES

[0022] The above-mentioned features and objects of the present invention 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:

[0023] Fig. 1 shows a side view schematic of a microcatheter with wire passing an embolus;

[0024] Fig. 2 shows a cross-sectional schematic of an embodiment of a microcatheter wire passing by an embolus at a point of least resistance;

[0025] Fig. 3 is a side view of an embodiment of a device for capturing emboli according to the present invention comprising a basket for capturing the embolus;

[0026] Fig. 4 is a side view of an embodiment of a device for capturing emboli according to the present invention used as a safety device in a reperfusion operation; and

[0027] Fig. 5 is a flow diagram of an embodiment of a method wherein an embolus is removed from a patient after a reperfusion operation is unsuccessful.

DETAILED DESCRIPTION OF THE INSTANT TEACHINGS

[0028] In the following detailed description of embodiments of the invention, reference is made to the accompanying drawings in which like references indicate similar elements, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that logical, mechanical, biological, electrical, functional, and other changes may be made without departing from the scope of the

present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined only by the appended claims. As used in the present invention, the term "or" shall be understood to be defined as a logical disjunction and shall not indicate an exclusive disjunction unless expressly indicated as such or notated as "xor."

[0029] The ideal stent for intracranial use would he flexible, precisely delivered, retrievable, able to be repositioned, atraumatic, available in various lengths and diameters, thin-walled and radiopaque. It should provide sufficient coverage to restrain coils, while having wide enough fenestrations to permit catheterisation with coil or other embolic agent delivery catheters. The currently available over-the-wire stents are not ideal. The balloon-expandable stents of sufficient length are too stiff to be reliably and safely deployed. While existing self-expanding stents offer some improvement in this respect there are still serious difficulties in deploying them in distal locations and the currently available or planned stents for intracranial use are not available in the small diameters necessary for distal intracranial use.

[0030] The stent is delivered through a micro-catheter, allowing standard microcatheter/wire techniques to reach locations inaccessible to over-the-wire stents. It fulfils all the criteria mentioned above. A particularly appealing characteristic is its ability to be retrieved and repositioned after complete delivery, if its position is felt to be suboptimal or if the stent proves not to be necessary. The stent conforms completely to the normal vessel geometry and is not prone to strut opening on convexities. It is compatible with all currently used embolic agents for aneurysm occlusion and is MR compatible.

[0031] Stents have been used widely in occlusive lesions in the peripheral, renal, and coronary arteries to treat stenosis of vessels narrowed by a variety of pathologic conditions. Initially used mainly in extracranial cerebral vessels for carotid artery stenosis or the treatment of pseudoaneurysms of the extracranial carotid artery, small stents are now increasingly used for intracranial vessel disease such as the treatment of wide-necked aneurysms not amenable to conventional endovascular techniques.

[0032] Major limitations of the currently available stents, usually cardiac stents, however, are their relatively stiffness, rendering them not flexible enough to pass the Cl /C2 vertebral artery or carotid siphon tortuousities.

[0033] The design constraints for the device used in this study were to develop an endovascular stent that is flexible enough to be delivered via a microcatheterand to be placed in small vessels but with sufficient radial forces to conform to the vessel wall when deployed.

[0034] Leaving the guidewire in place after stent deployment in curved vessels might be an option to stabilize the stent and thus prevent stent displacement while catheterizing the aneurysm with a second microcatheter. In contrast to the Neuroform, because of the design of our stent displacement should not be an issue.

[0035] The present inventors have realized that by leveraging a conventional self-expanding reperfusion device delivery platform, a poly-modic system can be iterated which crosses a embolus, 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. The instant system allows for natural lysis, perfusion of the challenged vessels, and importantly filters any particulates generated, to obviate the need to be concerned with distal migration of the particulates generated.

[0036] The present invention relates to emboli removal devices used to treat, among other things, ischemic stroke. Naturally, therefore, the emboli removal devices of the present invention are designed to be used in neuro-type applications, wherein the specifications of the present catheters and emboli removal devices may be deployed in the blood vessels of the cerebral vascular system. Similarly contemplated for the emboli removal systems and catheters of the present invention is deployment in other parts of the body wherein the specifications of the present invention may be used in other vessels of the body in a non-invasive manner. Specifically, the inventors of the present invention have devised devices and methods of the removal of neurocranial emboli

without causing distal complication arising from the passing of larger pieces of a recovered embolus distal to the location of the original embolus.

[0037] According to embodiments, disclosed herein is a catheter-emboli removal system. The emboli removal devices of the present invention are for reperfusion of blood vessels. When the catheter-emboli removal system of the present invention is deployed into a blood vessel having an embolus, the emboli removal device is expanded and moved proximally along the vessel so that the embolus is substantially contained with the mesh basket of the emboli removal device.

[0038] According to the instant teachings, deployment of the system of the present invention establishes immediate 50% of the diameter of the lumen patency of the vessel being addressed by removing the embolus occluding the vessel. Among the prior art, no system having adequately small profile with flexibility to promote improved access for insite treatment is known which may be used as a temporary (not implanted) solution and removed without substantial damage to the vasculature.

[0039] Additionally, in reperfusion applications the emboli removal device may be deployed as a safety device. As the embolus lyses, the deployed emboli removal device filters larger embolus particles from migrating distally, thereby reducing the chances of further complications. If reperfusion is unsuccessful, then the emboli removal device is retracted proximally, thereby substantially capturing the embolus. Then the entire device is removed together with the microcatheter.

[0040] According to embodiments and as illustrated in Fig. 1, a cross sectional view of an artery 110 having embolus 120 in artery lumen 112 is shown. Guidewire 130 inserted through a thrombus tends to follow the path of least resistance through the softest parts of embolus 120. When a microcatheter is inserted along guidewire 130, it likewise follows this path of least resistance. Accordingly, when a stent or embolus capture device is inserted via guidewire 130, it is deployed offset because guidewire 130 is not centered in the vessel in many cases, as illustrated in Fig. 2. Those skilled understand how struts of the line subject devices enable recapturability, flexibility and tracking.

[0041] To address the problem of the guidewire offset, the inventors devised an embolus capture device or basket 200 that is adept at capturing embolus 120 even when deployed in an offset way. As part of the embolus capture device/basket 200 design, pieces of embolus 120 that break away from embolus 120 are recaptured to prevent potential migration more distal in the vasculature which may potentially cause other emboli, too remote to safely address.

[0042] As illustrated in Fig. 3, blood vessel 110 is shown having vessel lumen 112 and embolus 120. As illustrated, embolus capture device/basket 200 is deployed for capture of embolus 120. As illustrated, embolus capture device/basket 200 is deployed along an offset guidewire. However, embolus capture device 200 is designed for offset deployment to deploy such that it occupies about the center of vessel 110, which ensure maximum efficiency in the capture of embolus 120. It will be readily recognized that the devices of the present invention need not be deployed offset.

[0043] Embolus capture device/basket 200 comprises mesh basket 210 and tethers 220 which are deployed from microcatheter 230. Mesh basket 210 comprises a radially expandable woven mesh or coil basket open on the proximal end and closed at the distal end. The mesh may be made from materials well known and understood by artisans, including polymers, flouropolymers, nitinol, stainless steel, vectran, or kevlar. Other biocompatible materials that may be woven or coiled are similarly contemplated. Mesh basket 210 connects to microcatheter 230 via tethers 220 and is designed to be compatible such that it is removable in its deployed state without causing dissection or other damage to the vasculature.

[0044] Mesh basket 210 comprises a plurality of individual cells, having a uniform size or spacing geometry or a variable size or spacing geometry. According to embodiments where the size or spacing geometry is variable, smaller size or spacing geometry is used to provide a tight mesh for preventing the passage of small pieces of embolus 120 that break away. Larger size or spacing geometry units allow from blood flow 110. In all cases, size or spacing geometry will not allow pieces of embolus 120 that may cause potential complications.

[0045] Tethers 220 serve to provide structure for mesh basket 110, while providing large openings whereby blood may freely flow from the proximal to distal end of embolus removal device/basket 200. According to embodiments, tethers 220 are made from the same material as mesh basket 210. Those skilled in the art will readily understand that materials for tethers and mesh may be the same, different, or interchangeable, as needed.

[0046] During deployment of embolus capture device/basket 200, mesh basket is stored in microcatheter 230 in an undeployed state. In the undeployed state, microcatheter 230 is advanced distal to embolus 120 and mesh basket 210 is deployed. According to embodiments, both mesh basket 210 and tethers 220 are deployed distal to embolus 120 to prevent tethers 220 from dislodging pieces of embolus 120 prior to full expansion of mesh basket 210, thereby preventing the pieces from advancing distal to the embolus 120 before mesh basket 210 is in place to filter them.

[0047] After deployment, according to embodiments, embolus removal system 200 is retracted proximally until embolus is substantially contained within mesh basket 210. Thereafter, mesh basket 210 and microcatheter 230 are removed from the vasculature of the patient. During removal of mesh basket 210 and microcatheter 230, embolus 120 is trapped within mesh basket 210 and withdrawn from vessel 110.

[0048] According to embodiments, microcatheter 230 length and diameter are suitable for inserting into a human patient and capable of reaching a target embolus in the region above the subclavian and common carotid arteries. For example, according to embodiments, microcatheter 230 is about 150 cm long; microcatheter has a proximal segment (at a control end of microcatheter 230) that is about 115 cm long with an outer diameter of about 3.5 French and a distal segment (at a deployment end of microcatheter 230) is about 35 cm with an outer diameter of about 2.7 French. The inventors contemplate, according to embodiments a gradual decrease or stepwise in the outer diameter dimension as a function of the distal distance from proximal segment, according to embodiments. For example, proximal segment is 3.5 French at the most proximal end and distal segment is 2.7 French at the most distal end. Disposed

between is a segment having one or more intermediate outer diameters between 3.5 French and 2.7 French, such as 3.2 French and 3.0 French. The inner diameter of microcatheter 230 is 0.012 to .029 inches, according to embodiments, which allows microcatheter to be inserted along a preinserted guidewire or used to infuse therapeutic agents. According to embodiments, the performance of microcatheter 230 is comparable to standard microcatheters 230 and is designed to track over a guidewire through the neuro-vasculature.

[0049] As illustrated by embodiments in Fig. 4, embolus capture device/basket 200 may be deployed concurrently with a tethered reperfusion device 111. As embolus 120 is reperfused with reperfusion device 111, embolus capture device/basket 200 provides a safety feature whereby pieces of embolus 120 that break away are captured in mesh basket 210 and removed with the reperfusion device generally. Additionally, as vessel 110 reperfuses due to natural lytic action, mesh basket 210 provides a minimum particle size permitted to pass distal to embolus capture device/basket 200. Consequently, embolus capture device/basket 200 prevents further complications distal to the original site of the occlusion by preventing larger embolus 120 pieces or particles from passing deeper into the neurovasculature and occluding it in more distal locations.

[0050] Alternately and as illustrated according to embodiments in Fig. 5, reperfusion device is used after reperfusion is unsuccessfully attempted or not successful to the desired level. Accordingly, microcatheter is inserted into the neurovasculature in operation 502 as well known and understood by artisans. Reperfusion is attempted, for example with the reperfusion device 210 of Fig. 4 in operation 504 of Fig. 5. After reperfusion is attempted, the success is determined in operation 506. For example, a contrast dye is used to determine the level to which the occluded vessel is reperfused, as is well known to artisans.

[0051] If reperfusion is not successful to a desired degree, then embolus capture device/basket 200 is inserted through the microcatheter as described herein and deployed distal to the embolus 120. For example, creating a channel for flow ideally includes making a vessel at least about halfway-patant, or 50% of diameter of a vessel

being open. According to embodiments, the channel created may be a cerebral equivalent of thrombolysis in myocardial infarction (TIMI) 0, TIMI 1, or TIMI 2, TIMI 3, and thrombolysis in cerebral infarction (TICI) and TICI 3In these cases, blood flow is not accomplished to a desired degree. It is therefore desirable to remove the entire embolus. Thus, after embolus capture device/basket 200 is deployed distal to the embolus, it is retreated proximal until embolus 120 is substantially inside of mesh basket 210 in operation 512. Thereafter, mesh basket 210, embolus 120, and microcatheter 230 are removed.

[0052] The embolus capture devices of the present invention may be designed for over the wire deployment or rapid exchange deployment, according to embodiments.

[0053] Expressly incorporated herein by a conference as if fully set forth herein are U.S. Letters Patents Number 5,928,260 and 5,972,219 along with 7,147,655; 7,160,317; 7,172,575; 7,175,607; and 7,201,770.

[0054] 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 invention 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 modifications and similar structures. The present invention includes any and all embodiments of the following claims.

[0055] 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 invention 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.

[0056] Further, each of the various elements of the invention and claims may also be achieved in a variety of manners. This invention 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.

[0057] Particularly, it should be understood that as the invention 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.

[0058] 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.

[0059] 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.

[0060] Similarly, each physical element disclosed should be understood to encompass a invention of the action which that physical element facilitates.

[0061] 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.

[0062] Finally, all referenced listed in the Information Invention 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).

[0063] 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.

[0064] 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.

[0065] 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.

[0066] 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 "compromise" 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.

[0067] Such terms should be interpreted in their most expansive forms so as to afford the applicant the broadest coverage legally permissible.

CLAIMS

1. An improved device for the removal of emboli comprising:

a mesh capturer/basket having at least an undeployed state and a deployed state, the mesh capturer being inserted into the neurovasculature in an undeployed state and removed from the microvasculature in its retracted state;

wherein the mesh capturer is deployed into its deployed state distal to an embolus and advanced proximally until the embolus is substantially contained within the mesh capturer;

wherein the mesh capturer/basket is deployed above the subclavian artery and common carotid artery.

- 2. The improved device of claim 1, wherein said mesh capturer/basket is eccentric.
- 3. The improved device of claim 2, whereby the eccentricity of said mesh capturer/basket at the proximal end improves capture of emboli and clots because of its geometric configuration.
- 4. The improved device of claim 3, further comprised of uniformly sized struts.
- 5. The improved device of claim 3, comprising struts having increased thickness adjacent to the proximate end.
- 6. The improved device of claim 4, having radiopacity at a distal end of the device.
- 7. The improved device of claim 6, said radiopacity further comprised of at least a peg, selected from the group consisting of platinum and gold, the peg being pressed into pre-laser cut apertures.

- 8. The improved device of claim 7, further comprising:a proximal stainless steel pusher and distal nitinol device.
- 9. The improved device of claim 8, wherein a polymeric liner is incorporated within the pusher to improve guidewire trackability.
- 10. The improved device of claim 9, where the polymeric liner is extended beyond the distal tip of the pusher to a length greater than the length of the nitinol device.
- 11. The improved device of claim 10 whereby guidewire entanglement in the nitinol device is prevented, by the extended polymeric liner.
 - 12. The improved device of claim 11, further comprising uniform cells.
 - 13. A system for removing an embolus comprising:
 - a microcatheter configured to be inserted distal to an embolus;
- a embolus capture device configured to be inserted distal to the microcatheter distal to the embolus;

wherein the embolus capture device is configured to be deployed;

wherein the deployed embolus capture device is configured to be retracted until the embolus is substantially contained within the embolus capture device; and

wherein the embolus capture device is configured to be removed.

- 14. The system of claim 13, wherein the embolus capture device is configured to be deployed over a guidewire.
- 15. The system of claim 14, wherein the embolus capture device is configured to be deployed as a component of a rapid exchange system.
 - 16. The system of claim 14, wherein a foreign body is the target of removal.

- 17. the system of claim 16, wherein the foreign body is a microcoil.
- 18. The system of claim 16, wherein said foreign body is a medical device.
- 19. The system of claim 16 wherein the said foreign body is a kidney stone.
- 20. The system of claim 16, wherein the said foreign body is a gallstone.

1/3

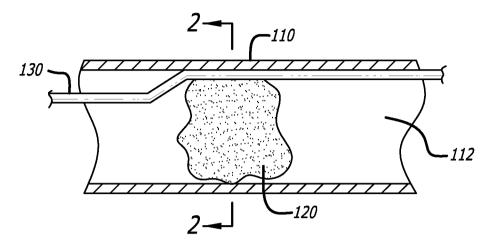


FIG. 1

