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(54) Title: NEUROVASCULAR MICROCATHETER DEVICE, SYSTEM AND METHODS FOR USE THEREOF

(57) Abstract: The present invention relates to neurovascular thrombectomy devices that include an occlusion microcatheter and fluid-assisted microcatheter fitted within the occlusion microcatheter. Also provided are systems and methods for neurovascular thrombectomy using the devices of the invention.

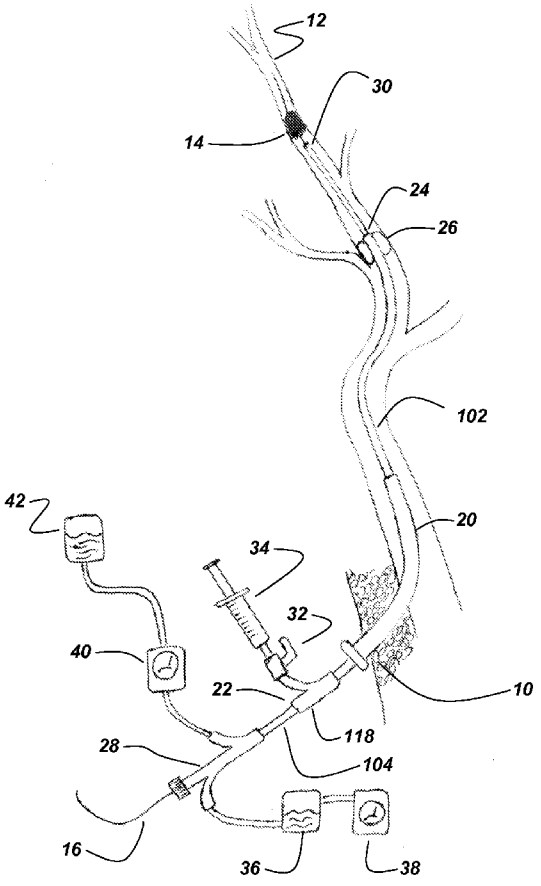

FIG. 1

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NEUROVASCULAR MICROCATHETER DEVICE, SYSTEM AND METHODS FOR USE THEREOF

RELATED APPLICATIONS

[0001] This application claims the benefit of priority under 35 USC §119 of U.S. Provisional Applications Serial No. 61/151,678 filed February 11, 2009, the entire disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to neurovascular catheters. Specifically, the invention relates to microcatheters and more particularly fluid jet assisted microcatheter systems for removal of organized and non-organized thrombetic material from occluded blood vessels.

BACKGROUND OF THE INVENTION

[0003] Thrombetic material occlusion or blood clots are the leading cause of neurological organ failure or brain damage, in the form of ischemic stroke, accounting for 85% of stroke incidents. More than 700,000 people in the U.S are affected by initial or recurrent ischemic stroke every year, with about 1 incident occurring every 45 seconds. The cost to treat stroke patients is over $56 billion dollars per year, and yet more than half of these patients die while the surviving patients may suffer long-term disability requiring continuing care and reducing quality of life.

[0004] Current treatment options for thrombetic occlusion include pharmaceutical intervention (e.g. administration of tissue plasminogen activators (tPAs)) and surgical thrombus removal strategies. For most patients (approximately 95%), tPAs are not a viable treatment due to clinical preconditions and delays in receiving treatment, which is limited to a three hour limited use window as the thrombetic burden becomes too organized for pharmaceutical treatment thereafter.

[0005] Surgical interventions utilize catheter-based devices for removing obstructions from small blood vessels including simple aspiration devices that pull thrombus into an evacuation tube; mechanical devices that utilize a wire, basket or coil to grab and extract thrombus; and devices that combine aspiration with a mechanical element. Fluid-assisted thrombus removal devices spray jets of saline or pharmaceutical formulations to facilitate thrombus removal while ultrasonic devices disrupt occluding thrombus using sound waves. Each of these types of devices is limited in effectiveness for various situations and involves inherent risks associated with the particular design.

[0006] **Aspiration Devices**. Simple aspiration devices are effective in removing only the most acute levels of thrombus and they do not extend the treatable period for ischemic stroke beyond the current pharmaceutical options. Simple aspiration devices tend to become blocked with thrombus which limits their effectiveness and can create treatment complications. Generally, simple aspiration catheters are limited to use in larger vessels not normally associated with neurovascular treatment.

[0007] **Mechanical Disruption Devices**. Mechanical thrombus removal devices use a physical capture element (e.g., wire, coil, basket) to contain thrombetic material for removal. Such devices are more suitable for removing organized thrombus than aspiration devices, thereby extending the time these devices can be used in stroke intervention strategies.

[0008] The primary limitation of mechanically-assisted devices is that the thrombus capture element needs to be deployed distally to the occluding thrombus. The act of passing the capture mechanism through and beyond the occluding thrombus will often break thrombetic material away from the primary thrombus site. Uncontrolled disruption risks distal embolism formation in the brain, lungs and other vital organs as thrombetic fragments travel within the circulation and may lodge in distant sites. Moreover, mechanical devices typically contact vessel walls, which can result in hemodynamic stress, intimal damage to the vessel wall, and in worst cases vessel perforation leading to hemorrhagic ischemia.

[0009] **Ultrasound Devices**. Ultrasound technology has also been used to open blocked or restricted arteries. However, ultrasonic devices are expensive, bulky and must also cross the thrombus target site, risking dislodging emboli as described above. The distal end of ultrasound devices has a relatively large profile, making them unsuitable for maneuvering through tortuous vasculature, such as found in the brain.

[0010] **Fluid-Assisted Devices**. Devices that use jets or sprays of saline or other fluids to dislodge thrombus can deliver the fluid within the catheter (internal devices) or dispense it from the catheter into the vessel (external devices). External devices that spray saline outward to dislodge thrombus from the vessel wall are inherently unsuitable for use in the small vessels of the neurologic field because they risk hemodynamic stress and intimal damage to the vessel wall. Internal jets can be used to emulsify or macerate occluding thrombus, for example, by providing a back-spray that is advanced beyond the thrombus and forces thrombetic material into the device catheter. Such devices can be complicated and bulky, and thus have limited applicability and effectiveness in neurovascular situations.

[0011] In addition, the overall instrument and procedural design must be contemplated for neurovascular surgical intervention as the catheter alone is not useful. In order to treat neurovascular regions for ischemic stroke it is often desirable to restrict blood flow immediately proximal to the occluding thrombus. Although systems and devices are available to perform this task, they are also limited by design drawbacks that can cause clinical complications. When blood flow restriction is available, the system must also assess and carefully control the method and rate at which reperfusion occurs following the procedure. If the reperfusion of the treated area is too rapid, vessel hemorrhage or further ischemic events may occur.

[0012] Thus, there is a continued need in the art for improved thrombus removal devices and methods that can be safely used in the neurovasculature to effectively remove blood clots without leading to serious complications.

SUMMARY OF THE INVENTION

[0013] The present invention provides a neurovascular thrombectomy device that includes a generally tubular, hollow occlusion microcatheter having a distal end adapted for vascular occlusion and a proximal end adapted for controlling said vascular occlusion; and a generally tubular fluid-assisted microcatheter fitted within said occlusion microcatheter having a distal end adapted for fluid-assisted thrombus removal and a proximal end adapted for controlling said fluid-assisted thrombus removal.

[0014] The fluid-assisted microcatheter is a generally hollow tubular body defining an evacuation path, where the hollow body includes an inner lumen and an outer lumen defining a sealed fluid delivery intra-luminal space. The fluid-assisted microcatheter can, for example, be slidably fitted within the occlusion microcatheter.

[0015] In certain embodiments, the neurovascular thrombectomy device includes a fluid access port in fluid communication with the fluid delivery intra-luminal space; and a fluid jet orifice disposed near the distal end of the inner lumen, which can deliver fluid under high pressure through the fluid delivery intra-luminal space to the fluid jet orifice and into the evacuation path.

[0016] In certain embodiments, the open distal end of the fluid-assisted microcatheter is generally perpendicular to the length of the neurovascular thrombectomy device, thereby forming a round aspiration orifice. In other embodiments, the distal end of the fluid-assisted microcatheter is angled 45 degrees relative to the length of the neurovascular thrombectomy device thereby forming an oval aspiration orifice. In certain of such embodiments, the fluid jet orifice can deliver fluid directly into the oval aspiration orifice when it is located.

[0017] The occlusion microcatheter will typically include an occlusion balloon and may have a haemostatic seal in an opening at its proximal end.

[0018] The occlusion microcatheter will generally include an inner tubular member surrounding a working channel and an outer tubular member surrounding the inner tubular member, said outer tubular member and said inner tubular member together defining an inflation intra-luminal space. Typically, the working channel has a diameter sufficient to slidably accept the fluid-assisted microcatheter.

[0019] In certain embodiments, the occlusion microcatheter includes an inflation opening disposed on the outer tubular member, and an balloon surrounds the inflation opening and is sealably secured to the outer tubular member, such that the balloon is in fluid communication with the inflation intra-luminal space through the inflation opening. In other embodiments, the balloon is formed as a contiguous outpocketing of the outer tubular member. In yet further

embodiments, the balloon sealably bridges the outer tubular member and the inner tubular member. In certain aspects, the inner tubular member is longer than and extends distally beyond the outer tubular member to provide a narrower entry profile for the occlusion microcatheter.

[0020] At its proximal end, the occlusion microcatheter is optionally sealed with a haemostatic seal and adapted for controlling vascular occlusion, which may be accomplished using a three-way reperfusion valve. Optionally, the three-way reperfusion valve is detachably disposed on the proximal end of the proximal end of the occlusion microcatheter.

[0021] The present invention also provides a neurovascular thrombectomy system that includes the neurovascular thrombectomy device of the invention and may also include: a fluid reservoir connected to the fluid access port; a high pressure fluid delivery means for conveying fluid from the fluid reservoir to the fluid access port; an aspiration means connected to the aspiration exit port; and/or an aspiration receptacle connected in-line between the aspiration means and the occlusion microcatheter for receiving thrombus and fluid.

[0022] The present invention also provides methods for treating neurovascular thrombus including the steps of: a) accessing a patient blood vessel using a Seldinger technique; b) inserting a guide wire through the accessed blood vessel and maneuvering the guide wire to a treatment site; c) placing a guide catheter over the guide wire and advancing the guide catheter to a position slightly proximal to the treatment site; d) inserting the occlusion microcatheter of the neurovascular thrombectomy system of the invention into the guide catheter and advancing the occlusion microcatheter to the treatment site; e) inserting the fluid-assisted microcatheter of the invention over the guide wire, into the occlusion microcatheter and sliding the fluid-assisted microcatheter to the treatment site; f) removing the guide wire; g) inflating the occlusion balloon, thereby occluding blood flow proximal to the treatment site; h) simultaneously activating the high pressure fluid delivery means and the aspiration means, thereby powering the fluid-assisted microcatheter of the neurovascular thrombectomy system; i) advancing the powered fluid-assisted microcatheter fluid to or through a thrombus at the treatment site, thereby removing thrombus; j) repeating step i) until all thrombus is removed from the treatment site; k) simultaneously deactivating the high pressure fluid delivery means and the aspiration means; l) withdrawing the fluid-assisted microcatheter from the treatment site; m) restoring blood flow to the treatment site by deflating the occlusion balloon; n) removing the fluid-assisted microcatheter, occlusion microcatheter and guide catheter from the patient, thereby removing neurovascular thrombus. Optionally, the method uses a three-way reperfusion valve adapted for controllably inflating and deflating the occlusion balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] **FIG. 1** is an overall schematic drawing of a neurovascular thrombectomy microcatheter system.

[0024] **FIG. 2** is a longitudinal section view of a fluid-assisted aspiration microcatheter **104** and multi-access hub **70** according to one embodiment of the invention.

[0025] **FIG. 3** is a cross sectional view of the distal tip **30** of a fluid-assisted aspiration microcatheter **104** of an embodiment of the invention having a tapered tip.

[0026] **FIG. 4** is a cross sectional view of the distal tip **30** of a fluid-assisted microcatheter **104** of an embodiment of the invention having a soft tapered tip.

[0027] **FIG. 5** shows a longitudinal section of the distal region of a neurovascular thrombectomy device within a treatment site in a patient cranial vasculature **12**, showing the placement of fluid-assisted aspiration microcatheter **104** relative to occlusion microcatheter **102**.

[0028] **FIG. 6** is a detailed longitudinal section view illustrating an embodiment of occlusion microcatheter **102** equipped with an in-line occlusion balloon **26** (shown inflated).

[0029] **FIG. 7** is a detailed longitudinal section view of occlusion microcatheter **102** equipped with an occlusion balloon **26** (shown inflated).

[0030] **FIGS. 8A** and **8B** show side and front views, respectively, of three-way reperfusion valve **33** in an "off" position.

[0031] **FIGS. 9A** and **9B** show side and front views, respectively, of three-way reperfusion valve **33** in a "reperfuse" position.

[0032] **FIGS. 10A** and **10B** show side and front views, respectively, of three-way reperfusion valve **33** in a "full flow" position.

[0033] The many advantages of the present invention will be apparent to those skilled in the art with the reading of this specification in conjunction with the enclosed drawings wherein like reference numerals are applied to like elements and wherein.

DETAILED DESCRIPTION

[0034] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention claimed. As used herein, the use of the singular includes the plural unless specifically stated otherwise. As used herein, "or" means "and/or" unless stated otherwise. Furthermore, use of the term "including" as well as other forms, such as "includes," and "included," is not limiting. The section headings used herein are for organizational purposes only and are not to be construed as limiting the subject matter described.

[0035] Unless specific definitions are provided, the nomenclatures utilized in connection with, and the laboratory procedures and techniques of neurology, vascular biology, neurosurgery and general medicine described herein are those known in the art. Standard symbols are used interchangeably with the full names represented by such symbols. Thus, for example, the terms "Fr" and "French" are understood to have identical meaning. Standard techniques may be used for surgical procedures, manufacturing of medical devices and .

Definitions

[0036] "About" as used herein means that a number referred to as "about" comprises the recited number plus or minus 1-10% of that recited number. For example, "about" 100 cm can mean 95-105 cm or as few as 99-101 cm depending on the situation. Whenever it appears herein, a numerical range such as "1 to 20" refers to cm to each integer in the given range; e.g., "1 to 20 cm" means that an a catheter be only 1 cm in length, 2 cm in length, 3 cm in length, etc., up to and including 20 cm in length.

[0037] "Vasculature" refers to the network of blood vessels of an organ or body part, including arteries, capillaries and veins. "Neurovasculature"is used herein to refer to blood vessels associated with the nervous system, and in particular, those within, supplying or returning blood to or from the brain.

[0038] As used herein, "thrombus" refers to an aggregation of blood factors, primarily platelets and fibrin with entrapment of cellular elements, frequently causing vascular obstruction at the point of its formation or restrictive capture. Most ischemic events are from coronary thrombus. Newly formed ("fresh" or "unorganized") thrombus is generally soft and malleable. As thrombus ages, it becomes more rigid or "organized" and is more difficult to remove from the vasculature.

[0039] As used herein, "embolism" refers to the sudden blocking of an artery by a thrombus or foreign material.

Neurovascular Thrombectomy Device

[0040] Referring to the drawings in detail, wherein like numerals indicate like elements, and specifically to **FIG. 1**, the present invention provides a neurovascular thrombectomy device, shown in the context of a complete thrombectomy system, that includes a fluid-assisted aspiration microcatheter **104** fitted within an occlusion microcatheter **102**. In order to maximize the cross-sectional area, components of the neurovascular thrombectomy device are generally tubular in shape, the occlusion microcatheter **102** having a generally larger diameter than the fluid-assisted aspiration microcatheter **104**. In operation, the occlusion microcatheter **102**

component of the device provides proximal blood flow restriction of the neurovasculature surrounding the treatment site, while the fluid-assisted aspiration microcatheter component **104** is adapted for removing thrombus. As used herein, "treatment site" refers the site of a thrombus in the neurovasculature of a patient and the area immediately surrounding the thrombus.

[0041] The occlusion microcatheter **102** is generally a hollow, tubular body defining a working channel **124** (identified e.g. in **FIG. 7**), having a proximal end **22** adapted for controlling an occlusion mechanism (such as an occlusion balloon as shown **26**) and a distal end **24** adapted to occlude a blood vessel. The skilled artisan will be aware of a variety of occlusion mechanisms suitable for use in the neurovascular thrombectomy device of the present invention. In one embodiment, the occlusion microcatheter **102** includes an occlusion balloon **26** adapted to reversibly and controllably restrict blood flow through a vessel of the neurovasculature. During insertion of the occlusion microcatheter **102** into the neurovasculature, the occlusion balloon **26** is deflated to allow ease of passage within the blood vessel. Once the occlusion microcatheter **102** has been advanced to a position near the site of a thrombus, the occlusion balloon **26** can be inflated until blood flow surrounding the balloon is stopped. With blood flood stopped, the fluid-assisted aspiration microcatheter **104** within the occlusion microcatheter **102** can safely be operated to remove thrombus **14** by aspiration and/or fluid-assisted aspiration as necessary. By restricting blood flow around a treatment site, repeated cycles of fluid application followed by thrombus aspiration are possible without the danger of the thrombus (or a portion thereof) traveling from site.

[0042] The fluid-assisted aspiration microcatheter **104** (illustrated e.g. in **FIG. 2** and **FIG. 5**) is a generally hollow, tubular body defining an evacuation path **126** (shown directionally in **FIG. 5** by arrows), having a proximal end **28** adapted for controlling both intravascular fluid application and aspiration of fluid and thrombus; and a main body or shaft **76** that terminates at a distal end **30** that is adapted to apply fluid within evacuation path **126**, and to accept thrombus and applied fluid through the evacuation path **126** upon application of suction via the proximal controls.

[0043] In certain embodiments of the invention, fluid-assisted aspiration microcatheter **104** is fitted snugly but slidably within the working channel **124** of occlusion microcatheter **102** as shown in **FIG. 2**. The distal end of fluid-assisted aspiration microcatheter **104** can be advanced to extend beyond the distal end of occlusion microcatheter **102** (**FIG. 5**). Providing a slidable aspiration microcatheter-occlusion microcatheter assembly permits the occlusion microcatheter **102** to first be advanced to a treatment site position near, but somewhat proximal to a thrombus. The occlusion mechanism can then be fully or partially activated (e.g., a balloon mechanism **26**

inflated) to secure the occlusion microcatheter at the desired location and/or restrict blood flow surrounding the treatment site. Once the occlusion microcatheter is positioned, the fluid-assisted aspiration microcatheter **104** can be advanced through the working channel **124** of occlusion microcatheter **102** to the position of the thrombus. In such embodiments, the distal end **30** of fluid-assisted aspiration microcatheter **104** typically exits the distal end **24** of occlusion microcatheter **102**, extending therethrough to a position at or near a thrombus. This configuration of the neurovascular thrombectomy device not only permits independent positioning of the occlusion microcatheter **102** and fluid-assisted aspiration microcatheter **104**, it also allows the operator to restrict blood flow around the treatment site prior to positioning the distal end **30** of fluid-assisted aspiration microcatheter **104**, and/or to reposition fluid-assisted aspiration microcatheter **104** as needed during thrombectomy.

[0044] In certain aspects of the invention, and particularly where the occlusion microcatheter **102** includes a balloon, inflating the balloon, in conjunction with the arrangement of fluid-assisted aspiration microcatheter **104** within occlusion microcatheter **102,** physically isolates and protects the surrounding vasculature from inadvertent contact with fluid-assisted aspiration microcatheter **104** before and during thrombus removal. Specifically, the fluid-assisted aspiration microcatheter **104**, by fitting within and thus having a narrower diameter than occlusion microcatheter **102**, is separated from the patient vessel wall by at least the thickness of the occlusion microcatheter **102**. Therefore the occlusion microcatheter **102** provides a barrier between fluid-assisted aspiration microcatheter **104** and the vessel wall. Inflation of occlusion balloon **26** expands the vasculature near the treatment site, further distancing the distal end **30** of fluid-assisted aspiration microcatheter **104** from the vessel wall.

Occlusion Microcatheter

[0045] Turning to occlusion microcatheter **102** as shown generally in **FIG. 1**, the occlusion microcatheter and any parts thereof, can be of any construction and of any material suitable for surgical instruments. Generally, the materials and construction of all components of the neurovascular thrombectomy device, such as occlusion microcatheter **102**, will provide sufficient strength, kink resistance and biocompatibility for operation in a human patient as described herein. Suitable materials for manufacturing the devices and systems of the invention are well known in the art.

[0046] The occlusion microcatheter **102** can be of any length sufficient to be advanced from a peripheral vein or artery to the desired treatment site. The occlusion microcatheter **102** will typically have a length of about 45 cm to about 170 cm, often a length of about 80 cm to about 140 cm, and frequently will be about 110 cm in length. Non-limiting examples of suitable

lengths for occlusion microcatheter **102** include about 50 cm, about 60 cm, about 70 cm, about 80 cm, about 90 cm, about 100 cm, about 110 cm, about 120 cm, about 130 cm, about 140 cm, about 150 cm, about 160 cm, and about 170 cm. In certain embodiments of the invention, even longer catheter lengths are contemplated to facilitate operation by robotics, electronic controls or remote operation. The occlusion microcatheter **102** is of a sufficient diameter to be mechanically and clinically compatible with introducer sheaths or guide catheters **20** ranging from 4 Fr to 9 Fr. Thus, the outer diameter of the occlusion microcatheter **102** will typically be less than about 4 Fr to about 8.9 Fr. However, only dimensions suitable for use in the contemplated treatment sites within the neurovasculature are included in the scope of this invention.

[0047] In certain embodiments, occlusion microcatheter **102** is reusable and is made from durable materials known in the art that can be cleaned and sterilized prior to use. In other embodiments, the occlusion microcatheter **102** is intended for single use (i.e. is disposable) and is provided pre-sterilized.

Operation of Neurovascular Thrombectomy Device

[0048] In operation, it is contemplated that occlusion microcatheter **102** will be inserted into the vasculature using a Seldinger or similar technique (although any suitable procedure for accessing the neurovasculature that is known in the art may be used for insertion of occlusion microcatheter **102)**. Briefly, the desired blood vessel is entered at a vascular access site **10** (e.g. an accessible peripheral artery) using a sharp, hollow needle (trocar; not shown). The vascular access site can be, for example, a region of the subclavian artery or femoral artery, or any accessible blood vessel from which the treatment site can be approached. A guide wire **16** is then advanced through the hollow lumen of the trocar under fluoroscopic guidance, and the trocar is withdrawn. An introducer sheath or guide catheter **20** is then passed over the guide wire **16** into the vessel and advanced to the treatment site where it is positioned in a manner permitting insertion of a microcatheter, such as the neurovascular thrombectomy device of the present invention, or other devices. Upon completion of the desired procedure, the guide catheter **20** and neurovascular thrombectomy device are withdrawn. The neurovascular thrombectomy device of the invention can thus be placed and operated at a treatment site within the neurovasculature. In certain embodiments, occlusion catheter **102** is permanently fitted within or is an integral part of the introducer or guide catheter **20**.

[0049] In use, the proximal end **22** of occlusion microcatheter **102** is retained outside the patient's body, and is adapted for reversibly controlling vascular occlusion. Such adaptation may, for example, include a stopcock or valve **32**, which can be three-way reperfusion valve **33** or any stopcock, valve or other means known in the art for controlling fluid flow**,** and/or a

balloon inflation syringe **34** in fluid communication with an occlusion balloon **26**, thereby permitting the operator to controllably inflate the occlusion balloon **26**. The skilled artisan will be knowledgeable of additional occlusion devices and control mechanisms suitable for use with the present invention.

[0050] **FIG. 7** illustrates an exemplary embodiment of an occlusion microcatheter **102** according to the invention, having a proximal end **22** and a distal end **24**. This figure shows a longitudinal section view of the occlusion microcatheter **102**, which is generally a hollow tubular body defining a path (working channel **124**) for accessing a vascular treatment site. In certain embodiments, the occlusion microcatheter **102** includes an inner tubular member **106** surrounding the working channel **124**, and an outer tubular member **108** surrounding the inner tubular member **106**. The inner (**106**) and outer (**108**) tubular members together define an inflation intra-luminal space **110**, which is a generally hollow, sealed space lying between the tubular members (**106** and **108**), through which inflation fluid can flow. According to the embodiment of the invention illustrated in **FIG. 7**, an inflation opening **116** is disposed on the distal end of the outer tubular member **108**. Surrounding inflation opening **116**, an occlusion balloon **26** is bonded, melted or otherwise sealably secured to the outer tubular member **108**, thereby providing fluid communication between the occlusion balloon **26** and inflation intra-luminal space **110**, whereby the balloon can be reversible inflated to provide vascular occlusion. In other embodiments, the outer tubular member and occlusion balloon **26** are fabricated, molded or otherwise manufactured as a single tubular member. In such embodiments, outer tubular member **108**, has disposed thereon a contiguous pouch or out pocket that serves as the occlusion balloon **26**. Whether formed as an integral part of the outer tubular member geometry or disposed upon the outer tubular member, inflation opening **116** is of sufficient size as not to limit overall inflation fluid flow rate within the inflation intra-luminal space **110**. The distal end of the inflation intra-luminal space **110** is sealed by an adhesive plug **122** or other suitable seal or closure that will be well known in the art.

[0051] In certain embodiments, exemplified by the illustration of the distal end **24** of occlusion microcatheter **102** shown in **FIG 6**, inner tubular member **106** is longer than outer tubular member **108**, and thus extends distally beyond the outer tubular member **108** at distal end **24** of occlusion microcatheter **102**. According to such embodiments, the extension of inner tubular member **106** creates a step between inner tubular member **106** and outer tubular member **108** that is bridged by occlusion balloon **26**. The occlusion balloon **26** according to this embodiment has two edges or openings, such that a first edge or opening is bonded, melted or otherwise sealably secured at or proximal to the distal end of outer tubular member **108**, and the

second edge or opening is bonded, melted or otherwise sealably secured at or distal to the distal end of inner tubular member **106**, thereby providing sealed fluid communication between the occlusion balloon **26** and inflation intra-luminal space **110**. Such balloons can be reversibly inflated to provide vascular occlusion. In these embodiments the outer diameter of the distal end **24** of occlusion microcatheter **102** is tapered, thereby facilitating a lower entry profile for occlusion microcatheter **102** which enhances enhancing deliverability to the treatment site. The balloon itself forms the seal between inner tubular member **106** and outer tubular member **108,** eliminating the need for an adhesive plug (shown as **122** in **FIG 7**). In addition, the bridging function of the balloon in this embodiment establishes fluid communication between the balloon **26** and inflation intra-luminal space **110**, thereby eliminating the need for inflation opening **116** **(**shown in **FIG. 7)**.

[0052] In one embodiment of the invention, the proximal end **22** of occlusion microcatheter **102** includes a two-channel hub **118**, that includes an inflation access port **120** adapted for controlling inflation fluid flow within the inflation intra-luminal space **110** and a proximal access port **128** that is in communication with working channel **124** through which fluid-assisted aspiration microcatheter **104** is slidably fitted. A haemostatic seal **112** is disposed on the inner tubular member at the proximal end **22** of occlusion microcatheter **102** to prevent blood or fluoroscopic fluids from escaping the vasculature through the proximal access port **128** during use.

[0053] The inflation access port **120** is adapted to receive inflation fluid, e.g., from a fluid filled inflation syringe **34**. Thus, in one embodiment, inflation access port **120** terminates proximally in a luer lock type connector. The rate and amount of occlusion balloon **26** inflation is determined by the flow of inflation fluid received through the inflation access port **120**, flowing through the inflation intra-luminal space and filling the occlusion balloon **26** via the intra-luminal inflation opening **116**. Control of balloon inflation can be by any means available, such as manual or mechanical operation of the inflation syringe **34**. Stopcocks and valves **32** suitable for controlling balloon inflation are known in the art. Following thrombectomy, the inflation process is reversed to deflate the balloon and allow reperfusion of the distal vasculature. The skilled artisan will recognize that controlled reperfusion is advantageous and may be required because rapid reperfusion within the delicate cranial vasculature can damage small vessel walls.

[0054] The present invention also provides an improved, three-way reperfusion valve **33** (described below), that facilitates superior control over balloon inflation and particularly reperfusion by preventing inadvertent and/or rapid deflation of occlusion balloon **26**, and can be

included used as stopcock or valve **32**. Thus, in certain embodiments of the invention, inflation access port **120** is adapted to accept three-way reperfusion valve **33** for accurately controlling fluid flow. In another embodiment, three-way reperfusion valve **33** is disposed on the two-channel hub **118** as an integral part of inflation access port **120**.

Fluid-assisted Aspiration Microcatheter

[0055] Turning to fluid-assisted aspiration microcatheter **104** as shown generally in **FIG. 1**, the fluid-assisted microcatheter and any parts thereof, can be of any construction and of any material suitable for surgical instruments. Generally, the materials and construction of all components of the neurovascular thrombectomy device, such as fluid-assisted aspiration microcatheter **104**, will provide sufficient strength, kink resistance and biocompatibility for operation in a human patient as described herein.

[0056] In certain embodiments, fluid-assisted aspiration microcatheter **104** is reusable and is made from durable materials known in the art that can be cleaned and sterilized prior to use. In other embodiments, the fluid-assisted aspiration microcatheter **104** is intended for single use (i.e. is disposable) and can be provided in a pre-sterilized form.

[0057] The fluid-assisted aspiration microcatheter **104** is a generally a hollow, tubular body defining an evacuation path **126** (shown directionally in **FIG. 5** by arrows), having a proximal end **28** adapted for controlling both fluid application and aspiration of fluid and thrombus; and a main body or shaft **76** that terminates at a distal end **30** that is adapted to apply fluid within the evacuation path **126**, and to accept thrombus and applied fluid through evacuation path **126** upon application of suction via the proximal controls.

[0058] The fluid-assisted aspiration microcatheter **104** can be of any length sufficient to be advanced through the occlusion microcatheter **102** to the desired treatment site. The fluid-assisted aspiration microcatheter **104** will typically be longer than occlusion microcatheter **102** such that it can be advanced through and extend beyond occlusion microcatheter **102** when in use in the cranial vasculature. Furthermore, fluid-assisted aspiration microcatheter **104** will typically be longer than occlusion microcatheter **102** by a sufficient amount to permit proximal control of aspiration and fluid application, as illustrated in **FIG. 1**. Thus, fluid-assisted aspiration microcatheter **104** will typically have a length of about 60 cm to about 200 cm; often, a length of about 100 cm to about 160 cm, and frequently will be about 130 cm in length. Non-limiting examples of suitable lengths for fluid-assisted aspiration microcatheter **104** include about 60 cm, about 70 cm, about 80 cm, about 90 cm, about 100 cm, about 110 cm, about 120 cm, about 130 cm, about 140 cm, about 150 cm, about 160 cm, 170 cm, about 180 cm, about 190

cm, and about 200 cm. In certain embodiments of the invention, even longer catheter lengths are contemplated to facilitate operation by robotics, electronic controls or remote operation.

[0059] The fluid-assisted aspiration microcatheter **104** has a sufficient diameter to be mechanically compatible with and fit slidably within the working channel **124** of occlusion microcatheter **102**. In certain embodiments, the main shaft **76** of fluid-assisted aspiration microcatheter **104** has an outer diameter ranging from less than about 3 Fr to about 8 Fr, typically about 3 Fr to about 7 Fr , and often about 3-4 Fr to about 6 Fr.

[0060] In certain aspects of the invention, space between fluid-assisted aspiration microcatheter **104** and occlusion microcatheter **102** is minimized to keep the overall size of the vascular thrombectomy device at a minimum, and is thereby only as large as absolutely necessary for sliding the fluid-assisted aspiration microcatheter **104** within working channel **124**. In other embodiments, sufficient space remains in working channel **124** between the slidably fitted fluid-assisted aspiration microcatheter **104** and the inner tubular member of occlusion microcatheter **102** to allow injection of fluoroscopic fluid into the working channel **124** and permit the fluid to flow through the working channel to the distal end of the occlusion catheter **102** where it can diffuse into the vasculature at the treatment site. Injection of fluoroscopic fluid may thus be advantageously employed with certain neurovascular thrombectomy devices according to the invention, to enhance vascular visibility.

[0061] **FIG. 2** provides a detailed longitudinal section view of fluid-assisted aspiration microcatheter **104**, showing the generally hollow, tubular body defining evacuation path **126** through which fluid and thrombus are evacuated. In one embodiment of the invention, a multi-access hub **70** is disposed at the proximal end **28** of the fluid-assisted aspiration microcatheter **104** to facilitate control over aspiration of thrombus and fluid, e.g. including an aspirate exit port **84** in communication with the evacuation path **126**. The multi-access hub **70** can also include fluid access port **82** adapted for controlling and applying fluid such as saline or another biocompatible fluid. The multi-access hub **70** also provides an independent channel for manipulating guide wire **16** within the evacuation path **126** while the device is being deployed at the treatment site. In this aspect, the invention includes a guide wire access port **86** that includes an adjustable (e.g. threaded) guide wire lock **72** that can be operated (e.g. turned clockwise) to compress a flexible bung **74,** thus sealing and constricting the movement of the guide wire. In some embodiments, multi-access hub **70** can be covered by a flexible cap **130** that when fitted over the guide wire access port **86,** seals the guide wire access port **86** to prevent aspirate material escaping or air entering through the evacuation path **126** during guide wire removal.

[0062] Distal to fluid access port **82**, the main shaft **76** of the fluid-assisted aspiration microcatheter **104** is a bi-walled structure. The main shaft **76** includes an inner lumen **100** and an outer lumen **98** that together define a fluid delivery intra-luminal space **94** in fluid communication with the fluid access port **82** and fluid jet orifice **92.** Fluid can be injected through fluid access port **82** into the fluid delivery intra-luminal space **94,** which has **a** cross sectional area sufficient to allow a minimum fluid flow rate of about 4 ml/min and a maximum fluid flow rate of about 20 ml/min therethrough.

[0063] In certain embodiment, a taper **80** may be included on main shaft **76** such that the distal end **30** of the fluid-assisted aspiration microcatheter **104** has a smaller diameter than the more proximal regions. According to such embodiments, proximal to taper **80**, main shaft **76** has a diameter that interfaces in an axial sliding motion with the occlusion microcatheter **102** (i.e. in working channel **124)** without binding or kinking. Distal to the taper **80**, main shaft **76** narrows. The narrowing of such embodiments of the invention permits fluid-assisted aspiration microcatheter **104** to access very small neurovascular vessels (e.g. between about 1.0 mm and about 2.0 mm in diameter), even when more proximal regions of the fluid-assisted aspiration microcatheter **104** are of a larger diameter due to mechanical or manufacturing requirements. Taper **80** allows the use of a larger diameter for the main shaft **76** within the occlusion microcatheter **102**, for example, to maintain high pressure within fluid delivery intra-luminal space **94** of the fluid-assisted aspiration microcatheter **104**. The taper **80** can be as long as the manufacturing process allows and is located about 1.0 cm to about 145.0 cm from the distal end of fluid-assisted microcatheter **104**.

[0064] In one exemplary embodiment, inner lumen **100** and outer lumen **98** are fused together at the distal end of the fluid-assisted microcatheter **104** thereby sealing the fluid delivery intra-luminal space **94**. According to this embodiment, the fluid-assisted microcatheter **104** thus terminates distally in a generally round aspiration orifice **96**, which is generally perpendicular to main shaft **76** of fluid assisted microcatheter **104**, for accepting thrombus from a treatment site. Optionally, a radiopaque marker band can be disposed at the distal end of the microcatheter **104** (e.g., within the fluid delivery intra-luminal space **94)** to facilitate fluoroscopic localization of the fluid-assisted microcatheter **104** when inserted into the neurovasculature of a patient. In certain aspects of the invention the radiopaque marker band **90** acts together with adhesive or other means to seal the fluid delivery intra-luminal space **94** at the distal end of the microcatheter **104**.

[0065] **FIG 3.** illustrates another embodiment of the distal tip **30** of fluid assisted microcatheter **104** in which aspiration orifice **96** is cut, formed, molded or otherwise constructed

at a about 15-80 degree angle, typically about 45 degrees, relative to main shaft **76** to form a generally oval shaped aspiration orifice **96**. In this embodiment, fluid jet orifice **92** can be positioned more distally and closer to aspiration orifice **96.**

[0066] In yet other embodiments, as shown in **FIG. 4,** fluid assisted microcatheter **104** can be constructed to have a distal soft tip **134.** In such embodiments, an angled distal plug **132** made of flexible material, is bonded melted or otherwise constructed to extend distally from main shaft **76** to form an atraumatic or soft distal tip. Such a soft distal tip is less likely to cause injury should it contact a vessel wall during use.

[0067] Inner lumen **100**, outer lumen **98** and multi-access hub **70** can be constructed or fabricated from any material with sufficient strength to maintain functionality and resist kinking. The radiopaque marker **90** band is constructed of a material that returns a visual indication to the operator under fluoroscopic guidance.

[0068] The fluid-assisted microcatheter **104** includes a fluid jet orifice **92** disposed at the distal end of the inner lumen **100**, through which saline or other biocompatible fluid can be applied to a thrombus. The fluid jet orifice **92** is directed to spray fluid within the evacuation path **126** of the fluid-assisted microcatheter **104**, rather than outward into the vasculature. Fluid jet orifice **92** is typically located within about 0.001 to about 0.150 inches from the distal end of the fluid-assisted microcatheter **104**. The fluid jet orifice **92** is typically about 0.0003 to 0.0110 square inches in cross sectional area. Fluid jet pressure through fluid jet orifice **92** is about 50 to about 600 psi. The pressure can be controlled by any means known in the art, such as by providing a regulated, high-pressure fluid delivery means **40**, such as a pump, and is calculated with the high pressure output and the ensuing system head loss.

[0069] In operation, fluid-assisted microcatheter **104** is advanced to the site of a thrombus and the thrombus is removed in a bimodal fashion. Upon contact, thrombus is drawn through aspiration orifice **96** toward aspiration exit port **84** by the application of suction to aspiration exit port **84** (e.g. via a vacuum means **38**). Fresh, unorganized thrombus will typically be aspirated completely. However, more organized thrombus that is drawn into the aspiration orifice **96** may become lodged in the evacuation path **126**, at or proximal to fluid jet orifice **92**. When organized thrombus is present and becomes lodged, an internal fluid jet **78** can be applied through fluid jet orifice **92** to section or emulsify the lodged thrombus so that it can be aspirated and removed. Following initial thrombus removal, additional thrombus, if present, is evacuated through aspiration orifice **96** (e.g. by the suction force of vacuum means **38)** thereby preventing loss of communication with thrombus. The aforementioned process can be continued until all occluding thrombus is removed.

[0070] The arrangement of fluid-assisted microcatheter **104** within occlusion microcatheter **102** coupled with the mechanical relationship between aspiration means **38**, aspiration orifice **96**, fluid jet orifice **92**, and internal fluid jet **78** ensures that all emulsified, sectioned or otherwise dislodged thrombus is securely captured within the evacuation path **126** of the fluid-assisted microcatheter **104** without the distal tip of the microcatheter **104** contacting the intima of the vessel wall or allowing thrombus to re-enter the intracranial vasculature. In other words, thrombus removal from a treatment site is accomplished by negative pressure (i.e. suction) rather than positive pressure (e.g. grasping or scraping). When thrombus is too large or rigid to pass easily through the evacuation path, thrombus is reduced *within* the microcatheter device by fluid jet force rather than outside of the microcatheter device which could lead to further embolism or vascular damage. The neurothrombectomy device of the present invention thus provides consistently safe neurovascular thrombectomy, thereby reducing the risk of distal embolization, hemorrhage or vessel damage.

[0071] The fluid applied through fluid-assisted microcatheter **104** is typically saline or another physiologically compatible solution, but may include agents (i.e. pharmaceuticals or biologicals) that facilitate thrombus emulsification and/or liquefaction. Advantageously, the neurothrombectomy device may permit use of such agents even when contraindicated for administration locally or systemically to a patient. Because fluid is applied within the fluid-assisted microcatheter **104** and is continually aspirated from the evacuation path without contacting with the treatment site, the risk of adverse effects accompanying administration of the agent to the patient are eliminated.

Three-way Reperfusion Valve

[0072] The present invention also provides an improved, three-way reperfusion valve **33**, for controlling occlusion balloon inflation, deflation and thereby vascular reperfusion. The three-way reperfusion valve **33** of the invention prevents rapid deflation of occlusion balloon **26**.

[0073] A nonlimiting embodiment of the three-way reperfusion valve of the invention is detailed in **FIGS. 8A-10B**, which illustrate side (**A**) and front (**B**) views of three-way reperfusion valve **33** in three operational positions. The three-way reperfusion valve **33** generally provides a controllable, bidirectional fluid path from a hollow, generally tubular first bidirectional fluid port **64**, to a hollow, generally tubular second bidirectional fluid port **66**, which ports are disposed on opposite sides of a generally tubular hollow valve body **68** and are of approximately the same diameter.

[0074] The three-way reperfusion valve **33** also includes a petcock **54** sealably seated within hollow valve body **68**. The petcock **54** is generally a solid cylindrical body terminating in a

small handle **56** or other mechanism for determining and adjusting the rotational position of the petcock **54** within the hollow valve body **68**; the petcock **54** having two channels for fluid to flow therethrough when the petcock is seated in the body **68** and either channel is aligned with the first bidirectional fluid port **64** on one side and the second bidirectional fluid port **66** on the other side. The first channel in petcock **54** is a generally cylindrical, hollow full flow channel **50** having a diameter approximately equal to the diameter of first bidirectional fluid port **64** and second fluid port **66**. The second channel in petcock **54** is a generally cylindrical, hollow reperfusion channel **52**, having a smaller effective diameter than the diameter of either first bidirectional fluid port **64** or second bidirectional fluid port **66**. In certain embodiments of the invention, the fluid flow axis of reperfusion channel **52** is oriented at approximately a 90° angle of rotation relative to the full flow channel and is physically separated from full flow channel **50** such that the two channels are not in fluid communication with each other. Rotation of the petcock allows the operator to align the bidirectional fluid ports **64** and **66** with either of the mutually exclusive channels (**50** and **52**), or with no channel.

[0075] Reperfusion channel **52** restricts fluid volume flowing therethrough to less that the amount flowing through full flow channel **50**, for example, by having a smaller diameter than first bidirectional fluid port **64** and second bidirectional fluid port **66**. The skilled artisan will be aware of addition mechanisms that may be suitable for restricting fluid flow through reperfusion channel **52** in the three-way reperfusion valve **33** of the invention, including for example narrowing orifices, needles and seats, fluid filters or any other means available to restrict fluid flow. When the petcock **54** is positioned such that the first bidirectional fluid port **64** and the second bidirectional fluid port **66** are not aligned with either full flow channel **50** or reperfusion channel **52**, the valve is sealed, thereby preventing fluid flow therethrough. In this position, no flow is allowed between first and second bidirectional fluid ports **64** and **66**.

[0076] Thus, three-way reperfusion valve **33** has three operating positions: off, full flow and reperfuse flow, corresponding to **FIGS 8A** and **8B**, **FIGS 9A** and **9B**, and **FIGS 10A** and **10B**, respectively. The skilled artisan will note that each of these 3 positions requires both a rotational alignment of the petcock **54** within the hollow valve body **68** and an "in" or "out" al alignment of petcock **54** within the hollow valve body **68**.

[0077] In certain embodiments of the invention, hollow valve body **68** includes a detent **62** having 3 positions disposed in the wall thereof, and petcock **54** includes a detent pin **60** disposed thereon that is mated with detent **62**, to restrict and facilitate positioning of petcock **54** to discrete "off," "full flow" and "reperfuse" positions. In certain aspects, the three-way reperfusion valve

33 includes detent spring **58** surrounding petcock **54** to apply tension to petcock **54** and provide tactile feedback to the operator.

[0078] **FIGS. 8A** and **8B** illustrate one embodiment of the three-way reperfusion valve **33** of the invention in the "off" position. In this position no fluid flow is permitted through the bidirectional fluid ports (**64** and **66)** via either the full flow channel **50** or the reperfusion channel **52**. The handle **56** of petcock **54** is fixed relative to the full flow and reperfusion channels; thus the position of the petcock can be detected by the operator as a means for assessing the operational state of the valve. **FIGS. 8A** and **8B** illustrate the "off" position having petcock handle **56** centered in-line with (parallel to) the first and second bidirectional fluid ports **64** and **66**. The skilled artisan will appreciate that petcock **54** can also be constructed in a configuration such that the "off" position is selected when the petcock handle **56** is perpendicular to the first and second bidirectional fluid ports **64** and **66**, or any position in between. Furthermore, detent pin **60** fits into a discrete position of detent **62**. The discrete positioning of detent pin **60** in detent **62**, together with tension from detent spring **58** provides a positive location for the "off" position using tactile feedback.

[0079] **FIGS. 9A** and **9B** illustrate three-way reperfusion valve **33** of the invention in the "reperfuse" position. In this position, the petcock handle **56** is rotated counter clockwise from the axis of the first and second bidirectional fluid ports **64** and **66**, such that communication is permitted between the first and second bidirectional fluid ports **64** and **66** through reperfusion channel **52**. Reperfusion channel **52** limits fluid flow by creating a restriction through the reperfusion valve **33**. In certain embodiments, the restriction results from a smaller overall diameter of reperfusion channel, **52**, as described above. Detent pin **60** fits into a discrete reperfusion position of detent **62**. The discrete positioning of detent pin **60** in detent **62** together with tension from detent spring **58** provide a positive location for the "reperfuse" position using tactile feedback.

[0080] **FIGS. 10A** and **10B** show the three-way reperfusion valve **33** in the "full flow" position. To achieve this position, petcock **54** is inserted more deeply into hollow valve body **68**, and then rotated (clockwise rotation shown) from the axis of the first and second bidirectional fluid ports (**64** and **66**), thereby aligning the fluid ports with full-flow channel **50** and permitting free fluid flow through the three-way reperfusion valve **33**. Full flow operation can be used, for example, to prep the occlusion microcatheter **102** prior to use and to inflate occlusion balloon **26**. Full fluid flow cannot be achieved using tactile feedback alone because detent pin **60** must be engaged in a position of detent **62** that requires significant force as well as rotation on petcock

54, while detent spring **58** creates resistance to that force. This feature of the valve creates a primary safety mechanism to prevent unintentional establishment of the full flow position.

Neurovascular Microcatheter System

[0081] The present invention also provides a neurovascular microcatheter system for intracranial thrombus removal including the neurovascular thrombectomy device described herein; a fluid reservoir **42** adapted for connection to fluid access port **82** on multi access hub **70**; a high pressure fluid delivery means **40** (such as a pump) for conveying fluid from the reservoir to the fluid access port; an aspiration means **38** (such as a vacuum pump) adapted for connection to aspiration exit port **84** on multi access hub **70;** and an aspiration receptacle **36** adapted for connection in-line between the aspiration means **38** and the occlusion microcatheter **102**, to receive thrombus and fluid aspirated from a treatment site..

[0082] The system may optionally include a sealed fluid delivery means to inflate occlusion balloon **26**, which can be, for example, a fluid filled inflation syringe **34** adapted for connection to bidirectional fluid port **64** or **66** on a three-way reperfusion valve **33**, which in turn is adapted for connection to inflation access port **120** disposed on the two-channel hub **118** of occlusion microcatheter **102**.

Methods for Removing Neurovascular Thrombus

[0083] The present invention also provides methods for removing thrombus from a neurovascular embolus including the steps of: introducing the occlusion microcatheter **102** of the neurovascular microcatheter device of the invention to a site proximal to a treatment site containing thrombus; restricting blood flow surrounding the treatment site by engaging an occlusion mechanism of the occlusion microcatheter **102;** advancing the fluid-assisted microcatheter **104** of the neurovascular microcatheter device of the invention through the occlusion microcatheter **102** until the distal end of the fluid-assisted microcatheter **104** contacts the thrombus; aspirating thrombus through aspiration orifice **96**, along the evacuation path **126** for removal; and reperfusing the treatment site by releasing the occlusion mechanism.

[0084] In certain embodiments, the occlusion microcatheter **102** and fluid-assisted microcatheter **104** are advanced over a guide wire **16**, which is subsequently withdrawn. Thrombus aspiration can be effected by activating an aspiration means **38** to draw the occluding thrombus **14** into the aspiration orifice **96** of fluid-assisted microcatheter **104**. When aspiration alone is insufficient to remove the thrombus due, for example, to organization of the thrombus, a high pressure fluid delivery means **40** can be used to deliver saline or another biocompatible fluid from a fluid reservoir **42** through fluid delivery intra-luminal space **94**, and deliver the pressurized fluid to the fluid jet orifice **92** in the distal end **30** of fluid-assisted microcatheter **104**.

In this embodiment of the invention, as thrombus **14** is drawn into the aspiration orifice **96**, it creates a pressure differential **114** that allows the fluid-assisted microcatheter **104** to maintain communication and control over the thrombus **14**. A fluid jet **78** is directed toward the retained thrombus from fluid jet orifice **92**. The fluid jet typically operates at between 50 and 600 pounds per square inch, thereby providing sufficient pressure to section off or emulsify the retained thrombus **14** without the risk of distal embolization from thrombetic fragments because the emulsification remains fully contained within the fluid-assisted microcatheter **104**. As each section of thrombus is aspirated, new thrombetic material is drawn into the aspiration orifice **96**, with the process repeating until all thrombus is removed.

[0085] Once all thrombus **14** is removed from the patient vasculature **12**, the aspiration means **38** and high pressure fluid delivery means **40** are disabled. After recanalization of the vasculature **12** distal to the occlusion mechanism, (e.g. occlusion balloon **26)** a second pressure differential exists between the patient vasculature that is proximal to the occlusion balloon **26** and the patient vasculature that is distal to occlusion balloon **26**. The three-way reperfusion valve **33**, when used, is turned to the "reperfuse" position to allow a controlled release of blood flow back into the treatment site and equalize the pressure differential around the occlusion balloon **26**.

CLAIMS

What is claimed is:

1. A neurovascular thrombectomy device comprising:
   a) a generally tubular, hollow occlusion microcatheter having a distal end adapted for vascular occlusion and a proximal end adapted for controlling said vascular occlusion; and
   b) a generally tubular fluid-assisted microcatheter fitted within said occlusion microcatheter having an open distal end adapted for fluid-assisted thrombus removal and a proximal end adapted for controlling said fluid-assisted thrombus removal.
2. The neurovascular thrombectomy device of claim 1, wherein the fluid-assisted microcatheter is slidably fitted within the occlusion microcatheter.
3. The neurovascular thrombectomy device of claim 1, wherein the fluid-assisted microcatheter is a generally hollow tubular body defining an evacuation path, wherein the hollow body comprises an inner lumen and an outer lumen defining a sealed fluid delivery intra-luminal space.
4. The neurovascular thrombectomy device of claim 3, further comprising:
   a) a fluid access port in fluid communication with the fluid delivery intra-luminal space; and
   b) a fluid jet orifice disposed near the distal end of the inner lumen.
5. The neurovascular thrombectomy device of claim 4, wherein the fluid-assisted microcatheter delivers fluid under high pressure through the fluid delivery intra-luminal space to the fluid jet orifice and into the evacuation path.
6. The neurovascular thrombectomy device of claim 5, wherein the open distal end of the fluid-assisted microcatheter is perpendicular to the length of the neurovascular thrombectomy device, thereby forming a round aspiration orifice.
7. The neurovascular thrombectomy device of claim 5, wherein the distal end of the fluid-assisted microcatheter is angled 45 degrees relative to the length of the neurovascular thrombectomy device thereby forming an oval aspiration orifice; wherein the fluid jet orifice delivers fluid into the oval aspiration orifice.
8. The neurovascular thrombectomy device of claim 1, wherein the occlusion microcatheter comprises an occlusion balloon.
9. The neurovascular thrombectomy device of claim 8, wherein the occlusion microcatheter comprises an inner tubular member surrounding a working channel and an outer tubular

member surrounding the inner tubular member, said outer tubular member and said inner tubular member together defining an inflation intra-luminal space.

10. The neurovascular thrombectomy device of claim 9, wherein the diameter of the working channel is sufficient to slidably accept the fluid-assisted microcatheter.
11. The neurovascular thrombectomy device of claim 9, further comprising an inflation opening disposed on the outer tubular member, wherein the balloon surrounds the inflation opening and is sealably secured to the outer tubular member, and wherein the balloon is in fluid communication with the inflation intra-luminal space through the inflation opening.
12. The neurovascular thrombectomy device of claim 9, wherein the balloon is formed as a contiguous outpocketing of the outer tubular member.
13. The neurovascular thrombectomy device of claim 9, wherein the balloon sealably bridges the outer tubular member and the inner tubular member.
14. The neurovascular thrombectomy device of claim 13, wherein the inner tubular member is longer than and extends distally beyond the outer tubular member.
15. The neurovascular thrombectomy device of claim 1, wherein the occlusion microcatheter comprises a haemostatic seal at an opening in the proximal end of said occlusion catheter.
16. The neurovascular thrombectomy device of claim 1, wherein the proximal end of the occlusion microcatheter adapted for controlling said vascular occlusion comprises a three-way reperfusion valve.
17. The neurovascular thrombectomy device of claim 1, wherein the three-way reperfusion valve is detachably disposed on the proximal end of the proximal end of the occlusion microcatheter adapted for controlling said vascular occlusion.
18. A neurovascular thrombectomy system comprising:
    a) the neurovascular thrombectomy device of claim 10;
    b) a fluid reservoir connected to the fluid access port;
    c) a high pressure fluid delivery means for conveying fluid from the fluid reservoir to the fluid access port;
    d) an aspiration means connected to the aspiration exit port; and
    e) an aspiration receptacle connected in-line between the aspiration means and the occlusion microcatheter for receiving thrombus and fluid.
19. A method for treating neurovascular thrombus comprising the steps of:
    a) accessing a patient blood vessel using a Seldinger technique;
    b) inserting a guide wire through the accessed blood vessel and maneuvering the guide wire to a treatment site;

c) placing a guide catheter over the guide wire and advancing the guide catheter to a position slightly proximal to the treatment site;

d) inserting the occlusion microcatheter of the neurovascular thrombectomy system of claim 18 into the guide catheter and advancing the occlusion microcatheter to the treatment site;

e) inserting the fluid-assisted microcatheter into the occlusion microcatheter and sliding the fluid-assisted microcatheter to the treatment site;

f) inflating the occlusion balloon, thereby occluding blood flow proximal to the treatment site;

g) removing the guide wire and capping the guide wire access port

h) simultaneously activating the high pressure fluid delivery means and the aspiration means, thereby powering the fluid-assisted microcatheter of the neurovascular thrombectomy system;.

i) advancing the powered fluid-assisted microcatheter to or through a thrombus at the treatment site, thereby removing thrombus;

j) Repeating step i) until all thrombus is removed from the treatment site;

k) simultaneously deactivating the high pressure fluid delivery means and the aspiration means;

l) withdrawing the fluid-assisted microcatheter from the treatment site;

m) restoring blood flow to the treatment site by deflating the occlusion balloon;

n) removing the fluid-assisted microcatheter, occlusion microcatheter and guide catheter from the patient, thereby removing neurovascular thrombus.

20. The method of claim 19, wherein the proximal end of the occlusion microcatheter adapted for controlling said vascular occlusion comprises a three-way reperfusion valve adapted for controllably inflating and deflating the occlusion balloon, wherein steps e) and m) are controlled by the three-way reperfusion valve.

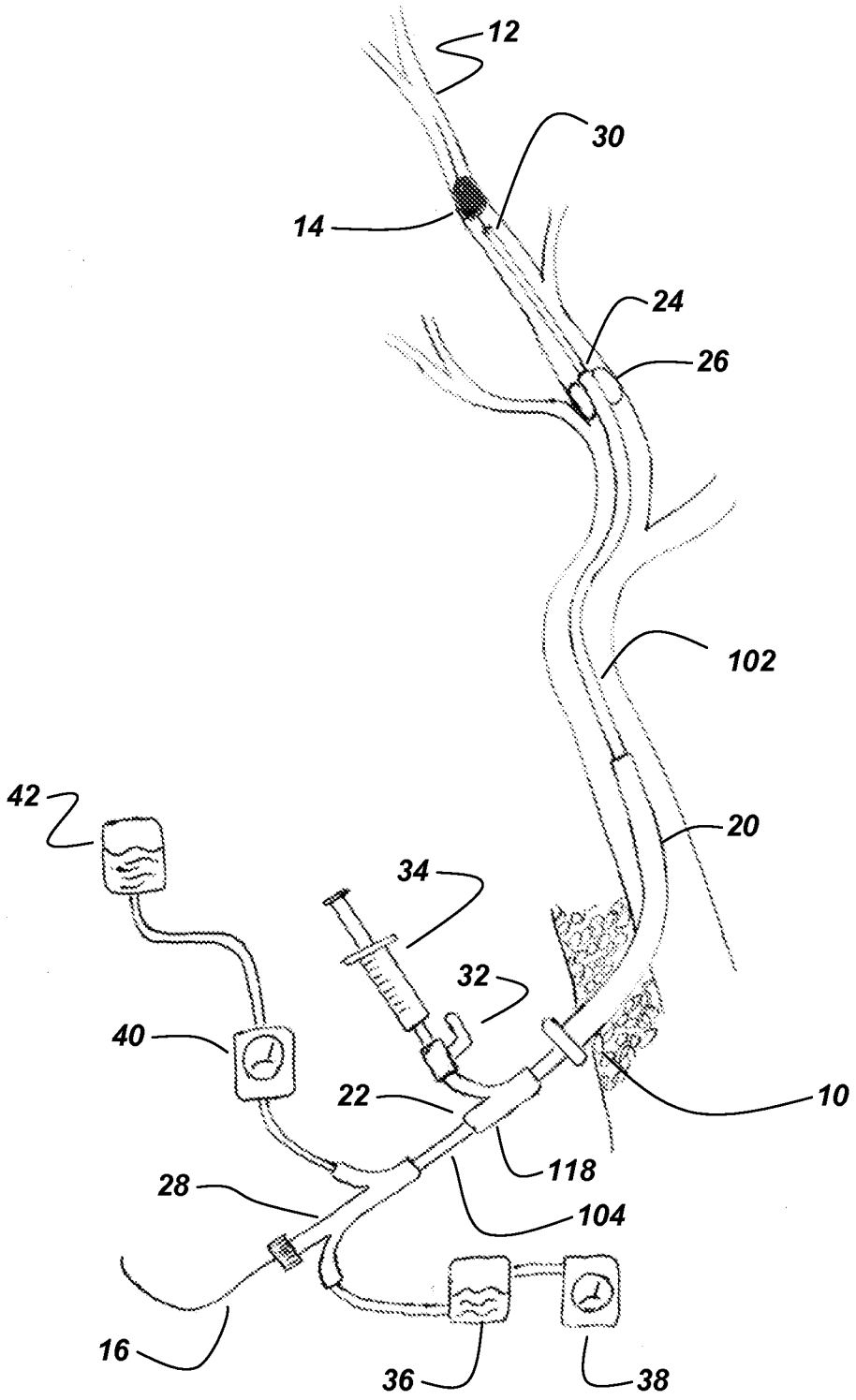

FIG. 1

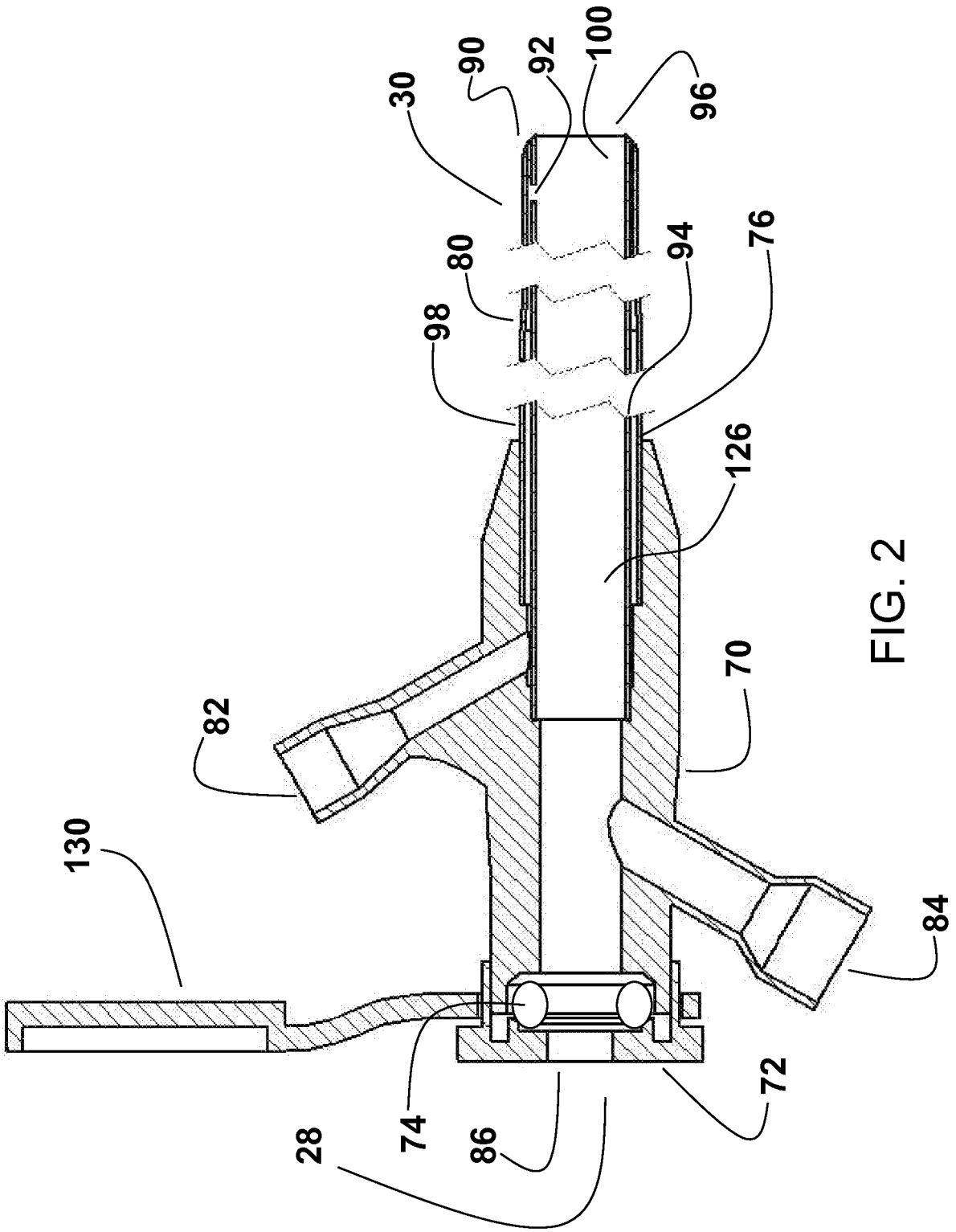

FIG. 2

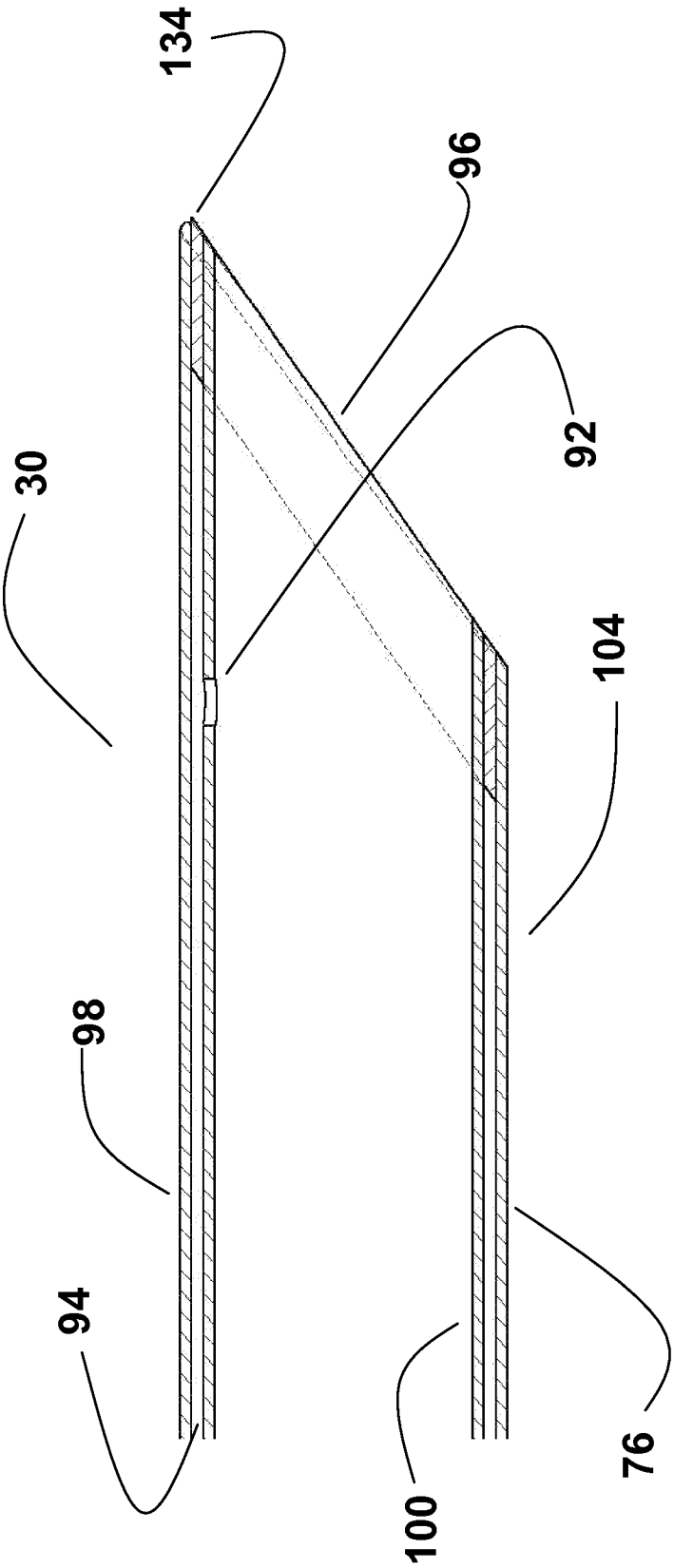

FIG. 3

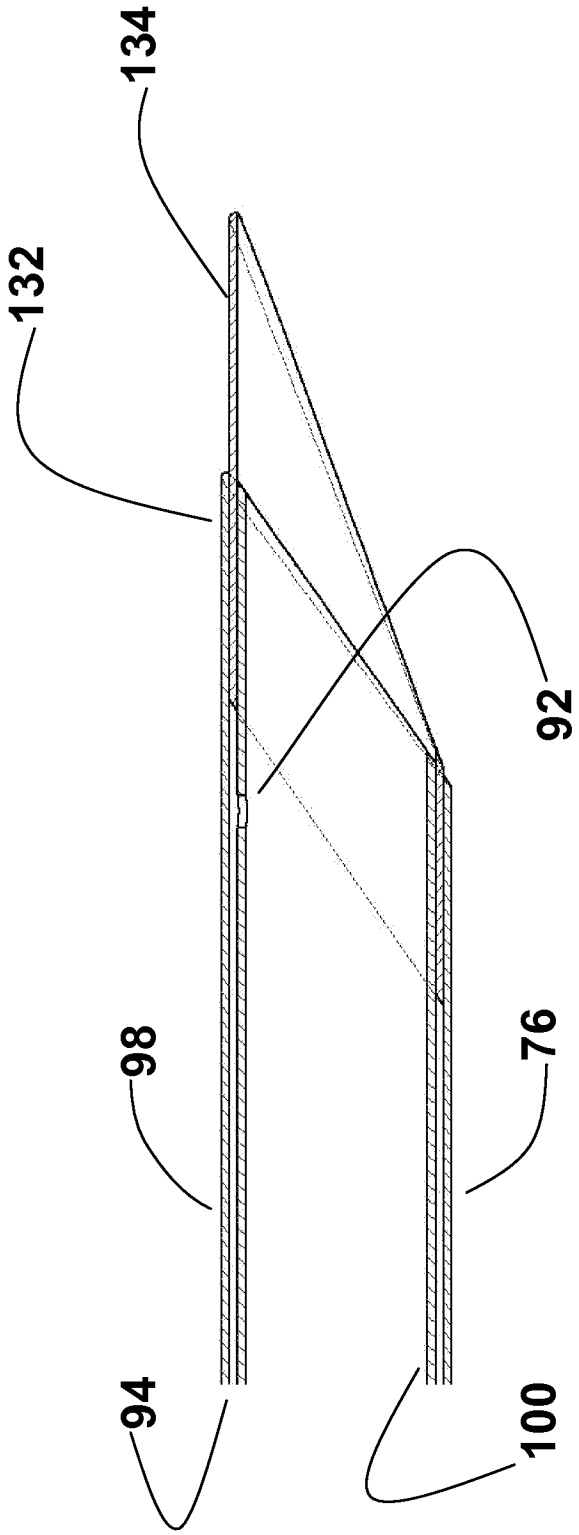

FIG. 4

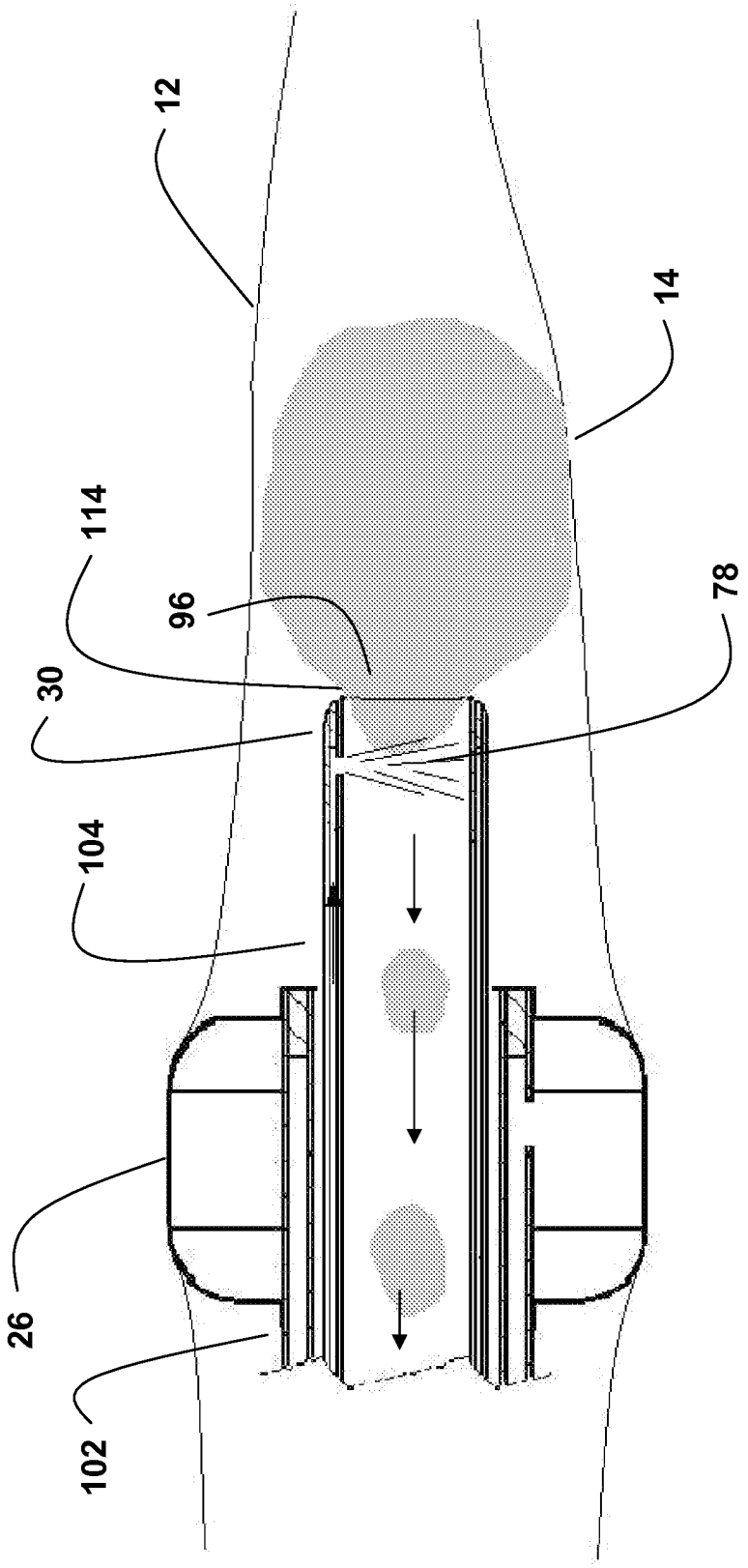

FIG. 5

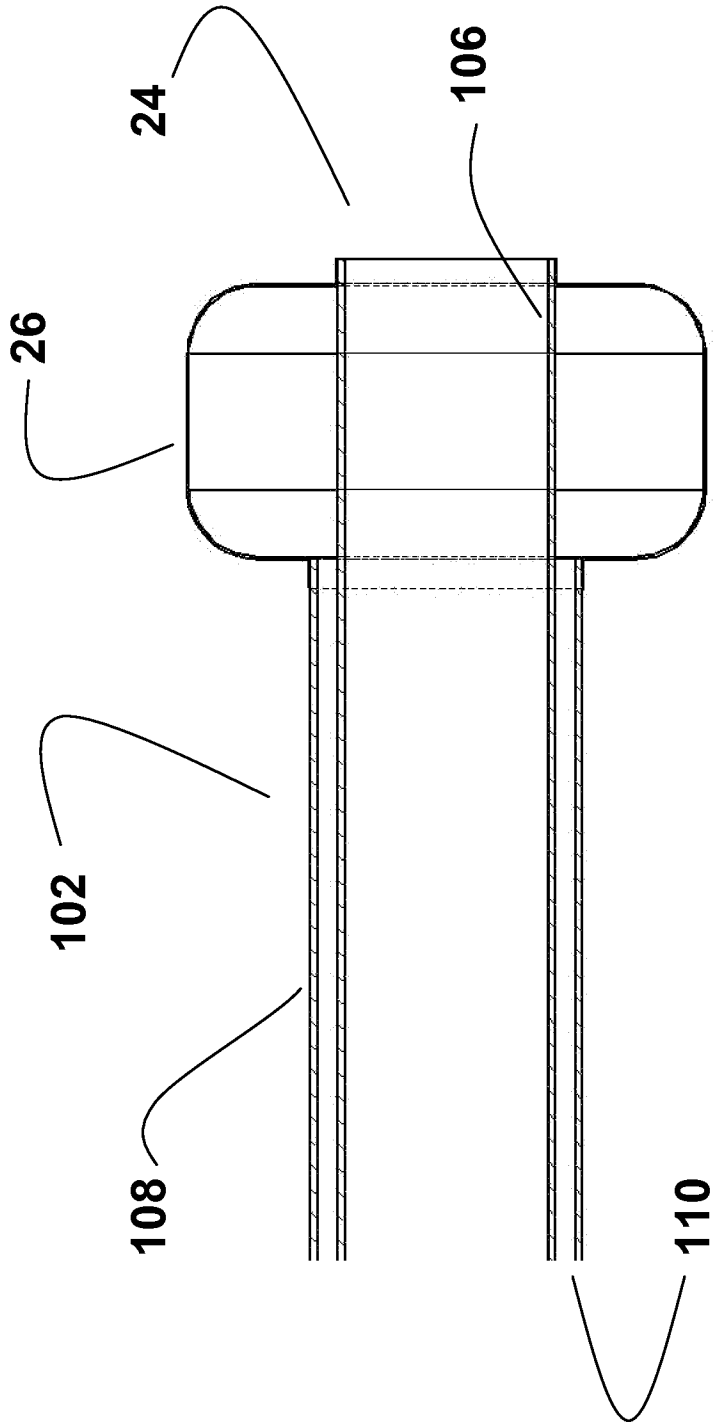

FIG. 6

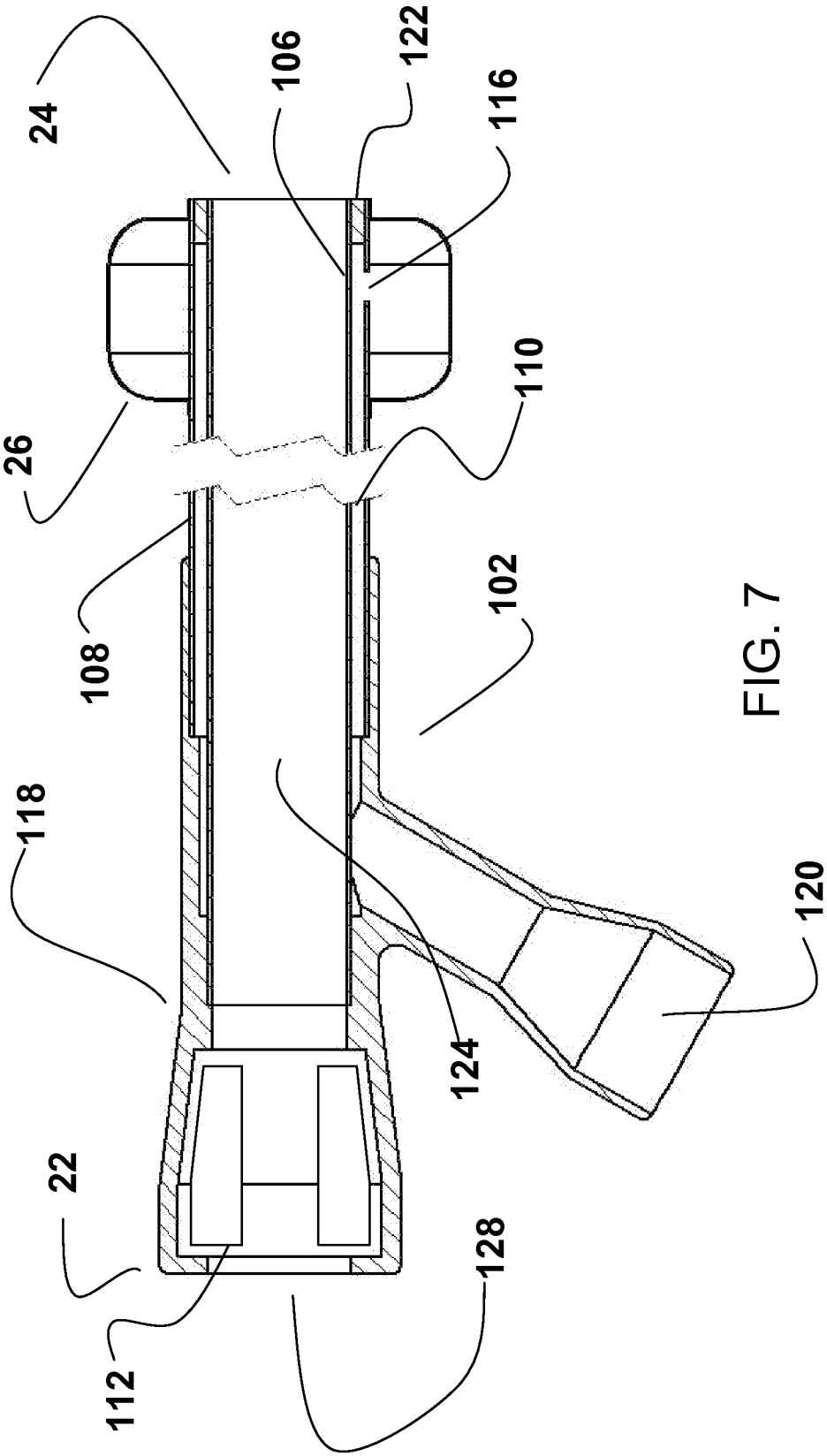

FIG. 7

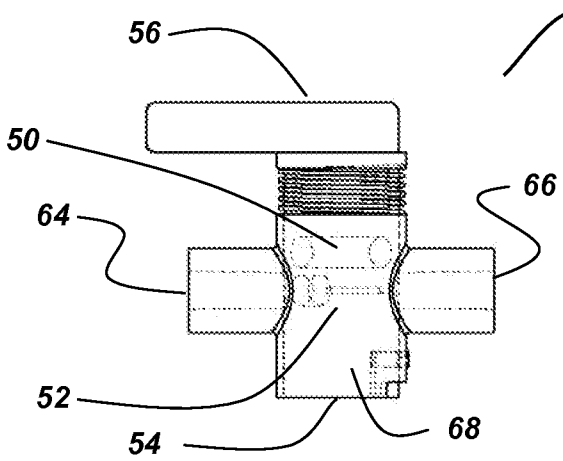

FIG. 8A

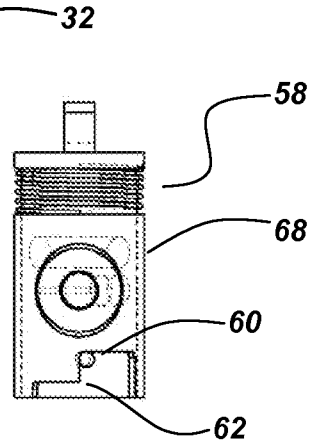

FIG. 8B

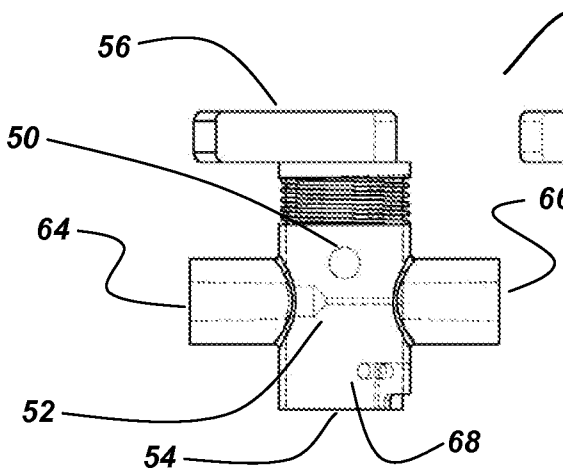

FIG. 9A

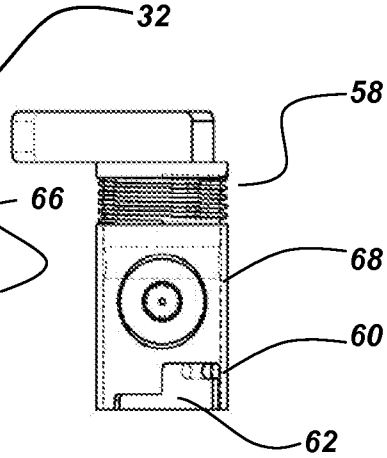

FIG. 9B

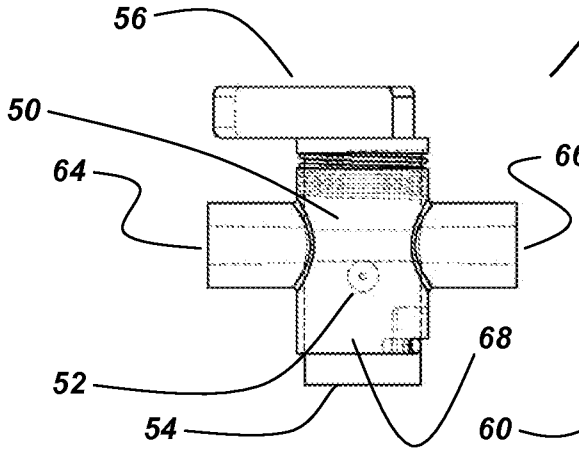

FIG. 10A

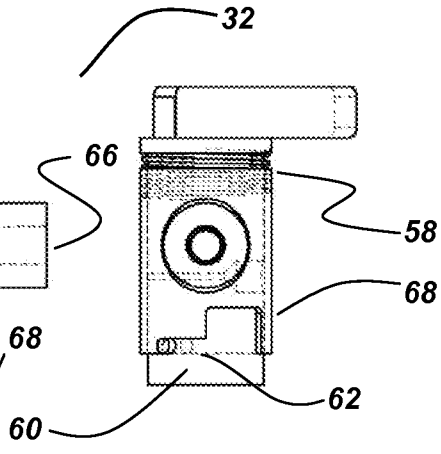

FIG. 10B