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(19) **United States**(12) **Patent Application Publication****Buck et al.**(10) **Pub. No.: US 2023/0015259 A1**(43) **Pub. Date: Jan. 19, 2023**(54) **INSERTER FOR GUIDING A DEVICE THROUGH A HEMOSTASIS VALVE AND METHOD THEREOF**

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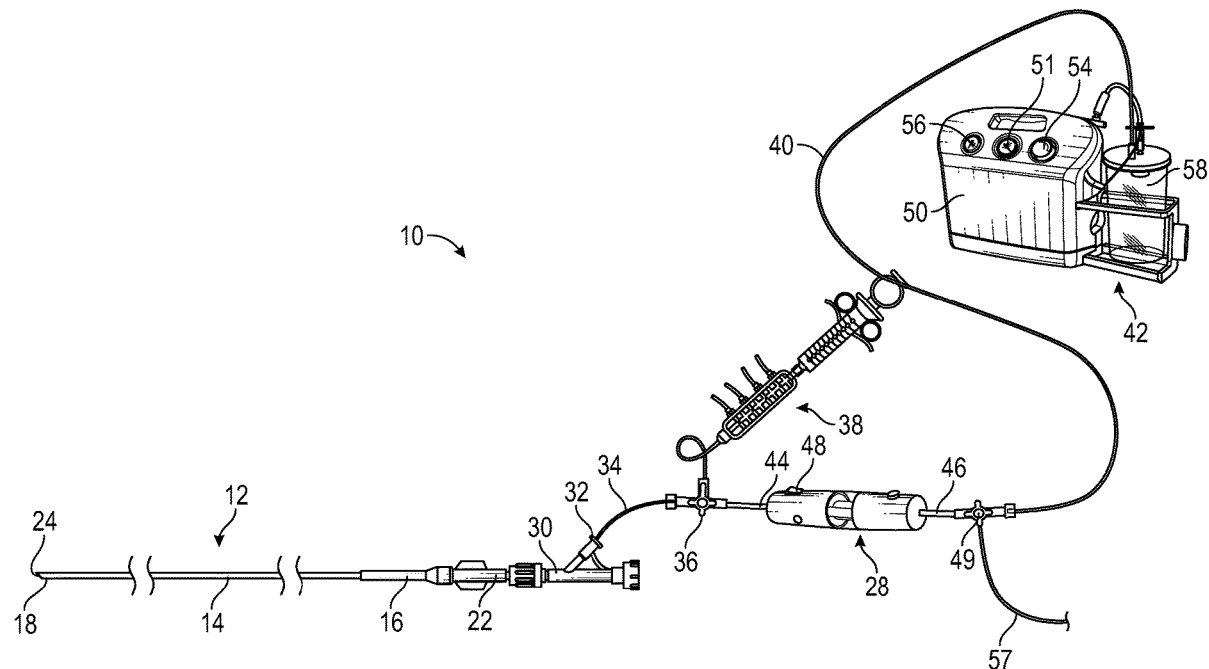
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A61M 39/06 (2006.01)**A61B 17/34** (2006.01)(72) Inventors: **Michael Buck**, Menlo Park, CA (US); **Julia Fox**, San Carlos, CA (US); **James Jacobs**, Danville, CA (US)(52) **U.S. Cl.**
CPC **A61M 39/0693** (2013.01); **A61B 17/3423** (2013.01); **A61B 17/3462** (2013.01); **A61B 2017/22079** (2013.01)(21) Appl. No.: **17/810,743**(22) Filed: **Jul. 5, 2022****Related U.S. Application Data**

(63) Continuation-in-part of application No. 17/357,490, filed on Jun. 24, 2021, now Pat. No. 11,457,936, which is a continuation-in-part of application No. 17/125,723, filed on Dec. 17, 2020, now Pat. No. 11,065,018.

(60) Provisional application No. 63/341,926, filed on May 13, 2022, provisional application No. 63/044,511, filed on Jun. 26, 2020, provisional application No.

(57) **ABSTRACT**

An inserter for guiding a device through a hemostasis valve. The inserter comprises an elongate tubular body, a concave landing zone, and an axially extending slit. The elongate body tubular body of the inserter partially defines a central lumen. A method a of passing a device through a valve comprises the steps of providing an inserter having a tubular body with a split sidewall, advancing the tubular body through a valve, advancing a device through the tubular body and beyond the valve and retracting the tubular body so that the device escapes laterally from the tubular body through the split sidewall, leaving the device in place across the valve.



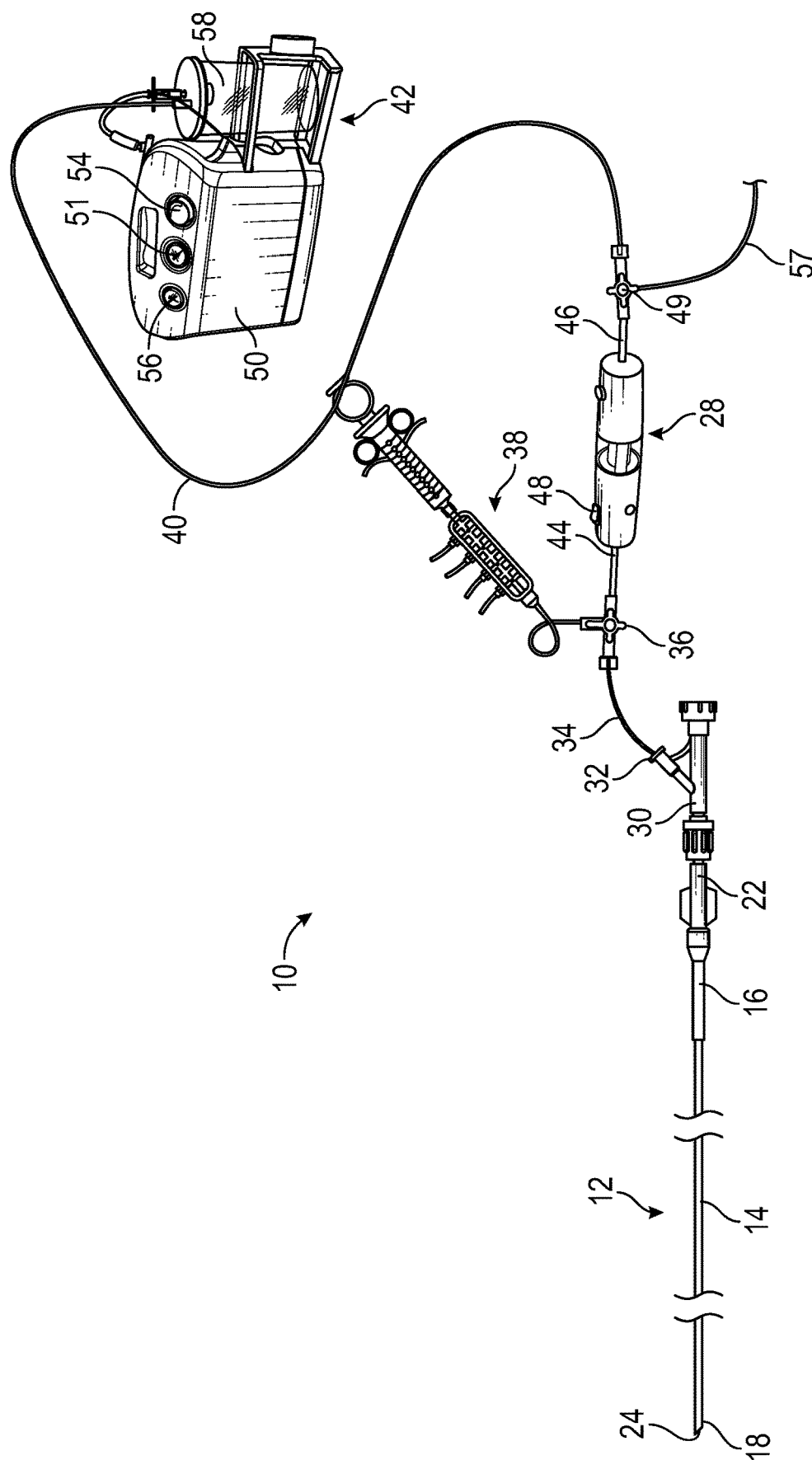


FIG. 1

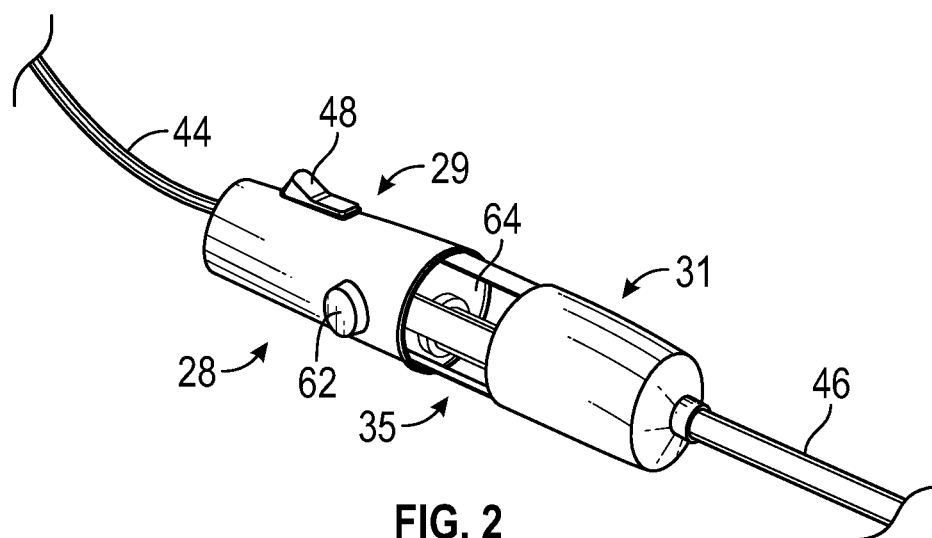


FIG. 2

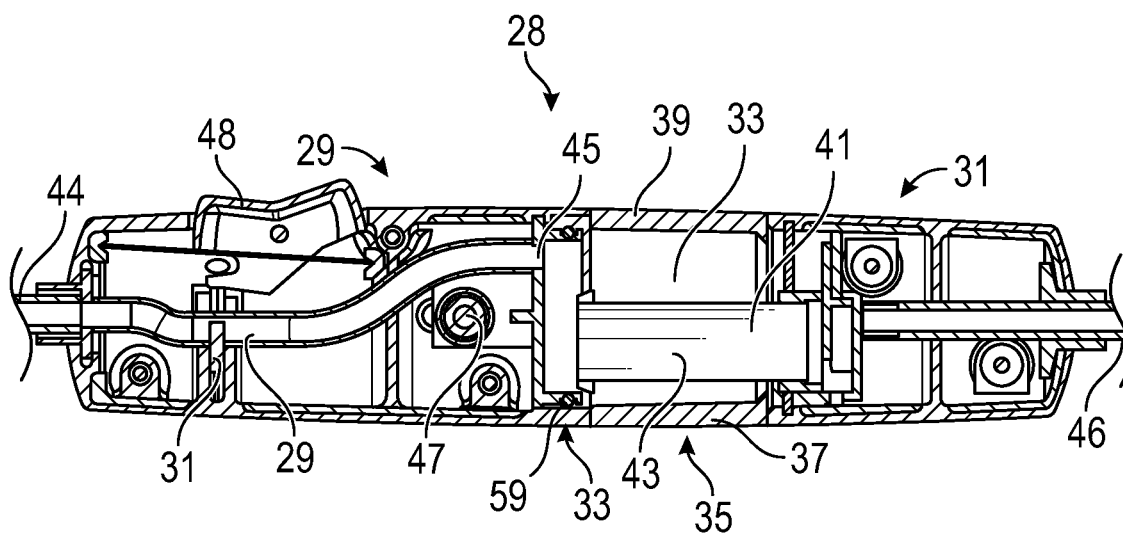


FIG. 3

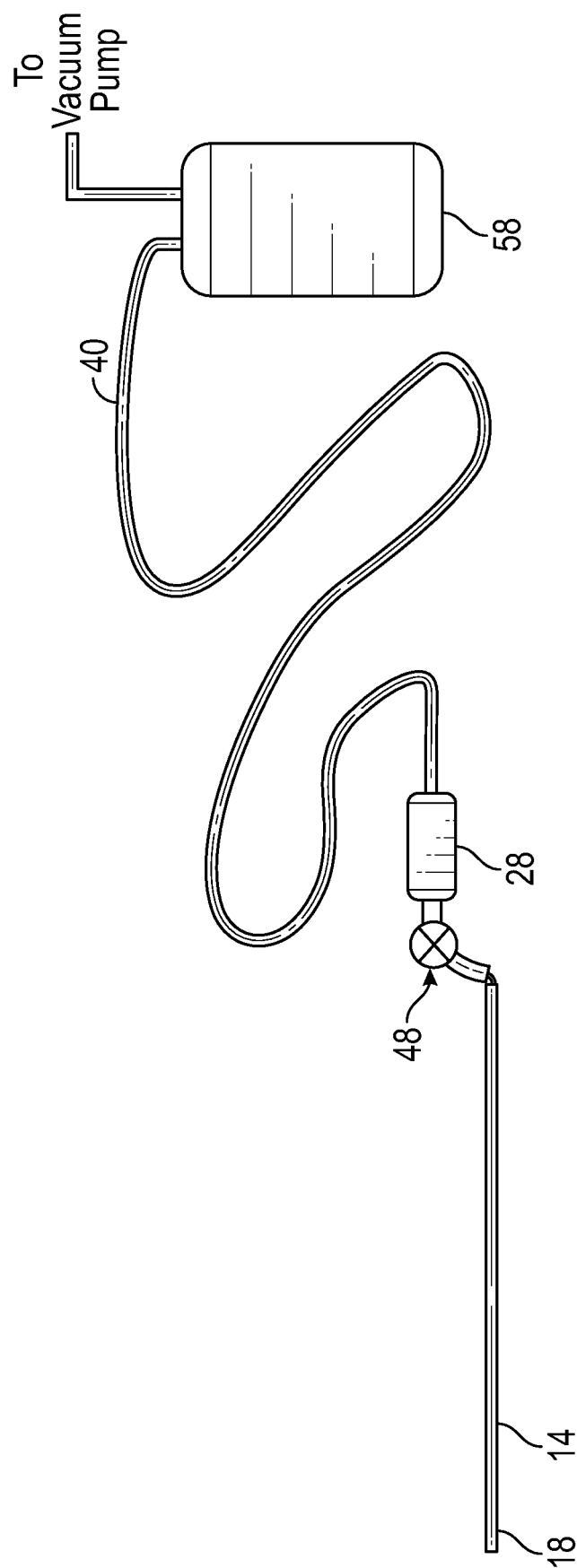


FIG. 4

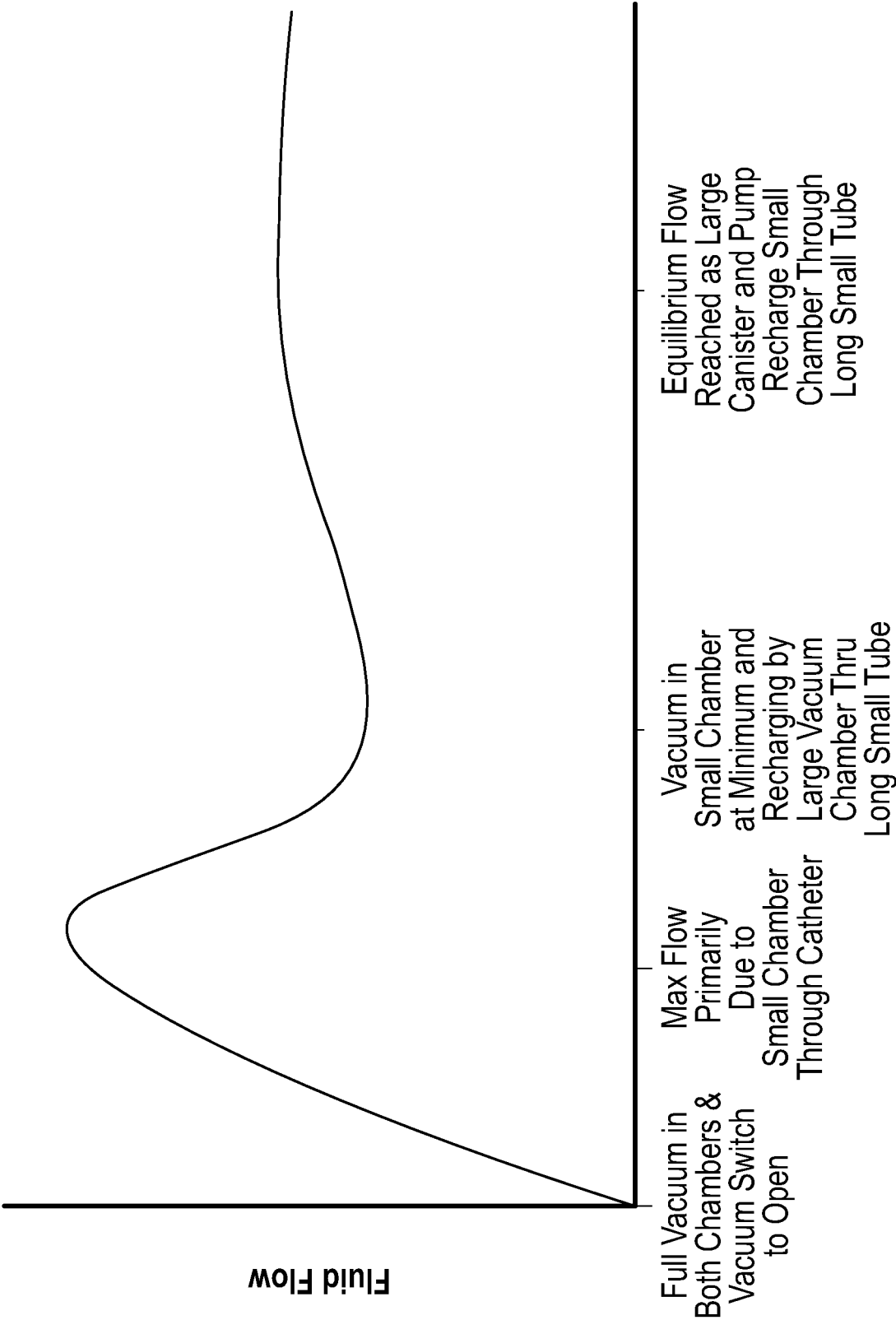


FIG. 5

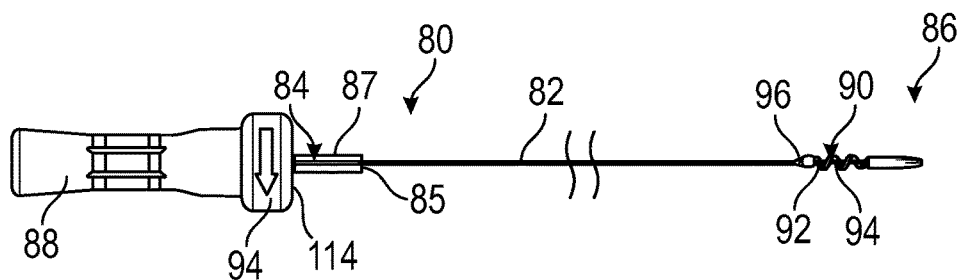


FIG. 6A

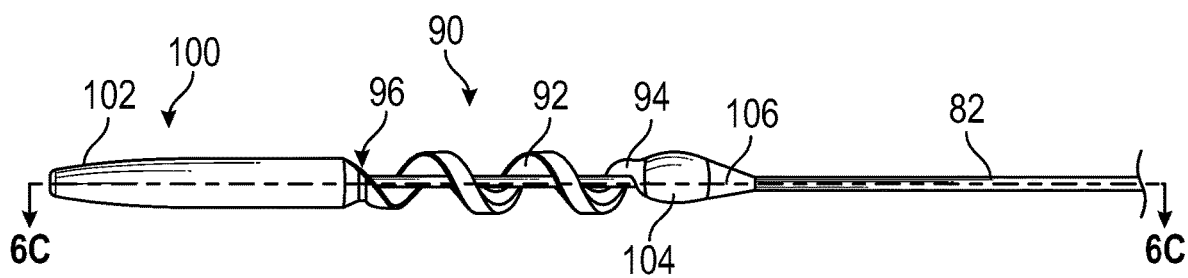


FIG. 6B

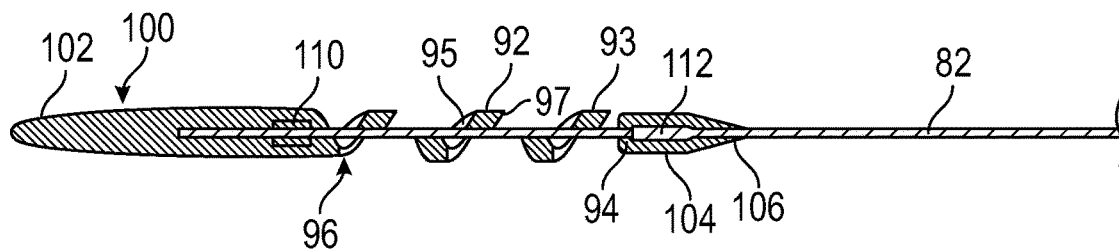


FIG. 6C

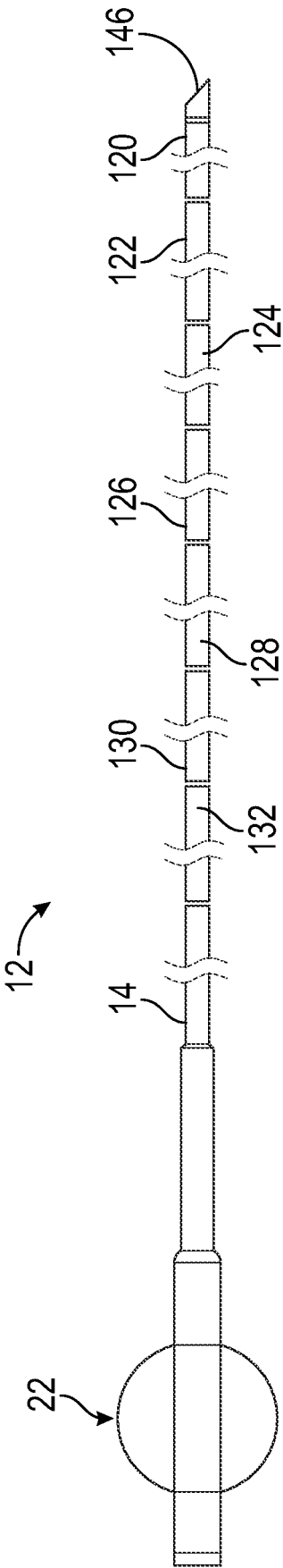
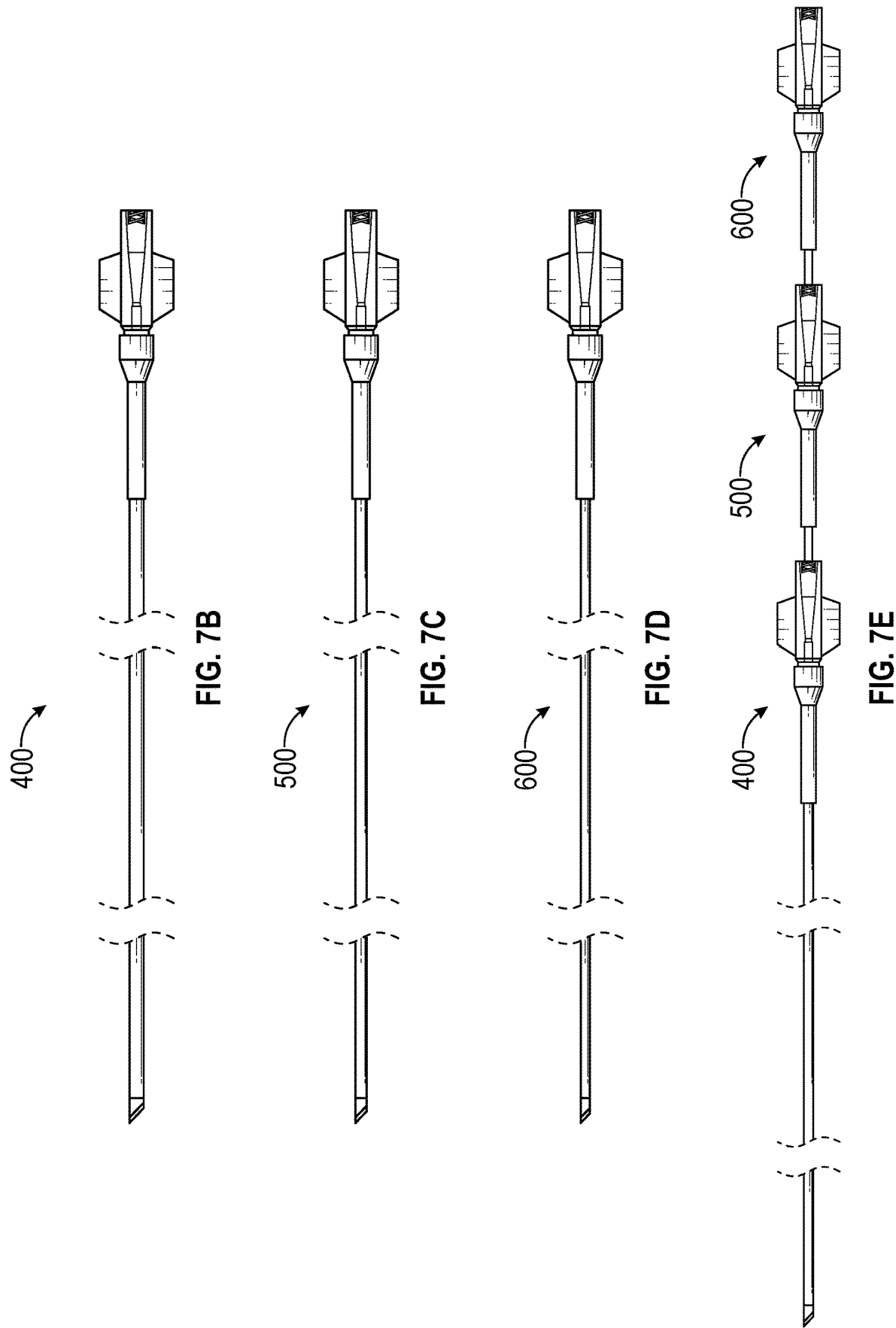


FIG. 7A



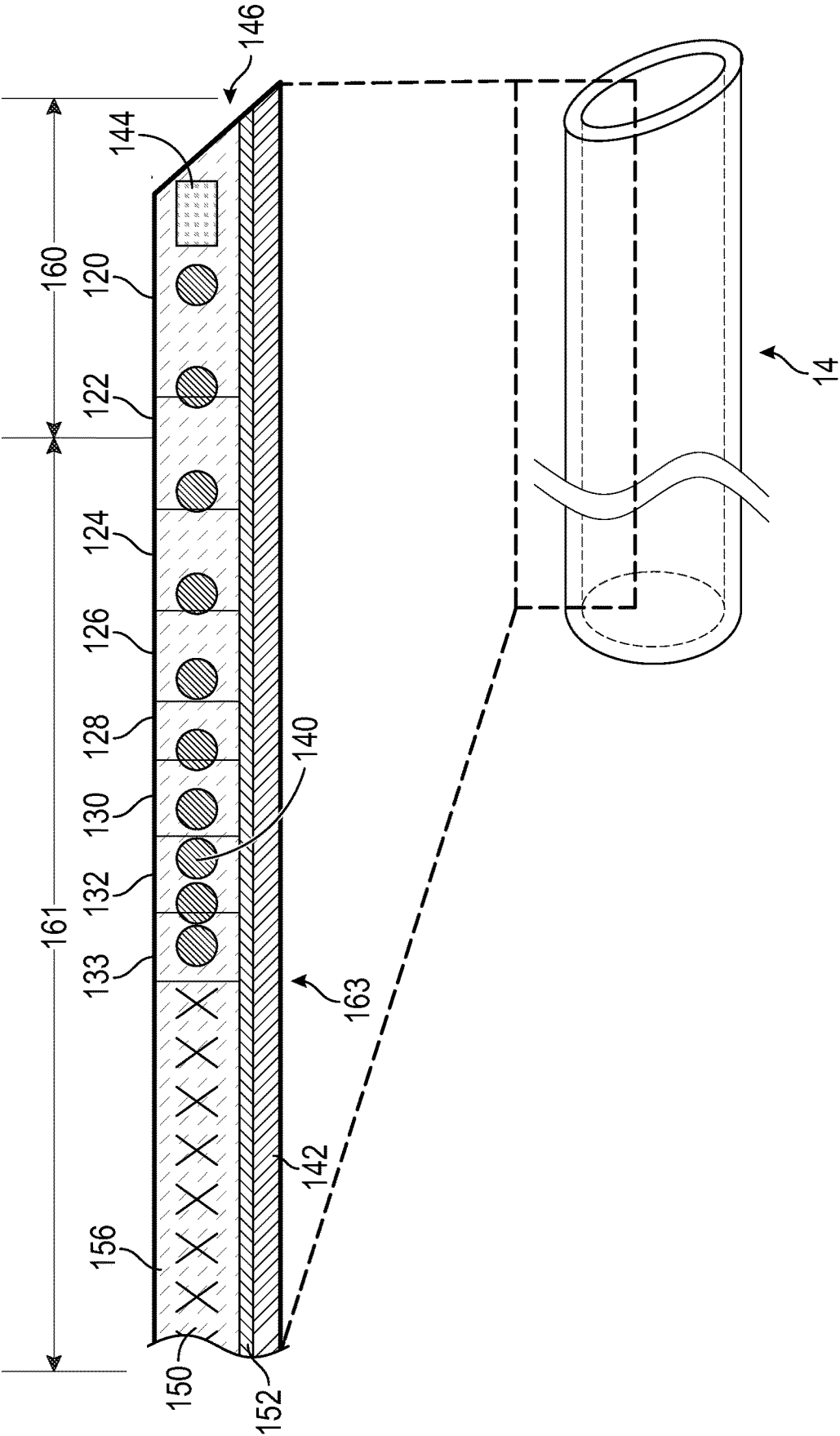


FIG. 8

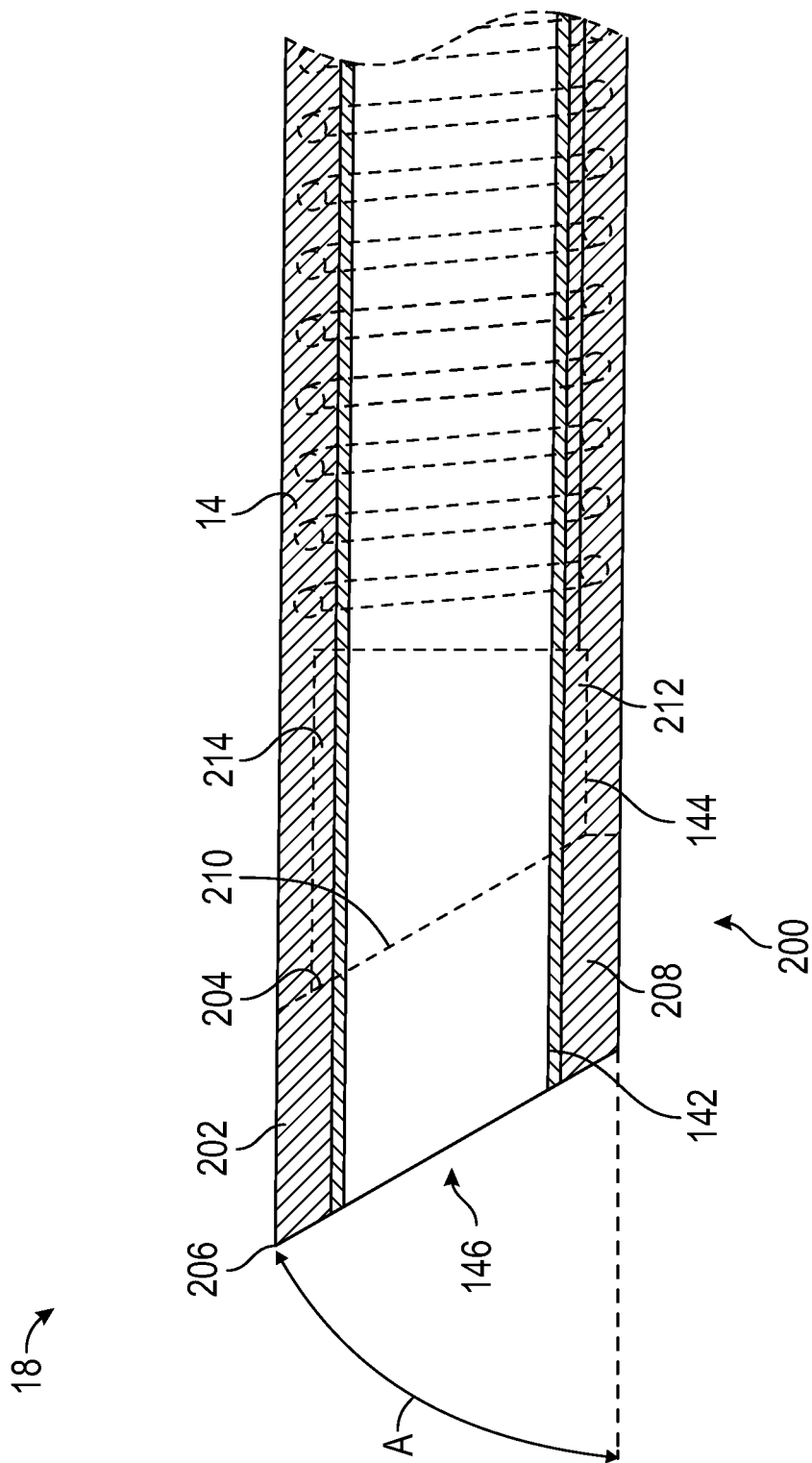


FIG. 9

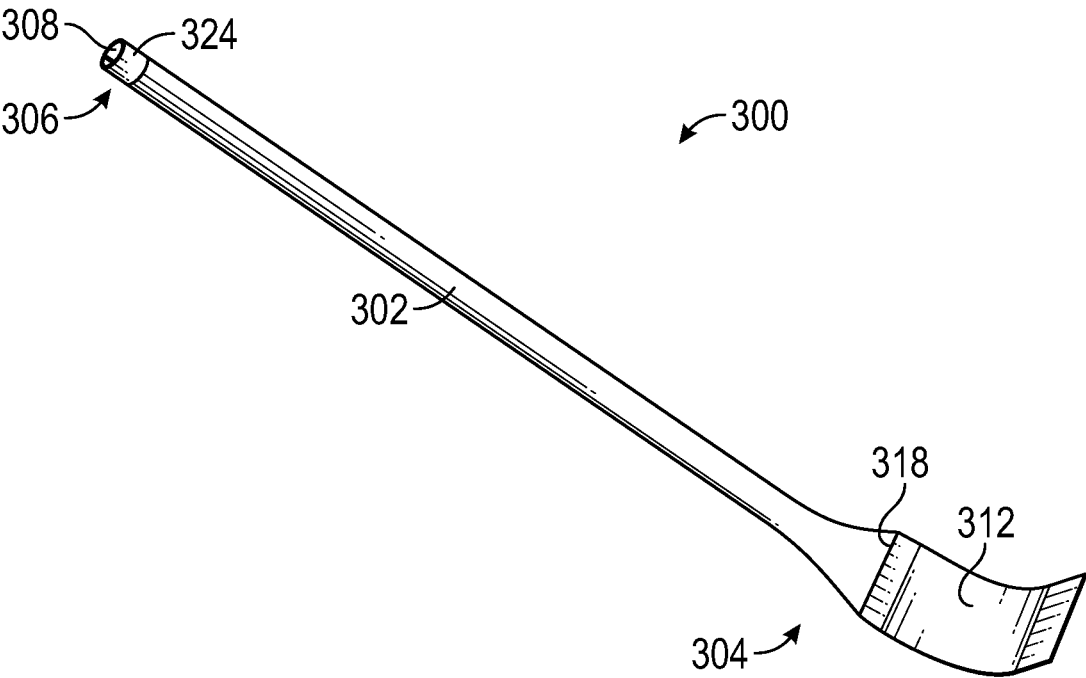


FIG. 10A

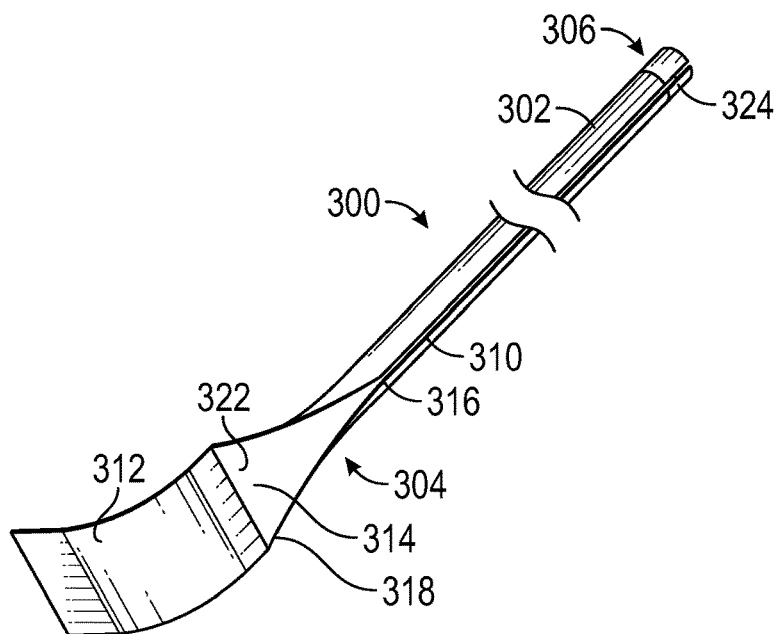


FIG. 10B

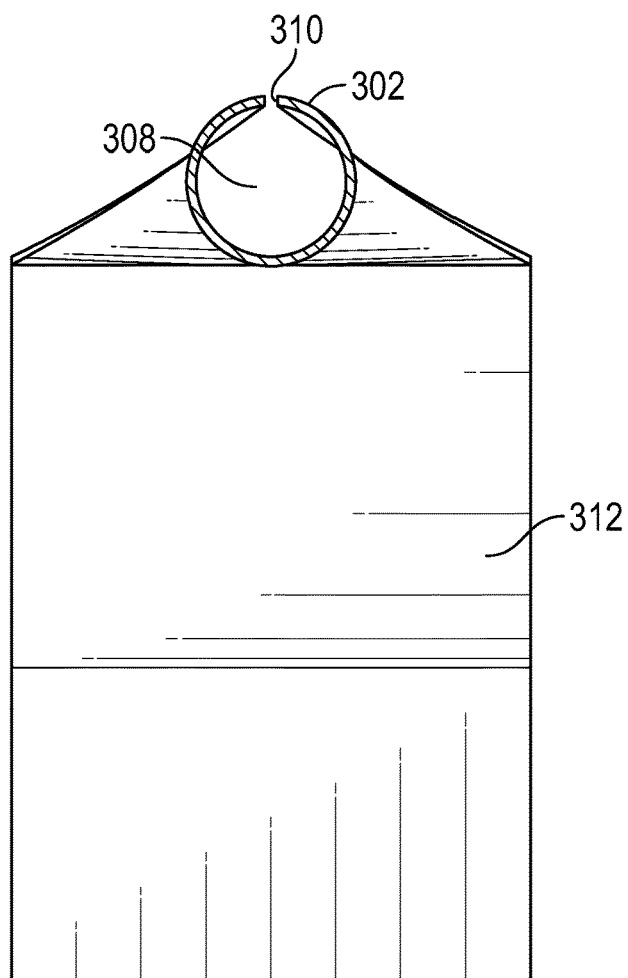


FIG. 10C

**INSERTER FOR GUIDING A DEVICE
THROUGH A HEMOSTASIS VALVE AND
METHOD THEREOF**

INCORPORATION BY REFERENCE

[0001] This application claims the priority benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application No. 63/341,926, filed May 13, 2022.

BACKGROUND

[0002] Removal of blood clots from the vascular system (thrombectomy) using a trans vascular approach may be accomplished at any of a variety of treatment sites, such as arteries in the extremities, veins for deep vein thrombosis (DVT), large veins and arteries (central vessels) such as iliac veins and arteries, the aorta, the inferior vena cava and pulmonary arteries to treat pulmonary emboli (PE).

[0003] For example, venous thromboembolic disease (VTE) is a worldwide crisis. There are over 10 million cases of DVT and PE diagnosed globally per year, with 1 million cases occurring in the United States and over 700,000 in France, Italy, Germany, Spain, Sweden, and the United Kingdom combined each year. There are approximately 60,000 to 100,000 deaths from PE in the United States each year. DVT and PE are part of the same continuum of disease, with over 95% of emboli originating in the lower extremities. When PE occurs, the severity depends on the embolic burden and its effect on the right ventricle as well as underlying cardiopulmonary comorbidities. Death can result from the acute increase in pulmonary artery (PA) pressure with increased right ventricular (RV) afterload and dysfunction.

[0004] Patients with high-risk PE have been treated primarily with thrombolytic therapy delivered systemically or more locally through Catheter Directed Thrombolytics. These approaches result in multiple catheterization lab visits, lengthy hospital stays and often lead to bleeding complications. Newer approaches to PE treatment include single session thrombectomy treatments without the use of thrombolytics. These thrombectomy treatments include delivering a catheter into the PA to remove the thrombus through aspiration, and secondary tools may also macerate or disrupt the thrombus prior to aspiration. While thrombectomy results in fewer bleeding complications and reduced hospital stays compared to thrombolytics, there is much to be improved upon given the challenges of the procedure itself, including the ability to capture a broad spectrum of thrombus types and reduce the total volume of blood loss during the procedure.

[0005] The thrombectomy catheter is introduced through an introducer puncture in a large diameter vein. A flexible guide wire is passed through the introducer into the vein and the introducer is removed. The flexible guidewire provides a rail for a flexible guide catheter to be advanced through the right atrium into the right ventricle and into the pulmonary artery. The flexible guidewire is removed and replaced with a stiff guidewire. The large diameter thrombectomy catheter with support dilator is then advanced over the stiff guidewire to the pulmonary artery and the dilator is removed. If the large diameter thrombectomy catheter is not successful in accessing or aspirating thrombus in a more distal portion of the vessel, a smaller diameter catheter may be inserted through the large diameter catheter.

[0006] In addition, peripheral arterial occlusive (PAO) disease occurs in more than 4% of individuals over age 40 and markedly increases in incidence after the age of 70. Acute PAO is usually due to thrombosis of the peripheral vasculature and is associated with a significant risk of limb loss. In order to preserve the limb, therapy for acute PAO centers on the rapid restoration of arterial patency and blood flow such as through mechanical thrombectomy in procedures similar to those described above.

[0007] Clot aspiration using certain commercial vacuum-assisted thrombectomy systems may sometimes need to be terminated due to the risk of excessive blood loss by the patient, especially when using large aspiration catheters. During aspiration thrombectomy, when the catheter tip falls out of contact with the thrombus or other occlusive material, the tip is exposed to healthy blood and full flow of blood through the catheter ensues. Under such conditions, the total volume of blood loss may be excessive, and in some cases, may result in premature termination of the procedure. For example, during a procedure when the catheter enters healthy blood and full aspiration flow ensues, the blood loss rate can be on the order of 30-40 cc per second with an 24 French size catheter. With a maximum tolerable blood loss on the order of about 500 mL, the catheter cannot run in unrestricted mode for more than approximately 10 to 15 seconds. The aggregate blood loss may reach an unacceptable level before sufficient clot is removed.

[0008] Thus, notwithstanding prior efforts, there remains a need for an improved technology for removing or reducing thrombotic restrictions and occlusions within either the patient's arterial or venous blood vessels.

SUMMARY

[0009] There is provided in accordance with one aspect of the present invention, a clot capture module for use in a thrombectomy system, such as within the sterile field. The clot capture module comprises a housing; a clot capture chamber in the housing; a window in the housing to permit visual inspection of the clot chamber; and a filter in the clot chamber, visible through the window, the filter having an upstream surface and a downstream surface.

[0010] An incoming flow path is configured to direct incoming blood from an aspiration catheter against the upstream surface of the filter. An aspiration control valve is provided in the incoming flow path, configured to block or permit the flow of incoming blood. An outgoing flow path is configured to direct blood from the second side of the filter to a remote vacuum canister.

[0011] The clot capture module may further comprise a vent valve, openable to permit an optically transparent media such as air or saline to be drawn into the clot chamber, enabling blood to be evacuated from the clot chamber to a remote canister. The upstream surface of the filter may be visible through the window, so that clot accumulated on the upstream surface can be visually observed through the window, once the vent has been opened to evacuate blood from the clot capture chamber. The window may comprise a transparent cylindrical portion of the housing.

[0012] The upstream surface of the filter may be substantially planar. Alternatively, the upstream surface of the filter may be convex. The filter may comprise a tubular porous membrane such as a cylinder, and the upstream surface of the filter may be on a radially outwardly facing surface of the

membrane. The tubular filter membrane may enclose a filtered blood chamber which is in communication with the outgoing flow path.

[0013] The module may further comprise an aspiration control, for controlling the aspiration control valve. The aspiration control may comprise a rocker switch, configured to selectively collapse or allow reopening of a collapsible tubing. The aspiration control valve may be normally closed, and may be spring biased into the closed configuration.

[0014] The clot capture module may be provided in combination with a vacuum line leading to an aspiration pump and canister, wherein the clot capture module is configured to reside within a sterile field and the aspiration pump and canister are outside of the sterile field. The vacuum line may be at least about 30 inches or 50 inches or more in length. In some instances, a manually actuated aspiration device (e.g., a syringe) may be used in addition to, or as an alternative to, an aspiration pump to permit a user to manually apply aspiration through the vacuum line.

[0015] There is provided in accordance with another aspect of the present invention, a thrombus engagement tool, configured to advance through an aspiration catheter and engage thrombus. The thrombus engagement tool comprises a rotatable core wire having a proximal end and a distal end; and a thrombus engagement tip on the distal end of the core wire. The tip may comprise a helical thread; an advance segment on a distal side of the thread and a trailing segment on a proximal side of the thread. The advance segment, helical thread and trailing segment may all be molded onto the core wire.

[0016] The thrombus engagement tool may further comprise a projection on the core wire, underneath at least one of the advance segment and the trailing segment, to form an interference fit with the thrombus engagement tip. The projection may comprise an annular ring, which may be a radiopaque marker. The thrombus engagement tool may comprise a first radiopaque marker under the advance segment and a second radiopaque marker under the trailing segment.

[0017] An outer periphery of the helical thread may substantially conform to an inside surface of a cylinder. The thread may comprise a proximal surface which inclines radially outwardly in a proximal direction to define a proximally opening undercut.

[0018] The thrombus engagement tool may further comprise a handle on the proximal end of the core wire configured for hand turning the core wire. A limit bearing surface may be provided on the handle, for limiting distal projection of the thrombus engagement tip relative to a distal end of the aspiration catheter.

[0019] There is further provided a method of removing embolic material from a vessel with mechanical and aspiration assistance. The method comprises the steps of providing an aspiration catheter having a central lumen and a distal end; advancing the distal end to obstructive material in a vessel; applying vacuum to the lumen to draw clot at least partially into the lumen; and introducing a thrombus engagement tool into the lumen. The thrombus engagement tool may have a tip with an axial length of no more than about 1 cm or about 5 mm and a helical thread having a major diameter that is at least about 0.015 inches smaller than an inside diameter of the lumen, to provide an aspiration flow path through the lumen around the outside of the tip. The

method further comprises manually rotating the tip to engage clot between the tip and an inside wall of the lumen.

[0020] A method of aspirating a vascular occlusion from a remote site, comprises the steps of advancing an elongate tubular body through a vascular access site and up to a vascular occlusion, the tubular body comprising a proximal end, a distal end, a central lumen, and a stop surface. A rotatable core is advanced distally through the lumen until a limit surface carried by the core rotatably slidably engages the stop surface to provide a rotatable bearing which limits further distal advance of the core within the lumen. Vacuum is applied to the lumen and the core is manually rotated to engage thrombus. The advancing the rotatable core may be accomplished after the step of advancing the elongate tubular body through the vascular access site and up to the vascular occlusion. The core may be a solid core wire or a cannulated structure such as a hypotube or microcatheter having a central lumen extending axially between a proximal opening and a distal opening.

[0021] The core may carry a proximal handle, and the limit surface may be carried by the handle. The tubular body may include a proximal hub, and the stop surface may be carried by the hub. The core may carry an engagement tip having a helical thread, and the engaging thrombus step may comprise pinning thrombus between a first side of the tip and an inside surface of the tubular body.

[0022] There is also provided an inserter for guiding a device through a hemostasis valve, comprising an elongate tubular body, having a proximal end, a distal end and a central lumen; a laterally facing concave landing zone on the proximal end, having a radius of curvature that increases in the proximal direction; and an axially extending slit in the sidewall, extending from the distal end to the landing zone. The tubular body may further comprise a tapered distal tip, and a proximal pull tab to facilitate removal of the inserter from the device. A surface of the landing zone may comprise a different color than an outside surface of the tubular body, to facilitate visualization of the landing zone and advancing the distal end of the device into the tubular body.

[0023] A method of passing a device through a hemostasis valve may comprise the steps of providing an inserter, having a tubular body with a split sidewall; advancing the tubular body through a hemostasis valve; advancing a device through the tubular body and beyond the hemostasis valve; and proximally retracting the tubular body so that the device escapes laterally from the tubular body through the split sidewall, leaving the device in place across the hemostasis valve.

[0024] The advancing the tubular body step may comprise advancing a tapered distal tip on the tubular body through the hemostasis valve. The advancing the tubular body through the hemostasis valve step may be accomplished with the device pre loaded inside the tubular body.

[0025] A distal nose segment of the tubular body may expand in diameter in response to advancing the device therethrough. The device may be a thrombus engagement tool or a secondary catheter. The secondary catheter may be an aspiration catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] FIG. 1 is a schematic view of a thrombus removal system in accordance with the present invention.

[0027] FIG. 2 is a perspective view of a flow control module.

[0028] FIG. 3 is an elevational or cross-sectional view through the flow control module of FIG. 2.

[0029] FIG. 4 is a schematic view of the dual vacuum chamber configuration that produces an accelerated aspiration response.

[0030] FIG. 5 is a qualitative fluid flow rate diagram at the catheter tip following opening of the vacuum control valve.

[0031] FIG. 6A is a side elevational view of a thrombus engagement tool.

[0032] FIG. 6B is an enlarged detail view of the distal end of the thrombus engagement tool of FIG. 6A.

[0033] FIG. 6C is a longitudinal elevational cross-section through the thrombus engagement tool of FIG. 6B.

[0034] FIGS. 7A-7E are side elevational views of various embodiments of thrombectomy catheters.

[0035] FIG. 8 is a cross-sectional view through a distal portion of the embolectomy catheter showing a side wall construction.

[0036] FIG. 9 is a cross-sectional view through a distal portion of the embolectomy catheter showing the radiopaque marker and inclined distal face.

[0037] FIGS. 10A-10B are perspective views of an inserter tool to facilitate passing a catheter through a hemostasis valve.

[0038] FIG. 10C is an end view of the inserter of FIGS. 10A and 10B.

DETAILED DESCRIPTION

[0039] Referring to FIG. 1, there is illustrated a thrombectomy system such as for PE or DVT aspiration procedures. The system 10 includes a thrombectomy catheter 12, having an elongate tubular body 14 extending between the proximal end 16 and a distal end 18. A central lumen 20 (not illustrated in FIG. 1) extends between a proximal catheter connector 22 and a distal port 24 on the distal end 18.

[0040] Although primarily described in the context of an aspiration catheter with a single central lumen, catheters of the present invention can readily be modified to incorporate additional structures, such as permanent or removable column strength enhancing mandrels, two or more lumen such as to permit drug, contrast or irrigant infusion or to supply inflation media to an inflatable balloon carried by the catheter, or any combinations of these features, as will be readily apparent to one of skill in the art in view of the disclosure herein. In addition, the disclosure will be described primarily in the context of removing obstructive material from the vasculature, but it will be understood to have applicability as an access catheter for delivery and removal of any of a variety of diagnostics or therapeutic devices with or without aspiration.

[0041] The catheters disclosed herein may readily be adapted for use throughout the body wherever it may be desirable to distally advance a low profile high flexibility catheter into a variety of type of vasculature, such as small or large vasculature and/or tortuous or relatively straight vasculature. For example, catheter shafts in accordance with any embodiment described herein may be dimensioned for use throughout the neurovascular, coronary and peripheral vasculature, the gastrointestinal tract, the urethra, ureters, Fallopian tubes and other lumens and potential lumens, as well. The catheter shaft construction of any embodiment herein may also be used to provide minimally invasive percutaneous tissue access, such as for diagnostic or therapeutic access to a solid tissue target (e.g., breast or liver or

brain biopsy or tissue excision), delivery of laparoscopic tools or access to bones such as the spine for delivery of screws, bone cement or other tools or implants.

[0042] Catheter 12 will have a length and diameter suitable for the intended access point and target location. In one example, referring to FIG. 1, the catheter 12 may have an effective length from the distal end of manifold or hub 22 to distal tip 18 generally no more than about 230 cm, no more than about 210 cm, no more than about 180 cm, or no more than about 160 cm, and typically from about 50 cm to about 150 cm, from about 90 cm to about 130 cm, or from about 105 cm to about 115 cm. The outer diameter of the catheter 10 may be from about 0.035 inches to about 0.15 inches, from about 0.09 inches to about 0.13 inches, and may be lower in a distal segment than in a proximal segment.

[0043] The inner diameter of the catheter 12 in a single central lumen embodiment may be greater than or equal to about 0.1 inches, greater than or equal to about 0.088 inches, or greater than or equal to about 0.08 inches, or greater than or equal to about 0.06. The inner diameter of the catheter 12 in a single central lumen embodiment may be less than about 0.20 inches or 0.15 inches, or less than or equal to about 0.11 inches, less than or equal to about 0.1 inches, less than or equal to about 0.088 inches, or less than or equal to about 0.07 inches, and often no more than about 0.095 inches.

[0044] In the illustrated embodiment, the catheter 12 is releasably connectable to a flow control module 28 by way of a complementary connector module 30. Connector module 30 provides a releasable connection to complementary catheter connector 22 and may include a side port 32 for releasable connection to tubing 34 which may lead to a valve 36. Connector module 30 may additionally comprise a hemostasis valve configured to receive another device such as a guidewire or thrombus engagement tool, discussed below.

[0045] Valve 36 may selectively place tubing 34 into communication with side port 37 or the flow control module 28 discussed in greater detail below. Side port 37 may be placed into communication with a source of media such as saline, contrast solution or medication, or a manifold 38 which can provide selective communication with each. The use of valve 36 allows infusion of a desired media without detaching the tubing 34 from the connector module 30.

[0046] Referring to FIGS. 2 and 3, the flow control module 28 is in communication with the valve 36 by way of a distal tube 44. Flow control module 28 is in communication with the selector valve 49 by way of a proximal tube 46. This establishes a flow path between the distal port 24 through the catheter 12 through the various tubing and flow control module 28 to the pump assembly 42. In an alternate implementation of the invention, the flow control module 28 may be integrally formed within the hub of thrombectomy catheter 12 to which the catheter 12 may be removably or non-removably attached or within the connector module 30. In some instances, a manually actuated aspiration device (e.g., a syringe) may be used in addition to, or as an alternative to, an aspiration pump assembly 42 to permit a user to manually apply aspiration through the vacuum line. It will be understood by one having skill in the art that a manually actuated aspiration device may be in addition to, or as an alternative to, the pump assembly described in any embodiment herein.

[0047] Flow control module 28 may include a flow regulator such as an on-off control for regulating flow through

the flow path between the catheter 12 and pump 42. The flow regulator is configured to provide a reversible restriction in the flow path, such as by an expandable or contractible iris, a ball valve or other rotary core valve, leaf valve, a pinch tubing, or others known in the art.

[0048] In one implementation, the flow regulator comprises a collapsible portion 29 of the tubular wall defining the flow path, such as a section of polymeric tubing. An actuator 31 positioned adjacent the tubing is movable in response to a control such as a push button or toggle switch 48 between a first position where it compresses the tubing, thereby completely restricting flow, and a second position where it has moved away from the tubing, allowing the tubing to resume its full inside diameter and allow fluid flow. The actuator 31 may be spring biased or have another default driver in the direction of the first (restricted) position, and only movable into the second (open) position in the presence of an affirmative mechanical force or release of a constraint allowing the flow path to open. Upon removal of the momentary “on” command, the actuator 31 automatically resumes the first position, obstructing flow.

[0049] The actuator 31 may be driven by a mechanical control such as a lever or rotatable knob, or an electrically driven system such as a solenoid, operated by any of a variety of buttons, levers, triggers, foot pedals or other switches known in the art, depending upon the desired functionality.

[0050] The flow control module 28 may contain a filter chamber 33 for example, which is in communication with the vacuum canister 58 on the pump assembly 42 by way of elongate aspiration tubing 40. The toggle switch 48 is in between the filter chamber 33 and the catheter 12. In a default off position of some embodiments, this allows the entire length of the aspiration tubing 40 and the filter chamber 33 to reach the same low pressure as the aspiration canister 58 on the pump 42.

[0051] Additional details of the filter assembly and related structures are illustrated in FIG. 3. A filter assembly 35 includes an outer tubular sidewall 37 having a transparent window 39. In some implementations the entire tubular sidewall 37 can be a transparent window. The side wall 37 encloses a filter 41. The filter 41 includes a filter sidewall 43 defining an interior (downstream) chamber (not illustrated) for filtered blood.

[0052] Upon opening the flow path by activating the switch 48, blood and thrombus are drawn in the direction from catheter 12 via vacuum line 44 through a first filter aperture 45 and into the clot collection chamber 33. Any thrombus will be captured on the outside (upstream side) of filter 43. Blood is drawn through the filter 43 and proximal tubing 46 en route to the canister 58. In the illustrated example, the filter 43 is tubular however it may alternatively be planar or other shape depending upon the desired configuration.

[0053] The switch 48 may thereafter be closed to compress tubing 29 and isolate the catheter 12 from the vacuum source. A normally closed vent 47 may be momentarily opened, to permit intake of an optically transparent media such as saline or ambient air. This allows residual blood in the chamber 33 to be drawn through the filter 43 and aspirated out via proximal tubing 46, enabling visualization of any clot on the surface of the filter 43 through the window 39. The vent 47 may be manually actuated by a user and/or automatically actuated by the system. In some instances, a

user may manually actuate the vent 47 through actuation of a button 62 located on the flow control module 28.

[0054] For example, the vent 67 may be normally closed, and then transitioned to an open configuration when the button 62 is being actuated (or vice versa). When in the open configuration, the vent 67 may expose the clot collection chamber 33 to an ambient environment. In some instances, exposure of the chamber 33 to the ambient environment allowing intake of air and acceleration of blood flow through the clot collection chamber 33 and towards the proximal tubing. Increased acceleration of blood flow due to vent 47 actuation may facilitate visualization of the clot by displacing the amount of blood or other fluids from the optical path between the window and the filter and/or decrease the amount of time required for the physician to accurately identify the clot in the chamber 33. The valved vent also allows the physician to deliver pulsatile negative pressure waves at the distal opening 24.

[0055] In the illustrated embodiment, the flow control module 28 comprises a proximal housing 31 and a distal housing 29 separated by the transparent tubular sidewall 35. The tubular sidewall 35 and the filter 43 are carried by the proximal housing 31. Housing 29 and tubular sidewall 35 may be joined at a releasable connection 33 that, in some instances, includes a gasket 59 to form a sealed connection. Complementary surface structures (e.g., inclined corresponding grooves and pins or flanges) may permit rapid attachment and detachment. For example, the proximal housing 31 and the distal housing 29 may be rotated relative to each other (e.g., by relative rotation across the gasket) to disconnect the housings from each other.

[0056] The filter 43 may be attached to any one of the distal housing 29 or the proximal housing 31 upon disconnection of the housings. The tubular sidewall 35 may be attached to either one of the distal housing 29 and/or the proximal housing 31 such that, upon disconnection, the tubular sidewall 35 may remain attached to one of the housings 29, 31. Upon detaching and separating the proximal housing 31 from the distal housing 29, the tubular sidewall 35 may be configured to remain around the filter 43 or may be configured to be removed from over the filter 43. In either instance, disconnection of the housings 29, 31 from each other can expose the filter 43 and allow a clot to be easily accessed and removed.

[0057] The interior surface of the clot collection container 33 may comprise a coating to provide one or more of a variety of properties to the clot collection containers 33. In some instances, the coating may be configured to enhance visualization through at least a portion of the clot collection container 33 (such as the transparent window 39). The coating may be configured to inhibit blood accumulation or increase blood repellent properties. In some instances, the clot collection container 33 may comprise a coating to inhibit foam formation during an aspiration procedure. The coatings may be located at least partially along an interior surface of the tubular sidewall 35 and/or the clot collection container 33 or along an entire interior surface of the tubular sidewall 35 and/or the clot collection container 33. In some instance, the coating is located along an interior surface of the transparent window 39. The coating can be both hydrophobic and oleophobic. In some instances, the coating may have some hydrophilic features on a portion of the polymer to increase oleophobic properties.

[0058] Aspiration pump assembly 42 may be releasably placed into communication with flow control module 28 such as by a luer connection between selector valve 45 and tubing 40. Aspiration pump assembly 42 may include a vacuum pump 50, and may also include a vacuum gauge 51, and an optional pressure adjustment control 54. The vacuum gauge 51 is in fluid communication with the vacuum pump and indicates the vacuum pressure generated by the pump. The pressure adjustment control 54 allows the user to set to a specific vacuum pressure. Power button 56 activates the pump 50.

[0059] The vacuum canister 58 may be provided with a vent 53 to atmosphere, opened or closed by a valve. In one implementation the valve is normally closed to permit vacuum in the canister to reach a desired low pressure. The valve may be momentarily opened as desired to permit introduction of air and reduction of the vacuum, such as to reduce foaming within the vacuum canister 58.

[0060] The vent may function to reduce foaming and increase visibility within the canister. In some instances, the vent 53 comprises a permanently opened vent such as in a lid or side wall of the vacuum canister. The vent may comprise an aperture formed through the lid or side wall having a diameter of no more than about 0.5 mm or 0.25 mm and may be a laser cut hole through a metal sheet which may be in the form of a disc carried by the lid.

[0061] In addition to or as an alternative to the vent, the inside surface of the canister 58 may be provided with a coating of one or more materials to inhibit foaming of blood under vacuum. The coatings may be located at least partially along or entirely along an interior surface of the vacuum canister 58. The coating can be both hydrophobic and oleophobic. In some instances, the coating may have some hydrophilic features on a portion of the polymer to increase oleophobic properties.

[0062] Any of a variety of controls may be utilized to operate the various pump functions, including switches, buttons, levers, rotatable knobs, and others which will be apparent to those of skill in the art in view of the disclosure herein. Aspiration pump 50 may alternatively be a manually activated pump such as a syringe.

[0063] In some applications, it may be desirable to provide a non occlusive restriction of flow between the vacuum canister 58 and the flow control module 28. A flow restrictor may be coupled such as by luer connectors in series with the vacuum line 40. In one implementation the flow restrictors enables toggling between a low flow and a high flow configuration. The flow restrictors may comprise a variable restrictor that may be adjusted by a user. This may be accomplished by selectively diverting flow between a relatively smaller diameter and larger diameter aperture, a variable diameter aperture, or other flow regulators such as any of those disclosed in the United States patent publication No. 2021/0315597 to Buck, et al, entitled Aspiration System with Accelerated Response, the disclosure of which is hereby incorporated in its entirety herein.

[0064] In one particular implementation, a rotatable drum is provided with a first transverse flow path having a first diameter. The drum is rotatable within a housing having an inlet port and an outlet port. The drum may be rotated to place the inlet port into fluid communication with the outlet port through the first flow path. A second flow path having a second, different diameter also extends transversely through the drum, rotationally offset from the first flow path.

The drum may be rotated to place the inlet port into communication with the outlet port through the second flow path, thereby providing a flow rate through the drum different from the flow rate provided by the first flow path.

[0065] The filter chamber 33 on the flow control module 28 or on the connector module 30 is spaced apart from the remote vacuum pump 42 and vacuum canister 58 to provide enhanced aspiration performance. Conventional aspiration pumps and filters are intended to be placed outside of the sterile field and may be far enough away from the patient to require a length of aspiration tubing 40 between the pump assembly 42 and the catheter 12 to be at least about 50 inches or about 100 inches or more. For example, the tubing 40 may be about 102 inches.

[0066] The pump typically includes an aspiration canister 58 for blood collection. When aspiration is desired in a prior art system, a valve is opened to place the low pressure canister 58 in communication with the catheter 12 by way of the aspiration tubing 40, to aspirate material from the patient. But the length of the aspiration tubing extending from inside to outside of the sterile field operates as a flow restrictor, causing a delay between the time of activating the vacuum button on the pump assembly 42 and actual application of suction to the clot at the distal end of the catheter.

[0067] In the illustrated implementation, the only flow restriction between a source of vacuum (filter chamber 33) and the patient is the relatively short aspiration pathway between the on/off valve in the handpiece actuated by toggle switch 48 and the distal end 18 of the catheter. When the aspiration control 48 is activated to open the flow path, the flow restriction and enclosed volume on the patient side of the filter chamber 33 is low relative to the flow restriction and enclosed volume through aspiration tubing 40 on the pump side of the filter chamber 33.

[0068] This dual chamber configuration produces a rapid spike in negative pressure experienced at the distal end 18 of the catheter 12 upon activation of the aspiration control 48, and rapid filling of the chamber 33. The response time between activating the aspiration control 48 and realizing suction actually experienced at the clot is significantly faster and allows significantly higher initial flow than the response time realized in a conventional system having only a vacuum chamber 58 located at the pump assembly 42 outside of the sterile field.

[0069] The spike of negative pressure experienced at the distal end of the catheter will fade as pressure equilibrium is reached between the filter chamber 33 and canister 58. When the aspiration control 48 is closed, the vacuum pump 50 will gradually bring the pressure in the filter chamber 33 back down to the level in the vacuum canister 58 at the pump.

[0070] A simplified fluid flow diagram is illustrated in FIG. 4, and a qualitative flow rate diagram is illustrated in FIG. 5. The flow restriction between chamber 33 and the distal end 18 of catheter 12 is small relative to the flow restriction between the vacuum canister 58 and the vacuum chamber 33. This allows a negative pressure peak experienced at distal end 18 almost instantaneously upon activation of vacuum switch 48. The flow rate of material into the catheter 12 rapidly reaches a peak and subsides as vacuum chamber 33 fills with aspirated material. The vacuum in chamber 33 declines to a minimum, and slowly recharges by the large vacuum chamber 58 and associated pump through tubing 40 when the toggle switch 48 is moved into the closed position. In some instances of use, a clinician may choose to

close the vacuum switch **48** at or shortly following the maximum flow rate, just giving a short burst or series of bursts of pulsatile vacuum to facilitate spiration of thrombus into the catheter **12**. In use, a similar effect may be established by utilizing the vent **47**. The vacuum in chamber **33** may decline to a minimum as the button **62** is actuated such that the vent is opened. Thereafter, the vacuum chamber **33** may slowly recharge by the large vacuum chamber **58** and associated pump through tubing **40** when the button **62** and vent **47** are moved into the closed position. In some instances of use, a clinician may choose to open the vent **47** at or shortly following the maximum flow rate, just giving a short burst or series of bursts of pulsatile vacuum to facilitate spiration of thrombus into the catheter **12**.

[0071] If the application of vacuum is not able to aspirate the clot into the catheter, an elongate flexible thrombus engagement tool may be advanced through the aspiration catheter, to facilitate retrieval of the clot. The thrombus engagement tool may comprise an elongate flexible shaft having a proximal hand piece such as a knob configured to be rotated by hand. The distal end carries a clot engagement tip which may include one or more radially outwardly extending engagement structures such as a helical thread.

[0072] Referring to FIGS. 6A-6C, a thrombus engagement tool **80** may comprise an elongate flexible shaft **82** having a proximal end **84** and a distal end **86**. A proximal hand piece such as a torquing handle **88** may be configured to be rotated by hand. Distal end **86** carries a clot engagement tip **90** which may include one or more radially outwardly extending structures such as a helical thread **92**. The handle **88** may have an indicium of rotational direction such as a printed or molded arrow **94** which indicates the direction to rotate the handle **88** in order for the helical thread **92** to engage clot.

[0073] Referring to FIG. 6B, the distal tip **90** includes a helical thread **92** extending between a distal thread end **96** and a proximal thread end **94** and supported by flexible shaft **98**. The axial length of the distal tip **90** is at least about 5 mm or 10 mm or 15 mm or 20 mm and in some embodiments no more than about 30 mm or 20 mm measured along the flexible shaft **98**. Preferably, the axial length will be within the range of from about 20 mm to about 25 mm.

[0074] The helical thread **92** wraps around the axis at least about 1 or 2 or 4 or more full revolutions, but in some embodiments no more than about 10 or no more than about 6 revolutions. Preferably, the thread **92** wraps around the axis within the range of from about 2.5 to about 4.5 revolutions. In some embodiments the axial length along the threaded portion of the tip is within the range of from about 5 to about 15 mm, and preferably within the range of from about 8 mm to about 12 mm.

[0075] The helical thread **92** on this implementation may have a constant pitch throughout its length. The pitch may be within the range of from about 5 to about 10 threads per inch depending upon desired performance. For example, the thread to thread spacing in the axial direction may be within the range of from about 2 mm to about 6 mm, preferably from about 3 mm to about 4 mm.

[0076] Alternatively, the thread may have multiple pitches (e.g. stepped or graduated) designed to engage, transport or grasp thrombus within the catheter lumen. A distal pitch may be less than a proximal pitch. The pitch may vary continuously along the length of the thread, or may step from a first, constant pitch in a proximal zone to a second, different pitch in a distal zone of the thread. The thread **92** may comprise

a continuous single helical flange or may have a plurality of discontinuities to produce a plurality of teeth or serrations, arranged helically around the core wire.

[0077] The maximum OD of the thread **92** is preferably smaller than the diameter of a sliding fit within the intended catheter lumen, and may generally be at least about 0.015 inches or at least about 0.010 inches smaller than the catheter lumen ID. In some implementations, the max OD of the tip may be significantly less than the inside diameter of the catheter lumen to allow more space for the thrombus along the side of the tip but still create significant grasping force via lateral engagement of the helical threads with the thrombus.

[0078] In one implementation, the maximum helical thread diameter is about 0.110 inches, and the catheter lumen ID is about 0.275 inches (24 F) (a 0.165 inch gap between the helical threads and catheter wall). In another implementation, the maximum OD of the tip is within the range of from about 0.03 to about 0.06 inches within a catheter having a distal end ID within the range from about 0.068 inches to about 0.073 inches. This leaves a substantial tip bypass flow path.

[0079] In certain applications, the max OD of the tip is no more than about 35% or no more than about 40% or no more than about 60% of the ID of the corresponding catheter and may be within the range of from about 35% to about 55% of the catheter ID. In some instances, the max OD of the tip may slightly less than the ID of the corresponding catheter to provide a sliding fit within the intended catheter lumen. For example, the max OD of the tip may be no less than about 90% or no less than about 95% or no less than about 97% of the ID of the corresponding catheter.

[0080] Since this implementation of the thrombus engagement tool does not have any centering structures for the tip **90** or shaft **82**, the tip **90** will normally be pushed to one side of the aspiration lumen. When a clot becomes lodged between the tip **90** and the opposing inside surface of the side wall of the catheter, manual manipulation such as rotation of the tip **90** can engage the clot like a worm gear and either grasp the clot (e.g., by pinning it against the opposing catheter sidewall) for retraction or facilitate freeing the blockage and aid in ingestion of the clot into the catheter. Manual manipulation may also include axial proximal and distal reciprocation along with rotation, during aspiration, which can facilitate ingestion of the clot into the catheter.

[0081] Thus, an unimpeded flow path is created in the annular (if the tip were centered) space between the maximum OD of the tip, and the ID of the catheter lumen. This annular flow path cooperates with the vacuum and helical tip to grab and pull obstructive material into the catheter under rotation and vacuum. The annular flow path is significantly greater than any flow path created by manufacturing tolerances in a tip configured to shear embolic material between the tip and the catheter wall.

[0082] Additional aspiration volume is obtained as a result of the helical channel defined between each two adjacent threads of the tip. A cross sectional area of the helical flow path of a tip having a maximum OD in the range of from about 0.0400 to about 0.0406 inches will generally be at least about 0.0003 square inches, and in some embodiments at least about 0.00035 or at least about 0.000375 inches. The total aspiration flow path across the helical tip is therefore

the sum of the helical flow path through the tip and the annular flow path defined between the OD of the tip and the ID of the catheter lumen.

[0083] Aspiration occurs both through the helical channel formed between adjacent helical threads as well as around the outside of the tip such that the assembly is configured for engaging and capturing embolic material but not shearing it between a sharp edge of the thread and the inside wall of the catheter.

[0084] The distal advance segment **100** advantageously permits the thrombus engagement device **80** to at least partially move past the thrombus without “pushing” the thrombus in a distal direction as the tip **90** is advanced. This may inhibit the thrombus (or any particulate thereof) from passing downstream within the vessel during engagement of the device **80** with the thrombus.

[0085] In some instances, the distal advance segment **100** can comprise a continuation of the helical thread **92**. For example, the distal advance segment **100** may comprise a threaded segment continuing from the helical thread **92**. The threaded distal advance segment **100**, in some instances, may maintain an outer diameter consistent with the remainder of the helical thread **92**. The threaded distal advance segment **100**, in some instances, may comprise a thread that tapers in a distal direction towards a smaller outer diameter relative to the remainder of the helical thread **92**. For example, the helical thread **92** may comprise a proximal cylindrical segment and a distal tapered segment that extends along the distal advance segment **100**.

[0086] The profile of the tip **90** in an end view along the axis of rotation may be circular and/or, in some instances, may vary to create a non circular pattern around the axis of rotation. For example, profile may comprise a helical pattern, such as an oval cross-section that rotates along the axis of rotation to create the helical profile. The tip as seen in an end elevational view thus may exhibit a major diameter and a minor diameter. The minor diameter may be no more than about 95% or 90% or 80% or 70% of the major diameter, depending upon desired performance. In the illustrated example, the outer edge **93** of the thread **92** lies along the surface of a cylinder.

[0087] In the illustrated implementation, an outer edge **93** of the thread **92** thus has a linear surface in the axial direction, substantially conforming to the surface of a cylinder. A distal side **95** of the thread **92** is inclined radially outwardly in a proximal direction. A proximal side **97** of the thread **92** also inclines radially outwardly in a proximal direction thereby defining a proximally facing undercut along the length of the thread.

[0088] Referring to FIGS. 6B and 6C, the illustrated tip **90** includes an atraumatic, tapered distal advance segment **100** extending between an atraumatic distal tip at **102** and a transition to the distal end **96** of the thread **92**. Helical thread **92** extends proximally from the transition to a proximal end **94** of the helical thread **92**. In some instances, a trailing segment **104** may extend between the proximal end **94** of the thread and the proximal end **106** of the tip.

[0089] The axial length of the distal advance segment **100** may be at least about 5 mm or at least about 8 mm or 9 mm and generally less than about 15 mm, and in some implementations is within the range of from about 8 mm to about 12 mm.

[0090] The outside diameter of the flexible shaft **82** is generally less than about 0.02 inches, or less than about

0.015 inches and, in one implementation, is about 0.008 inches. In some instances, the flexible shaft **82** may comprise a distal tapered section. The distal tapered section may advantageously increase tip flexibility and/or maximize aspiration. The outside diameter at the distal end of the distal tapered section of the flexible shaft **82** is generally less than about 0.01 inches, or less than about 0.008 inches and, in one implementation, is no more than about 0.006 inches.

[0091] The outside diameter of the advance segment **100** at distal tip **102** is generally less than about 0.024 inches, or less than about 0.020 inches and, in one implementation, is about 0.018 inches. The maximum outside diameter of the advance segment **100** and helical thread **92** may be within the range from about 0.020 to about 0.045 inches, and, in one implementation, is less than about 0.040 inches, such as about 0.035 inches. The advance segment, helical thread and trailing segment of the tip **90** may be molded as a single piece over the flexible shaft **82** using any of a variety of polymers known in the catheter arts.

[0092] Referring to FIG. 6C, a first radiopaque marker **110** may be carried on the flexible shaft **82** beneath the advance segment **100**. A second radiopaque marker **112** may be carried on the flexible shaft **82** within the trailing segment **104**. Each radiopaque marker may comprise a radiopaque tube or a coil of radiopaque wire such as a platinum iridium alloy wire having a diameter about 0.002 inches and positioned or wrapped around the flexible shaft **82** and soldered to the flexible shaft **82** to produce an RO sleeve or coil having an outside diameter of less than about 0.020 inches, such as about 0.012 inches. The radiopaque markers may also provide an axial interference fit between the flexible shaft **82** and the advance segment **100** and trailing segment **104** to resist core wire axial pull out from the tip **90** (tip detachment).

[0093] In certain implementations, the maximum OD of the thread **92** exceeds the maximum OD of the advance segment **100** by at least about 15% or 25% or 30% or more of the OD of the advance segment **100**, to facilitate crossing the clot with the advance segment **100** and engaging the clot with the thread **92**.

[0094] Depending upon the clinical application, it may be desirable to control the extent to which, if any, the distal tip **102** can extend beyond the distal end of the catheter **12**. In certain implementations, the distal tip **102** may be permitted to extend at least about 2 cm or 3 cm and preferably as much as 4 to 8 cm beyond the catheter (such as to permit manual removal of engaged thrombus), but generally will be limited to extend no more than a preset distance such as 12 cm or 8 cm or 5 cm beyond the catheter (e.g., within the range of from about 5 cm to about 10 cm) depending upon desired performance.

[0095] Distal advance of the tip **102** may be limited by providing mechanical interference at the desired distal limit of travel. In one implementation, a distal stop surface **114** which may be on the handle **88** (see FIG. 6A) provides an interference engagement with a complementary proximal surface (e.g. proximal surface **33** on connector module **30** or on the catheter hub) carried by the aspiration catheter through which the thrombus engagement tool **80** is advanced. Alternatively, a distal engagement surface can be carried anywhere along the length of the thrombus engagement tool **80**, for sliding rotational engagement with a complementary proximally facing stop surface carried by the catheter. Additional details of distal limit configurations

may be found in U.S. patent application Ser. No. 17/036,258 filed Sep. 29, 2020 and entitled Embolic Retrieval Catheter, which is hereby expressly incorporated in its entirety herein by reference.

[0096] The limit on distal advance of the helical tip may enable a first configuration in which the distal tip may be advanced through the catheter and placed at a first position approximately aligned with the distal end of the catheter **12**. The physician may then advance the tip to a second position extending beyond the distal end of the catheter such as for inspection and cleaning purposes.

[0097] A position indicator **85** may be carried by the flexible shaft **82** spaced apart from the distal surface **114** by a distance corresponding to the maximum length of the thrombus engagement tool intended to extend beyond the distal end of the catheter. When the position indicator **85** is located at a corresponding reference point relative to the catheter hub, the distal tip **102** may be positioned approximately at the distal end of the catheter. This way the physician will know that any further distal advance of the thrombus engagement tool will be extending beyond the distal end of the catheter. The maximum extension will be reached when the distal surface **114** contacts the catheter hub.

[0098] The position indicator **85** may comprise any of a variety of visual or tactile features, such as a color change or a colored band surrounding the flexible shaft **82**. In a visual indicium implementation (color change or circumferential line) the distal tip **102** may be positioned approximately at the distal end of the catheter when the indicator is visible just outside of the hub. In another implementation, the position indicator **85** comprises the transition between the distal end of the hypo tube **87** and the underlying flexible shaft **82**. This provides haptic feedback as the indicator (step in outside diameter) encounters and passes through the valve of the RHV. The hypo tube **87** additionally functions as a strain relief or anti buckling feature and may have an axial length within the range of from about 3 cm to about 15 cm and in some implementations within the range of from about 5 cm to about 9 cm.

[0099] Referring to FIG. 7A, there is illustrated one example of an outer jacket segment stacking pattern for a progressive flexibility catheter of the type discussed in connection with FIG. 1. A distal segment **120** may have a length within the range of about 1-3 cm and a durometer of less than about 35 D or 30 D. An adjacent proximal segment **122** may have a length within the range of about 4-6 cm, and a durometer of less than about 35 D or 30 D. An adjacent proximal segment **124** may have a length within the range of about 4-6 cm, and a durometer of about 35 D or less. An adjacent proximal segment **126** may have a length within the range of about 1-3 cm, and a durometer within the range of from about 35 D to about 45 D (e.g., 40 D). An adjacent proximal segment **128** may have a length within the range of about 1-3 cm, and a durometer within the range of from about 50 D to about 60 D (e.g., about 55 D). An adjacent proximal segment **130** may have a length within the range of about 1-3 cm, and a durometer within the range of from about 35 D to about 50 D to about 60 D (e.g., about 55 D). An adjacent proximal segment **132** may have a length within the range of about 1-3 cm, and a durometer of at least about 60 D and typically less than about 75 D. More proximal segments may have a durometer of at least about 65 D or 70 D.

[0100] The distal most two or three segments may comprise a material such as Tecothane and/or PEBAX, and more proximal segments may comprise PEBAX or other catheter jacket materials known in the art. At least three or five or seven or nine or more discrete segments may be utilized, having a change in durometer between highest and lowest along the length of the catheter shaft of at least about 10 D, preferably at least about 20 D and in some implementations at least about 30 D or 40 D or more.

[0101] FIGS. 7A-7E illustrate various embodiments of catheters, at least some of which incorporate a plurality of catheter outer jacket segments with varying lengths and/or hardness for varying flexibility along the length of the catheter body. It will be understood that any of the features shown or described in connection with any of the catheters of FIGS. 7A-7E can be used with any of the embodiments described and/or contemplated herein. It will also be understood that any of the features described and/or contemplated in connection with any of the embodiments disclosed herein can be utilized with any of the catheters described in connection with FIGS. 7A-7E. As with all embodiments in this specification, any feature, structure, material, method, or step that is described and/or illustrated in the embodiments of FIGS. 7A-7E can be used with or instead of any feature, structure, material, method, or step that is described and/or illustrated in any other embodiment of this specification.

[0102] FIGS. 7B-7E illustrates embodiments of various catheters **400**, **500**, **600**. The catheters **400**, **500**, **600** may include differing properties (e.g., such as length, diameter, etc.) such that one or more of the catheters **400**, **500**, **600** may interact with any of the other catheters **400**, **500**, **600** in any various manner. In one instance, as illustrated by FIG. 7E, each of catheters **400**, **500**, **600** may comprise a different size to permit the catheters **400**, **500**, **600** to at least partially extend through one or more of the other catheters **400**, **500**, **600**. The lengths of each of the catheters **400**, **500**, **600** may vary so as to permit a smaller catheter to pass through and extend distally beyond a larger catheter in a telescoping manner.

[0103] For instance, catheter **500** may be configured to pass through and extend beyond catheter **400**. By way of further example, catheter **600** may be configured to pass through and extend beyond at least one of catheter **500** or catheter **400** in a telescoping manner. While FIG. 7E illustrates an example telescoping catheter stack including each of catheters **400**, **500**, **600**, it will be understood by one having skill in the art that any combination of catheters **400**, **500**, **600** may be utilized. For example, a system may incorporate the use of catheter **400** and catheter **500**, the use of catheter **400** and catheter **600**, or the use of catheter **500** and catheter **600**.

[0104] Catheter **400** may comprise an 8 F catheter. In some instances, catheter **400** comprises a diameter larger than the diameter of any of the remaining catheters in a system. Additionally, or alternatively, catheter **400** may comprise an overall length shorter than the length of any of the remaining catheters in a system. In this manner, catheter **400** may comprise the outermost catheter in a telescoping system and may permit any of the remaining catheters **500**, **600** to extend distally beyond a distal end of catheter **400**. The catheter **400** may comprise a length between about 35 cm and about 105 cm or, a length between about 45 cm and about 95 cm. The catheter **400** may comprise a length of from about 50 cm to about 90 cm. The catheter **400** may

comprise a length at least shorter than any catheter with a diameter smaller than catheter **400** (e.g., such as catheter **500**, **600**).

[0105] Catheter **500** may comprise a 6 F catheter. In some instances, catheter **500** comprises a diameter in between the diameters of the remaining catheters in a system. Additionally, or alternatively, catheter **500** may comprise a length in between the lengths of the remaining catheters in the system. In this manner, catheter **500** may comprise a middle catheter in a telescoping system and may be configured to pass through and extend beyond one or more catheters while also permitting another catheter to extend distally beyond a distal end of catheter **500**. The catheter **500** may comprise a length between about 120 cm and about 155 cm or between about 130 cm and about 145 cm. The catheter **500** may comprise a length of about from 135 cm to about 137 cm. The catheter **500** may comprise a length at least longer than any catheter with a diameter larger than catheter **500** (e.g., such as catheter **400**). The catheter **500** may comprise a length at least shorter than any catheter with a diameter smaller than catheter **500** (e.g., such as catheter **600**).

[0106] Catheter **600** may comprise a 5 F catheter. In some instances, catheter **600** comprises a diameter smaller than the diameters of the remaining catheters in a system. Additionally, or alternatively, catheter **600** may comprise a length longer than the lengths of any of the remaining catheters in the system. In this manner, catheter **600** may comprise an innermost catheter in a telescoping system and may be configured to pass through and extend beyond one or more of the other catheters. The catheter **600** may comprise a length between about 145 cm and about 175 cm or between about 155 cm and about 165 cm. The catheter **600** may comprise a length of about 160 cm. The catheter **600** may comprise a length at least longer than any catheter with a diameter larger than catheter **600** (e.g., such as catheter **400**, **500**).

[0107] One or more of the catheters **400**, **500**, **600** may include a coil and/or a braid in the sidewall extending through at least a portion of the sidewall of the catheter **400**, **500**, **600**, as discussed herein. The braid may have properties that vary along the length of each catheter **400**, **500**, **600** to generate a variety of desired characteristics of the catheter **400**, **500**, **600**. For example, a wire density of the braid may vary gradually or in steps along the length of the catheter **400**, **500**, **600** and/or vary between discrete sections of the catheter **400**, **500**, **600**.

[0108] Catheter **600** may comprise one or more discrete sections with braid properties varying between one or more of the sections. In some instances, catheter **600** may comprise a first section, a second (e.g., intermediate) section, and a third distal section. However, it will be understood by one having skill in the art that the catheter **600** may comprise a fewer number of sections (e.g., one section or two sections) or a greater number of sections (e.g., four sections or greater). A sidewall property, such as a length and/or a wire density the braid along a respective section, may vary between the sections. In some instances, a ppi count of the braid in connection with the wire density of the braid may gradually transition between one or more of the catheter sections. For example, the ppi count of the braid, in some instances, may remain generally consistent through a length of the first section and a length of the third section but gradually transition along the length of the second, intermediate section.

[0109] The first section of catheter **600** may have a length of at least about 20 cm. For example, the length of the first section may be from about 25 cm to about 35 cm or, in one example, about 30 cm. The braid through the first section may have a wire density of at least about 100 ppi. For example, the braid through the first section may have wire density of at least about 120 ppi or, more specifically, about 130 ppi.

[0110] The third section of catheter **600** may have a length of at least about 100 cm. For example, the length of the third section may be from about 120 cm to about 140 cm or, more specifically, about 130 cm. The braid through the third section may have a wire density of no greater than about 85 ppi. For example, the braid through the third section may have wire density from about 70 ppi to about 80 ppi.

[0111] The second section of catheter **600** may be an intermediate section between the first section and the third section. The second section may have a length of at least about 3 cm. In some instances, the second section may have a length no greater than about 20 cm or, more specifically, no greater than about 10 cm. For example, the length of the second section may be about 5 cm. The braid through the second section may have a wire density of no greater than the wire density of the first section and no less than the wire density of the third section.

[0112] Catheter **500** may comprise one or more discrete sections with braid properties varying between one or more of the sections. In some instances, catheter **500** may comprise a first section, a second (e.g., intermediate) section, and a third section. However, it will be understood by one having skill in the art that the catheter may comprise a fewer number of sections (e.g., one section or two sections) or a greater number of sections (e.g., four sections or greater). A sidewall property, such as a length and/or a wire density the braid along a respective section, may vary between the sections. In some instances, a ppi count of the braid in connection with the wire density of the braid may gradually transition between one or more of the catheter sections. For example, the ppi count of the braid, in some instances, may remain generally consistent through a length of the first section and a length of the third section but gradually transition along the length of the second, intermediate section.

[0113] The first section of catheter **500** may have a length of at least about 20 cm. For example, the length of the first section may be from about 25 cm to about 35 cm or, in one example, about 30 cm. The braid through the first section may have a wire density of at least about 100 ppi. For example, the braid through the first section may have wire density of at least about 120 ppi or, in one example, about 130 ppi.

[0114] The third section of catheter **500** may have a length of at least about 80 cm. For example, the length of the third section may be from about 100 cm to about 120 cm or, in one example, about 105 cm. The braid through the third section may have a wire density of no greater than about 100 ppi. For example, the braid through the third section may have wire density from about 80 ppi to about 90 ppi.

[0115] The second section of catheter **600** may be an intermediate section between the first section and the third section. The second section may have a length of at least about 3 cm. In some instances, the second section may have a length no greater than about 20 cm or, more specifically, no greater than about 10 cm. For example, the length of the

second section may be about 5 cm. The braid through the second section may have a wire density of no greater than the wire density of the first section and no less than the wire density of the third section.

[0116] Catheter **400** may comprise one or more discrete sections with braid properties varying between one or more of the sections. In some instances, catheter **400** may comprise one section. However, it will be understood by one having skill in the art that the catheter **400** may comprise a greater number of sections (e.g., two sections, three sections, four sections, or greater). For example, catheter **400** may comprise three sections as described in connection with either one or catheter **500** or catheter **600**. A sidewall property, such as a length and/or a wire density the braid, may vary along catheter **400**. In some instances, a ppi count of the braid in connection with the wire density of the braid may gradually transition to increasing flexibility in a distal direction along catheter **400**. The section of catheter **400** may have a length of at least about 40 cm. For example, the length of the section may be from about 50 cm to about 60 cm or, in one example, about 55 cm. The braid through the section may have a wire density of at least about 80 ppi. For example, the braid through the section may have wire density of at least about 90 ppi.

[0117] The braid, in some instances, may extend along an entire length of the catheter sidewall. In some instance, a junction between the braid and a coil is not present in the catheter and/or the catheter sidewall does not incorporate a coil. It will be understood that this braid configuration may be applied to any catheter disclosed herein, including, but not limited to, catheters **400**, **500**, **600**.

[0118] One or more of the catheters **400**, **500**, **600** may an outer jacket segment stacking pattern for a progressive flexibility catheter. The outer jacket segment may each have properties that vary along the length of each catheter **400**, **500**, **600** to generate a variety of desired characteristics of the catheter **400**, **500**, **600**. For example, each segment of the outer jacket may have a corresponding Shore D hardness to vary the flexibility along the length of the catheter **400**, **500**, **600**. The outer jacket segments may be made of a thermoplastic elastomer made of flexible polyether and rigid polyamide (e.g., Pebax®). In some instances, each segment of the outer jacket may comprise a different variation of the thermoplastic elastomer to alter flexibility.

[0119] Catheter **600** may comprise a plurality of discrete segments of the outer jacket with varying flexibility between one or more of the segments. In some instances, catheter **600** may comprise a plurality of segments. A sidewall property, such as Shore D hardness and/or flexibility, may vary between the segments. In some instances, a Shore D hardness of the outer jacket segments may gradually transition from higher at proximal end segment of the outer jacket to lower at a distal end segment of the outer jacket.

[0120] The proximal end segment of the outer jacket of the catheter **600** may have a Shore D hardness of at least about 60. For example, the Shore D hardness of the proximal end segment may be from about 70 to about 80 or, more specifically, at least about 75.

[0121] The distal end segment of the outer jacket of the catheter **600** may have a Shore D hardness of at most about 40. For example, the Shore D hardness of the distal end segment may be from about 30 to about 20 or, more specifically, no more than about 27.

[0122] A plurality of the intermediate segments between the distal end segment and the proximal end segment may each comprise a variety of Shore D hardness. In some instances, each segment decreases in a Shore D hardness in a distal direction and may have a smaller Shore D hardness than a proximally adjacent segment. For example, the Shore D hardness of a first segment may be from about 30 to about 50 or, more specifically, about 40. The first segment, in some instances, may be between positioned about 120 cm to about 160 cm or, more specifically, about 140 cm away from a distal end face of the catheter **600**. By way of another example, the Shore D hardness of the second segment may be from about 50 to about 70 or, more specifically, about 65. The second segment, in some instances, may be between positioned about 220 cm to about 260 cm or, more specifically, about 240 cm away from a distal end face of the catheter **600**.

[0123] Catheter **500** may comprise a plurality of discrete segments of the outer jacket with varying flexibility between one or more of the segments. In some instances, catheter may comprise a plurality of segments. A sidewall property, such as Shore D hardness and/or flexibility, may vary between the segments. In some instances, a Shore D hardness of the outer jacket segments may gradually transition from higher at a proximal end segment of the outer jacket to lower at a distal end segment of the outer jacket.

[0124] The proximal end segment of the outer jacket of the catheter **500** may have a Shore D hardness of at least about 60. For example, the Shore D hardness of the proximal end segment may be from about 70 to about 80 or, more specifically, at least about 75.

[0125] The distal end segment of the outer jacket of the catheter **500** may have a Shore D hardness of at most about 40. For example, the Shore D hardness of the distal end segment may be from about 30 to about 20 or, more specifically, no more than about 27.

[0126] a plurality of the intermediate segments between the distal end segment and the proximal end segment may each comprise a variety of Shore D hardness. In some instances, each segment decreases in a Shore D hardness in a distal direction and may have a smaller Shore D hardness than a proximally adjacent segment. For example, the Shore D hardness of a first segment may be from about 30 to about 50 or, more specifically, about 40. The first segment, in some instances, may be between positioned about 70 cm to about 110 cm or, more specifically, about 90 cm away from a distal end face of the catheter **500**. By way of another example, the Shore D hardness of a second segment may be from about 50 to about 70 or, more specifically, about 65. The second segment, in some instances, may be between positioned about 160 cm to about 200 cm or, more specifically, about 180 cm away from a distal end face of the catheter **500**.

[0127] Catheter **400** may comprise a plurality of discrete segments of the outer jacket with varying flexibility between one or more of the segments. In some instances, catheter **400** may comprise a plurality of segments. A sidewall property, such as Shore D hardness and/or flexibility, may vary between the segments. In some instances, a Shore D hardness of the outer jacket segments may gradually transition from a proximal end segment of the outer jacket to a distal end segment of the outer jacket.

[0128] The proximal end segment of the outer jacket of the catheter **400** may have a Shore D hardness of at least about

60. For example, the Shore D hardness of the proximal end segment may be from about 70 to about 80 or, more specifically, about 75.

[0129] The distal end segment of the outer jacket of the catheter **400** may have a Shore D hardness of at most about 40. For example, the Shore D hardness of the distal end segment may be from about 30 to about 20 or, more specifically, no more than about 27.

[0130] A plurality of the intermediate segments between the distal end segment and the proximal end segment may each comprise a variety of Shore D hardness. In some instances, each segment decreases in a Shore D hardness in a distal direction and may have a smaller Shore D hardness than a proximally adjacent segment. For example, the Shore D hardness of a first segment may be from about 30 to about 50 or, more specifically, about 40. A first segment, in some instances, may be between positioned about 65 cm to about 105 cm or, more specifically, about 85 cm away from a distal end face of the catheter **400**. By way of another example, the Shore D hardness of a second segment may be from about 40 to about 65 or, more specifically, about 55. The second segment, in some instances, may be between positioned about 105 cm to about 145 cm or, more specifically, about 125 cm away from a distal end face of the catheter **400**. By way of further example, the Shore D hardness of a third segment may be from about 60 to about 80 or, more specifically, about 70. The third segment, in some instances, may be between positioned about 140 cm to about 180 cm or, more specifically, about 160 cm away from a distal end face of the catheter **400**.

[0131] Catheter **400** may comprise a tubular body length of about 90+/-5 cm. In some instances, catheter **400** may comprise a tubular body length of about 50+/-5 cm. A number of the plurality of discrete segments of the outer jacket of catheter **400** may vary with respect to the tubular body length of catheter **400**. A length of the respective segments of the plurality of discrete segments of the outer jacket of catheter **400** may vary with respect to the tubular body length of catheter **400**.

[0132] A coating, in some instances, may be located along an outer diameter of a distal portion of the catheter sidewall. The coating can be configured to decrease frictional resistance of the distal portion of the catheter sidewall with any adjacent structure (e.g., a vessel wall). In some instances, the coating increases the lubriciousness of the catheter distal portion outer sidewall. The coating may advantageously reduce friction on the distal end of the catheter going through tortuous vasculature. This may facilitate advancement and rotation of the catheter distal end, particularly in situations where the catheter contains an increased flexibility along a distal end portion of the catheter. The coating may extend in a proximal direction from, or proximate to, a catheter distal end face. The coating may extend at least about 20 cm in a proximal direction. In some instances, the coating extends no farther than about 50 cm from the catheter distal end face. For example, the coating may extend for a length of about 25 cm to about 35 cm or, more specifically, about 30 cm from a catheter distal end face. It will be understood that the coating may be applied to any catheter disclosed herein, including, but not limited to, catheters **400**, **500**, **600**.

[0133] FIG. 8 illustrates a cross section through the sidewall of a distal portion of a single lumen catheter. An internal support layer may comprise either a coil or braid. In a coil

implementation, adjacent loops or filars of the coil **140** may have a constant pitch throughout the length of the coil or may be closely tightly wound in a proximal zone with a distal section having looser spacing between adjacent loops. In an embodiment having a coil section **140** with an axial length of at least between about 20% and about 30% of the overall catheter length, (e.g., 28 cm coil length in a 110 cm catheter shaft **16**), at least the distal about 1 cm or about 2 cm or about 3 cm or about 4 cm of the coil will have a spacing that is at least about 130%, and in some implementations at least about 150% or more than the spacing in the proximal coil section. In a 110 cm catheter shaft **3000** having a Nitinol coil, the spacing in the proximal coil may be about 0.004 inches and in the distal section may be at least about 0.006 inches or about 0.007 inches or more.

[0134] The distal end of the coil or braid **140** can be spaced proximally from the distal end of the inner liner **142**, for example, to provide room for an annular radiopaque marker **144**. The coil or braid **140** may be set back proximally from the distal end, in some embodiments, by approximately no more than about 1 cm, about 2 cm, or about 3 cm. In one embodiment, the distal end of the catheter **12** is provided with a beveled (inclined) distal surface **146** residing on a plane having an angle of at least about 10 degrees or about 20 degrees and in one embodiment about 30 degrees with respect to a longitudinal axis of the catheter **10**. At least a distally facing edge of the annular radiopaque marker **144** may be an ellipse, residing on a plane which is inclined with respect to the longitudinal axis to complement the bevel angle of the distal surface **146**. Additional details are described in connection with FIG. 9 below.

[0135] After applying a braid or braid and coil over tie layer **152** and/or over a liner, the distal braid or coil and the RO marker **144** are provided with an outer jacket **156** such as a polymer tube formed from a plurality of axially adjacent cylindrical segments to enclose the catheter body **16**. The outer sleeve **156** may comprise any of a variety of materials, such as polyethylene, polyurethane, polyether block amide (e.g., PEBAX™), nylon or others known in the art. Sufficient heat is applied to cause the polymer to flow into and embed the proximal braid and distal coil.

[0136] In one implementation, the outer jacket **156** is formed by sequentially advancing a plurality of short tubular segments **133**, **132**, **130**, **128**, **126**, **124**, **122**, **120** concentrically over the catheter shaft subassembly, and applying heat to shrink the sections on to the catheter **12** and provide a smooth continuous outer tubular body. The foregoing segmented construction may extend along at least the most distal about 10 cm, and preferably at least about the most distal about 20 cm, about 25 cm, about 30 cm, about 35 cm, about 40 cm, or more than about 40 cm of the catheter body **10**. The entire length of the outer jacket **156** may be formed from tubular segments and the length of the distal tubular segments may be shorter than the one or more tubular segments forming the proximal portion of the outer jacket **156** proximal to the junction between the braid **150** and coil **140** in order to provide proximal backup support and steeper transitions in flexibility toward the distal end of the catheter **12**.

[0137] The durometer of the outer wall segments may decrease in a distal direction. For example, proximal segments such as **133** and **132**, may have a durometer of at least about 60 D or about 70 D, with gradual decrease in durometer of successive segments in a distal direction to a durom-

eter of no more than about 35 D or about 25 D or lower. A 25 cm section may have at least about 3 or about 5 or about 7 or more segments and the catheter **12** overall may have at least about 6 or about 8 or about 10 or more distinct flexibility zones. The distal 1 or 2 or 4 or more segments **122**, **120**, may have a smaller OD following shrinking than the more proximal segments **133-124** to produce a step down in OD for the finished catheter body **16**. The length of a lower OD section **160** may be within the range of from about 3 cm to about 15 cm and, in some embodiments, is within the range of from about 5 cm to about 10 cm such as about 7 cm or about 8 cm and may be accomplished by providing the distal segments **122**, **120** with a lower wall thickness.

[0138] In another embodiment, the most distal portion of the catheter **12** may comprise a durometer of less than approximately 35 D (e.g., 25 D) to form a highly flexible distal portion of the catheter and have a length between approximately 25 cm and approximately 35 cm. The distal portion may comprise one or more tubular segments of the same durometer (e.g., segment **120**). A series of proximally adjacent tubular segments may form a transition region between a proximal stiffer portion of the catheter **12** and the distal highly flexible portion of the catheter. The series of tubular segments forming the transition region may have the same or substantially similar lengths, such as approximately 1 cm.

[0139] The relatively short length of each of the series of tubular segments may provide a steep drop in durometer over the transition region. For example, the transition region may have a proximal tubular segment **122** (proximally adjacent the distal portion) having a durometer of approximately 35 D. An adjacent proximal segment **124** may have a durometer of approximately 55 D. An adjacent proximal segment **126** may have a durometer of approximately 63 D. An adjacent proximal segment **128** may have a durometer of approximately 72 D.

[0140] More proximal segments may comprise a durometer or durometers greater than approximately 72 D and may extend to the proximal end of the catheter. For instance, a catheter segment may comprise a proximal portion greater than approximately 72 D between about 1 cm and about 3 cm. In some embodiments, the proximal portion may be about 2 cm long. In some embodiments, the most distal segments (e.g., **120**, **122**) may comprise PEBAX™ and more proximal segments may comprise a generally stiffer material, such as Vestamid®.

[0141] The inner diameter of the catheter **10** may be between approximately 0.06 and 0.08 inches, between approximately 0.065 and 0.075 inches, or between approximately 0.068 and 0.073 inches. In some embodiments, the inner diameter is approximately 0.071 inches.

[0142] In some embodiments, the distal most portion may step or taper to a decreased inner diameter such as under segments **122** and **120**. The taper may occur approximately between the distal highly flexible portion and the transition region (e.g., over the most proximal portion of the distal highly flexible portion). The taper may be relatively gradual (e.g., occurring over approximately 10 or more cm) or may be relatively steep (e.g., occurring over less than approximately 5 cm). The inner diameter may taper to an inner diameter between about 0.03 and about 0.06 inches. For example, the inner diameter may be about 0.035 inches, about 0.045 inches, or about 0.055 inches at the distal end

of the catheter **12**. In some embodiments, the inner diameter may remain constant, at least over the catheter extension segment.

[0143] In some hybrid coil/braid embodiments, the coil **140** may extend proximally from a distal end of the catheter **12** along the highly flexible distal portion ending at or overlapping with the distal end of the braid **150**. In other embodiments, the coil **140** may extend the entire length of the catheter **12**. The braid **150**, when present, may extend from about the transition **163** the proximal end of the coil **140** to the proximal end of the catheter **12**.

[0144] Any of the catheters disclosed herein may be provided with an angled distal tip. Referring to FIG. 9, distal catheter tip **18** comprises a tubular body **14** which includes an advance segment **200**, and a marker band **144**. An inner tubular liner **142** may extend throughout the length of the distal catheter tip and may comprise dip coated PTFE.

[0145] A reinforcing element **140** such as a braid and/or spring coil is embedded in an outer jacket which may extend the entire length of the catheter proximally of the radiopaque marker.

[0146] The advance segment **200** terminates distally in an angled face **146**, to provide a leading side wall portion **202** having a length measured between the distal end **204** of the marker band **144** and a distal tip **206**. A trailing side wall portion **208** of the advance segment **200**, has an axial length in the illustrated embodiment of approximately equal to the axial length of the leading side wall portion **202** as measured at approximately 180 degrees around the catheter from the leading side wall portion **202**. The leading side wall portion **202** may have an axial length within the range of from about 0.1 mm to about 5 mm and generally within the range of from about 1 to 3 mm. The trailing side wall portion **208** may be at least about 0.1 or 0.5 or 1 mm or 2 mm or more shorter than the axial length of the leading side wall portion **202**, depending upon the desired performance.

[0147] The angled face **146** inclines at an angle A within the range of from about 45 degrees to about 80 degrees from the longitudinal axis of the catheter. For certain implementations, the angle is within the range of from about 50 degrees to about 70 degrees or within the range of from about 55 degrees to about 65 degrees from the longitudinal axis of the catheter. In one implementation, the angle A is about 60 degrees. One consequence of an angle A of less than 90 degrees is an elongation of a major axis of the area of the distal port which increases the surface area of the port and may enhance clot aspiration or clot retention. Compared to the surface area of the circular, transverse port (angle A is 90 degrees), the area of the angled port is generally at least about 105%, and no more than about 130%, in some implementations within the range of from about 110% and about 125% and in one example is about 115%.

[0148] In the illustrated embodiment, the axial length of the advance segment is substantially constant around the circumference of the catheter, so that the angled face **146** is approximately parallel to the distal surface **210** of the marker band **144**. The marker band **144** has a proximal surface approximately transverse to the longitudinal axis of the catheter, producing a marker band **144** having a right trapezoid configuration in a side elevational view. A short sidewall **212** is rotationally aligned with the trailing side wall portion **208**, and has an axial length within the range of from about 0.2 mm to about 4 mm, and typically from about 0.5 mm to about 2 mm. An opposing long sidewall **214** is

rotationally aligned with the leading side wall portion **202**. Long sidewall **214** of the marker band **144** is generally at least about 10% or 20% longer than short sidewall **212** and may be at least about 50% or 70% or 90% or more longer than short sidewall **212**, depending upon desired performance. Generally, the long sidewall **214** will have a length of at least about 0.5 mm or 1 mm and less than about 5 mm or about 4 mm.

[0149] Any of the marker bands described herein may be a continuous annular structure, or may optionally have at least one and optionally two or three or more axially extending slits throughout its length. The slit may be located on the short sidewall **212** or the long sidewall **214** or in between, depending upon desired bending characteristics. Any of the marker bands described herein may comprise any of a variety of radiopaque materials, such as a platinum/iridium alloy, with a wall thickness preferably no more than about 0.003 inches and in one implementation is about 0.001 inches.

[0150] The advance segment **200** may comprise a distal extension of the outer polymer jacket and optionally the inner liner, without other internal supporting structures distally of the marker band **144**. The outer jacket may comprise extruded Tecothane and/or PEBAX. The advance segment **200** may have a bending stiffness and radial crush stiffness that is no more than about 50%, and in some implementations no more than about 25% or 15% or 5% or less than the corresponding value for the adjacent proximal catheter body.

[0151] The proximal end of the catheter **12** is preferably provided with a hemostasis valve, to facilitate introduction of a thrombus engagement tool or a secondary catheter there through. The hemostasis valve may be carried by the connector module **30**, or directly by the proximal catheter connector **22**. Any of a variety of hemostasis valve configurations may be used.

[0152] Referring to FIGS. **10A-10C**, there is illustrated a valve inserter in accordance with another embodiment. The inserter enables opening a valve (e.g., the hemostasis valve and/or an introducer sheath valve having an elastomeric membrane valve with a passive slit) and supporting it in an open configuration while providing an access lumen therethrough to enable a delicate secondary device such as a thrombus engagement tool or a catheter to advance therethrough without encountering any resistance or damage from the valve.

[0153] The inserter **300** comprises an elongate tubular body **302** having a proximal end **304**, a distal end **306**, and a central lumen **308** extending therethrough. The tubular body **302** has an inside diameter sufficient to accommodate the secondary device, and an OD capable of passing through a compatible hemostasis valve. In general, tubular body will have an outside diameter within the range of from about 0.04" to about 0.1, and a length within the range of from about 1" to about 4". Tubular body **302** can be formed as an extrusion from any of a variety of common catheter polymers such as Nylon, PEEK, polyethylene, polyimide or others known in the art having sufficient crush resistance and column strength to enter and to maintain patency under the closing pressure of a hemostasis valve.

[0154] The proximal end **304** of the tubular body **302** may be provided with a funnel shaped landing zone **322** leading to the central lumen, to facilitate introducing the distal tip of the secondary device into the inserter. In the illustrated

embodiment, the proximal end of the tubular body is provided with an inclined face **314**. A distal, leading edge **316** of the inclined face **314** is axially distally spaced apart from the trailing proximal edge **318** of the face **314** by a distance D. The distance D [between 316 and 318] may be at least about 0.1" and typically no more than about 0.5".

[0155] The inclined face cooperates with the curved sidewall of the tube to create a side opening for funneling the distal tip of the secondary device into the proximal end of the lumen. For this purpose, the side wall at the trailing edge **318** may be provided with a curvature having a greater radius than the radius of curvature at the leading edge **316** with a progressively changing radius in between, creating a funnel shape for the landing zone **322**.

[0156] The tubular body **302** is provided with an axially extending slit **310** extending between the distal end **306** and the leading edge **316** of the inclined face **314**, to enable the inserter to be peeled away laterally from the secondary device extending therethrough once the inserter has enabled passage of the secondary device through the hemostasis valve.

[0157] A pull tab **312** may be provided on the proximal end of the tubular body **302** to enable the inserter **300** to be grasped and pulled away from the secondary device extending therethrough. The pull tab **312** may be integrally formed with the tubular body **302** (e.g., as a portion of the sidewall of the tube stock as illustrated) or attached thereto such as by adhesive bonding or mechanical compression or interference engagement. In the illustrated embodiment, the pull tab **312** inclines laterally away from the longitudinal axis of the tubular body, to allow coaxial approach and introduction of the catheter into the inserter **300**.

[0158] In one implementation of the inserter, the tubular body has a substantially constant diameter throughout most (e.g., at least about 80% or 90%) of its length overall. However, at least the outside diameter in a distal nose segment **324** may be necked down to a smaller outside diameter at the distal end. This enables the inserter to better enter the hemostasis valve under distal compression. In one example, the tubular body has an 8 French ID along most of its length but necks down to 6 French in the distal nose segment **324**. This inserter will facilitate the introduction of either a 6 French or an 8 French catheter through the hemostasis valve, since the 8 French catheter can simply forcibly dilate the necked distal end due to the axial slit **310**.

[0159] In one implementation, the concave entrance funnel surface of the landing zone **322** may be provided with a visual indicium such as a different color than the outside surface of the tubular body **302**, to facilitate visualization of the funnel opening and assist in loading the secondary catheter into the funnel. This may be accomplished by providing a colored coating on either the inside or outside surface of the tube stock, or by forming at least a portion of the tube stock as a coextrusion of dissimilar colored materials.

Example Embodiments

[0160] A clot capture module for use in a thrombectomy system, the clot capture module comprising one or more of the following:

[0161] a housing;

[0162] a clot capture chamber in the housing;

[0163] a window in the housing to permit visual inspection of the clot capture chamber;

[0164] a filter in the clot capture chamber, the filter being visible through the window, the filter having an upstream surface and a downstream surface;

[0165] an incoming flow path configured to direct incoming blood from an aspiration catheter against the upstream surface of the filter;

[0166] a normally closed aspiration control valve in the incoming flow path, the aspiration control valve configured to block flow of incoming aspirated blood until actuated to permit inflow of aspirated blood; and

[0167] an outgoing flow path configured to direct blood from a downstream side of the filter to a remote vacuum canister.

[0168] A clot capture module as described in any embodiment herein, further comprising a normally closed vent being openable to permit air to be drawn into the clot capture chamber.

[0169] A clot capture module as described in any embodiment herein, wherein the upstream surface of the filter is visible through the window.

[0170] A clot capture module as described in any embodiment herein, wherein the upstream surface of the filter is substantially planar.

[0171] A clot capture module as described in any embodiment herein, wherein the upstream surface of the filter is convex.

[0172] A clot capture module as described in any embodiment herein, wherein the filter comprises a blood permeable membrane, and wherein the upstream surface of the filter is on a radially outwardly facing surface of the blood permeable membrane.

[0173] A clot capture module as described in any embodiment herein, wherein the blood permeable membrane at least partially encloses a filtered blood chamber which is in fluid communication with the outgoing flow path.

[0174] A clot capture module as described in any embodiment herein, wherein the window comprises a transparent tubular portion of the housing.

[0175] A clot capture module as described in any embodiment herein, further comprising an aspiration actuator, configured to control the aspiration control valve.

[0176] A clot capture module as described in any embodiment herein, wherein the aspiration actuator comprises a rocker switch.

[0177] A clot capture module as described in any embodiment herein in combination with a vacuum line leading to an aspiration pump and canister, wherein the clot capture module is configured to reside within a sterile field while the aspiration pump and canister reside outside of the sterile field.

[0178] A clot capture module as described in any embodiment herein, wherein the vacuum line is at least about 30 inches in length.

[0179] A clot capture module as described in any embodiment herein, wherein the aspiration control valve comprises collapsible tubing.

[0180] A clot capture module as described in any embodiment herein, further comprising a selector valve in the vacuum line.

[0181] A clot capture module as described in any embodiment herein, wherein the aspiration pump comprises a syringe.

[0182] A clot capture module as described in any embodiment herein, comprising a proximal housing, and a distal housing separated by a transparent tubular side wall.

[0183] A clot capture module as described in any embodiment herein, wherein at least one of the proximal housing and distal housing is releasably connected to the transparent tubular side wall.

[0184] A clot capture module as described in any embodiment herein, further comprising a coating to inhibit blood accumulation on an interior surface of the window.

[0185] A thrombus engagement tool configured to be advanced through a catheter and to engage thrombus, the thrombus engagement tool comprising one or more of the following:

[0186] a rotatable core having a proximal end and a distal end; and

[0187] a thrombus engagement tip on the distal end of the rotatable core, the thrombus engagement tip comprising:

[0188] a helical thread;

[0189] an advance segment on a distal side of the helical thread; and

[0190] a trailing segment on a proximal side of the helical thread.

[0191] A thrombus engagement tool as described in any embodiment herein, further comprising a projection carried by the rotatable core, the projection being underneath at least one of the advance segment and the trailing segment to form an interference fit with the thrombus engagement tip.

[0192] A thrombus engagement tool as described in any embodiment herein, wherein the projection comprises an annular ring.

[0193] A thrombus engagement tool as described in any embodiment herein, wherein the projection comprises a radiopaque marker.

[0194] A thrombus engagement tool as described in any embodiment herein, comprising a first radiopaque marker under the advance segment and a second radiopaque marker under the trailing segment.

[0195] A thrombus engagement tool as described in any embodiment herein, wherein an outer periphery of the helical thread substantially conforms to a surface of a cylinder.

[0196] A thrombus engagement tool as described in any embodiment herein, wherein the helical thread comprises a proximal surface which inclines radially outwardly in a proximal direction to define a proximally opening undercut.

[0197] A thrombus engagement tool as described in any embodiment herein, further comprising a handle on the proximal end of the rotatable core.

[0198] A thrombus engagement tool as described in any embodiment herein, comprising a limit bearing surface on the handle, the limit bearing surface being configured to limit projection of the thrombus engagement tip in a distal direction relative to a distal end of the aspiration catheter.

[0199] A thrombus engagement tool as described in any embodiment herein, wherein the advance segment, the helical thread, and the trailing segment are all molded onto the rotatable core.

[0200] A thrombus engagement tool as described in any embodiment herein, wherein the rotatable core is cannulated.

[0201] A thrombus engagement tool as described in any embodiment herein, wherein the rotatable core is a solid wire.

[0202] A thrombus engagement tool as described in any embodiment herein, wherein the advance segment comprises an atraumatic tip.

[0203] A thrombus engagement tool as described in any embodiment herein, wherein the atraumatic tip comprises a soft polymer.

[0204] A thrombus engagement tool as described in any embodiment herein, wherein the handle further comprises an indicium of rotational direction.

[0205] A thrombus engagement tool as described in any embodiment herein, wherein the thrombus engagement tip has an axial length within the range of from about 15 mm to about 30 mm.

[0206] A thrombus engagement tool as described in any embodiment herein in combination with a catheter having an inside diameter, wherein an outside diameter of the helical thread is no more than about 60% of the inside diameter of the catheter.

[0207] A thrombus engagement tool as described in any embodiment herein, wherein the outside diameter of the helical thread is no more than about 40% of the inside diameter of the catheter.

[0208] A thrombus engagement tool as described in any embodiment herein, further comprising a position indicator carried by the rotatable core.

[0209] A thrombus engagement tool as described in any embodiment herein, wherein the position indicator comprises a distal end of a tube surrounding the rotatable core.

[0210] A method of removing embolic material from a vessel with mechanical and aspiration assistance, the method comprising one or more of the following:

[0211] providing an aspiration catheter having a central lumen and a distal end;

[0212] advancing the distal end to obstructive material in a vessel;

[0213] applying vacuum to the central lumen to draw clot into the central lumen;

[0214] introducing a thrombus engagement tool into the central lumen, the thrombus engagement tool having a tip comprising a helical thread having a major diameter that is at least about 0.015 inches smaller than an inside diameter of the central lumen, the helical thread being configured to provide an aspiration flow path around the tip; and

[0215] manually manipulating the tip to engage clot between the tip and an inside wall of the central lumen.

[0216] A method of removing embolic material as described in any embodiment herein, wherein the tip is carried by a rotatable core having a proximal handle.

[0217] A method of removing embolic material as described in any embodiment herein, wherein the rotatable core is cannulated.

[0218] A method of removing embolic material as described in any embodiment herein, wherein the rotatable core is a microcatheter.

[0219] A method of removing embolic material as described in any embodiment herein, wherein the rotatable core is a wire.

[0220] A method of removing embolic material as described in any embodiment herein, wherein the axial length of the threaded portion of the tip is within the range of from about 5 mm to about 15 mm.

[0221] A method of removing embolic material as described in any embodiment herein, further comprising the step of introducing the catheter via a femoral artery prior to the advancing step.

[0222] A method of removing embolic material as described in any embodiment herein, comprising the step of advancing the catheter to a pulmonary embolism.

[0223] A method of removing embolic material as described in any embodiment herein, comprising the step of advancing the catheter to a deep venous thrombosis.

[0224] A method of removing embolic material as described in any embodiment herein, comprising the step of introducing a thrombus engagement tool having a tip with a major diameter that is no more than about 60% of the inside diameter of the central lumen.

[0225] A method of removing embolic material as described in any embodiment herein, comprising introducing a thrombus engagement tool having a tip with a major diameter that is no more than about 40% of the inside diameter of the central lumen.

[0226] A method of removing embolic material as described in any embodiment herein, wherein the tip is laterally displaced within the central lumen in response to the ingestion of clot.

[0227] A method of removing embolic material as described in any embodiment herein, wherein an outer profile of the threaded tip in an end view is substantially circular.

[0228] A method of removing embolic material as described in any embodiment herein, wherein the thread has a proximal face and a distal face, and the proximal face inclines radially outwardly in a proximal direction.

[0229] A method of removing embolic material as described in any embodiment herein further comprising axially reciprocating the thrombus engagement tool within the catheter.

[0230] A method of removing embolic material as described in any embodiment herein, further comprising axially extending the tip beyond the distal end of the catheter.

[0231] A method of removing embolic material as described in any embodiment herein, comprising extending the distal tip at least about 2 cm beyond the distal end of the catheter.

[0232] A method of removing embolic material as described in any embodiment herein, comprising axially aligning the distal tip with the distal end of the catheter using a position indicator on the rotatable core.

[0233] A method of removing embolic material as described in any embodiment herein, further comprising advancing the thrombus engagement tool through a rotating hemostasis valve before introducing the thrombus engagement tool into the central lumen.

[0234] A method of removing embolic material as described in any embodiment herein, wherein the position indicator provides haptic feedback as the position indicator passes through the hemostasis valve.

[0235] An inserter for guiding a device through a valve, the inserter comprising one or more of the following:

[0236] an elongate tubular body having a proximal end, a distal end, and a sidewall at least partially defining a central lumen;

[0237] a laterally facing concave landing zone on the proximal end, the concave landing zone having a radius of curvature that increases in a proximal direction; and

[0238] an axially extending slit in the sidewall, the axially extending slit extending from the distal end to the concave landing zone.

[0239] An inserter as described in any embodiment herein, further comprising a tapered distal tip.

[0240] An inserter as described in any embodiment herein, further comprising a pull tab.

[0241] An inserter as described in any embodiment herein, wherein a surface of the concave landing zone comprises a different color than an outside surface of the elongate tubular body.

[0242] A method of passing a device through a valve, the method comprising one or more of the following:

[0243] providing an inserter having a tubular body with a split sidewall;

[0244] advancing the tubular body through a valve;

[0245] advancing a device through the tubular body and beyond the valve; and

[0246] proximally retracting the tubular body so that the device escapes laterally from the tubular body through the split sidewall, leaving the device in place across the valve.

[0247] A method of passing a device through a valve as described in any embodiment herein, wherein advancing the tubular body through the valve comprises advancing a tapered distal tip on the tubular body through the valve.

[0248] A method of passing a device through a valve as described in any embodiment herein, wherein advancing the tubular body through the valve is accomplished with the device pre loaded inside the tubular body.

[0249] A method of passing a device through a valve as described in any embodiment herein, wherein a distal nose segment of the tubular body expands in diameter in response to advancing the device therethrough.

[0250] A method of passing a device through a valve as described in any embodiment herein, wherein the device is a thrombus engagement tool.

[0251] A method of passing a device through a valve as described in any embodiment herein, wherein the device is a secondary catheter.

[0252] A method of passing a device through a valve as described in any embodiment herein, wherein the device is an aspiration catheter.

What is claimed is:

1. An inserter for guiding a device through a valve, the inserter comprising:

an elongate tubular body having a proximal end, a distal end, and a sidewall at least partially defining a central lumen;

a laterally facing concave landing zone on the proximal end, the concave landing zone having a radius of curvature that increases in a proximal direction; and an axially extending slit in the sidewall, the axially extending slit extending from the distal end to the concave landing zone.

2. An inserter as in claim 1, further comprising a tapered distal tip.

3. An inserter as in claim 1, further comprising a pull tab.

4. An inserter as in claim 1, wherein a surface of the concave landing zone comprises a different color than an outside surface of the elongate tubular body.

5. A method of passing a device through a valve, the method comprising:

providing an inserter having a tubular body with a split sidewall;

advancing the tubular body through a valve;

advancing a device through the tubular body and beyond the valve; and

proximally retracting the tubular body so that the device escapes laterally from the tubular body through the split sidewall, leaving the device in place across the valve.

6. A method as in claim 5, wherein advancing the tubular body through the valve comprises advancing a tapered distal tip on the tubular body through the valve.

7. A method as in claim 5, wherein advancing the tubular body through the valve is accomplished with the device pre loaded inside the tubular body.

8. A method as in claim 5, wherein a distal nose segment of the tubular body expands in diameter in response to advancing the device therethrough.

9. A method as in claim 5, wherein the device is a thrombus engagement tool.

10. A method as in claim 5, wherein the device is a secondary catheter.

11. A method as in claim 5, wherein the device is an aspiration catheter.

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