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(54) **Title:** THROMBUS REMOVAL SYSTEMS AND ASSOCIATED METHODS

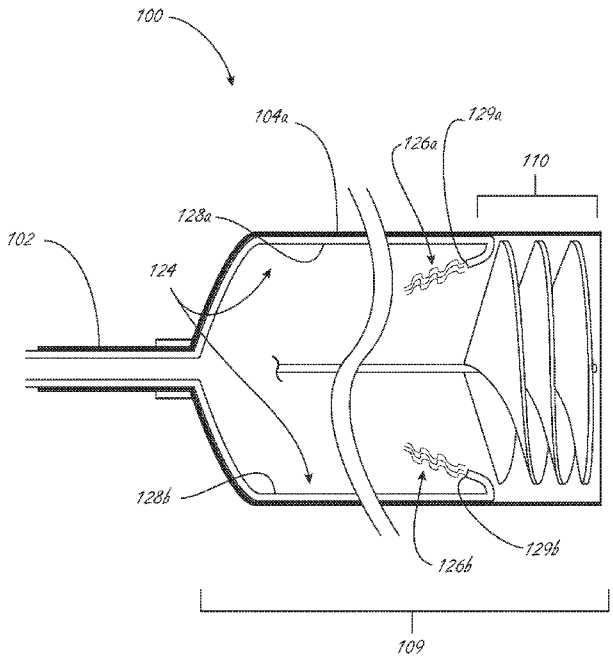

Fig. 1E

(57) **Abstract:** The present technology relates to systems and methods for removing a thrombus from a blood vessel of a patient. In some embodiments, the present technology is directed to systems including an elongated catheter having a distal portion configured to be positioned within the blood vessel of the patient, a proximal portion configured to be external to the patient, and a lumen extending therebetween. The system can also include an imaging element at the distal portion, an illumination source at the distal portion, a capture element at the distal portion and configured to engage the thrombus, a fluid delivery mechanism within the lumen and configured to apply fluid to (1) at least partially fragment the thrombus and (2) provide an optical path for the imaging element, and an aspiration mechanism fluidly coupled to the lumen and configured to aspirate the fragmented thrombus.

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THROMBUS REMOVAL SYSTEMS AND ASSOCIATED METHODS

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims priority to the following pending applications:

[0002] U.S. Provisional Patent Application No. 62/984,918, filed March 4, 2020; and

[0003] U.S. Provisional Patent Application No. 63/050,039, filed July 9, 2020.

[0004] All of the foregoing applications are incorporated herein by reference in their entireties. Further, components and features disclosed in the applications incorporated by reference may be combined with various components and features disclosed and claimed in the present application.

TECHNICAL FIELD

[0005] The present technology generally relates to medical devices and, in particular, to systems and associated methods for removing a thrombus from a patient's blood vessel.

BACKGROUND

[0006] A pulmonary embolism is a blockage in one of the pulmonary arteries supplying blood to the lungs. Pulmonary embolisms typically arise when a thrombus originating from another part of the body (e.g., a vein in the pelvis or leg) becomes dislodged and travels to the lungs. Anticoagulation therapy is the current standard of care for treating pulmonary embolisms, but may not be effective in some patients. Additionally, conventional devices for removing thrombotic material may not be capable of navigating the vascular anatomy of the lungs, may not be effective in removing thrombotic material, and/or may lack the ability to provide sensor data or other feedback to the clinician during the thrombectomy procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1A illustrates a thrombus removal system including an elongated catheter positioned within a patient's pulmonary vasculature and configured in accordance with an embodiment of the present technology.

[0008] FIG. 1B illustrates a proximal portion of the elongated catheter of FIG. 1A.

[0009] FIG. 1C is a closeup view of a distal portion of the elongated catheter of FIG. 1A.

[0010] FIG. 1D is a side cross-sectional view of the distal portion of FIG. 1C.

[0011] FIG. 1E is a side cross-sectional view of a distal portion configured in accordance with another embodiment of the present technology.

[0012] FIG. 1F is a side cross-sectional view of a distal portion configured in accordance with other embodiments of the present technology.

[0013] FIG. 1G is a side cross-sectional view of a distal portion configured in accordance with another embodiment of the present technology.

DETAILED DESCRIPTION

[0014] The present technology is generally directed to thrombus removal systems and associated methods. A system configured in accordance with an embodiment of the present technology can include, for example, an elongated catheter having a distal portion configured to be positioned within the blood vessel of the patient, a proximal portion configured to be external to the patient, and a lumen extending therebetween. The system can also include an imaging element at the distal portion for imaging the patient's vasculature and/or the thrombus. In some embodiments, the system also includes a capture element configured to engage and draw the thrombus into the lumen, a fluid delivery mechanism configured to fragment the thrombus with pressurized fluid, and/or an aspiration mechanism configured to aspirate the fragments of the thrombus.

[0015] The terminology used in the description presented below is intended to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain specific embodiments of the present technology. Certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section. Additionally, the present technology can include other embodiments that are within the scope of the examples but are not described in detail with respect to FIGS. 1A-1G.

[0016] Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present technology. Thus, the appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this

specification are not necessarily all referring to the same embodiment. Furthermore, the particular features or characteristics may be combined in any suitable manner in one or more embodiments.

[0017] Reference throughout this specification to relative terms such as, for example, "generally," "approximately," and "about" are used herein to mean the stated value plus or minus 10%.

[0018] Although some embodiments herein are described in terms of thrombus removal, it will be appreciated that the present technology can be used and/or modified to remove other types of emboli that may occlude a blood vessel, such as fat, tissue, or a foreign substance. Additionally, although some embodiments herein are described in the context of thrombus removal from a pulmonary artery (e.g., pulmonary embolectomy), the technology may be applied to removal of thrombi and/or emboli from other portions of the vasculature (e.g., in neurovascular, coronary, or peripheral applications). Moreover, although some embodiments are discussed in terms of maceration of a thrombus with a fluid, the present technology can be adapted for use with other techniques for breaking up a thrombus into smaller fragments or particles (e.g., ultrasonic, mechanical, enzymatic, etc.).

[0019] The headings provided herein are for convenience only and do not interpret the scope or meaning of the claimed present technology.

Systems for Thrombus Removal

[0020] As provided above, the present technology is generally directed to thrombus removal systems. Such systems include an elongated catheter having a distal portion positionable within a blood vessel of the patient (e.g., an artery or vein), a proximal portion positionable outside the patient's body, and a lumen extending between the distal and proximal portions. In some embodiments, the systems herein are configured to engage a thrombus in the patient's blood vessel, break the thrombus into small fragments, and aspirate the fragments out of the patient's body. Optionally, the systems described herein can include one or more sensors (e.g., a camera) integrated in the elongated catheter (e.g., at the distal portion) to facilitate positioning of the elongated catheter, measure thrombus characteristics, and/or otherwise provide feedback to the clinician during the thrombectomy procedure. As used herein, “thrombus” and “embolism” are used somewhat interchangeably in various respects.

[0021] FIGS. 1A-1G illustrate a thrombus removal system 100 configured in accordance with various embodiments of the present technology. More specifically, FIG. 1A illustrates an elongated catheter 102 of the system 100 positioned within a patient's pulmonary vasculature, FIG. 1B illustrates a proximal portion 104b of the elongated catheter 102, FIG. 1C is a closeup view of a distal portion 104a of the elongated catheter 102, FIG. 1D is a side cross-sectional view of the distal portion 104a, FIG. 1E is a side cross-sectional view of some embodiments of the distal portion 104a, FIG. 1F is a side cross-sectional view of other embodiments of the distal portion 104a, and FIG. 1G is a side cross-sectional view of other embodiments of the distal portion 104a.

[0022] Referring first to FIG. 1A, the patient's pulmonary vasculature includes a pulmonary valve (PV) separating the right ventricle of the heart (not shown) from the main pulmonary artery or pulmonary trunk (PT). The pulmonary trunk PT splits into the left pulmonary artery (LPA) and the right pulmonary artery (RPA), which connect to the left and right lungs (not shown), respectively. The diameter of the pulmonary trunk PT can vary significantly, e.g., between about 22 mm to about 43 mm during systole and diastole. The left pulmonary artery LPA and right pulmonary artery RPA can each have a diameter within a range from 16 mm to 49 mm, and a length within a range from about 80 mm to about 100 mm. A pulmonary embolism occurs when one or more portions of the pulmonary vasculature are occluded by a thrombus T. For example, in the illustrated embodiment, the thrombus (T) is blocking the left pulmonary artery (LPA).

[0023] Referring to FIGS. 1A and 1B together, the thrombus removal system 100 can be used to remove the thrombus T from the patient's vasculature. The elongated catheter 102 of the system 100 includes a lumen 106 extending therethrough between distal and proximal portions 104a-b. The distal portion 104a is configured to be positioned within a blood vessel at a location near or adjacent to the thrombus T. The elongated catheter 102 or at least a portion thereof (e.g., the distal portion 104a) can be introduced into the patient's body (e.g., via a delivery sheath-not shown) and advanced to the site of the thrombus T. For example, in the illustrated embodiment, the elongated catheter 102 is advanced through the pulmonary valve PV into the pulmonary trunk PT and at least partially into the left pulmonary artery LPA or right pulmonary artery RPA so that distal portion 104a is adjacent to the thrombus T. The proximal portion 104b is configured to remain external to the patient's body, as described in greater detail below. The proximal portion 104b can include or be coupled to a handle (not shown) for controlling movement and/or other functions of the elongated catheter 102. Although described in relation to a procedure in the pulmonary artery, one will appreciate from the description

herein that the systems, devices, and methods described may be applied equally to other locations in the body and other diseases. For example, the systems and devices may be used to remove thrombus from any type of occluded arteries, veins, or prostheses (e.g. vascular grafts). The systems, devices, and methods may be used as adjunctive therapy or as a sole therapy. In various embodiments, the system is configured to remove pulmonary emboli, iliofemoral emboli, and/or deep venous thromboses.

[0024] In some embodiments, the elongated catheter 102 or a portion thereof (e.g., the distal portion 104a, an intermediate portion between the distal and proximal portions 104a-b-not shown) has a relatively small outer diameter suitable for introduction into the patient's vasculature (e.g., the pulmonary vasculature). The outer diameter can be smaller than the diameter of the target blood vessel so that the elongated catheter 102 does not completely occlude the blood vessel when introduced therein. For example, the outer diameter can be less than or equal to about 10 mm, less than or equal to about 9 mm, less than or equal to about 8 mm, less than or equal to about 7.5 mm, less than or equal to about 7 mm, less than or equal to about 6.5 mm, less than or equal to about 6 mm, less than or equal to about 5.5 mm, less than or equal to about 5 mm, less than or equal to about 4.5 mm, less than or equal to about 4 mm, less than or equal to about 3.5 mm, less than or equal to about 3 mm, less than or equal to about 2.5 mm, less than or equal to about 2 mm, less than or equal to about 1.5 mm, or less than or equal to about 1 mm. In some embodiments, the outer diameter is less than or equal to 21 French (Fr), less than or equal to 10 Fr, or within a range from about 10 Fr to about 4 Fr. The distal portion 104a of the elongated catheter 102 can be configured to facilitate navigation through the patient's vasculature. For example, the catheter can be steerable. The catheter may be relatively flexible to be guided over a guidewire or have a tip configured to be pushed through the vasculature. Optionally, the elongated catheter 102 or a portion thereof can have sufficient stiffness to reduce or prevent kinking, pinching, etc. as the elongated catheter 102 is introduced through bends, curves, branches, or other tortuous portions of the vascular anatomy.

[0025] Referring to FIG. 1C, in some embodiments the distal portion 104a of the elongated catheter 102 includes an imaging element 108 (e.g., a camera, such as CCD camera, or CMOS camera). The imaging element 108 can be operably coupled to an exterior surface of the distal portion 104a, operably coupled to an interior surface of the distal portion 104a (e.g., within the lumen 106), or can be embedded within a wall of the distal portion 104a around the lumen 106. The imaging element 108 can be configured to generate an image and/or data representative of the patient's

vasculature and/or the thrombus (not shown in FIG. 1C) to guide the clinician in performing the thrombectomy procedure. For example, image data can be displayed to assist the clinician in positioning the distal portion 104a near the thrombus. The image data can also help the clinician assess the type of thrombus (e.g., soft and acute, slightly organized with some fibrin, highly organized and fibrotic, etc.) to determine the appropriate procedure and/or tools for removing the thrombus. Optionally, the imaging element 108 can generate image data before, during, and/or after the thrombectomy procedure so the clinician can evaluate whether the thrombus has been completely removed, whether there are any portions or other thrombi remaining in the blood vessel, whether other treatment procedures would be beneficial, etc.

[0026] The system 100 can include additional components configured to facilitate visualization of the treatment site with the imaging element 108. For example, the system 100 can include an illumination source (e.g., one or more LEDS-not shown) at or near the distal portion 104a. The system 100 can also be configured to deliver a fluid (e.g., a fluid that is transparent in the visible spectrum) to provide an optical path to the location of interest. The fluid can be delivered from the distal portion 104a to displace opaque blood away from the treatment site and provide an optically transparent medium for imaging. In some embodiments, the fluid for imaging is the same as the fluid used to fragment the thrombus, as described further below. In other embodiments the fluid for imaging is different from the fluid for fragmenting the thrombus.

[0027] Referring to FIGS. 1C and 1D together, in some embodiments the distal portion 104a of the elongated catheter 102 includes an expandable chamber 109. The interior space within the expandable chamber 109 can be part of or be connected to the lumen 106 so that materials can enter and/or exit the elongated catheter 102 via the expandable chamber 109. The expandable chamber 109 can be transformed between a deployed configuration (e.g., an expanded and/or generally cylindrical configuration as shown in FIGS. 1C and 1D) and a low-profile configuration (e.g., a collapsed, contracted and/or flattened configuration-not shown). The expandable chamber 109 can assume the low-profile configuration to allow the distal portion 104a of the elongated catheter 102 to be intravascularly introduced into the patient's body via a delivery sheath or other minimally invasive techniques. Once the distal portion 104a is positioned at the target site within the blood vessel, the expandable chamber 109 can be transformed into the deployed configuration for capturing and macerating the thrombus, as described in greater detail below. The expandable chamber 109 can be self-expanding so that it automatically transforms into the deployed configuration when released from

the delivery sheath. Subsequently, when the thrombectomy procedure is completed, the expandable chamber 109 can be transformed back into the low-profile configuration and withdrawn into the delivery sheath for removal from the patient's body. Alternatively or additionally, the expandable chamber 109 can be inflatable (e.g., by a fluid or a gas) to transform from the low-profile configuration to the deployed configuration.

[0028] The geometry (e.g., size, shape) of the expandable chamber 109 can be configured in a number of different ways. For example, the expandable chamber 109 can have a circular, elliptical, square, rectangular, polygonal, curvilinear, star, or other cross-sectional shape. In some embodiments, the expandable chamber 109 has a uniform cross-sectional shape throughout its entire length (e.g., the expandable chamber 109 is a generally cylindrical structure), while in other embodiments the expandable chamber 109 has a variable cross-sectional shape (e.g., the expandable chamber 109 is a funnel-like structure). The expandable chamber 109 can have a length at least about 5 cm, at least about 6 cm, at least about 7 cm, at least about 7.5 cm, at least about 8 cm, at least about 8.5 cm, at least about 9 cm, at least about 9.5 cm, at least about 10 cm, at least about 10.5 cm, at least about 11 cm, or at least about 12 cm. In some embodiments, the length of the expandable chamber 109 is within a range from about 8 cm to about 10 cm. When in the deployed configuration, the expandable chamber 109 can have an outer diameter at least about 5 mm, at least about 5.5 mm, at least about 6 mm, at least about 6.5 mm, at least about 7 mm, at least about 7.5 mm, at least about 8 mm, at least about 8.5 mm, at least about 9 mm, at least about 9.5 mm, at least about 10 mm, at least about 15 mm, at least about 20 mm, at least about 25 mm, at least about 30 mm, at least about 35 mm, or at least about 40 mm. When in the low-profile configuration, the expandable chamber 109 can have an outer diameter at most about 7 mm, at most about 6.5 mm, at most about 6 mm, at most about 5.5 mm, at most about 5 mm, at most about 4.5 mm, at most about 4 mm, at most about 3.5 mm, at most about 3 mm, at most about 2.5 mm, at most about 2 mm, at most about 1.5 mm, or at most about 1 mm. The cross-sectional dimension (e.g., area, diameter, width, etc.) of the expandable chamber 109 in the deployed configuration can be at least about 50%, at least about 60%, at least about 70%, at least about 80%, at least about 90%, at least about 100%, at least about 150%, at least about 200%, at least about 250%, at least about 300%, at least about 400%, at least about 500%, at least about 600%, at least about 700%, at least about 800%, at least about 900%, or at least about 1000% greater than the cross-sectional dimension of the expandable chamber 109 in the low-profile configuration. In some embodiments, when in the deployed configuration, the cross-sectional dimension of the expandable

chamber 109 is at least about 50%, at least about 60%, at least about 70%, at least about 80%, at least about 90%, at least about 100%, at least about 150%, at least about 200%, at least about 250%, at least about 300%, at least about 400%, or at least about 500% greater than a cross-sectional dimension of a remaining portion of the elongated catheter 102 (e.g., the intermediate portion between the distal and proximal portions 104a-b).

[0029] Optionally, when in the deployed configuration, the cross-sectional dimension of the expandable chamber 109 can be less than the cross-sectional dimension of the blood vessel in which the expandable chamber 109 is positioned. For example, the diameter of the expandable chamber 109 can be about 10%, about 20%, about 30%, about 40%, about 50%, about 60%, about 70%, about 80%, or about 90% of the diameter (e.g., minimum or maximum diameter) of the blood vessel. In some embodiments, when deployed, the expandable chamber 109 is configured to engage and form a seal against the thrombus while permitting blood flow around the exterior of the expandable chamber 109 and/or thrombus to maintain perfusion. The sealing of the expandable chamber 109 against the thrombus can allow fluid (e.g., for imaging and/or fragmenting thrombus) to be delivered, contained, and aspirated from the expandable chamber 109 with little or no leakage into the patient's bloodstream, as described further below.

[0030] Alternatively, when in the deployed configuration, the cross-sectional dimension of the expandable chamber 109 can be equal or approximately equal to the cross-sectional dimension of the blood vessel such that the expandable chamber 109 partially or completely occludes fluid flow therethrough. For example, the expandable chamber 109 in the deployed configuration can form a fluid seal about a perimeter of the expandable chamber 109, against the wall of the blood vessel. The seal may a partial fluid seal or complete fluid seal (clinically and/or functionally complete seal). This approach is designed to prevent thrombus fragments from traveling to other parts of the patient's body during the thrombectomy procedure, and can be utilized in situations where tissues downstream of the expandable chamber 109 are still perfused by other blood vessels and/or where temporary upstream occlusion by the expandable chamber 109 can be tolerated. In some embodiments, the expandable chamber 109 can include one or more valves (not shown) configured to selectively permit fluid flow along an exterior of the system 100. For example, the one or more valves can be located about the perimeter of the expandable chamber 109. This approach can be advantageous in situations where tissue perfusion downstream of the expandable chamber 109 may be compromised in the case of a total or near-total occlusion by the expandable chamber 109.

[0031] The expandable chamber 109 can be used to house one or more components of the system 100. In some embodiments, for example, the system 100 includes a capture element 110 at the distal portion 104a and at least partially within the expandable chamber 109. The capture element 110 can be configured to contact and engage the thrombus to draw the thrombus at least partially into the lumen 106 and the expandable chamber 109. Various types of capture elements are suitable for use with the embodiments described herein. For example, as best seen in FIG. 1D, the capture element 110 can be configured as an auger, screw (e.g., an Archimedes screw), or other helical structure that is configured to rotate (e.g., along direction D1) to penetrate into the thrombus and/or progressively draw the thrombus into the lumen 106. The geometry (e.g., size, shape) of the capture element 110 can be configured in a number of different ways. In some embodiments, the capture element is formed to have an outer perimeter (e.g., profile) that is generally uniform along its axial length (e.g., along direction D2). In some embodiments, the capture element 110 has a variable profile. For example, the capture element 110 can have a conical profile that is tapered in the distal direction and/or in the proximal direction. Alternatively or in combination with rotation, the capture element 110 can be movable in a longitudinal direction (e.g., direction D2) to engage and progressively draw the thrombus into the lumen 106 and the expandable chamber 109. In some embodiments, the capture element 110 is movable along a distance that is at least about 10%, at least about 20%, at least about 30%, at least about 40%, at least about 50%, at least about 60%, at least about 70%, at least about 80%, at least about 90%, or at least about 100% of the length of the capture element 110. Longitudinal movement of the capture element 110 (e.g., out of the lumen 106 and the expandable chamber 109) can also be used to clear the capture element 110 if it becomes jammed or clogged.

[0032] The rotational and/or longitudinal movement of the capture element 110 relative to the distal portion 104a can be actuated by a drive shaft 112 extending through the elongated catheter 102 and into the expandable chamber 109. The drive shaft 112 can operably couple the capture element 110 to a motor, cam, and/or other actuation mechanism at the proximal portion of the elongated catheter 102 (not shown). In some embodiments, the rotation speed of the capture element 110 is adjustable (e.g., between high, medium, and low speeds) to facilitate engagement with different thrombus types. For example, slower rotation speeds can be used to capture softer, less organized, and/or less fibrotic thrombi, while faster rotation speeds can be used to capture harder, more organized, and/or more fibrotic thrombi.

[0033] Optionally, the properties of the capture element 110 (e.g., thread size, thread pitch, and/or durometer) can be selected based on the type and/or the characteristics of the thrombus (e.g., stiffness, density, degree of organization, fibrin content, size, etc.). In some embodiments, the capture element 110 includes at least one sensor 113 (e.g., located at a distal portion of the capture element 110) for sensing one or more characteristics of the thrombus. For example, the sensor 113 can be configured to measure strain, stiffness, and/or other mechanical properties of the thrombus. As another example, the sensor 113 can be configured to measure current, impedance, and/or other electrical properties of the thrombus (e.g., while the capture element 110 is rotating). Other types of sensors suitable for use with the embodiments herein include pressure sensors, accelerometers, temperature sensors, flow sensors, optical sensors, microphones or other acoustic sensors, ultrasonic sensors, ECG or other cardiac rhythm sensors, SpO2 sensors, electrical impedance sensors, and other sensors adapted to measure tissue and/or blood gas levels, blood volume sensors, and other sensors known to those who are skilled in the art. The sensor data generated by the sensor 113 can be transmitted to an external computing device via wired or wireless communication so that the sensor data can be processed and/or displayed to the clinician.

[0034] In some embodiments, the capture element 110 is expandable (e.g., inflatable) and can be transformed between a low-profile configuration (e.g., a flattened and/or collapsed configuration-not shown) and a deployed configuration (e.g., an operating and/or expanded configuration for engaging a thrombus, as shown in FIGS. 1C and 1D). The capture element 110 can be transformed into the low-profile configuration while the expandable chamber 109 is also in the low-profile configuration, e.g., for introduction into the patient's blood vessel. Once the distal portion 104a is properly positioned within the blood vessel, the capture element 110 can be transformed into the deployed configuration, e.g., concurrently with or after transformation of the expandable chamber 109 into the deployed configuration. In some embodiments, a portion or an entirety of the capture element 110 is inflatable using delivered fluid and/or gas. A portion can comprise a). one or more blades (e.g., of an impeller), or b). one or more blade portions (e.g., peripheral edge of a given blade). In some embodiments, the body of the capture element comprises a membrane that includes an outer portion (e.g., edge) that is inflatable. In some embodiments, the capture element 110 is configured to be self-expanding so that it automatically transforms along with the expandable chamber 109 into the deployed configuration when unsheathed and/or unrestrained. The capture element 110 can then be used to engage and draw a thrombus into the expandable chamber 109, as described herein. The

capture element 110 can be transformed back into the low-profile configuration, e.g., after the thrombus has been collected and/or along with transformation of the expandable chamber 109 into the low-profile configuration.

[0035] Referring to FIG. 1D, the system 100 can also include a fluid delivery mechanism 114 at the distal portion 104a and at least partially within the expandable chamber 109. The fluid delivery mechanism 114 can be configured to apply a fluid 116 (e.g., saline) to fragment, macerate, cut, pulverize, and/or otherwise break up the thrombus into a plurality of smaller particles. For example, the delivery mechanism 114 can be positioned proximal to the capture element 110 so that as a section of the thrombus is drawn proximally into the expandable chamber 109 by the capture element 110, the fluid delivery mechanism 114 fragments the section of the thrombus with the fluid 116. In some embodiments, the fluid 116 is pressurized to contact the thrombus with sufficient force to fragment the thrombus. The fluid 116 can be delivered in a continuous stream or jet, or can be delivered intermittently at a specified timing, frequency, etc. The pressure and/or flow rate of the fluid 116 can be sufficiently large to break up the thrombus, but sufficiently small so that little or no fluid 116 escapes from the lumen 106 and into the patient's blood stream. In some embodiments, the applied fluid 116 is delivered proximal to a seal that is formed by the expandable chamber 109. Advantageously, applied fluid 116 that is delivered proximal to a seal is expected to improve the efficacy and/or efficiency of a) maceration/fragmentation of the thrombus, and/or b) aspiration of thrombus fragments. Optionally, the pressure and/or flow rate can be selectively adjusted based on the type and/or characteristics of the thrombus (e.g., a higher pressure and/or flow rate for harder, more organized, and/or more fibrotic thrombi; a lower pressure and/or flow rate for softer, less organized, and/or less fibrotic thrombi). In some embodiments, the applied fluid 116 is delivered at a pressure that is at least about 50 pounds per square inch (psi), at least about 70 psi, at least about 90 psi, at least about 110 psi, at least about 130 psi, or at least about 150 psi. In some embodiments, the applied fluid 116 can be delivered at a pressure from at least about 50 psi to at least about 1000 psi – for example, at least about 50 psi, at least about 100 psi, at least about 200 psi, at least about 300 psi, at least about 400 psi, at least about 500 psi, at least about 600 psi, at least about 700 psi, at least about 800 psi, at least about 900 psi, or at least about 1000 psi. The applied fluid 116 can be delivered at any pressure within the aforementioned ranges of pressures. In some embodiments, the applied fluid 116 is delivered for a given duration, for example, at least about 100 milliseconds (ms), at least about 200 ms, at least about 300 ms, at least about 400 ms, at least about 500 ms, at least about 600 ms, at

least about 700 ms, at least about 800 ms, at least about 900 ms, or at least about 1 second. The applied fluid 116 can be delivered for any duration within the aforementioned range of durations. In some embodiments, the applied fluid 116 is delivered intermittently and/or periodically (e.g., in pulses), for a given duration. Advantageously, pulsing the applied fluid 116 can reduce a total volume of fluid that delivered to patient. For example, the applied fluid 116 can be delivered periodically with an (application) frequency of about 0.1 hertz (Hz), about 0.3 Hz, about 0.5 Hz, about 0.7 Hz, about 1 Hz, about 2 Hz, about 3 Hz, about 4 Hz, or about 5 Hz. The delivery of the applied fluid 116 can be at any frequency within the aforementioned range of frequencies. In some embodiments, a frequency with which the applied fluid 116 is delivered may be varied – for example, varied before, during, and/or after application of a given pulse of delivered fluid.

[0036] The fluid delivery mechanism 114 can be configured in a number of different ways. In the illustrated embodiment, for example, the fluid delivery mechanism 114 includes a single elongated tube 118 terminating in an opening 120 (e.g., a fluid port or nozzle). The opening 120 can be positioned within the expandable chamber 109 proximal to and spaced apart from the capture element 110 so that a thrombus or section thereof can be received within the expandable chamber 109 between the opening 120 and the capture element 110. The elongated tube 118 and opening 120 are oriented along the longitudinal axis of the distal portion 104a such that fluid 116 is directed distally toward the capture element 110. Accordingly, when a thrombus is drawn proximally into the expandable chamber 109 by the capture element 110, the fluid 116 is applied distally against the thrombus to fragment the thrombus.

[0037] Referring to FIG. 1E, in other embodiments the system 100 can include a fluid delivery mechanism 124 configured to produce two or more fluid jets or streams (e.g., two fluid jets 126a-b). The fluid delivery mechanism 124 can include two elongated tubes 128a-b each terminating in a respective opening 129a-b. The elongated tubes 128a-b can extend along opposite interior surfaces of the expandable chamber 109 with the openings 129a-b located adjacent to or near the proximal portion of the capture element 110. The openings 129a-b and/or the distal portions of the elongated tubes 128a-b can be oriented proximally toward the central longitudinal axis of the expandable chamber 109. As a result, the fluid jets 126a-b are directed proximally away from the capture element 110 and toward the center of the expandable chamber 109. When a thrombus is drawn proximally into the expandable chamber 109 by the capture element 110, the fluid jets 126a-b are applied proximally against the thrombus to fragment the thrombus.

[0038] It will be appreciated that the system 100 can include fluid delivery mechanisms that differ from the embodiments shown in FIGS. 1D, 1E and 1G. For example, a fluid delivery mechanism can include any suitable number of elongated tubes or like structures for transporting fluid (e.g., one, two, three, four, five, ten, twenty, thirty or more elongated tubes). The fluid delivery mechanism can include any number of structures within the aforementioned ranges. Each elongated tube can include one or more openings (e.g., one, two, three, four, five, or more openings) for delivering fluid therethrough. In some embodiments, a single elongated tube includes a plurality of openings at different locations along the length of the tube so as to apply fluid to different portions of a captured thrombus. The fluid can be directed proximally, distally, toward a central longitudinal axis (e.g., FIG. 1G, 141), combinations of the foregoing, or in any other direction suitable for fragmenting the thrombus. In some embodiments, openings are arranged to direct the fluid streams generally along an inner wall of the distal portion 104a.

[0039] In some embodiments a pressure with which the fluid is delivered in a given stream is selected such that the stream dissipates prior to impacting an inner wall of the distal portion 104a. For example, the pressure may be sufficiently low such that, for an opening that directs a fluid stream from a first wall portion in a path toward a second wall portion, the fluid stream will dissipate prior to impacting the second wall portion. In some embodiments, the second wall portion is opposite the first wall portion. Dissipation may comprise a loss of cohesion for a fluid stream, a reduction in fluid stream momentum, or a change in fluid stream momentum (e.g., toward a proximal direction). Dissipation of a fluid stream may comprise a reduction in a magnitude of at most about 60%, at most about 50%, at most about 40%, at most about 30%, at most about 20%, at most about 10%, at most about 5%, or at most about 1% of the (e.g., initial) momentum with which the fluid stream was delivered to its given opening. The reduction in momentum can be any reduction within the aforementioned range of reduced momentums. Optionally, in some embodiments some or all of the elongated tubes can be used to deliver fluid to create a transparent optical path for imaging, e.g., in addition or alternatively to delivering fluid for breaking up the thrombus.

[0040] Referring to FIGS. 1B and 1D together, the system 100 also includes an aspiration mechanism 140 (best seen in FIG. 1B-shown schematically) fluidly coupled to the lumen 106. The aspiration mechanism 140 can be an active aspiration mechanism or a passive aspiration mechanism, and can include any device suitable for generating a vacuum (e.g., a vacuum pump). In operation, the aspiration mechanism is placed (e.g., via lumen 106) in fluid communication with the distal portion

104a. The aspiration mechanism 140 can be configured to aspirate the fragmented thrombus from the distal portion 104a of the elongated catheter 102 (e.g., from the expandable chamber 109) to the proximal portion 104b, and optionally to a collection container 142. In some embodiments, the aspiration mechanism 140 can be configured to supplement and/or replace the capture element 110 to draw the thrombus into the lumen 106 (best seen in FIG. 1G). For example, the aspiration mechanism 140 can be activated when the distal portion 104a is near and/or in contact with the thrombus, to reduce (e.g., lower) pressure within the distal portion 104a. For example, the aspiration mechanism 140 can be a Venturi vacuum pump in which a pump fluid (e.g., water) is passed through the pump to create a vacuum in a side port, as is known to those of skill in the art. The pump fluid and aspirated materials can be collected in the container 142. Optionally, collected fluids can be filtered and reused to continue running the pump.

[0041] The amount of vacuum pressure applied by the aspiration mechanism 140 can be selected (e.g., sufficiently high) to effectively aspirate the thrombus through the length of the elongated catheter 102. The vacuum pressure can also be selected (e.g., sufficiently high) so that most or all of the fluid 116 produced by the fluid delivery mechanism (e.g., fluid delivery mechanism 114 of FIG. 1D or fluid delivery mechanism 124 of FIG. 1E) is aspirated and does not accumulate in the patient's blood stream. However, the vacuum pressure can also be selected (e.g., sufficiently low) so that the aspiration mechanism 140 aspirates little or no blood out of the patient's body. In some embodiments, the system 100 includes one or more sensors (e.g., pressure sensors, flow sensors, etc.-not shown) configured to monitor fluid flow, volume, and/or pressure of fluids moving into and/or out of the patient's blood stream. Based on the sensor data, the operating parameters of the fluid delivery mechanism (e.g., fluid delivery mechanism 114 of FIG. 1D or fluid delivery mechanism 124 of FIG. 1E) and/or aspiration mechanism 140 can be adjusted to regulate the amount of fluid flow into and/or out of the patient's blood stream.

[0042] In some embodiments, the system 100 includes an expandable housing. The expandable housing can comprise, for example, an expandable scaffold or frame, an inflatable shroud, or a balloon. In some embodiments, the system 100 includes a plurality of imaging elements and/or a plurality of illumination elements. In some embodiments, one or more imaging elements and/or illumination elements are housed in the expandable housing. The expandable housing can be at least partially transparent to light generated by the illumination elements and/or detected by the imaging element. The inflatable shroud can be positioned at a distal portion of the elongated catheter (e.g.,

104a). In some embodiments the inflatable shroud at least partially (e.g., completely) encompasses the chamber 109. The inflatable shroud can be expandable by ingress of fluid or gas. For example, the inflatable shroud can be expanded by saline, oil, CO_2, and/or a substantially inert gas. In some embodiments, the aspiration fluid and the fluid filling the inflatable shroud are the same. In some embodiments, the inflatable shroud is reversibly adjustable from a collapsed first configuration to an expanded second configuration. In some embodiments, the inflatable shroud can be collapsed in an axially-variable manner, wherein a first axial portion of the inflatable shroud is collapsed at a different time than a second axial portion of the inflatable shroud. For example, the inflatable shroud may be collapsed in a distal-to-proximal manner (e.g., is distally collapsible). In some embodiments, the inflatable shroud can be collapsed in a proximal-to-distal manner. Advantageously, collapsing the inflatable shroud in an axially-variable can assist in a) fragmentation of the thrombus, and/or b) proximal motivation of the thrombus and/or of thrombus fragments. In some embodiments, fluid delivery openings (e.g., 129a-b) that are carried by an inflatable shroud may be directed (e.g., targeted) by inflation of the inflatable shroud to transform to a selected geometry and/or configuration. For example, an angle with which one or more fluid streams are directed toward a thrombus may be selected or altered according to a pressure with which the inflatable shroud is inflated. Advantageously, the collapsed configuration can improve translation of the catheter during advancement and retraction, and the expanded configuration can improve illumination/imaging pathways during material removal.

[0043] FIG. 1F is similar to the embodiments depicted in FIGS. 1D and 1E, but further includes a plurality of imaging elements 108 (e.g., a camera, such as CCD camera, or CMOS camera) and/or illuminators 115 within an expandable housing 117 at the distal portion 104a of the elongated catheter 102. The imaging elements and illuminators may be collectively described as "visualization elements." The expandable housing 117 substantially surrounds the expandable chamber 109. The plurality of imaging elements 108 and/or illuminators 115 can be operably coupled to 1) a distal end, 2) an exterior surface, 3) interior surface, and/or 4) embedded within a wall of, the expandable housing 117. The plurality of imaging element 108 and/or illuminators 115 can be arranged in a variety of ways. For example, the arrangement can be a) individual, b) in pairs, c) triplets, d) quartets, e) quintets, and/or f) sextets. In some embodiments, at least one imaging element and/or illuminator 115 is steerable. In some embodiments, the expanded configuration of the expandable housing 117 can advantageously assist in seating an outer perimeter of the distal portion 104a against a lumen wall

(e.g., forming a seal therewith). In some embodiments, the expandable housing 117 is generally annular in cross-section (e.g., cross-section in variation 1F-A). In some embodiments, the expandable housing 117 has a radially outermost wall that is generally undulating (e.g., cross- section in variation 1F-B). Regions 121 of the undulating outermost wall that are radially further from a central axis of the catheter can contact the vessel wall, while regions 123 that are radially closer to the central axis can provide a pathway for fluid flow. In some embodiments, maintaining fluid flow can advantageously promote continued perfusion for the patient, during thrombus removal.

[0044] In some embodiments, at least one vizualization element is steerable. Steering can be accomplished by an inflatable channel. In some embodiments, the inflatable channel for steering is the same as (or forms a portion of) an inflatable channel for inflating the expandable housing 117. In some embodiments, a separate (e.g., dedicated) inflatable channel is provided for steering. In various embodiments, any gas or fluid described herein for inflation of the inflatable shroud may be used for the inflatable channel for steering. In some embodiments, steering of the vizualization element may be (e.g., passively) responsive to pressure, for example the pressure within the inflatable shroud 117. In some embodiments, steering of the vizualization element may be via mechanical means, e.g., a wire.

[0045] In some embodiments, the system 100 can capture, macerate and/or fragment a thrombus using irrigation alone. FIG. 1G is similar to the embodiment depicted in FIG. 1E, but without a capture element 110. In the example of FIG. 1G, openings 139a-b of fluid delivery mechanism 124 are arranged to direct fluid streams 136a-b along a given path of travel. In some embodiments, at least two openings 139a-b (e.g., fluid ports) are arranged to direct fluid streams to intersect with one another (e.g., at fluid intersection 137). Advantageously, intersecting fluid streams can collide and impart increased forces to a portion of a thrombus that is near the point of collision. As used herein, "intersecting" does not necessarily mean physically intersecting. Intersecting is intended in its most general sense. Intersecting may include the fluid being directed towards a common region or volume as opposed to a specific point. Additionally or alternatively, the intersecting point or region may be within or behind the thrombus such that the fluid streams hit the target thrombus before they can physically intersect each other. The increased forces can be with respect to the forces imparted by similar fluid streams that contact the thrombus singly, that is, without any collision between fluid streams. In some embodiments, the openings 139a-b are arranged such that fluid streams are directed at least partially proximally (e.g., backward). In some embodiments,

the openings 139a-b are arranged such that fluid streams are directed at an angle that is a) substantially normal to a central axis 141 of the chamber 109, or b) at least partially distally (e.g., toward distal opening). While intersection 137 is depicted near a central region of the expandable chamber 109, it will be appreciated that the intersection of the fluid streams can be arranged in a variety of locations within the chamber 109. Forces generated by the fluid streams 136a-b at the intersection 137 can be sufficient to 1) macerate/fragment a thrombus, as well as 2) urge the thrombus fragment(s) to be evacuated proximally along the catheter 102.

[0046] The system 100 can include a console 130 (best seen in FIG. 1B-shown schematically) including various components for controlling the operation of the system 100. For example, the console 130 can include the aspiration mechanism 140 and can be coupled to the collection container 142. The console 130 can also include a fluid source 144 that is fluidly coupled to the fluid delivery mechanism (e.g., fluid delivery mechanism 114 of FIG. 1D or fluid delivery mechanism 124 of FIG. 1E). The fluid source 144 can be configured to pressurize the fluid contained therein (e.g., saline) to a sufficiently high pressure for macerating thrombus. The console 130 can optionally include or be coupled with a gas source (not shown) that is fluidly coupled to a gas delivery mechanism (not shown) that is configured to inflate one or more components of the system.

[0047] The console 130 can also include a controller 146 for controlling the movement (e.g., rotational and/or longitudinal movement) of the capture element 110. In some embodiments, the consoles 130 also includes an actuation mechanism (e.g., a motor, cam, etc.-not shown) for actuating the movement of the capture element 110. Alternatively, the actuation mechanism can be located within, at, or near the proximal portion 104b of the elongated catheter 102, and the controller 146 can be operably coupled to the actuation mechanism to control the operation thereof.

[0048] The console 130 can include other electronic components 148 for powering and/or controlling operation of the system 100, such as a microcontroller, FPGA, ASIC, or other programmable component or system capable of storing and executing software and/or firmware that drives operation of the system 100 or a component thereof; memory such as RAM or ROM to store data and/or software/firmware; wireless communication hardware such as an antenna system configured to transmit via Bluetooth, Wi-Fi, or other protocols as would be understood by one of skill from the description herein; a display, monitor, or other user interface elements; and/or one or more sensors. For example, the electronic components 148 can be configured to control operation of the capture element 110, the fluid delivery mechanism (e.g., fluid delivery mechanism 114 of FIG. 1D or

fluid delivery mechanism 124 of FIG. 1E), one or more sensors (e.g., sensor 113, imaging element 108 of FIG. 1C), the aspiration mechanism 140, the fluid source 144, and/or the controller 146.

[0049] The console 130 can be coupled to the proximal portion 104b of the elongated catheter 102. In some embodiments, the console 130 is coupled to the proximal portion 104b via a hub or adapter 150. The hub 150 can include multiple different connectors to operably couple the various components of the console 130 to the components of the elongated catheter 102. For example, the hub 150 can include a vacuum connection between the aspiration mechanism 140 and the lumen 106. The hub 150 can also include a fluid connection between the fluid source 144 and the fluid delivery mechanism (e.g., fluid delivery mechanism 114 of FIG. 1D or fluid delivery mechanism 124 of FIG. 1E). In some embodiments, the hub 150 includes one or more components (e.g., tubes, connectors, joints, etc.) configured to withstand high vacuum pressures and/or fluid pressures produced by the aspiration mechanism 140 and the fluid source 144, respectively. The hub 150 can also include an electronic connection between the controller 146 and an actuation mechanism for the capture element 110. The hub 150 can also electrically couple the electronic components 148 of the console 130 to other components of the system 100 (e.g., sensors).

[0050] In some embodiments, the system 100 is also configured to deliver one or more thrombolytic agents, such as a tissue plasminogen activator, a streptokinase, a urokinase, or a derivative or combination thereof. The thrombolytic agent(s) can be delivered from the elongated catheter 102 (e.g., through the lumen 106, a separate channel, or an opening in the distal portion 104a) prior to, concurrently with, or after capture and/or maceration of the thrombus. The thrombolytic agent(s) can be delivered locally to the site of the thrombus within the patient's blood vessel and/or can be delivered into the expandable chamber 109 to facilitate thrombus maceration.

[0051] As one of skill in the art will appreciate from the disclosure herein, various components of the thrombus removal systems described above can be omitted without deviating from the scope of the present technology. As discussed previously, for example, the present technology can be used and/or modified to remove other types of emboli that may occlude a blood vessel, such as fat, tissue, or a foreign substance. Further, although some embodiments herein are described in the context of thrombus removal from a pulmonary artery, the disclosed technology may be applied to removal of thrombi and/or emboli from other portions of the vasculature (e.g., in neurovascular, coronary, or peripheral applications). Likewise, additional components not explicitly described above may be added to the thrombus removal systems without deviating from the scope of the present technology.

Accordingly, the systems described herein are not limited to those configurations expressly identified, but rather encompasses variations and alterations of the described systems.

Examples

[0052] Several aspects of the present technology are set forth in the following examples:

1. A method for removing a thrombus from a blood vessel of a patient, the method comprising:

introducing a distal portion of an elongate catheter to a thrombus location in a blood vessel;

drawing at least a section of the thrombus into the distal portion; and

directing fluid from at least two different points toward the thrombus.

2. The method of example 1 wherein introducing the distal portion is into the blood vessel in a low-profile configuration, and wherein the method further comprises expanding the distal portion into a deployed configuration.

3. The method of example 2 wherein the drawing is into the distal portion using a capture element, and wherein the method further comprises expanding the capture element from the low-profile configuration to the deployed configuration.

4. The method of any one of examples 1–3 wherein the drawing is into the distal portion using a rotatable screw or auger.

5. The method of example 4, further comprising:

sensing a characteristic of the thrombus; and

adjusting a rotation speed of the rotatable screw or auger based on the sensed characteristic.

6. The method of any one of examples 1–5, further comprising applying the fluid by one or more nozzles within the distal portion to form at least two fluid streams.

7. The method of example 6, further comprising directing the at least two fluid streams along intersecting paths.

8. The method of any one of examples 1–6 wherein the blood vessel comprises a pulmonary artery.

9. The method of any one of examples 1–8, further comprising, prior to the drawing, imaging the thrombus with an imaging element at the distal portion.

10. The method of example 9 wherein the imaging is through a fluid path.

11. The method of example 10, further comprising forming the fluid path using the fluid that is being directed from the at least two different points.

12. The method of any one of examples 1–11, further comprising aspirating fragments of the thrombus to a proximal portion of the elongate catheter.

13. The method of any one of examples 1–11, further comprising engaging the thrombus with the distal portion to form a seal against the thrombus.

14. A system for removing a thrombus from a blood vessel of a patient, the system comprising:

an elongated catheter device having—

a distal portion configured to be positioned within the blood vessel of the patient, the distal portion comprising at least two fluid ports configured to direct respective fluid streams along respective paths that intersect,

a proximal portion configured to be positioned external to the patient, and

a lumen extending therebetween;

an aspiration mechanism positioned external to the patient and fluidly coupled with the lumen, the aspiration mechanism configured to reduce a pressure at the distal portion (a) to engage the thrombus therewith and/or (b) to draw the thrombus and/or thrombus fragments proximally; and

a fluid delivery mechanism configured to supply fluid through the elongated catheter device to the at least two fluid ports.

15. The system of example 14 wherein the fluid delivery mechanism comprises at least two structures configured to fluidly couple with the at least two fluid ports.

16. The system of example 14 wherein the at least two fluid ports are arranged such that, when delivered, the respective fluid streams intersect within an expandable housing at the distal portion.

17. The system of example 14 wherein at least one fluid port of the at least two fluid ports is arranged to deliver a respective fluid jet proximally.

18. The system of example 14 wherein the at least one fluid port is arranged to deliver the respective fluid jet toward a central axis of the elongated catheter device.

19. The system of example 14, further comprising an imaging element and/or an illumination source disposed within an expandable housing at the distal portion.

20. The system of example19 wherein the fluid delivery mechanism is further configured to apply the fluid to provide an optical path for the imaging element and/or illumination source.

21. A system for removing a thrombus from a blood vessel of a patient, the system comprising:

an elongated catheter having a distal portion configured to be positioned within the blood vessel of the patient, a proximal portion configured to be positioned external to the patient, and a lumen extending therebetween;

a capture element at the distal portion and configured to engage the thrombus;

a fluid delivery mechanism within the lumen and configured to apply fluid to at least partially fragment the thrombus; and

an aspiration mechanism fluidly coupled to the lumen and configured to aspirate the fragmented thrombus.

22. The system of example 21 wherein the capture element comprises a rotatable screw or auger.

23. The system of example 21 or example 22 wherein the capture element is positioned at least partially within the lumen.

24. The system of any one of examples 21–23 wherein the capture element is generally conical in axial cross-section.

25. The system of any one of examples 21–23 wherein the capture element is expandable.

26. The system of example 25 wherein at least a portion of the capture element is inflatable.

27. The system of any one of examples 21–26 wherein the capture element is configured to move relative to the distal portion to draw the thrombus into the lumen.

28. The system of any one of examples 21–26 wherein the capture element comprises a sensing element configured to measure a characteristic of the thrombus.

29. The system of any one of examples 21–28 wherein the fluid delivery mechanism is proximal to the capture element.

30. The system of any one of examples 21–29 wherein the fluid is pressurized saline.

31. The system of any one of examples 21–30 wherein the distal portion includes an expandable chamber transformable between a low-profile configuration and a deployed configuration.

32. The system of example 31 wherein the elongated catheter includes an intermediate portion between the proximal and distal portions, and wherein when in the deployed configuration,

the expandable chamber has a cross-sectional dimension greater than a cross-sectional dimension of the intermediate portion.

33. The system of example 31 wherein the expandable chamber has a cross-sectional dimension that varies along its axial length.

34. The system of example 33 wherein the expandable chamber is generally funnel-shaped.

35. The system of example 31 wherein the expandable chamber comprises at least one wall that is expandable by fluid or gas inflation.

36. The system of any of the examples 31–35 wherein the capture element is configured to withdraw the thrombus into the expandable chamber.

37. The system of any one of examples 31–36 wherein the fluid delivery mechanism is within the expandable chamber.

38. The system of any one of examples 21–37, further comprising an imaging element at the distal portion and configured to visualize at least a portion of the thrombus.

39. The system of example 38 wherein the fluid delivery mechanism is further configured to apply the fluid to provide an optical path for the imaging element.

40. The system of example 21 wherein the fluid is optically transparent in a visible spectrum.

41. The system of any one of examples 38–40, further comprising an illumination source at the distal portion.

42. The system of example 41 wherein at least one of the imaging element and the illumination source is steerable.

43. The system of example 42, further comprising an inflatable channel having a distal portion that is coupled with the at least one of the imaging element and the illumination source, and a proximal portion that is fluidly coupled with the fluid delivery mechanism, wherein the inflatable channel.

44. The system any one of examples 21–43, further comprising a console operably coupled to the proximal portion of the elongated catheter.

45. The system of example 44 wherein the console is configured to control one or more of the imaging element, the capture element, the fluid delivery mechanism, or the aspiration mechanism.

46. A method for treating a patient, the method comprising:

intravascularly delivering a distal portion of a catheter to a location adjacent to a thrombus within vasculature of the patient;

generating image data of the vasculature and/or the thrombus via an imaging element carried by the distal portion of the catheter;

drawing at least a section of the thrombus into the distal portion; and

delivering fluid having a selected pressure and selected flow rate via one or more openings at the distal portion of the catheter to at least partially fragment the thrombus,

wherein the selected pressure and/or the selected flow rate are based, at least in part, on the image data.

47. The method of example 46 wherein generating image data comprises generating image data before, during, and/or after at least partially fragmenting the thrombus.

48. The method of example 46 wherein the image data comprises information regarding a type and/or characteristic of the thrombus, and wherein the selected pressure and/or selected flow rate are based, at least in part, on the type and/or characteristic of the thrombus.

49. A method for treating a patient, the method comprising:

delivering a distal portion of a catheter to a location proximate a thrombus within vasculature of the patient;

generating image data of the thrombus via an imaging element carried by the distal portion of the catheter; and

engaging the thrombus with a capture element at the distal portion of the catheter, wherein one or more properties of the capture element are based, at least in part, on the image data of the thrombus.

50. The method of example 49 wherein generating image data comprises generating data regarding the type of thrombus.

51. The method of example 49 wherein the one or more properties of the capture element comprises thread size, thread pitch, and/or durometer.

Conclusion

[0053] The above detailed description of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise forms disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0054] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0055] Unless the context clearly requires otherwise, throughout the description and the examples, the words "comprise," "comprising," and the like are to be construed in an inclusive sense, as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not

limited to." As used herein, the terms "connected," "coupled," or any variant thereof, means any connection or coupling, either direct or indirect, between two or more elements; the coupling of connection between the elements can be physical, logical, or a combination thereof. Additionally, the words "herein," "above," "below," and words of similar import, when used in this application, shall refer to this application as a whole and not to any particular portions of this application. Where the context permits, words in the above Detailed Description using the singular or plural number may also include the plural or singular number respectively. As used herein, the phrase "and/or" as in "A and/or B" refers to A alone, B alone, and A and B. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A method for removing a thrombus from a blood vessel of a patient, the method comprising:

introducing a distal portion of an elongate catheter to a thrombus location in a blood vessel;

drawing at least a section of the thrombus into the distal portion; and

directing fluid from at least two different points toward the thrombus.

2. The method of claim 1 wherein introducing the distal portion is into the blood vessel in a low-profile configuration, and wherein the method further comprises expanding the distal portion into a deployed configuration.

3. The method of claim 2 wherein the drawing is into the distal portion using a capture element, and wherein the method further comprises expanding the capture element from the low-profile configuration to the deployed configuration.

4. The method of any one of claims 1–3 wherein the drawing is into the distal portion using a rotatable screw or auger.

5. The method of claim 4, further comprising:

sensing a characteristic of the thrombus; and

adjusting a rotation speed of the rotatable screw or auger based on the sensed characteristic.

6. The method of any one of claims 1–5, further comprising applying the fluid by one or more nozzles within the distal portion to form at least two fluid streams.

7. The method of claim 6, further comprising directing the at least two fluid streams along intersecting paths.

8. The method of any one of claims 1–6 wherein the blood vessel comprises a pulmonary artery.

9. The method of any one of claims 1–8, further comprising, prior to the drawing, imaging the thrombus with an imaging element at the distal portion.

10. The method of claim 9 wherein the imaging is through a fluid path.

11. The method of claim 10, further comprising forming the fluid path using the fluid that is being directed from the at least two different points.

12. The method of any one of claims 1–11, further comprising aspirating fragments of the thrombus to a proximal portion of the elongate catheter.

13. The method of any one of claims 1–11, further comprising engaging the thrombus with the distal portion to form a seal against the thrombus.

14. A system for removing a thrombus from a blood vessel of a patient, the system comprising:

an elongated catheter device having—

a distal portion configured to be positioned within the blood vessel of the patient, the distal portion comprising at least two fluid ports configured to direct respective fluid streams along respective paths that intersect,

a proximal portion configured to be positioned external to the patient, and

a lumen extending therebetween;

an aspiration mechanism positioned external to the patient and fluidly coupled with the lumen, the aspiration mechanism configured to reduce a pressure at the distal portion (a) to engage the thrombus therewith and/or (b) to draw the thrombus and/or thrombus fragments proximally; and

a fluid delivery mechanism configured to supply fluid through the elongated catheter device to the at least two fluid ports.

15. The system of claim 14 wherein the fluid delivery mechanism comprises at least two structures configured to fluidly couple with the at least two fluid ports.

16. The system of claim 14 wherein the at least two fluid ports are arranged such that, when delivered, the respective fluid streams intersect within an expandable housing at the distal portion.

17. The system of claim 14 wherein at least one fluid port of the at least two fluid ports is arranged to deliver a respective fluid jet proximally.

18. The system of claim 14 wherein the at least one fluid port is arranged to deliver the respective fluid jet toward a central axis of the elongated catheter device.

19. The system of claim 14, further comprising an imaging element and/or an illumination source disposed within an expandable housing at the distal portion.

20. The system of claim19 wherein the fluid delivery mechanism is further configured to apply the fluid to provide an optical path for the imaging element and/or illumination source.

21. A system for removing a thrombus from a blood vessel of a patient, the system comprising:

an elongated catheter having a distal portion configured to be positioned within the blood vessel of the patient, a proximal portion configured to be positioned external to the patient, and a lumen extending therebetween;

a capture element at the distal portion and configured to engage the thrombus;

a fluid delivery mechanism within the lumen and configured to apply fluid to at least partially fragment the thrombus; and

an aspiration mechanism fluidly coupled to the lumen and configured to aspirate the fragmented thrombus.

22. The system of claim 21 wherein the capture element comprises a rotatable screw or auger.

23. The system of claim 21 or claim 22 wherein the capture element is positioned at least partially within the lumen.

24. The system of any one of claims 21–23 wherein the capture element is generally conical in axial cross-section.

25. The system of any one of claims 21–23 wherein the capture element is expandable.

26. The system of claim 25 wherein at least a portion of the capture element is inflatable.

27. The system of any one of claims 21–26 wherein the capture element is configured to move relative to the distal portion to draw the thrombus into the lumen.

28. The system of any one of claims 21–26 wherein the capture element comprises a sensing element configured to measure a characteristic of the thrombus.

29. The system of any one of claims 21–28 wherein the fluid delivery mechanism is proximal to the capture element.

30. The system of any one of claims 21–29 wherein the fluid is pressurized saline.

31. The system of any one of claims 21–30 wherein the distal portion includes an expandable chamber transformable between a low-profile configuration and a deployed configuration.

32. The system of claim 31 wherein the elongated catheter includes an intermediate portion between the proximal and distal portions, and wherein when in the deployed configuration,

the expandable chamber has a cross-sectional dimension greater than a cross-sectional dimension of the intermediate portion.

33. The system of claim 31 wherein the expandable chamber has a cross-sectional dimension that varies along its axial length.

34. The system of claim 33 wherein the expandable chamber is generally funnel-shaped.

35. The system of claim 31 wherein the expandable chamber comprises at least one wall that is expandable by fluid or gas inflation.

36. The system of any of the claims 31–35 wherein the capture element is configured to withdraw the thrombus into the expandable chamber.

37. The system of any one of claims 31–36 wherein the fluid delivery mechanism is within the expandable chamber.

38. The system of any one of claims 21–37, further comprising an imaging element at the distal portion and configured to visualize at least a portion of the thrombus.

39. The system of claim 38 wherein the fluid delivery mechanism is further configured to apply the fluid to provide an optical path for the imaging element.

40. The system of claim 21 wherein the fluid is optically transparent in a visible spectrum.

41. The system of any one of claims 38–40, further comprising an illumination source at the distal portion.

42. The system of claim 41 wherein at least one of the imaging element and the illumination source is steerable.

43. The system of claim 42, further comprising an inflatable channel having a distal portion that is coupled with the at least one of the imaging element and the illumination source, and a proximal portion that is fluidly coupled with the fluid delivery mechanism, wherein the inflatable channel.

44. The system any one of claims 21–43, further comprising a console operably coupled to the proximal portion of the elongated catheter.

45. The system of claim 44 wherein the console is configured to control one or more of the imaging element, the capture element, the fluid delivery mechanism, or the aspiration mechanism.

46. A method for treating a patient, the method comprising:

intravascularly delivering a distal portion of a catheter to a location adjacent to a thrombus within vasculature of the patient;

generating image data of the vasculature and/or the thrombus via an imaging element carried by the distal portion of the catheter;

drawing at least a section of the thrombus into the distal portion; and

delivering fluid having a selected pressure and selected flow rate via one or more openings at the distal portion of the catheter to at least partially fragment the thrombus,

wherein the selected pressure and/or the selected flow rate are based, at least in part, on the image data.

47. The method of claim 46 wherein generating image data comprises generating image data before, during, and/or after at least partially fragmenting the thrombus.

48. The method of claim 46 wherein the image data comprises information regarding a type and/or characteristic of the thrombus, and wherein the selected pressure and/or selected flow rate are based, at least in part, on the type and/or characteristic of the thrombus.

49. A method for treating a patient, the method comprising:

delivering a distal portion of a catheter to a location proximate a thrombus within vasculature of the patient;

generating image data of the thrombus via an imaging element carried by the distal portion of the catheter; and

engaging the thrombus with a capture element at the distal portion of the catheter, wherein one or more properties of the capture element are based, at least in part, on the image data of the thrombus.

50. The method of claim 49 wherein generating image data comprises generating data regarding the type of thrombus.

51. The method of claim 49 wherein the one or more properties of the capture element comprises thread size, thread pitch, and/or durometer.

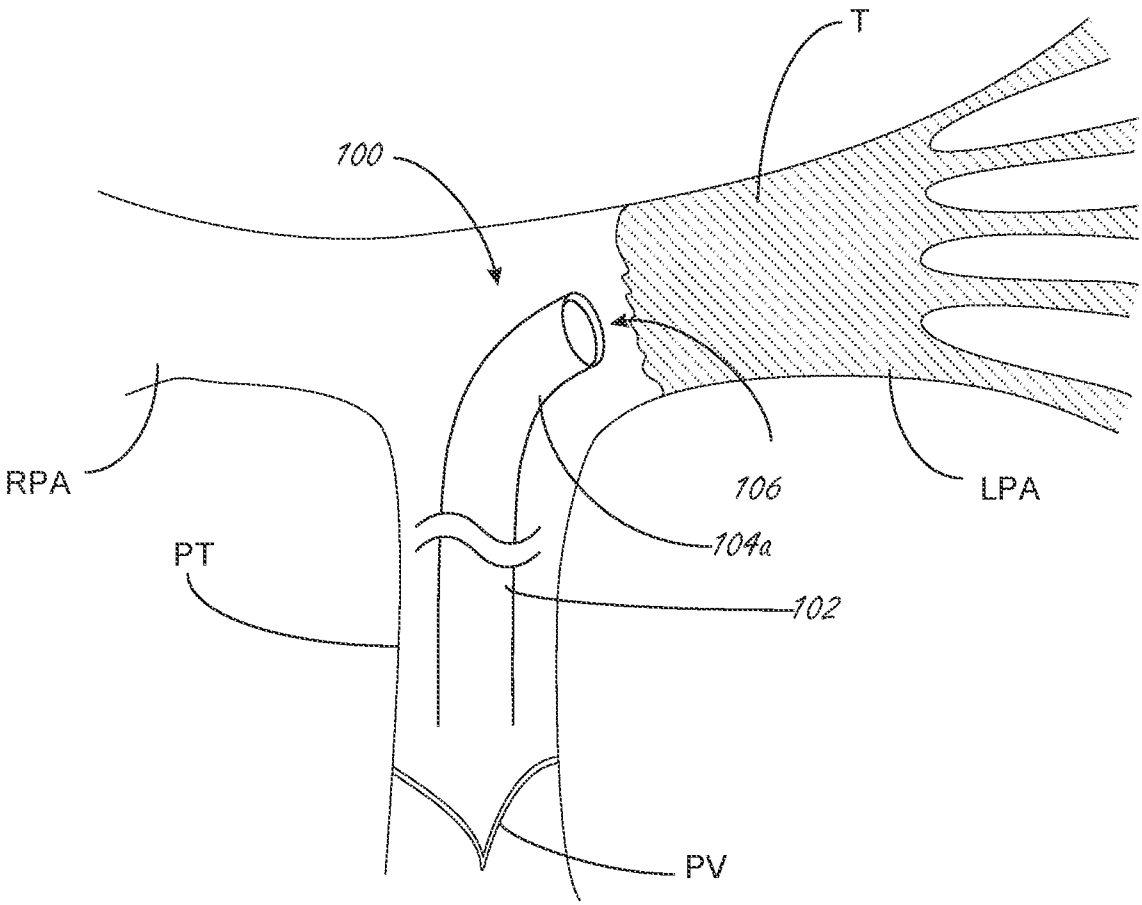


Fig. 1A

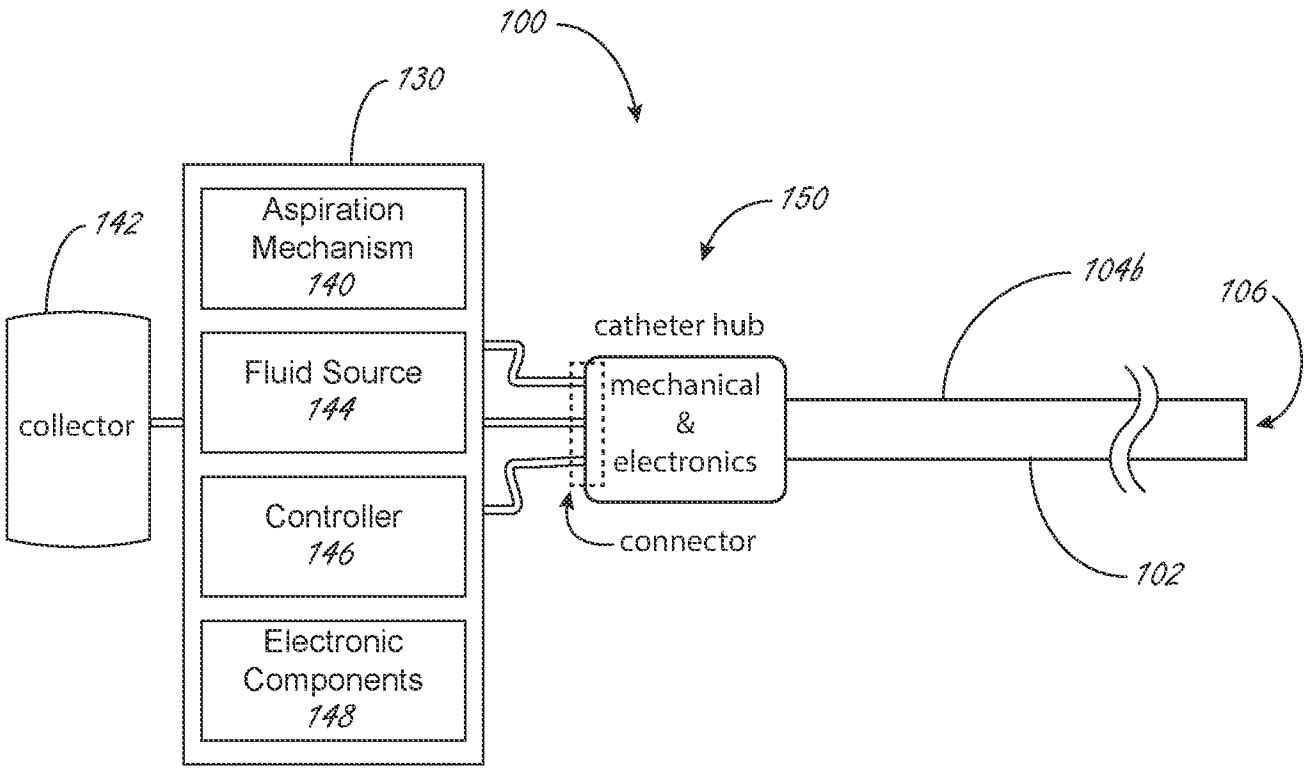

100
130
142
Aspiration Mechanism 140
150
1046
106
catheter hub
collector
Fluid Source 144
mechanical & electronics
Controller 146
connector
102
Electronic Components 148

Fig. 1B

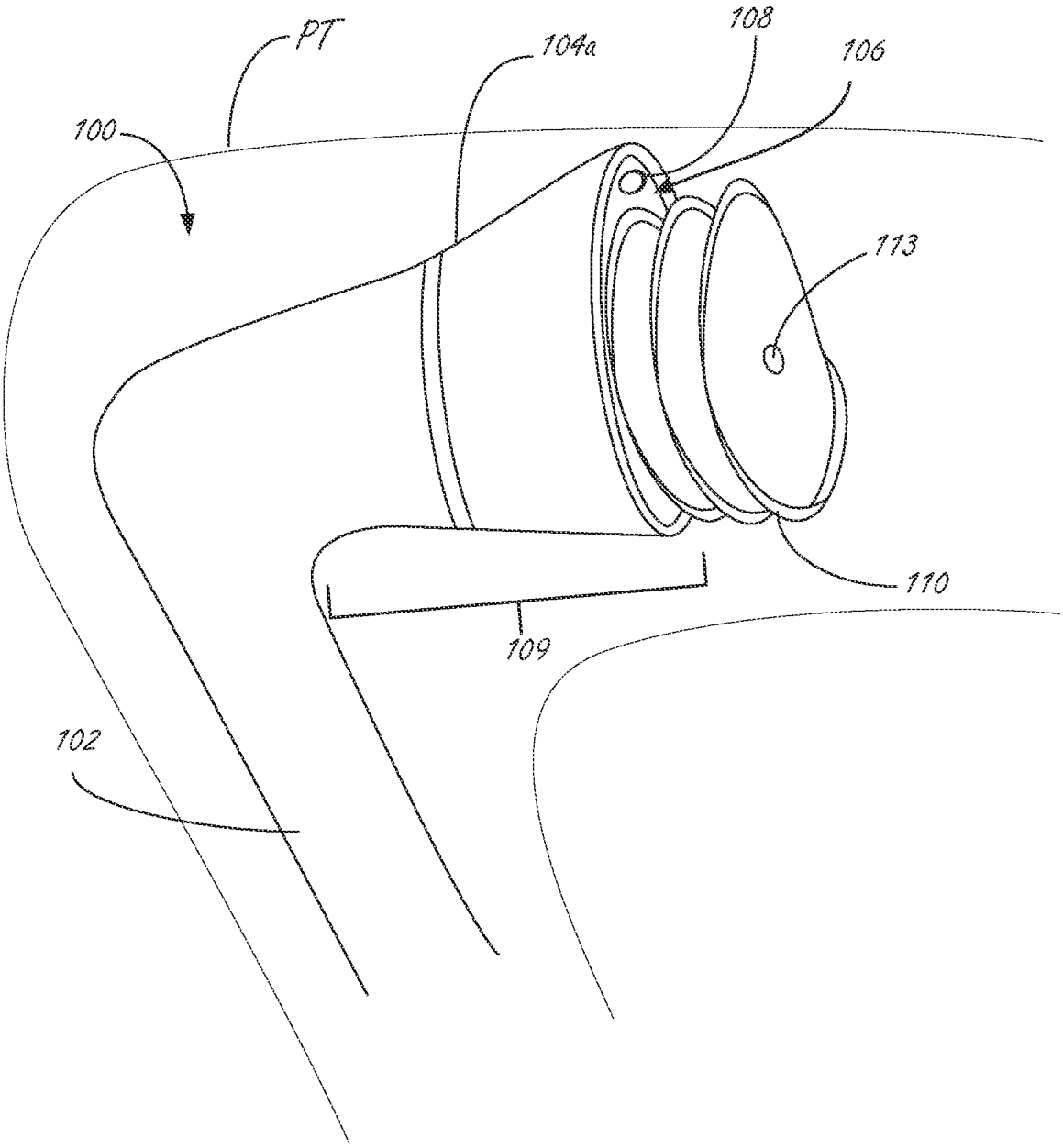


Fig. 1C

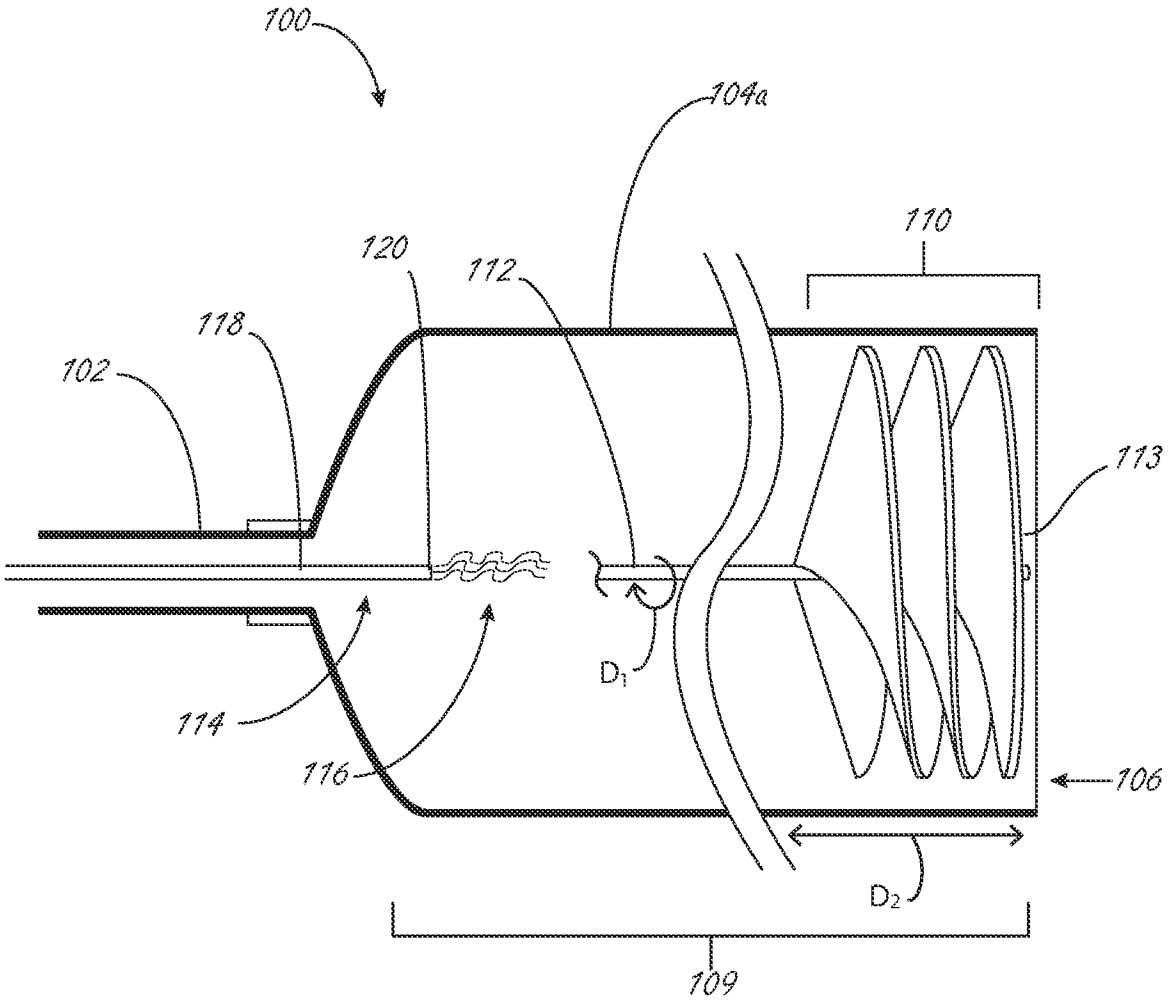


Fig. 10

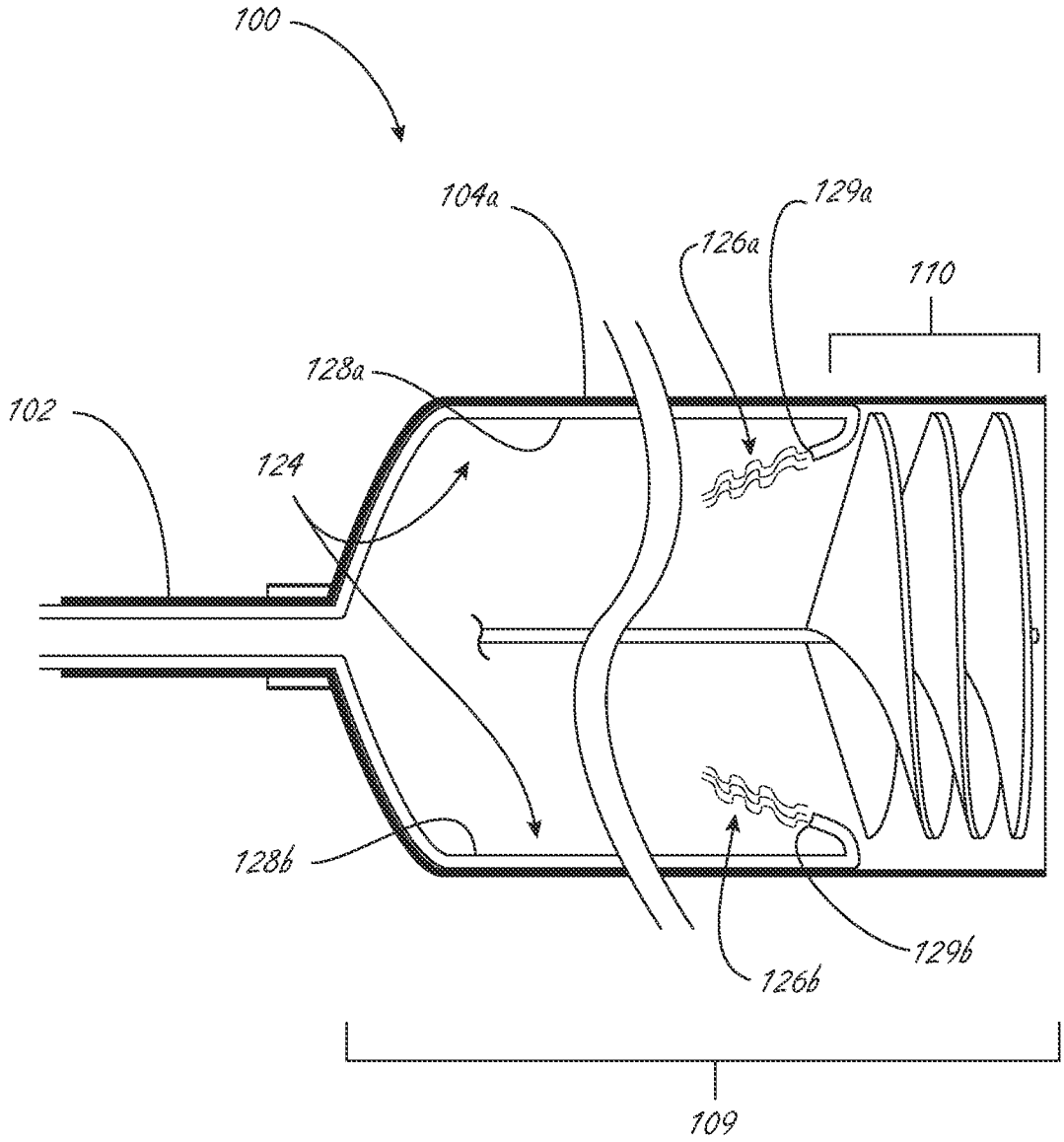


Fig. 1E

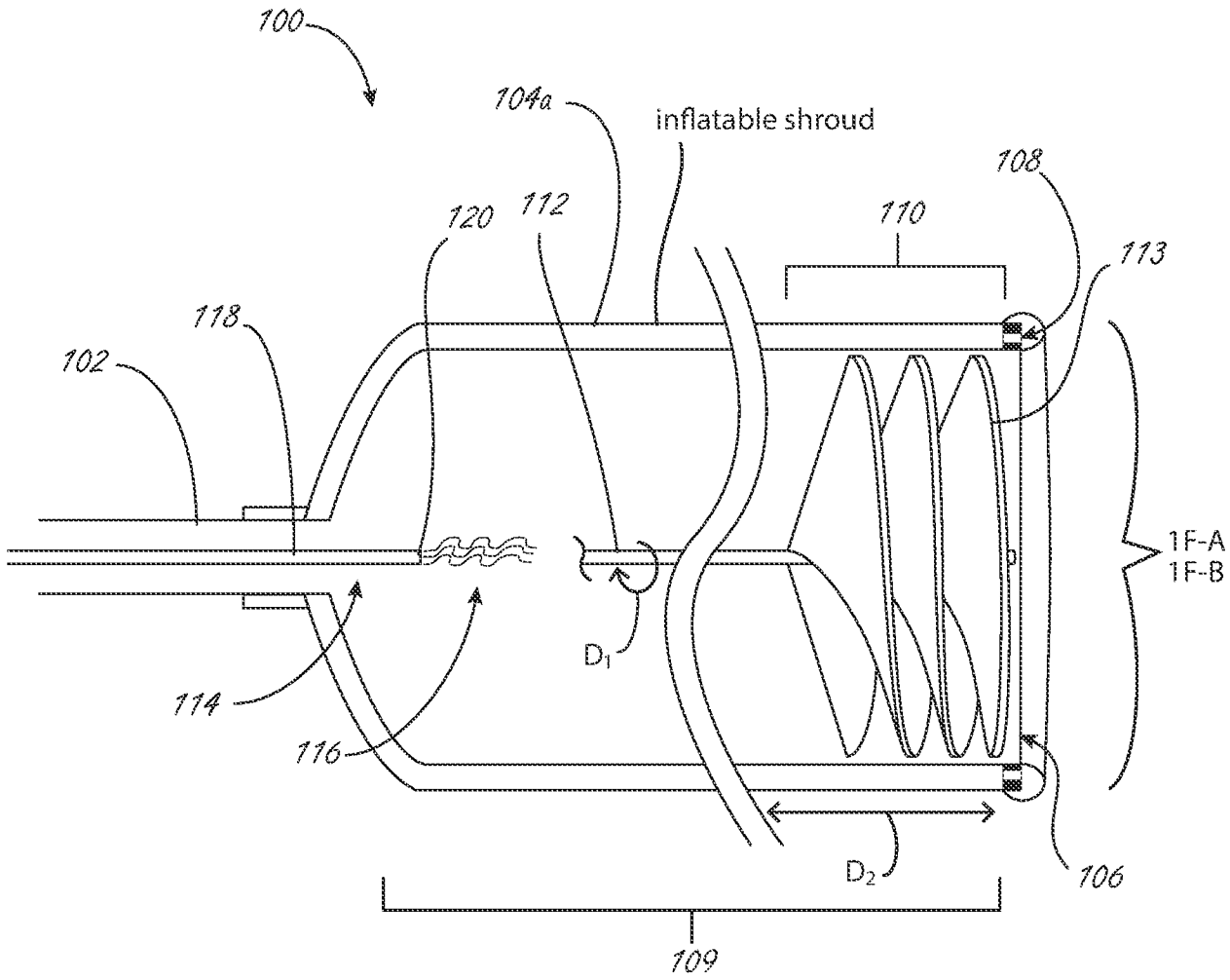
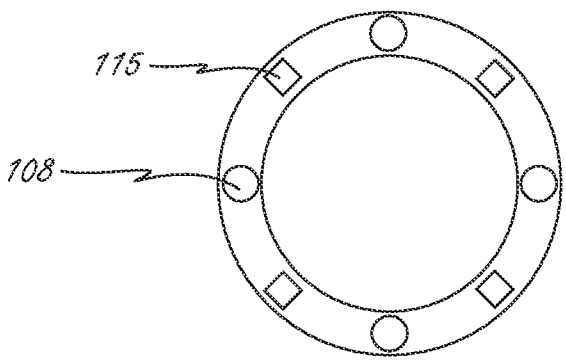
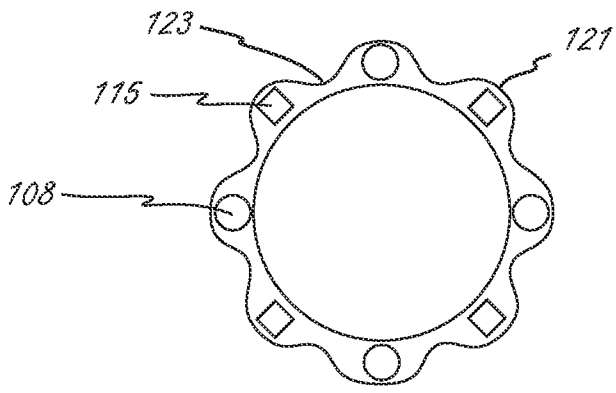


Fig. 1F

Variation 1F-A



Variation 1F-B



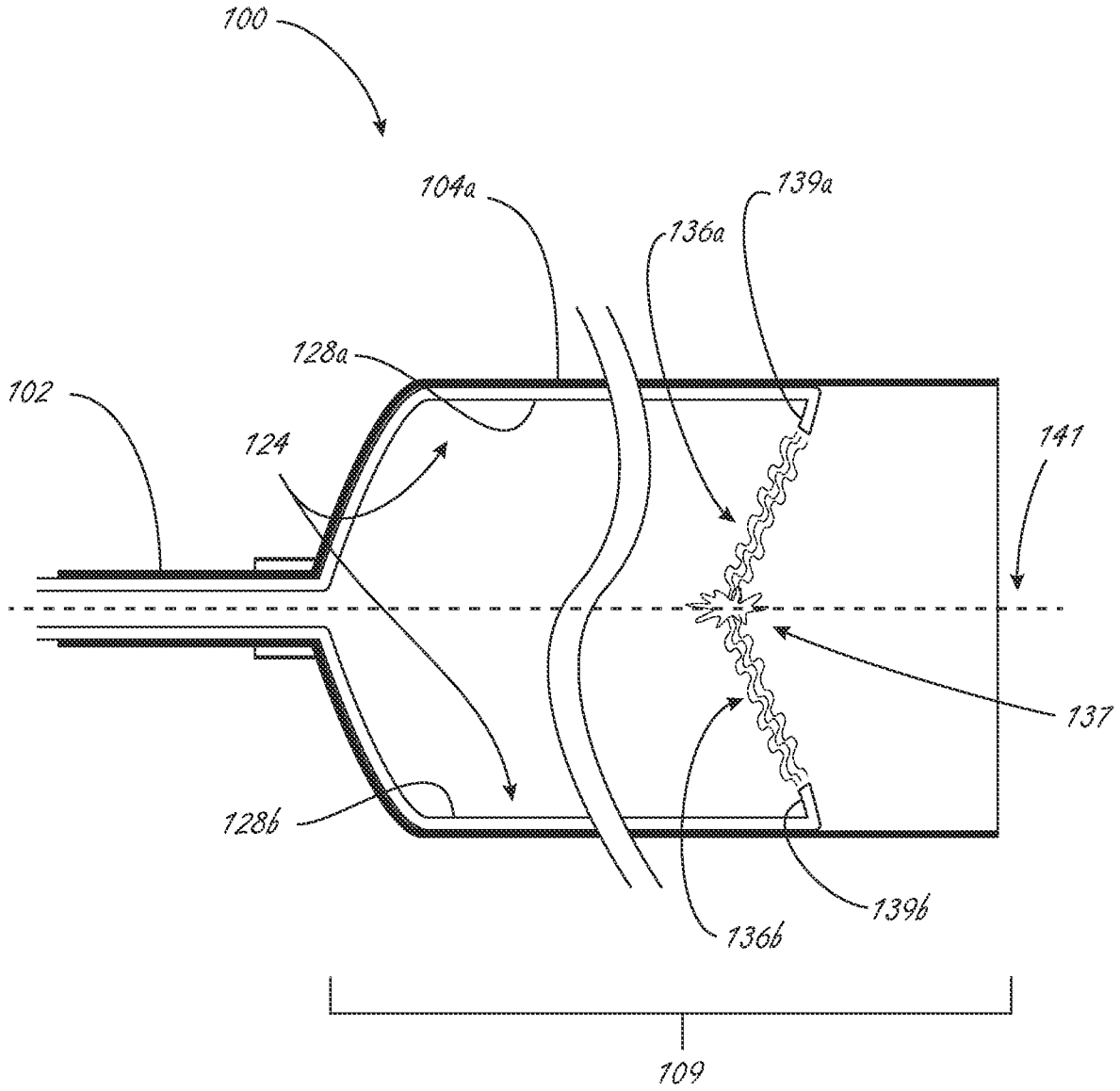


Fig. 1C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/020915

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/22(2006.01)i; **A61B 17/3207**(2006.01)i; **A61M 1/00**(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 17/22(2006.01); A61B 6/00(2006.01); A61M 25/00(2006.01); A61M 25/09(2006.01); A61M 29/00(2006.01); A61M 36/04(2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & keywords: thrombus, catheter, blood vessel, fluid, camera

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009-0171267 A1 (MICHAEL J. BONNETTE et al.) 02 July 2009 (2009-07-02) See paragraphs [0053]-[0071] and figures 2-7.	1-2,14-18
Y		3-5,19-23,40,46-51
Y	US 2012-0059210 A1 (JAMES J. FRASSICA) 08 March 2012 (2012-03-08) See paragraphs [0183]-[0232] and figure 3.	3-5,19-23,40,49-51
Y	US 2009-0048577 A1 (GEORGE T. GILLIES et al.) 19 February 2009 (2009-02-19) See paragraph [0055], claims 41-58 and figure 4.	46-51
A	US 2013-0131691 A1 (MEDRAD, INC.) 23 May 2013 (2013-05-23) See paragraphs [0083]-[0089] and figure 7.	1-5,14-23,40,46-51
A	US 2008-0167678 A1 (HESHAM MORSI) 10 July 2008 (2008-07-10) See paragraphs [0026]-[0030] and figures 1-2.	1-5,14-23,40,46-51

☐ Further documents are listed in the continuation of Box C. ☑ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 June 2021	**24 June 2021**

Name and mailing address of the ISA/KR	Authorized officer
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INTERNATIONAL SEARCH REPORT
Information on patent family members

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PCT/US2021/020915

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		JP	5726726	B2	03 June 2015
		JP	5763101	B2	12 August 2015
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Information on patent family members

International application No.
PCT/US2021/020915

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/020915

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☑ Claims Nos.: **7,10-11,26,32-35,39,42-43,45**
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claims 7,10-11,26,32-35,39,42-43,45 are unclear, because they refer to multiple dependent claims which do not comply with PCT Rule 6.4(a).

3. ☑ Claims Nos.: **6,8-9,12-13,24-25,27-31,36-38,41,44**
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).